RECOMMENDATIONS FOR THE DEVELOPMENT, IMPLEMENTATION, AND REPORTING OF (SHAM) CONTROL INTERVENTIONS IN EFFICACY TRIALS OF PHYSICAL, PSYCHOLOGICAL, AND SELF-MANAGEMENT THERAPIES: THE CoPPS STATEMENT

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Abstract

Background

Specifically designed control interventions can account for expectation effects in clinical trials. For the interpretation of efficacy trials of physical, psychological, and self-management interventions for people living with pain, the design, conduct, and reporting of control interventions is crucial.

Objectives

To establish a quality standard in the field, core recommendations are presented alongside additional considerations and a reporting checklist for control interventions.

Methods

Three Delphi rounds with 64 experts in placebo research and/or non-pharmacological clinical trials were conducted. The panel was presented with a systematic review and meta-analysis of control and blinding methods. A draft guidance document included 63 consensus items (≥80% agreement) and was discussed with patient partners. Finally, the draft guidance and results from stakeholder interviews were discussed at consensus meetings with Delphi participants and patient representatives.

Results

Forty-four experts completed the process. When treatment efficacy or mechanisms are to be studied, the advocated principle is to design control interventions as similar as possible to the tested intervention, apart from the components that the study examines. Structured reasoning in the planning phase, early engagement with stakeholders, feasibility work, and piloting will enhance the quality and acceptability of control interventions. With participant blinding being a primary objective, blinding effectiveness should be routinely assessed and reported. Transparent and detailed reporting will improve interpretability and repeatability of clinical trials.

Conclusion

This guideline provides the much-needed standards to enhance the quality of efficacy clinical trials in physical, psychological, and self-management intervention research, ultimately improving patient care.

Study registration: https://osf.io/jmyhq/

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