

Research integrity in randomised clinical trials: an umbrella review.

Maria Nunez-Nunez¹, Marta Maes-Carballo², Luciano Mignini³, Patrick Chien⁴, Yakoub Khalaf⁵, Mohamed Fawzy⁶, Javier Zamora⁷, Khalid Khan⁸, and Aurora Bueno-Cavanillas⁹

¹Hospital Universitario San Cecilio

²Complejo Hospitalario de Ourense

³Unidad de Mastología de Grupo Oroño

⁴Ninewells Hospital and Medical School

⁵Guy's and St.Thomas NHS foundation trust

⁶IbnSina (Sohag), Banon (Assiut), Qena (Qena), Amshag (Sohag) IVF facilities, Egypt

⁷Affiliation not available

⁸University of Granada

⁹Universidad de Granada

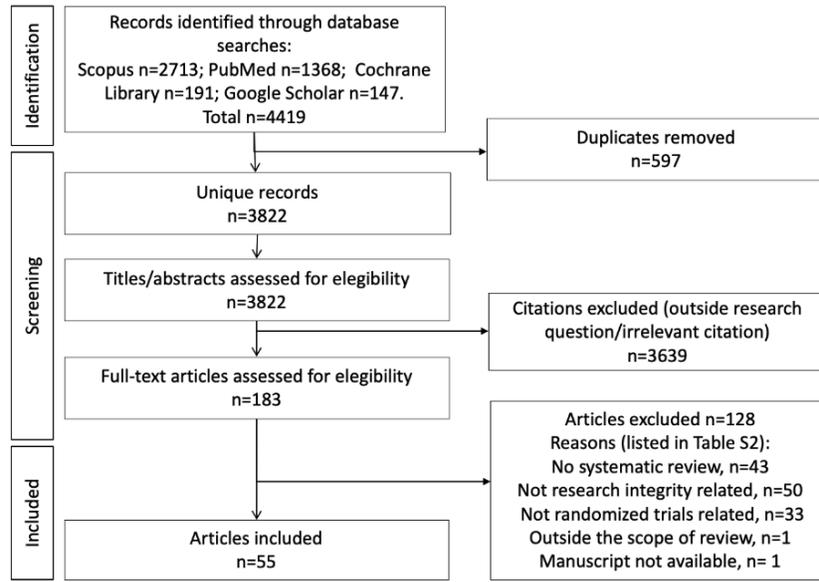
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Abstract

Background: The trustworthiness of randomised clinical trials (RCTs) is suffering a crisis of confidence. **Objectives:** We undertook an umbrella review of the research integrity literature concerning RCTs. **Search strategy and selection criteria:** Following prospective registration (<https://osf.io/3ursn>), two reviewers independently searched PubMed, Scopus, Cochrane Library and Google Scholar, without language or time restrictions until November 2021. We included systematic reviews covering any aspect of research integrity throughout the RCT lifecycle. **Data collection and analysis:** We assessed methodological quality using a modified AMSTAR-2 tool and collated the main findings. **Main results:** There were 55 relevant reviews summarising a total of 6001 studies (median per review 63; range 8-1106 studies). The overall quality of 53 (96.4%) reviews was critically low. Eight (14.6%) reviews focused on the general aspects of a RCT, 12 (21.8%) on the design and approval, 6 (10.9%) on the conduct and monitoring, 21 (38.2%) on the reporting of protocols and findings, one (1.8%) on post-publication concerns and 7 (12.7%) on future research and development. The integrity issues covered were varied, the most common being the importance of ethics (10/55, 18.2%) and transparency (10/55, 18.2%). **Conclusions:** Various research integrity issues covering RCT lifecycle, captured from mostly low-quality reviews, provided a broad overview emphasising the need for high level of ethical standards and professionalism. Many gaps in the RCT integrity landscape were also identified. There is a need to generate multistakeholder consensus to create specific RCT integrity standards.

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