PROTOCOL BRIEF

Examining Reporting Bias in Randomized Controlled Trials from Two Network Meta-Analyses: Comparison of Clinical Trial Registrations and Their Respective Publications

Rationale

The validity of a network meta-analysis (NMA) is dependent on the quality of primary studies. Registration of clinical trials provides transparency in interpreting published results because the intended primary outcome is known. Similarly, summary results for adverse outcomes reported in trial registries should be identical to those reported in the published manuscript. Any discrepancy between the information provided in the registry and publication may indicate concealment of results, leading to reporting bias. Previous studies revealed changes in summary estimates with addition of trial registry data for pair-wise meta-analyses, but findings for NMAs have not been reported.

Implications

- Identify the presence (or lack of) selective reporting in randomized controlled trials (RCTs) of cognitive enhancers for Alzheimer's disease and long-acting inhalers for chronic obstructive pulmonary disease (COPD)
- Allow systematic review authors to judge whether they need to verify data in the registries or can abstract data from the published version

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Background

- Selective or incomplete reporting of clinical trial results can lead to erroneous conclusions of drug safety and efficacy
- In response, clinical trial registries were developed for investigators to disclose ongoing clinical trials with planned outcomes
- Despite regulatory changes, compliance with trial registration and consistency in outcome reporting continue to be low, and adverse events are often incompletely reported in manuscripts compared with trial registries
- A previous study found only 11% of registered trials consistently reported SAEs in the respective publications. The remaining trials had inconsistent, incomplete, or no reporting of SAEs in respective publications
- We aim to build on this literature by examining the consistency of serious adverse events reporting using RCTs from the two recent NMAs

Objective

- To determine if there is a difference (i.e., selective reporting) in the frequency of overall serious adverse events reported in the clinical trial registrations and the respective published manuscripts

Methodology

- A retrospective review of published RCTs included in the recent NMAs investigating cognitive enhancer trials for Alzheimer's disease and long acting inhaled agents for COPD, with their associated trial registrations
- If the RCT is published in English in the year 2005 or later, and is registered in a trial registry (i.e., inclusion criteria for this study), two reviewers will independently abstract details about the included studies, its registration details, and adverse event reporting in the registry and manuscript
- Chi-squared test of proportions will be used to analyze changes to the primary outcome

Knowledge Translation Strategy

- We will disseminate findings to the study team network, and more broadly through conference presentations, and open-access publications.

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