



FACT SHEET | MAY 2022 | OPRE REPORT 2022-105

How Does the Prevention Services Clearinghouse Rate the Design and Execution of Studies?



After a study is deemed eligible for review, it is systematically reviewed using the Prevention Services Clearinghouse design and execution standards. Studies are assigned a rating of high, moderate, or low support of causal evidence, based on the extent to which they meet the standards.

The study design and execution standards assess the extent to which a study was designed and executed in a manner that indicates the program or service, and not any other factors, caused the observed outcomes. Chapter 5 of the <u>Handbook</u> provides details on the design and execution standards, and the <u>Reporting Guide</u> for <u>Study Authors</u> provides table shells and guidance on how to report information needed to evaluate studies against the design and execution standards.



How often do studies meet the Clearinghouse's study design and execution standards?

Just under a quarter of studies reviewed by the Clearinghouse receive high ratings (23%) and provide rigorous evidence indicating that the program or service caused the outcomes observed. Nearly a third of studies receive moderate ratings (28%) and provide some evidence that it was the program or service, and not other factors, that caused the outcomes observed. Nearly half of the studies receive low ratings (49%) and do not provide credible evidence that the program or service caused the outcomes observed. **Figure 1** depicts the distribution of study ratings.

Studies that receive moderate or high ratings **and** that have favorable effects in a target outcome domain can contribute to the Clearinghouse's program or service ratings of promising, supported, and well-supported.

What are the most common reasons that studies receive low ratings on the design and execution standards?

Studies may fail to meet design and execution standards for a variety of reasons, and some studies fail for multiple reasons. The most common reasons that studies do not meet design and execution standards are detailed below.

• The study does not establish baseline equivalence on pre-intervention measures (applicable to QEDs and RCTs with high attrition). If a study does not use random assignment, or random assignment is compromised due to attrition or other factors, the study must establish that the analytic samples of the intervention and comparison groups were equivalent on baseline measures prior to the implementation of the intervention. If the groups are different at the





beginning of a study, it is not clear whether differences observed at the end of a study are due to the program or to pre-existing differences across groups (Handbook Section 5.7).

• The impact of the intervention is confounded with another factor that is related to the outcome and only aligns with one group. In such cases, the study cannot isolate the effect of the intervention from the effect of the confounding factor (Handbook section 5.9). • The study includes participants who are missing some data, and the analysis does not use an acceptable approach for addressing missing data. Some approaches to missing data may bias the findings in favor of one group over the other, compromising the ability to assess whether the program or service was responsible for the outcomes observed (Handbook section 5.9).

Less frequently, studies fail to meet outcome standards or statistical model standards.

Can design and execution issues be addressed, and if so, how?

• Some design and execution issues cannot be addressed after the completion of a study, such as

when there is a design confound. For example, if an intervention is administered by a single therapist who does not also provide services to the control group (n=1 person-provider confound).

- Comprehensive reporting allows the Clearinghouse to assess whether design and execution standards can be met (see the <u>Reporting Guide for Study</u> <u>Authors</u> for advice on how to describe studies completely), or by responding to an author query from the Clearinghouse (e.g., providing internal consistency statistics for study measures).
- **Table 1** presents guidance to address common issues with design and execution standards along with examples of studies that do and do not meet standards.

Design or Execution Standard	Examples of Studies Not Meeting Standards	Approaches to Design and Execute Studies in Alignment with Standards
Baseline Equivalence Baseline equivalence is the extent to which the analytic intervention and comparison groups appear similar at baseline.	At baseline (just prior to the intervention), the treatment group's average score on the outcome measure is more than 0.25 standard deviations above or below the comparison group's average score.	Use matching techniques to ensure that treatment and comparison groups are similar at baseline. If the difference between the groups at baseline is between 0.05 and 0.25 standard deviations, include the pretest in the statistical model to adjust for these differences. See p. 14 of the <u>Reporting Guide for Study Authors</u> for a table shell example.
Confounds: N=1 Person- Provider Intervention effects cannot be separated from the skills/abilities of the treatment provider when the treatment group has a single provider, and the comparison group receives no treatment or has a different treatment provider.	A single therapist provides treatment to treatment group; comparison group is waitlisted and receives no treatment. The intervention is delivered in 2-person teams. A single team delivers all treatment; comparison group referred to services in the community.	Use two or more treatment provider units (e.g. therapists) in the treatment and comparison group. If only able to conduct a study with a single provider, have the provider also administer business-as-usual treatment to the comparison group.
 Missing Data Acceptable approaches to missing data on post-tests, pre-tests, or pre-test alternatives include: Complete case analysis Regression imputation Maximum likelihood Non-response weights Constant replacement 	A study author finds that 15% of the sample is missing information on an outcome measure. They decide to impute missing outcome data by carrying forward baseline data.	Use an eligible missing data technique: complete case analysis, regression imputation, maximum likelihood, non-response weights, or constant replacement. If missing data are imputed, include sample counts, means, and standard deviations on imputed and complete case samples for the comparison and intervention groups so the Clearinghouse can assess potential imputation bias. See the Appendix of the <u>Reporting Guide for Study</u> <u>Authors</u> for guidance on reporting missing or imputed data.
Outcome Measurement Standards To satisfy the reliability standards, the measure must have reliability of 0.50 or higher on internal consistency, test-retest reliability, or inter-rater reliability.	Study authors created their own measure of child well-being by adapting questions from an established measure. The authors did not report any reliability metrics.	Ensure that the study includes at least one outcome with internal consistency, test-retest reliability, or inter-rater reliability of 0.50 or greater, either by using measures with known reliability or by checking the reliability of customized measures. Report the reliability metrics of all outcomes in the study.
Statistical Model Impact models cannot include endogenous measures as covariates.	Study authors collected data on time spent in therapy sessions during the intervention period and included this measure in the statistical mode l of program impact.	Ensure that the statistical model does not include time-variant variables collected or obtained after baseline that could have been influenced by group status, such as implementation fidelity, attendance, or time spent in therapy sessions. Describe all covariates included in the model.

Table 1. Guidance for Addressing Common Issues with Design and Execution Standards

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