Clinical Trials and Limited Health Literacy: A Scoping Review

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Background: Clinical trials are essential for the advancement of medicine. However, the complex nature of clinical trials can impede recruitment and retention of participants. This affects those with low health literacy (HL) which is associated with lower education and income, older age, and non-white patients. These individuals are therefore unequally represented in clinical trials - putting them at a significant disadvantage as well as affecting the validity of trials.

Purpose: A scoping review will be conducted to explore what is known about health literacy and clinical trials.

Methods: The following databases were searched between 1992-May 2020: Medline ALL, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Embase, Emcare, and PsycINFO. Articles were included if the context is clinical trials, if they explore HL at the patient/provider/systems level, and the study population is adults (>18). The search yielded 25471 studies and 10125 duplicates were removed. Five independent reviewers are conducting title and abstract review and conflicts are resolved by a sixth reviewer. Eligible articles will undergo full-text review, followed by data extraction, analysis, and reporting.

Significance: This is the first attempt to systematically explore the literature for knowledge of the relationship between HL and clinical trials. This work can identify gaps in current knowledge and inform the design of clinical trial materials.