

## **CONSORT Extension for Trials Conducted in Existing Data Structures**

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## **Background**

Large-scale randomized trials (RCTs) are complex and expensive to perform. Less than one-third of RCTs achieve their planned recruitment target, follow-up is labor intensive, and many trials have limited real-world generalizability. Alternative trial models have been sought to overcome these challenges. An increasingly common approach involves conducting trials within existing data structures, including trials with participants from researcher-generated cohorts<sup>1</sup>, registries<sup>2</sup>, electronic health records<sup>3</sup> and administrative databases<sup>4</sup>. These designs, however, reflect relatively recent innovations, and published trial reports often do not adequately describe important aspects of trials. Reporting guidelines increase the reporting quality and utility of research, but there is no guideline for trials embedded in existing datasets.

## **Objective**

The objective of the proposed project is to develop a consensus driven guideline to improve the reporting of trials conducted in existing data structures, including researcher-generated cohorts, registries, electronic health records, and administrative databases. This will be done as an extension of the Consolidated Standards of Reporting Trials (CONSORT) for trials conducted in existing data structures.

## **Trials in existing data structures**

This CONSORT extension will focus on the reporting of results from RCTs that select individuals from an existing data structure to be included in trials of healthcare interventions. Although there are some differences in how types of existing data structures are set up, including how participants are enrolled, how data are collected, and the quality of the data collection, RCTs embedded in researcher-generated cohorts, registries, electronic health records and administrative databases are epidemiologically similar. Whereas CONSORT provides guidance for the reporting of RCTs, it focuses primarily on reporting of individually randomized, parallel-groups trials. RCTs embedded in existing data structures share certain common elements with such “standard” trials, but there are also some important differences. For instance, it is particularly important in the reporting of trials embedded in existing data structures to include a description of how participants were recruited to or entered into the data structure, information on maintenance of the data structure, information that was provided or not provided to participants about trial participation upon entry, how ethical approval and consent were handled for the conduct of embedded RCTs, how participants were selected and allocated to trial arms, and how data quality was ascertained or may have influenced interpretability of results, given that the control researchers have over the data structures and data quality may vary.

## **Methods/design**

We will follow the guideline development procedure as described by Moher et al (PLOS Medicine, 2010) to develop the CONSORT extension for trials embedded in existing data structures. In short, to create the guideline, the following steps are proposed: (1) Perform a systematic review to identify publications (a) that describe methods or reporting considerations for trials conducted in existing data structures, including researcher-generated cohorts, registries, electronic health records, or

administrative databases; or (b) that are protocols or report results from RCTs embedded in existing data structures. Since these types of trials are relatively new, there are few articles on methods and reporting, so our team will use both types of sources to determine important aspects of reporting and where reporting can be improved; (2) Based on the results of the systematic review, generate a list of possible modifications to items in the standard CONSORT statement and a list of possible new items for reporting of trials conducted in existing data structures; (3) Conduct a Delphi exercise with methods experts and content experts to evaluate the list of items for consideration to be included in the CONSORT extension and to identify any possible items that may not have been generated in the systematic review; (4) Hold a face-to-face meeting to establish consensus on the items to be included in the CONSORT extension and to develop item explanations; (5) Develop the guidance statement, including a pilot test of the checklist, and explanatory documents; (6) Broadly disseminate and support implementation of the CONSORT extension.

### **Discussion**

Development of the CONSORT extension for trials conducted in existing data structures, based on the Enhancing QUALity and Transparency Of health Research (EQUATOR) Network guidance for developing reporting guidelines, will contribute to transparent reporting of trials conducted in existing data structures, including researcher-generated cohorts, registries, electronic health records, and administrative databases. Grant funding is being sought to support proposed activities.

### **References**

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