WRITING REPORTS FOR RANDOMIZED CONTROL TRIALS – CONSORT

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Introduction

The CONSORT statement—an acronym that represents the Consolidated Standards of Reporting Trials—is a checklist writers should utilize when they report a randomized control trial. To clarify, researchers often compare two or more conditions, such as two teaching methods. In many of these studies, the participants or units are randomly assigned to these conditions. This design is called a randomized control trial or, sometimes, merely an experiment. CONSORT is a set of principles that researchers should apply whenever they report a randomized control trial.

**Illustration**

 Suppose a researcher wants to explore whether lecturers who wear casual attire enhance student engagement more than do lectures who wear formal attire. In this study, computer software is utilised to random allocate students to these lecturers. That is, half the students watch a lecturer who wears casual attire. The other students watch the same lecturer wearing formal attire.

**Purpose of this document**

 This document specifies every CONSORT principle, clarifies these principles, and presents some examples to illustrate each principle. These principles do not encompass every paragraph you should include. Instead, these principles stipulate the most important details you should include. After you read this document, you might then enter “tinyurl.com/y3e8j7ak” into your web browser to peruse more detailed examples and explanations.

**CONSORT CHECKLIST**

This first series of tables specifies each principle. In addition, the third column includes some comments to clarify each principle.

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| Title and abstract |
| Item | Description of the item | Clarification |
| 1 Title and abstract | 1a Identification as a randomised trial in the title | * Often, when conducting systematic literature reviews, researcher may want to limit their searches to randomized control trial
* Thus, the phrase “randomized control trial” in the title, often after a colon, enables researchers to achieve this goal
 |
|   | 1b Structured summary of trial design, methods, results, and conclusions | * Some journals encourage or permit authors to write abstracts that include subheadings, such as aim, trial design, methods, results, and conclusions
* When an abstract comprises a series of subheadings, the key information is easier for other readers to distil
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| Introductionn |
| Item | Description of the item | Clarification |
| 2 Background and objectives | 2a Scientific background and explanation of rationale | The reader needs to understand the rationale to justify the treatment or intervention the study evaluates |
|   | 2b Specific objectives or hypotheses |  |

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| Methods |
| Item | Description of the item | Clarification |
| 3 Trial design | 3a Description of trial design, such as parallel or factorial, including allocation ratio | Researchers can apply a variety of designs such a* parallel designs in which participants are merely allocated to one of two conditions—usually an intervention and a control.
* multi-arm parallel designs—in which participants are allocated to one of several treatments or a control condition
* multi-arm, multi-stage designs—the same as multi-arm parallel designs except, if one treatment is not working, researchers will refrain from assigning more participants to this condition midway during the study
* cluster randomized control designs—in which clusters of individuals, such as communities or schools, rather than specific individuals, are randomly allocated to conditions
* cross-over designs—in which half the participants complete the first condition and then the second condition and the other participants receive the opposite order
* factorial designs—in which usually two treatments are tested; individuals are randomly allocated to receive zero, one, or both treatments.

In most but not all instances, the same number of individuals is assigned to each condition.  |
|   | 3b Important changes to methods after trial commencement—such as eligibility criteria—with reasons | Researchers may need to change the design because of* financial constraints
* problems with recruiting participants
* insights from other studies that could suggest a treatment might need to be adapted
 |
| 4 Participants | 4a Eligibility criteria for participants | * For example, you might need to exclude people who report a specific problem and, therefore, could be vulnerable to the harms or risks of this study
 |
|  | 4b Settings and locations where the data were collected | For example, researchers might specify* the country or city in which data were collected
* the immediate environment, such as whether the data were collected in a hospital, office, community centre, and so forth
* other circumstances that might have affected the results, such as transportation problems for participants

This information helps readers ascertain whether the results are likely to apply to other circumstances or settings.  |
| 5 Interventions | The interventions for each group with sufficient details to enable replication, including how and when they were actually administered | To illustrate, for research that compares some drug to a placebo* specify the dose, how the drug was administered, the schedule and duration of administration, the titration regiment if applicable, and any necessary variations from this protocol.
* If participants in the control condition merely receive care as usual, this care should be described as comprehensively as possible
 |
| 6 Outcomes | 6a Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | * If possible, researchers should specify one primary outcome measure—such as a measure of health
* If the study comprises too many primary outcome measures, the results may be harder to interpret if some, but not all, measures support the hypotheses
* Researchers may also include measures that are not as central but informative anyway, called secondary outcome measures
 |
|  | 6b Any changes to trial outcomes after the trial commenced, with reasons |   |
| 7 Sample size | 7a How sample size was determined | * To estimate the necessary sample size, many researchers utilize software called GPower
* Ideally, the power of a study—the probability of generating a significant effect if the conditions actually differ from each other—should be around 0.8 or 80%
 |
|  | 7b When applicable, explanation of any interim analyses and stopping guidelines | * To illustrate, researchers might want to analyse the results after 25%, 50%, and 75% of the participants have been recruited
* If a significant result is uncovered, the researcher might then decide not to recruit more participants—primarily to save time and resources
* If this approach is utilized, researchers need to use a more conservative alpha level for each analysis—a level smaller than 0.05. To identify these levels, they should consult relevant textbooks or articles on this approach, called interim analysis.
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| Randomization |
| Item | Description of the item | Clarification |
| 8 Sequence generation | 8a Method used to generate the random allocation sequence |  |
|   | 8b Type of randomisation; details of any restriction, such as blocking and block size | Ideally, researchers would use a computer program, such as a program in Excel or other software, to randomly assign participants. But, they might utilize other methods, and these methods should be described in detail. For example* blocked randomisation refers to instances in which the researcher might randomly allocate blocks or subsets of participants to each condition evenly. For example, the research might utilize blocks of 10, in which 5 participants will be randomly assigned to the treatment and participants 5 will be randomly assigned to the control
* stratification randomisation is utilised to randomly allocate participants of each demographic—such as each gender or age group—separately. The benefit is the two conditions will be equivalent on these demographic characteristics
* other techniques, such as an approach called minimisation, are possible as well

Some researcher utilize other features, such as allocate people born between January and June to one condition and people born between July and December to another condition. This procedure, however, is not strictly random. The month in which individuals were born could affect the outcome |
| 9 Allocation concealment mechanism | Mechanism used to implement the random allocation sequence, such as sequentially numbered containers, describing steps to conceal the sequence until interventions were assigned | * To illustrate, you might need to distribute distinct instructions, materials, or drugs to each person, depending on the condition to which this individual was allocated
* You could, for example, insert these instructions, materials, or drugs into an opaque envelope or bottle with an ID on a label
* Ideally, anyone who participates in this activity should not participate in subsequent phases, such as implementing the treatments or evaluating the outcomes; otherwise, these individuals might be biased during these subsequent phases.
* To illustrate, you could organize an independent contractor to prepare these materials—so the researchers are not aware of which participants received which materials. Or, some machine or computer program could achieve a similar role.
 |
| 10 Implementation | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions |   |
| 11 Blinding | 11a Who was blinded after assignment to interventions—such as participants, care providers, or people assessing outcomes—and how | Indicate which individuals were aware and which individuals were unaware of the condition to which each participant was assigned. In particular, consider* the participants
* the individuals who implemented the treatment or control
* the individuals who evaluated the outcomes
* other people who assisted these activities
 |
|  | 11b If relevant, description of the similarity of interventions | * Estimate the similarities between the treatment and control; for example, in drug interventions, indicate whether the drug and placebo were similar on appearance, smell, taste, and so forth.
* To assess this similarity, at the end of this research, some researchers ask participants whether they believe they were assigned the treatment or control.
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| 12 Statistical methods | 12a Statistical methods used to compare groups for primary and secondary outcomes |   |
|  | 12b Methods for additional analyses, such as subgroup analyses and adjusted analyses | * Do not include too many additional statistical analyses
* These analyses are not as credible because readers assume you might be searching excessively to uncover significant effects, increasing the likelihood of false positives or type I errors.
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| Results |
| Item | Description of the item | Clarification |
| 13 Participant flow—often with a diagram | 13a For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome | * Differentiate participants who decided to withdraw from participants the researchers withdrew because of other reasons
 |
|   | 13b For each group, losses and exclusions after randomisation, together with reasons | *
 |
| 14 Recruitment | 14a Dates defining the periods of recruitment and follow-up | *
 |
|  | 14b Why the trial ended or was stopped | * Usually relevant only if you had conducted interim analyses
 |
| 15 Baseline data | A table showing baseline demographic and clinical characteristics for each group | * You might specify sex, age, education, ethnicity, and main diagnosis, for example
 |
| 16 Numbers analysed  | For each group, number of participants—denominator—included in each analysis and whether the analysis was by original assigned groups | *
 |
| 17 Outcomes and estimation | 17a For each primary and secondary outcome, results for each group, and the estimated effect size and its precision, such as 95% CI |  |
|  | 17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended |   |
| 18 Ancillary analyses | 18a Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory |   |
| 19 Harms | All important harms or unintended effects in each group |   |

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| Discussion |
| Item | Description of the item | Clarification |
| 20 Limitations | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | * Consider other extraneous differences between the treatment and control
* Consider problems with the accuracy of measures
 |
| 21 Generalizability | Generalisability—external validity or applicability—of the trial findings | * Clarify whether the findings are likely to apply to other populations, in other settings, with other measures, for example
 |
| 22 Interpretation | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | * Researchers often include a systematic review of previous investigations into overlapping interventions
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| Other information |
| Item | Description of the item | Clarification |
| 23 Registration | Registration number and name of trial registry | * For clinical trials, the researcher should register the study with ClinicalTrials.gov or a comparable register
* They should also report the number assigned to this trial
 |
| 24 Protocol | Where the full trial protocol can be accessed, if available | * You might, for example, indicate that full details of the trial protocol can be found in the Supplementary Appendix, available with the full text of this article, and then specify the website
 |
| 25 Funding | Sources of funding and other support—such as supply of drugs—and role of funders | * This information is vital, because readers need to be able to decide whether the funding body might have biased the results
* Accordingly, the researchers should clarify the extent to which these funding bodies contributed to the design, implementation, analysis, and reporting of the study
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**CONSORT examples**

This next series of tables again specifies each principle. But, this time, the third column presents some examples to illustrate each principle.

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| Title and abstract |
| Item | Description of the item | Example |
| 1 Title and abstract | 1a Identification as a randomised trial in the title | * The effect of lecturer attire on student engagement: A randomized control trial
 |
|   | 1b Structured summary of trial design, methods, results, and conclusions |   |

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| Introduction |
| Item | Description of the item | Example |
| 2 Background and objectives | 2a Scientific background and explanation of rationale | * According to the deviant hypothesis, when individuals are exposed to cues that typify convention, such as formal attire, they tend to behave more conventionally. Their creativity diminishes.
* Because creativity has been shown to promote positive emotions, this decrease in creativity is likely to limit student engagement.
 |
|   | 2b Specific objectives or hypotheses | * This study assesses the hypothesis that lectures who wear casual attire promote student engagement
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| Methods |
| Item | Description of the item | Example |
| 3 Trial design | 3a Description of trial design, such as parallel or factorial, including allocation ratio | * We utilized a parallel randomized control trial in which the participants were evenly and randomly allocated to one of two conditions: lecturers with casual attire and lecturers with formal attire.
 |
|   | 3b Important changes to methods after trial commencement—such as eligibility criteria—with reasons | * NA
 |
| 4 Participants | 4a Eligibility criteria for participants | * We invited all external students—that is, students who study online—who were enrolled in a specific first year psychology unit to participate.
 |
|  | 4b Settings and locations where the data were collected | * Students received online surveys during the first week and last week of the semester, immediately after the class.
* The students were prompted to complete these surveys within 5 days of receiving the survey at a time and location of their choice.
* They were encouraged to complete the surveys in a location in which they will not be disturbed.
* Students recorded a video of themselves while watching the tutorials
 |
| 5 Interventions | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | * All students watched 12 recorded lectures, each spanning between 100 and 140 minutes.
* Every participant watched the same sequence of lectures
* However, for half the participants, casual attire was superimposed onto the lecture.
* For the other participant, professional attire was superimposed onto the lecture.
 |
| 6 Outcomes | 6a Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | * To measure student engagement, participants completed the student engagement scale—a scale that comprises 15 items, such as “I felt absorbed during the class”.
* In addition, we also analysed the nonverbal behaviours that participants exhibited during the first and last lectures
* In particular, we counted four behaviours: number of times the participants shifted their gaze from the screen, duration of time in which they doodled, number of times they yawned, and duration of time they recorded notes
 |
|  | 6b Any changes to trial outcomes after the trial commenced, with reasons | * Initially, we had planned to count the behaviours during every lecture but, because of changes in the availability of personnel, behaviour during only the first and last lectures were coded.
 |
| 7 Sample size | 7a How sample size was determined | * An a priori power analysis was conducted using GPower. This analysis indicated that 100 participants would generate a power of 0.8, assuming a medium effect size. Hence, the sample size of 100 was deemed as suitable for these circumstances.
 |
|  | 7b When applicable, explanation of any interim analyses and stopping guidelines | * NA
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| Randomization |
| Item | Description of the item | Example |
| 8 Sequence generation | 8a Method used to generate the random allocation sequence | * The random sequence generator in Qualtrics was utilized to randomly allocate participants to one of the two conditions
 |
|   | 8b Type of randomisation; details of any restriction, such as blocking and block size | * The software was programmed to allocate participants evenly to the two conditions; that is, the sample size of each condition was equivalent
 |
| 9 Allocation concealment mechanism | Mechanism used to implement the random allocation sequence, such as sequentially numbered containers, describing steps to conceal the sequence until interventions were assigned | * NA
 |
| 10 Implementation | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | * Participants were not explicitly informed of which condition they were assigned and were not informed the study was designed to compare the effects of casual attire and formal attire
* Instead, the Qualtrics program distributed one of two links to participants, depending on the condition to which they had been allotted
* This link activated one of the two versions of the online lectures
 |
| 11 Blinding | 11a Who was blinded after assignment to interventions—such as participants, care providers, or people assessing outcomes—and how | * In addition to the participants, the researchers who evaluated the videos of participants were also blinded to the condition that was assigned to each person.
* In particular, the videos these researchers evaluated only displayed the behaviour of participants and not the lecture they were watching.
 |
|  | 11b If relevant, description of the similarity of interventions | * Implied earlier
 |
| 12 Statistical methods | 12a Statistical methods used to compare groups for primary and secondary outcomes | * A MANOVA was utilized to ascertain whether the two conditions differ on student engagement and the four behavioural measures
 |
|  | 12b Methods for additional analyses, such as subgroup analyses and adjusted analyses | * If the Wilks lambda generates a significant effect of condition, univariate ANOVAs will be conducted to ascertain which measures differentiate the conditions.
* The Hochberg procedure—a modified Bonferroni adjustment—will be utilized to control family-wise Type I error rate.
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| Results |
| Item | Description of the item | Example |
| 13 Participant flow—often with a diagram | 13a For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome | * Table 1 specifies the number of participants who were assigned to each condition. Furthermore, for each condition, this table indicates the number of participants who watched the first lecture and last lecture and the number of participants who completed the measure of student engagement.
 |
|   | 13b For each group, losses and exclusions after randomisation, together with reasons | * To clarify why they withdrew, Participants who were assigned to conditions but did not watch the lectures received emails
* Their responses indicated that 70% of these participants withdrew because of work commitments and 30% of these participants withdrew because of family commitments
 |
| 14 Recruitment | 14a Dates defining the periods of recruitment and follow-up | * In June 2018, participants received a plain language statement about the study—a study that purportedly investigates how the style of lectures affects student engagement. They were then invited to consent to complete the questionnaires and submit videos that record their behaviour during the lecture.
* Participants received the link to watch the first lecture during July 2018. Each week participants received an additional link to watch subsequent lectures. In particular, they received the link to watch the last lecture during October 2018.
* They were instructed to watch the lecture within five days of receiving the link
* Immediately after the first lecture and last lecture, they received an online questionnaire, assessing their engagement.
 |
|  | 14b Why the trial ended or was stopped | * NA
 |
| 15 Baseline data | A table showing baseline demographic and clinical characteristics for each group | * Table 2 specifies the gender, age, education level, and whether the students identified as Indigenous for both conditions. This information was derived from their student records.
 |
| 16 Numbers analysed  | For each group, number of participants—denominator—included in each analysis and whether the analysis was by original assigned groups | * The data from 120 participants who watched a lecturer in casual attire and 119 participants who watched a lecturer in formal attire were subjected to the MANOVA and subsequent ANOVAs.
* The data of one participant who had watched the lecturer in formal attire were excluded because this person had indicated the maximum level of engagement on the survey but showed minimal engagement in the video—and had been identified as an outlier, generating a high Mahalanobis distance.
 |
| 17 Outcomes and estimation | 17a For each primary and secondary outcome, results for each group, and the estimated effect size and its precision, such as 95% CI | * Table 3 presents the mean level of engagement and the mean score on the four behavioural measures for each condition. In addition, this table presents the partial eta squared—a measure of effect size—for each measure as well as a 95% confidence interval.
 |
|  | 17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended | * NA
 |
| 18 Ancillary analyses | 18a Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | * NA
 |
| 19 Harms | All important harms or unintended effects in each group | * NA
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| Discussion |
| Item | Description of the item | Example |
| 20 Limitations | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | * Future research should redress several limitations of this study.
* First, the casual attire and formal attire might not have appeared equally realistic.
* For example, the casual attire may have matched the hair style of this lecture more than did the formal attire
* Hence, this sense of compatibility, rather than formality of clothing, could have affected student engagement
 |
| 21 Generalizability | Generalisability—external validity or applicability—of the trial findings | * Future research should also explore whether these findings generalize to lectures that are live rather than video recordings
* In addition, these findings might not generalize to disciplines in which traditions are more likely to be valued
 |
| 22 Interpretation | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | * These findings support the hypothesis that casual attire might promote student engagement, at least in online psychology lectures.
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| Other information |
| Item | Description of the item | Example |
| 23 Registration | Registration number and name of trial registry | * NA. Researchers tend to use registers more for clinical trials.
 |
| 24 Protocol | Where the full trial protocol can be accessed, if available | * NA
 |
| 25 Funding | Sources of funding and other support—such as supply of drugs—and role of funders | * The study was funded by the Australian Research Council.
* This body did not contribute to the design, implementation, analysis, and reporting of the study
 |