Home Visiting Evidence of Effectiveness Standards for Randomized Controlled Trials with Individual-Level Randomization

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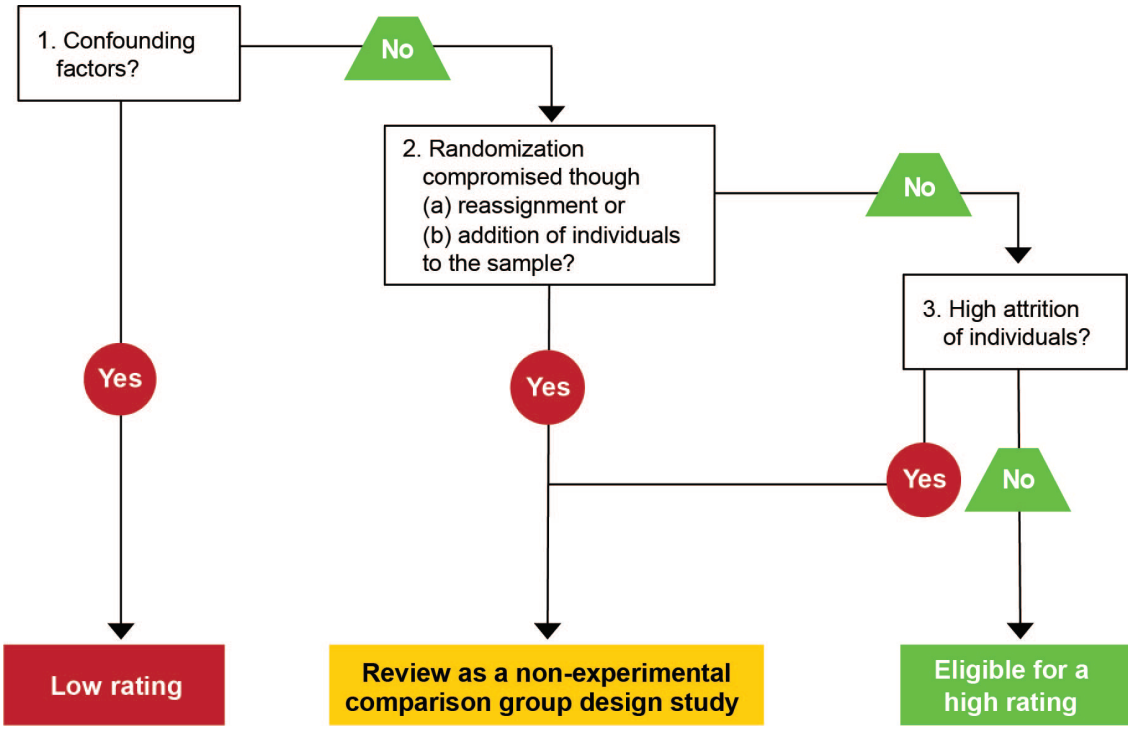

Note: To receive a rating of high, the research under review must also have at least one finding that is based on an eligible outcome and that meets the validity and reliability requirements described in Section III.B.4 of the HomVEE Procedures and Evidence Standards: Version 2. Additionally, if findings are based on imputed missing outcome data, they must meet additional requirements, as described in Appendix E.

Source: HomVEE Handbook of Procedures and Evidence Standards: Version 2. Available at https://homvee.acf.hhs.gov/publications/methods-standards

Flowchart definitions for randomized controlled trials with individual-level randomization

Confounding factors: Confounding factors occur when an element of the research design or methods, other than the model of interest, is associated with only the intervention or only the comparison group. This creates a difference that is in addition to the intervention between the intervention and comparison groups, making it impossible to isolate the impact of the intervention from that of the confounding element. A confounding factor is any observed element that is completely aligned with either the intervention or comparison group. This means, that the factor is present only in the intervention group or only in the comparison group, but not both. For example, if a single home visitor administers all the intervention services but none of the comparison services, it is impossible to distinguish the effect of that home visitor from the effect of the intervention. Confounding factors may also arise from systematic differences in the way data are collected for the intervention group versus the comparison group. For example, if program staff collected data from all participants in the intervention group, but data for the comparison group came from an administrative data set, the difference in data collection approach would be considered a confounding factor.

Reassignment: Sample members are moved from their originally assigned condition to another condition after random assignment and/or are analyzed in different groups than the ones to which they were randomly assigned. For example, a woman was randomly assigned to the comparison group but was analyzed as part of the intervention group.

Addition of individuals to the sample: Individuals who enter the intervention or comparison groups in an individual-level RCT after random assignment has occurred are known as *joiners*. Joiners compromise an individual-level RCT because they change the composition of the randomly assigned intervention and comparison groups. That is, after joiners enter the sample, the intervention and comparison groups in an individual-level RCT are no longer the same groups that were originally assigned (randomly) to each condition (intervention or comparison).

High attrition: Attrition is the loss of sample members from the study. Attrition typically occurs if: (1) some sample members refuse to participate; (2) researchers are unable to locate some sample members; or (3) researchers exclude originally assigned sample members from the study (for any reason). High attrition occurs when too large a portion of the original sample is not included in the analysis. This can be a problem in a random assignment study if the people remaining in the groups are no longer equivalent, on average. For more information about HomVEE's attrition standards, see https://homvee.acf.hhs.gov/sites/default/files/2019-06/HomVEE-Attrition-White_Paper-7-2015.pdf and https://homvee.acf.hhs.gov/publications/methods-standards.

Imputation: Imputation is a statistical approach that authors use to estimate missing data points when data are missing from a study or for some cases overall or at some follow-up points.