Evans Center for Implementation & Improvement Sciences

BOSTON UNIVERSITY

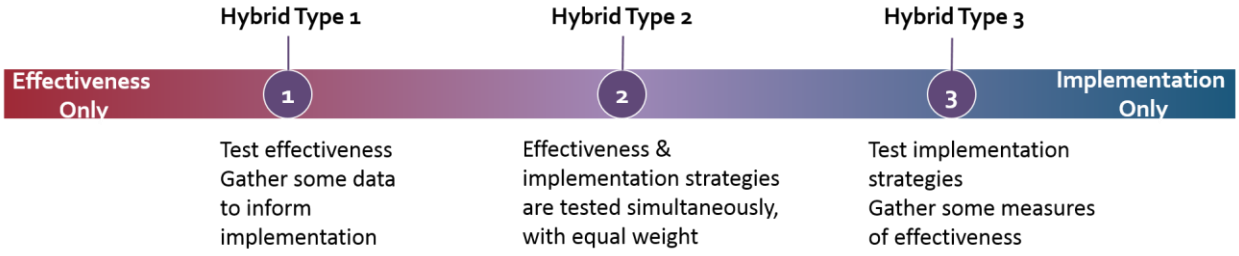
Study Design Toolkit

Overview: There is no best study design for all research questions. Each design has strengths and weaknesses. Choose study designs that correspond to your individual research questions. Considering the three questions below can help guide your design decisions. A brief overview of different study design types is included on pages 2-4.

Question 1: Am I interested in measuring both the effectiveness of an intervention and the implementation strategies?

No: Determine whether you are only studying the intervention's effectiveness (not implementation science) or are only studying the implementation strategies (implementation science).

Yes: Consider using a hybrid design approach. Hybrid design approaches evaluate both effectiveness and implementation strategies, and can be applied to most study designs. The figure below provides a visual description of hybrid types 1, 2, and 3.



Question 2: Do I want to collect quantitative or qualitative data, or use mixed methods?

Quantitative and qualitative data collection and analysis represent analytic approaches, not study designs. Quantitative and qualitative analysis, and mixed methods can be applied to almost any study design. Refer to the study design descriptions (pages 2-4) to consider how analytic approaches apply.

Question 3: Can I assign the exposure (e.g. intervention, implementation strategies)?

No: Observational design is the only study design option. See observational design options on page 2.

Yes: Consider whether you want to use an experimental or quasi-experimental design by asking Question 3.

Question 4: Can I randomize how the exposure (e.g. intervention, implementation strategies) is assigned?

No: If randomization is not an option, quasi-experimental designs may be used. See quasi-experimental design options on page 3.

Yes: An experimental design may be appropriate. See experimental design options on page 4.

OBSERVATIONAL STUDY DESIGNS

Overview: Observational studies allow you to observe but not manipulate variables. Observational designs are useful when you cannot assign the exposure.

Design	Strengths & Weaknesses
Cohort One or more samples are identified based on a defining characteristic, and observed prospectively/retrospectively to identify risk factors for an outcome of interest, and/or are interviewed/surveyed to describe their experience with an outcome of interest	+ Can assess multiple exposures, outcomes + Ability to control for multiple confounders + Can apply quantitative and/or qualitative analytic approaches – Requires interventions/implementation strategies to be studied in temporal sequence – Can be costly, time intensive
Cross-Sectional Identify a population based on exposure status to measure prevalence of an outcome, or common qualitative themes at one point in time	+ Can be less costly, less time consuming + Can assess multiple outcomes + Can apply quantitative and/or qualitative analytic approaches – Ambiguous temporal precedence – Exposure and outcome are simultaneously determined for individual participants
Case Study Identify a single phenomenon to focus on (e.g. patient, setting, event) within the context of the phenomenon's real-world setting	+ Useful for pre-implementation activities: in-depth understanding of studying readiness to change, identifying barriers and facilitators + No ambiguity of temporal precedence + Can apply quantitative and/or qualitative analytic approaches – No counterfactual – Multiple threats to internal validity
Case-Control Compare participants with the outcome of interest (cases) to participants who do not have the outcome (controls) to retrospectively analyze exposure risk factors and/or themes	+ Useful for identifying risk factors, predictors of outcomes + Can be less costly, less time-consuming + Can apply quantitative and/or qualitative analytic approaches – Selection bias – Difficult to calculate absolute risk of incidence

QUASI-EXPERIMENTAL STUDY DESIGNS

Overview: Quasi-experimental studies are useful when you cannot randomize.

Design	Strengths & Weaknesses
Uncontrolled Pre-Post Examines effect of an intervention by comparing a baseline quantitative measure or qualitative description to a post-intervention measure or description in a non-randomized group of participants	+ Simple + Can adjust for measured confounders + Can be improved by taking multiple pre-test observations, using a nonequivalent dependent variable, repeating treatment + Can apply quantitative and/or qualitative analytic approaches – No counterfactual – Common threats: history, maturation, selection bias
Controlled Pre-Post Pre- and post-intervention quantitative measures or qualitative descriptions are gathered on participants who are non-randomly assigned to receive the exposure (treatment group) and participants who are non-randomly assigned to not receive the exposure (control group)	+ Simple + Addition of the control group helps rule out history, maturity + Can apply quantitative and/or qualitative analytic approaches – Selection bias
Interrupted Time Series Multiple observations are taken before and after an intervention, with causal impact measured by a change in intercept or slope identified in post-intervention observations	+ Rules out several threats: maturation, secular trends – Common threats: history (potentially), selection (if the composition of the experimental group changes at the time of the intervention) – Time intensive – Requires knowledge about the timing of the intervention, potential for delayed effects – Quantitative by design (may add qualitative component by adding a second design)
Controlled Interrupted Time Series A control group that does not receive the intervention (interruption) is added to the interrupted time series design	+ Addition of control group helps rule out threat of history, maturation – Time intensive – Requires knowledge about the timing of the intervention, potential for delayed effects – Quantitative by design (may add qualitative component by adding a second design)
Regression Discontinuity A threshold is set for an assignment variable, and participants are assigned to treatment or control groups based on whether they fall above or below the threshold/cutoff score	+ Allows you to choose a clinically meaningful value to implement on + Participants assigned just above or below the threshold serve as counterfactuals – Requires identification of a meaningful threshold – Requires large sample size – Quantitative by design (may add qualitative component by adding a second design)

EXPERIMENTAL STUDY DESIGNS

Overview: Experimental studies use random assignment to determine the causal effect of an exposure (e.g. treatment, strategy) on an outcome.

Design	Strengths & Weaknesses
Cluster Randomized Trial Organization-level randomization is used to assign which cluster will receive the intervention as it is sequentially rolled out over time	+ Rules out contamination, secular time trends + Waived consent + Can apply quantitative and/or qualitative analytic approaches – Difficult power calculations – Not all sites receive the intervention, ethical concerns
Randomized Stepped-Wedge The intervention is sequentially rolled-out to individuals/clusters over time until all individuals/clusters are exposed, with the order of intervention roll-out randomly assigned	+ Intervention is rolled-out to all participants, avoiding ethical concerns + Waived consent + Can apply quantitative and/or qualitative analytic approaches – Requires multiple sites – Difficult power calculations – Confounding by secular time trends
Individual-Level Randomized Controlled Trial Individual participants are randomly assigned to receive the exposure (treatment group) or serve as a comparison (control group)	+ Gold standard for causal inference + Can measure potential confounders + Individual randomization controls selection bias + Can apply quantitative and/or qualitative analytic approaches – Potential for contamination – Expensive – Ethical concerns