The ARRIVE Guidelines Checklist

Item	Item No	RECOMMENDATION	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title	1	Provide as accurate and concise a description of the content of the article as possible.	Page 1, line 3-4	Title
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.	Page 2, line 34-65	Abstract paragraph 1-4
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.	Page 3-4, line 81-125	Introduction, paragraph 1-3
Objectives	4	Clearly describe the primary and any secondary objectives of the study, or specific hypotheses being tested.	Page 4, line 126-141	Introduction, paragraph 4
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.	Page 5, line 152-158; Page 9, line 290-296	Methods, Paragraph 2 & paragraph 12
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.	Page 5-6, line 162-177; Page 7, line 219-238	Methods, Paragraph 3 & Paragraph 7,8

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).	Page 6, line 179-199; Page 7-9, line 241-287	Methods, Paragraph 4,5 & Paragraph 9-11

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.	Page 5, line 152-158;	Methods, Paragraph 2
Housing and husbandry	9	Provide details of: a. Housing (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 prior to, during, or after the experiment.	Page 5, line 152-158;	Methods, Paragraph 2
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 arrived at. Provide details of any sample size calculation used. c. Indicate the number of independent replications of each experiment, if relevant.	Page 5-6, line 162-177; Page 6-7, line 203-216	Methods, Paragraph 3 & Paragraph 6
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.	Page 5-6, line 162-177;	Methods, Paragraph 3
Experimental outcomes	12	Clearly define the primary and secondary experimental outcomes assessed (e.g. cell death, molecular markers, behavioural changes).	Page 6, line 179-199;	Methods, Paragraph 4,5
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.	Page 9, line 299-307	Methods, Paragraph 13
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) prior to treatment or testing. (This information can often be tabulated).	Page 9-14, all control data	Results

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%[2]). b. If any animals or data were not included in the analysis, explain why.	Included all animals and patients 'data	NA
Outcomes and estimation	16	Report the results for each analysis carried out, with a measure of precision (e.g. standard error or confidence interval).	Yes	Results
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.	NA	NA

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[2]. 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.	Page 14-17, line 464-567	Discussion, Paragraph 1-6
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.	Page 17, line 568-582	Discussion, Paragraph 7
Funding	20	List all funding sources (including grant number) and the role of the funder(s) in the study.	Page 1, line 20-25; Page 18, line 585-588	Contributions Paragraph1; Acknowledgements Paragraph 1

From:

Animal Research: Reporting In Vivo Experiments

Carol Kilkenny[1], William J Browne[2], Innes C Cuthill[3], Michael Emerson[4] and Douglas G Altman[5]

[1]The National Centre for the Replacement, Refinement and Reduction of Animals in Research, London, UK, [2]School of Veterinary Science, University of Bristol, Bristol, UK, [3]School of Biological Sciences, University of Bristol, Bristol, UK, [4]National Heart and Lung Institute, Imperial College London, UK, [5]Centre for Statistics in Medicine, University of Oxford, Oxford, UK.

References:

1. 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
2. Schulz KF, Altman DG, Moher D, the CONSORT Group (2010) CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMJ 340:c332.

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

Section/Topic	Item No	Checklist item	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title and abstract				
	1a	Identification as a randomised trial in the title	Pg 1. Line 3-4.	Title Page
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2)	Pg 3. Lines 50-80.	Abstract
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Pg 4-5. Lines 102-161.	Intro, Paragraph 1-3
	2b	Specific objectives or hypotheses	Pg 5-6. Lines 161-170.	Intro, Paragraph 3
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Pg 8-9. Lines 254-271.	Methods, Paragraph 7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A	N/A
Participants	4a	Eligibility criteria for participants	Pg 7-8. Lines 237-252.	Methods, Paragraph 6
	4b	Settings and locations where the data were collected	Pg 8. Lines 255-256.	Methods, Paragraph 7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Pg 8. Lines 258-259.	Methods, Paragraph 7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Pg 8-9. Lines 263-282.	Methods, Paragraphs 7-8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A	N/A
Sample size	7a	How sample size was determined	N/A	N/A
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A	N/A
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence	N/A	N/A
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	N/A	N/A
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	N/A	N/A

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	N/A	N/A
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Pg. 8. Lines 258-259.	Methods, Paragraph 7
	11b	If relevant, description of the similarity of interventions	Pg 8. Lines 262-263.	Methods, Paragraph 7
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Pg 10-11. Lines 343-353.	Methods, Paragraph 13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A	N/A
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	Pg 12. Lines 395-397.	Results, Paragraph 4
	13b	For each group, losses and exclusions after randomisation, together with reasons	Pg 12. Lines 395-397.	Results, Paragraph 4
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Pg 12. Lines 393-395.	Results, Paragraph 4
	14b	Why the trial ended or was stopped	N/A	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 3 (Pg 25-26).	Table 3
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 4 (Pg 27).	Table 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)	Pg 13. Lines 397-411. Table 4. (Pg 27).	Results, Paragraph 6 Table 4
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Pg 12. Lines 404-411.	Results, Paragraph 5
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Pg 18-19. Lines 606-619.	Discussion, Paragraph 6
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Pg 19. Lines 620-635.	Discussion, Paragraph 7-8
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Pg 15-19. Lines 513-635.	Discussion, Paragraph 1-8
Other information				
Registration	23	Registration number and name of trial registry	N/A	N/A

Protocol	24	Where the full trial protocol can be accessed, if available	Pg 19. Lines 646.	Footnote
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Pg 19. 638-651.	Acknowledgement

*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.

Table 2 Items to include when reporting a randomized trial in a journal or conference abstract

Item	Description	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title	Identification of the study as randomized	Pg 1. Lines 3-4.	Title Page
Authors *	Contact details for the corresponding author	Pg 2. Lines 43-47.	Title Page
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	Pg 3. Lines 64-68.	Abstract
Methods			
Participants	Eligibility criteria for participants and the settings where the data were collected	N/A	N/A
Interventions	Interventions intended for each group	Pg 3. Lines 64-66.	Abstract
Objective	Specific objective or hypothesis	Pg 3. Lines 55-58.	Abstract
Outcome	Clearly defined primary outcome for this report	Pg 3. Lines 66.	Abstract
Randomization	How participants were allocated to interventions	Pg 3. Lines 64-66.	Abstract
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	Pg 3. Lines 67.	Abstract
Results			
Numbers randomized	Number of participants randomized to each group	Pg 3. Lines 64-66.	Abstract
Recruitment	Trial status	N/A	N/A
Numbers analysed	Number of participants analysed in each group	Pg 3. Lines 73-75.	Abstract
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	Pg 3. Lines 73-75.	Abstract
Harms	Important adverse events or side effects	N/A	N/A

Conclusions	General interpretation of the results	Pg 4. Lines 79-81.	Abstract
Trial registration	Registration number and name of trial register	N/A	N/A
Funding	Source of funding	N/A	N/A

** this item is specific to conference abstracts*

From: Hopewell S, Clarke M, Moher D, et al. CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. PLoS Med. 2008;5(1):e20

Article information: https://dx.doi.org/10.21037/atm-22-458
*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.