Atención Primaria

GUIDE FOR AUTHORS

INTRODUCTION

Atención Primaria is a journal that publishes works relative to the field of Primary Healthcare. From a conceptual point of view, Atención Primaria adopts the new model of Primary Healthcare, not only directed at the treatment and curing of the disease, but also of its prevention and the promotion of health, both at an individual level as well as at a family and community level. In these new characteristics that define the Primary Healthcare models, are included those that are focused on the research works that Atención Primaria publishes, the leading journal of Spanish originals created to gather and disseminate the scientific production from Primary Care Centres on topics that include, among others, the producing of health care protocols, prevention programs, follow-up and control of patients with chronic illnesses, as well as the organisation and management of Primary Healthcare. In addition to the rigorously selected, systematically peer-reviewed manuscripts published in the research sections (research articles, scientific letters, editorials, and letters to the editor), the journal also contains other important sections, such as review articles, consensus and clinical guides from the most important scientific societies. The journal is included in Medline/PubMed, Science Citation Index Expanded, and SCOPUS.

Types of article

ORIGINAL ARTICLES

In this section articles will be published that present clinical and / or epidemiological studies carried out by the authors. Additionally, works on organisational aspects and quality control could be included in the section. The studies must have been carried in the Primary Health Care setting or their results are of interest in this field. The maximum number of authors is 6.

The structure of the articles that are requested to be published in this section depends on the type of investigation presented:

- Quantitative research.

- Systematic review (meta-analysis).

- Qualitative research.

ORIGINAL ARTICLES: QUANTITATIVE RESEARCH

Articles will be included here that present clinical and epidemiological studies that have used quantitative methodology in their design and analysis (for example, prevalence studies, follow-
up of a cohort, case control studies, randomised clinical trial, etc.).

The structure of the articles must be as follows:

- Cover letter (see general guidelines).

- First page (see general guidelines)

- A structured abstract (maximum: 250 words).

- Text: a maximum of 2500 words, not counting Tables, references or the Abstracts.

- From 3 to 6 key points.

- Tables and Figures: maximum 6 (See general guidelines).

- Diagram of the study.

Each one of the previous parts must be started on a new page.

The structured ABSTRACT will include the title of the article and must have the following structure:

**Objective:** clear identification of the main purpose of the study. **Design:** description of the basic design of the study (randomised clinical trial, case control study...), and its basic characteristics if they are relevant (double blind, multicentre...). If the design of the study is not clear, its main characteristics must be mentioned (cross-sectional or longitudinal, prospective or retrospective, observational or intervention, controlled or uncontrolled...).

**Location:** place where the study was performed and the type and level of health care (Primary, Hospital, Community Care...).

**Participants:** patient characteristics, selection criteria, number of enrolled subjects and non-responders and drop-outs that have occurred.

**Interventions** (in intervention studies): main characteristics, including the administration schedule and duration, of the interventions performed in the study groups, as well as any in the comparison groups.

**Main measurements:** primary variables of the study, especially the response variable used and its evaluation method.

**Results:** main quantitative results, identifying the type of measurement used and its corresponding confidence interval. Where applicable, it should contain the level of statistical significance.

**Conclusions:** the main conclusions arising from the results of the study, including their practical application.

The TEXT must be adapted to the Introduction/Materials and Methods/Results and Discussion structure, following the recommendations set out below:

**Introduction:** It must present the current situation on the knowledge of the topic and the context in which the study is framed. The objective of the study must be clearly defined. The
introduction must be as brief as possible and be supported in a reduced number of key literature references.

*Material and methods:* It must include the design of the study, the centre where the research was carried out, the inclusion and exclusion criteria and the screening procedure of the participants, the interventions performed (if applicable), the definitions, and the measurement techniques of the variables, the follow-up of the subjects and the analysis strategy, as well as the statistical tests used. It must be written with sufficient detail so that the study could be repeated. The use of headings is recommended in order to organise the information (study population, interventions, follow-up, statistical analysis...).

*Results:* This must present, not interpret, the principle findings associated with the aims of the study. Headings may be used to make the presentation clearer. It is advised to use Tables and Figures without the unnecessary repetition of the data in the text. The main results must include the corresponding confidence intervals, and must clearly indicate the type of measurement and the statistical tests used, where applicable. When the significance level is less than 0.20, it is preferable to present its exact value. It is recommended to highlight the Table or Figure that contain the principal results of the study, with a description of these in the legend.

*Discussion:* It is advised to structure it with the following headings (where relevant): limitations of the design used: a comparison with the scientific literature, attempting to explain the differences observed; practical application of the results, performing an evaluation on their clinical relevance; and directions for future research on the topic.

*Acknowledgements:* To individuals or institutions that, not having fulfilled the requirements of authorship, may have collaborated in the performing of the work, providing material, technical or financial help. The type of contribution should be mentioned.

*Bibliography:* A maximum of 30 literature references is recommended, which must be as recent and relevant as possible, and carefully written in accordance with the Vancouver format.

*Key points:* All original works must include a Table with the key points to help in the understanding of the work by those readers that do not wish to read the full article. It must include a maximum of 3 short and precise sentences that indicate what is known on the topic before carrying out the study and the need to have carried it out (under the heading “What is known on the topic”), and another maximum of 3 sentences that indicate what this study has contributed to the previous knowledge of the topic (under the heading What this study contributes).

*Study Outline:* A Figure will also be included of the study outline that shows the number of subjects in each of the stages of the study and the reasons of the non-responses, losses and drop-outs that may have occurred. The Figure legend must summarise the main characteristics of the study design. If the study is a randomised clinical trial, this Figure must follow that of the most up to date CONSORT statement, available at [http://www.consort-statement.org](http://www.consort-statement.org)

**ORIGINAL ARTICLES: SYSTEMATIC REVIEWS (META-ANALYSIS)**

This section will include all articles that present systematic reviews of the literature and other sources of evidence, which are critically evaluated in order to provide an answer to a particular question. therefore, narrative type reviews or knowledge update articles are not included.

The structure of the articles must be as follows:
- Cover letter (see general guidelines).

- First page (see general guidelines)

- A structured abstract (maximum: 250 words).

- Text: a maximum of 2500 words, not counting tables, references or the abstract.

- From 3 to 6 key points.

- Tables and Figures: maximum 6 (See general guidelines).

- Study outline.

Each one of the previous parts must be started on a new page.

The structured ABSTRACT will include the title of the article and must have the following structure:

**Objective**: clear identification of the main purpose of the review. If there is more than one, it is advised to point out the primary one and the secondary ones.

**Design**: It study must be identified as a systematic review.

**Data sources**: Data bases consulted, period covered and main characteristics of the search strategy of the individual studies used.

**Selection of studies**: selection criteria of the studies, number of studies included and excluded, main characteristics of the studies included.

**Data extraction**: method for assessing the validity of the studies and data collection, and main variables collected.

**Results**: main quantitative results, identifying the type of measurement used and its corresponding confidence intervals. Where applicable, it should include the level of statistical significance. Where applicable, the results of the sensitivity analysis should be included.

**Conclusions**: the main conclusions arising from the results of the study, including their practical application.

The TEXT must be adapted to the Introduction/Materials and Methods/Results and Discussion structure, following the recommendations set out below:

**Introduction**: It must present the current situation on the knowledge of the topic and the context in which the study is framed. The question that the review seeks to answer must be clearly defined. The introduction must be as brief as possible and be supported with a reduced number of key literature references.

**Material and methods**: The strategy for identifying the relevant studies must be described, including the data bases consulted and the descriptive terms used, the inclusion and exclusion criteria of the studies, the procedure for assessing their validity, the data extraction methods and the analysis strategy, as well as the statistical tests used for the data analysis. It must be written with sufficient detail so that the study could be repeated. The use of headings is recommended in order to organise the information (identification of studies, selection of
Results: It must present, not interpret, the principle findings associated with the aims of the review. Headings may be used to make the presentation clearer. It is advised to use Tables and Figures without the unnecessary repetition of the data in the text. It is recommended to include a Table with a breakdown of the main characteristics and results of the studies included in the review. The main results must include the corresponding confidence intervals, and must clearly indicate the type of measurement and the statistical tests used, where applicable. It is recommended to graphically present the confidence intervals in a Figure. When the significance level is less than 0.20, it is preferable to present its exact value. It is recommended to highlight the Table or Figure that contain the main results of the study, with a description of these in the legend.

Discussion: It is advised to structure it with the following headings (where relevant): limitations of the review, including suggestions on the effect of a possible publication bias, and comments on the homogeneity of the individual studies and the possible influence of variability on the final results; a comparison with the scientific literature, attempting to explain the differences observed; practical application of the results, performing an evaluation on their clinical relevance; and directions for future research on the topic.

Acknowledgements: To individuals or institutions that, not having fulfilled the requirements of authorship, may have collaborated in the performing of the work, providing material, technical or financial help. The type of contribution should be mentioned.

Bibliography: The literature references must be numbered consecutively in the order in which they appear for the first time in the text, identifying them using Arabic numbers (in parentheses). A maximum of 30 literature references is recommended, which must be as recent and relevant as possible, and carefully written in accordance with the Vancouver format. The studies included in the review must be included in the literature references.

Key points: All original works must include a Table with the key points to help in the understanding of the work by those readers that do not wish to read the full article. It must include a maximum of 3 short and precise sentences that indicate what is known on the topic before carrying out the study and the need to have carried it out (under the heading "What is known on the topic"), and another maximum of 3 sentences that indicate what this study has contributed to the previous knowledge of the topic (under the heading "What this study contributes").

Outline of the Study: A Figure will also be included with an outline that shows the number of studies selected in each of the stages of the review and the reasons for the exclusions. It is recommended that the outline follows the most up to date PRISMA statement, available at: http://www.prisma-statement.org/

ORIGINAL ARTICLES: QUALITATIVE RESEARCH.

Articles will be included here that present studies that have used qualitative methodologies for the approach to the topic of the research.

The structure of the articles must be as follows:

- Cover letter (see general guidelines).

- First page (see general guidelines)
- A structured abstract (maximum: 250 words).

- Text: a maximum of 2500 words, not counting tables, references or Abstract.

- From 3 to 6 key points.

- Tables and Figures: maximum 6 (See general guidelines).

- Study outline.

Each one of the previous parts must be started on a new page.

The structured ABSTRACT will include the title of the article and should have the following structure:

**Objective:** clear identification of the main purpose of the study. If there is more than one, it is advised to point out the primary one and any secondary ones.

**Location:** place where the study was performed and the type and level of health care (Primary Care, hospital, Community Care...).

**Participants and / or contexts:** Selection criteria and acquisition process.

**Method:** Sample design, description of the information collection technique/s, mechanisms for ensuring information saturation, strategy and theoretical framework of the analysis.

**Results:** the main findings, interpretations, topics and concepts identified, structure of the segmentation and categories constructed, and relationship within the conceptual framework.

**Conclusions:** the main conclusions arising from the study and their use for the understanding of the problem and for action and change.

The TEXT must be adapted to the Introduction/Materials and Methods/Results and Discussion structure, following the recommendations set out below (adapted by: Fernández de Sanmamed Santos MJ. Adecuación de las normas de publicación en revistas científicas a las investigaciones cualitativas.(Adaptation of the guidelines published in scientific journals to qualitative research) Aten Primaria. 2000;25:502–4).

**Introduction:** The current situation on the knowledge of the topic must be presented, the relevance and the context in which the study is framed, including the formal and informal documental sources, opinions, intuitions and general theoretical and interpretative frameworks, where necessary, all of them in the most concise and brief form as possible, being supported in a reduced number of key literature references. The objective of the study must be clearly defined.

**Participants and methods:** It is recommended to structure this section into the following headings:

- **Design:** projected design and methodological strategies, justification for their use, temporal contextualisation, information collection techniques, changes in the design or emerging design, if applicable, etc.

- **Sample and participants and/or contexts:** sample design, number and description of participants and/ or contexts, selection criteria of the informants and/or contexts, collection
procedure, mechanisms for ensuring information saturation, etc.

- **Analysis**: strategy and theoretical framework of the analysis, description and validation of the analysis, strategies for ensuring the reliability of the results, etc.

**Results and Discussion**: In qualitative research it is difficult to separate the results from the discussion. The results must be presented in a form that makes the analysis method and the structure of the segmentation and categories constructed clear, and associating them within the prior conceptual framework. An exhaustive presentation of the results must be avoided, only showing the most relevant and significant, that may be real contributions to the knowledge of what examined. It is advisable to use narrative fragments or observations to support the analytical synthesis, and to use illustrative matrices and Tables to facilitate the reading and comprehension of the results. It is recommended to highlight the Table or Figure that contain the main results of the study, with a description of these in the legend.

**Conclusions, usefulness and limitations**: The key findings and interpretations of the research must be highlighted, along with their use in the knowledge of the problem and for action or change. The limitations of the study must be included, as well as proposals for new questions or research lines.

**Acknowledgements**: To individuals or institutions that, not having fulfilled the requirements of authorship, may have collaborated in the performing of the work, providing material, technical or financial help. The type of contribution should be mentioned.

**Bibliography**: The literature references must be numbered consecutively in the order in which they appear for the first time in the text, identifying them using Arabic numbers (in parentheses). A maximum of 30 literature references is recommended, which must as recent and relevant as possible, and carefully written in accordance with the Vancouver format.

**Key points**

All original articles must include a Table with the key points to help in the understanding of the work by those readers that do not wish to read the full article. It must include a maximum of 3 short and precise sentences that indicate what is known on the topic before carrying out the study and the need to have carried it out (under the heading “What is known on the topic”), and another maximum of 3 sentences that indicate what this study has contributed to the previous knowledge of the topic (under the heading “What this study contributes”).

**EDITORIALS**

The articles published in this section are usually commissioned by the editors. However, the Editorial Board may consider non-solicited editorial reviews for publication and submission to the review process, with no obligation of corresponding about them. It is expected that the articles of this section are opinions and reflections of interest in Primary Health Care, that might stimulate debate, or present new perspectives on a topic. The maximum number of authors is 3.

The structure of the works must be as follows:

- Cover letter (see general guidelines).
- First page (see general guidelines)
- Text (maximum: 1,000 words. not counting the bibliography).

- Tables and Figures (maximum: 1 (See general guidelines).

- The maximum number of literature references is 12.

Each one of the previous parts must be started on a new page.

With the aim of helping in its understanding, it is recommended that the text is structured as follows: establishment of the problem, positioning of the author, arguments in favour, arguments against, and conclusions. It is important that the discussion is presented logically and that it cites the type of tests on which the key statements are based (personal or expert opinions, observational studies, clinical trials, systematic reviews...).

LETTERS TO THE EDITOR

Letter that comment on articles that have recently appeared in the Journal will be published preferentially and as quickly as possible. The letter will be sent to the authors of the article to which it refers and, and if they wish to reply to it, the letter and its reply will be published simultaneously.

Letters to the Editor will also be accepted that present experiences and opinions of interest for Primary Health Care, such as short reports on research studies and descriptions of series of clinical cases. In the text of these types of letters, it must mention the aims, design of the study, measurements, results and main conclusions.

The Editorial Committee reserves the decision to publish Letters to the Editor in paper form or on-line. In both cases the reference to the article will be published in the Contents.

The maximum number of authors will be 4.

The structure of the works must be as follows:

- Cover letter (see general guidelines).

- First page (see general guidelines)

- Text (maximum: 600 words, not counting literature references or Tables).

- Tables and/or Figures (maximum: 1 (See general guidelines).

Each one of the previous parts must be started on a new page. The maximum number of literature references is 6. In the case of letters that refer to a published article, one of the references must correspond to this article.

SPECIAL ARTICLES

Special Articles are usually commissioned, and will be published under different headings, depending on their contents (consensus conference, continuing education, technical reports, or in-depth reviews of a topic). The Editorial Board may consider non-solicited editorial reviews for publication and submission to the review process, with no obligation of corresponding about them.

The maximum number of authors is 6.
The structure of the works must be as follows:
- Cover letter (see general guidelines).
- First page (see general guidelines)
- Abstract (maximum: 150 words that present the key ideas of the study).
- Text (maximum: 3,000 words, not counting Tables, literature references or the Abstract.
- Tables and Figures (maximum: 6 (See general guidelines).

Each one of the previous parts must be started on a new page.

The maximum number of literature references is 24.

**UPDATED RECOMMENDATIONS IN PRIMARY HEALTH CARE**

This section will publish those recommendations in Primary Health Care that support the need for them to be updated due to new evidence. It will give a concise presentation of the new evidence and will explain the relevance of its practical application. The text will have a maximum of 700 words, not including the literature references, which will be a maximum of 6 recent references. The title will be the updated topic, and will be as short as possible. Only one Table may be included with the text of the updated recommendation, with no other Tables or Figures being accepted. The maximum number of authors will be 3, with the working group to which it represents being added at the end.

**MEDICAL IMAGES**

Images that by themselves allow to perform a visual diagnosis will be accepted. These images should be accompanied by a brief explanatory text, which may be simply the description of what is shown in the image, or the comment in the form of a brief clinical case. Up to 3 authors will be allowed.

The maximum length of the text will be 600 words.

A maximum of 2 figures.

A maximum of 6 bibliographical references.

**Contact details for submission**

You can send your manuscript at [http://www.evise.com/evise/jrnl/aprim](http://www.evise.com/evise/jrnl/aprim)

**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:
• E-mail address
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All necessary files have been uploaded:

**Manuscript:**
• Include keywords
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• All tables (including titles, description, footnotes)
• Ensure all figure and table citations in the text match the files provided
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**Graphical Abstracts / Highlights files** (where applicable)

**Supplemental files** (where applicable)

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  • Journal policies detailed in this guide have been reviewed
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**BEFORE YOU BEGIN**

**Cover Letter**

The text will be accompanied by a Cover Letter addressed to the Editorial Secretary of the Journal, in which it will include the title of the work and requesting its publication in one of the sections, mentioning that the content of the work has not been previously published and that the article, or part of it, has not been submitted simultaneously to another journal.

Furthermore, it must state the explicit acceptance, by all the authors, of the content of the version submitted, as well as a postal and e-mail address and a contact telephone number in order to speed up the correspondence related to the editorial process.

It should also indicate the funding source of the study in this letter, as well as an explicit declaration of any possible conflicts of interests, especially when the study is centred on the evaluation of diagnostic methods or the efficacy of pharmacological treatments.

Thus, the Cover Letter will include the following information:

Originality of the material: a statement that the content of the article is original and has not been published previously and has not been submitted for consideration to any other publication, either wholly or in any of its parts. *Atención Primaria* (Primary Care) will not consider any manuscripts for publication that are simultaneously submitted to other journals, or redundant or duplicate publications, that is, articles that substantially overlap another article already published, printed, or in electronic media. In this sense, the authors are obliged to provide information on any previous or duplicated publication or on the submitting of part of the work in another journal or circulation media.

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The authors must be aware that not to reveal that the material submitted for publication has been wholly or partially published is a severe breach of scientific ethics.

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Conflict of interests: a statement on the aspects of funding or any other type that could give rise to a conflict of interests. When the authors submit a manuscript for publication they are responsible for disclosing all financial and personal relationships that could bias the work. To avoid ambiguity, the authors must explicitly state whether or not there are any conflicts of interests, providing additional details, if necessary, in a letter that accompanies the manuscript.

Authorship: a statement that all authors have read and approved the manuscript and that the requirements for authorship have been met. Each one of the persons that appear as an author of an article should have participated significantly in the design and development of this, as well as to assume responsibility for the contents and, furthermore, should agree with the definitive version of the article. Thus, in general, to appear as an author the following requirements should be met; to have substantially contributed to the conception and design, or to the data acquisition, or the analysis and interpretation of the data: to have written the draft of the article or have critically reviewed its intellectual content, and to have approved the version that will finally be published.

Atención Primaria declines any responsibility for any conflicts arising from the authorship of works published in the Journal.

Informed Consent: a statement on the obtaining of the written informed consent of the patients. If the article reproduces photographs or patient data (including names, initials, or patient hospital numbers), these must not be able to identify the subject. In all cases, the authors must have obtained the written informed consent of the patient (or parent or guardian, if the patient is a minor) that authorises their publication, reproduction and circulation on paper support and on the Internet in Atención Primaria.

Similarly, the authors must state that they have followed the protocols established by their respective health centres in order to access data from medical records in order to write this type of publication for research / disclosure purposes for the scientific community.

Protection of human and animal research subjects: when results of experiments performed on humans are presented it must state the compliance with the ethical guidelines of the corresponding committees (institutional or national) and with the 1975 Helsinki Declaration in its most current version. In necessary, the authors must mention the obtaining of the corresponding informed consents. When experiments on animals are described, it must indicate whether they have followed the corresponding institutional recommendations and national regulatory laws on the care and use of laboratory animals. This information must also be explicitly stated in the Materials and Methods Sections of the articles.

**Ethics in publishing**

Please see our information pages on Ethics in publishing and Ethical guidelines for journal publication.
**Human and animal rights**

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](https://www.wma.net/en/30publications/10ethics-code/) (Declaration of Helsinki) for experiments involving humans; [Uniform Requirements for manuscripts submitted to Biomedical journals](https://www.journals.com/). Authors should 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.

All animal experiments should comply with the [ARRIVE guidelines](https://arriveguidelines.org/) 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](https://ec.europa.eu/health/scientific_committees/animals/2010_63), or the National Institutes of Health guide for the care and use of Laboratory animals (NIH Publications No. 8023, revised 1978) and the authors should clearly indicate in the manuscript that such guidelines have been followed.

**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 conflicts of interest 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-blind) or the manuscript file (if single-blind). If there are no interests to declare then please state this: ‘Declarations of interest: none’. This summary statement will be ultimately published if the article is accepted. 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](https://www.crossref.org/services/). 

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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 or as part of a published lecture or academic thesis, see 'Multiple, redundant or concurrent publication' section of our ethics policy 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 published elsewhere in the same form, in English or in any other language, including electronically without the written consent of the copyright-holder. To verify originality, your article may be checked by the originality detection service [Crossref Similarity Check](https://www.crossref.org/services/).

**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.

Only in exceptional circumstances will the Editor consider the addition, deletion or rearrangement of authors after the manuscript has been accepted. While the Editor considers the request, publication of the manuscript will be suspended. If the manuscript has already been published in an online issue, any requests approved by the Editor will result in a corrigendum.

Clinical trial results

In line with the position of the International Committee of Medical Journal Editors, the journal will not consider results posted in the same clinical trials registry in which primary registration resides to be prior publication if the results posted are presented in the form of a brief structured (less than 500 words) abstract or table. However, divulging results in other circumstances (e.g., investors' meetings) is discouraged and may jeopardise consideration of the manuscript. Authors should fully disclose all posting in registries of results of the same or closely related work.

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, enrollment, 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. Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration.

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If no funding has been provided for the research, please include the following sentence:

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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