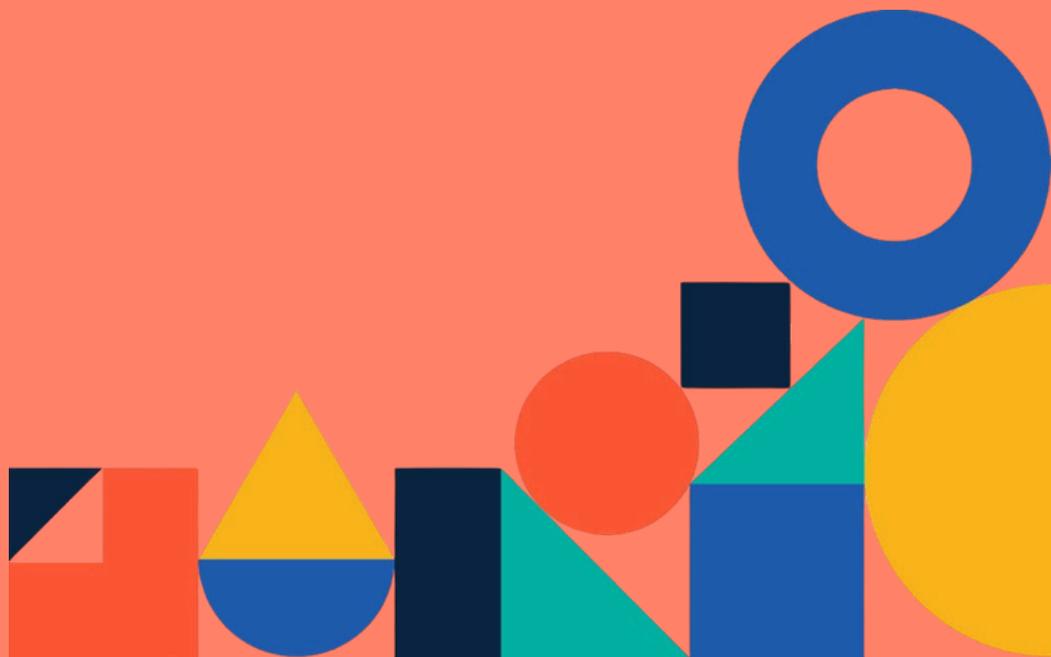


CONSORT Checklist



CONSORT Checklist

Introduction	<p>The CONSORT Checklist is intended for use in Stage 3 of an experiment, to facilitate the transparent reporting of trial results.</p> <p>Standardised reporting allows the wider research community to assess the quality of a trial and determine the reliability of its findings. While originally developed for the medical sciences, this checklist is appropriate for any field experiment, and has been adapted with examples from innovation, entrepreneurship, and growth (IEG) research.</p>
How to use this template	<p>To use this template, download/open and save a copy for your personal use.</p> <p>As you draft your final report or journal article, add content to the checklist by identifying the page numbers where specific trial details are described.</p>
Key terms	<p>Trial registration: Documentation of the registry name, identifying number, and the date the trial was officially registered.</p> <p>Allocation concealment mechanism: The specific method used to implement the randomisation sequence and to ensure assignments are hidden until the moment of allocation.</p> <p>Blinding: Reporting who was kept unaware of group assignments after the trial began, such as the participants, intervention providers, or outcome assessors.</p> <p>Fidelity: Describing how the intervention was actually administered and whether participants adhered to the intended protocol.</p>
Version	1.1 (23/02/2026)
	<p>This template was adapted from Hopewell S, Chan AW, Collins GS, Hróbjartsson A, Moher D, Schulz KF, et al. CONSORT 2025 Statement: updated guideline for reporting randomised trials. <i>BMJ</i>. 2025; 388:e081123. https://dx.doi.org/10.1136/bmj-2024-081123, which is an open access resource.</p>

Section/topic	No	Item description	Reported on page no.
Title and abstract			
Title and structured abstract	1a	Identification as a randomised trial	_____
	1b	Structured summary of the trial design, methods, results, and conclusions	_____
Open science			
Trial registration	2	Name of trial registry, identifying number (with URL) and date of registration	_____
Protocol and statistical analysis plan	3	Where the trial protocol and statistical analysis plan can be accessed	_____
Data sharing	4	Where and how the individual de-identified participant data (including data dictionary), statistical code and any other materials can be accessed	_____
Funding and conflicts of interest	5a	Sources of funding and other support (e.g., access to firm data), and role of funders in the design, conduct, analysis and reporting of the trial	_____
	5b	Financial and other conflicts of interest of the manuscript authors	_____
Introduction			
Background and rationale	6	Scientific background and rationale	_____
Objectives	7	Specific objectives related to benefits and harms	_____
Methods			
Patient and public involvement	8	Details of patient or public involvement in the design, conduct and reporting of the trial	_____
Trial design	9	Description of trial design including type of trial (e.g., parallel group, crossover), allocation ratio, and framework (e.g., superiority, equivalence, non-inferiority, exploratory)	_____
Changes to trial protocol	10	Important changes to the trial after it commenced including any outcomes or analyses that were not prespecified, with reason	_____
Trial setting	11	Settings (e.g., community, university) and locations (e.g., countries, sites) where the trial was conducted	_____
Eligibility criteria	12a	Eligibility criteria for participants	_____
	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions (e.g., business mentors, startup accelerators, development agencies)	_____
Intervention and comparator	13	Intervention and comparator with sufficient details to allow replication. If relevant, where additional materials describing the intervention and comparator (e.g., intervention manual) can be accessed	_____
Outcomes	14	Prespecified primary and secondary outcomes, including the specific measurement variable (e.g., firm growth, survival rates), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome	_____
Harms	15	How harms were defined and assessed (e.g., systematically, non-systematically)	_____
Sample size	16a	How sample size was determined, including all assumptions supporting the sample size calculation	_____
	16b	Explanation of any interim analyses and stopping guidelines	_____
Randomisation:			_____

Sequence generation	17a	Who generated the random allocation sequence and the method used	_____
	17b	Type of randomisation and details of any restriction (e.g., stratification, blocking and block size)	_____
			Reported on page no.
Allocation concealment mechanism	18	Mechanism used to implement the random allocation sequence (e.g., automated randomisation script), describing any steps to conceal the sequence until interventions were assigned	_____
Implementation	19	Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence	_____
Blinding	20a	Who was blinded after assignment to interventions (e.g., participants, intervention providers, outcome assessors, data analysts)	_____
	20b	If blinded, how blinding was achieved and description of the similarity of interventions	_____
Statistical methods	21a	Statistical methods used to compare groups for primary and secondary outcomes, including harms	_____
	21b	Definition of who is included in each analysis (e.g., all randomised participants), and in which group	_____
	21c	How missing data were handled in the analysis	_____
	21d	Methods for any additional analyses (e.g., subgroup and sensitivity analyses), distinguishing prespecified from post hoc	_____
Results			
Participant flow, including flow diagram	22a	For each group, the numbers of participants who were randomly assigned, received intended intervention, and were analysed for the primary outcome	_____
	22b	For each group, losses and exclusions after randomisation, together with reasons	_____
Recruitment	23a	Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms	_____
	23b	If relevant, why the trial ended or was stopped	_____
Intervention and comparator delivery	24a	Intervention and comparator as they were actually administered (e.g., where appropriate, who delivered the intervention/comparator, how participants adhered, whether they were delivered as intended (fidelity))	_____
	24b	Concomitant care received during the trial for each group	_____
Baseline data	25	A table showing baseline demographic and clinical characteristics for each group	_____
Numbers analysed, outcomes and estimation	26	For each primary and secondary outcome, by group: <ul style="list-style-type: none"> • the number of participants included in the analysis • the number of participants with available data at the outcome time point • result for each group, and the estimated effect size and its precision (such as 95% confidence interval) • for binary outcomes, presentation of both absolute and relative effect size 	_____
Harms	27	All harms or unintended events in each group	_____
Ancillary analyses	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified from post hoc	_____
Discussion			
Interpretation	29	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	_____
Limitations	30	Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses	_____

*The CONSORT 2025 Explanation and Elaboration and the CONSORT 2025 Expanded Checklist contain important clarifications on all the items, see www.consort-spirit.org.