Evidence Synthesis Ireland Fellowship Scheme
Review Identification Form

Review Centre/Group Mentor

Dr Linda Biesty, Evidence Synthesis Ireland

Review title

Ethical and Practical Considerations in Hospital-Based Treatment Trial Design: A Qualitative Evidence Synthesis to Optimise Trial Accessibility

Review type and methods

Type: Qualitative Evidence Synthesis (QES)

Methods: The methodology and methods of the reviews will be underpinned by the guidance offered by the Cochrane Qualitative and Implementation Methods Group including the Cochrane Handbook (Noyes et al 2022) and the Cochrane QES Protocol and Review Template (Glenton et al 2023).

Review information

The review sits within a larger Horizon 2020 funded programme of activity - the EU-PROACT (European PROactive Adaptive Clinical Trials network) project. The aim of this project is to prepare Europe for future diseases of epidemic or pandemic potential by strengthening and building upon existing networks of experts and civil society focused on clinical therapeutic platform trials within hospital inpatient settings across Europe.

This QES will contribute to a body of qualitative work to contextual understanding of trial participation among adults, included marginalised groups to optimise trial design.

Key interested parties (those with methodological and topic knowledge including public representation) will be including in the review from the development of the protocol stage.

Review details

Background: The recent global health crises have demonstrated the profound vulnerability of European societies to pandemic threats. To effectively combat future outbreaks, Europe must ensure rapid access to vital medical interventions. EU-PROACT aims to enhance European pandemic preparedness by building on and reinforcing established collaborations between clinical experts and community stakeholders who specialize in hospital-based therapeutic

platform trials across the continent. During an outbreak, this established infrastructure will enable swift deployment of large-scale, cross-border platform trials to evaluate both therapeutic interventions and diagnostic capabilities.

This QES will contribute to a body of qualitative work to contextual understanding of trial participation among adults, included marginalised groups and so optimise inclusive trial design.

Aim of the Review: to synthesise existing qualitative evidence to optimise trial design and reach and inform public health messaging to reduce health inequities. This review, using the methodology of QES, will identify, appraise, and synthesise qualitative studies exploring key stakeholders attitudes and views in relation to the ethical and practice considerations in designing hospital-based treatment trials.

Methods: The SPIDER (Sample, Phenomenon of Interest, Design, Evaluation and Research Type) Framework (Cooke et al 2012) will help refine the research question, identify the main concepts of the review and generate search terms.

S: Healthcare professionals / researchers involved in trial design, hospital administrators, ethics committee members, trial participants from diverse populations, health equity experts
Pi: ethical considerations in trial design, practical challenges in implementing hospital-based treatment trials, trial accessibility barriers and facilitators
D: interviews, focus groups, case studies, ethnographic observations, qualitative components of mixed methods studies
E: experiences, attitudes, perceptions, barriers, facilitators, decision making processes
R: Qualitative Studies, mixed methods studies with qualitative data.

Relevant electronic databases will be searched and studies included based on predefined inclusion criteria. A search reference lists, grey literature, conduct forward citation searches and contact relevant content experts will also be conducted. The Critical Appraisal Skills Programme tool will be used to assess the methodological quality of included studies. Two authors will review the search output, extract data and assess methodological quality independently, resolving any disagreements by consensus. A thematic synthesis approach, as described by Thomas and Harding (2008), will be used to analyse and synthesise the data. Two review authors will use the GRADE-CERQual (Lewin et al 2018) (Confidence in the Evidence from Reviews of Qualitative research) approach to assess confidence in each finding. Summaries of the findings and the assessments of confidence in these findings will be presented in Summary of Qualitative Findings tables.

Review current status

Not started

Any specific/desirable requirements for fellow (e.g. clinical expertise, methodological expertise)

Some experience of conducting qualitative research would be helpful

Estimated start and completion dates

Feb 2025 – Feb 2026