Reporting Guidelines

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Guidance for writing up a randomised trial

Section/Topic	Item No	Checklist item
Title & abstract	1	Identification as a randomised trial in the title Structured abstract as per EJVES guidelines, with primary outcome measure results presented first
Background and objectives	2a	Scientific background and explanation of rationale. with the specific hypothesis being tested
Trial Registration number	2b	Registration number and name of registry
Methods	3a	Description of trial design including allocation ratio & any changes
Trial design		to trial after commencement e.g revised power calculation and where the full protocol can be accessed (eg web site, chief investigator)
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Participants	4a	Eligibility criteria for participants
	4b	Recruitment time period & locations where the data were collected
Interventions	5	The interventions for each group with sufficient details to allow replication
Outcomes	6	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
Sample size	7	How sample size was determined and details of any interim analyses
Randomisation	8	Method used to generate the random allocation sequence with details of any restriction (such as blocking and block size)
Sequence generation		
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
Implementation	10	Method of randomization (eg internet-computer/sealed opaque envelopes), who enrolled participants, and who assigned participants to interventions
Blinding	11	Who was blinded after assignment to interventions for relevant assessments (eg ulcer healing, vessel patency) and how
Statistical methods	12	Statistical methods used to compare groups for primary and secondary outcomes and address missing data
Results Participant flow (a diagram is essential)	13	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome. Also report those not analysed (with reasons) and patients lost to follow up.
Baseline data	14	A table showing baseline demographic and clinical characteristics for each group
Outcomes and estimation	15	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
Ancillary analyses	16	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory
Harms	17	All important harms or unintended effects in each group
Discussion	18	Summarise findings for primary outcome measure and relevant secondary outcomes or subgroups

Limitations	19	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
Interpretation	20	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence. with respect to generalisability of the findings
Other information		
Funding	21	Sources of funding and other support (such as supply of drugs), role of funders

This is an adaption of the CONSORT statement at www.consort-statement.org/consort-statement

Guidance for writing up a systematic review and meta-analysis

Section/Topic	Item No	Checklist item
Title	1	Identification as a systematic review, meta-analysis or both.
Abstract	2	Structured abstract including background, objective, data sources, study eligibility criteria, methodological assessment, synthesis method, results, conclusions and implications of key findings.
Introduction		
Rationale	3	Describe the rationale for the review in the context of what is already known.
Objectives		Provide an explicit statement of questions being addressed with reference to participants, interventions, outcomes (PICO design).
Methods		
Protocol and registration	4	Indicate if a review protocol exists, and where it can be accessed.
Eligibility criteria	5	Specify study characteristics and report characteristics (such as years considered, language, publication status) used as criteria for eligibility
Information sources	6	Describe all information sources (such as databases with dates of coverage, contact with study authors, experts) in the search, and the date of last search.
Search	7	Present full electronic search strategy, including limits used, such that it could be repeated.
Study selection	8	State the process for selecting studies (i.e. screening, eligibility) and make sure that this is done by 2 authors.
Data collection	9	Describe method of data abstraction from reports (such as standardized forms, independently by 2 authors) and any processes for obtaining data from other investigators.
Data items	10	List and define all variables for which data were sought.
Risk of bias in individual studies	11	Describe methods used for assessing risk of bias of individual studies, and how this information is to be used in any data synthesis.
Summary measures	12	State the principal summary measures, such as risk ratio, weighted mean difference for intervention studies, or pooled sensitivity and specificity or summary ROC curves for diagnostic studies.
Synthesis of results	13	Describe the methods of handling data, and combining results of studies, including measures of consistency (such as the I^2 statistic) for each meta-analysis.
Risk of bias across studies	14	Specify assessment of risk of bias that may affect the cumulative evidence (such as publication bias, selective reporting).
Additional analyses	15	Describe methods of additional analyses (such as sensitivity, sub-group or meta-regression) and if they were pre-specified.
Results		
Study selection	16	Give numbers of studies screened, assessed for eligibility, and include in the review, with reasons for exclusion at each stage, illustrated with a flow diagram.
Study characteristics	17	For each study, present characteristics for which data were extracted and provide the citations.

Risk of bias within studies	18	Present data on the risk of bias for each individual study. (see #14) Preferrably, use RevMan 5 to display results.
Results of individual studies	19	For all outcomes considered, present simple summary data for each group (control, intervention) and confidence intervals, ideally with a forest plot.
Synthesis of results	20	Present results of each meta-analysis, including 95% confidence interval and measures of consistency.
Additional analyses	21	Give results of additional analyses (if applicable),such as sensitivity- or subgroup analysis or meta-regression analysis.
Discussion		
Summary of evidence	22	Summarize main findings, including strength of evidence for each main outcome. Consider their relevance to key groups (patients, health care providers, policy makers).
Limitations	22	Discuss limitations at study and outcome level (such as risk of bias), and at review level (search results, publication bias).
Conclusion	23	Provide a general interpretation of the results in the context of other evidence, and implications for future research.
Other information		
Funding	24	Sources of funding and other support, role of funders.

This is an adaption of the PRISMA statement at www.prisma-statement.org

Guidance for writing up observational studies

	Item No	Recommendation
Title and abstract	1	Indicate the study's design with a commonly used term in the title or the abstract eg cohort, case-control or cross-sectional
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, average follow-up, and data collection
		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
Variables	7	Clearly define all outcomes, predictors and potential confounders. Give diagnostic criteria
Study size	9	Explain how the study size was arrived at
Statistical methods	10	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Explain how missing data were addressed
		(*c*) *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

Continued on next page

Results		
Participants	11	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Consider use of a flow diagram
Descriptive data	12	Give characteristics of study participants (eg demographic, clinical, social) and information on potential confounders and summarise follow-up time
Outcome data	13	*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
Main results	14	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
Other analyses	15	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	16	Summarise key results with reference to study objectives
Limitations	17	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	18	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	19	Discuss the generalisability (external validity) of the study results
Other information		
Funding	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

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Note: For the full STROBE guidelines, an Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Guidance for writing up studies involving animals

Table 2. Animal Research: Reporting *In Vivo* experiments: The ARRIVE guidelines.

	ITEM	RECOMMENDATION
TITLE	1	Provide as accurate and concise a description of the content of the article as possible.
ABSTRACT	2	Provide an accurate summary of the background, research objectives (including details of the species or strain of animal used), key methods, principal findings, and conclusions of the study.
INTRODUCTION		
Background	3	a. Include sufficient scientific background (including relevant references to previous work) to understand the motivation and context for the study, and explain the experimental approach and rationale. b. Explain how and why the animal species and model being used can address the scientific objectives and, where appropriate, the study's relevance to human biology.
Objectives	4	Clearly describe the primary and any secondary objectives of the study, or specific hypotheses being tested.
METHODS		
Ethical statement	5	Indicate the nature of the ethical review permissions, relevant licences (e.g. Animal [Scientific Procedures] Act 1986), and national or institutional guidelines for the care and use of animals, that cover the research.
Study design	6	For each experiment, give brief details of the study design, including: a. The number of experimental and control groups. b. Any steps taken to minimise the effects of subjective bias when allocating animals to treatment (e.g., randomisation procedure) and when assessing results (e.g., if done, describe who was blinded and when). c. The experimental unit (e.g. a single animal, group, or cage of animals). A time-line diagram or flow chart can be useful to illustrate how complex study designs were carried out.
Experimental procedures	7	For each experiment and each experimental group, including controls, provide precise details of all procedures carried out. For example: a. How (e.g., drug formulation and dose, site and route of administration, anaesthesia and analgesia used [including monitoring], surgical procedure, method of euthanasia). Provide details of any specialist equipment used, including supplier(s). b. When (e.g., time of day). c. Where (e.g., home cage, laboratory, water maze). d. Why (e.g., rationale for choice of specific anaesthetic, route of administration, drug dose used).
Experimental animals	8	a. Provide details of the animals used, including species, strain, sex, developmental stage (e.g., mean or median age plus age range), and weight (e.g., mean or median weight plus weight range). b. Provide further relevant information such as the source of animals, international strain nomenclature, genetic modification status (e.g. knock-out or transgenic), genotype, health/immune status, drug- or test-naïve, previous procedures, etc.
Housing and husbandry	9	Provide details of: a. Housing (e.g., type of facility, e.g., specific pathogen free (SPF); type of cage or housing; bedding material; number of cage companions; tank shape and material etc. for fish). b. Husbandry conditions (e.g., breeding programme, light/dark cycle, temperature, quality of water etc. for fish, type of food, access to food and water, environmental enrichment). c. Welfare-related assessments and interventions that were carried out before, during, or after the experiment.
Sample size	10	a. Specify the total number of animals used in each experiment and the number of animals in each experimental group. b. Explain how the number of animals was decided. Provide details of any sample size calculation used. c. Indicate the number of independent replications of each experiment, if relevant.
Allocating animals to experimental groups	11	a. Give full details of how animals were allocated to experimental groups, including randomisation or matching if done. b. Describe the order in which the animals in the different experimental groups were treated and assessed.
Experimental outcomes	12	Clearly define the primary and secondary experimental outcomes assessed (e.g., cell death, molecular markers, behavioural changes).
Statistical methods	13	a. Provide details of the statistical methods used for each analysis. b. Specify the unit of analysis for each dataset (e.g. single animal, group of animals, single neuron). c. Describe any methods used to assess whether the data met the assumptions of the statistical approach.
RESULTS		
Baseline data	14	For each experimental group, report relevant characteristics and health status of animals (e.g., weight, microbiological status, and drug- or test-naïve) before treatment or testing (this information can often be tabulated).
Numbers analysed	15	a. Report the number of animals in each group included in each analysis. Report absolute numbers (e.g. 10/20, not 50%[a]). b. If any animals or data were not included in the analysis, explain why.
Outcomes and estimation	16	Report the results for each analysis carried out, with a measure of precision (e.g., standard error or confidence interval).
Adverse events	17	a. Give details of all important adverse events in each experimental group. b. Describe any modifications to the experimental protocols made to reduce adverse events.

DISCUSSION		
Interpretation/scientific implications	18	a. Interpret the results, taking into account the study objectives and hypotheses, current theory, and other relevant studies in the literature. b. Comment on the study limitations including any potential sources of bias, any limitations of the animal model, and the imprecision associated with the results[a]. c. Describe any implications of your experimental methods or findings for the replacement, refinement, or reduction (the 3Rs) of the use of animals in research.
Generalisability/translation	19	Comment on whether, and how, the findings of this study are likely to translate to other species or systems, including any relevance to human biology.
Funding	20	List all funding sources (including grant number) and the role of the funder(s) in the study.

[a]Schulz, et al. (2010) [24].
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These guidelines are taken from: Kilkenny C, Browne WJ, Cuthill IC, Emerson M, Altman DG (2010) Improving Bioscience Research Reporting: The ARRIVE Guidelines for Reporting Animal Research. PLoS Biol 8(6): e1000412. doi:10.1371/ journal.pbio.1000412.