Randomised trials in *The Lancet*: formatting guidelines

To assist authors with submission and to streamline the peer review and editing process, we have compiled the following guidance for reporting of randomised trials in *The Lancet*. Please provide a non-declamatory title, including the trial descriptor (eg, Once-weekly dulaglutide versus once-daily liraglutide in patients with type 2 diabetes (AWARD-6): a randomised, open-label, phase 3, non-inferiority trial). A structured summary should be included, of maximum length 300 words. The main text of the Article should be 3000 words, but can be extended up to 4500 words for randomised trials, with up to 30 references. All reports of randomised trials should include a trial profile, table of baseline characteristics, and a panel that puts their results into context with previous work. Extra description or analyses can be included as an appendix. Please submit your text and tables in a Word document (removing Endnote or other referencing software), and your figures as editable files (eg, .eps, .pdf). Reports of trials must conform to CONSORT 2025 guidelines. Abstracts, cluster-randomised trials, and trials that report harms must be reported according to CONSORT extended guidelines.

Authorship line: please include first names and surnames for all authors. Affiliations and degrees should be supplied as shown in the margin; only one degree is listed per author, and indicate any full professors. For papers with more than 30 authors we suggest that a collaborative group authorship is considered, to be listed at the end of the paper or in an appendix, dependent on length. Collaborators listed in this way are recognised by PubMed. Author statement forms and International Committee of Medical Journal Editors conflicts of interest forms should be submitted and should match summary statements at the end of your paper. Please list one corresponding author and state their preferred title, postal address including zip code or postcode, and email address.

Last updated July, 2025

For **information on preparing your manuscript and author statement forms** see https://www.thelancet.com/preparing-your-manuscript

For **conflicts of interest forms** see http://www.icmje.org/conflicts-of-interest

For **formatting and artwork guidelines** see https://www.thelancet.com/pb-assets/Lancet/authors/artwork-guidelines-1688984488897.pdf

For the **CONSORT 2025 guidelines** https://www.consort-spirit.org

For **CONSORT extensions** see http://www.consort-statement.org/extensions

Summary (maximum length 300 words)

Background

- State briefly why the study was done, followed by a specific aim or hypothesis; do not include references here.

Methods

- State study design (eg, randomised, parallel, cluster, non-inferiority, open-label, double-blind).
- Indicate the setting (community, hospital) where participants were recruited (which countries, how many centres or hospitals), and the key eligibility criteria for participants and study sites.
- Explain the groups participants were randomly assigned to, and provide information about the methods of randomisation, masking, and stratification. How were participants allocated to groups and by whom? Were participants, investigators, and those assessing outcomes masked to group assignment?
- Give details of interventions and concomitant care (type, method of delivery, duration). For drugs please provide the generic name (rINN), doses, route, and schedule of administration.
- What was the main outcome of this report and when was it assessed? We do not as standard include additional outcomes in the Summary.
- State who is included in primary efficacy and harms analyses (eg, "all randomised participants" or "patients were analysed according to treatment received"), and how missing data were handled in the analysis.
- For non-inferiority studies, state the margin used to establish non-inferiority.
- Provide the trial registration number, name of registry, and trial status (is the trial closed to new participants?).

Findings

- Provide exact dates between which participants were recruited and the number of participants assigned and analysed in each group (including the total number of participants in each sex and/or gender category), accounting for dropouts.
- For the primary outcome give a result for each group (provide actual numbers of participants or events alongside any percentages), and estimated effect size (eg, odds ratio) and its precision (eg, 95% CI, p value). Report SDs for mean values and IQRs for medians, and give p values to two significant figures (capped at four decimal places), or p<0·0001. For risk changes or effect sizes, give absolute values rather than relative changes.
- Summarise adverse events (actual numbers and percentages in both groups; include treatment-related deaths).
- Results stated should agree with what is in the main paper, and all data here should also appear in the main paper.

Interpretation

- Provide a general interpretation of the results and their significance rather than reiterating them. The interpretation should be justified by the results and should explain their importance or relevance to clinical practice.

Funding

- Source of study funding (if none, say so).

Copyright

- See Copyright and reuse information in the Information for Authors guidelines.

Translated abstracts
The Lancet journals encourage the submission of translated summaries in languages that are relevant to the country where the research was done. If you are interested in submitting a Summary translation, please let your handling Editor know.

Department of XX, University of XX, City, State (for USA, Canada, and Australia), Country (X X Surname PhD); **Department of XX, XX Hospital, City, State, Country** (Prof X Surname MD); **Company XX, City, State, Country** (X X Surname MSc)

Correspondence to:
Dr Firstname X Surname, Department of XX, University of XX, City, Postcode, Country
email@address.com

***Panel:* Research in context**

Evidence before this study

This section should include a description of all the evidence that the authors considered before undertaking this study. Authors should state: the sources (databases, journal or book reference lists, etc) searched; the criteria used to include or exclude studies (including the exact start and end dates of the search), which should not be limited to English language publications; the search terms used; the quality (risk of bias) of that evidence; and the pooled estimate derived from meta-analysis of the evidence, if appropriate.

Added value of this study

Authors should describe here how their findings add value to the existing evidence (including an updated meta-analysis, if appropriate).

Implications of all the available evidence

Authors should state the implications for practice or policy and future research of their study combined with existing evidence.

Research in context panels should not have references; anything mentioned that needs referencing should appear in the main text.

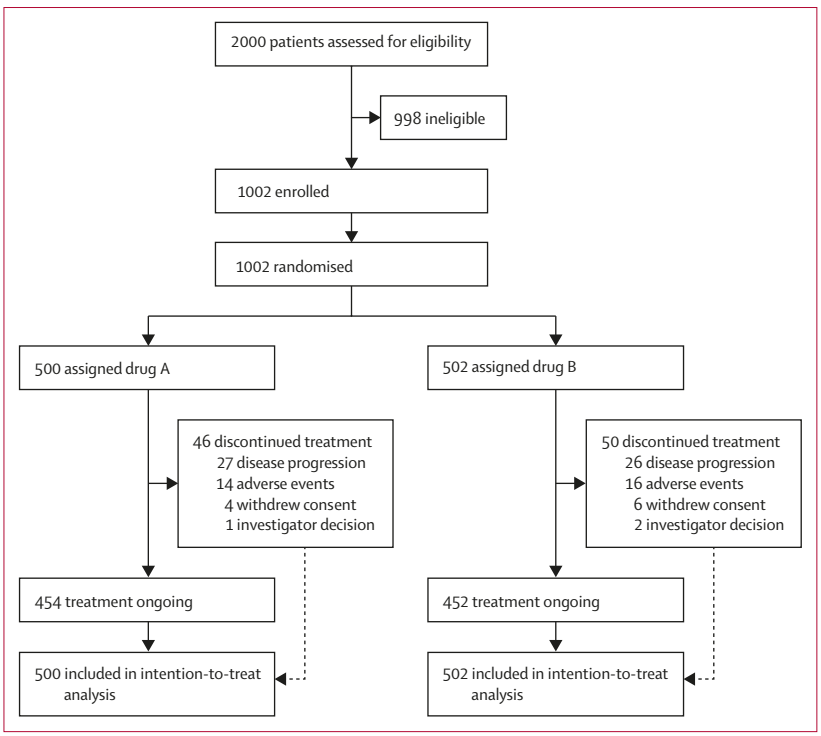

Figure 1: **Trial profile**

Please account for all dropouts and supply in an editable format such as Word or Powerpoint. See http://www.thelancet.com/pb/assets/raw/Lancet/authors/trial-profile-template.pptx for a template. Keep figure legends to a minimum length; do not repeat methods of analysis or interpretation of findings from the main text.

Introduction

- Give the background to your study, providing references for data presented and all previous studies mentioned.
- End with the aim of your study.

Methods

Study design

- Start with the study descriptor (randomised, parallel, cluster, non-inferiority, open-label, double-blind, etc).
- Indicate where the study was done (community, hospital), in which countries, and in how many centres or hospitals, as well as eligibility criteria for those sites.
- State the centre where ethics approval was obtained and add main ethics approval number.
- Provide a link to the study protocol and statistical analysis plan if available online, and detail any important changes to the trial after it commenced.
- Add details of any patient or public involvement in the design, conduct, and reporting of the trial.
- Provide the trial registration number, name of registry, and trial status (is the trial closed to new participants?).

Participants (or patients)

- Describe the planned population, with inclusion and exclusion criteria and how participants were recruited.
- State the method used to collect sex/gender data (eg, self-report, genetic testing). If self-reported by study participants, indicate what options were provided.
- State the method used to collect race/ethnicity data (eg, self-report, census, registry data).
- State whether participants gave written or oral informed consent.

Randomisation and masking

- Explain the groups to which participants were randomly assigned, describe the method of randomisation—ie, that used to generate the sequence with which participants are allocated to comparison groups (eg, computer, random-number tables, coin-toss), including details of the methods used to restrict the randomisation (block, stratification) and any stratification or minimisation factors.
- State method of allocation concealment (eg, sealed opaque envelopes).
- State who generated the sequence, who enrolled participants, and who assigned them to the trial groups and whether they had any involvement in the rest of the trial.
- Describe how masking (blinding) was achieved (eg, tablets with identical appearance, syringe taped up to

conceal colour of liquid inside). Include a statement of whether participants, people giving the interventions, those assessing outcomes, and those analysing the data were masked to group assignment, and how the success of masking was assessed.

Procedures

- Give details of interventions and concomitant care (type, method of delivery, duration), as well as who delivered the intervention/comparator. For drugs please provide the recommended international non-proprietary name, dose, route, and schedule of administration. For all commercial tests or devices, state the name of the manufacturer and place of manufacture.
- If applicable, add eligibility criteria for individuals delivering the interventions (eg, surgeons, physiotherapists).
- State the follow-up intervals and assessments done at each visit.
- If AI technology was used in any part of the study methods, please describe: how it was used (with sufficient detail to enable replication); the name of the tool; the version of the tool; and what prompts were used, if applicable.

Outcomes

- State the prespecified primary and secondary outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline), method of aggregation (eg, median, proportion), and timepoint for each outcome; for multicentre trials, state whether they were centrally assessed.
- List secondary outcomes (a complete list).
- Describe assessment of harms and adverse events.

Statistical analysis

- Indicate how the target sample size was calculated and what power the study had to detect a significant difference between treatment groups.
- Give details of main comparative analyses.
- State which participants were included each analysis (eg, "all randomised participants" or "patients were analysed according to treatment received"), and how missing data were handled in the analysis.
- Add explanation of any interim analyses and stopping guidelines.
- State statistics program and version number used for analyses.
- For non-inferiority studies, state the margin used to establish non-inferiority.
- State whether there was a data monitoring committee.

Role of the funding source

- Detail sources of study funding and other support (eg, supply of drugs), as well as the role of funders in the design, conduct, analysis, and reporting of the trial.
- Include standard statement (if funder had no role in study) or amend as necessary: "The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report."
- If the study had no funder, state: "There was no funding source for this study".

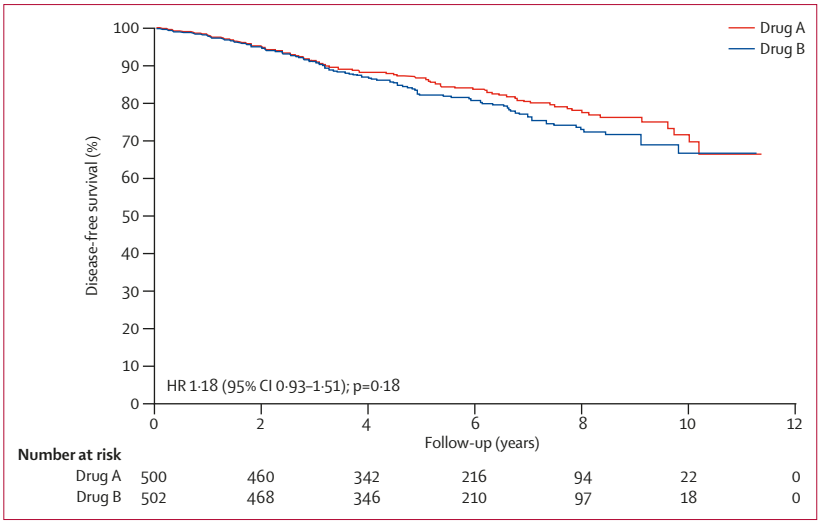

Figure 2: **Kaplan-Meier plot**
If you include a Kaplan-Meier plot, please supply in an editable format, with numbers at risk at each timepoint under the x axis (we also encourage authors to include the number of censored participants), include a measure of effect on the graph (usually log-rank p, plus hazard ratio and 95% CI), and do not break the y axis.

	Drug A (n=500)	Drug B (n=502)
Sex		
Male	247 (49%)	253 (50%)
Female	253 (51%)	249 (50%)
Age (years)	62 (57–68)	62 (54–68)
Ethnic origin		
White	240 (48%)	244 (49%)
Black	151 (30%)	156 (31%)
Asian	107 (21%)	98 (20%)
Other	2 (<1%)	4 (1%)
ECOG performance status		
0	239 (48%)	245 (49%)
1	261 (52%)	257 (51%)
BMI (kg/m²)	31·1 (4·5)	30·5 (5·3)
Mutation status*		
Wild-type *EGFR*	37/298 (12%)	32/296 (11%)
Unknown	261/298 (88%)	264/296 (89%)

Data are n (%), median (IQR), mean (SD), or n/N (%). ECOG=Eastern Cooperative Oncology Group. BMI=body-mass index. *Data not available for all randomised patients. Supply tables in Word, rather than Excel or pdf. Use the % symbol alongside any percentage data. Keep legends to a minimum length; do not repeat details of analysis from Methods.

Table 1: **Baseline characteristics of the intention-to-treat population**

Results

- Paragraphs in this section should follow the order: a description of number of participants recruited and included in analysis; baseline characteristics; findings for the primary outcome, secondary outcomes, adverse events, and finally any post-hoc or sensitivity analyses. No subheadings should be used in the Results or the Discussion sections.
- The first paragraph should state the exact dates (eg, Jan 1, 2023, to Dec 31, 2024) between which participants were recruited, and include with a trial profile (see figure 1 for an example; template available online) the number of participants assessed for eligibility, the number ineligible, the number eligible, the number randomised to each group, the number of exclusions or dropouts (including numbers adhering to treatment) at each stage, and the number assessed for the primary endpoint.
- Details of participants' baseline characteristics should be provided (table), but a formal statistical comparison (p value) should not be given because any differences between groups at this point must arise by chance (if randomised properly).
- The main outcome measures must include a point estimate (eg, relative risk, hazard ratio) plus a measure of precision (95% CI) of the difference between groups.
- State absolute numbers of participants or events alongside percentages. Mean values should be accompanied by SDs or 95% CI, and medians by IQRs. Supply p values to two significant figures (capped at four decimal places), or $p<0·0001$.
- Estimates of survival (either median or at a specific timepoint) should be accompanied by 95% CI.
- Ensure that any Kaplan-Meier survival curves (figure 2) have unbroken y axes, include numbers at risk below the x axis (we also encourage authors to include the cumulative number of censored participants in parentheses), and state a measure of effect (usually log-rank p, plus hazard ratio and 95% CI) on the graph. Similar guidance applies to cumulative incidence figures.
- Any histology figures should include magnification bars, and images of patients should only be used with signed consent from the patient or their representative (please do not send signed forms to *The Lancet*; please instead complete the patient consent section of the author statement form while retaining copies of the signed patient forms).

For the **trial profile template** see https://www.thelancet.com/pb-assets/Lancet/authors/trial-profile-template-1420559166003.pptx

Discussion

- The Discussion section should contain a full description and discussion of the context.
- Start with a sentence summarising your main findings and move on to relate your results to your hypothesis and data previously published. Authors must either to report their own, up-to-date systematic review or cite a recent systematic review of other trials as part of a panel putting your research into context with existing evidence (see panel for details). No subheadings should be used in this section.
- Discuss limitations and strengths of your study, noting sources of bias or imprecision.
- Discuss any controversies raised by this study.
- Discuss the representativeness of the study population, to help readers assess the applicability of the findings to their setting.
- Consider possible underlying mechanisms for your findings.
- Suggest future research directions.
- State general interpretation of data in light of all evidence available, noting the clinical significance and effects on patient care and policy, expanding on the summary provided in your Research in context panel.

Contributors

Provide a statement outlining what every author named at the start of the Article contributed to the study—eg, AB did the statistical analysis. BCD wrote the first draft of the report with input from EF. Please confirm here that all authors had full access to all the data in the study and had final responsibility for the decision to submit for publication. We require that more than one author (identified in this section by their initials) has directly accessed and verified the underlying data reported in the manuscript. For research articles that are the result of an academic and commercial partnership, at least one of the authors named as having accessed and verified data must be from the academic team.

Declaration of interests

Declare any competing interest for all authors, if none then add "I/We declare no competing interests." This statement must match what is reported on the signed forms submitted for all authors.

Data sharing

All submitted research Articles must contain a data sharing statement, which must include: whether data collected for the study, including individual participant data, statistical code, and a data dictionary defining each field in the set, will be made available to others ("undecided" is not an acceptable answer); what data will be made available (deidentified participant data, participant data with identifiers, data dictionary, or other specified data set); whether additional, related documents will be available (eg, study protocol, statistical analysis plan, informed consent form); when these data will be available (beginning and end date, or "with publication", as applicable); where the data will be made available (including complete URLs or email addresses if relevant); by what access criteria data will be shared (including with whom, for what types of analyses, by what mechanism—eg, with or without investigator support, after approval of a proposal, with a signed data access agreement, or any additional restrictions).

Acknowledgments

State the funding source for your work, including grant numbers here if applicable. If you wish to thank or acknowledge any individuals, please provide signed statements from them agreeing to be cited in your Article. If a medical writer or editor was involved in the creation of the manuscript, their name and who they were funded by should be added here or to the Contributors section. If you have used AI or AI-assisted technologies in the writing process, this assistance must be disclosed here.

References (maximum of 30 for primary research articles)

- Cite references in the text sequentially in the Vancouver numbering style, as a superscripted number after any punctuation mark—eg, as reported by Saito and colleagues.[15] Two references are cited

separated by a comma, with no space. Three or more consecutive references are given as a range. References in tables, figures, and panels should be in numerical order according to where the item is cited in the text. Do not include references in the Summary. See below for formatting examples of different reference types.

Journal references

- In print—eg, Author A, Author B. Title. *Journal* Year; **volume number:** page range linked by en rule.
- Published online before print—eg, Author A, Author B. Title. *Journal* Year; published online month day. DOI:xxx.xxx.xxx.
- Journal names are abbreviated in their standard form as in *Index Medicus*.
- If there are six authors or fewer, list all six (in the format: Smith R, Jones EH, Brown D, Green A); if there are seven or more give the first three, followed by et al.
- If the reference is to an abstract, we note that after the page range—eg, *BMJ* 1998; **255** (suppl 1)**:** 25–26 (abstr).

Book or published report references

- For references to a whole book or report, list the authors or editors and the publisher, the city of publication, and year of publication—eg, Editor A, Editor B, eds. Title of book. City of publication: Publisher, Year of publication.
- For a chapter or section of a book or report, also give the authors and title of the section, and the page numbers—eg, Author A, Author B. Title of chapter. In: Editor A, Editor B, eds. Title of book. City of publication: Publisher, Year of publication: page range of chapter.

Other

- For online material, please cite the authors of the page, the title, and the date created, along with the URL and the date you accessed the website—eg, Author A, Author B (if available). Title of document. Date (if available). URL (accessed month day, year).
- Unpublished material is cited in the text as unpublished if it is the author's own observation, or as a personal communication from a named individual (with their institution stated) if it is by someone else. Written permission is needed to cite personal communications.
- References that have been submitted to a journal but not accepted for publication should be cited as unpublished data in the text and not included in the reference list. References that have been accepted by a journal and are in press can be included in the list; please supply a copy of the letter of acceptance.

For **journal name abbreviations** see http://www.ncbi.nlm.nih.gov/nlmcatalog/journals