Checklist For Reviewing a Randomized Controlled Trial of a Social Program or Project, To Assess Whether It Produced Valid Evidence

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This is a checklist of key items to look for in reading the results of a randomized controlled trial of a social program, project, or strategy ("intervention"), to assess whether it produced valid evidence on the intervention's effectiveness. This checklist closely tracks guidance from both the U.S. Office of Management and Budget (OMB) and the U.S. Education Department's Institute of Education Sciences (IES)[1]; however, the views expressed herein do not necessarily reflect the views of OMB or IES.

This checklist limits itself to key items, and does not try to address all contingencies that may affect the validity of a study's results. It is meant to aid – not substitute for – good judgment, which may be needed for example to gauge whether a deviation from one or more checklist items is serious enough to undermine the study's findings.

A brief appendix addresses *how many* well-conducted randomized controlled trials are needed to produce strong evidence that an intervention is effective.

Checklist for overall study design

☐ **Random assignment was conducted at the appropriate level – either groups (e.g., classrooms, housing projects), or individuals (e.g., students, housing tenants), or both.**

Random assignment of individuals is usually the most efficient and least expensive approach. However, it may be necessary to randomly assign groups – instead of, or in addition to, individuals – in order to evaluate (i) interventions that may have sizeable "spillover" effects on nonparticipants, and (ii) interventions that are delivered to whole groups such as classrooms, housing projects, or communities. (See reference 2 for additional detail.[2])

☐ **The study had an adequate sample size – one large enough to detect meaningful effects of the intervention.**

Whether the sample is sufficiently large depends on specific features of the intervention, the sample population, and the study design, as discussed elsewhere.[3] Here are two items that can help you judge whether the study you're reading had an adequate sample size:

- If the study found that the intervention produced *statistically-significant* effects (as discussed later in this checklist), then you can probably assume that the sample was large enough.

- If the study found that the intervention did *not* produce statistically-significant effects, the study report should include an analysis showing that the sample was large enough to detect meaningful effects of the intervention. (Such an analysis is known as a "power" analysis.[4])

Reference 5 contains illustrative examples of sample sizes from well-conducted randomized controlled trials conducted in various areas of social policy.[5]

Checklist to ensure that the intervention and control groups remained equivalent during the study

- ☐ **The study report shows that the intervention and control groups were highly similar in key characteristics prior to the intervention (e.g., demographics, behavior).**

- ☐ **If the study asked sample members to consent to study participation, they provided such consent *before* learning whether they were assigned to the intervention versus control group.**

  If they provided consent afterward, their knowledge of which group they are in could have affected their decision on whether to consent, thus undermining the equivalence of the two groups.

- ☐ **Few or no control group members participated in the intervention, or otherwise benefited from it (i.e., there was minimal "cross-over" or "contamination" of controls).**

- ☐ **The study collected outcome data in the same way, and at the same time, from intervention and control group members.**

- ☐ **The study obtained outcome data for a high proportion of the sample members originally randomized (i.e., the study had low sample "attrition").**

  As a general guideline, the study should obtain outcome data for at least 80 percent of the sample members originally randomized, including members assigned to the intervention group who did not participate in or complete the intervention. Furthermore, the follow-up rate should be approximately the same for the intervention and the control groups.

  The study report should include an analysis showing that sample attrition (if any) did not undermine the equivalence of the intervention and control groups.

- ☐ **The study, in estimating the effects of the intervention, kept sample members in the original group to which they were randomly assigned.** This even applies to:

  - Intervention group members who failed to participate in or complete the intervention (retaining them in the intervention group is consistent with an "intention-to-treat" approach); and

  - Control group members who may have participated in or benefited from the intervention (i.e., "cross-overs," or "contaminated" members of the control group).[6]

Checklist for the study's outcome measures

- ☐ **The study used "valid" outcome measures – i.e., outcome measures that are highly correlated with the true outcomes that the intervention seeks to affect.** For example:

  - Tests that the study used to measure outcomes (e.g., tests of academic achievement or psychological well-being) are ones whose ability to measure true outcomes is well-established.

- If sample members were asked to self-report outcomes (e.g., criminal behavior), their reports were corroborated with independent and/or objective measures if possible (e.g., police records).

- The outcome measures did not favor the intervention group over the control group, or vice-versa. For instance, a study of a computerized program to teach mathematics to young students should not measure outcomes using a computerized test, since the intervention group will likely have greater facility with the computer than the control group.[7]

☐ **The study measured outcomes that are of policy or practical importance – not just intermediate outcomes that may or may not predict important outcomes.**

As illustrative examples: (i) the study of a pregnancy prevention program should measure outcomes such as actual pregnancies, and not just participants' attitudes toward sex; and (ii) the study of a remedial reading program should measure outcomes such as reading comprehension, and not just the ability to sound out words.

☐ **Where appropriate, the members of the study team who collected outcome data were "blinded" – i.e., kept unaware of who was in the intervention and control groups.**

Blinding is important when the study measures outcomes using interviews, tests, or other instruments that are not fully structured, possibly allowing the person doing the measuring some room for subjective judgment. Blinding protects against the possibility that the measurer's bias (e.g., as a proponent of the intervention) might influence his or her outcome measurements. Blinding would be important, for example, in a study that measures the incidence of hitting on the playground through playground observations, or a study that measures the word identification skills of first graders through individually-administered tests.

☐ **Preferably, the study measured whether the intervention's effects lasted long enough to constitute meaningful improvement in participants' lives (e.g., a year, hopefully longer).**

This is important because initial intervention effects often diminish over time – for example, as changes in intervention group behavior wane, or as the control group "catches up" on their own.

Checklist for the study's reporting of the intervention's effects

☐ **If the study claims that the intervention has an effect on outcomes, it reports (i) the size of the effect, and whether the size is of policy or practical importance; and (ii) tests showing the effect is statistically significant (i.e., unlikely to be due to chance).**

These tests for statistical significance should take into account key features of the study design, including:

- Whether individuals (e.g., students) or groups (e.g., classrooms) were randomly assigned;

- Whether the sample was sorted into groups prior to randomization (i.e., "stratified," "blocked," or "paired"); and

- Whether the study intends its estimates of the intervention's effect to apply only to the sites (e.g., housing projects) in the study, or to be generalizable to a larger population.

- **The study reports the intervention's effects on all the outcomes that the study measured, not just those for which there is a positive effect.**

  This is so you can gauge whether any positive effects are the exception or the pattern. In addition, if the study found only a limited number of statistically-significant effects among many outcomes measured, it should report tests showing that such effects were unlikely to have occurred by chance.

Appendix: How many randomized controlled trials are needed to produce strong evidence of effectiveness?

To have strong confidence that an intervention would be effective if faithfully replicated, one generally would look for evidence including the following:

- **The intervention has been demonstrated effective, through well-conducted randomized controlled trials, in more than one site of implementation.**

  Such a demonstration might consist of two or more trials conducted in different implementation sites, or alternatively one large multi-site trial.

- **The trial(s) evaluated the intervention in the real-world community settings and conditions where it would normally be implemented** (e.g., community drug abuse clinics, public schools, job training program sites).

  This is as opposed to tightly-controlled conditions, such as specialized sites that researchers set up at a university for purposes of the study, or settings where the researchers themselves administer the intervention.

- **There is no strong countervailing evidence, such as well-conducted randomized controlled trials of the intervention showing an absence of effects.**

References

[1] U.S. Office of Management and Budget (OMB), What Constitutes Strong Evidence of Program Effectiveness, https://obamawhitehouse.archives.gov/sites/default/files/omb/part/2004_program_eval.pdf, 2004; U.S. Department of Education's Institute of Education Sciences, Identifying and Implementing Educational Practices Supported By Rigorous Evidence, http://www.ed.gov/rschstat/research/pubs/rigorousevid/index.html, December 2003; What Works Clearinghouse of the U.S. Education Department's Institute of Education Sciences, Key Items To Get Right When Conducting A Randomized Controlled Trial in Education, prepared by the Coalition for Evidence-Based Policy, http://coalition4evidence.org/wp-content/uploads/2012/05/Guide-Key-items-to-Get-Right-RCT.pdf.

[2] Random assignment of groups rather than, or in addition to, individuals may be necessary in situations such as the following:

(a) The intervention may have sizeable "spillover" effects on individuals other than those who receive it.

For example, if there is good reason to believe that a drug-abuse prevention program for youth in a public housing project may produce sizeable reductions in drug use not only among program participants, but also among their peers in the same housing project (through peer-influence), it is probably necessary to randomly assign whole housing projects to intervention and control groups to determine the program's effect. A study that only randomizes individual youth within a housing project to intervention versus control groups will underestimate the program's effect to the extent the program reduces drug use among both intervention and control-group students in the project.

(b) The intervention is delivered to groups such as classrooms or schools (e.g., a classroom curriculum or schoolwide reform program), and the study seeks to distinguish the effect of the intervention from the effect of other group characteristics (e.g., quality of the classroom teacher).

For example, in a study of a new classroom curriculum, classrooms in the sample will usually differ in two ways: (i) whether they use the new curriculum or not, and (ii) who is teaching the class. Therefore, if the study (for example) randomly assigns individual students to two classrooms that use the curriculum versus two classrooms that don't, the study will not be able to distinguish the effect of the curriculum from the effect of other classroom characteristics, such as the quality of the teacher. Such a study therefore probably needs to randomly assign whole classrooms and teachers (a sufficient sample of each) to intervention and control groups, to ensure that the two groups are equivalent not only in student characteristics but also in classroom and teacher characteristics.

For similar reasons, a study of a schoolwide reform program will probably need to randomly assign whole schools to intervention and control groups, to ensure that the two groups are equivalent not only in student characteristics but also school characteristics (e.g., teacher quality, average class size).

[3] What Works Clearinghouse of the U.S. Education Department's Institute of Education Sciences, *Key Items To Get Right When Conducting A Randomized Controlled Trial in Education*, op. cit., no. 1.

[4] Resources that may be helpful in reviewing or conducting power analyses include: Power Up! for designing and analyzing randomized experiments, at https://www.causalevaluation.org/power-analysis.html; Steve Raudenbush et. al., *Optimal Design Software for Group Randomized Trials*, at http://hlmsoft.net/od/; Peter Z. Schochet, *Statistical Power for Random Assignment Evaluations of Education Programs* (https://cire.mathematica-mpr.com/~/media/publications/pdfs/statisticalpower.pdf), prepared for the U.S. Education Department's Institute of Education Sciences, June 22, 2005; and Howard S. Bloom, "Randomizing Groups to Evaluate Place-Based Programs," in *Learning More from Social Experiments: Evolving Analytical Approaches*, edited by Howard S. Bloom. New York: Russell Sage Foundation Publications, 2005, pp. 115-172.

[5] Here are illustrative examples of sample sizes from well-conducted randomized controlled trials in various areas of social policy: (i) 4,028 welfare applicants and recipients were randomized in a trial of Portland Oregon's Job Opportunities and Basic Skills Training Program (a welfare-to work program), to evaluate the program's effects on employment and earnings – see https://evidencebasedprograms.org/programs/portland-jobs-training-program/; (ii) between 400 and 800 women were randomized in each of three trials of the Nurse-Family Partnership (a nurse home visitation program for low-income, pregnant women), to evaluate the program's effects on a range of maternal and child outcomes, such as child abuse and neglect, criminal arrests, and welfare dependency – see https://evidencebasedprograms.org/programs/nurse-family-partnership/; 206 9th graders were randomized in a trial

of Check and Connect (a school dropout prevention program for at-risk students), to evaluate the program's effects on dropping out of school – see https://evidencebasedprograms.org/programs/check-and-connect/; 56 schools containing nearly 6000 students were randomized in a trial of LifeSkills Training (a substance-abuse prevention program), to evaluate the program's effects on students' use of drugs, alcohol, and tobacco – see https://evidencebasedprograms.org/programs/lifeskills-training/.

[6] The study, after obtaining estimates of the intervention's effect with sample members kept in their original groups, can sometimes use a "no-show" adjustment to estimate the effect on intervention group members who actually participated in the intervention (as opposed to no-shows). A variation on this technique can sometimes be used to adjust for "cross-overs." See Larry L. Orr, *Social Experimentation: Evaluating Public Programs With Experimental Methods*, Sage Publications, Inc., 1999, p. 62 and 210; and Howard S. Bloom, "Accounting for No-Shows in Experimental Evaluation Designs," *Evaluation Review*, vol. 8, April 1984, pp. 225-246.

[7] Similarly, a study of a crime prevention program that involves close police supervision of program participants should not use arrest rates as a measure of criminal outcomes, because the supervision itself may lead to more arrests for the intervention group.