

Reporting of sex and gender in randomized controlled trials in Canada: a cross-sectional methods study

V. Welch^{1,2}, M. Doull³, M. Yoganathan¹, J. Jull^{2,4}, M. Boscoe⁵, S. Coen⁶, Z. Marshall⁷, J. Pardo Pardo⁴, A. Pederson⁸, J. Petkovic^{1,2}, L. Puil⁹, L. Quinlan¹, B. Shea^{1,2}, T. Rader¹⁰, V. Runnels², S. Tudiver⁵

¹ Bruyère Research Institute; Bruyère Continuing Care, Canada

² School of Epidemiology, Public Health and Preventive Medicine, University of Ottawa, Canada

³ School of Nursing, University of British Columbia, Canada

⁴ Ottawa Hospital Research Institute, Canada

⁵ Consultant/Research Sex/Gender and Health

⁶ Department of Geography & Planning, Queen's University, Canada

⁷ School of Social Work, McGill University, Canada

⁸ B.C. Women's Hospital + Health Centre, Canada

⁹ Department of Anesthesiology, Pharmacology & Therapeutics, Faculty of Medicine, University of British Columbia, Canada

¹⁰ Canadian Agency for Drugs and Technology in Health, Canada

Summary Accurate reporting on sex and gender in health research is integral to ensuring that health interventions are safe and effective. In this study we assessed the extent and nature of reporting about sex and/or gender in a sample of Canadian randomized controlled trials. This work connects directly to the Gender Summit goals of gender equality in research, and explores one facet of the ways gender equality is embedded in study design, data analysis, and reporting.

1. Relevance

In Canada and internationally, governments, research organizations, journal editors and health agencies have called for more inclusive research, provision of sex-disaggregated data, and the integration of sex and gender analysis throughout the research process. Sex and gender analysis is generally defined as an approach for considering how and why different subpopulations (e.g., of diverse genders, ages, and social locations) may experience health conditions and interventions in different or similar ways.

2. Aims & Objectives

The objective of this study was to assess the extent and nature of reporting about sex and/or gender, including whether sex and gender analysis (SGA) was carried out in a sample of Canadian randomized controlled trials (RCTs) with human participants.

3. Methods

Two reviewers screened 256 records of 1,433 records from a MEDLINE search limited to January 2013 to July 2014, to identify the first 100 RCTs that were either identified in the trial publication as funded by a Canadian organization or which had a first or last author based in Canada. Data were extracted in duplicate during an initial training period for 10% of the RCTs; once agreement was reached, the remainder of the data was extracted by one person and verified by a second.

4. Results

The median sample size of the RCTs was 107 participants (range 12 - 6085). While 98% of studies described the demographic composition of their participants by sex, only 6% conducted a subgroup analysis across sex and 4% reported sex-disaggregated data. No article defined "sex" and/or "gender." No publication carried out a comprehensive sex and gender analysis.

5. Conclusions

Findings highlight poor uptake of sex and gender considerations in the Canadian RCT context and underscore the need for better articulated guidance on sex and gender analysis to improve reporting of evidence, inform policy development and guide future research.

6. Contact details: Zack Marshall, zack.marshall@mcgill.ca