

## **CONSORT Extension for Cohort- and Registry-embedded Trials**

*Project team:*

Linda Kwakkenbos

Clare Relton

Isabelle Boutron

Ole Frøbert

David Moher

Jon Nicholl

Philippe Ravaud

Margaret Sampson

Lehana Thabane

David Torgerson

Rudolf Uher

Lenny Verkooijen

Merrick Zwarenstein

Brett D. Thombs

## **Background**

Designs in which individuals who are enrolled in a cohort or registry are recruited to participate in randomized controlled trials (RCTs) are increasingly used across disciplines to assess the effectiveness of experimental treatments. Different examples and models for cohort- and registry- embedded RCTs have been described, including the cohort multiple RCT (cmRCT) design (Relton et al, 2010). Cohort- and registry-embedded RCT designs are increasingly used, but trial reports often do not adequately report important aspects of the design, such as steps taken in recruitment and maintenance of the cohort, information provided or not provided to cohort participants about trial participation, and how cohort participants are selected and allocated to trial arms.

## **Objective**

The objective of the proposed project is to develop a consensus driven guideline to improve the reporting of cohort- and registry-embedded RCTs. This will be done as an extension of the Consolidated Standards of Reporting Trials (CONSORT) for cohort- and registry-embedded trials.

## **Cohort- and Registry-embedded Trials**

This CONSORT extension will focus on the reporting of results from RCTs that select individuals from an ongoing cohort or registry to be included in trials of healthcare interventions. The proposed CONSORT extension will focus on cohort-based RCTs in which patients are enrolled in a cohort and data are collected at multiple time points, including prior to a time point that marks the initiation of one or more trials conducted within the cohort, as well as health registries described as “a health resource that allows authorized parties to collect and accurately access patients’ health information for clinical, administrative, scientific, and/or policy-related purposes to improve clinical decision making” (Li, 2016).

## **Methods/design**

We will follow the guideline development procedure as described by Moher et al (PLOS Medicine, 2010) to develop the CONSORT extension for cohort- and registry-embedded trials. In short, to create the guideline, the following steps are proposed: (1) conduct two systematic reviews, one to identify trials embedded within cohorts, and one to identify trials embedded within registries, to identify potential concerns with reporting of these trials; (2) conduct a Delphi study with methods experts and content experts to generate a list of items for consideration to be included in the CONSORT extension for cohort- and registry-embedded trials; (3) organize a face-to-face meeting to establish consensus on the items to be included in the CONSORT extension for cohort- and registry-embedded trials; (4) develop the guidance statement (including a pilot test of the checklist), the explanatory document and publications; (5) broadly disseminate and encourage implementation of the CONSORT extension for cohort- and registry-embedded trials.

## **Discussion**

Development of the CONSORT extension for cohort- and registry-embedded trials,

based on the Enhancing QUALity and Transparency Of health Research (EQUATOR) Network guidance for developing reporting guidelines, will contribute to transparent reporting of cohort- and registry-embedded RCTs. Grant funding is being sought to support proposed activities.

## **References**

Li G, Sajobi TT, Menon BK, Korngut L, Lowerison M, James M, Wilton SB, Williamson T, Gill S, Drogos LL, Smith EE, Vohra S, Hill MD, Thabane L; 2016 Symposium on Registry-Based Randomized Controlled Trials in Calgary. Registry-based randomized controlled trials- what are the advantages, challenges, and areas for future research? *J Clin Epidemiol.* 2016;80:16-24.

Relton C, Torgerson D, O'Cathain A, Nicholl J. Rethinking pragmatic randomised controlled trials: introducing the "cohort multiple randomised controlled trial" design. *BMJ.* 2010;340:c1066.