



Abstract Template

Project title Including vulnerable groups in clinical trial research: A scoping review.

Institution University of Limerick

Project details (max 250 words)

Members of vulnerable populations are underrepresented in clinical trials. They are often excluded on the basis of scientific, ethical and practical reasons. Although intended to protect vulnerable people exclusion of vulnerable groups from clinical trials through use of standard exclusion criteria and consent processes may not always be necessary and may result in findings that are not generalisable, with concomitant decreased access to interventions and relative under treatment.

Vulnerability is a complex topic; with its definition complicated by the way vulnerability can be shaped by many interacting influences such as individual perceptions, situational, social, historical, political and cultural factors (Goldson, 2002; Dixon- Woods et al., 2005). Lone parents, people with disabilities, older people, children, ethnic minority groups, pregnant women, mentally ill, homeless, and refugees have all been identified as vulnerable groups.

A scoping review is an effective method of clarifying a complex concept to help refine subsequent research inquiries (Levac et al., 2010).

Aim: The aim of this project is to conduct a scoping review to determine the extent, range, and nature of inclusion of vulnerable groups in clinical trials.

Methods: The scoping review will be based on the framework developed by Levac et al. (2010) that is informed by an original Methodological Framework for Conducting Scoping Studies devised by Arksey and O'Malley (2005).

Outcome: This scoping review will provide an insight into the current extent, range and nature of inclusion of vulnerable groups in trials particularly in relation to exclusion criteria and consent processes. The scoping review will identify gaps in the research methodological evidence base.

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References

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