Home Visiting Evidence of Effectiveness Reporting Guide for Authors

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This document provides guidance on how to describe randomized controlled trials (RCTs) and quasi-experimental group design studies (QEDs) including single-case design studies (SCDs), regression discontinuity designs (RDDs) and non-experimental comparison group designs (NEDs), and to report their findings in a way that is clear, complete, and transparent. Reporting the information described below is considered a best practice in general, but can also help the Home Visiting Evidence of Effectiveness (HomVEE) review assess the appropriate rating to assign to the manuscript.[1]

If authors do not include in their manuscript information that HomVEE needs to rate the research, HomVEE will query the author for more information. HomVEE incorporates new information from authors only if (1) it is provided in direct response to an author query, and (2) authors submit it in time for reviewers to examine it during the same annual review cycle in which HomVEE issued the query. If authors provide new research (additional findings or new analyses of research in a previously reviewed manuscript, or it could be an entirely new set of findings) that was not requested in the author query, HomVEE treats the new research as a submission to the following year's call for research.

I. Manuscript characteristics

A. Abstract	Information provided in the manuscript abstract is useful for screening manuscripts and determining whether they are eligible for review. In the abstract, authors are encouraged to indicate what the intervention and comparison conditions are, how the intervention and comparison groups were formed, the setting of the research, who are the participants in the research, the outcomes examined, and the main findings of the research. Although a manuscript will not screen out due to missing information in the abstract, if the model is not named in the abstract it may not be included when that model is reviewed.
B. Intervention condition	Describe the early childhood home visiting model in enough detail for readers to know what is being tested. Clearly define the components of the model as implemented for the research described in the manuscript. Describe qualities such as frequency, intended duration, intensity, content, and delivery; required and available training and assistance for home visitors (and the source of that training or other implementation support); and caseload size and supervision for home visitors. If the model includes services in addition to home visits, describe the duration and intensity of each type of service. Describe the actual implementation of the early childhood home visiting model studied, including whether, and if so how the model has been adapted, the level and variation in duration and intensity, and home visitor training and assistance received. Indicate the model's name (including any former names), whether the model is a demonstration project, and how long the model had been operating when the study began.
C. Comparison condition	Indicate, ideally in both the abstract and the manuscript itself, how the comparison group was formed for group design studies (such as through random assignment or a matching procedure). Describe the comparison condition on dimensions similar to those described for the intervention condition. If it includes an intervention, describe the comparison intervention and clearly define the components such as frequency, intended duration, intensity, content, and delivery of services as actually implemented (rather than as intended to be implemented).

[1] This author reporting guide is modeled after and includes language from an author reporting guide developed by the What Works Clearinghouse (WWC), a project of the U.S. Department of Education's Institute of Education Sciences. The HomVEE review is grateful to the WWC for introducing the concept of an author reporting guide and for having published the guide on which this is modeled.

D. Setting	Describe the location and timing of the research described in the manuscript, including when (that is, date) intervention services began and ended; indicators of the characteristics of the setting, such as region and urbanicity; and whether the study was conducted in the United States. If relevant, clarify how the manuscript relates to any larger study or evaluation effort (for example, noting that it is part of an evaluation whose design and results are also reported in other specific manuscripts).
E. Participants	Include as much of the following as possible in the manuscript itself, with a summary of participant information in the manuscript abstract: • Indicate the number of individuals and/or families in the study sample being examined in the manuscript. • If relevant, indicate whether the study sample is a subgroup of a larger evaluation. • Describe the characteristics of the study participants before program services began (at baseline), • including: – Race and ethnicity, including any tribal or indigenous affiliation, ideally for both parents and children. – Age of participants, both parents and children. – Socioeconomic status (SES). Specific economic well-being measures (such as income, earnings, or poverty levels according to federal thresholds) and maternal education are the preferred measures of SES. Alternative measures of SES, such as mean-tested assistance and employment of at least one member in the household are sufficient if at least two of those alternative measures are provided. – Baseline measures of the outcomes of interest, if they are age or developmentally appropriate to collect. (For instance, child outcomes are not feasible to collect at baseline if the sample enrolls members during the mother's pregnancy.) • Indicate whether **all** families or participants in the study sample are members of any of the following populations:[2] – Families with low income – Families who are pregnant women who have not attained age 21 – Families that have a history of child abuse or neglect or have had interactions with child welfare services – Families that have a history of substance abuse or need substance abuse treatment – Families that have users of tobacco products in the home – Families that are or have children with low student achievement – Families with children with developmental delays or disabilities – Families who, or that include, individuals who are serving or have formerly served in the Armed Forces, including such families that have members of the Armed Forces who have had multiple deployments outside of the United States
F. Funding source and author affiliation	Describe the source of support for research on the early childhood home visiting model, indicate whether the manuscript has been peer-reviewed, and report any author(s)' affiliation as a developer of the model.

[2] The study populations listed are priority populations in the Maternal, Infant, and Early Childhood Home Visiting statute (42 U.S.C. § 711 (d) (4)).

II. Study design and analysis

A. Sample formation	Describe how the study sample was identified, including what constitutes eligibility for the study and for the early childhood home visiting intervention, if that differs from eligibility for the study in general. Clearly state the unit of assignment, especially if it differs from the unit of analysis (for instance, counties assigned to different conditions in a study that analyzes children's outcomes and not county averages). For randomized controlled trials, describe the random assignment process and any anomalies in it. For non-experimental comparison group designs, describe how the intervention and comparison groups were formed.
B. Measures	In the abstract, indicate the key outcomes that the study was testing. In the manuscript itself, for each outcome measure used in the study and for variables describing participants' characteristics, describe the measure, how it was collected, when it was collected, and how to interpret it if necessary. For each measure, provide the source of the measure and indicate what it was designed to measure. If available, provide a reliability statistic for each outcome measure (for example, inter-assessor agreement measures for observational data, or Cronbach's alpha for internal consistency). See Appendix B of the HomVEE Version 2 Handbook of Procedures and Evidence Standards (Version 2 Handbook) for more detail on which outcomes HomVEE sorts into which domains.
C. Analytic approach	For RCTs NEDs and RDDs the authors must describe the analytic models and methods used to estimate the effects of the home visiting program and, where relevant, the method used to calculate reported effect sizes. Describe the unit of analysis. If the analysis uses a structural equation model approach, HomVEE requires authors to include the degrees of freedom and a path diagram of the analysis approach. For single-case design studies, describe the design type(s), such as reversal-withdrawal or multiple baseline. For each case, document the number of phases and the number of data points within each phase. Authors must also specify whether the researcher determined when and how the treatment conditions (or phases) changed.
D. Statistical adjustments	Include controls for race/ethnicity, SES (see Table I, row E), and any measures of the outcomes that were feasible to assess at baseline. Describe all control variables used in the analyses (definitions, means, and standard deviations). Where relevant, also describe adjustments made to standard errors to account for clustering of the sample (for example, within counties) and adjustments made to statistical significance levels to account for the analysis of multiple outcomes within the same domain or use of the same intervention or comparison groups in multiple analyses of the same outcomes.
E. Missing data	Describe the method for addressing missing data (for example, case deletion, nonresponse weights, imputation) for both outcomes and control variables and, if relevant, the method used to adjust the standard errors of the impact estimates to account for the missing data.
F. Analyses not eligible for review	HomVEE's annual review focuses on the question of whether an early childhood home visiting model is effective, so research that isolates the effectiveness of a feature of a model or that calculates the combined impact of multiple models is generally ineligible for review. Mediating analyses are excluded by HomVEE, unless authors depict the analyses as structural equation models (see Section C.3 in Chapter III of the HomVEE Version 2 Handbook for reviewing structural equation models), which are eligible for review by HomVEE. HomVEE also excludes analyses with continuous moderator variables. Exception: if a moderator variable is binary (for example, primiparous versus multiparous mothers), and if authors provide enough data to complete the review, HomVEE may review moderating analyses as subgroup analyses. (See Exhibit II.10 in the HomVEE Version 2 Handbook for details on how HomVEE handles subgroup research.) In addition, HomVEE excludes analyses that control for endogenous characteristics, including analyses of endogenous subgroups.

III. Data *(see associated tables on pages 5–6)*

A. Pre-intervention data, baseline sample (Table 1)	If the design is a randomized controlled trial, provide sample sizes for key background characteristics (including race/ethnicity and SES) and for baseline measures of the outcomes (if feasible to collect at baseline) for the sample that was randomly assigned. If the unit of assignment to condition is not the same as the unit of analysis, provide sample sizes at both the level of group assignment (such as counties) and level of analysis (for example, mother or child). If multiple samples are analyzed, provide this information separately for each research group (intervention and comparison) within each sample. In study designs in which random assignment occurred at the individual/family unit level (so the unit of assignment and the unit of analysis are the same: the individuals/family units), the measures used to establish baseline equivalence of individuals/family units must be at the individual/family unit level. That is, measures at an aggregate level (such as community- or county-level measures, for example) are not acceptable to show baseline equivalence of the sample of individuals/family units in designs in which individual or family units are assigned to intervention or comparison groups.
B. Pre-intervention data, analytic sample (Table 2)	For RCTs, NEDs, and RDDs, provide sample sizes, means, and standard deviations for race/ethnicity and SES and for baseline measures of the outcomes (or closely associated variables) for the sample that was analyzed.
C. Post-intervention data and findings (Table 3)	For RCTs, NEDs, and RDDs, provide means and standard deviations for the intervention and comparison groups, and the impact estimate along with the p-value for this estimate, for each outcome measure used in the study and for each follow-up period assessed. HomVEE prefers adjusted means, unadjusted standard deviations, and adjusted p-values, but will rely on whatever authors submit. Clear labeling of what has and has not been adjusted is helpful. HomVEE also prefers to report author-calculated effect sizes,[3] if available, but this is not a requirement
D. Special cases	For studies that calculated both the effect of the intent to treat (ITT) and the effect of the treatment on the treated, HomVEE prefers to see and review the ITT findings. For group designs (RCTs and NEDs) HomVEE requests authors provide the sample sizes for both intervention and comparison groups in the assigned and the analytic samples so HomVEE can compute attrition for the analytic sample. For regression discontinuity design studies, HomVEE requests authors report overall and differential attrition rates for the analytic sample (those above and below the threshold or cut-off point) following the criteria described in Appendix C in the HomVEE Version 2 Handbook. For studies that include repeated measures analyses, HomVEE requests that authors report estimates separately for each follow-up time point. For studies with single-case designs, HomVEE requests that authors submit their raw data in graphical or tabular format, to support analyses that will calculate a design-comparable effect size (see Table 4 and Appendix D of the HomVEE Version 2 Handbook for details on standards and procedures for reviewing these studies). These data should be provided for all cases and phases.
E. Open science practices	HomVEE wishes to emphasize the importance of open science practices, and encourages authors to clearly indicate details related to all eight open science practices (see Table 5).

[3] HomVEE is interested in knowing the approach authors used to calculate effect sizes. For that reason, HomVEE suggests (but does not require) that authors report the approach they used to calculate effect sizes.

The first four tables below are examples that can be used to report the data from studies based on randomized controlled trials, non-experimental comparison group designs, and single-case designs, as described in Section III on page 4. The fifth defines core open science practices that HomVEE encourages authors to adopt.

Table 1. Pre-intervention sample sizes and characteristics for the baseline sample (see III.A.)

	Intervention group		Comparison group	
	Sample sizes		Sample sizes	
Baseline measures	Unit of assignment	Unit of analysis	Unit of assignment	Unit of analysis
Measure 1				
Measure 2				
Measure 3				

*Table 1 gives information on **sample sizes** for the **baseline sample**, for both the intervention and comparison groups. This information is useful for determining **sample attrition** in randomized controlled trials.*

Table 2. Pre-intervention sample sizes and characteristics for the analytic sample (see III.B.)

	Intervention group				Comparison group			
	Sample sizes		Sample characteristics		Sample sizes		Sample characteristics	
Baseline measures	Unit of assignment	Unit of analysis	Mean	Standard deviation	Unit of assignment	Unit of analysis	Mean	Standard deviation
Measure 1								
Measure 2								
Measure 3								

*Table 2 gives information on **sample sizes** and **pre-intervention characteristics** for the **analytic sample**, for both the intervention and comparison groups. This information on **sample sizes**, **means**, and **standard deviations** is needed to calculate the **effect size** of the difference between intervention and comparison groups in the pre-intervention measure. HomVEE uses effect sizes to confirm baseline equivalence**; it is also used in conjunction with information in Table 1 to determine sample attrition for randomized controlled trials**.*

Table 3. Post-intervention outcomes for the analytic sample, and estimated effects (see III.C.)

	Intervention group		Comparison group		Estimated effects		
Outcome measures	Mean	Standard deviation	Mean	Standard deviation	Mean difference	*p*-value (0.XXXX)	Effect size
Measure 1							
Measure 2							
Measure 3							

*Table 3 gives information on **post-intervention** outcomes for the **analytic sample**, for both the intervention and comparison groups, along with information useful for determining t**he magnitude and significance of mean differences in outcomes between the intervention and comparison groups in their outcomes**. Reporting both the effect size and statistical significance is preferred, but not required.*

Table 4. Raw data for each case and phase, from each single-case design (see III.D.)

Case	Outcome	Phase	Session number (x-axis)	Outcome value (y-value)

*Table 4 contains raw outcome data for **each case** by **phase** and **session number**, which are necessary to compute a **design-comparable effect size (D-CES)** for **single-case design experiments**. A D-CES can be computed for multiple baseline and multiple probe designs across cases, if the design has three or more cases; a D-CES can be computed for a study by using a series of reversal withdrawal designs if the study includes reversal withdrawal design data, on the same outcome, for three or more cases. In addition to data provided in this table, authors should report: (1) whether **inter-assessor agreement (IAA) data** were collected for each eligible outcome at least once in each phase, (2) the percentage of sessions **in each condition** for which IAA data were collected, (3) and the inter-assessor agreement value for **each outcome variable**.*

Table 5. Open science practices based on the Transparency and Openness Promotion guidelines

Practice	Definition
Study registration	Studies should be included in a structured, web-based, publicly accessible registry.
Protocol and statistical analysis plan	Study methods and analytical procedures should be established before starting data collection.
Data, code, and materials sharing	Data, code, and research materials should be made available to the public.
Design and analysis transparency	Study methods should be reported according to discipline- and design-specific standards.
Public availability of results	Summary information on study outcomes should be freely available to the public.
Replication	Original studies showing beneficial effects should be repeated on a new sample.
Investigator conflicts of interest	Interests that could influence the validity of research should be declared in study reports.
Citation standards	Data, code, and research materials should be cited appropriately in References section of reports.

Source: Transparency of Research Underpinning Social Intervention Tiers (TRUST) Initiative summary provided to HomVEE. For more information, please see https://www.trustinitiative.org/home.

Note: HomVEE encourages authors to clearly indicate details related to all eight open science practices described in this table.