Supplemental Digital Content 1

Survey Responses: Items on the CONSORT and STROBE Statements Requiring an Extension for Simulation-based Research

Checklist Item	CONSORT Description[1]	STROBE Description[2]	Respondents, n (%) indicating extension required*
Title and abstract	1a: Identification as a randomized trial in the title 1b: Structured summary of trial design, methods, results, and conclusions	1a: Indicate the study's design with a commonly used term in the title or the abstract. 1b: Provide in the abstract an informative and balanced summary of what was done and what was found.	17/57 (30%)
Introduction			
Background/rationale	2a: Scientific background and explanation of rationale 2b: Specific objectives or hypotheses	2:Explain the scientific background and rationale for the investigation being reported.	15/53 (28%)
Objectives	N/A	3:State specific objectives, including any pre-specified hypotheses.	11/52 (21%)
Methods			
Trial Design / Study Design	3a: Description of trial design (such as parallel, factorial) including allocation ratio 3b: Important changes to methods after trial commencement (such as eligibility criteria), with reasons	4:Present key elements of study design early in the paper.	18/52(35%)
Setting	N/A	5:Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection.	24/51 (47%)

Checklist Item	CONSORT Description	STROBE Description[2]	Respondents, n (%) indicating extension required*
Participants	4a: Eligibility criteria for participants 4b: Settings and locations where the data were collected	6a: Cohort study: Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up. Case–control study: Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls. Cross-sectional study: Give the eligibility criteria, and the sources and methods of selection of participants. 6b: Cohort study: For matched studies, give matching criteria and number of exposed and unexposed. Case–control study: For matched studies, give matching criteria and the number of controls per case.	17/51 (33%)
Interventions	5: The interventions for each group with sufficient details to allow for replication, including how and when they were actually administered	N/A	27/46 (59%)
Variables	N/A	7: Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.	16/47 (34%)
Data sources / measurement	N/A	8: For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	23/48 (48%)

Checklist Item	CONSORT Description	STROBE Description[2]	Respondents, n (%) indicating extension required*
Outcomes	6a: Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed 6b: Any changes to trial outcomes after the trial commenced, with reasons	N/A	7/45 (16%)
Bias	N/A	9: Describe any efforts to address potential sources of bias	7/47 (15%)
Sample size / Study size	7a: How sample size was determined 7b: When applicable, explanation of any interim analyses and stopping guidelines	10: Explain how the study size was arrived at.	10/46 (22%)
Randomization: Sequence generation	8a: Method used to generate the random allocation sequence 8b: Type of randomization; details of any restriction (such as blocking and block size)	N/A	7/46 (15%)
Randomization: Allocation concealment mechanism	9:Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A	7/47 (15%)
Randomization: Implementation	10: Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	N/A	7/45 (16%)

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Blinding (masking)	11a: If done, who was blinded after assignments to interventions (for example, participants, care providers, those assessing outcomes) and how 11b: If relevant, description of the similarity of interventions	N/A	13/47 (28%)
Quantitative variables	N/A	11: Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why.	5/47 (11%)
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	12a: Describe all statistical methods, including those used to control for confounding. 12b: Describe any methods used to examine subgroups and interactions. 12c: Explain how missing data were addressed. 12d: Cohort study: If applicable, explain how loss to follow-up was addressed. Case–control study: If applicable, explain how matching of cases and controls was addressed. Cross-sectional study: If applicable, describe analytical methods taking account of sampling strategy. 12e: Describe any sensitivity analyses.	7/47 (15%)

Checklist Item	CONSORT Description	STROBE Description[2]	Respondents, n (%) indicating extension required*
Results			
Participants / Participant flow	13a: For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome 13b: For each group, losses and exclusions after randomization, together with reasons	13a: Report the numbers of individuals at each stage of the study—e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed. 13b: Give reasons for nonparticipation at each stage. 13c: Consider use of a flow diagram.	5/46 (11%)
Recruitment	14a: Dates defining the periods of recruitment and follow-up 14b: Why the trial ended or was stopped	N/A	8/47 (17%)
Baseline data / Descriptive data	15: A table showing baseline demographic and clinical characteristics of each group	14a: Give characteristics of study participants (e.g., demographic, clinical, social) and information on exposures and potential confounders. 14b: Indicate the number of participants with missing data for each variable of interest. 14c: Cohort study: Summarize follow-up time—e.g., average and total amount.	10/47 (21%)
Numbers analyzed	16: For each group, number of participants (denominator) included in each analysis and whether analysis was by original assigned groups	N/A	5/46 (11%)

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Outcomes and estimation / Outcome data	17a: For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) 17b: For binary outcomes, presentation of both absolute and relative effect sizes is recommended	15: Cohort study: Report numbers of outcome events or summary measures over time. Case–control study: Report numbers in each exposure category or summary measures of exposure. Cross-sectional study: Report numbers of outcome events or summary measures.	6/46 (13%)
Main results	N/A	16a: Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence intervals). Make clear which confounders were adjusted for and why they were included. 16b: Report category boundaries when continuous variables were categorized. 16c: If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period.	9/45 (20%)
Ancillary analyses / Other analyses	18: Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	17: Report other analyses done—e.g., analyses of subgroups and interactions and sensitivity analyses.	4/46 (9%)
Adverse Events	19: All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A	3/46 (7%)
Discussion			
Key results	N/A	18: Summarize key results with reference to study objectives.	3/46 (7%)

Checklist Item	CONSORT Description	STROBE Description[2]	Respondents, n (%) indicating extension required*
Limitations	20: Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	19: Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	7/46 (15%)
Generalizability	21:Generalizability (external validity) of the trial findings	21: Discuss the generalizability (external validity) of the study results.	4/46 (9%)
Interpretation	22:Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	20: Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	4/46 (9%)
Other Information			
Registration	23: Registration number and name of trial registry	N/A	1/46 (2%)
Protocol	24: Where the full trial protocol can be accessed, if available	N/A	1/46 (2%)
Funding	25: Sources of funding and other support (such as supply of drugs), role of funders	22: Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based.	7/46 (15%)

*denominator represents number of respondents for the question

References

1. Moher D, Hopewell S, Schulz KF et al. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010; 340:c869.
2. Vandenbroucke JP, von Elm E, Altman DG, Gøtzsche PC, Mulrow CD, Pocock SJ, et al., for the STROBE Initiative. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): explanation and elaboration. *PLoS Med*. 2007; 4:e297