

The need for using theory to consider the transferability of interventions

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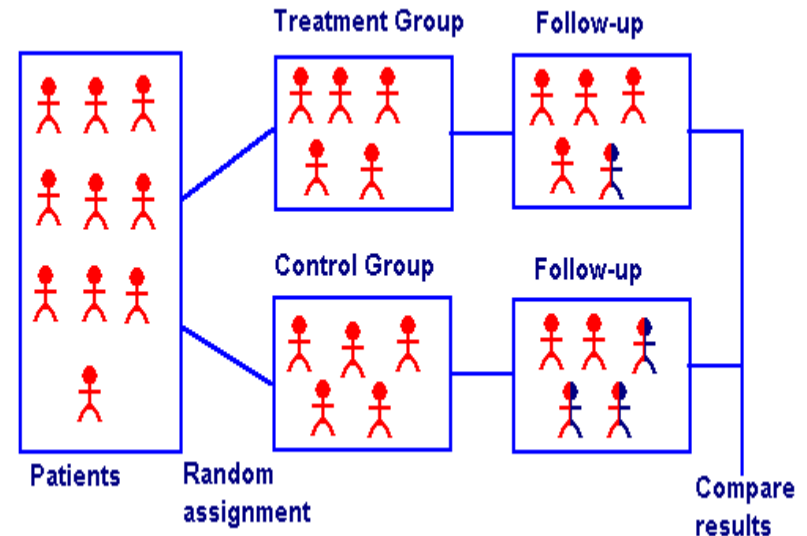
Randomised trials

Randomising individuals/clusters of individuals to intervention/comparison arms reduces bias

Randomising also aims to balance arms on measured and unmeasured factors to reduce confounding

In a non-random schools study for example the schools already taking more effective action to reduce bullying might opt for the intervention

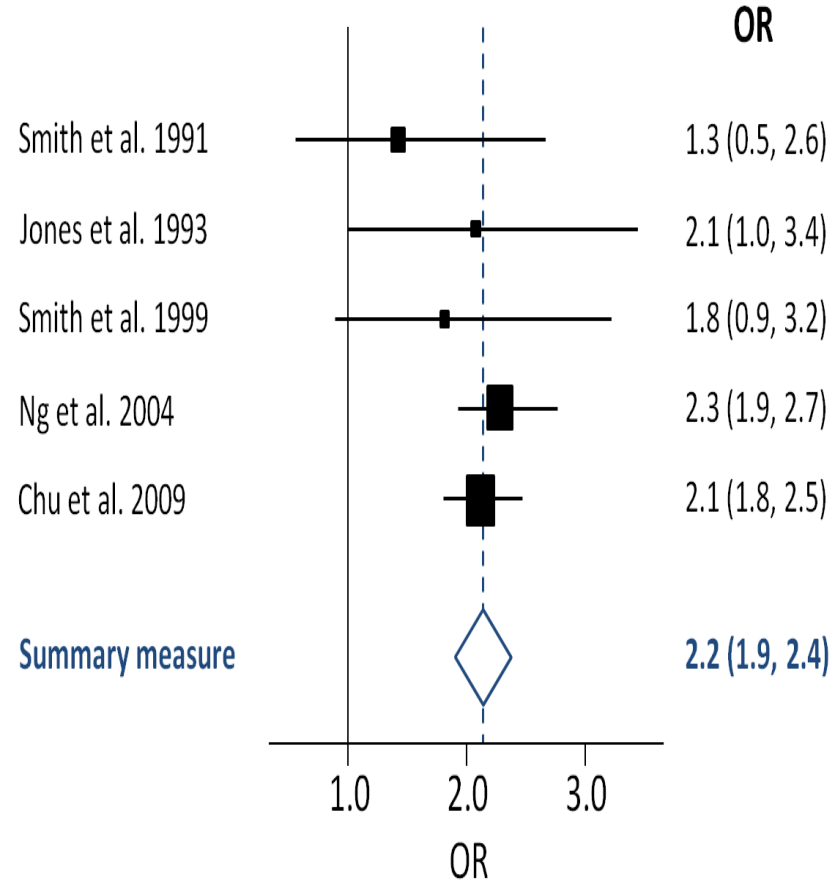
Then aim to minimise error and bias in measurement and analysis e.g. retention, blinding, validated measures, intention-to-treat analysis



Systematic reviews

Trials generate effect estimates in situ usually for overall population

Systematic reviews pool effect estimates of studies homogeneous for PICO (population, intervention comparisons and outcomes) to produce general effect estimate

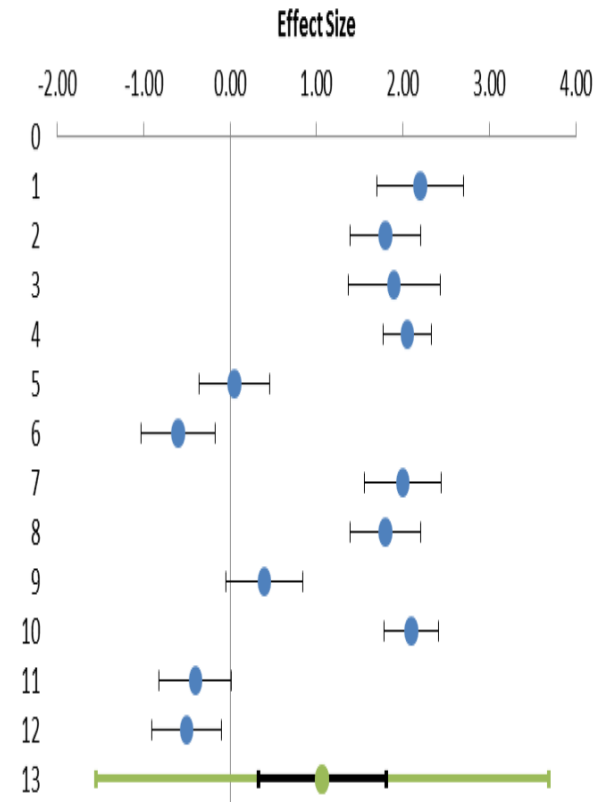


Trials and reviews don't tell us whether the intervention will work elsewhere

Trial reports often make bland statements about uncertain generalisability

Systematic reviews pool trial results more often than explaining differences in results between trials

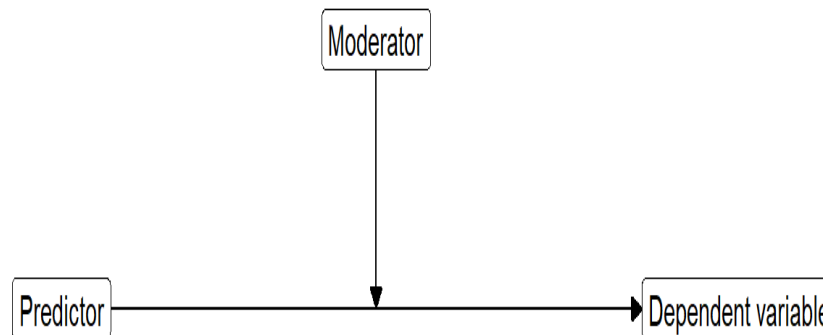
Trials in meta-analysis may be homogeneous for PICO but heterogeneous for other factors that moderate intervention effects



Variables that directly measure or act as a proxy measure for some factor modifying the effect of allocation to receive an intervention on an outcome.

Can explain

- differences in effect between sub-groups within a trial or
- differences in the effect found in one trial and that found in another trial (or that which would be found were the intervention delivered elsewhere)



Example: sexual health promotion with MSM

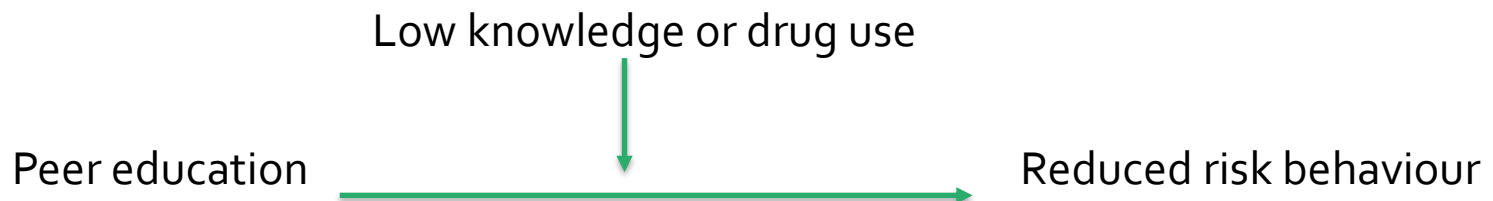
Peer education effective in reducing risk of STIs among MSM in small US mid-western cities in early 1990s

Not effective in reducing risk among Scottish MSM in late 1990s – why?

=Inadequate fidelity?

=Difference in moderators?

- Low knowledge less prevalent and/or weaker moderator in late 1990s?
- Drug use more prevalent and stronger moderator in late 1990s?



Implications for assessing transferability

You could reanalyse the original trial data, reweighting strata defined by within-trial moderators to take account of different prevalence of moderators in the new context

e.g. model overall effect to take account of different prevalence of low knowledge

-requires evidence about prevalence of moderators in trial and in new context

Moderator	Original trial		New setting	
	Effect	Prevalence	Effect	Prevalence
Low knowledge	OR=0.5	75	OR=0.5	25
High knowledge	OR=1.00	25	OR=1.00	75
Overall	Or=0.625	100	OR=0.875	100

-addresses issue in difference between contexts in prevalence but not strength of moderators or existence of new moderators

Implications for assessing transferability

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Moderator	Original trial		New setting	
	Effect	Prevalence	Effect	Prevalence
Low knowledge	OR=0.5	75%	OR=0.75	75%
High knowledge	OR=1.0	25%	OR=1.0	25%
Overall	OR=0.625	100%	OR=0.8	100%

- but you won't know the strength of moderator across different contexts
- we might guesstimate this based on observational research from new context e.g. association between drug use and sexual risk - but very crude

Need to generalise on basis of theory

Statistical modelling challenging:

- we won't know which moderators to examine in trials
- we will never have perfect information about prevalence and strengths of these moderators in new settings to develop precise estimates

And we don't understand what real mechanisms of action underlie – e.g. is low knowledge a moderator because mechanism concerns education or is it a proxy for something else?

Therefore important complement to statistical modelling is theory

Realist approaches to social science and evaluation provide useful insights

Realist evaluation

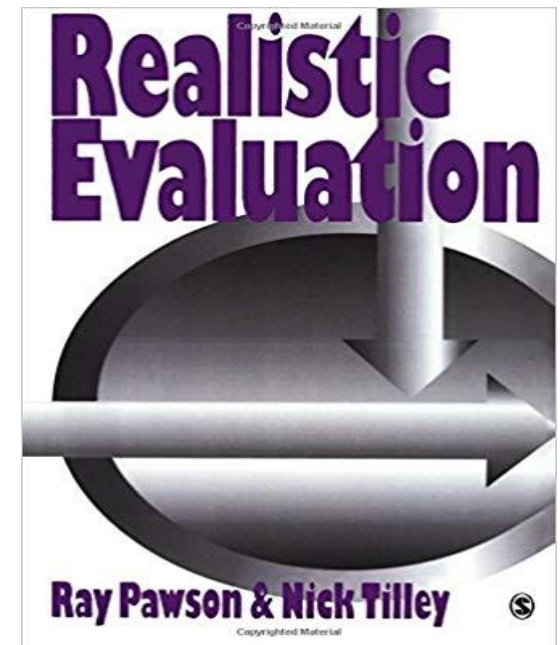
Informed by critical realist philosophy

Interventions viewed as providing resources for actors who will change their practices to trigger mechanisms which generate outcomes

Implementation and mechanisms will vary by context (person or place) and therefore so will outcomes

Causation is unobservable but real

Measures are observable but indirect window on reality



Realist evaluation

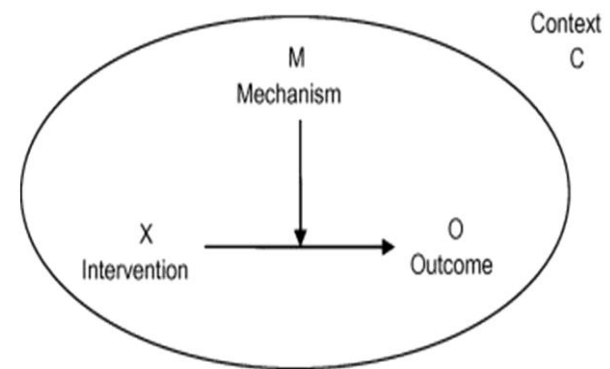
Realist evaluators formulate hypotheses about how mechanisms interact with context to generate outcomes (CMO configurations)

Test these hypotheses using natural experiments

For example, CCTV in car parks working via increasing natural surveillance, removing core offenders or signalling priority

Realists against RCTs but their insights could inform interpretation of trial evidence in order to predict effectiveness of interventions in new settings

CMO Configurations



Goals of realist intervention research

Conventional evaluation goal of estimating intervention effects and understanding what factors moderate this: what works for whom under what conditions

Less conventional (at least within evaluation research) goal of using RCTs and systematic reviews to build and refine scientific theories about:

- how interventions trigger mechanisms that then generate outcomes
- how these mechanisms will vary with context

Might provide more informed predictions about transferability of effects

Potential for realist RCTs?

Use qualitative research nested within RCT to build/refine CMO hypotheses

Test these in additional trial analyses e.g. moderator and mediator analyses

Randomised trials can encompass sufficient variety of contexts to test some but not all CMOs

(variation in context can exist as long as it is similar in each arm)

Systematic reviews can encompass more variety of contexts to test more CMOs

Example: INCLUSIVE trial

Conventional basic design with post-baseline random allocation of 40 schools across SE England (2014-7)

Single blinded follow up of students in year 7 t baseline to 24 and 36 months

Encompass variation in students (SES, ethnicity, sex) and schools (e.g. good/poor inspection rating, inner city/suburban)

Examine intervention which 'disrupts' school environment via multiple mechanisms

Effects of the Learning Together intervention on bullying and aggression in English secondary schools (INCLUSIVE): a cluster randomised controlled trial



Chris Bonell, Elizabeth Allen, Emily Warren, Jennifer McGowan, Leonardo Bevilacqua, Farah Jamal, Rosa Legood, Meg Wiggins, Charles Opondo, Anne Mathiot, Jo Sturgess, Adam Fletcher, Zia Sadique, Diana Elbourne, Deborah Christie, Lyndal Bond, Stephen Scott, Russell M Viner



Summary

Background Bullying, aggression, and violence among children and young people are some of the most consequential public mental health problems. We tested the Learning Together intervention, which involved students in efforts to modify their school environment using restorative practice and by developing social and emotional skills.

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[http://dx.doi.org/10.1016/S0140-6736\(18\)31782-3](http://dx.doi.org/10.1016/S0140-6736(18)31782-3)

Methods We did a cluster randomised trial, with economic and process evaluations, of the Learning Together intervention compared with standard practice (controls) over 3 years in secondary schools in south-east England. Learning Together consisted of staff training in restorative practice; convening and facilitating a school action group; and a student social and emotional skills curriculum. Primary outcomes were self-reported experience of bullying victimisation (Gatehouse Bullying Scale; GBS) and perpetration of aggression (Edinburgh Study of Youth Transitions and Crime (ESYTC) school misbehaviour subscale) measured at 36 months. We analysed data using intention-to-treat longitudinal mixed-effects models. This trial was registered with the ISRCTN registry (10751359).

See Online Comment
[http://dx.doi.org/10.1016/S0140-6736\(18\)31782-3](http://dx.doi.org/10.1016/S0140-6736(18)31782-3)
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Findings We included 40 schools (20 in each group); no schools withdrew. 6667 (93.6%) of 7121 students participated at baseline and 5960 (83.3%) of 7154 at 36 months. Mean GBS bullying score at 36 months was 0.34 (SE 0.02) in the control group versus 0.29 (SE 0.02) in the intervention group, with a significant adjusted mean difference (−0.03, 95% CI −0.06 to −0.001; adjusted effect size −0.08). Mean ESYTC score at 36 months was 4.33 (SE 0.20) in the control group versus 4.04 (SE 0.21) in the intervention group, with no evidence of a difference between groups (adjusted difference −0.13, 95% CI −0.43 to 0.18; adjusted effect size −0.03). Costs were an additional £58 per pupil in intervention schools than in control schools.

Interpretation Learning Together had small but significant effects on bullying, which could be important for public health, but no effect on aggression. Interventions to promote student health by modifying the whole-school environment are likely to be one of the most feasible and efficient ways of addressing closely related risk and health outcomes in children and young people.

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Introduction

Bullying, aggression, and violence among children and young people are among the most consequential public mental health problems.¹ WHO defines bullying as the intentional use of physical or psychological force against others,² and violence as the intentional use of physical force against oneself or others.³ Aggression consists of hostile or destructive behaviour, and is a common part of bullying or violence. Bullying is more prevalent among British young people⁴ than in other western European countries,⁵ with cyber-bullying becoming one of the most common forms.⁶ Childhood exposure to bullying and violence results in multiple physical and mental health harms in childhood and in adult life,^{6–10} as well as lower educational attainment.¹⁰ Prevention of bullying and violence is therefore a major priority for public health and education systems internationally,^{1,10} with schools a

key focus of initiatives to improve young people's mental health and wellbeing.¹¹ A challenge is to address these inter-related behaviours using single coherent interventions rather than overburdening busy schools with multiple interventions.

We developed and piloted a school-based intervention based on the three most promising approaches to reducing bullying and other health risks. The first are whole-school interventions aiming to modify overall school policies and systems rather than merely to deliver classroom-based lessons addressing bullying or other outcomes.¹² A key element of many such interventions is to increase student engagement with school as a social determinant of health, particularly for the most socially disadvantaged students.^{13,14} Systematic reviews and trials suggest that such approaches reduce risk behaviours including violence and anti-social behaviour^{15–21} and

Starting theory of change

'Intervention' provides data, manual, training, facilitator, curriculum materials



Teachers use these to implement student-staff policy-making, restorative practices, social & emotional skills lessons (*especially in schools with higher management capacity*)



Teachers and students develop better relationships and new skills, and build student commitment to school (*especially of low SES students*)



Reduced student engagement with anti-school peer groups and health risk behaviours including bullying (*especially in schools with high capacity / more students of low SES*)

Trial analyses

Overall intervention effective in

Reductions in:

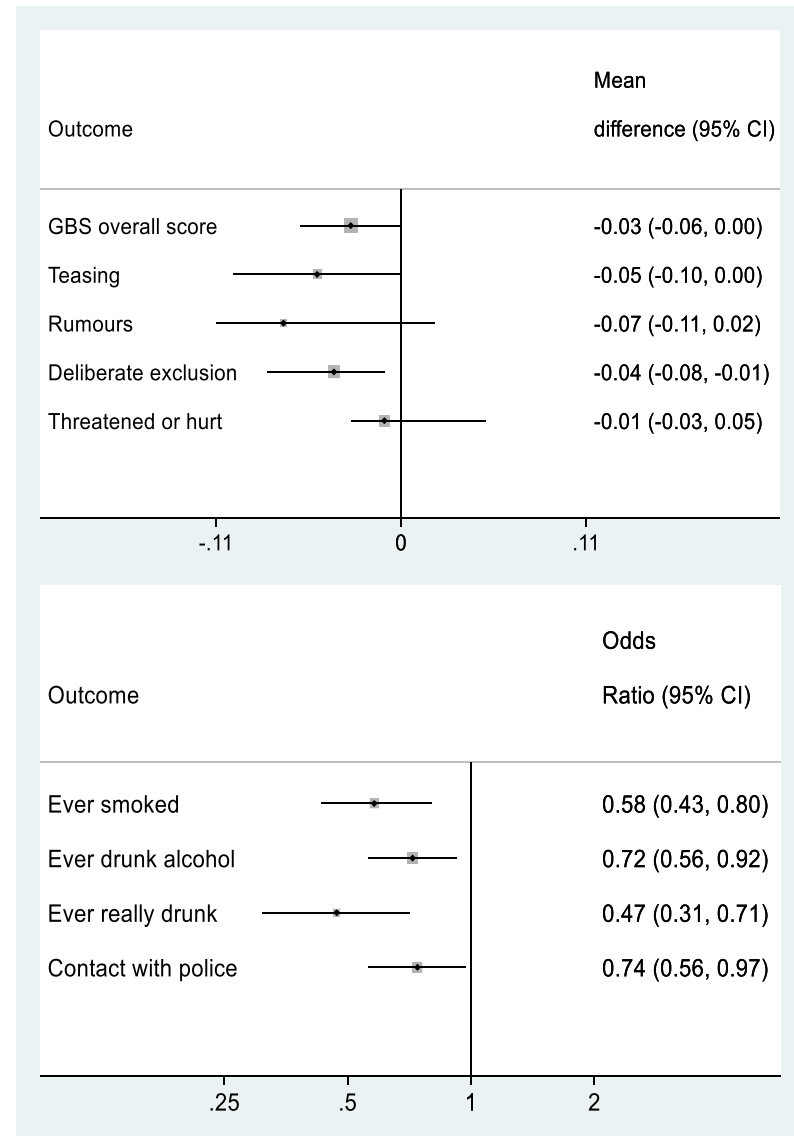
- bullying (but not school based aggression
- smoking
- alcohol
- drug use

But not:

- school based aggression
- sexual risk behaviour

Improvements in:

- mental health
- psychological functioning
- quality of life



Process evaluation

- better fidelity in schools with more capacity but also with more baseline orientation towards student inclusion or holistic development
- social & emotional skills curriculum very poorly delivered
- intervention encouraged students and staff to see each other's points of view

Mediation analyses

- effects on bullying might be partly explained by increased commitment to school and reduced engagement with anti-school peers

Moderation analyses

- no evidence that more effective for students of low SES but evidence that more effective for boys and those reporting baseline bullying victimisation

Exploratory analyses of other outcomes

- reduced truancy, aggression in/outside school, involvement in school discipline systems

Refined theory of change

'Intervention' provides data, manual, training, facilitator **but not curriculum materials**



Teachers use these to implement student-staff policy-making, restorative practices, *(especially in schools with high capacity & inclusive ethos)* **but not social & emotional skills lessons**



Teachers and students develop **more empathy**, and build student commitment to school *(especially of boys and those involved in risk)*



Reduced student engagement with anti-school peer groups and **multiple health and educational** risk behaviours *(especially in schools with high capacity / inclusive ethos / more boys / more baseline risk)*

Use refined theory to predict effects (description not quantitative estimate) in other settings, for example:

- Intervention stronger candidate in
 - inclusive schools
 - schools with more boys and baseline risk
- Need to focus on activities that allow staff and students to build empathy
- Social & emotional skills education not a key ingredient in this intervention
- Need to work harder on gender equity through refined or additional intervention
- Might be an intervention for school improvement not just public health – more marketable to schools

What do realist trials offer?

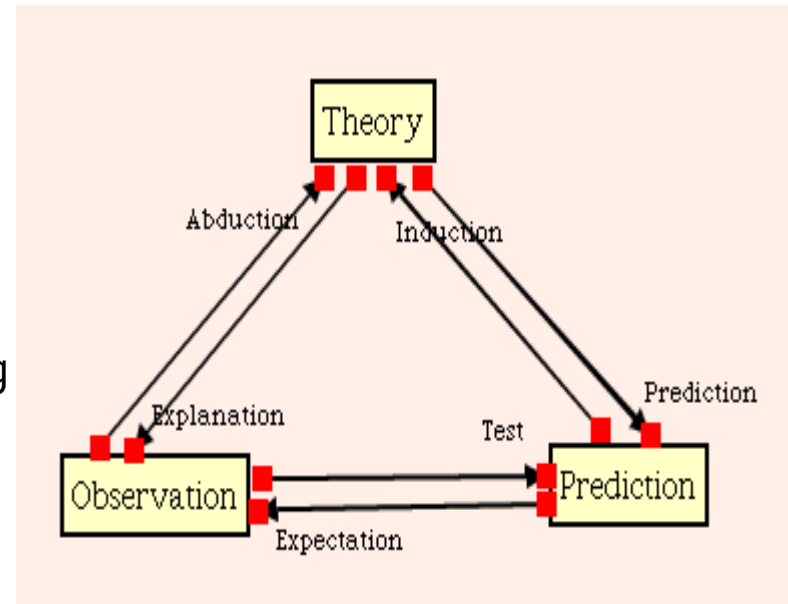
Better:

understanding of how outcomes vary between people and places

understanding of actual mechanisms underlying these from iterative qualitative and quantitative analyses

predictions of potential effectiveness in new settings

as theory refined iteratively across trials in diverse settings, we might move from descriptive predictions of effectiveness to more precise quantitative estimates of effects



Potential limitations

Larger RCTs powered to assess moderators cost more money

Within trial, won't always have the quantitative measures to test hypotheses emerging from qualitative research e.g. inclusive culture

Hard to get multiple studies to focus on similar mechanisms across divergent contexts using comparable measures

More analysis mean more false positives but at least hypothesis-led– could add limited no. of new hypotheses to amended protocol to minimise bad practice

None of these problems are specific to randomised trials

Thank you – any questions?

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