Revista Clínica Española (English Edition)

Guide for authors

Introduction

Introduction

Revista Clínica Española published its first issue in 1940 and is the communication channel of the Spanish Society of Internal Medicine (SEMI).

Revista Clínica Española fully endorses the goals of updating knowledge and facilitating the understanding of key developments in internal medicine applied to clinical practice.

Revista Clínica Española is subject to a thorough double-blind review of the received articles written in Spanish or English. Nine issues are published each year, including mostly originals, reviews and consensus documents.

Revista Clínica Española is included, amongst other databases, in: Current Contents/Clinical Medicine, JCR/SCI-Expanded, Index Medicus/Medline and Excerpta Medica/EMBASE.

Articles by Spanish authors should comply with the general criteria of Law 14/2007, from 3rd July, for biomedical research (BOE n 159), which protects the rights of individuals who are subjects of research. Clinical trials should be registered with public databases prior to their initiation and patient recruitment, and only after approval of the institutional or regional Clinical Research Ethics Committee. The authors should provide the archive number and database where the trial is registered. For all clinical trials that initiate patient recruitment as of 1 January 2017, registration in public databases will be mandatory. Trials with patient recruitment prior to this date may still be submitted to the Journal for evaluation.

USE OF PUBLISHING GUIDELINES

When preparing articles, the international guidelines should be followed in order to express health research results and apply them to the specific type of study. Authors must provide a check-list, indicating the page number of the manuscript that refers to each section of the guidelines. This check-list will make it easier to review, but it will not be published with the work.

EQUATOR contains an introduction and several aids (toolkits) for authors and manuscript reviewers. Some are also in Spanish. Each type of article requires specific guidelines:

Clinical trials: CONSORT. These guidelines are required, with the flow diagram being included in the manuscript, as well as its adjustment to non-pharmacological treatments. The check-list will be provided on the last page of the manuscript.

Observational studies: STROBE following the checklist appropriate to the type of study (cohort, case-control, or cross-sectional), and including the flow diagram in the manuscript. The checklist will be provided on the last page of the manuscript.

Diagnostic tests: STARD, including the checklist on the last page of the manuscript.

Systematic reviews and meta-analysis: PRISMA, including the flow diagram in the manuscript, and providing the check-list on the last page of the manuscript.

Qualitative studies and focus groups: COREQ.

Studies on quality improvement: SQUIRE.

For other types of studies, consult EQUATOR.

Types of article

Any article submitted to this journal must include a series of statements both on the title page and within the body of the article in certain cases. Statements will be required even if they are

also requested on the submission platform, or if the author believes they do not exist or are not applicable.

TITLE PAGE

The following statements must be included on the title page:

Ethical considerations

Any article that includes experiments involving human subjects will require a statement from the author confirming that all procedures were conducted in accordance with the Declaration of Helsinki, relevant laws, and institutional guidelines. The study's ethical approval reference number should be included in works involving human experimentation. When experimentation involves animals, compliance with the relevant regulations must also be noted.

This is a mandatory statement for Original Articles, Short Originals, and Clinical-Pathological Conferences. Depending on the nature of Special Articles and Protocols, an ethical statement may be required. Authors of Special Articles and Protocols must always include a statement one way or another: that it has been obtained or that it is not applicable. While systematic reviews do not require ethical approval, they must be based on original research that does meet those ethical requirements.

Informed consent

It must be stated that there are no patient data in the article, and if there are, that they do not violate the privacy and confidentiality of the patient, nor allow for their identification, and that in any case, informed consent for participation in research and for the presentation of results in a publication is in place.

The rights of privacy of human subjects must always be respected. Appropriate consents and permissions must be obtained when presenting one or more cases (anonymised) without experimentation or when an author wishes to include details or other personal information or images of patients and any other individuals in an Elsevier publication. Isolated data such as age, sex, service, or institution presented together can breach patient privacy and confidentiality. Images accompanied by any patient data always require a statement.

The author will retain written consents and provide Elsevier with copies of the consents or proof of their acquisition when requested.

When Original research refers to retrospective studies where obtaining informed consent is not possible, the author must obtain exemption from this statement from their institution's Ethics Committee to proceed with the research.

This is a mandatory statement for Original Articles, Short Originals, Clinical Eye, Scientific-Clinical Letters, and Clinical-Pathological Conferences. While systematic reviews do not require informed consent, they must be based on original research that does comply with this requirement.

Funding

The author will identify who provided financial support for the research and/or preparation of the article and briefly describe the role of the sponsor(s), if applicable, in the study design; in the collection, analysis, and interpretation of data; in the drafting of the report; and in the decision to submit the article for publication. If the funding source(s) did not have such involvement, this should be declared.

This is a mandatory statement for all sections. In the absence of funding, it should state: "Funding: none."

Conflict of interests

Any financial or personal relationships with other people or organisations that may have influenced the work must be specified, even if not directly related to the current manuscript. Examples of potential competing interests include employment, consultancy, share ownership, fees, paid expert testimony, patent applications/registrations, and other funding, as well as travel grants and participation in courses and conferences as a paid expert.

If a member of the Editorial Board contributes as an author to any manuscript submitted to the Journal, the responsible editor must include the following statement in the conflict of interest section: “As ABC is a member of the Editorial Board of the Journal, they have not participated in or had access to information regarding the review and acceptance process of the manuscript.”

This statement is always mandatory. There will be a statement from each of the participating authors. In the absence of any conflict, it should state: "Conflict of interest: none."

Use of generative artificial intelligence in scientific writing Single permitted use.

Please see the description further down in these guidelines.

Mandatory statement whenever it is used.

Authorship

All authors must have made substantial contributions in each of the following aspects: (1) the conception and design of the study, or the acquisition of data, or the analysis and interpretation of data, (2) drafting the article or critically revising its intellectual content, (3) final approval of the version to be submitted. No changes to authorship or alterations to the order of authors may be made once the article has been submitted without prior justification and approval from the Chief Editor.

BODY OF THE ARTICLE In cases where experiments are conducted with animals or human subjects, certain statements must be included within the manuscript even if they are also required on the submission platform or on the title page. These statements will always be declared in Original Articles or Short Originals, regardless of whether the author believes they do not exist or are not applicable.

Ethics and informed consent

In the case of experiments involving human or animal subjects, the author must declare in the materials and methods section (of the originals, short originals, or case series articles) that the guidelines on Human and Animal Rights described in the "Ethics in Publishing" section of this author guideline have been followed. In particular, if human experimentation is involved, the authors will confirm that the research has been conducted in accordance with the ethical code of the World Medical Association (Declaration of Helsinki), and in the case of animals, that the ARRIVE guidelines have been followed or that they are acting in accordance with the Animal Welfare Act and, where applicable, the Animal Welfare Act. The authors must also declare in the materials and methods section (original or short original) that they have obtained informed consent and approval from the Clinical Research Ethics Committee (CREC) or the relevant committee without revealing data that would hinder blind evaluation. Please note that Spanish Biomedical Research Law stipulates that the Ethics Committees for Research corresponding to each institution must evaluate all biomedical research involving interventions in humans or the use of their biological samples.

Appropriate consents and permissions must be obtained when presenting one or more cases without experimentation or when an author wishes to include details or other personal information or images of patients and any other individuals in an Elsevier publication. The author

will retain written consent forms and provide Elsevier with copies of the consent forms or evidence of their acquisition upon request.

ORIGINAL ARTICLES

Clinical or experimental studies, randomised clinical trials, cohort studies, screening studies or diagnostic tests, cost-effectiveness analyses, decision-making evaluation studies, interventional studies, case-control studies, and survey-based studies with a high response rate will be considered. They may cover any field related to Internal Medicine, with particular emphasis on their clinical relevance.

Occasionally, study protocols that are deemed relevant, innovative, and potentially citable may be accepted for publication, subject to evaluation by the Editorial Committee. The topics of the articles may cover any field related to Medicine, with particular emphasis on their clinical relevance.

They will have a maximum length of 4,000 words, excluding the title page or first page with its statements, the structured abstract of 250 words, keywords, figure legends, and references (maximum 50). A maximum of 6 tables or figures will be allowed. The number of authors will not exceed 10 but may increase if the corresponding author provides justification and in cases of collaborative studies. Preparation of a graphical abstract summarising the most important aspects of the manuscript will be mandatory; the author may submit it initially or when they know their article will be accepted. You can find information for creating it at (https://www.elsevier.com/researcher/author/tools-and-resources/graphical-abstract).

Revista Clínica Española requires registration of all clinical trials that have been published, as well as acceptance of the studies by the relevant ethics committees. For the preparation of controlled clinical trials, the CONSORT guidelines must be followed, available at: http://www.consort-statement.org/. In the case of observational studies, the points outlined in the checklist available at: http://www.strobe-statement.org/ must be followed. For studies on the validity of diagnostic tests, the STARD guidelines available at: http://www.stard-statement.org/ must be adhered to.

The required statements will be included on the title page or first page.

SHORT ORIGINALS

These will be considered research works that, due to their characteristics, may be published in abbreviated form. They will be structured like original articles. The length will not exceed 1,500 words, excluding the title page or first page with its statements, the abstract (of 150 words), keywords, figure legends, and references (no more than 20). Up to 2 figures or tables may be included. The number of authors will not exceed 8. Preparation of a graphical abstract summarising the most important aspects of the manuscript will be mandatory; the author may submit it initially or when they know their article will be accepted. Information for creating it can be found at (https://www.elsevier.com/researcher/author/tools-and-resources/graphical-abstract).

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CLINICAL REVIEW

This section will feature commissioned articles on topics that the Editorial Committee considers relevant and worthy of updating knowledge. It may appear in one of the following formats:

1. A narrative clinical review with a maximum length of 4,000 words in the manuscript, excluding the title page or first page with statements, an unstructured abstract of 150 words, keywords, bibliography (maximum 80 references), and figure legends. Up to 4 tables or figures may be included;

2. A brief clinical review with a maximum length of 2,000 words in the manuscript, excluding the title page or first page with statements, an unstructured abstract of 150 words, keywords, bibliography (maximum 50 references), and figure legends. Up to 2 tables or figures may be included.

The maximum number of authors will be 4 for either format. Any author may submit unsolicited manuscripts for consideration in this section, subject to prior contact and acceptance of the topic by the Editorial Team.

The required statements will be included on the title page or first page.

SYSTEMATIC REVIEWS AND META-ANALYSES

Systematic reviews may or may not use statistical methods (meta-analysis) to analyse and summarise the results of the included studies. The PRISMA guidelines will be followed, available at: http://prisma-statement.org/. The maximum length of the manuscript will be 4,000 words, excluding the title page or first page with statements, the structured abstract (maximum 250), keywords, bibliography (maximum 80 references), and figure legends. Up to 5 tables or figures may be included. The maximum number of authors will not exceed 6. Preparation of a graphical abstract summarising the most important aspects of the manuscript is recommended. Information for creating it can be found at (https://www.elsevier.com/researcher/author/tools-and-resources/graphical-abstract).

The required statements will be included on the title page or first page.

THE CLINICAL EYE

This section will publish an image that has high educational or training value on its own. The image must be detailed and accompanied by arrows or symbols for clarification. A maximum of 3 authors and 150 words (excluding the title) may be included, as well as 2 references at the authors' discretion (not mandatory).

The required statements will be included on the title page or first page.

CLINICAL-PATHOLOGICAL CONFERENCES

Sessions that meet the following criteria may be submitted to this section:

a) Clinical discussion of a case, accompanied by an anatomical-pathological correlation, held in any of the Spanish hospitals; b) The clinical speaker will discuss the most relevant aspects of the case, establish a series of differential diagnoses based on the provided data, and suggest a diagnosis. The discussion will always centre around the clinical data of the presented case. The initial diagnosis established by the responsible physicians will then be detailed. Subsequently, some of the interventions or comments (a maximum of 4) raised by attendees at the session will be collected; c) After the clinical discussion, a pathologist will detail the main histopathological findings and specify the cytological-histological diagnosis; d) Following this, the clinical speaker may perform the anatomical-clinical correlation; e) The maximum length of the work will be 4,000 words, excluding the title page and abstract, as well as a maximum of 20 bibliographic citations. Up to 3 tables and 4 figures will be permitted. The maximum number of authors will be 5; f) The clinical speaker and the pathologist will be listed as authors in the manuscript. If a third person is responsible for organising the Clinical-Pathological Conferences (CPC) and collaborates in its editing, they will be listed as an Associate Editor, not as an author; g) All CPCs must be evaluated by the Editorial Board of Rev Clin Esp before acceptance and publication.

The required statements will be included on the title page or first page.

SCIENTIFIC LETTERS

These will consist of observations or experiences that can be summarised in a brief text and communicated concisely. A maximum of 750 words, 1 figure or table, and up to 15 bibliographic citations will be permitted, with a maximum of 4 authors.

The required statements will be included on the title page or first page.

LETTERS TO THE EDITOR

These will be objections or comments on articles recently published in the Journal. Letters regarding articles previously published in the Journal will take precedence for publication, as well as the right to reply. These letters will be shorter, with a maximum of 300 words and 5 bibliographic references; they must not reference unpublished personal studies or experiences. They will be sent to the author of the original work, who may respond in a similarly sized written piece within a month. The Letter and the reply will be published continuously.

The required statements will be included on the title page or first page.

SPECIAL ARTICLES

This section aims to accommodate manuscripts that, due to their unique content, cannot be included in other sections. They will have a maximum length of 2,000 words, excluding the title page or first page where the required statements will be included, the unstructured abstract of 150 words, keywords, and a maximum of 40 bibliographic citations. Up to 3 tables or figures may be included. The maximum number of authors will be 3.

The required statements will be included on the title page or first page.

CONSENSUS DOCUMENTS

The submission of the final manuscript for evaluation in Revista Clínica Española must be accompanied by the corresponding authorisation from the Board of Directors of the Spanish Society of Internal Medicine, as well as from any other societies that may be represented in the document. Ideally, consensus works with a multidisciplinary perspective will be valued, including specialists who typically address a particular pathology. The required statements must be included on the title page or first page of the manuscript. The journal will publish the accepted consensus document as an Executive Summary. The aim of publishing the Executive Summary is to provide readers with a synthesis of the consensus document, while offering sufficient detail and clarity to understand the scope and most relevant points of the complete document. The following guidelines should be followed for its preparation:

1. Title in Spanish and English. It should preferably begin with the phrase: "Executive summary of the consensus document on..."
2. Maximum of 10 authors. The authorship of a working group may be included as an annex at the end of the manuscript. Professional affiliations are required for all authors.
3. Summary in Spanish and English. Maximum of 150 words.
4. Keywords in Spanish and English according to MeSH.
5. The body of the executive summary will have a maximum length of 3,000 words:
    - An introduction describing the need or rationale for the document.
    - A methods section explaining how the consensus document was created, how the points to be addressed were selected, and whether there was any discussion or agreement on each point and what the percentage of agreement was.
    - A results section highlighting the most significant aspects of the document.

- A brief discussion on the applicability, limitations, and implications of the document.
- Reference to the complete document in one of the sections, accessible via a link.
- Bibliography (maximum of 15 citations) following the guidelines of Revista Clínica Española.
- Tables and figures that aid in interpreting the information clearly and concisely.

6. Each component of the executive summary must be uploaded to the RCE platform, along with associated documents or additional material, including the complete document that will be published as an annex.

The required statements will be included on the title page or first page.

EDITORIALS

These will be commissioned, although unsolicited editorials may occasionally be considered after prior consultation with the Editor. The text is limited to a maximum of 1,500 words. No tables or figures are permitted, but a graphical abstract summarising the most important aspects of the manuscript is recommended. Up to 15 references will be accepted. Up to 2 authors will be permitted.

The required statements will be included on the title page or first page.

Contact details for submission

All manuscripts must be submitted online at https://www.editorialmanager.com/rce.

Language

This journal is published in Spanish and in English language

Submission checklist

You can use this list to carry out a final check of your submission before you send it to the journal for review. Please check the relevant section in this Guide for Authors for more details.

Ensure that the following items are present:

One author has been designated as the corresponding author with contact details:

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All necessary files have been uploaded:

Manuscript

- Include keywords
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- All tables (including titles, description, footnotes)
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• Indicate clearly if color should be used for any figures in print

Graphical Abstracts / Highlights files (where applicable)

Supplemental files (where applicable)

Further considerations:

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- All references mentioned in the Reference List are cited in the text, and vice versa
- Permission has been obtained for use of copyrighted material from other sources (including the Internet)
- A competing interests statement is provided, even if the authors have no competing interests to declare
- Journal policies detailed in this guide have been reviewed

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Before you begin

Ethics in publishing

Please see our information on Ethics in publishing.

Studies in humans and animals

If the work involves the use of human subjects, the author should ensure that the work described has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. The manuscript should be in line with the Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals and aim for the inclusion of representative human populations (sex, age and ethnicity) as per those recommendations. The terms sex and gender should be used correctly.

The author should ensure that the manuscript contains a statement that all procedures were performed in compliance with relevant laws and institutional guidelines and have been approved by the appropriate institutional committee(s). This statement should contain the date and reference number of the ethical approval(s) obtained. Authors should also include a statement in the manuscript that informed consent was obtained for experimentation with human subjects. The privacy rights of human subjects must always be observed.

The journal will not accept manuscripts that contain data derived from unethically sourced organs or tissue, including from executed prisoners or prisoners of conscience, consistent with recommendations by Global Rights Compliance on Mitigating Human Rights Risks in Transplantation Medicine. For all studies that use human organs or tissues authors must provide sufficient evidence that they were procured in line with WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. The source of the organs or tissues used in clinical research must be transparent and traceable. Authors of manuscripts describing organ transplantation must additionally declare within the manuscript:

1. that autonomous consent free from coercion was obtained from the donor(s) or their next of kin; and
2. that organs/tissues were not sourced from executed prisoners or prisoners of conscience.

All animal experiments should comply with the ARRIVE guidelines and should be carried out in accordance with the U.K. Animals (Scientific Procedures) Act, 1986 and associated guidelines, EU Directive 2010/63/EU for animal experiments, or the National Research Council's Guide for the Care and Use of Laboratory Animals and the authors should clearly indicate in the manuscript that such guidelines have been followed. The sex of animals must be indicated, and where appropriate, the influence (or association) of sex on the results of the study.

Informed consent and patient details

Studies on patients or volunteers (including organ/tissue donors) require informed consent, which should be documented in the paper. Appropriate consents, permissions and releases must be obtained where an author wishes to include case details or other personal information or images of patients and any other individuals in an Elsevier publication. Written consents must be retained by the author, but copies should not be provided to the journal.

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Unless the author has written permission from the patient (or, where applicable, the next of kin), the personal details of any patient included in any part of the article and in any supplementary materials (including all illustrations and videos) must be removed before submission.

Declaration of interest

All authors must disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work. Examples of potential competing interests include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding. Authors must disclose any interests in two places: 1. A summary declaration of interest statement in the title page file (if double anonymized) or the manuscript file (if single anonymized). If there are no interests to declare then please state this: 'Declarations of interest: none'. 2. Detailed disclosures as part of a separate Declaration of Interest form, which forms part of the journal's official records. It is important for potential interests to be declared in both places and that the information matches. More information.

Declaration of generative AI in scientific writing

The below guidance only refers to the writing process, and not to the use of AI tools to analyse and draw insights from data as part of the research process.

Where authors use generative artificial intelligence (AI) and AI-assisted technologies in the writing process, authors should only use these technologies to improve readability and language. Applying the technology should be done with human oversight and control, and authors should carefully review and edit the result, as AI can generate authoritative-sounding output that can be incorrect, incomplete or biased. AI and AI-assisted technologies should not be listed as an author or co-author, or be cited as an author. Authorship implies responsibilities and tasks that can only be attributed to and performed by humans, as outlined in Elsevier's AI policy for authors.

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Statement: During the preparation of this work the author(s) used [NAME TOOL / SERVICE] in order to [REASON]. After using this tool/service, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the publication

This declaration does not apply to the use of basic tools for checking grammar, spelling, references etc. If there is nothing to disclose, there is no need to add a statement.

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Submission of an article implies that the work described has not been published previously (except in the form of an abstract, a published lecture or academic thesis, see 'Multiple, redundant or concurrent publication' for more information), that it is not under consideration for publication elsewhere, that its publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out, and that, if accepted, it will not be

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Use of inclusive language

Inclusive language acknowledges diversity, conveys respect to all people, is sensitive to differences, and promotes equal opportunities. Content should make no assumptions about the beliefs or commitments of any reader; contain nothing which might imply that one individual is superior to another on the grounds of age, gender, race, ethnicity, culture, sexual orientation, disability or health condition; and use inclusive language throughout. Authors should ensure that writing is free from bias, stereotypes, slang, reference to dominant culture and/or cultural assumptions. We advise to seek gender neutrality by using plural nouns ("clinicians, patients/clients") as default/wherever possible to avoid using "he, she," or "he/she." We recommend avoiding the use of descriptors that refer to personal attributes such as age, gender, race, ethnicity, culture, sexual orientation, disability or health condition unless they are relevant and valid. When coding terminology is used, we recommend to avoid offensive or exclusionary terms such as "master", "slave", "blacklist" and "whitelist". We suggest using alternatives that are more appropriate and (self-) explanatory such as "primary", "secondary", "blocklist" and "allowlist". These guidelines are meant as a point of reference to help identify appropriate language but are by no means exhaustive or definitive.

Reporting sex- and gender-based analyses

Reporting guidance

For research involving or pertaining to humans, animals or eukaryotic cells, investigators should integrate sex and gender-based analyses (SGBA) into their research design according to funder/sponsor requirements and best practices within a field. Authors should address the sex and/or gender dimensions of their research in their article. In cases where they cannot, they should discuss this as a limitation to their research's generalizability. Importantly, authors should explicitly state what definitions of sex and/or gender they are applying to enhance the precision, rigor and reproducibility of their research and to avoid ambiguity or conflation of terms and the constructs to which they refer (see Definitions section below). Authors can refer to the Sex and Gender Equity in Research (SAGER) guidelines and the SAGER guidelines checklist. These offer systematic approaches to the use and editorial review of sex and gender information in study design, data analysis, outcome reporting and research interpretation - however, please note there is no single, universally agreed-upon set of guidelines for defining sex and gender.

Definitions

Sex generally refers to a set of biological attributes that are associated with physical and physiological features (e.g., chromosomal genotype, hormonal levels, internal and external anatomy). A binary sex categorization (male/female) is usually designated at birth ("sex assigned at birth"), most often based solely on the visible external anatomy of a newborn. Gender generally refers to socially constructed roles, behaviors, and identities of women, men and gender-diverse people that occur in a historical and cultural context and may vary across societies and over time. Gender influences how people view themselves and each other, how they behave and interact and how power is distributed in society. Sex and gender are often incorrectly portrayed as binary (female/male or woman/man) and unchanging whereas these constructs actually exist along a spectrum and include additional sex categorizations and gender identities such as people who are intersex/have differences of sex development (DSD) or identify as non-binary. Moreover, the terms "sex" and "gender" can be ambiguous--thus it is important for authors to define the manner

in which they are used. In addition to this definition guidance and the SAGER guidelines, the resources on this page offer further insight around sex and gender in research studies.

Authorship

All authors should have made substantial contributions to all of the following: (1) the conception and design of the study, or acquisition of data, or analysis and interpretation of data, (2) drafting the article or revising it critically for important intellectual content, (3) final approval of the version to be submitted.

Changes to authorship

Authors are expected to consider carefully the list and order of authors **before** submitting their manuscript and provide the definitive list of authors at the time of the original submission. Any addition, deletion or rearrangement of author names in the authorship list should be made only **before** the manuscript has been accepted and only if approved by the journal Editor. To request such a change, the Editor must receive the following from the **corresponding author**: (a) the reason for the change in author list and (b) written confirmation (e-mail, letter) from all authors that they agree with the addition, removal or rearrangement. In the case of addition or removal of authors, this includes confirmation from the author being added or removed.

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Reporting clinical trials

Randomized controlled trials should be presented according to the CONSORT guidelines. At manuscript submission, authors must provide the CONSORT checklist accompanied by a flow diagram that illustrates the progress of patients through the trial, including recruitment, enrolment, randomization, withdrawal and completion, and a detailed description of the randomization procedure. The CONSORT checklist and template flow diagram are available online.

Registration of clinical trials

Registration in a public trials registry is a condition for publication of clinical trials in this journal in accordance with International Committee of Medical Journal Editors recommendations. Trials must register at or before the onset of patient enrolment. The clinical trial registration number should be included at the end of the abstract of the article. A clinical trial is defined as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects of health outcomes. Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example drugs, surgical procedures, devices, behavioural treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

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