Energy Psychology JOURNAL

CONSORT 2010 Checklist

Checklist of information to include when reporting a randomised trial. Required for all RCT submissions to the Energy Psychology Journal. Consult the CONSORT 2010 Explanation and Elaboration (Moher et al., 2010, BMJ 340:c869) for detailed guidance on each item.

Legend: EPJ — Specific to Energy Psychology Journal; Required — Mandatory — must not be omitted; Recommended

How to use this checklist

For each item, tick the checkbox (☐) and note the manuscript page number where the information appears. Items marked Required must be addressed in all submissions. Items marked Recommended are strongly encouraged for EPJ submissions. We also recommend consulting the CONSORT extension for Non-Pharmacological Treatments (Boutron et al., 2008, Ann Intern Med 148:295–309) for psychotherapy and behavioral intervention trials.

Item	Checklist Item	Note	Page #
Title and Abstract			
1a	☐ Identification as a randomised trial in the title	Required	p. ___
1b	☐ Structured summary of trial design, methods, results, and conclusions *For specific guidance see CONSORT for abstracts*	Required	p. ___
Introduction — Background and Objectives			
2a	☐ Scientific background and explanation of rationale		p. ___
2b	☐ Specific objectives or hypotheses		p. ___
Methods — Trial Design			
3a	☐ Description of trial design (such as parallel, factorial) including allocation ratio	Required	p. ___
3b	☐ Important changes to methods after trial commencement (such as eligibility criteria), with reasons		p. ___
Methods — Participants			
4a	☐ Eligibility criteria for participants	Required	p. ___
4b	☐ Settings and locations where the data were collected		p. ___

Methods — Interventions

5	☐ The interventions for each group with sufficient detail to allow replication, including how and when they were actually administered	Required	p. ___

Methods — Outcomes

6a	☐ Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Required	p. ___
6b	☐ Any changes to trial outcomes after the trial commenced, with reasons		p. ___

Methods — Sample Size

7a	☐ How sample size was determined	Required	p. ___
7b	☐ When applicable, explanation of any interim analyses and stopping guidelines		p. ___

Methods — Randomisation: Sequence Generation

8a	☐ Method used to generate the random allocation sequence	Required	p. ___
8b	☐ Type of randomisation; details of any restriction (such as blocking and block size)		p. ___

Methods — Randomisation: Allocation Concealment Mechanism

9	☐ Mechanism used to implement the random allocation sequence (e.g., sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Required	p. ___

Methods — Randomisation: Implementation

10	☐ Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions		p. ___

Methods — Blinding

11a	☐ If done, who was blinded after assignment to interventions (e.g., participants, care providers, outcome assessors) and how		p. ___
11b	☐ If relevant, description of the similarity of interventions		p. ___

Methods — Statistical Methods

12a	☐ Statistical methods used to compare groups for primary and secondary outcomes	Required	p. ___
12b	☐ Methods for additional analyses, such as subgroup analyses and adjusted analyses		p. ___

Results — Participant Flow

A CONSORT flow diagram is strongly recommended

13a	☐ For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Required	p. ___
13b	☐ For each group, losses and exclusions after randomisation, together with reasons	Required	p. ___

Results — Recruitment

14a	☐ Dates defining the periods of recruitment and follow-up		p. ___
14b	☐ Why the trial ended or was stopped		p. ___

Results — Baseline Data

15	☐ A table showing baseline demographic and clinical characteristics for each group	Required	p. ___

Results — Numbers Analysed

16	☐ For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups		p. ___

Results — 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% confidence interval)	Required	p. ___
17b	☐ For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Recommended	p. ___

Results — Ancillary Analyses

18	☐ Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		p. ___

Results — Harms

19	☐ All important harms or unintended effects in each group *For specific guidance see CONSORT for harms*	Required	p. ___

Discussion

20	☐ Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		p. ___
21	☐ Generalisability (external validity, applicability) of the trial findings		p. ___
22	☐ Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		p. ___

Other Information

23	☐ Registration number and name of trial registry *Pre-registration strongly recommended for EPJ submissions (e.g., ClinicalTrials.gov, ANZCTR)*	Required	p. ___
24	☐ Where the full trial protocol can be accessed, if available		p. ___
25	☐ Sources of funding and other support (such as supply of drugs), role of funders	Required	p. ___

** We strongly recommend reading this checklist in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all items. If relevant, also read CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. See: www.consort-statement.org*