International Platform of Registered Systematic Review and Meta-analysis Protocols

INPLASY

Barriers and facilitators to Advanced Clinical Practitioners' engagement with Phase 3 interventional clinical trials in the NHS? How will the new UK clinical trial regulations in 2026 influence these barriers and facilitators?

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ADMINISTRATIVE INFORMATION

Support - Self.

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202650120

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 May 2026 and was last updated on 22 May 2026.

INTRODUCTION

Review question / Objective This review seeks to understand the existing barriers and facilitators to ACP engagement in phase 3 interventional clinical trials and to explore how changes associated with the new UK CTR may shape future practice or affect current barriers and facilitators.

Rationale Although ACPs are increasingly contributing to clinical research, their involvement in phase 3 interventional clinical trials remains poorly understood (Fielding et al., 2022). For the purposes of this scoping review, "engagement" is defined as participation in delegated or lead roles in the delivery of phase 3 interventional clinical trials, including clinical, governance, and leadership activities as permitted by clinical research protocols and research regulatory guidelines. Some existing literature has highlighted several barriers to heath research in general such as limited access to health research training, unclear governance pathways, lack of protected research time, and organisational cultures that do not always support ACP research (Lavery et al., 2025; Mann et al., 2023; Badu, 2023a; Braun-Inglis et al., 2022). The introduction of the 2026 UK CTR represents a timely opportunity to examine the current barriers and facilitators shaping ACP engagement in phase 3 interventional clinical trials and to explore how the regulatory changes might influence practice and increase capacity for phase 3 interventional clinical trials.

Condition being studied N/A.

METHODS

Search strategy Definition Search Terms / Keywords
Sample
Advanced clinical practitioners in the UK who may engage in phase 3 clinical interventional trials "advanced clinical practitioner*"; "advanced clinical practice"; "advanced nurse practitioner*"; "advanced practitioner*"; "nurse practitioner*";

"physician associate*"; "physician assistant*"; clinician*; "health professional*"; NHS staff
PI – Phenomenon of Interest
Engagement in phase 3 interventional clinical trials and determinants of engagement "phase 3" OR "phase III"; "clinical trial*"; "interventional trial*"; CTIMP*; "clinical research"; engag*; participat*; involv*; "research role*"; "trial role*"; investigator*; "sub investigator*"
D – Design
Qualitative or mixed methods study designs qualitative; "mixed methods"; interview*; "focus group*"; "semi structured"; "in depth"; "case stud*"
E – Evaluation
Barriers, facilitators, perceptions, experiences, attitudes barrier*; obstacle*; challenge*; constraint*; facilitator*; enabler*; "supporting factor*"; "promoting factor*"; attitude*; perception*; experienc*; view*; belief*;

motivat*
R – Research Type
Empirical qualitative or mixed methods research qualitative; "mixed method*"; survey*; questionnaire*; interview*; "focus group*" UK Context UK setting and health system UK; "United Kingdom"; "Great Britain"; England; Scotland; Wales; NHS; "National Health Service" Regulatory Context UK clinical trial regulations and reforms "clinical trial* regulation*"; "clinical trials regulations"; "regulatory reform*"; MHRA; HRA; "UK clinical trial regulations"; "Clinical Trials Regulation"

The search strategy in the table above, including all identified keywords, will be adapted for each included database.The following databases and Medical Subject Headings (CINAHL and MEDLINE) will be searched individually
CINAHL Ultimate (EBSCO interface)
MEDLINE (EBSCOinterface)
PubMEd
Web of Science
EllicitGrey literature sources will include:
National Institute for Health and Care Research (NIHR)
Health Research Authority (HRA)
Medicines and Healthcare products Regulatory Agency (MHRA)
National Institute for Health and Care Excellence (NICE).

Participant or population Advanced Clinical Practitioners
Although the review primarily focuses on ACPs, some studies referring to other professional groups may also be considered, as researchers may describe ACP roles using terms such as AHPs or nurses. Eligible participants will be ACPs who are directly involved in clinical research or trials within NHS settings, including primary, secondary, and acute trusts. Studies that explicitly state or refer to ACPs will be prioritised, although articles including broader Allied Health Professional (AHP) or nursing groups may also be considered where ACP roles may be described interchangeably or where relevant contextual insights can be applied.

Intervention N/A.

Comparator N/A.

Study designs to be included Mixed methods or just qualitative design.

Eligibility criteria English language studies
The search strategy will aim to locate both published and unpublished studies, including non–peer-reviewed articles
Date range -10 years.

Information sources The search strategy will aim to locate both published and unpublished studies, including non–peer-reviewed articles
Grey literature sources will include:
National Institute for Health and Care Research (NIHR)
Health Research Authority (HRA)
Medicines and Healthcare products Regulatory Agency (MHRA)
National Institute for Health and Care Excellence (NICE.

Main outcome(s) Main Outcome of the Scoping Review
The primary outcome of this scoping review will be a systematic evidence map identifying and categorising:
Barriers that limit ACP engagement in phase III interventional clinical trials in the NHS
Facilitators that enable or support ACP involvement in these trials
Regulatory influences, specifically how the 2026 UK Clinical Trial Regulations may modify, remove, or introduce new barriers and facilitators
Gaps in the literature that require further empirical investigation.

Additional outcome(s) N/A.

Data management Following the search, all identified citations will be collated and uploaded into a citation management system (Ryaann), and duplicates will be removed. A pilot test will be undertaken, and titles and abstracts will be screened by the researcher. A copy of each article or document will be obtained and reviewed, and data will be charted by the researcher. The data extraction will be presented in a table format. Full-text retrieval of relevant articles will be undertaken, and these will be assessed against the inclusion and exclusion criteria. Reasons for exclusion of sources of evidence at the full-text stage that do not meet the inclusion criteria will be recorded and reported in the scoping review.The results of the search and the study selection process will be reported in full in the final scoping review and presented in a PRISMA flow diagram. A modified PRISMA-ScR approach, including a basic numerical count of the amount, type, and distribution of studies in the review, alongside thematic analysis, will be used to present the data. A narrative summary of the themes will accompany the tabulated results and will describe how the findings relate to the review objectives and research questions.

Quality assessment / Risk of bias analysis N/A as this a scoping review. Instead, studies will be descriptively categorised according to JBI levels of evidence to provide insight into the nature of the evidence base.

Strategy of data synthesis A narrative summary of the themes will accompany the tabulated results and will describe how the findings relate to the review objectives and research questions.

Subgroup analysis N/A.

Sensitivity analysis N/A.

Language restriction English.

Country(ies) involved United Kingdom.

Other relevant information This scoping review is part of a doctoral thesis

Keywords As in search strategy section.

Dissemination plans As the scoping review forms part of a doctoral thesis, no other professional groups will be formally consulted. However, the researcher will share the findings with the local ACP Lead and Deputy Chief Nurse within the Trust and may discuss the findings at internal meetings. The local NHS Trust is currently implementing an ACP strategy, and discussion of these findings with key stakeholders may provide further insight. The scoping review findings may also inform workforce development strategies, research governance structures, and policy discussions regarding ACP roles in interventional research within the NHS.

Contributions of each author

Author 1 - Nyasha Nago - Drafted the scooping protocol and will be main reviewer.
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