CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	1-2
	2b	Specific objectives or hypotheses	2
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	3
Participants	4a	Eligibility criteria for participants	3
	4b	Settings and locations where the data were collected	3
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	3
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	3
	6b	Any changes to trial outcomes after the trial commenced, with reasons	3
Sample size	7a	How sample size was determined	3
	7b	When applicable, explanation of any interim analyses and stopping guidelines	3-4
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	3
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	3
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	3
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	3
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	3

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	3
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	4
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	4
Results			
Participant flow (a 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	4
	13b	For each group, losses and exclusions after randomisation, together with reasons	4
Recruitment	14a	Dates defining the periods of recruitment and follow-up	4
	14b	Why the trial ended or was stopped	4
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	11
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	4
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)	5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	5
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	5
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	5
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	7
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	7
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	6
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	-
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	10

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Materials Design Analysis Reporting (MDAR) Checklist for Authors

The MDAR framework establishes a minimum set of requirements in transparent reporting applicable to studies in the life sciences (see Statement of Task: doi:10.31222/osf.io/9sm4x.). The MDAR checklist is a tool for authors, editors and others seeking to adopt the MDAR framework for transparent reporting in manuscripts and other outputs. Please refer to the MDAR Elaboration Document for additional context for the MDAR framework.

Materials

Antibodies	Yes (indicate where	n/a
For commercial reagents, provide supplier name, catalogue number and RRID, if available.		Our study was a phase I clinical trial, so we didn't need antibodies

Cell materials	Yes (indicate where	n/a
Cell lines: Provide species information, strain. Provide accession number in repository **OR** supplier name, catalog number, clone number, **OR** RRID		Our study was a phase I clinical trial, so we didn't undergo cell related experiment.
Primary cultures: Provide species, strain, sex of origin, genetic modification status.		Our study was a phase I clinical trial, so we didn't undergo cell related experiment.

Experimental animals	Yes (indicate where	n/a
Laboratory animals: Provide species, strain, sex, age, genetic modification status. Provide accession number in repository **OR** supplier name, catalog number, clone number, **OR** RRID		Our study was a phase I clinical trial, so we didn't undergo animals related experiment.
Animal observed in or captured from the field: Provide species, sex and age where possible		Our study was a phase I clinical trial, so we didn't undergo animals related experiment.
Model organisms: Provide Accession number in repository (where relevant) **OR** RRID		Our study was a phase I clinical trial, so we didn't undergo animals related experiment.

Plants and microbes	Yes (indicate where	n/a
Plants: provide species and strain, unique accession number if available, and source (including location for collected wild specimens)		Our study was a phase I clinical trial, so we didn't undergo plants and microbes related experiment.
Microbes: provide species and strain, unique accession number if available, and source		Our study was a phase I clinical trial, so we didn't undergo plants and microbes related experiment.

Human research participants	Yes (indicate where	n/a
Identify authority granting ethics approval (IRB or equivalent committee(s), provide reference number for approval.	Page7 line 13-17	
Provide statement confirming informed consent obtained from study participants.	Page8 line12-13	
Report on age and sex for all study participants.	Page 22 Table1 AND page 12 line 2-3	

Design

Study protocol	Yes (indicate	n/a
For clinical trials, provide the trial registration number **OR** cite DOI in manuscript.	Page 4 Line 6-7	

Laboratory protocol	Yes (indicate	n/a
Provide DOI or other citation details if detailed step-by-step protocols are available.		We didn't provide detailed protocol in our manuscript. But if needed， we can provide it.

Experimental study design (statistics details)	Yes (indicate	n/a
State whether and how the following have been done**, or** if they were not carried out.	Page7 line 12-13	
Sample size determination	Page8 line21	
Randomisation	Page8 line21	
Blinding		Our study was self-control, so it didn't need blinding
Inclusion/exclusion criteria	Page8 line 2-19	

Sample definition and in-laboratory replication	Yes (indicate	n/a
State number of times the experiment was replicated in laboratory		Our study was a phase I clinical trial, so we didn't carry out laboratory experiments.
Define whether data describe technical or biological replicates		Our study was a phase I clinical trial, so we didn't carry out laboratory experiments.

Ethics	Yes (indicate	n/a
Studies involving human participants: State details of authority granting ethics approval (IRB or equivalent committee(s), provide reference number for approval.	Page18 line 3-5	
Studies involving experimental animals: State details of authority granting ethics approval (IRB or equivalent committee(s), provide reference number for approval.		Our study didn't involve experimental animals
Studies involving specimen and field samples: State if relevant permits obtained, provide details of authority approving study; if none were required, explain why.		Our study didn't involve specimen and field samples

Dual Use Research of Concern (DURC)	Yes (indicate	n/a
If study is subject to dual use research of concern, state the authority granting approval and reference number for the regulatory approval		Our study wasn't subject to dual use research of concern

Analysis

Attrition	Yes (indicate where provided:	n/a
State if sample or data point from the analysis is excluded, and whether the criteria for exclusion were determined and specified in advance.	Page 12 Line 2	

Statistics	Yes (indicate where provided:	n/a
Describe statistical tests used and justify choice of tests.	Page 11 Line6-14	

Data Availability	Yes (indicate where provided:	n/a
State whether newly created datasets are available, including protocols for access or restriction on access.	Page 12 Line 12	
If data are publicly available, provide accession number in repository or DOI or URL.	Page 12 Line 12	
If publicly available data are reused, provide accession number in repository or DOI or URL, where possible.		Our data weren't reused.

Code Availability	Yes (indicate where provided:	n/a
For all newly generated code and software essential for replicating the main findings of the study:		Our study did not involve code
State whether the code or software is available.		Our study did not
If code is publicly available, provide accession number in repository, or DOI or URL.		Our study did not involve code

Reporting

Adherence to community standards	Yes (indicate where provided: section/paragraph)	n/a
MDAR framework recommends adoption of discipline-specific guidelines, established and endorsed through community initiatives. Journals have their own policy about requiring specific guidelines and recommendations to complement MDAR.		
State if relevant guidelines (eg., ICMJE, MIBBI, ARRIVE) have been followed, and whether a checklist (eg., CONSORT, PRISMA, ARRIVE) is provided with the manuscript.	ICMJE guidelines were followed, as the journal follows ICMJE recommendations for publication. And CONSORT can be provided with the manuscript.	

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