Gac Sanit. 2025;39(S2):441

Gaceta Sanitaria

https://www.gacetasanitaria.org

1026 - RANDOMISED CLINICAL TRIALS INTEGRITY AND PATIENT, CARER AND PUBLIC INVOLVEMENT: A SCOPING UMBRELLA REVIEW AND INTERNATIONAL MULTI-STAKEHOLDER CONSENSUS STATEMENT

B. Juhász, N. Cano-Ibáñez, A. Bueno-Cavanillas, K. Saeed Khan, M. Fawzy

University of Granada, Department of Preventive Medicine and Public Health; CIBER Epidemiología y Salud Pública (CIBERESP). Instituto de Salud Carlos III (ISCIII); Instituto de Investigación Biosanitaria de Granada (ibs.GRANADA); IbnSina (Sohag), Banon (Assiut), Qena (Qena), Amshag (Sohag) IVF Facilities, Sohag, Assiut, Qena, Egypt; Semmelweis University, Department of Family Medicine.

Resumen

Background/Objectives: The recent update of the Declaration of Helsinki has emphasised community engagement and research integrity. Patient, carer and public involvement (PCPI) throughout the research lifecycle of randomised clinical trials (RCTs) can enhance their integrity. However, no specific PCPI guidance exists for trialists. Therefore, we undertook a scoping umbrella review and an international multi-stakeholder consensus to generate a set of actionable statements on how to improve responsible research conduct in RCTs with respect to PCPI.

Methods: PubMed, EMBASE and CINAHL were searched using a comprehensive search strategy and a double-blind selection process. The inclusion criteria consisted of systematic reviews that addressed PCPI issues related to research integrity applicable to RCTs. Results were synthesised narratively. Based on the findings of a literature review and a stakeholder consultation, an initial long list of recommendations was created. It was submitted to a two-round modified Delphi survey before being finalised in a hybrid online-face-to-face meeting.

Results: Out of 3,155 citations identified from the literature search, we included 27 reviews. Following data extraction, the content analysis examined 47 review findings. The initial list consisted of 46 statements (39 literature based and 7 stakeholder provided), with nine additional provided during the consensus rounds. Delphi survey response rate was 59.2% and 61.2% for the two rounds, respectively. The final set consolidated of 39 statements, grouped into seven categories: General; Design, Approval and Funding; Conduct and Monitoring; Reporting of protocols and findings, Dissemination and Implementation; and, Future Research and Development.

Conclusions/Recommendations: Our international consensus statement provides the basis for the development of best practice guidelines by trialist, institutions, ethics committees, funding bodies, journal editors, patient representatives and PCPI members.

0213-9111 © 2025 SESPAS. Publicado por Elsevier España, S.L.U. Todos los derechos reservados