JREE Randomized Trial Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify as a randomised trial in the title	
ABSTRACT			
Methods	2a	Description of the trial design (e.g. individual vs. cluster random assignment)	
	2b	Grade level or settings where the data were collected	
	2c	Intervention description	
Results	2d	Number in the analytic sample at each relevant level (e.g., students and schools)	
	2e	Findings for all main/confirmatory outcome(s)	
INTRODUCTION			
Background	3	Background and explanation of rationale	
	4	How the intervention is hypothesized to work	
Objectives	5	Specific objectives or hypotheses or research questions	
METHODS[1]			
Trial Design	6a	Describe of trial design (e.g., individual vs. cluster random assignment; blocking), including allocation ratio	
	6b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	7a	Eligibility criteria for participants	
	7b	When applicable, eligibility criteria for settings and those delivering the interventions	
	7c	Settings and locations where the data were collected	
Interventions	8a	The interventions for each group, including how and when they are actually administered	
	8b	Extent to which interventions were actually delivered by providers and taken up by participants as planned	
	8c	When applicable, how intervention providers were assigned to each group	
Outcomes	9a	Completely defined pre-specified confirmatory and exploratory outcomes (see Schochet, 2008), including how and when they were assessed	
	9b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample Size	10a	How sample size was determined	
	10b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomization	11a	Method used to generate the random allocation sequence	
	11b	Type of randomization; detail of any restriction (such as blocking and block size)	

[1] Some of this may be included in an online only appendix.

	11c	Mechanism used to implement the random allocation sequence, describing any steps taken to conceal the sequence until interventions were assigned	
	11d	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Awareness of assignment	12	Who was aware of intervention assignment after allocation (for example, participants, providers, those assessing outcomes), and how any masking was done	
Analytical methods	13a	Statistical methods used to compare group outcomes	
	13b	Define the estimand for each analysis (e.g., the person vs. site-average program effect; the effect for a finite or broader population)	
	13c	Methods for additional analyses, such as subgroup analyses, adjusted analyses, and process evaluations	
	13d	How missing data were handled, with details of any imputation method	
RESULTS			
Participant flow (see Figure)	14a	For each research group, the numbers randomly assigned, receiving the intended intervention, and analysed for the outcomes	
	14b	Where possible, the number approached, screened, and eligible prior to random assignment, with reasons for non-enrolment	
	14c	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	15a	Dates defining the periods of recruitment and follow-up	
	15b	Why the trial ended or was stopped	
Baseline data	16	A table showing baseline characteristics for each group	
Numbers analysed	17	For each group, number included in each analysis	
Outcomes and estimation	18a	For each outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	18b	For binary outcomes, the presentation of absolute effects in percentage points is strongly recommended	
Ancillary analyses	19	Results of any other analyses performed, including subgroup analyses, adjusted analyses, and process evaluations, distinguishing pre-specified from exploratory	
DISCUSSION			
Summary	20	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	
Limitations	21	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	22	Generalisability (external validity, applicability) of the trial findings	
Interpretation	23	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	

Adapated from: Grant, S., Mayo-Wilson, E., Montgomery, P., Macdonald, G., Michie, S., Hopewell, S., & Moher, D. (2018). CONSORT-SPI 2018 Explanation and Elaboration: guidance for reporting social and psychological intervention trials. *Trials*, *19*(1), 406.

For more information, visit: http://www.consort-statement.org/extensions/overview/social-and-psychological-interventions

Example of a participant flow diagram