

AACPDM Systematic Review Method: Rating the Strength of the Conduct of Group Studies

This paper was developed to guide and improve the reliability of decision-making when evaluating the group studies in a systematic review for the strength of how well the study was conducted. There are six conduct study questions but they should be analyzed as follows to assist in understanding whether the maximum controls permitted by the study design (level of evidence) were, indeed, present in how this study was conducted.

Also, note the Dictionary section below to understand the definitions of terms used in this methodology.

Select one answer for each of the following questions.

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SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?

- 1. very likely
- 2. somewhat likely
- 3. not likely
- 4. can't tell

(Q2) What percentage of selected individuals agreed to participate?

- 1. 80-100% agreement
- 2. 60-79% agreement
- 3. less than 60% agreement
- 4. not applicable
- 5. can't tell

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STUDY DESIGN

(Q1) Indicate the study design

- 1. Randomized controlled trial
- 2. Controlled clinical trial
- 3. Cohort analytic (two group pre+post)
- 4. Case-control
- 5. Cohort (one group pre + post (before and after))
- 6. Interrupted time series
- 7. Other specify _____

- 8. Can't tell

(Q2) Was the study described as randomized? If NO, go to Component C.

- 1. No • 2. Yes

(Q3) If Yes, was the method of randomization described? (See dictionary)

- 1. No • 2. Yes

(Q4) If Yes, was the method appropriate? (See dictionary)

- 1. No • 2. Yes

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CONFOUNDERS

(Q1) Were there important differences between groups prior to the intervention?

- 1. Yes
- 2. No
- 3. Can't tell

The following are examples of confounders:

- Race
- Sex
- Marital status/family
- Age
- SES (income or class)
- Education
- Health status
- Pre-intervention score on outcome measure

(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?

- 1. 80-100%

- 2. 60-79%
- 3. Less than 60%
- 4. Can't tell

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BLINDING

(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?

- 1. Yes
- 2. No
- 3. Can't tell

(Q2) Were the study participants aware of the research question?

- 1. Yes
- 2. No
- 3. Can't tell

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DATA COLLECTION METHODS

(Q1) Were data collection tools shown to be valid?

- 1. Yes
- 2. No
- 3. Can't tell

(Q2) Were data collection tools shown to be reliable?

- 1. Yes
- 2. No
- 3. Can't tell

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WITHDRAWALS AND DROP-OUTS

(Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?

- 1. Yes
- 2. No
- 3. Can't tell

(Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).

- 1. 80-100%
- 2. 60-79%
- 3. Less than 60%
- 4. Can't tell

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INTERVENTION INTEGRITY

(Q1) What percentage of participants received the allocated intervention or exposure of interest?

- 1. 80-100%
- 2. 60-79%
- 3. Less than 60%
- 4. Can't tell

(Q2) Was the consistency of the intervention measured?

- 1. Yes
- 2. No
- 3. Can't tell

(Q3) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?

- 1. Yes
- 2. No
- 3. Can't tell

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ANALYSIS

(Q1) Indicate the unit of allocation (check one)

- 1. community
- 2. organization/institution
- 3. practice/office
- 4. individual

(Q2) Indicate the unit of analysis (check one)

- 1. community
- 2. organization/institution
- 3. practice/office
- 4. individual

(Q3) Are the statistical methods appropriate for the study design?

- 1. Yes
- 2. No
- 3. Can't tell

(Q4) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?

- 1. Yes
- 2. No
- 3. Can't tell

Dictionary

The purpose of this dictionary is to describe items in the tool thereby assisting raters to score study quality. Due to under-reporting or lack of clarity in the primary study, raters will need to make judgments about the extent that bias may be present. When making judgments about each component, raters should form their opinion based upon information contained in the study rather than making inferences about what the authors intended.

A) SELECTION BIAS

(Q1) Participants are more likely to be representative of the target population if they are randomly selected from a comprehensive list of individuals in the target population (score very likely). They may not be representative if they are referred from a source (e.g. clinic) in a systematic manner (score somewhat likely) or self-referred (score not likely).

(Q2) Refers to the % of subjects in the control and intervention groups that agreed to participate in the study before they were assigned to intervention or control groups.

B) STUDY DESIGN

In this section, raters assess the likelihood of bias due to the allocation process in an experimental study. For observational studies, raters assess the extent that assessments of exposure and outcome are likely to be independent. Generally, the type of design is a good indicator of the extent of bias. In stronger designs, an equivalent control group is present and the allocation process is such that the investigators are unable to predict the sequence.

Randomized Controlled Trial (RCT)

An experimental design where investigators randomly allocate eligible people to an intervention or control group. A rater should describe a study as an RCT if the randomization sequence allows each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. If the investigators do not describe the allocation process and only use the words 'random' or 'randomly', the study is described as a controlled clinical trial.

See below for more details.

Was the study described as randomized?

Score **YES**, if the authors used words such as random allocation, randomly assigned, and random assignment.

Score **NO**, if no mention of randomization is made.

Was the method of randomization described?

Score **YES**, if the authors describe any method used to generate a random allocation sequence.

Score **NO**, if the authors do not describe the allocation method or describe methods of allocation such as alternation, case record numbers, dates of birth, day of the week, and any allocation procedure that is entirely transparent before assignment, such as an open list of random numbers of assignments. If **NO** is scored, then the study is a controlled clinical trial.

Was the method appropriate?

Score **YES**, if the randomization sequence allowed each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. Examples of appropriate approaches include assignment of subjects by a central office unaware of subject characteristics, or sequentially numbered, sealed, opaque envelopes.

Score **NO**, if the randomization sequence is open to the individuals responsible for recruiting and allocating participants or providing the intervention, since those individuals can influence the allocation process, either knowingly or unknowingly.

If **NO** is scored, then the study is a controlled clinical trial.

Controlled Clinical Trial (CCT) An experimental study design where the method of allocating study subjects to intervention or control groups is open to individuals responsible for recruiting subjects or providing the intervention. The method of allocation is transparent before assignment, e.g. an open list of random numbers or allocation by date of birth, etc.

Cohort analytic (two group pre and post) An observational study design where groups are assembled according to whether or not exposure to the intervention has occurred. Exposure to the intervention is not under the control of the investigators. Study groups might be non-equivalent or not comparable on some feature that affects outcome.

Case control study A retrospective study design where the investigators gather 'cases' of people who already have the outcome of interest and 'controls' who do not. Both groups are then questioned or their records examined about whether they received the intervention exposure of interest.

Cohort (one group pre + post (before and after)) The same group is pretested, given an intervention, and tested immediately after the intervention. The intervention group, by means of the pretest, act as their own control group.

Interrupted time series A time series consists of multiple observations over time. Observations can be on the same units (e.g. individuals over time) or on different but similar units (e.g. student achievement scores for particular grade and school). Interrupted time series analysis requires knowing the specific point in the series when an intervention occurred.

C) CONFOUNDERS

By definition, a confounder is a variable that is associated with the intervention or exposure and causally related to the outcome of interest. Even in a robust study design, groups may not be balanced with respect to important variables prior to the intervention. The authors should indicate if confounders were controlled in the design (by stratification or matching) or in the analysis. If the allocation to intervention and control groups is randomized, the authors must report that the groups were balanced at baseline with respect to confounders (either in the text or a table).

D) BLINDING

(Q1) Assessors should be described as blinded to which participants were in the control and intervention groups. The purpose of blinding the outcome assessors (who might also be the care providers) is to protect against detection bias.

(Q2) Study participants should not be aware of (i.e. blinded to) the research question. The purpose of blinding the participants is to protect against reporting bias.

E) DATA COLLECTION METHODS

Tools for primary outcome measures must be described as reliable and valid. If 'face' validity or 'content' validity has been demonstrated, this is acceptable. Some sources from which data may be collected are described below:

Self reported data includes data that is collected from participants in the study (e.g. completing a questionnaire, survey, answering questions during an interview, etc.).

Assessment/Screening includes objective data that is retrieved by the researchers. (e.g. observations by investigators).

Medical Records/Vital Statistics refers to the types of formal records used for the extraction of the data.

Reliability and validity can be reported in the study or in a separate study. For example, some standard assessment tools have known reliability and validity.

F) WITHDRAWALS AND DROP-OUTS

Score **YES** if the authors describe BOTH the numbers and reasons for withdrawals and drop-outs. Score **NO** if either the numbers or reasons for withdrawals and drop-outs are not reported. The percentage of participants completing the study refers to the % of subjects remaining in the study at the final data collection period in all groups (i.e. control and intervention groups).

G) INTERVENTION INTEGRITY

The number of participants receiving the intended intervention should be noted (consider both frequency and intensity). For example, the authors may have reported that at least 80 percent of the participants received the complete intervention. The authors should describe a method of measuring if the intervention was provided to all participants the same way. As well, the authors should indicate if subjects received an unintended intervention that may have influenced the outcomes. For example, co-intervention occurs when the study group receives an additional intervention (other than that intended). In this case, it is possible that the effect of the intervention may be over-estimated. Contamination refers to situations where the control group accidentally receives the study intervention. This could result in an under-estimation of the impact of the intervention.

H) ANALYSIS APPROPRIATE TO QUESTION

Was the quantitative analysis appropriate to the research question being asked?

An intention-to-treat analysis is one in which all the participants in a trial are analyzed according to the intervention to which they were allocated, whether they received it or not. Intention-to-treat analyses are favoured in assessments of effectiveness as they mirror the noncompliance and treatment changes that are likely to occur when the intervention is used in practice, and because of the risk of attrition bias when participants are excluded from the analysis.