ISRCTN89854824 https://doi.org/10.1186/ISRCTN89854824

Perioperative medicine for older people undergoing surgery scale-up

Submission date
16/04/2024

Recruitment status
Recruiting

Registration date
13/12/2024

Overall study status
Ongoing

Last Edited
20/11/2025

Condition category
Surgery

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Older people have more operations than younger people but often have more complications after surgery, such as chest infections, kidney problems, slow recovery and longer hospital stays. This is because older people may have other problems like heart disease or poor memory. These problems need treatment from experts called geriatricians. It is not usual to have geriatricians care for older people who need operations in the NHS right now. A service called Perioperative medicine for Older People undergoing Surgery (POPS) was set up at one NHS hospital to help older people get better outcomes after operations. POPS was set up together with patients, carers, surgeons, anaesthetists, nurses, therapists and managers. POPS teams assess and treat patients before and after surgery. They look after patients having planned surgery, as well as those who are admitted in an emergency. POPS services have been shown to reduce complications after surgery, help people leave the hospital sooner and save the NHS money. Some NHS hospitals have now set up POPS services, but some have not. This means that not all NHS patients can get this care. It is known that setting up a POPS service can be hard, but prior work has shown that this can be done successfully. This research will test how new POPS services can be set up in more NHS hospitals across the UK to improve care for older patients having operations and save money for the NHS.

Who can participate?
Geriatricians and hospital executive board members supporting implementation, NHS staff engaged in POPS intervention implementation or perioperative care at hospital sites in the UK offering general and/or orthopaedic and/or urological and/or vascular surgery, and patients aged 50 years old and over undergoing relevant surgical care who have received input from a POPS service at participating hospitals.

What does the study involve?
This study will be conducted to see if the new POPS services can be established in 18 NHS hospitals. The researchers aim to assess how quickly these services can be implemented, their effectiveness in operation, whether they contribute to faster recovery post-operation, and if they lead to cost savings for the NHS. Information will be gathered on hospital stay durations after surgeries, post-surgery complications, and the quality of life of patients. Additionally, feedback will be sought from patients and staff regarding their experiences with the new POPS

services. The research will use a mix of data from staff, hospital records, and directly from patients and caregivers. By summarizing this information, the researchers hope to determine the feasibility of implementing POPS services across the NHS, assess patient benefits, and evaluate potential cost savings.

For dissemination, the research team has already engaged with various groups including patients, the public, charities, policymakers, and healthcare professionals to design the study. This collaboration will continue throughout the research process. The findings will be shared with patients, the public, NHS staff, and policymakers through various channels such as talks, articles, press releases, social media, videos, websites, and meetings. It is believed that this research will enhance patient care, influence NHS policies, and result in cost savings.

What are the possible benefits and risks of participating?
Benefits include a holistic assessment with continuity of care throughout the surgical pathway. There are no significant risks to patient/carer or staff participants in taking part in the study.

Where is the study run from?
Older Persons Assessment Unit, Bermondsey Wing, Guy's Hospital

When is the study starting and how long is it expected to run for?
March 2024 to May 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) Health and Social Care Delivery Research (HSDR)

Who is the main contact?
Prof Jugdeep Dhesi, jugdeep.dhesi@gstt.nhs.uk

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
335587

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 64334, NIHR157443

Study information

Scientific Title
Implementation of comprehensive geriatric assessment-based perioperative medicine services to improve clinical outcomes for older patients undergoing elective and emergency surgery with cost-effectiveness

Acronym

POPS-SUp

Study objectives
Can CGA-based perioperative medicine services (POPS services) be implemented throughout the NHS, to improve clinical outcomes for older patients undergoing elective and emergency surgery with cost effectiveness?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/09/2024, London - South East Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048129; londonsoutheast.rec@hra.nhs.uk), ref: 24/LO/0663

Study design
Multicentre mixed methods study with embedded process evaluation - hybrid implementation-effectiveness interrupted time series study

Primary study design
Interventional

Study type(s)
Diagnostic, Safety, Treatment

Health condition(s) or problem(s) studied
Improving outcomes in older patients undergoing surgery

Interventions
Overview of methods and justification
POPS-SUp is a hybrid implementation-effectiveness interrupted time series multicentre study using mixed methods to examine the use of a coproduced implementation strategy, to support the implementation of POPS services and evaluate clinical and cost-effectiveness across the NHS. Evaluation will use mixed qualitative and quantitative methods, through embedded process evaluation, quantitative evaluation of clinical and cost effectiveness and qualitative appraisal of patient and staff experience.

POPS-SUp will examine two inter-linked interventions:
-The first intervention is a trimodal implementation strategy designed to support the implementation of POPS services (this means an implementation plan with three strands)
-The second intervention is the POPS service delivering perioperative CGA-based care

This study design and methodology have been chosen for the following reasons: interrupted time series methodology is acknowledged as the best alternative to RCT methodology. It allows consistent data collection before and after implementation to address our research question relating to both implementation and clinical effectiveness - interrupted time series methodology has the advantage of limiting selection bias and confounding due to between-site differences. Instead, sites provide internal comparison avoiding inherent bias related to heterogeneous patient populations, differing contexts and workforce across sites. This is important in a study where there is not a single 'index condition'.

- With covid recovery and impetus to establishing POPS services, potential participating sites and NHS policymakers have told us that randomisation is not acceptable. As part of POPS-SUp, we have formed an organisational stakeholder group called PPIE3. This group consists of national organisations including NHSE, surgical, geriatric medical and anaesthetic societies and has been involved in the codesign of POPS-SUp.

-The control group in POPS-SUp will be the 'before implementation' group of patients

Implementation strategy and pops-sup study intervention
The implementation strategy:
-The trimodal POPS implementation strategy uses a toolkit, quality improvement coaching and mentoring, and training in the use of data and measurement to deliver improvement. The toolkit includes clinical resources, education and training and business resources.

-NHS Elect will support the delivery of this implementation strategy through structured, online meetings between participating hospital site teams and expert coaches (with expertise in clinical POPS services, improvement science and data management). The NHS Elect POPS programme will include an initial site visit, two weekly team meetings, monthly events for the cohort and regular webinars. POPS-SUp will study the impact of this co-produced implementation strategy on implementation outcomes.

Perioperative CGA-based care delivered through a POPS service:
-The POPS services to be evaluated in POPS-SUp use Comprehensive Geriatric Assessment and optimisation (CGA) methodology. CGA involves a holistic assessment of a patient across medical, functional, social and psychological domains, using objective measures to inform multidisciplinary optimisation. The POPS service, using CGA methodology at each of the eighteen participating hospitals, will be delivered by a geriatrician-led multidisciplinary team from that hospital, supported by the trimodal NHS Elect POPS implementation strategy. All patients under the care of general and/or orthopaedic and/or urological and/or vascular surgery teams at all study sites will receive perioperative care delivered through the planned intervention, namely the POPS service implemented through the trimodal implementation strategy, supported by the NHS Elect POPS programme. The POPS service will deliver perioperative care for patients living with frailty, multimorbidity, cognitive issues and/or those in whom the decision to operate is not clear, who are being considered for major emergency and /or elective general and/or orthopaedic and/or urological and /or vascular surgery.

Coprimary outcomes
In keeping with the MRC framework for complex interventions POPS-SUp will use coprimary outcomes. These coprimary outcomes are:

Reach out to assess the implementation
Reach - no. patients seen by pops/no. Of patients eligible for pops review this will be defined according to which surgical specialty the service is being established in e.g. egs/urology etc and which patients will be seen e.g. >65 years/frailty CFS 5/ multimorbidity etc. it might be different between sites.

-Length of hospital stay in days to assess clinical and cost-effectiveness

Secondary implementation outcomes include:
-Fidelity to clinical components of perioperative CGA

This will be a case note review of all patients seen by the pops services to establish fidelity to the core components checklist for CGA
-Fidelity to core components of POPS services

This will be measured against POPS logic model core components which will be adjusted according to the service being established eg some teams may not be providing postoperative care will be measured through process evaluation ie staff members will be interviewed/observed /surveyed.

- Acceptability and feasibility of the implementation strategy will be assessed through process evaluation.

Acceptability - staff and patient interviews - through process evaluation

Feasibility - staff and patient interviews in addition to questions on how long does clinic take/is there enough space / sufficient staff through process evaluation

Baseline patient characteristics
-Age
-Gender
-Clinical Frailty Scale (CFS)
-Number of regular medications
-count of comorbidities

Secondary effectiveness outcomes include:
-30 day readmission (HES linkage/eDRIS linkage)
-Postoperative complications
-Postoperative delirium recorded 4AT through retrospective notes review one timepoint close to the date of discharge according to SNAP 3 methodology (https://www.rcoa.ac.uk/snap3-frailty-delirium)
-Same-day cancellation
-Return to a preoperative place of residence (a clinical record)
-Days alive and out of hospital 90 days (HES linkage/eDRIS linkage)
-90-day and 12-month mortality (HES linkage/eDRIS linkage)
-Operative or non-operative management

Was the initially suggested procedure undertaken or did the patient undergo a different or no procedure?

Clinician defined, 'medically fit for discharge'

Notes review at or after discharge

-Shared decision making (SDMQ9) (collected in a purposively sampled consented subgroup of patients) to be
-Decisional regret (Decision Regret Scale) (collected in a purposively sampled consented subgroup of patients) to be collected in the pre-implementation and postimplementation phase (6 pts per site to be consented in each of the pre and post-implementation phases across 18 sites. Purposive sampling to include elective/emergency, surgery/no surgery and LoS</> 5 days. This applies to SDMQ9 and DRS. Estimated total 216 patients/carers/family members).

Electronic consent and data entry
To simplify interactions with participants, we plan to implement electronically enhanced data collection. All sites will also have access to traditional paper consent, patient information sheets and data collection forms. The choice of electronic or traditional paper consent and data collection will be determined by the individual sites. All precautions will be taken to safeguard patient data and ensure confidentiality. No data will be stored on individual electronic devices. The online portal (REDCap)is a secure internet-based platform that is controlled by the University of Birmingham. Any data entered into the portal (via a secure web browser) is stored in a password-protected, secure database at the University of Birmingham. Data held here will be treated in accordance with Information Governance Policies at the university.

Participants
Eighteen hospitals (two sequential cohorts of nine hospitals) providing general and/or orthopaedic and/or urological and/or vascular surgery located across England, Scotland, Wales and Northern Ireland, with representation of rural and urban NHS services, serving diverse populations in terms of socioeconomic circumstances, race and ethnicity.

(i) NHS staff at the eighteen sites implementing POPS services, including geriatricians, anaesthetists, surgeons, nursing and allied health professionals, and managers
(ii) - Patients aged over 50 years under the care of general and/or orthopaedic and/or urological and/or vascular surgeons who have received care from a POPS service at participating hospitals.

Carers/family members closely involved in the care of patients aged over 50 years under the care of general and/or orthopaedic and/or urological and/or vascular surgeons who have received care from a POPS service at participating hospitals (some of these carers/family members will be related to patient participants from and others may be related to patients who do not display the capacity to consent to the study)

Our inclusion and exclusion criteria at the hospital site level are designed to maximise participation by hospitals regardless of geography, type of hospital, patient population or resources. Recruitment at the hospital site level (as opposed to at the individual patient level) aims to ensure the participation of patients often underrepresented in research; those living with frailty, those living in care homes, those lacking the capacity to consent, those who do not speak English, those with sensory impairments.

Hospital sites in the UK that provide general and/or orthopaedic and/or urological and/or vascular surgery in elective and/or emergency settings with access to a geriatrician (consultant, speciality and specialist doctors, SAS) with allocated time to support implementation and with a hospital executive board member who will sponsor support for participation.

The sampling of hospital sites
Purposive sampling will occur at the hospital level. Our research sites will be NHS hospitals providing general and/or orthopaedic and/or urological and/or vascular surgery. Eighteen sites, in two consecutive cohorts, will be identified and purposively selected for participation in the study. These sites will be selected to ensure coverage across NHS regions in England and the devolved nations to represent geographic, ethnic and socioeconomic diversity in the United Kingdom. This sampling frame will also ensure variation in size and type of hospital (district general or teaching hospital).

The sampling of NHS staff
Healthcare professionals at participating hospital sites involved in the implementation of POPS services will be recruited to:

- Participate in the process evaluation as detailed below (three staff members per site for rapid, high-level mapping and ten staff members at six purposively sampled sites for an in-depth case study with a range of professional backgrounds)
- Provide detail on their involvement in implementation and patient care to support health economic evaluation (diary of hours spent in NHS Elect activities and delivery of clinical care)

The sampling of patients/carers
POPS-SUp will be recruiting at the hospital site as opposed to at the individual patient level. Patient metrics will be collected from routinely available data and therefore individual consent will not be taken with CAG approval (n-2,500 patients). In a subset of patients/carers or family members (n-216) informed consent will allow qualitative and quantitative evaluation of satisfaction of care delivered through POPS service, satisfaction with shared decision making, decisional regret and quality of life data for health economic evaluation.

This approach to sampling/power has been taken for the following reasons; in the main study, 18 hospitals will be recruited in two cohorts. This temporal separation allows for iterative learning and refinement of the implementation strategy from the first to second cohort and is in keeping with the Medical Research Council guidance on the development and evaluation of complex or multicomponent interventions. The power calculation was undertaken by the study statistician, Professor John Norrie. Statistical oversight for pops-sup will be provided by Professor Janet Peacock who is a member of the TSC.

Estimating the required sample size for a given power and level of significance in an interrupted time series design is challenging. We know that we have enough time and resources to recruit 18 hospitals which we will examine for three months before implementation, six months during implementation and the three-month follow-up period. In its simplest form, an unweighted one sample t-test with each of 18 sites contributing a single after-before data point would have 90% power at 5% level of significance to detect an effect size of 0.8 i.e. a difference in mean length of stay after over before implementation of 0.8 standard deviations. If the standard deviation at the site level was five days, this would equate to being able to detect a mean difference of four days, which would be sufficient to impact clinical practice. The true power of the study will be greater (for example, allowing us to detect a smaller mean difference, of two to three days) and will be accurately assessed using simulation informed by early data from the study and using the statistical model to be employed, which will depend on individual-level data within each site, potentially at multiple time points (eg each week for around 12 times in each of the three months before and after periods), and fully account for dependency across participants within sites, and adjusting for known prognostic factors. At present, we are expecting each site to contribute on average 15 participants per month, with nela data showing a median length of stay of ten days in those without return to theatre.

The purposive sampling strategy was chosen following co-design with PPIE partners to ensure geographical spread across the NHS with the inclusion of both teaching and district general hospitals (this will ensure that patients of different ethnicities and socioeconomic backgrounds will be included).

Recruitment for process evaluation
A summary of the study with poster/leaflet and participant information sheets (PIS) will be circulated by the local Pl at the participating hospital site to all relevant healthcare staff prior to the beginning of the study. A poster/leaflet will also be on display in all relevant clinical areas to promote awareness of the study.

Observations with NHS staff
-The poster/leaflet and PIS will be circulated to relevant clinical and managerial staff by the PI before the study launch for general information and introduction. The poster/leaflet and PIS will give staff information on the background and purpose of the evaluation, how collected data will be anonymised, and explain the opportunity for members to opt out of any observation. Before attending any specific meetings/sessions, the researcher will contact and seek permission to attend from the meeting chair. The poster/leaflet and PIS will be circulated to all members with the meeting papers; this will re-iterate the study details and will give another opportunity for members to opt out of the observation. The poster/leaflet and PIS will also be available at the beginning of the meeting in handout form. If a member declines consent, their contributions to the meeting will not be recorded in the field notes. We perceive the risk for participants to be low.

Semi-structured interviews with NHS staff
-The PIS and a consent form will be sent via email or directly provided to all potential interviewees in advance of any planned interview. Potential participants will then be given the opportunity to discuss the PIS with the researchers and ask questions. If participants agree to the interview, the researchers will be available to answer any questions related to the PIS and the consent form with interviewees to ensure understanding before requesting informed consent from them prior to interviews. In the event that the participant would like to be interviewed by telephone or over teleconferencing software (MS Teams), the researcher will request contact information. The consent form may be given directly to the researcher before the planned interview or emailed back to the research team prior to the interview (considering the typing of names and initials as proof of consent).

Participants will be able to withdraw consent at any time before or during interviews. In the event of consent being withdrawn after the completion of an interview, the data provided prior to withdrawal will be retained (anonymised fully) for analysis and publication. Interviews may occur at the hospital, or via telephone/teleconferencing (MS Teams).

Recruitment of patients for qualitative and quantitative evaluation of satisfaction with pops service, shared decision making, decisional regret and quality of life.

In a group of patients, we will obtain informed consent to undertake:
- Qualitative evaluation using semistructured interviews which will be transcribed via a transcription company and analysed
- Questionnaire evaluating satisfaction with shared decision-making (SDMQ9)
- Questionnaire examining decisional regret (DRS)

In this subset of consented patients and carers, initial contact will be made by the direct care team. Posters/leaflets in all clinical areas will be used to promote awareness of the study. Patient information sheets will be provided and patients will be recruited and consented in one meeting to avoid burden; a process that has been informed by our PPIE partners. Once the patient has consented to the study, the research team will approach the patient to find a suitable time for the interview. It is not anticipated that the patients will be returning in a separate visit for these interviews which will be undertaken in either the outpatient clinic or ward.

Recruitment of carers/family members for qualitative and quantitative evaluation of satisfaction with pops service, shared decision making, decisional regret and quality of life.

We will recruit a consented group of carers/family members to understand their experience of POPS services - provide their experience of observing shared decision-making and decisional regret in patients who do not display the capacity to consent.

In these carers/family members, we will obtain informed consent to undertake:
- Qualitative evaluation using semistructured interviews which will be transcribed via a transcription company and analysed questionnaire evaluating satisfaction with shared decision-making (SDMQ9)
- Questionnaire examining decisional regret (DRS)

In this subset of carers/family members, initial contact will be made by the direct care team. Posters/leaflets in all clinical areas will be used to promote awareness of the study. The participant information sheet will be provided and carers/family members will be recruited and consented in one meeting to avoid burden; a process that has been informed by our PPIE partners. Once the carer/ family members has consented to the study, the research team will approach them to find a suitable time for the interview. It is not anticipated that they will be returning in a separate visit for these interviews which will be undertaken in either the outpatient clinic or ward.

Data collection
Patient metrics will be collected from routinely available data for all service users and therefore individual consent for clinical data collection from routinely collected hospital records will not be required (n=2,500) with CAG approval obtained (for England, Wales) and pending PBPP (for Scotland). We will however ensure that the national opt-out is checked. In addition, the posters raising awareness of POPS-SUp clearly state that patients can opt out of the study at any point.

Schedule of assessment for NHS staff
-Ethnographic observation will be conducted by the research team
-Semistructured interviews will be conducted by the research team, recorded, and transcribed by a transcription company. This will occur in the pre-implementation phase (1st 3 months) and postimplementation phase (last 3 months).
-Interviews will occur at the staff member's place of work.
-Diary cards will be completed by staff throughout the study

Schedule of assessment for patients
-Ethnographic observation will be conducted by the research team
-Semistructured interviews will be conducted by the research team, recorded, and transcribed by a transcription company. --This will occur in the pre-implementation phase (1st 3 months) and postimplementation phase (last 3 months).
-Interviews will occur at the hospital either in the outpatient clinic or on the ward

Schedule of assessment for carers/family members
-Ethnographic observation will be conducted by the research team

-Semistructured interviews will be conducted by the research team, recorded, and transcribed by a transcription company (see topic guide). --This will occur in the pre-implementation phase (1st 3 months) and postimplementation phase (last 3 months).
-Interviews will occur at the hospital either in the outpatient clinic or on the ward

Patient/carer/family or staff participants will not need to attend additional assessment visits as part of POPS-SUp.

Once participants have completed the activities they consented to there is no further involvement from them as different people will be approached pre- intra- and post-implementation.

POPS-SUp will run over 39 months.

The process evaluation will occur in 'real-time' with rapid feedback loops to inform iterative learning and refinement of the implementation strategy. There are no planned interim analyses of other outcome measures as these require HES data linkage/eDRIS linkage at the end of the study. To mitigate researcher bias pops-sup will:
-Use a routinely collected metric, length of hospital stay, as the coprimary clinical effectiveness outcome
-Define the coprimary implementation outcome, reach, and apriori to avoid the use of differing definitions
-Define all secondary outcomes apriori
-Use routinely collected data wherever possible
-Use validated scores wherever possible
-Use researchers separate from the clinical team responsible for the implementation of the intervention to conduct the 'rapid real-time embedded process evaluation'
-The statistical analysis plan has anticipated potential bias from seasonal variation in length of hospital stay and infective respiratory illnesses.

Public and patient involvement and engagement are central to POPS-SUp.

Intervention Type
Other

Primary outcome(s)
In keeping with the MRC framework for complex interventions POPS-SUp will use the following coprimary outcome measures:
1. Reach to assess implementation will be measured using data collected in case note records at onetime point via:
1.1. The number of patients seen by POPS
1.2. The number of patientseligible for POPS review, defined according to which surgical specialty the service is being established in e.g. EGS/urology etc and which patients will be seen e.g. >65 years/frailty CFS 5/multimorbidity etc
2. Length of hospital stay in days to assess clinical and cost-effectiveness measured using data collected in case note records at one timepoint

Key secondary outcome(s))
1. Fidelity to clinical components of perioperative CGAmeasured using a case note review of all patients seen by the POPS services to establish fidelity to the core components checklist for CGA at one timepoint
2. Fidelity to core components of POPS services measured against POPS logic model core components which will be adjusted according to the service being established eg some teams may not be providing postoperative care will be measured through process evaluation ie staff members will be interviewed/observed/surveys at one timepoint
3. Acceptability and feasibility of the implementation strategy will be assessed through process evaluation. Acceptability – staff and patient interviews - through process evaluation at one

timepoint . Feasibility – staff and patient interviews in addition to questions on how long the clinic takes/whether there is enough space / sufficient staff etc - through process evaluation at one timepoint

Secondary effectiveness outcomes include:
1. 30-day readmission measured using Hospital Episode Statistics (HES) data linkage at one timepoint
2. Postoperative complications retrospectively measured using predefined characteristics at one timepoint close to date of discharge
3. Post-operative delirium recorded through 4AT through retrospective notes review at one timepoint close to the date of discharge according to SNAP 3 methodology
4. Same-day cancellation measured using data collected from clinical records at one timepoint
5. Return to the preoperative place of residence measured using data collected in the clinical record at one timepoint
6. Days alive and out of hospital 90 days measured using HES data linkage and eDRIS data linkage at one timepoint
7. 90-day and 12-month mortality measured using HES data linkage and eDRIS data linkage at one timepoint
8. Operative or nonoperative managementmeasured using data collected in the clinical record at one timepoint
9. Was the initially suggested procedure undertaken or did the patient undergo a different or no procedure? measured using data collected in the clinical record at one timepoint
10. Clinician defined, 'medically fit for discharge'measured using data collected in the clinical record at one timepoint

The following secondary outcome measures are assessed using a notes review at or after discharge:
1. Decision-making in the consultation measured using the Shared Decision-Making Questionnaire (SDMQ9)
2. Decisional regret measured using the Decisional Regret Scale (DRS)

Completion date
01/05/2027

Eligibility

Key inclusion criteria
Inclusion criteria at the hospital site level:
1. Hospital site in the UK that provides general and/or orthopaedic and/or urological and /or vascular surgery in elective and/or emergency settings
2. Geriatrician (consultant, speciality and specialist doctors, SAS) with allocated time to support implementation
3. Hospital executive board member who will sponsor support for participation

Inclusion criteria at the NHS staff level:
NHS staff employed at the participating site involved in implementation of POPS intervention and/or delivery of perioperative care

Inclusion criteria at the patient participant level:
Patients aged over 50 years undergoing general and/or orthopaedic and/or urological and /or vascular surgical care who have received input from a POPS service at participating hospitals

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 years

Upper age limit
120 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Exclusion criteria at the hospital site level:
No healthcare professional with expertise in CGA available to participate in the NHS Elect POPS programme

Exclusion criteria at the NHS staff level:
None

Exclusion criteria at the patient participant level:
1. Prisoners
2. Dementia or delirium so severe as to preclude completion of Shared Decision Making Q9/EQ 5D 5L / Decisional regret scale / No capacity to consent to study (in the individually consented group only)

Date of first enrolment
11/11/2024

Date of final enrolment
01/06/2026

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Guys' and St Thomas' NHS Foundation Trust
-
London
England
SE1 9RT

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Government

Funder Name
Health and Social Care Delivery Research

Alternative Name(s)
Health and Social Care Delivery Research Programme, HSDR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		30/10/2025	20/11/2025	Yes	No
Other files	version 1.2	07/10/2024	25/11/2024	No	No
Participant information sheet	version 1.1	17/09/2024	25/11/2024	No	Yes
Participant information sheet	version 1.1	17/09/2024	25/11/2024	No	Yes
Protocol file	version 1.1	17/09/2024	25/11/2024	No	No
Statistical Analysis Plan	version 1	23/07/2024	25/11/2024	No	No