



Title Randomized Control Trials for Policy Interventions: A Review of Reviews and Meta-Regression

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Aim

To determine whether randomized controlled trials (RCTs) lead to the same effect size and variance as nonrandomized studies (NRSs) of similar policy interventions, and whether these findings can be explained by other factors associated with the interventions or their evaluation.

Conclusions and results

Prior methodological reviews and meta-analyses of reviews comparing effects from RCTs and nonrandomized controlled trials (nRCTs) suggested that effect sizes from RCTs and nRCTs may differ in some circumstances, and these differences may be associated with factors confounded with design. Resampling studies offered no evidence that the absence of randomization directly influences the effect size of policy interventions in a systematic way. At the level of individual studies, nonrandomized trials may lead to different effect sizes, but this is unpredictable. Many of the examples reviewed and the new analyses in the current study reveal that randomization is associated with changes in effect sizes of policy interventions in field trials. Despite extensive analysis, we have identified no consistent explanations for these differences.

Recommendations

1) Policy evaluations should adopt randomized designs whenever possible. 2) Policy evaluations should also adopt other standard procedures for minimizing bias and conducting high-quality assessment of effects of intervention, particularly blinded allocation of either individuals or groups and the avoidance of small sample sizes. 3) Clear descriptions should be included in systematic reviews of how judgments of equivalence (or otherwise) have been reached when comparing the effects found in randomized and nonrandomized studies of policy interventions.

Methods

This study employed four approaches: 1) Resampling studies: comparing controlled trials that are identical in all respects other than the use of randomization by “breaking” the randomization in a trial to create smaller nonrandomized trials and smaller randomized trials by resampling randomized and nonrandomized comparisons from the data. 2) Replication studies: comparing randomized and nonrandomized arms of controlled trials mounted simultaneously in the field. 3) Investigating comparable field studies: controlled trials drawn from systematic reviews that include both randomized and nonrandomized studies. 4) Meta-epidemiology: investigating associations between randomization and effect size using a pool of more diverse randomized and nonrandomized studies in broadly similar areas. These more diverse studies can be drawn from across reviews addressing different questions, or from broad sections of literature. See Executive Summary link at www.hta.ac.uk/project/1572.asp.

Further research/reviews required

1) Feasibility studies of randomizing geographical areas, communities, and regions should be carried out to evaluate policy interventions in a range of sectors, implemented within interventions, communities, and across regions. 2) Feasibility studies of blinded allocation should be carried out for policy interventions in a range of sectors, implemented within interventions, communities, and across regions. 3) Research is required into the reasons for choosing randomization, or not, particularly in the presence and absence of an explicit collective plan of action.