

A Guide to Incorporating Multiple Methods in Randomized Controlled Trials to Assess Intervention Effects

<http://www.apa.org/ed/schools/cpse/activities/mixed-methods.aspx>

1. Motivating policy/research questions

Given a desired policy outcome Y for population(s) P1, P1 . . . , what intervention (potential policy), X, might be effective, and under what conditions?

Construct an Intervention X to be tested by a study:

- What does theory suggest would be effective?
- What is known from previous research?
- Consider relevance for the population(s) of interest.

2. Desirability/feasibility of an RCT study

Desirability

- Is Intervention X well-enough developed/defined to warrant a controlled study, or are efficacy studies needed first to clarify constructs and establish the basic efficacy of the proposed interventions?
- Are the results generated likely to be worth the expense?

Feasibility

- Are the factors of interest amenable to experimental manipulation and control in the real world?
- Can an RCT be conducted without encountering ethical constraints?
- Is it likely that the study would gain the necessary cooperation and enough recruits to be assigned randomly to treatment conditions?
- Will funding be sufficient to support an RCT design with adequate statistical power?
- Will I know afterward what conditions are necessary for the intervention to be effective?

3. Employing multiple methods in designing and implementing RCTs

In light of what theory and prior research suggest, plan a study design that optimally addresses internal and external validity. In doing so, consider how multiple methods could enrich the information generated by the design.

CONSIDERATIONS FOR INTERNAL VALIDITY

Key question

What factors led to Intervention X working? Failing?
What factors led to Intervention X working for some groups and not others?

Research methods that might be employed to address this question

Include collection of baseline demographic and other measures to confirm that randomization was accomplished.

Use structured observations, and/or surveys to (1) assess fidelity of implementation, (2) document the existence of local policies and practices that might affect the outcomes of interest, and (3) document changes that occurred before and during the study (i.e., "history").

Use interviews or surveys to learn how subjects experienced the intervention.

Check measured outcomes for indications that Intervention X worked better for some groups than others.

Use more intensive interviews, case studies, and ethnographic research to investigate reasons for variability of effects within and between groups.

Does Intervention X remain effective when different outcome measures are used?

Include multiple quantitative outcome measures to assess different aspects of the desired outcomes (e.g., specialized outcome measures aligned with the purposes of Intervention X as well as more general measures such as standardized test scores).

Use case studies, interviews, and observations to detect unanticipated/unmeasured outcomes.

Are all of the components of Intervention X necessary for it to work, or are some unnecessary? Are some needed components missing?

Plan to measure the various intervention components; build in case studies to learn which components mattered to different subjects and to generate hypotheses about other components that might have made Intervention X more effective.

Are the treatment effects sustained over time?

Plan extended follow-ups, particularly of treatment group members, using both quantitative and qualitative data (e.g., achievement data, case studies, interviews).

CONSIDERATIONS FOR EXTERNAL VALIDITY

Key question

How do contextual factors affect the impact of Intervention X?

Research methods that might be employed to address this question

Use case studies, administrative data, interviews, and observations to document contextual factors (e.g., local policy environment, resources, cultural concerns, history) and how they might interact with Intervention X.

How close are the measured outcomes to outcomes of interest?

When designing the study, interview key stakeholders to determine the relevance/appropriateness of the outcome measures proposed for the study.

How would resource constraints affect the institutionalization of Intervention X if it were found to be effective?

Build collection of cost data into the study and conduct cost, cost-effectiveness, and cost-benefit analyses.

How do the details of the intervention and the controls imposed by the study design differ from the real-world conditions under which Intervention X might be implemented?

Collect and report descriptive data that will allow policymakers to assess the similarity of the sample population and setting to those in other situations to which they might want to generalize the results.

5. Exploring implications of research, policy, and next steps

Relate outcomes of the current study to findings from prior research:

- Do the results of this RCT confirm or contradict the results of other studies of similar interventions? Consider results from RCTs and other types of studies (e.g., quasi-experimental, correlational, and ethnographic).
- What factors may account for differences in results between this RCT and previous studies? Take account of variations in study design, characteristics of participants, outcome measures, settings, times, and fidelity of implementation.

Respond to finding positive effects:

- Consider policy implications.
- Decide whether further scale-up is needed. If so, decide whether replicate studies are needed before going to scale, and what the cost, cost-effectiveness, and cost-benefit of going to scale would be.

Respond to finding marginal effects:

- Examine the implementation data.
- Examine the design; check the analyses.
- Design new or additional studies to clarify results or abandon effort.

Respond to finding no effect:

- Examine the implementation data.
- Examine the design; check the analyses.
- Rethink theoretical model; plan for a new study or abandon effort.

4. Role of multiple methods in providing a deeper understanding of study findings

- In addition to using quantitative measures to assess outcomes, use data from case studies, interviews, surveys, and/or observations to interpret the observed outcomes (e.g., how intervention was experienced and responded to by subjects in differing circumstances).
- Use data from case studies and/or interviews to illustrate findings in a compelling manner.
- Examine quantitative and qualitative results to determine whether additional hypotheses (e.g., about additional outcomes, modifications to the intervention) might be pursued in subsequent studies or different stages of the current RCT.