



## Review

## Realist randomised controlled trials: A new approach to evaluating complex public health interventions

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## ARTICLE INFO

## Article history:

Available online 7 September 2012

## Keywords:

Public health  
Complex interventions  
Evaluation  
Randomized controlled trials  
Social experiments  
Realism  
Generalizability  
Social epidemiology

## ABSTRACT

Randomized trials of complex public health interventions generally aim to identify what works, accrediting specific intervention ‘products’ as effective. This approach often fails to give sufficient consideration to how intervention components interact with each other and with local context. ‘Realists’ argue that trials misunderstand the scientific method, offer only a ‘successionist’ approach to causation, which brackets out the complexity of social causation, and fail to ask which interventions work, for whom and under what circumstances. We counter-argue that trials are useful in evaluating social interventions because randomized control groups actually take proper account of rather than bracket out the complexity of social causation. Nonetheless, realists are right to stress understanding of ‘what works, for whom and under what circumstances’ and to argue for the importance of theorizing and empirically examining underlying mechanisms. We propose that these aims can be (and sometimes already are) examined within randomized trials. Such ‘realist’ trials should aim to: examine the effects of intervention components separately and in combination, for example using multi-arm studies and factorial trials; explore mechanisms of change, for example analysing how pathway variables mediate intervention effects; use multiple trials across contexts to test how intervention effects vary with context; draw on complementary qualitative and quantitative data; and be oriented towards building and validating ‘mid-level’ program theories which would set out how interventions interact with context to produce outcomes. This last suggestion resonates with recent suggestions that, in delivering truly ‘complex’ interventions, fidelity is important not so much in terms of precise activities but, rather, key intervention ‘processes’ and ‘functions’. Realist trials would additionally determine the validity of program theory rather than only examining ‘what works’ to better inform policy and practice in the long-term.

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## Introduction

In this paper, we outline problems with the way complex public health interventions are sometimes evaluated using randomized controlled trials (RCTs) before examining ‘realist’ critiques of and proposed alternatives to RCTs. Realism in evaluation represents a paradigm through which the world is seen as an open system of dynamic structures, mechanisms and contexts that intricately influence the change phenomena that evaluations aim to capture (Kazi, 2003). Realistic evaluators argue that RCTs fail to test hypotheses rooted in theory and embrace a crude notion of causality based on comparison groups and statistical association

rather than understanding mechanisms. They argue that evaluators must develop a priori theories about how, for whom and under what conditions interventions will work and then use observational data to examine how context and intervention mechanism interact to generate outcomes. While we dispute the realists’ rejection of experimental designs in the social sciences (Pawson & Tilley, 1997), we agree with their arguments concerning the need for evaluation: to examine how, why and for whom interventions work; to give more attention to context; and to focus on the elaboration and validation of program theory. Some previous authors (Blackwood, O’Halloran et al., 2010) have argued for a synergistic, rather than oppositional, relationship between realist and randomized evaluation:

*The RCT can be used to ascertain whether, all other things being equal, a particular causal mechanism (intervention) is efficacious [i.e. effective under optimum conditions], while realistic evaluation*

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can establish what effect the interaction of other mechanisms operating in the open contexts studied has upon its effectiveness, and identify which mechanisms promote, and which inhibit that effectiveness (Blackwood et al., 2010, p. 519).

We would go further than this, however, to propose that RCTs themselves could contribute to a realist approach to evaluation. We examine the extent to which some RCTs are already embracing many of these issues and, bringing together some of these existing innovations alongside our own ideas, sketch out what 'realist RCTs' might look like. We argue that it is possible to benefit from the insights provided by realist evaluation without relinquishing the RCT as the best means of examining intervention causality.

### Current approaches to evaluating complex public health interventions

RCTs aim to generate minimally biased estimates of intervention effects by ensuring that intervention and control groups are not systematically different from each other in terms of measured and/or unmeasured characteristics. RCTs may randomly allocate individuals or 'clusters' of individuals, such as schools or villages; a method that should ensure that the groups are similar other than differences that occur due to chance. Random allocation is widely regarded as ethical if there is uncertainty about whether intervention confers significant benefits (Bonell, Bennett, & Oakley, 2003). There are formidable challenges to conducting RCTs to evaluate the impacts of complex interventions. Stakeholders, for instance, may resist RCTs out of a belief that randomly assigning participants could unduly deny some the expected benefits of an intervention, even if those benefits have not been demonstrated through rigorous evaluation. The results of RCTs of complex interventions may in some cases be diluted by 'contamination' effects, such as participants assigned to a control group participating in intervention group activities or other services that are similar to the intervention studied. Moreover, whereas RCTs of, for example, pharmacological interventions are commonly double-blinded (neither provider nor patient is aware to which arm the patient has been allocated), this is rarely the case with social interventions where such blinding is typically impractical. Thus, information bias in RCTs of complex social interventions is more likely. Despite these limitations, we support the view that RCTs provide the strongest evidence about the causal effects of social interventions and are generally feasible except in situations, for example, where intervention delivery is already universal or the pattern decided. They are generally ethical except in situations where some important intervention benefits are already known. In such cases, quasi-experimental designs that form comparison groups based on methods other than randomization, such as 'natural experiments' or trials using statistical matching techniques may be appropriate (Bonell, Hargreaves et al., 2011; Craig et al., 2008).

The predominant current approach to trialling complex public health interventions aims to identify which interventions work and replicate those that do via translation studies (Craig, Dieppe et al., 2008). There is concern that RCTs designed primarily to identify whether or not a specific intervention is effective have focused too much on the internal validity of the trial, addressing the question of efficacy rather than broader questions of reach, effectiveness, adoption, implementation and maintenance (Glasgow, Klesges et al., 2006). This has led to an evidence base that is dominated by high quality RCTs of poorly theorised interventions, with effects that are poorly understood and unlikely to be universally replicated in translation studies or real world implementation. This model of evidence generation is oriented towards 'accrediting' as effective specific intervention 'products'. This is quite explicit, for example,

in the conclusions of some systematic reviews (Farrington & Tofi, 2010) and the work of organisations such as Blueprints for Violence Prevention (Center for the Study and Prevention of Violence, 2011). Public health trialists do recognise a balance between maintaining fidelity and enabling adaptation of interventions (Breitenstein, Gross et al., 2010; Dane & Schneider, 1998), and some suggest that maintaining the integrity of an intervention's key functions (the elements in the process of change that the intervention components aim to facilitate) should be more important than maintaining the integrity of the specific actions used to achieve these (Durlack, 1998; Hawe, Shiell et al., 2004a). Nonetheless, these debates retain their focus on interventions as potentially generalizable products. The validation of theory does not generally receive the same emphasis in randomized trials or systematic reviews of complex public health interventions, although there are exceptions.

We argue that this product-oriented focus may not be appropriate because complex social interventions are different from other interventions, such as pharmacological ones. First, by definition, complex social interventions combine multiple, synergistic components, which are hypothesized to interact so that the sum of their effects is greater than the effects of their individual parts. One set of guidance suggests that "the greater the difficulty in defining precisely what exactly are the 'active ingredients' of an intervention and how they relate to each other, the greater the likelihood that you are dealing with a complex intervention" (Medical Research Council, 2000). Consider the example of the Intervention with Microfinance for AIDS and Gender Empowerment (IMAGE) intervention, which aims to reduce HIV infections among poor women and their children in rural South Africa by providing HIV health-education workshops, empowerment through peer-led community-development projects, and poverty relief through microfinance (Pronyk, Hargreaves et al., 2006). IMAGE is intended to work via an interaction of these components (Hargreaves, Bonell et al., 2008).

Second, complex interventions interact with context, meaning that their effectiveness will be dependent upon factors such as socio-economic and environmental conditions, organisational readiness, policy context and target population (Bonell, Oakley et al., 2006). Thus, the program theory needs to incorporate both the intervention theory and also an understanding of how the intervention interacts with context (Weiss, 1995). This is because local capacity to implement, as well as benefit from, such complex interventions varies and because such interventions usually exert effects via extended causal pathways, which play out differently in different settings.

Consider the example of youth development as a means to reduce teenage pregnancies. Such interventions, comprising mentoring, supplementary education on academic and life skills, and group activities to strengthen self-esteem and aspirations, have been found to be effective in New York City but not all parts of the USA (Kirby, Rhodes et al., 2005; Philliber et al., 2001). They may even have increased rates of teenage pregnancy in England (Wiggins, Bonell et al., 2009). Such variations in effect might plausibly be explained not only by variations in capacity and fidelity (e.g., programs outside of New York were not as well delivered so may have been less likely to bring benefits), but also by differences in how the interventions interact with mainstream services in different contexts (e.g., in England, the program was often an alternative rather than supplement to normal schooling; consequently participation may have caused young people to miss out educationally and feel labelled) and in the social determinants through which both intended and unintended effects operate (e.g., whereas in the USA, the intervention was delivered to all young people living in areas of dense deprivation, in England, where

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