SNAP 3: An observational study to understand frailty and delirium in older surgical patients

Submission date 05/11/2021	Recruitment status No longer recruiting	[X] Prospectively registered [X] Protocol		
Registration date	Overall study status	[X] The second secon		
08/12/2021	Completed	[X] Results		
Last Edited 08/04/2025	Condition category Other	Individual participant data		

Plain English summary of protocol

Background and study aims

More older people are undergoing surgery as the population ages and surgical care improves. Frailty is an age-related syndrome that increases an individuals' vulnerability to adverse outcomes in response to illness, injury and surgery. Delirium is a period of temporarily altered, fluctuating consciousness, triggered by illness, surgery or environment. There is evidence that surgical outcomes are worse in patients with these conditions.

The aim of SNAP3 is to investigate which patients are frail and which are at risk of delirium. It will investigate current perioperative care and its outcomes.

Who can participate?

Surgical patients who are 60 years and over undergoing surgery from 21st-25th March 2022

What does the study involve?

Participants recruited will have the following information collected:

1. Notes review and data linkage with government agencies, for demographic, medical and socioeconomic details

2. Frailty assessments: 2 requiring active participant involvement, 2 using electronic medical records

- 3. Assessments for delirium and medical complications from a survey
- 4. Quality of life email/telephone survey 4 months postoperatively

What are the possible benefits and risks of participating?

The benefit to participants is the knowledge that they have contributed to the care of older surgical patients, there is no direct clinical benefit. The interventions are survey based only, the only risk is that participants could potentially be upset by survey content, however, this is unlikely.

Where is the study run from? University of Nottingham (UK)

When is the study starting and how long is it expected to run for? June 2021 to May 2022 Who is funding the study? Royal College of Anaesthetists (UK) Frances and Augustus Newman Foundation (UK)

Who is the main contact? Dr Samuel Nava, Samuel.Nava@nottingham.ac.uk

Study website https://www.niaa-hsrc.org.uk/SNAP-3-Frailty-and-Delirium-Hospital-List

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number 294618, 302033

ClinicalTrials.gov number Nil known

Secondary identifying numbers IRAS 294618 (England, Wales, Northern Ireland), IRAS 302033 (Scotland), CPMS 49713

Study information

Scientific Title

The 3rd Sprint National Anaesthesia Project (SNAP): An observational study of frailty, multimorbidity and delirium in older people in the perioperative period

Acronym

SNAP 3

Study objectives

Current study hypothesis as of 09/08/2022:

To characterise the epidemiology of frailty, multi-morbidity and postoperative delirium in approximately 8,000 older people undergoing surgery in the UK

1. Examine the relationship between frailty, multimorbidity and perioperative outcomes across all surgery types

2. Describe the variation in hospital-level and patient-level frailty-related interventions

3. Identify associations between hospital-level and patient-level frailty-related interventions and outcome

4. Develop and internally validate a risk-prediction tool for postoperative delirium

Previous study hypothesis:

To characterise the epidemiology of frailty, multi-morbidity and postoperative delirium in approximately 12,000 older people undergoing surgery in the UK

1. Examine the relationship between frailty, multimorbidity and perioperative outcomes across all surgery types

2. Describe the variation in hospital-level and patient-level frailty-related interventions

3. Identify associations between hospital-level and patient-level frailty-related interventions and outcome

4. Develop and internally validate a risk-prediction tool for postoperative delirium

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 28/06/2021, Wales Research Ethics Committee 7 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44(0)2920 230457; Wales.REC7@wales.nhs.uk), ref 21/WA/0203

2. Approved 05/08/2021, Scotland A REC (2nd Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, UK; +44(0)1314655680; manx.neill@nhslothian.scot.nhs.uk), ref: 302033

Study design

Multi-centre prospective observational cohort study

Primary study design Observational

Secondary study design Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

https://www.niaa-hsrc.org.uk/SNAP-3-Frailty-and-Delirium-Hospital-List

Health condition(s) or problem(s) studied

The identification and management of frailty in older surgical patients. The identification and prevention of delirium in older surgical patients. The identification and management of multimorbidity in older surgical patients.

Interventions

This study is observational, all interventions are surveys or validated tools that involve speaking with participants.

The study will record details of participants' medical history, surgical history, comorbidities, laboratory results, and surgical risk score preoperatively. Two frailty assessments will be completed with the participant; a Clinical Frailty Scale and the Edmonton Frail Scale. If a hospital

records an Electronic Frailty Index, then this will be recorded. After the participant has had surgery, details of intraoperative and immediate postoperative care will be recorded.

If the participant remains in hospital, they will be followed up on days one, three, and seven postoperatively. On days one and three, a delirium screening tool (the 4AT) and a notes review for delirium trigger words will be used to identify delirium. On days three and seven, a postoperative morbidity score (POMS) will be used to identify postoperative morbidity.

At four months postoperatively, participants will receive either an email or phone call for followup with the EQ-5D-5L and assess the number of days spent alive and at home.

All patients who are 60 years or older, attending for surgery (day-case, elective and emergency) during up to two periods, of up to seven days, will be considered for inclusion. Patients will be given a participant information sheet (PIS) whilst waiting in the preoperative areas.

1. Patients will be identified from operating lists by clinical teams, given a PIS and referred to the research team if they are willing. They will be approached by the research team to discuss the study and consent.

2. Consent will be taken either on an electronic device using electronic signatures with declarations and tick boxes or a traditional paper consent form.

3. Pre-operative data collection

Primarily through a review of the medical notes, with participant confirmation if necessary. Medical data, admission information, demographic and socioeconomic data will be sought. 4. Frailty assessments

Four tools will be used to assess presence and severity of frailty. Two tools require participant involvement and two are passive.

4a. The Clinical Frailty Scale (CFS) provides a word and pictorial representation of the frailty syndrome and is recommended in the UK as a national screening tool for frailty, with prior use in surgical populations. The use of the CFS requires observation of the patient and a brief discussion of their activities of daily living. This will be completed by researchers before other frailty tools are seen to avoid confirmation bias.

4b. The Reported Edmonton Frailty Scale is brief, feasible and has also been used in surgical populations. It involves answering 10 short questions and participating in drawing a clock face. 4c. The electronic Frailty Index (eFI) uses the deficit accumulation model of frailty. It isn't available in all areas of the UK, it will be collected wherever it is currently recorded.

4d. The Hospital Frailty Risk Score can be calculated from HES data at discharge. We will report this, as it may be a useful automated method to highlight frailty to primary care colleagues. 5. Process of care data

Primarily a notes review with participant confirmation if necessary. This will assess the process of preoperative assessment, modes of anaesthesia, use of a catheter and level of postoperative care.

6. Delirium

The presence or absence of delirium will be assessed on days one and three if the participant remains in hospital. The 4AT (delirium assessment tool) or CAM ICU (Confusion Assessment Method Intensive Care Unit) and a review of nursing and medical notes of delirium trigger words will be used. The 4AT is a brief assessment tool requiring patients to answer six questions. CAM ICU is a brief 4 stage assessment tool for delirium that is validated for use in ICU. Notes review will be done manually by local researchers. These processes together will optimise our chances of detecting delirium.

7. Postoperative morbidity

Postoperative Morbidity Survey (POMS) (with appropriate speciality specific modifications for cardiac and hip fracture patients) will be used on days three and seven if the participant remains in hospital. POMS is a tool used to assess postoperative morbidity. This is mainly a notes review

but may require brief face to face interaction with the participant.

8. Quality of life (QoL)

QoL will be assessed using the EQ-5D-5L questionnaire and a patient/carer estimate of days alive at home (DAH) via telephone interview or electronic email questionnaire. The EQ-5D-5L is a six question tool suitable for use over the telephone or electronic device. DAH is a patient preferred QoL outcome. We will cross check reported DAH with data linked by Hospital Episode Statistics/ Office for National Statistics/ Health and Social Care Wales/ Electronic Data Research and Innovation Services/ NHS Services Scotland (collected for DAOH). This will account for hospital length of stay and readmissions but not residence out of hospital but not at home (this specifically relies on patient/carer reports).

Initial data linkage will be approximately four months after final enrolment, then one year mortality data will be linked at 12 months. Last participant contact will be four months after recruitment. The final data linkage will occur at 10 years when we will look for mortality.

Data linkage will be carried out with NHS Digital, Health and Social Care Wales, NHS National Services Scotland and individual trusts as appropriate. The following will be collected: 1. Length of stay: Acute hospital stay and days alive and out of hospital (DAOH) within 30 and 90 days will be recorded.

- 2. Mortality: in hospital death, mortality at one year, two, five and ten years
- 3. Readmission: Readmission of participants within 30 days will be recorded
- 4. Discharge destination
- 5. Socio-economic status: post code will be linked with indices of deprivation

Length of acute hospital stay (days) will be the primary outcome as it is expected to be affected by both medical complications and discharge planning issues. The other outcomes are important either as mechanistic explanations or as complementary patient-relevant metrics.

Intervention Type

Other

Primary outcome measure

Length of acute hospital stay (days) after surgery collected via data linkage at the end of the study

Secondary outcome measures

1. Planned surgical procedure taken from participant notes on day of surgery

2. Urgency of surgery (emergency, urgent, expedited, planned) taken from participant notes on day of surgery

- 3. Indication for surgery: cancer / non-cancer taken from participant notes on day of surgery
- 4. Co-morbidities from defined list taken from participant or participant notes on day of surgery 5. Count of regular medications from defined list taken from participant or participant notes on

day of surgery

- 6. Age from participant notes on day of surgery
- 7. Sex at birth from participant on day of surgery
- 8. Gender from participant on day of surgery
- 9. Ethnicity from participant on day of surgery
- 10. Body mass index from participant notes/height/weight measurement on day of surgery

11. Most recent laboratory test results (measured within 6 weeks of admission) recorded on day of surgery:

11.1 Full blood count (Haemoglobin, red cell distribution width, white cell count (total),

lymphocyte: neutrophil ratio

11.2 Creatinine & electrolyte

11.3 SARS-Cov-2 status (Positive/not positive (nasopharyngeal swab)

12. Surgery specific risk score: ASA status recorded on day of surgery

13. Surgery specific risk score: SORT version 2 score recorded on day of surgery

14. Comorbidity/multimorbidity measured using Charlson Comorbidity Index on day of surgery

15. Source of admission (Home (including level of support), residential home / retirement

complex, care home) reported by participant or participant notes on day of surgery

16. Postcode (surrogate for socio-economic deprivation status) recorded from participant or participant notes on day of surgery

17. Highest education level (surrogate for a socioeconomic model) using UK Census 2011 list, recorded from participant or participant notes on day of surgery

18. Frailty recorded by Clinical Frailty Scale and Edmonton Frail Scale on day of surgery

19. Frailty recorded by electronic Frailty Index (eFI) recorded from hospital notes

20. Frailty recorded by Hospital Frailty Risk Score calculated from Hospital Episode Statistics at discharge.

21. Model of perioperative assessment (nurse-led, anaesthetist-led, physician-led) recorded from participant or participant notes on day of surgery

22. Mode of anaesthesia (general, local, regional, neuraxial anaesthesia) recorded from participant notes on day of surgery

23. Urinary catheterisation recorded from participant or participant notes on day of surgery

24. Level of postoperative care (ward, HDU, ICU) recorded from participant or participant notes on day of surgery

25. Delirium measured by 4AT and delirium trigger words from participant and participant notes respectively, reported on days one and three.

26. Postoperative morbidity measured by Postoperative Morbidity Score (general, cardiac and hip fracture) on days three and seven.

27. In hospital mortality measured by data linkage

28. Mortality measured via data linkage at one, two, five and ten years

29. Days alive and out of hospital measured through data linkage from discharge date and mortality within 30 and 90 days.

30. Readmission within 30 days measured through data linkage

31. Quality of life measured by EQ-5D-5L and EQ-VAS four months postoperatively by email or telephone survey.

32. Discharge deposition measured via data linkage after discharge

33. Quality of life measured by days alive at home, measured at four months postoperatively from participant and data linkage.

Overall study start date

28/06/2021

Completion date

20/05/2022

Eligibility

Key inclusion criteria

1.60 years or older

2. Undergoing a surgical procedure on 21st-25th March 2022 (either elective or emergency)

3. Either have the capacity or have an appropriate consultee/personal legal representative to agree to participation on the participant's behalf

Participant type(s) Patient

Age group Senior

Lower age limit 60 Years

Sex Both

Target number of participants 8,000

Total final enrolment 7794

Key exclusion criteria 1. Very minor surgery eg. cataracts, endoscopy, tracheostomy 2. ASA VI

Date of first enrolment 21/03/2022

Date of final enrolment 13/05/2022

Locations

Countries of recruitment England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre Royal Devon and Exeter Hospital Tremona Road Exeter United Kingdom EX2 5DW

Sponsor information

Organisation University of Nottingham

Sponsor details

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Sponsor type University/education

Website https://www.nottingham.ac.uk/

ROR https://ror.org/01ee9ar58

Funder(s)

Funder type Research organisation

Funder Name Royal College of Anaesthetists

Alternative Name(s) RCoA

Funding Body Type Private sector organisation

Funding Body Subtype Associations and societies (private and public)

Location United Kingdom **Funder Name** Frances and Augustus Newman Foundation

Alternative Name(s)

Funding Body Type Private sector organisation

Funding Body Subtype Trusts, charities, foundations (both public and private)

Location United Kingdom

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 04/06/2024: Planned publications in a high-impact peer-reviewed journal for descriptive and outcome data.

Methodology paper reference: Swarbrick C, Poulton T, Martin P, Partridge J, Moppett IK; SNAP 3 Project Team. Study protocol for a national observational cohort investigating frailty, delirium and multimorbidity in older surgical patients: the third Sprint National Anaesthesia Project (SNAP 3). BMJ Open. 2023 Dec 21;13(12):e076803. doi: 10.1136/bmjopen-2023-076803. PMID: 38135325; PMCID: PMC10748966.

Previous publication and dissemination plan: Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/01/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository.

We intend that the data is available for seven years after final data linkage (2039) as per sponsor policy.

All data will be anonymised and where group are small enough to allow possible identification, they will be grouped together to ensure anonymity.

Participants consent form contains the fact their results will be shared with other researchers interested in this topic.

IPD sharing plan summary

Study outputs

Stored in publicly available repository

Study outputs					
Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol file</u>	version 1.0	28/05/2021	05/11/2021	No	No

HRA research summary	28/06/2023	No	No	
Protocol article	21/12/2023	27/12/2023	Yes	No
Results article	06/01/2025	08/04/2025	Yes	No