

Formatting Guide for Original Clinical Research Quantitative

On first review, we are very flexible about the format of the manuscript in order to facilitate reviews of manuscripts that have been prepared without our journal in mind or which have been previously submitted and declined elsewhere. If a manuscript has standard or sensible structure and meets ethical standards, we will consider it.

However, if you are preparing the manuscript specifically for CJKHD, please follow these guidelines as you develop your work.

If you receive a decision of major or minor revisions, one of the requirements at that time is to comply with mandatory formatting requirements.

Mandatory formatting requirements

- **Non-declarative title that includes the study design**
- **Structured abstract using headings below, no more than 4096 characters including spaces (about 650 words)**
- **Structured manuscript using headings below**
- **Ethical considerations (see end of document)**

Overview

This publication type covers original clinical research such as trials and cohort studies, and also other forms of quantitative research involving people, such as translational research, population research, epidemiology, systematic reviews of quantitative data, and metaanalyses.

Mixed methods studies should be submitted as Original Clinical Research Qualitative, and should provide a structured abstract that covers both methodologies (i.e., quantitative headings below and qualitative headings from the Original Clinical Research Qualitative formatting guide). The introduction should justify both components of the work. The methods and results sections should report qualitative and quantitative methodologies separately, following the formatting guidelines for Original Clinical Research Quantitative and for Original Clinical Research Qualitative. The ordering of the two components should be consistent throughout. The discussion should integrate the findings from both methodologies.

Title Page

The title page should:

- Present a title that includes, if appropriate, the study design e.g.:
 - "A versus B in the treatment of C: a randomized controlled trial", "X as a risk factor for Y: a case control study", "What is the impact of factor X on subject Y: A systematic review"
 - Because the scientific process is rarely unequivocal, we do not favor declarative titles (e.g. "A reduces Y in the treatment of C"). However, if you feel your work is best served by a declarative title, you may use one and justify it in the cover letter.
 - or for non-clinical or non-research studies a description of what the article reports (e.g.,

“Guideline on the management of C”; “Program report from Z”

- List the full names, institutional addresses and email addresses for all authors
 - if a collaboration group should be listed as an author, please list the Group name as an author. If you would like the names of the individual members of the Group to be searchable through their individual PubMed records, please include this information in the “Acknowledgements” section in accordance with the instructions below
- Indicate the corresponding author

Abstract

The Abstract should not exceed 4096 characters including spaces (about 650 words), and will usually be less than 500 words. (PubMed truncates abstracts at 4096 characters.) Please minimize the use of abbreviations and do not cite references in the abstract. When a report is of a type for which standard reporting guidelines have been published, you may use either the guidelines’ headings or CJKHD’s own for your structured abstract.

Abstracts for **translational, clinical, and population research**, including **systematic reviews and metaanalyses**, should include the following separate sections; or they may follow the most recent iteration of the abstract structure suggested by the relevant guidance document for studies of this type

- Background
- Objective
- Design
- Setting
- Patients
- Measurements
- Methods
- Results
- Limitations
- Conclusions
- Trial registration: If your article is a randomized trial in humans, it must be registered in an appropriate registry and the registration number and date of registration should be in stated in this section. For other study types with non-mandatory registration, please include the study registration details if the study was registered, or write ‘not registered’.

The abstract will be translated into French by CJKHD staff once the English is finalised.

Keywords

Five keywords representing the main content of the article.

Introduction

The background section should explain the background to the study, its aims, a summary of the existing literature and why this study was necessary or its contribution to the field. The following is a suggestion rather than a mandated format:

- Why did you do it? (why problem is important)

- What was there before? (and what is currently lacking)
- Aims and hypotheses? (including PICODT-type research question: Population, Intervention or Investigation, Comparison, Outcome, Design, Timeframe)

Methods

The methods section should include:

- The design and setting of the study
- The characteristics of participants
- A clear description of all processes, laboratory methods, sampling strategies, recruitment procedures, randomization procedures, variable definitions, data instruments and their validity, interventions, outcomes definitions, and comparisons. Generic drug names should generally be used: when proprietary brands are used, give the generic name first and include the brand names in parentheses.
- The type of statistical analysis used, including a hierarchy of outcomes (primary, secondary), a power calculation, and the software used and to be used (including version, manufacturer, city of origin).

Results

This should include the findings of the study including, if appropriate, results of statistical analysis, which must be included either in the text or as tables and figures. Include measures of statistical significance such as p values, and measures of effect size and variance, such as odds ratios, risk differences, and hazard ratios, and their confidence intervals.

Discussion

This section should discuss the implications of the findings in context of existing research and highlight limitations of the study. Use any logical structure that you prefer, or consider using one of these suggestions to ensure that major points are covered in a logical way.

1. Statement of principal findings
2. Strengths and weaknesses of the study
3. Strengths and weaknesses in relation to other studies, discussing particularly any differences in results
4. Meaning of the study: possible mechanism and implications for clinicians or policymakers
5. Unanswered questions and future research

(Source: Docherty M, Smith R. The case for structuring the discussion of scientific papers : Much the same as that for structuring abstracts . BMJ : British Medical Journal. 1999;318(7193):1224-1225.

Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1115625/>)

1. Provide a brief synopsis of key findings, with particular emphasis on how the findings add to the body of pertinent knowledge.
2. Discuss possible mechanisms and explanations for the findings.
3. Compare study results with relevant findings from other published work. Briefly state literature search sources and methods (e.g., English-language MEDLINE search to Jan 2007) that identified previous pertinent work. Use tables and figures to help summarize previous work when

possible.

4. Discuss the limitations of the present study and any methods used to minimize or compensate for those limitations.
5. Mention any crucial future research directions.
6. Conclude with a brief section that summarizes in a straightforward and circumspect manner the clinical implications of the work.

(Source: Annals of Internal Medicine. Information for Authors.)

Conclusions

This should state clearly the main conclusions and provide an explanation of the importance and relevance of the study reported. Implications for clinical practice and for further research should be mentioned, if relevant.

Ethical considerations

This can be a separate section or integrated into methods.

- Clinical trials should be registered and the number included in the manuscript
- All studies that involve human investigation need to state in the manuscript that they have REB approval