Dear Editor:

In your previous two numbers, you published the manuscripts “Systematic reviews, basic concepts” (Aguilera-Eguía, 2019) and “Steps for the development of a systematic review” (Aguilera-Eguía & Ramírez-Parada, 2019). The first one defines and classifies systematic reviews (qualitative and quantitative). It also establishes the differences between systematic reviews and narrative reviews. The second manuscript reveals the increasing interest that currently exists in the development of systematic reviews, due to their relevance for making clinical decisions. However, the increased interest in these publications has caused the proliferation of studies with serious methodological issues, which results in faulty results concerning overestimation or underestimation of the real effect of the assessed intervention. Additionally, the manuscripts briefly addressed the steps for the development of a systematic review, which are: a) Research Protocol; b) To define a specific research question; c) Thorough search and selection of the studies that answer the previously stated question; d) To extract the data from the studies that met the eligibility criteria and e) Analysis, presentation and interpretation of the results.

This manuscript aims at explaining the usefulness of a research protocol in a systematic review. It also contains reliable resources for extracting information for its proper development and further registration and publication.

Therefore, what is a research protocol and what is it for?

Generally, the research protocol is called “project” or “research proposal”. Hence, it is a document that comprises the maximum detail of what will be carried out, that must be precise on the addressed points and, above all, that reflects clarity on the work plan to be performed.

In the case of a research protocol for a systematic review, it should contain the following points (only some of them are mentioned):

- Description of the condition;
- Description of the intervention;
- How might the intervention work;
- Why is it important to carry out this systematic review;
- Objectives;
- Methods;
- Criteria for considering studies for this review (Types of studies; Types of participants; Types of interventions);
- Types of outcome measures;
- Primary and secondary outcomes;
- Timing of outcome measurement;
- Adverse outcomes and economic data;
- Search methods for identification of studies (Electronic search, Search in other sources (Grey literature, manual search, reference lists)); Data extraction and analysis;
- Selection of studies; Data extraction and management;
- Evaluation of risk of bias of included studies;
- Measures of treatment effect;
- Management of non-available data;
- Assessment of heterogeneity;
- Assessment of report bias;
- Synthesis of data; Subgroup Analyses; Sensitivity Analyses, among others.

In order to obtain information on how to carry out a systematic review protocol, we recommend the Cochrane Handbook for Systematic Reviews and Interventions. In Chapter 4 (Higgins & Green, 2011), you will find the explanation of each one of the previously mentioned elements.
Where can I register the protocol?

Currently, in order to register the systematic review protocol, it is advised to use PROSPERO (https://www.crd.york.ac.uk/prospero/). PROSPERO is an international database of systematic reviews, which is characterized by providing a permanent register for protocols. Therefore, it aims at providing a thorough list of registered systematic reviews, in order to avoid duplication and reduce the chance of report bias by allowing the comparison of the full systematic review with the protocol plan.

As a conclusion, developing a protocol for a systematic review is a quite complex task, which implies performing multiple activities before the development of the systematic review. It is, in this sense, a fundamental process that every systematic review must carry out before its development.

Therefore, it will allow researchers to work in an organized manner in the planning of their duties. Finally, the registration of the protocol is key, since this can prove if there is a similar protocol and, thus, avoid duplication.

REFERENCES

