

Submitting your Protocol article to the *Journal of Multimorbidity and Comorbidity*

Types of protocols

Protocols that describe the design of planned or ongoing research will be considered for publication in the *Journal of Multimorbidity and Comorbidity*. Protocols for any study design will be considered, including observational, qualitative, exploratory studies, experimental studies, and systematic reviews. The submission of protocols for studies that will evaluate specific aspects of clinical trial design are encouraged.

General protocol guidelines

The Journal of Multimorbidity and Comorbidity endorses the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) Statement, which provides important guidance on drafting protocols, and the PRISMA-P (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines, which provide a 17-item checklist for preparing systematic review and meta-analysis protocols. Authors are encouraged to follow these guidelines, where appropriate, when preparing their protocol, with specific attention being paid to the challenges of comorbidity/multimorbidity research. More detailed explanation on how to use the PRISMA-P guidance can be found here.

Study protocols should provide a comprehensive overview of all aspects of the study conduct and contain a summary of the roles and responsibilities, the rationale and study objectives, a full description of the study design/methodology, including study settings, sample size, eligibility criteria, interventions and timelines, data collection and statistical methodologies, data monitoring, dissemination policies, and analysis of the proposed research.

For studies investigating issues relating to comorbidity/multimorbidity, protocols should clearly define the comorbid or multimorbid conditions under investigation and outline any restrictions based on predetermined lists of conditions; they should explain how any proposed interventions will address these conditions, and they should outline how the study will overcome issues relating to generalizability and/or external validity that can complicate comorbidity/multimorbidity studies. When developing a protocol for a cohort study, ideally using a prospective design, consideration should be given to how the study might enhance understanding of the natural history and trajectory of the comorbid/multimorbid conditions, illness and treatment burden, patient quality of life and well-being, as well as the quality, safety, and cost-effectiveness of care.

Preparing the protocol

The outline of the protocol should follow the general author guidelines for preparing an article for publication, with the following variations:

Organization of the article

Where applicable, the protocol should be clearly structured with appropriate sections, such as:

Objective(s)



- Methods/Design and Analysis
- Discussion/Conclusion
- Acknowledgements
- Conflicts of interest
- Funding
- References.

Abstract

The abstract should be structured, if applicable, with the following sections: Background, Objective, Design, Results, Conclusions.

Introduction/Background

Describe the current setting that is the basis for the proposed research, including an outline of the problem (with references) and a review of current literature. Include a critical evaluation of current knowledge and preliminary studies related to the proposed research and describe how the proposal will enhance this knowledge. Describe the purpose of the study, including any specific primary or secondary objectives/hypotheses as appropriate.

Methods/Design and Analysis

Study protocols should be presented with sufficient detail to enable replication of the methods by others. The following information should be included where applicable:

- Description of study design
- Description of study population/framework and/or development of research proposal/questions
- Description of sample selection/data collection
- Clear description of all interventions and comparisons
- Sample size determination and power analyses, if appropriate
- Study outcomes/endpoints when and how measured
- Data analysis plan
- Ethics approval and dissemination: ethics approval, and safety considerations, where applicable, should be outlined, and any plans for dissemination of findings should be included.

Discussion/Conclusion

The following information can be considered for inclusion:

- Any practical/operational issues or other challenges involved in performing the study
- The importance/benefits of the study
- How the proposed study will fill any evidence gaps
- Future directions.