

The POPPY Study

RAFT 4

‘Patient reported outcomes, postoperative pain and pain relief after day case surgery’

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This protocol describes the study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the NHS UK Policy Framework for Health and Social Care Research (2017). It will be conducted in compliance with the protocol, the Data Protection Act (2018) and other regulatory requirements as appropriate.

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor’s SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:

Date:

Name (please print):

Position:

Chief Investigator:

Signature: 

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GLOSSARY OF ABBREVIATIONS

BPI	Brief Pain Inventory
CI	Chief Investigator
DPIA	Data Protection Impact Assessment
EQ5D	EuroQol 5 Dimensions 5 Levels
FPS	Functional Pain Score
GAD-7	Generalised Anxiety Disorder Scale - 7
HES	Hospital Episode Statistics
HRA	Health Research Authority
IMMPACT	Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials
NHS	National Health Service
PenPEG	Peninsula Patient Experience Group
PHQ-8	Patient Health Questionnaire - 8
PIS	Participant/ Patient Information Sheet
PMG	Project Management Group
PPIE	Patient and Public Involvement and Engagement
PPOU	Persistent Post-Operative Opioid Use
PPSP	Persistent Post-Surgical Pain
PROMs	Patient Reported Outcome Measures
QOR-15	Quality of Recovery 15 Score
RAFT	Research and Audit Federation of Trainees
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
SAP	Statistical Analysis Plan
SOP	Standard Operating Procedure
SMS	Short Messaging Service
SSC	Study Steering Committee
UHP	University Hospitals Plymouth NHS Trust

KEY WORDS

Patient reported outcomes
 Acute pain
 Persistent postsurgical pain
 Persistent postoperative opioid use
 Pain relief after day-case surgery
 Quality of recovery

STUDY SUMMARY

Study Title	Patient Reported Outcomes, Postoperative Pain, and Pain Relief after Day-Case Surgery
Study Design	Prospective, multi-centre, observational cohort study. The study will include a pilot phase.
Study Participants	Adults undergoing day-case surgery in the UK
Primary Objectives	<p>To measure short and long-term patient reported outcomes in UK day-case surgery patients in relation to recovery, post-surgical pain and opiate use.</p> <p>Short-term: to describe the quality of recovery over the first postoperative week</p> <p>Long-term: to establish the prevalence of persistent postsurgical pain (PPSP) and persistent postoperative opioid use (PPOU) in day case surgical patients.</p>
Secondary Objectives	<p>To conduct a pilot study over 4 hospital sites to confirm the feasibility of the large-scale multi-centre study</p> <p>To identify those patient, medication, anaesthetic, and surgical characteristics that are associated with poor quality of recovery, and PPSP and/or PPOU</p> <p>To describe the acute pain experience and analgesia use in the first postoperative week</p> <p>To estimate the need for further healthcare support in the first postoperative week</p> <p>To determine the patient reported acceptability of SMS prompted follow-up</p> <p>To determine the difference in quality of life between participants with and without PPSP</p> <p>To investigate the difficulty in reducing opioid use in participants with PPOU</p>

Qualitative objectives:

To explore patient experience of;

- Preparation for day case surgery and pre-operative expectations
- Acute recovery (first postoperative week)
- Longer-term recovery and post-operative pain (after 3 months)
- Opioids: intake, type, duration and experience

Eligibility Criteria**Inclusion Criteria:**

- Aged 18 years or older on day of surgery
- Day-case surgery as defined by National Day Surgery Delivery Pack¹
- An anaesthetist must be present for case
- The procedure must involve one or more of: sedation, regional anaesthesia, central neuraxial anaesthesia or general anaesthesia
- Able to read and understand English

Exclusion Criteria:

- Less than 18 years of age on day of surgery
- No access to a smartphone
- No anaesthetist involved with the procedure (such as local anaesthesia provided by a surgeon)
- Overnight stay (admission to hospital)
- Participant lacking capacity for consent
- Diagnostic and/or minimally invasive procedures (e.g., radiology, endoscopy, or cardiology procedures)
- Pregnancy or obstetric related procedures (being pregnant is not an exclusion criterion if surgery is unrelated to pregnancy)
- Currently breast feeding
- Ophthalmic procedures
- Prisoners

Eligibility for qualitative component:

As above, plus reporting PPSP and PPOU at day 97 post operative

Planned Sample Size

6,000
(Including 30 participants for qualitative analysis)

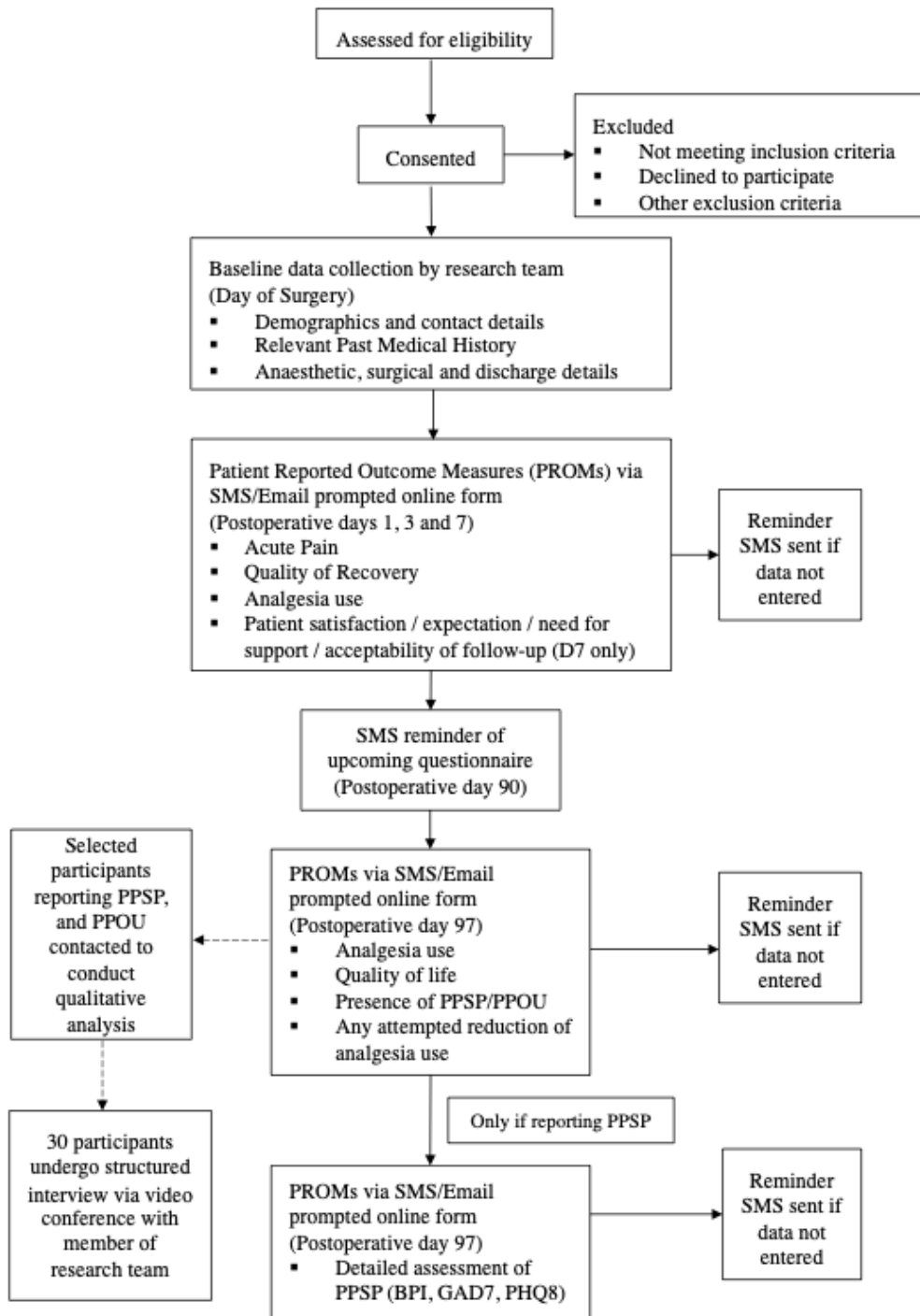
Follow-up Duration

97 days
(With additional time to conduct qualitative component)

Planned Study Period

June 2023 – August 2024

POPPY Study Flow Chart



1. INTRODUCTION

1.1 Background

Around seventy percent of all surgical procedures in the UK are carried out as day-cases¹, with six million day-case procedures performed annually². Whilst many day-case units successfully employ next day follow-up, meaningful longer-term assessment is lacking despite recognition that full functional recovery may take several months³. There is a lack of UK population data reporting how these patients recover in the months following day-case surgery and limited understanding of relevant longer-term outcomes.

Patient-reported outcome measures (PROMs), such as ability to return to carrying out usual activities and a good quality of life⁴ following surgery, are increasingly recognised as important and valuable to patients and healthcare providers⁵⁻⁶ over more traditional clinician-centred outcomes such as morbidity and mortality. PROMS can provide a more thorough understanding of the impact interventions may have upon patients and lead to improved service delivery⁷.

There is increasing evidence that day-case patients commonly develop longer term health problems following surgery including Persistent Postsurgical Pain (PPSP)⁸. The prevention of chronic pain was identified as a top priority for anaesthetic research by the National Institute for Academic Anaesthesia and James Lind Alliance in 2015⁹. A population study in Northern Norway showed that PPSP, pain continuing beyond 3-months post-operatively, is common with up to 18.3% of surgical patients suffering long-term moderate to severe pain¹⁰.

Inappropriate long term opioid use after surgery from mismanaged PPSP or opioid misuse disorder is also a major public health issue¹¹⁻¹², with 6% of opioid-naïve patients using opioids beyond three-months postoperatively in the US¹³. In one recent retrospective cohort study of over 340,000 ambulatory surgery patients in Canada 13% went on to develop PPOU¹⁴. Discharge opioid prescriptions in both North America and the UK are frequently not patient or procedure-specific, and over-prescription is a serious concern¹⁵⁻¹⁷.

Importantly, the literature suggests that PPSP may affect patients following day case (ambulatory) surgery as commonly as those who undergo major surgery. An observational study of 3121 European patients reported an incidence of moderate to severe chronic postsurgical pain (CPSP – used interchangeably with PPSP in the literature) of 11.8% at 12 months postoperatively. Multivariate analysis of this cohort identified preoperative chronic pain, percentage of time in severe pain on postoperative day one and orthopaedic procedures as risk factors¹⁸. A study of Dutch ambulatory patients suggests that PPSP is an equally common problem following day-case procedures, with 15.3% of 908 patients reporting moderate to severe pain at one year postoperatively¹⁹.

We can postulate from international studies that PPSP and PPOU may also be significant problems in UK day-case patients¹³⁻²⁰, but evidence for this in the British population is lacking²¹⁻²². As an illustration, a conservative extrapolation of North American results suggest more than 18,000 British day-case patients are at risk of developing PPOU annually²¹. As more complex day-case procedures are performed on increasingly comorbid patients, the incidence of PPSP and PPOU may rise.

1.2 Rationale for current study

This study aims to understand the nature of patient recovery more fully, using PROMS, following day surgery in both the short-term and longer-term phases. This hasn't been undertaken before in the UK and will be implemented by the Research and Audit Federation of Trainees (RAFT)²³, an umbrella organisation representing 19 trainee research networks across the United Kingdom. As mentioned, we are particularly interested in the acute quality of recovery and then the prevalence of persistent

postsurgical pain and postoperative opioid use in this population. Importantly we aim to identify the factors that are associated with these problems occurring. Our proposal aligns with the James Lind Alliance priority setting partnership²⁴ which identified ‘What can we do to stop patients developing chronic pain after surgery?’ and ‘What outcomes should we use to measure the ‘success’ of anaesthesia and perioperative care?’ as two of the top ten questions.

We plan to use an innovative secure SMS prompted online patient feedback system to gather data when study participants have left hospital after their operation. This system has already been implemented successfully for postoperative feedback in multiple NHS centres across the UK. Streamlining and utilising this system on a national scale may have benefits for future trainee led network research projects and future PROMS data collection in the UK.

Remote data collection is well established; in 2021 92% of all adults in the UK owned a smartphone²⁵, and 96% of households had internet access²⁶. Text message follow-up demonstrated higher response rates than other means of contact over both short-term²⁷⁻³⁰ and longer-term time frames³¹ especially when combined with other contact modalities³².

We will record Quality of Recovery-15 (QoR-15) on postoperative days 1, 3 and 7. This is a brief, validated questionnaire assessing patient-reported postoperative recovery in day-case patients^{33 34} and recommended as a core outcome for perioperative research³⁵. This will assess the quality of perioperative care and recovery trajectory for a wide range of day-case procedures and anaesthetic techniques.

The prevalence of PPSP and PPOU in the study population will be defined using our predetermined criteria (See Appendix B). Long term pain in participants with PPSP will be characterised using the Brief Pain Inventory (BPI)³⁶ (See Appendix B). Participants with PPSP will be asked to complete the GAD-7³⁷ and PHQ-8^{38 39} tools; these are easy to complete which minimises the burden on participants and their use follows IMMPACT recommendations for chronic pain studies⁴⁰. The study will review risk factors associated with developing PPSP and PPOU and aim to describe the link between reporting PPSP or PPOU and quality of life using the EQ-5D-5L⁴¹ score at day 97 post-operative in this cohort.

The results have potential to inform changes in day-case techniques, prescribing practice, patient preparation and follow up nationally. In addition, our methods of remotely collecting patient reported outcome data may expand the scope of future studies in perioperative medicine.

We would also like to perform an in-depth qualitative analysis on a purposive sample of participants that report PPSP and PPOU three months after surgery (day 97 post-operative). The POPPY study will use a pragmatic methodology to sample a subset of participants from the main study. Experience of pain is subjective and complex and therefore the addition of the qualitative analysis will add substantial detail and insight into this particular and important sub-group and contextualise the outcomes. It may be used to inform improvements to the patient-facing aspects of day case surgical pathways including how we prepare patients for surgery, information they are given on the day of surgery, and how we conduct short and long-term post-operative follow up. The insight into patient experience of the problems of PPSP and PPOU may help tailor behavioural interventions for the treatment of these conditions. The qualitative aspect of the POPPY study will be described in section 8 of this protocol.

1.3 Participant and Public Involvement and Engagement

PPIE groups have been involved with POPPY from its inception. Peninsula Patient Experience Group (PenPEG)⁴² PPIE has been embedded in all phases of study development including topic selection, study aims, proposed methodology and development and have been supportive of the study.

A schedule of ongoing PPIE has been costed into the study budget, and a group of members with relevant lived experience and research experience has been formed.

The schedule of PPIE is as follows:

Initial meeting: A meeting with the Peninsula Patient Experience Group (PenPEG)⁴² in November 2021 was attended by five patients all with a variety of experience of research involvement.

Session 1: introductory meeting, familiarisation with research questions, aims and broad methods (undertaken 26th July 2022).

Session 2: development of qualitative interview script and processes (undertaken 2nd February 2023)

Session 3: development of patient-facing aspects, PIS, consent form and consultation regarding ethics application (undertaken 20th February 2023)

Session 4: consultation with results of embedded pilot prior to national rollout

Session 5: discussion of results and dissemination

We do not expect members of our PPIE group to be involved in undertaking the study itself (i.e., recruitment/consent/data collection/ analysis). One or two of the PPIE members are on the SSC (Study steering committee). We will also ask the group to be involved with the discussion of results, conclusions, co-authorship, and invited to present and disseminate research findings.

2. STUDY OBJECTIVES

2.1 Primary objectives

To measure short and long-term patient reported outcomes in UK day-case surgery patients in relation to recovery, post-surgical pain and opiate use.

Short-term: to describe the quality of recovery in these patients in the first postoperative week

Long-term: to establish the prevalence of persistent postsurgical pain (PPSP), and persistent postoperative opioid use (PPOU) in these patients.

2.2 Secondary objectives

To identify those patient, medication, anaesthetic, and surgical characteristics that are associated with poor quality of recovery, and development of PPSP and PPOU.

To describe the acute pain and analgesia use of all patients in the first postoperative week

To estimate the demand of these patients for further healthcare support in the first postoperative week

To determine the patient reported acceptability of SMS prompted follow-up.

To determine the difference in quality of life between those with and without PPSP.

To investigate the difficulty in reducing opioid use in patients with PPOU.

Qualitative objectives:

To explore patient experience of;

- Preparation for day case surgery and pre-operative expectations
- Acute recovery (first postoperative week)
- Longer-term recovery and post-operative pain (after 3 months)
- Opioids; intake, type and duration and experience.

2.3 Embedded Pilot Study

The main study will be preceded by an internal pilot study of 3 months duration involving 4 hospital sites. This will follow the same processes as the main study, with the aim for patients recruited to the pilot study to be included in the final analysis. The aim of the pilot study is to confirm recruitment rates, protocol compliance and data collection. In particular, we will audit: (a) screening data; (b) recruitment; (c) reasons for exclusion; (d) completion rates of electronic data collection (including SMS and email contact). This will be done through the use of screening logs, case report forms and virtual site visits.

Trial progression criteria will be:

Possibility of proceeding to main study	Green (possible with no changes to protocol +/- close monitoring)	Amber (possible with changes)	Red (not possible)
Of all eligible participants:			
Recruitment on day of surgery	>50%	40-49%	<39%

Of all recruited participants:			
Day of surgery data completed	>60%	40-59%	<39%
Completion of Day 1 data	>60%	40-59%	<39%
Completion of Day 3 data	>60%	40-59%	<39%
Completion of Day 7 data	>60%	40-59%	<39%
Completion of Day 97 data	>60%	40-59%	<39%

Table 1. Pilot study response rate targets

The pilot study results will be reported in accordance with the CONSORT guideline for pilot studies, and will be reviewed by Study Steering Committee (SSC). If the pre-defined success criteria are reached, the internal pilot will run seamlessly into the main trial. Any recommended changes to the protocol and ways to improve adherence through learning from pilot sites will be clearly outlined.

Study population of pilot:

- The inclusion and exclusion criteria are the same as the main study.
- 5 days of recruitment at 4 separate hospitals sites within a defined data collection window (as per the main study):
 - Derriford Hospital, Plymouth, England
 - Leicester Royal Infirmary, Leicester, England
 - Rotherham Hospital, Rotherham, England
 - York Teaching Hospital, York, England
- At these sites, we will display informative posters in the admission areas to raise patients' awareness of the pilot study. As per the main study, all eligible patients will be approached by a member of their usual care team (most commonly a member of the theatre anaesthesia team) and asked about their willingness to participate. They will be given a participant information sheet. Once eligible subjects agree to consideration of participation, a member of the research team will approach the participant, inform them fully of the study, and consent if they agree.

Data collected:

This is planned to be an internal pilot study that will predominantly assess our study processes. We will include pilot data in the main analysis, unless we identify significant errors in our pilot, in which case the PMG, in consultation with the SSC, will decide whether pilot data is suitable for inclusion in the main analysis. If it is deemed not to be suitable, then the pilot data will not be included in the main analysis.

Pilot Analysis & Study Endpoint:

Pilot data will consist of the same outcome data as detailed in the main study. The pilot will cease when day 97 follow up data is collected.

Two key decision-making meetings will be held as part of the pilot:

- After day 7 follow up for the pilot site with the latest start date and before day 97. Data will be extracted, cleaned and analysed by our statistician. A meeting will then be held with the PMG initially and then SSC to discuss the data and compare against the pilot progression criteria.
- After day 97 follow up. Data will be extracted, cleaned and analysed by our statistician. A meeting will then be held with the PMG initially and then SSC to discuss the data, against the pilot study objectives.

The reason for two separate meetings is to make decisions over the progression of the study and allow implementation of key changes, if necessary, at an earlier point during the pilot.

Monitoring and quality assurance of pilot:

The CI will be responsible for monitoring of safety, adverse events, protocol deviations, and outcomes. The pilot data will be monitored by the CI after day 7 and day 97. The CI is ultimately responsible for determining whether the research should be altered or stopped, in conjunction with the PMG and SSC.

2.4 Outcome measures

Outcome Measure	Timing of Data Collection For Outcome Measures				
	D0	D1	Day 3	Day 7	Day 97
Baseline data	Y				
QOR-15 score		Y	Y	Y	
BPI derived pain questions	Y	Y	Y	Y	
FPS		Y	Y	Y	
Analgesic use	Y	Y	Y	Y	Y
Acceptability of SMS follow-up				Y	
Patient satisfaction				Y	
Need for additional help				Y	
PPSP prevalence					Y
Outcome Measure	Timing of Data Collection For Outcome Measures				
	D0	D1	Day 3	Day 7	Day 97
PPOU prevalence					Y
EQ-5D-5L score	Y				Y
BPI score					Y (conditional)
GAD-7 Score					Y (conditional)
PHQ-8 Score					Y (conditional)
Attempted reduction of opioid use					Y (conditional)

Table 2. Timing of data collection for outcome measures

Quality of Recovery 15 score (QoR-15) will be used to describe the recovery profile of participants on postoperative days 1, 3, and 7. This is a patient reported outcome questionnaire which is validated and

psychometrically tested for use in day surgery patients³³. There are five domains assessed: emotional state, psychological support, pain, physical comfort and physical independence each rated from 0-10 giving a maximum score of 150 which would correlate with ‘excellent recovery’³⁴ (See Appendix C).

Questions derived from the Brief Pain Inventory (BPI)³⁶ will be used to ask about pain at its ‘worst’ in the preceding 24 hours, ‘on average’ in the preceding 24 hours and ‘right now’ using an 11-point numerical scale. This will be asked at baseline (D0) and on postoperative days 1, 3, and 7. The 11-point scale uses 0 to represent ‘no pain’ and 10 to represent ‘worst pain imaginable’ (See Appendix C).

The Functional Pain Scale we will employ assesses the impact of pain upon activities of daily living using a five-level Likert scale response, this is based upon a functional pain assessment scale described by Halm et al in 2019⁴³ (See Appendix C).

Analgesia use will be described by allowing participants to select the analgesia they take from a drop-down menu and then enabling them to select the frequency with which they take these medications. This information will be requested preoperatively and on postoperative days 1, 3, 7 and 97 (See Appendix C).

We will assess acceptability to patients of SMS prompted online follow-up using a specifically designed five-point Likert scale on postoperative day 7 (See Appendix C).

Prevalence of PPSP will be calculated from patients reporting ongoing pain related to their surgery on postoperative day 97 based on questions derived from the BPI score³⁶. Prevalence of PPOU will be calculated from those patients reporting ongoing opioid use (or an increase relative to their preoperative opioid use) on postoperative day 97. These definitions are available in Appendix B and have been discussed with our PPIE group. We will expand upon these in our statistical analysis plan.

The EQ-5D-5L score⁴¹ will be used to assess quality of life at baseline and on postoperative day 97. This is a validated patient reported outcome measure which allows the participant to select a response from five different levels ranging from ‘no problems’ to ‘extreme problems’ across five domains referring to their condition that day. These are mobility, self-care, usual activities, pain/discomfort, and anxiety/depression (See Appendix C).

An adapted short form Brief Pain Inventory (BPI) score will be used to characterise the pain experienced by those reporting pain at the surgical site on postoperative day 97. This validated tool assesses pain and its impact on daily function. The main body of the BPI includes four questions related to severity of pain (which we will assess over the preceding 24 hours), and seven questions assessing interference of pain with normal life (also over the preceding 24 hours). Each of these questions is answered using a 0-10 scale with 0 being ‘no pain or no interference’ to 10 being ‘pain as bad as you can imagine or complete interference’ (See Appendix C). The answers to the BPI will determine whether participants have PPSP (see Appendix B). Participants with PPSP will then undertake the GAD-7 and PHQ-8 questionnaires to characterise their chronic pain more fully, as per the best practice guidance outlined in the IMMPACT recommendations⁴⁰.

The Generalised Anxiety Disorder 7 (GAD-7) score³⁷ will be undertaken on postoperative day 97 by participants with PPSP. This is a validated, seven-item, self-administered questionnaire used to assess the severity of generalised anxiety disorder and asks the participant to rank the frequency of symptoms over the preceding two weeks. The responses range from ‘not at all’ to ‘nearly every day’ with scores from 0-3 respectively for each question (See Appendix C). Scores of 10 or more are thought likely to represent moderate to severe anxiety⁴⁴.

The Patient Health Questionnaire 8 (PHQ-8) score³⁸ will also be assessed in those reporting PPSP on postoperative day 97. This is a validated, eight-item, self-administered screening questionnaire used to

assess the severity of depression and similarly to the GAD-7 asks the participant to report frequency of symptoms in the preceding two weeks. (See Appendix C). Scores of 10 or more reflect a 50% chance of the participant having a major depressive disorder³⁸.

Participants who report PPOU at D97 will be asked if they have attempted to reduce their analgesia use. If they answer 'Yes' then a follow up question using a specifically designed five-point Likert scale will determine how difficult they have found this process (See Appendix C).

3. STUDY DESIGN AND METHODS

The POPPY Study will be a prospective, multi-centre, consented, observational cohort study with an embedded pilot study prior to wider national implementation. There will also be a nested qualitative subgroup analysis.

A purpose-built secure online platform will be employed to collect and manage anonymised patient data at each participating centre throughout the study. This service, run by NewcastlePROMS⁴⁵, enables the input of anonymised patient data at baseline on the day of surgery by investigators and then subsequent follow up of participants using automated SMS. The platform has been used successfully at day-case units across England and is secured in line with the UK government's 'Cyber Essentials' scheme⁴⁶.

Following the recommendations of our PPIE group, our system will also enable links to online forms to be emailed to participants. This will facilitate the entering of data using a computer, laptop or tablet device to improve accessibility should the participant request this feature. The primary means of contact will remain SMS throughout the study period, if participants wish to receive the link in an email, they can select this option via a link on the automated SMS that they receive. The email contact option will be evaluated as part of the pilot study and will not be included in the full study if it adds little benefit to response rates.

The study will run in two phases. An initial recruitment phase, delivered by RAFT trainees with consent and electronic data collection performed on the day of surgery. Once participants are consented and recruited, their anonymised details will be uploaded to the NewcastlePROMS platform and linked to a unique patient identifier (the study number will be a sequential number). Subsequent patient reported or investigator uploaded data will be linked to this baseline entry.

The second phase of the study will be follow-up focussed on patient reported outcomes using specifically designed and validated tools as detailed above. Follow-up will occur at days 1, 3, 7 and 97 postoperatively using the SMS prompted online system. The system has been extensively tested and developed in conjunction with our PPIE team. Site research teams will contact participants' GPs if GAD-7 and/or PHQ-8 identify new moderate to severe anxiety or depression on day 97. In addition to this these participants will receive an SMS message signposting them to appropriate healthcare services.

4. STUDY PARTICIPANTS

4.1 Screening procedures

- All patients undergoing day case surgery who are aged 18 or over on the day of operation will be identified and eligible for screening.
- Potential participants will be identified using theatre lists or electronic theatre management systems on the day of surgery by members of their usual care team (usually the anaesthetist involved in the case).
- The precise method of identifying patients for screening will vary between institutions as local resources and protocols differ. Participants may be identified prior to the day of surgery, e.g., pre-assessment clinic, and participant information sheet given or sent with appointment letters, if systems allow. Posters will also be displayed on admission wards to inform potential candidates of the study.
- During the pilot study, a screening log will be kept using a proforma, undertaken by a member of the local research team at each institution once potential participants have been identified by their usual care team (anaesthetist).

4.2 Inclusion criteria

- Aged 18 years or older on day of surgery
- Day-case surgery as defined by National Day Surgery Delivery Pack¹
- An anaesthetist must be present for case
- The procedure must involve one or more of: sedation, regional anaesthesia, central neuraxial anaesthesia or general anaesthesia
- Able to read and understand English

4.3 Exclusion criteria

The participant may not enter the study if ANY of the following apply:

- Less than 18 years of age on day of surgery
- No access to a smartphone
- No anaesthetist involved with the procedure (such as local anaesthesia provided by a surgeon)
- Overnight stay (admission to hospital)
- Participant lacking capacity for consent
- Diagnostic and/or minimally invasive procedures (e.g., radiology, endoscopy, or cardiology procedures)
- Pregnancy or obstetric related procedures (being pregnant is not an exclusion criterion if surgery is unrelated to pregnancy)
- Currently breast feeding
- Ophthalmic procedures
- Prisoners

4.4 Withdrawal criteria (if applicable)

Participants will be able to withdraw from the study at any time should they choose to do so. The nature of our methodology is such that participants can decide to simply not reply to SMS contact at the specified time points. They will, however, continue to be contacted by the automated system in

accordance with the protocol, unless they specifically request the study team to cease further communications. This option will be facilitated by a 'withdrawal link' included on each SMS sent which, when selected, will take participants to an online page allowing them to signify their intent to withdraw from the rest of the study.

The participants will be made aware that any withdrawal will not affect their future care (via the information sheet and consent form) but that should they withdraw, the data collected up to that point will not be erased and may still be used in the final analysis.

As part of the embedded pilot study, we will assess participant drop-out rates as well as reported acceptability of our methodology. We will work with our PPIE group to improve response rates wherever feasible.

Further withdrawal criteria include:

- Unplanned readmission in the first 7 days post-surgery
- Those who do not undergo a surgical procedure (e.g., cancelled on the day of surgery)

Those who undergo unplanned admission to hospital will be monitored remotely using questions built in to the NewcastlePROMS system at two different time points. These will be D1 and D7 postoperatively. Those who do not undergo a surgical procedure will be identified on D0 by the local research team.

5. STUDY PROCEDURES AND INTERVENTIONS

5.1 Recruitment

This study will take place in secondary care hospitals in the four nations of the United Kingdom. It is anticipated that the recruitment will take place over a five-day period within a four-week period to ensure maximum flexibility at each participating site. Estimated participant recruitment numbers have been generated using Hospital Episode Statistics (HES) data on day-case procedures and figures from previous national trainee collaborative research studies. We will undertake an embedded pilot study in four sites in the UK prior to wider national roll out.

Participants will be recruited from preoperative waiting areas on the day of surgery. The study will be advertised using posters in these areas, and the initial approach will be undertaken by a member of the participant's usual healthcare team (i.e. not a member of the research team). As mentioned above, depending on local resources and protocols, it may be possible to identify participants prior to the day of surgery for example, at pre-assessment clinics where they could be given a patient information sheet with their appointment letter.

The participant will be initially approached by a member of the usual care team. This member of the usual care team is likely to be an anaesthetist but could include other members of the peri-operative team (for example, surgeon, pre-assessment nurse, admission nurse). They will give the potential participant a participant information sheet and allow them time to read and consider this.

A local investigator, or their nominee, will then approach the participant and inform the participant of all aspects pertaining to participation in the study after initial approach.

This study will be conducted in English. If needed, the usual hospital interpreter and translator services will be available to assist with discussion of the study, the participant information sheets, and consent forms, however, the data entry platform will only be in English. The consent forms and information sheets will not be available printed in other languages. The main reason for this is the lack of validity of translating questions relating to pain into other languages. Non-English versions of the BPI and other questionnaires will not be validated or comparable. Therefore, the study will only capture data in English. For similar reasons, the qualitative study will be conducted in spoken English.

The potential participant will be made aware that their entry into the study is entirely voluntary and that their care will not be affected by a decision to participate or not. It will also be explained that they can withdraw at any time, either by not replying to messages sent via SMS or by specifically requesting this via the method explained in section 4.4 above. In the event of their withdrawal, it will be explained that their data collected so far cannot be erased.

5.2 Consent

All participants must provide written informed consent to be included in the study. This will be undertaken only after the patient has been initially approached by their usual care team, and has been given a participant information sheet (PIS). Potential participants will be given sufficient time to consider their involvement and will also be given the opportunity to ask questions of the investigating team. As the burden of harm involved in participating is low, and following PPIE consultation, participants will be recruited and consented in the initial meeting rather than having a specified 'cooling off' period. Participants will be consented on a paper consent form. As there is no formal site file for recruiting sites, a copy of the consent form will not be retained by the site investigators. It will be the responsibility of the local research team to ensure a copy of the consent form is received by the participant and is in the participants' hospital records.

Consent to storage of limited patient identifiable information will also be gained at this point, including name, hospital number, age, post code and mobile telephone number. The consent form will be labelled with the participant's name and hospital number. One copy will be stored in their clinical notes and the other given to the participant. The research team will not keep a copy of the consent forms.

All participants will be informed of the qualitative aspect of the study at enrolment. They will be informed that they may be contacted, by telephone, later, if eligible for this aspect of the study. Full consent for the qualitative aspect will be gained verbally after postoperative day 97, over a secure telephone line, allowing for two-way communication.

All participants are free to withdraw at any time from the study without giving reasons and without prejudicing further treatment.

For patient participants without capacity to consent

Potential participants will be assessed for their capacity to consent by the investigating team. Those who lack capacity will be excluded. This is due to the premise of this study being based upon electronically entered patient reported outcome measures. A participant will be deemed to lack capacity in this study if they have their surgical consent on a 'consent form 4 form' or they are assessed by the research team to lack capacity to make the decision to engage with the study.

5.3 Study assessments/ interventions

For each study centre, a total count of all eligible patients undergoing a day-case surgical procedure will be collected each day of the study. This will be used to determine the denominator of all patients meeting our inclusion / exclusion criteria on the day of surgery.

Once the participant has given consent, data will be collected pre- and postoperatively according to the following regimen. All data will be collected electronically, pseudonymised and stored on a secure centralised database developed by the NewcastlePROMS team in collaboration with the project management group. Burden upon participants will be kept to a minimum, free text answers will be avoided and there will be inbuilt conditional logic to ensure participants only answer questions relevant to them. Estimated time to complete responses is detailed in the table below.

	Participant	Local researchers
Day 0 - Recruitment and Consent	10 minutes	5 minutes
Day 0 - Baseline data collection pre-operative	5 minutes	10 minutes
Day 0 - Baseline data collection post-operative	0 minutes	5 minutes
Day 1 - Early postoperative recovery outcomes, acute pain scores, analgesia use	<5 minutes	n/a
Day 3 - Early postoperative recovery outcomes, acute pain scores, analgesia use	<5 minutes	n/a
Day 7 - Early postoperative recovery outcomes, acute pain scores, analgesia use and acceptability to participants of NewcastlePROMS system	<5 minutes	n/a

Day 97 – Persistent pain assessments, analgesia use and quality of life assessment	<4 minutes if no PPSP / PPOU <9 minutes if PPSP / PPOU reported	n/a
After Day 97 – researchers will contact the participant’s GP with a letter alerting them that their patient has elevated results on a screening test for anxiety or depression	0 minutes	10 minutes (for selected participants)

Table 3. Estimated time to completion of data collection.

Baseline data collection

Preoperative phase

Data collection preoperatively will be undertaken by local investigators using an electronic proforma. Data collected will be linked to an anonymised participant identifier, and then subsequently linked to any submissions using the SMS prompted system. This will all be stored securely on the NewcastlePROMS centralised database. Data collection will be completed using a combination of medical notes review, and participant involvement where necessary.

The data to be collected are listed below.

Demographic data:

- Mobile phone number
- Age
- Sex
- Ethnicity
- Postcode

Medical data

- Body mass index
- ASA grade
- Rockwood frailty scale score
- Smoking status
- Alcohol or drug misuse
- Depression
- Anxiety
- Quality of Life score

Surgical Data

- Planned procedure
- Urgency of Surgery

Pain Data – quantifying pain severity will be omitted if no pain present

- Pain at surgical site (Y/N)
- Have you had this pain >3 months? (Y/N)
- Pain at surgical site at its **worst** in the last 24 hours? (0-10)

- Pain at surgical site on **average** in the last 24 hours? (0-10)
- Pain at surgical site **right now**? (0-10)
- Pain elsewhere in the body away from surgical site for >3 months? (Y/N)
- Pain elsewhere at its **worst** in the last 24 hours? (0-10)
- Pain elsewhere on **average** in the last 24 hours? (0-10)
- Pain elsewhere **right now**? (0-10)

Medication Data

- Analgesic use in the last 3 months
- Analgesic use >3 months
- Frequency of analgesic use for each medication selected
- Analgesic use for pain at surgical site or pain elsewhere

Postoperative phase

Postoperative data on day 0 to be collected by local investigators postoperatively, using an electronic proforma.

- Procedure performed
- Mode of anaesthesia
- New discharge analgesia (either entered by researcher on D0 or participant on D1)

Data on days 1, 3, 7 and 97 to be entered remotely by participants following SMS reminder messages which will be sent as per the study flow chart. If data is not entered within a specified time period of the initial prompt, an additional reminder message will be sent at day 90 postoperatively to prepare the participant for the final data collection stage. If participants fail to enter data on D1, they will still continue to be contacted for data collection at subsequent time points.

Postoperative Day 1

- Did participant require overnight inpatient stay?

Postoperative Days 1, 3 and 7

- Surgical site pain severity at **worst** and on **average at** in last 24 hours, and pain **right now**
- Functional Pain Scale
- New Discharge Analgesia (if not completed by local investigator on D0)
- Analgesia use
- Frequency of analgesic use for each medication selected
- Quality of Recovery score

Additional questions Day 7 only

- Satisfaction with discharge analgesia
- Pain experienced compared with expectation
- Needed to seek additional analgesia from other sources
- Acceptability to participants of SMS prompted online follow up
- Did participant require overnight stay in hospital at any point?

Postoperative Day 97

- Presence of pain at surgical site

- Analgesia use
- Frequency of analgesic use for each medication selected
- Analgesic use for pain at surgical site or pain elsewhere
- Quality of life score

Additional questions Day 97 if any surgical site pain

- Brief Pain Inventory. This will determine presence of PPSP
- If PPSP criteria met: Generalised Anxiety Disorder assessment
- If PPSP criteria met: Patient Health Questionnaire 8

Additional questions Day 97 if PPOU

- Has participant attempted to reduce analgesic use? (Y/N). If so, how difficult was this?

5.4 Definition of End of Study

This will be defined as the date of the last piece of data entry by the last participant enrolled in the study. The sponsor will notify the REC, in writing, within 90 days of the end of the study.

6. SAFETY REPORTING

Given the observational nature of this study the occurrence of an adverse event because of participation within this study is not expected.

Participants may report high scores on the GAD-7 and/or PHQ-8 scores at day 97 postoperatively. Those with undiagnosed mental health disorders may come to harm. Anxiety and depression are common in the general population with a prevalence of 6% and 3% respectively. One quarter of the UK population will suffer from a mental health problem at some point each year (<https://mind.org.uk> accessed 27/4/23). At baseline, we record whether participants already have a diagnosis of anxiety or depression. These participants will have a treatment plan in place for these disorders.

For participants potentially developing anxiety or depression during the study, research sites will contact the participant's GP with a standardised letter, either via email or paper alerting them that their patient has elevated results on a screening test for anxiety or depression. There will also be a supportive text message sent to the participant with details of sources of help with mental illness. These participants will be identified as answering the GAD-7 or PHQ-8 with scores ≥ 10 representing moderate or severe anxiety or depression without pre-existing mental health diagnosis.

The PHQ-8 score omits the ninth item of the PHQ-9 score which asks about suicidal ideation and deliberate self-harm. The PHQ-8 score has very similar sensitivity and specificity to the PHQ-9 for detecting major depression³⁹.

Please see Appendix E for an example of the automated message we will send should participants meet the criteria above. We will include the possibility of these actions in the consent process at the beginning of the study.

Safety pathway for adverse events during qualitative study

The more in-depth questioning nature of the qualitative part of the study may lead to identification of a patient who reports self-harm or suicidal intent. The safety pathway will follow the steps below:

- All patients will be informed of this, in the consent process, at the beginning of the interview.
- In patients exhibiting symptoms of self-harm or suicide to the interviewer, the interview will be paused.
- The interviewer will immediately seek attendance of a registered professional to complete a risk assessment (see appendix E).
- After the risk assessment, the registered professional will need to allocate the participant into an outcome category (see appendix E).
- The registered professional will use and signpost the interviewee to appropriate resources (see appendix E)

We will include the possibility of these actions in the consent process at the beginning of the interview by stating:

“The research team may not be able to keep confidential any disclosure or endorsement of thoughts to harm yourself. In the event that you tell the research staff that you are thinking about killing yourself or you answer yes to a question about having thoughts about suicide, the research staff will ask you further questions about these thoughts. Depending on the intensity of your thoughts or how much you feel like hurting yourself, the research staff may provide you with referrals for treatment, work with you to contact your GP, trusted family member or therapist to discuss your thoughts of harming yourself; or work with you on a plan that may include getting you to a hospital for safety.”

7. STATISTICS

7.1 The number of participants

We are aiming to obtain a sample size of approximately 6,000 day-case patients, from approximately 100 sites, allowing for participant drop out. This is based on the recruitment numbers from comparable previous trainee-led RAFT snapshot studies^{47 48} which have demonstrated this to be feasible, and data on current day case surgery activity in the UK². A sample size of 6,000 with a 95% confidence level will allow estimated prevalence of PPSP and PPOU with a marginal error of 1.3%.

7.2 Sampling

Participating sites will be encouraged to approach all eligible patients within their organisation. The aim is to collect all participants to reduce sampling bias. Each site will choose a five-day window of data collection, starting on a Monday, and sure that this time period is not particularly under representative in any way.

7.3 Analysis of endpoints

Participant, anaesthetic, medication use, and surgical characteristics will be summarised using appropriate descriptive statistics, such as frequencies and percentages for categorical data, mean and standard deviation for continuous data.

The prevalence of PPOU and PPSP at 3-months will be presented alongside corresponding 95% confidence intervals.

Separate mixed effects logistic regression models will be used to identify patient, anaesthetic, medication use, and surgical characteristics associated with PPSP and PPOU, adjusting for sites and geography as random effects. Model estimates will be presented with 95% confidence intervals with a p-value <0.05 considered statistically significant. Consideration will be given to the joint modelling of PPOU and PPSP in future work.

Short-term outcomes will be summarised descriptively and graphically, with regression models used to identify associations between variables of interest and the outcome, where appropriate.

A statistical analysis plan (SAP) detailing the planned analyses will be developed by the statistician.

8 EMBEDDED QUALITATIVE STUDY

8.1 Embedded qualitative study aims

The embedded qualitative portion of the POPPY study will include a small purposive sample of patients that report PPSP and PPOU after 3 months of surgery. The addition of the qualitative analysis will add substantial detail and insight into this important sub-group of patients and contextualise their long-term postoperative experiences and outcomes.

8.2 Embedded qualitative study objectives

To explore patients' experience of:

- Preparation for day case surgery and pre-operative expectations of postoperative pain and pain management
- Acute recovery (first postoperative week)
- Longer-term recovery and post-operative pain (after 3 months)
- Opioids; intake, type and duration and experience

8.3 Embedded qualitative study design

The embedded qualitative portion of the POPPY study has been designed to be a detailed exploration of PPSP and PPOU based on qualitative research techniques. As the experience of pain is subjective and complex, collecting qualitative data will enable more in-depth investigation of the impact of PPSP and PPOU. It may be used to inform improvements to the patient-facing aspects of day case surgical pathways including how we prepare patients for surgery, information they are supplied with on the day of surgery, and how we conduct short and long-term post-operative follow up. The insight into patient experience of the problems of PPOU and PPSP may help tailor behavioural interventions for the treatment of these conditions.

8.4 Embedded qualitative study sampling

The qualitative subgroup interview study will include a purposive sample of thirty individual participants of the POPPY study that report PPOU and PPSP at 97 days. We will select participants who have complete data (including baseline, and all points of follow up), and gave consent to receive a phone call from the study team after completion of the 97-day follow up inviting them to take part in an interview. To ensure that certain key characteristics are represented within our sample we will select participants to approach according to pre-defined primary and secondary criteria using a sampling matrix⁴⁹(see table 4.).

We have assigned demographic and baseline characteristics of our population to be primary or secondary criteria based on the perceived importance of these variables on PPSP and PPOU. Primary criteria include age, sex, whether the participant reports pre-operative opioid use, or prior pain including pre-existing pain condition/chronic pain/ attendance at pain clinic/ high pre-operative pain score at site of planned surgery. The sample selected according to primary criteria will be monitored to ensure diversity of secondary criteria, which include ethnicity, region of the UK, postcode, anaesthetic type and surgical type, poorly controlled post-operative pain and low initial quality of recovery scores. These criteria are based on known risk factors for PPSP and PPOU^{22 50}.

8.5 Qualitative study participants, inclusion and exclusion criteria

Inclusion Criteria:

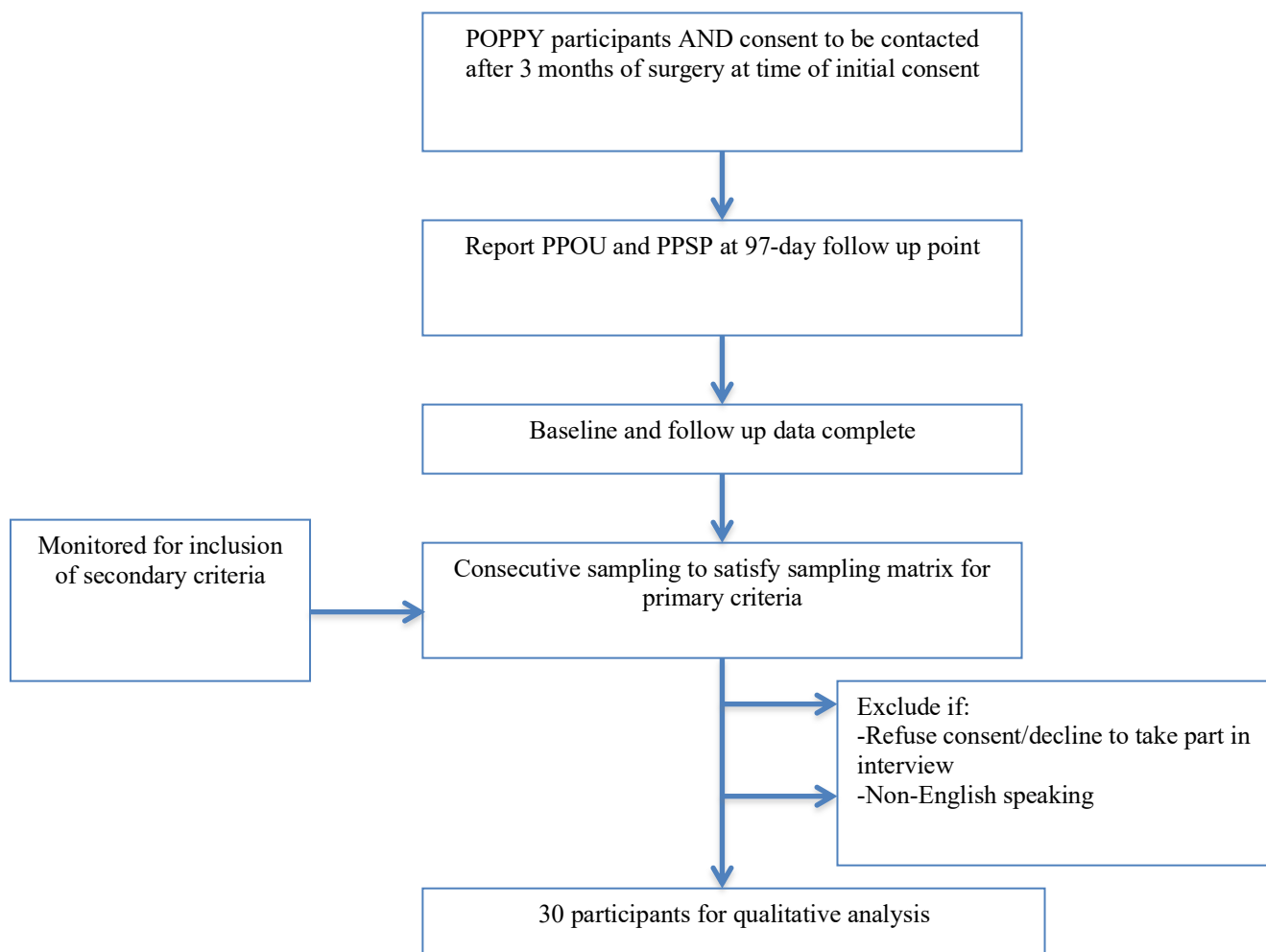
- Report PPOU and PPSP at 97 days

- Complete baseline and follow up data
- Consented to be contacted after 97-day follow up for this purpose

Exclusion Criteria:

- Those lacking capacity to consent
- Those who are not fluent in English

Qualitative study flow chart



		Opioid naive		Pre op opioid use	
		male	female	male	female
Age	18-39	1-4	1-4	1-4	1-4
	40-64	1-4	1-4	1-4	1-4
	65+	1-4	1-4	1-4	1-4
Pre-op pain >3 months at the surgical site across opioid use					
Pre-op pain		5-10		5-10	
No pain		5-10		5-10	

Table 4. Primary sampling matrix. Numbers represent number of sample units to be collected per category. Ranges in each category allow the researcher flexibility to reflect the distribution of the study population.

8.6 Qualitative study consent

Participants will be informed of the qualitative study at time of the original consent process as described previously. They will be reminded of this at the completion of Day 97 data via SMS and informed they may be phoned to discuss the study. After Day 97 participants will be telephoned by a researcher to discuss the qualitative study. They will be sent, via email or post, the qualitative study PIS. Allowing sufficient time (likely 1-2 weeks) for the participant to receive, read and consider the PIS, they will be recontacted using videoconferencing, at a pre-arranged time. The researcher will gain verbal consent, using the 'Remote Participant Consent Form'. Virtual consent for the recording will be obtained at least 24 hours prior to the online interview and will be stored in a password protected drive within the University of Plymouth system, separately from the video recording. When the consent form is complete, the participants will proceed onto the qualitative study.

8.7 Embedded qualitative study data collection

Participants will be interviewed individually over the telephone or on Zoom meetings (Zoom video communications) videoconferencing software by a member of the University of Plymouth research team using an interview script (see Appendix D). Interviews will last for up to one hour. They will be recorded, identifiers removed, and data stored on a password protected cloud drive and later transcribed verbatim and content analysis conducted using a framework method in NVivo qualitative analysis computer software (QSR international). During the consenting process, participants will be advised that the zoom meeting will be recorded, therefore, they will be advised that they can join the meeting without their camera. Any other identifiers (name) will be removed from the recording as per the recommendations of Agrawal & Narayanan (2010)⁵¹.

Any concerns over participants expressing suicidal ideation or thoughts of self-harm will be addressed as per the description in Section 6.

8.8 Embedded qualitative study data analysis

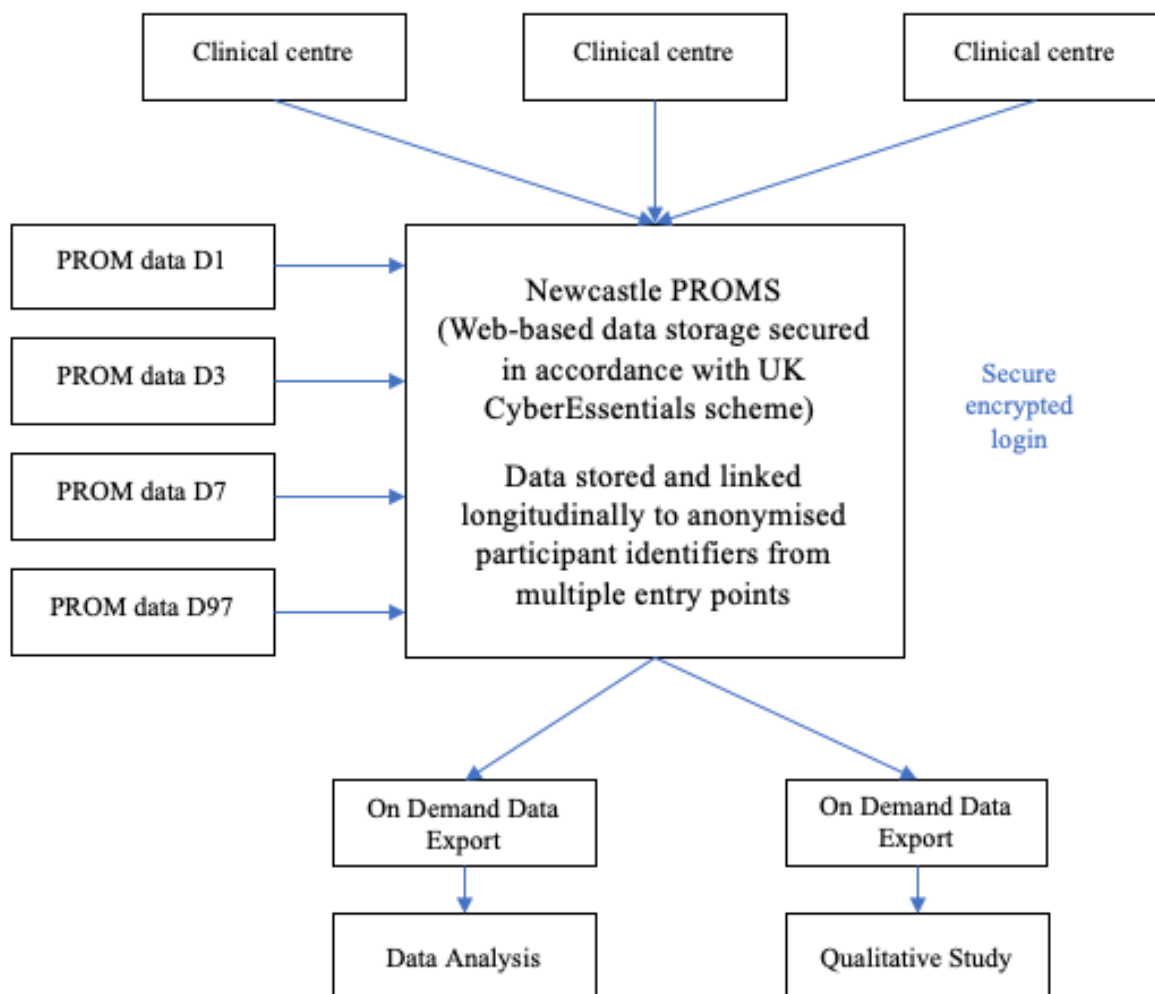
Transcripts will be imported into NVivo and analysed using framework analysis to address the thematic categories that relate to our objectives, plus any important additional categories which emerge from the interviews. A codebook will be developed to facilitate team-based analysis.

9 DATA MANAGEMENT AND DATA SHARING PLAN

To comply with the Data Protection legislation information will be collected and used fairly, stored safely and not disclosed to any unauthorised person. This applies to both manual and electronically held data.

The Chief Investigator will preserve the confidentiality of participants taking part in the study and ensure the EU General Data Protection Regulation (GDPR) in conjunction with the UK Data Protection Act 2018, which sets out the statutory requirements for the processing of personal data, is adhered to.

9.1 Data flow diagram



9.2 Description of the Data

Data collection is outlined in section 5.3.

9.3 Collection of Data and Study Materials

Data will be collected digitally and stored on the NewcastlePROMS database as described earlier. Data will be inputted by the research team on the day of surgery and then by the patient on postoperative follow up dates (day 1, 3, 7 and 97).

Data collected subsequently by the qualitative study team will be stored securely on a password protected cloud-based database as described above.

Consent will be recorded on paper with one copy given to the patient and another stored in the participants' medical notes.

Some of the data stored is bespoke to this study, but the standardised tools (EQ-5D-5L, QoR-15, BPI, GAD-7, PHQ-8) are reproduced with permission where necessary.

9.4 Data Storage and Security

Data will be stored on the NewcastlePROMs database. The NewcastlePROMS service is well established and has been employed by several NHS trusts to follow up patients remotely as part of a variety of initiatives. The security of the system is guaranteed by the 'Cyber Essentials' government backed scheme⁴⁶. A Data Protection Impact Assessment (DPIA) has also been completed by the Sponsor.

The advantages of employing the NewcastlePROMS service include:

- Sensitive information encrypted using bank grade technology
- Specifically designed to be patient facing
- Inbuilt complex conditional logic to ensure participants only view relevant questions
- Integrated with an SMS provider to enable data collection
- Data available to download into suitable statistical software

Data will be stored securely with NewcastlePROMS for up to twelve months from the beginning of the recruitment period. Following this, the pseudoanonymised data will be downloaded to a secure password protected folder based on a computer at the University of Plymouth and no data will be held by NewcastlePROMs from this point. See section 9.5 for details on archiving.

The data controller will be the Sponsor, University Hospitals Plymouth NHS Trust. Dr Adnaan Qureshi (of Newcastle PROMs) will be the data processor.

9.5 Archiving, Preservation and Curation

Archiving will be authorised by the Sponsor following submission of the end of study declaration. Upon completion of the study, any paper documents will be scanned and then destroyed as per the Research Archiving SOP (SC2). All electronic copies will be transferred to the Trust Research Archivist for archiving.

Upon completion of the study, study documents will be archived for a minimum of 5 years as per the participating Trust's Research Archiving SOP. Once the archiving retention period has been reached, the Sponsor will liaise with the sites regarding destruction.

9.6 Data Sharing

Requests for data sharing can be made after publication of the primary results paper. Requests should be made to the Chief Investigator in the first instance. Requesters will be asked to complete an application form detailing specific requirements, rationale, and proposed usage. The CI and study sponsor (including the sponsor's Research Governance Manager (or deputy), the Information Governance Team, Caldicott Guardian, IM&T Security Officer and the researcher funder, as appropriate) will review all requests.

Consideration will be given to:

1. The viability and suitability of the request
2. Appropriate steps have been taken to minimise the risk of identifying participants

3. Data security policies and procedures of recipient organisation (including country if abroad) and other regulatory requirements are applicable
4. The credentials of the requestor

Where access to requested data is granted, requesters organisation must sign a data sharing agreement before they can access any data. Requested data will be made available, along with supporting documentation (e.g., data dictionary) on a secure server or through other secure data transfer method.

10. ETHICAL AND REGULATORY COMPLIANCE

10.1 Ethics and HRA approval

The Chief Investigator will obtain approval from the Health Research Authority (HRA) and Research Ethics Committee (REC). The Investigator will ensure that this study is conducted in full conformity with relevant regulations and with the UK Policy Framework for Health and Social Care Research (2017), which have their basis in the Declaration of Helsinki.

10.2 Indemnity

This is an NHS-sponsored research study. If an individual suffers negligent harm as a result of participating in the study, NHS indemnity covers NHS staff and those people responsible for conducting the trial who have honorary contracts with the relevant NHS Trust. In the case of non-negligent harm, the NHS is unable to agree in advance to pay compensation, but an *ex-gratia* payment may be considered in the event of a claim.

10.3 Sponsor

University Hospitals Plymouth NHS Trust will act as the main sponsor for this study assuming overall responsibility for the initiation and management of the trial. Delegated responsibilities may be assigned to other relevant parties taking part in this study and appropriately documented.

10.4 Funding

The Association of Anaesthetists of Great Britain and Ireland (AAGBI) via the National Institute for Academic Anaesthesia (NIAA) and the University Hospitals Plymouth NHS Trust (UHPNT) Charitable Funds are funding this study.

The funding includes payments for:

- NewcastlePROMS system design, ongoing technical support, automated SMS messaging, initial data storage and analytical features.
- Medical statistician support from the University of Plymouth
- Research and Development sponsorship administration fee
- PPIE group funding
- Funding of a research assistant to aid aspects of the embedded qualitative study

10.5 Monitoring

The study will be subject to monitoring by UHP under their remit as sponsor to ensure adherence to the UK Policy Framework for Health and Social Care Research (2017). UHP as the lead site will be initially monitored at 25 days (+/- 7 days) after R&D capability and capacity has been given. To ensure the TMF and ISF are in order and recruitment has started. Monitoring will be mainly by central monitoring of the Newcastle Proms data base checking data for completion and plausibility. Any subsequent site monitoring will be determined by a risk assessment, or on a for cause basis. The study may also be audited/ inspected by regulatory bodies to ensure compliance with national regulations.

11. STUDY MANAGEMENT

This study will be delivered by RAFT (Research and Audit Federation of Trainees), the UK national perioperative trainee research group. This is an umbrella organisation representing 19 trainee research networks, with representatives in trusts across the UK. Trainees will be recruited to deliver this study in their local trusts alongside research nurses where the resources are available. We anticipate a great deal of enthusiasm amongst the trainee body for this study given the opportunity it offers to participate in interesting and important national research, to have individual contributions recognised in future publications and due to our intended participation in the associate principal investigator scheme.

A project management group will coordinate and manage day to day running of the study. A study steering committee, including the CI, co-investigators, the statistician, a PPIE representative and a sponsor representative will maintain study oversight.

12. PUBLICATION & DISSEMINATION POLICY

The study team will prepare a plain English summary of the study results which will be published on our study website. Participants will be contacted, via SMS, when this is available at the end of the study.

The final results of the study will be disseminated via presentations at appropriate scientific meetings and conferences and publications in appropriate peer-reviewed scientific journals.

13. REFERENCES

1. Stocker M. National Day Surgery Delivery Pack. Getting It Right First Time: GIRFT, 2020.
2. Digital N. Hospital Episode Statistics for Admitted Patient Care and Outpatient Data 2022 [Available from: <https://digital.nhs.uk/data-and-information/publications/statistical/hospital-episode-statistics-for-admitted-patient-care-outpatient-and-accident-and-emergency-data/april-2021---january-2022> accessed 12/04 2022.
3. Bailey CR, Ahuja M, Bartholomew K, et al. Guidelines for day-case surgery 2019. *Anaesthesia* 2019;74(6):778-92. doi: <https://doi.org/10.1111/anae.14639>
4. Herrera FJ, Wong J, Chung F. A systematic review of postoperative recovery outcomes measurements after ambulatory surgery. *Anesth Analg* 2007;105(1):63-9. doi: 10.1213/01.ane.0000265534.73169.95
5. Calvert M, Kyte D, Price G, et al. Maximising the impact of patient reported outcome assessment for patients and society. *BMJ* 2019;364:k5267. doi: 10.1136/bmj.k5267
6. Aiyegbusi OL, Isa F, Kyte D, et al. Patient and clinician opinions of patient reported outcome measures (PROMs) in the management of patients with rare diseases: a qualitative study. *Health and Quality of Life Outcomes* 2020;18(1):177. doi: 10.1186/s12955-020-01438-5
7. Weldring T, Smith SMS. Patient-Reported Outcomes (PROs) and Patient-Reported Outcome Measures (PROMs). *Health Serv Insights* 2013;6:61-68. doi: 10.4137/HSI.S11093
8. Schug SA, Lavand'homme P, Barke A, et al. The IASP classification of chronic pain for ICD-11: chronic postsurgical or posttraumatic pain. *Pain* 2019;160(1):45-52. doi: 10.1097/j.pain.0000000000001413
9. Alliance JL. Anaesthesia and Perioperative Care Top 10: James Lind Alliance Priority Setting Partnerships; 2015 [Available from: <https://www.jla.nihr.ac.uk/priority-setting-partnerships/anaesthesia-and-perioperative-care/top-10-priorities/> accessed 10/12 2021.
10. Johansen A, Romundstad L, Nielsen CS, et al. Persistent postsurgical pain in a general population: Prevalence and predictors in the Tromsø study. *PAIN* 2012;153(7):1390-96. doi: 10.1016/j.pain.2012.02.018
11. Berterame S, Erthal J, Thomas J, et al. Use of and barriers to access to opioid analgesics: a worldwide, regional, and national study. *Lancet* 2016;387(10028):1644-56. doi: 10.1016/s0140-6736(16)00161-6 [published Online First: 20160203]
12. FPM. Opioids Aware Campaign Faculty of Pain Medicine 2016 [Available from: <https://www.fpm.ac.uk/opioids-aware> accessed 20/03/2022 2022.
13. Brummett CM, Waljee JF, Goesling J, et al. New Persistent Opioid Use After Minor and Major Surgical Procedures in US Adults. *JAMA Surg* 2017;152(6):e170504-e04. doi: 10.1001/jamasurg.2017.0504 [published Online First: 2017/06/21]

14. Hamilton GM, Ladha K, Wheeler K, et al. Incidence of persistent postoperative opioid use in patients undergoing ambulatory surgery: a retrospective cohort study. *Anaesthesia* 2023;78(2):170-79. doi: <https://doi.org/10.1111/anae.15900>
15. Chen EY, Marcantonio A, Tornetta P, 3rd. Correlation Between 24-Hour PredischARGE Opioid Use and Amount of Opioids Prescribed at Hospital Discharge. *JAMA Surg* 2018;153(2):e174859. doi: 10.1001/jamasurg.2017.4859 [published Online First: 20180221]
16. Delaney LD, Gunaseelan V, Rieck H, et al. High-Risk Prescribing Increases Rates of New Persistent Opioid Use in Total Hip Arthroplasty Patients. *J Arthroplasty* 2020;35(9):2472-79.e2. doi: 10.1016/j.arth.2020.04.019 [published Online First: 2020/04/14]
17. Daliya P, Adiamah A, Roslan F, et al. Opioid prescription at postoperative discharge: a retrospective observational cohort study. *Anaesthesia* 2021;76(10):1367-76. doi: <https://doi.org/10.1111/anae.15460>
18. Fletcher D, Stamer UM, Pogatzki-Zahn E, et al. Chronic postsurgical pain in Europe: An observational study. *European Journal of Anaesthesiology | EJA* 2015;32(10):725-34. doi: 10.1097/eja.0000000000000319
19. Hoofwijk DM, Fiddelers AA, Peters ML, et al. Prevalence and Predictive Factors of Chronic Postsurgical Pain and Poor Global Recovery 1 Year After Outpatient Surgery. *Clin J Pain* 2015;31(12):1017-25. doi: 10.1097/ajp.0000000000000207
20. Alam A, Gomes T, Zheng H, et al. Long-term analgesic use after low-risk surgery: a retrospective cohort study. *Arch Intern Med* 2012;172(5):425-30. doi: 10.1001/archinternmed.2011.1827
21. Srivastava D, Wilkinson P. Surgery and opioids: some cracks in an enduring romance. *British Journal of Anaesthesia* 2021;126(6):1088-92. doi: 10.1016/j.bja.2021.02.003
22. Sitter T, Forget P. Persistent postoperative opioid use in Europe: A systematic review. *European Journal of Anaesthesiology | EJA* 2021;38(5):505-11. doi: 10.1097/eja.0000000000001346
23. RAFT. RAFT4 2021 [Available from: <https://www.rafrainees.org/raft-4.html> accessed 19/04 2022.
24. Alliance JL. Anaesthesia and Perioperative Care Top 10 2015 [Available from: <https://www.jla.nihr.ac.uk/priority-setting-partnerships/anaesthesia-and-perioperative-care/top-10-priorities/> accessed 20/04 2022.
25. Statista. Smartphone Ownership By Age In The UK 2012-2021 2021 [Available from: <https://www.statista.com/statistics/271851/smartphone-owners-in-the-united-kingdom-uk-by-age/> accessed 12/04/2022 2022.
26. Prescott C. Internet access – households and individuals, Great Britain: 2020 2020 [Available from: <https://www.ons.gov.uk/peoplepopulationandcommunity/householdcharacteristics/homeinternetandsocialmediausage/bulletins/internetaccesshouseholdsandindividuals/2020> accessed 12/04/2022 2022.

27. Gessner D, Hunter OO, Kou A, et al. Automated text messaging follow-up for patients who receive peripheral nerve blocks. *Reg Anesth Pain Med* 2021;46(6):524-28. doi: 10.1136/rapm-2021-102472 [published Online First: 20210301]
28. Carrier G, Cotte E, Beyer-Berjot L, et al. Post-discharge follow-up using text messaging within an enhanced recovery program after colorectal surgery. *J Visc Surg* 2016;153(4):249-52. doi: 10.1016/j.jviscsurg.2016.05.016 [published Online First: 20160808]
29. Cittanova M-L, Chauvier S, Combettes E, et al. Association of Automated Text Messaging With Patient Response Rate After Same-Day Surgery. *JAMA Network Open* 2021;4(1):e2033312-e12. doi: 10.1001/jamanetworkopen.2020.33312
30. Leconte D, Beloeil H, Dreano T, et al. Post Ambulatory Discharge Follow-up Using Automated Text Messaging. *J Med Syst* 2019;43(7):217. doi: 10.1007/s10916-019-1278-5 [published Online First: 20190606]
31. Premkumar A, Lovecchio FC, Stepan JG, et al. A Novel Mobile Phone Text Messaging Platform Improves Collection of Patient-Reported Post-operative Pain and Opioid Use Following Orthopedic Surgery. *HSS J* 2019;15(1):37-41. doi: 10.1007/s11420-018-9635-3 [published Online First: 2018/10/22]
32. Ng S, Pusic A, Parker E, et al. Patient-Reported Outcome Measures for Breast Implant Surgery: A Pilot Study. *Aesthet Surg J* 2019;39(8):Np314-np21. doi: 10.1093/asj/sjz023
33. Chazapis M, Walker EMK, Rooms MA, et al. Measuring quality of recovery-15 after day case surgery. *British Journal of Anaesthesia* 2016;116(2):241-48. doi: <https://doi.org/10.1093/bja/aev413>
34. Stark PA, Myles PS, Burke JA. Development and psychometric evaluation of a postoperative quality of recovery score: the QoR-15. *Anesthesiology* 2013;118(6):1332-40. doi: 10.1097/ALN.0b013e318289b84b
35. Myles PS, Boney O, Botti M, et al. Systematic review and consensus definitions for the Standardised Endpoints in Perioperative Medicine (StEP) initiative: patient comfort. *Br J Anaesth* 2018;120(4):705-11. doi: 10.1016/j.bja.2017.12.037 [published Online First: 20180202]
36. Cleeland CS, Ryan KM. Pain assessment: global use of the Brief Pain Inventory. *Ann Acad Med Singap* 1994;23(2):129-38.
37. Spitzer RL, Kroenke K, Williams JB, et al. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med* 2006;166(10):1092-7. doi: 10.1001/archinte.166.10.1092
38. Kroenke K, Strine TW, Spitzer RL, et al. The PHQ-8 as a measure of current depression in the general population. *J Affect Disord* 2009;114(1-3):163-73. doi: 10.1016/j.jad.2008.06.026 [published Online First: 20080827]
39. Wu Y, Levis B, Riehm KE, et al. Equivalency of the diagnostic accuracy of the PHQ-8 and PHQ-9: a systematic review and individual participant data meta-analysis. *Psychological Medicine* 2020;50(8):1368-80. doi: 10.1017/S0033291719001314 [published Online First: 2019/07/12]

40. Dworkin RH, Turk DC, Farrar JT, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. *Pain* 2005;113(1-2):9-19. doi: 10.1016/j.pain.2004.09.012
41. Group TE. EuroQol - a new facility for the measurement of health-related quality of life. *Health Policy* 1990;16(3):199-208. doi: [https://doi.org/10.1016/0168-8510\(90\)90421-9](https://doi.org/10.1016/0168-8510(90)90421-9)
42. NIHR. Peninsula Patient Experience Group (PenPEG) 2023 [Available from: <https://arc-swp.nihr.ac.uk/patient-public-involvement-engagement/groups-we-work-with/penpeg/> accessed 07/02 2023.
43. Halm M, Bailey C, St. Pierre J, et al. Pilot Evaluation of a Functional Pain Assessment Scale. *Clinical Nurse Specialist* 2019;33(1):12-21. doi: 10.1097/nur.0000000000000416
44. Jordan P, Shedden-Mora MC, Löwe B. Psychometric analysis of the Generalized Anxiety Disorder scale (GAD-7) in primary care using modern item response theory. *PLoS One* 2017;12(8):e0182162. doi: 10.1371/journal.pone.0182162 [published Online First: 20170803]
45. Qureshi A. Newcastle PROMS 2023 [Available from: <https://newcastleproms.co.uk/> accessed 07/02/2023 2023.
46. NCSC. National Cyber Security Centre Cyber Essentials Scheme 2023 [Available from: <https://www.ncsc.gov.uk/cyberessentials/overview> accessed 07/02/2023 2023.
47. Savic L, Thomas C, Fallaha D, et al. DALES, Drug Allergy Labels in Elective Surgical patients: a prospective multicentre cross-sectional study of incidence, risks, and attitudes in penicillin de-labelling strategies. *British Journal of Anaesthesia* 2020;125(6):962-69. doi: 10.1016/j.bja.2020.07.048
48. Walker EMK, Bell M, Cook TM, et al. Patient reported outcome of adult perioperative anaesthesia in the United Kingdom: a cross-sectional observational study†. *BJA: British Journal of Anaesthesia* 2016;117(6):758-66. doi: 10.1093/bja/aew381
49. Ritchie JL, Jane; Elam, Gilliam; Tennant, Rosalind; Rahim, Nilufer. Designing and Selecting Samples. In: Ritchie JL, Jane; McNaughton Nicholls, Carol; Ormston, Rachel, ed. *Qualitative Research Practice: A Guide for Social Science Students and Researchers*: SAGE Publications Ltd 2013.
50. Rosenberger DC, Pogatzki-Zahn EM. Chronic post-surgical pain - update on incidence, risk factors and preventive treatment options. *BJA Educ* 2022;22(5):190-96. doi: 10.1016/j.bjae.2021.11.008 [published Online First: 20220224]
51. Zha H, Taniguchi R-i, Maybank S, eds. *Person De-identification in Videos. Computer Vision – ACCV 2009; 2010 2010//*; Berlin, Heidelberg. Springer Berlin Heidelberg.

APPENDICES**APPENDIX A: SCHEDULE OF EVENTS**

Please also see study flow chart & Table 2.

Procedures	Participant Contact					
	D0	D1	D3	D7	D97	Beyond D97
Informed consent	Y					
Demographics	Y					
Medical history	Y					
Baseline Information	Y					
Pain Scores	Y	Y	Y	Y		
Analgesia Use	Y	Y	Y	Y	Y	
Participant Satisfaction				Y		
Need for Additional Support				Y		
Quality of Recovery		Y	Y	Y		
PPSP/PPOU					Y	
EQ-5D-5L	Y				Y	
BPI/GAD-7/PHQ-8 (if PPSP)					Y	
Analgesia Reduction (if PPOU)					Y	
Qualitative Interviews						Y

APPENDIX B: PPOU AND PPSP DEFINITIONS

The ICD-11 definition is that chronic postsurgical or posttraumatic pain is pain that develops or increases in intensity after a surgical procedure or a tissue injury and persists beyond the healing process, ie, at least 3 months after the initiating event.

Data will be collected on the character of PPSP for all participants with any report of pain at the surgical site at D97. This will include BPI. For patients meeting the study criteria for PPSP, we will also record GAD 7 and PHQ 8. Sensitivity analyses will be carried out after data collection, using clinically relevant definitions of PPSP. For example, one such analysis would be: pain of moderate or severe intensity on average or severe at worst or now. Consensus for “average pain” in non-cancer pain in adults is 0-3 mild, 4-7 moderate and 8-10 severe. For participants with pre-existing pain at the surgical site, report of an increase in pain on BPI scores at D97 may be defined as PPSP. In line with other studies of clinically relevant pain, we will not include patients with mild pain or less on the 4 BPI pain severity questions in the definition of PPSP.

PPOU is defined as any opioid use in opioid naïve patients or an increase in use in opioid exposed or tolerant patients at 3 months post-operatively. Sensitivity analyses will be carried out after data collection, using clinically relevant definitions of PPOU. For example, this may be any opioid use more than weekly for opioid naïve participants or an increase in opioid use in participants with chronic pre-operative opioid use.

APPENDIX C: VARIABLES, PATIENT FACING QUESTIONS & ASSESSMENT TOOLS

Day 0 (inputted by investigators in two parts: pre-op and post-op):

Day 0 First data collection (pre-operative).

Site registration details as per data collection update.

Baseline patient data inputted by local research team:

Background patient information:

- 1) Patient study identifiable number
 - i) Unique study identifier (sequential numbering generated on registration)
- 2) Local hospital number (to allow easy local identification of participants for TTO entry).
- 3) Smartphone access Y/N if N patient is excluded
- 4) Mobile number
- 5) Age (years)
 - a) Ranging from 18 (inclusive) to 110.
- 6) Biological sex
 - a) Male/female/intersex - drop down menu choice, one option only
- 7) Ethnicity
 - a) Asian or Asian British
 - i) Indian
 - ii) Pakistani
 - iii) Bangladeshi
 - iv) Chinese
 - v) Any other Asian background
 - b) Black, Black British, Caribbean or African
 - i) Caribbean
 - ii) African
 - iii) Any other Black, Black British, or Caribbean background
 - c) Mixed or multiple ethnic groups
 - i) White and Black Caribbean
 - ii) White and Black African
 - iii) White and Asian
 - iv) Any other Mixed or multiple ethnic background
 - d) White
 - i) English, Welsh, Scottish, Northern Irish or British
 - ii) Irish
 - iii) Gypsy or Irish Traveller
 - iv) Roma
 - v) Any other White background

- e) Other ethnic group
 - i) Arab
 - ii) Any other ethnic group
- f) Prefer not to say
- 8) Full postcode
- 9) Height (cm) + Weight (kg)
- 10) ASA grade (pop up link to descriptors, one choice only)
 - a) ASA 1: A normal healthy patient (non-smoking, minimal alcohol intake)
 - b) ASA 2: A patient with mild systemic disease (mild diseases only, without substantive functional limitations)
 - c) ASA 3: A patient with severe systemic disease (substantive functional limitations)
 - d) ASA 4: A patient with severe systemic disease that is a constant threat to life (recent (<3 months) MI, CVA, TIA or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction)
- 11) Rockwood frailty score (pop up link to descriptors, one choice only)
 - 1: Very fit (People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.)
 - 2: Well (People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally, e.g. seasonally.)
 - 3: Managing well (People whose medical problems are well controlled, but are not regularly active beyond routine walking.)
 - 4: Vulnerable (While not dependent on others for daily help, often symptoms limit activities. A common complaint is being “slowed up”, and/or being tired during the day.)
 - 5: Mildly Frail (These people often have more evident slowing, and need help in high order instrumental activities of daily living (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.)
 - 6: Moderately Frail (People need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing.)
 - 7: Severely Frail (Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).)
 - 8: Very Severely Frail (Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.)
 - 9: Terminally Ill (Approaching the end of life. This category applies to people with a life expectancy <6 months, who are not otherwise evidently frail.)

Surgical information:

- 12) Surgical specialty

- a) Drop down of list of specialty operations (this will code severity)
 - b) Other operation (free text)
- 13) Urgency of surgery:
- a) Elective or
 - b) Non-elective

Medications entered by researcher:

“Which of the following medications has the participant taken in the last three months”.

Choice from menu.

- 14) Are you a current smoker?
- a) Y/N
- 16) Do you have, or consider yourself to have, a diagnosis of alcohol or drug misuse?
- a) Y/N
- 17) Are you currently being treated for depression with medicines and/or talking therapy?
- a) Y/N
- 18) Are you currently being treated for anxiety with medicines and/or talking therapy?
- a) Y/N

Pain:

Pain at surgical site:

- 19) Do you have pain in the part of your body to be operated on today?
- a) Y/N
 - b) If N skip to pain elsewhere (22)
- 20) Have you had this pain for more than 3 months?”
- a) Y/N
 - b) If N it's acute pain, if Y then recorded as chronic
- 21) Quantify the pain in either case.

“Please rate this pain on a 0-10 scale. 0 is no pain and 10 is the worst pain you can imagine”.

- a) “Please rate this pain by selecting the one number which best describes your pain at its worst in the last 24 hours”.
- b) “Please rate this pain by selecting the one number which best describes your pain on the average over the last 24 hours”.
- c) “Please rate this pain by selecting the one number which best describes your pain right now”.

Pain elsewhere:

- 22) “Other than everyday aches and pains have you had pain elsewhere in your body for more than 3 months?”
- a) Y/N
 - b) If N skip to EQ5L (23)

“Please rate this pain on a 0-10 scale. 0 is no pain and 10 is the worst pain you can imagine”.

- c) “Please rate this pain by selecting the one number which best describes your pain at its worst in the last 24 hours”.
- d) “Please rate this pain by selecting the one number which best describes your pain on the average over the last 24 hours”.
- e) “Please rate this pain by selecting the one number which best describes your pain right now”.

23) EQ5D – this is recorded at baseline and D97. “Under each heading, please select the one that best describes your health today:”

- a) Mobility
 - i) I have no problems in walking about
 - ii) I have slight problems in walking about
 - iii) I have moderate problems in walking about
 - iv) I have severe problems in walking about
 - v) I am unable to walk about
- b) Self-care
 - i) I have no problems washing or dressing myself
 - ii) I have slight problems washing or dressing myself
 - iii) I have moderate problems washing or dressing myself
 - iv) I have severe problems washing or dressing myself
 - v) I am unable to wash or dress myself
- c) Usual activities (e.g. work, study, housework, family or leisure activities)
 - i) I have no problems doing my usual activities
 - ii) I have slight problems doing my usual activities
 - iii) I have moderate problems doing my usual activities
 - iv) I have severe problems doing my usual activities
 - v) I am unable to do my usual activities
- d) Pain or discomfort
 - i) I have no pain or discomfort
 - ii) I have slight pain or discomfort
 - iii) I have moderate pain or discomfort
 - iv) I have severe pain or discomfort
 - v) I extreme pain or discomfort
- e) Anxiety or depression
 - i) I am not anxious or depressed
 - ii) I am slightly anxious or depressed
 - iii) I am moderately anxious or depressed
 - iv) I am severely anxious or depressed
 - v) I extremely anxious or depressed

- 24) We would like to know how good or bad your health is **today**. This scale is numbered 0 to 100. 100 means the **best** health you can imagine. 0 means the **worst** health you can imagine. Select a number on the scale to indicate how your health is **today**.
- a) 0-100

Medications: May be NONE, may be multiple

- 25) Which of the following pain killer medications (analgesia) have you taken **in the last 3 months**? (choice of any/multiple from any or more than one subsection)
- a) *Medication list.*
- b) *A positive answer to above question will lead to this question for each medication (next two questions for each medication)*
- 26) How often do you use XXX medication (from list for each medication)?
- a) Never
- b) Less than once a week, when you need it
- c) More than once a week, when you need it
- d) Daily, when you need it
- e) Regularly, every day
- 27) Are you taking these pain killer medications (analgesia) for pain at the site of your expected surgery?
- a) Yes
- b) No, I am taking them for pain in another part of my body
- c) I am taking them for both pain related to my expected surgery, and another pain problem

Day 0 secondary data collection (post-operative)

Post-operative patient information data inputted by local research team:

- 28) Study centre identifier
- a) Number/code
- 29) Patient study identifiable number
- a) Mobile phone number
- 30) Was the expected surgery actually performed?
- a) Yes/no
- b) The previously entered surgical procedure to be 're-shown' and, if needed, edited
- 31) Mode of anaesthesia used: (tick all that apply, can have more than one)
- a) Local anaesthetic infiltration
- b) Regional anaesthesia
- c) Central neuraxial anaesthesia
- d) Sedation
- e) General anaesthesia

D0 Discharge medications data – if able to determine discharge medication, investigator enters this.

- 32) If you (as the research team) have access to this information, what new drugs were given to the patient at the time of discharge (not including medications taken pre-operatively)?
- a) *Medication list in excel spreadsheet*

Day 1, 3 or 7 (inputted post-operative by participant):

These questions relate to your surgery that took place on XX/XX/XX.

Intro:

- 33) **D1 only:** Did you stay overnight in hospital after your surgery?
- a) Yes (proceed)/no (exclusion criteria)

Pain:

- 34) Regarding pain at the **site of your surgery**, please rate your pain by selecting the one number that best describes your pain at its **worst** in the last 24 hours? [BPI Q3]
- a) 0 (no pain) to 10 (pain as bad as you can imagine)
- 35) Regarding pain at the **site of your surgery**, please rate your pain by selecting the one number that best describes your pain on **average** in the last 24 hours? [BPI Q5]
- a) 0 (no pain) to 10 (pain as bad as you can imagine)
- 36) Regarding pain at the **site of your surgery**, please rate your pain by selecting the one number that tells how much pain you have **right now**? [BPI Q6]
- a) 0 (no pain) to 10 (pain as bad as you can imagine)
- 37) Which statement best describes how pain affects your activities today (including washing, dressing, household tasks, caring for others, work activities, exercise)?
- a) I can function normally without pain
- b) I can function normally with pain
- c) My function is limited because of pain
- d) I cannot function because of pain
- e) I cannot function normally, but this is not caused by pain.

Medication:

- 38) If discharge medications (Section 32) completed on D0: then redisplay to patient for them to be able to amend on D1.
Or if discharge medications (Section 32) NOT completed on D0: then patient enters TTO meds below on D1 only.
- a) Allow multiple entries from list of analgesia
- b) What new pain killers (analgesics) were you sent home with after your surgery (in addition to your usual medications)?
- c) *Medication list in excel spreadsheet*
- 39) What pain killers have you taken today (in the last 24 hours)?
- a) Present list options from pre-operative and discharge medications
- b) *This will display the pre-op medications AND post-op new medications from Day 0/1 data. Then allow frequency of medications to be added for each medication.*

- 40) In the last 24 hours (one day), how often did you use XXX medication (from list for each medication)?
- a) I did not take this medicine
 - b) Once
 - c) More than once, when you needed it
 - d) Regularly as prescribed
- 41) Did you take any other painkillers (analgesia) in addition to these? For example, someone else's medication that are not prescribed for you or medications from your GP or Emergency Department.
- a) Yes/no
 - b) If yes, Allow multiple entries from list of analgesia
 - i) *Medication list in excel spreadsheet*
 - ii) In the last 24 hours (one day), how often did you use XXX medication (from list for each medication)?
 - c) I did not take this medicine
 - d) Once
 - e) More than once, when you needed it
 - f) Regularly as prescribed

Add these to the list of patient meds offered on all data collection days

QoR-15 score (asked on D1, 3, 7)

- 42) How have you been feeling in the last 24 hours?
- a) Able to breath easily
 - i) 0 (none of the time) to 10 (all of the time)
 - b) Been able to enjoy food
 - i) 0 (none of the time) to 10 (all of the time)
 - c) Feeling rested
 - i) 0 (none of the time) to 10 (all of the time)
 - d) Have had a good sleep
 - i) 0 (none of the time) to 10 (all of the time)
 - e) Able to look after personal toilet and hygiene unaided
 - i) 0 (none of the time) to 10 (all of the time)
 - f) Able to communicate with family or friends
 - i) 0 (none of the time) to 10 (all of the time)
 - g) Getting support from hospital doctors and nurses
 - i) 0 (none of the time) to 10 (all of the time)
 - h) Able to return to work or usual home activities
 - i) 0 (none of the time) to 10 (all of the time)
 - i) Feeling comfortable and in control
 - i) 0 (none of the time) to 10 (all of the time)

- j) Having a feeling of general well-being
 - i) 0 (none of the time) to 10 (all of the time)
- 43) Have you had any of the following in the last 24 hours?
 - a) Moderate pain
 - i) 0 (none of the time) to 10 (all of the time)
 - b) Severe pain
 - i) 0 (none of the time) to 10 (all of the time)
 - c) Nausea and vomiting
 - i) 0 (none of the time) to 10 (all of the time)
 - d) Feeling worried or anxious
 - i) 0 (none of the time) to 10 (all of the time)
 - e) Feeling sad or depressed
 - i) 0 (none of the time) to 10 (all of the time)

Additional (in addition to above) Day 7 only questions:

- 44) How satisfied were you with the pain relief medication (analgesia) you received from the hospital after your surgery? (one option only)
 - a) Completely satisfied
 - b) Satisfied
 - c) Neither satisfied or dissatisfied
 - d) Dissatisfied
 - e) Completely dissatisfied
- 45) Which statement do you agree with most. Regarding your experience of the pain from your surgery was it? (one option only drop down menu)
 - a) What I expected it to be
 - b) More than I expected
 - c) Less than I expected
- 46) Since your surgery, did you seek help or advice regarding pain or pain killer medications (analgesia) from any of the following: (tick all that apply, can choose multiple)?
 - a) General Practitioner (GP)
 - b) NHS online or telephone advise services (e.g. NHS 111)
 - c) Emergency Department (ED) or Minor Injury Unity (MIU)
 - d) Day case surgical unit
 - e) Surgical or Anaesthesia team
 - f) Pharmacist
 - g) Other
- 47) How suitable did you think SMS text messaging was for contacting you about your experiences after surgery?
 - a) Completely suitable
 - b) Moderately suitable
 - c) Neutral

- d) Moderately unsuitable
- e) Completely unsuitable

Day 97 (inputted post-op by patient):

“These questions relate to your surgery that took place on XX/XX/XX.”

Pain:

- 48) Do you still have pain at the **site of your surgery** that took place on XX/XX/XX?
- a) Yes (complete BPI, EQ5D)
 - b) No (complete EQ5D only)
 - c) If BPI result indicates PPSP (more than mild pain on any of the 4 pain severity questions ie: score 4 or more), record GAD 7 and PHQ 8

Medication: Present options from pre-op analgesics list and discharge medication list and additional medications Q39-Q41

- 49) How often do you use XXX medication (from list for each medication)?
- a) Never
 - b) Less than once a week, when you need it
 - c) More than once a week, when you need it
 - d) Daily, when you need it
 - e) Regularly, every day
- 50) Did you take any other painkillers (analgesia) in addition to these? For example: medications from your GP, pharmacy, or Emergency Department.
- a. Yes/no
 - b. If yes, allow multiple entries from list of analgesics
 - i) *Medication list in excel spreadsheet*
 - ii) How often did you use XXX medication (from list for each medication)?
 - a) Never
 - b) Less than once a week, when you need it
 - c) More than once a week, when you need it
 - d) Daily, when you need it
 - e) Regularly, every day
- 51) Are you taking these pain killer medications (analgesics) for pain at the site of your expected surgery?
- a) Yes
 - b) No, I am taking them for pain in another part of my body
 - c) I am taking them for both pain related to my expected surgery, and another pain problem
- 52) Have you tried to reduce your use of painkillers?
- a. Yes / No
 - b. If yes, ask “How difficult was it for you to try and reduce your painkillers?”
 - a. Very difficult

- b. Difficult
- c. Neutral
- d. Easy
- e. Very easy

Brief Pain Inventory

Thinking about pain at the **site of your surgery** that took place on XX/XX/XX

- Please rate your pain by selecting the one number that best describes your pain at its **worst** in the last 24 hours
 - 0 (no pain) to 10 (pain as bad as you can imagine)
- Please rate your pain by selecting the one number that best describes your pain at its **least** in the last 24 hours.
 - 0 (no pain) to 10 (pain as bad as you can imagine)
- Please rate your pain by selecting the one number that best describes your pain on the **average** over the last 24 hours.
 - 0 (no pain) to 10 (pain as bad as you can imagine)
- Please rate your pain by selecting the one number that tells how much pain you have **right now**.
 - 0 (no pain) to 10 (pain as bad as you can imagine)
- Select the one number that describes how, during the past 24 hours, pain has interfered with your:
 - General activity
 - 0 (does not interfere) to 10 (completely interferes)
 - Mood
 - 0 (does not interfere) to 10 (completely interferes)
 - Walking ability
 - 0 (does not interfere) to 10 (completely interferes)
 - Normal work (includes both work outside the home and housework)
 - 0 (does not interfere) to 10 (completely interferes)
 - Relations with other people
 - 0 (does not interfere) to 10 (completely interferes)
 - Sleep
 - 0 (does not interfere) to 10 (completely interferes)
 - Enjoyment of life
 - 0 (does not interfere) to 10 (completely interferes)

EQ5D

- Under each heading, please select the one that best describes your health **today**:
 - Mobility
 - I have no problems in walking about
 - I have slight problems in walking about
 - I have moderate problems in walking about

- I have severe problems in walking about
 - I am unable to walk about
 - Self-care
 - I have no problems washing or dressing myself
 - I have slight problems washing or dressing myself
 - I have moderate problems washing or dressing myself
 - I have severe problems washing or dressing myself
 - I am unable to wash or dress myself
 - Usual activities (e.g. work, study, housework, family or leisure activities)
 - I have no problems doing my usual activities
 - I have slight problems doing my usual activities
 - I have moderate problems doing my usual activities
 - I have severe problems doing my usual activities
 - I am unable to do my usual activities
 - Pain or discomfort
 - I have no pain or discomfort
 - I have slight pain or discomfort
 - I have moderate pain or discomfort
 - I have severe pain or discomfort
 - I extreme pain or discomfort
 - Anxiety or depression
 - I am not anxious or depressed
 - I am slightly anxious or depressed
 - I am moderately anxious or depressed
 - I am severely anxious or depressed
 - I extremely anxious or depressed
- We would like to know how good or bad your health is **today**. This scale is numbered 0 to 100. 100 means the **best** health you can imagine. 0 means the **worst** health you can imagine. Select a number on the scale to indicate how your health is **today**.
 - 0-100

PHQ8

- Over the **last 2 weeks**, how often have you been bothered by any of the following problems?
 - Little interest or pleasure in doing things
 - Not at all
 - Several days
 - More than half the days
 - Nearly every day
 - Feeling down, depressed or hopeless
 - Not at all

- Several days
 - More than half the days
 - Nearly every day
- Trouble falling or staying asleep, or sleeping too much
 - Not at all
 - Several days
 - More than half the days
 - Nearly every day
- Feeling tired or having little energy
 - Not at all
 - Several days
 - More than half the days
 - Nearly every day
- Poor appetite or overeating
 - Not at all
 - Several days
 - More than half the days
 - Nearly every day
- Feeling bad about yourself – or that you are a failure or have let yourself or your family down
 - Not at all
 - Several days
 - More than half the days
 - Nearly every day
- Trouble concentrating on things, such as reading the newspaper or watching television
 - Not at all
 - Several days
 - More than half the days
 - Nearly every day
- Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual
 - Not at all
 - Several days
 - More than half the days
 - Nearly every day
- *If a positive response to any of the above...*
- How difficult have these made it for you to do your work, take care of things at home or get along with other people?
 - Not difficult at all
 - Somewhat difficult

- Very difficult
- Extremely difficult

GAD7

- Over the **last 2 weeks**, how often have you been bothered by any of the following problems?
 - Feeling nervous, anxious or on edge
 - Not at all
 - Several days
 - Over half the days
 - Nearly every day
 - Not being able to stop or control worrying
 - Not at all
 - Several days
 - Over half the days
 - Nearly every day
 - Worrying too much about different things
 - Not at all
 - Several days
 - Over half the days
 - Nearly every day
 - Trouble relaxing
 - Not at all
 - Several days
 - Over half the days
 - Nearly every day
 - Being so restless that it's hard to sit still
 - Not at all
 - Several days
 - Over half the days
 - Nearly every day
 - Becoming easily annoyed or irritable
 - Not at all
 - Several days
 - Over half the days
 - Nearly every day
 - Feeling afraid as if something awful might happen
 - Not at all
 - Several days
 - Over half the days
 - Nearly every day

APPENDIX D: QUALITATIVE STUDY INTERVIEW SCHEDULE

Questions	Prompts	2 nd Prompts
Think back to before your surgery and the interactions and appointments that you had with the healthcare professionals you saw in preparation (for example surgeon, nurse specialist, pre-assessment clinic, anaesthetist). Did you feel adequately informed on what pain management you were likely to receive post-operatively?	<p>If Yes- in what way/ how did they prepare you? (in what ways did staff do a good job in reducing your pain and anxiety AFTER surgery)</p> <p>If no- why not? What would you have liked in the way of information/preparation?</p> <p>What did you like or dislike about the information regarding pain relief that was given to you in the pre-operative process?</p>	<i>Prompt-including interactions both prior to, and on the day of surgery</i>
Did you have any pre-operative expectations regarding pain relief? Was there anything you were NOT prepared for	Did you expect a lot of pain/not much pain	
Did you have negative, challenging or troubling thoughts or feelings surrounding pain and your surgery before the operation		
<u>Initial recovery (1st post-operative week)</u> Think back to the first week after your surgery. Was your pain management as you'd expected it to be?	Was the experience good or bad?	If it was bad, do you think there is anything the doctors/nurses/hospital could have done to make it better?
What follow up did you have with doctors or nurses after your operation?	<p>If none- would you have liked some? What would you have liked in way of follow up?</p> <p>If yes- was this in person/ phone call</p>	Did it help/ what about it helped/ if it didn't help-? what would have been better?
Did you need to go back into the hospital or seek help for problems with your surgery	prompt- for example pain/pain relief/ surgical complications	Who did you contact
Can you tell us more about your memory of the pain you experienced after your surgery, either at the site of surgery or at another site if you have long-term pain.	<p>How did you feel about it? Was it better or worse than you expected it to be?</p> <p>What did you use to manage your pain</p>	Prompt- include both pharmacological and non-pharmacological

Questions	Prompts	2 nd Prompts
<u>Longer-term recovery and post-operative pain</u> You reported that you are still experiencing pain at the site of your surgery at your 3-month follow up text message. Is this still the case?	What have you found that has helped? Would you have found it helpful to have more follow up from the surgical or anaesthetic team that you met on the day of surgery? Or is there anything looking back that you think they could have done at any point (before, during or after) that might have helped you now?	Have you had any interaction with healthcare professionals about this pain? (e.g GP, surgeon, physiotherapist, pain clinic, any other doctors or clinics at the hospital, or alternative approaches e.g. osteopath other holistic/non-medical)
Describe the pain and the impact it is having on your daily life		
<u>Opioids- intake, type, duration and experience</u> You reported that you are still taking strong (opioid) pain relief medications in your 3-month follow up text message What pain relief are you taking now?	List meds req for analgesia with dose etc. Do you feel that they help your pain? Have you tried any non-medication pain management strategies? Who is managing your pain relief?	(Completely/partially/not at all?) (prompt: physio, heat, ice, mindfulness etc) (e.g GP, pain clinic, hospital, Nurse, pharmacist, no one)
Is there anything you could do before your surgery that you can't do now? Either due to pain or side-effects of the pain relief	Hobbies, work etc..	
How do you feel about taking these types of medications?	Do you have any concerns about taking them? Do you have plan for reducing them? What is your knowledge of the side effects? Are you experiencing side effects/ please describe the side affects you are experiencing? Has anyone discussed the potential risks for taking opioid medication long term?	

Questions	Prompts	2 nd Prompts
<p>Thinking about your experience of your recovery and in particular managing your post-operative pain</p>	<p>What information do you think would have been helpful to know?</p> <p>What do you know now about managing pain and pain relief that you wish you'd known before your surgery?</p> <p>What suggestions do you have for others about managing pain after surgery? Has access to a clinician effected your ability to get support in weaning medication.</p>	

APPENDIX E: AUTOMATED SMS ‘SAFETY’ MESSAGE, QUALITATIVE STUDY RISK ASSESSMENT, RISK ASSESSMENT OUTCOME TABLE AND PATIENT RESOURCES

Automated SMS ‘Safety’ Message:

"Thank you for completing the POPPY study questionnaire. This is an automatically generated message in responses to answers you have given. They suggest you may be trying to manage difficult feelings and thoughts. We have sent a message to your GP to let them know about this.

There is support available to you and we recommend doing one or more of the following:

- Contact a healthcare professional (your GP, call **111**, call your mental health team if you are under one),
- Contact a helpline (Samaritans 116 123, jo@samaritans.org; Campaign Against Living Miserably (CALM) **0800 58 58 58**; Text 'SHOUT' to 85258)
- Visit the NHS website (www.nhs.uk/mental-health/feelings-symptoms-behaviours/behaviours/help-for-suicidal-thoughts/).
- Speak to someone close to you (a close friend or family member)"

Qualitative Study Risk Assessment

1. Does the patient have a previous history of suicide attempts?

This is one of the biggest indicators of risk

2. Are their thoughts fleeting or do you feel that there might be a danger of them acting on their thoughts?

3. Have they planned of how they would do it?

The more specific their ideas the higher the risk.

4. Is there available means of carrying it out?

I.e. have they got the tablets, rope, time available on their own

5. Does their planning include preparations for actually dying?

E.g. have they written a suicide note or started putting their affairs in order?

6. What would stop him/her? What has stopped him/her acting so far?

7. What social support or family is around?

Do they live alone or are they socially isolated

8. Do they perceive any hope for the future?

Do they feel very hopeless?

9. Is the patient depressed and coming up from it?

People who have been very deeply depressed and suicidal may have lacked the impetus to actually carry out plans of suicide, but when their mood lifts, they may feel more energised making this a risky time

10. What has the person been able to do in the past when feeling low or having suicidal thoughts?

11. Is alcohol or drugs of any kind involved?

12. Is the person liable to making impulsive acts?

13. In a crisis who would they contact?

G.P., helpline, Samaritans.

Risk Assessment Outcome Table

Category	<i>Green category – low risk</i>	<i>Amber category – medium risk</i>	<i>Red category – high risk</i>
Signs & Symptoms	Has protective factors. Fleeting thoughts. No previous attempts of suicide/self-harm. Has social support/co-habiting. Making plans for the future (e.g. career, social). No recent acute stressors. No history of psychopathology or addiction.	Unable to give protective factors or give name of person who can support. Has not told GP/healthcare profession of concerns? Regular/ persistent/ intrusive thoughts of suicide/self-harm. Has made plans on how to act out self-harm/suicide History of being impulsive.	Visually highly distressed OR very low. History of self-harm/suicide. No support present in the building. Unable to clarify risk on questioning.
Outcome	Continue with interview if patient happy. Give reassurance and self-help information.	Stop interview. Contact GP and give self-help information. Follow-up with letter to GP.	Stop interview. Call 999. Reassure patient. Inform GP. Follow-up with letter to GP.

Self-Help Resources

If appropriate, participants will be signposted to the following support:

“Talk to someone you trust”

“Let family or friends know what's going on for you. They may be able to offer support and help keep you safe.”

There's no right or wrong way to talk about suicidal feelings – starting the conversation is what's important.

“Who else you can talk to?”

“If you find it difficult to talk to someone you know, you could:

Call a GP – ask for an emergency appointment

Call 111 out of hours – they will help you find the support and help you need

Contact your mental health crisis team – if you have one

If appropriate, participants maybe signposted to the following organisations:

Samaritans Call: 116 123 Email: jo@samaritans.org

Campaign Against Living Miserably (CALM) Call: 0800 58 58 58 Visit the webchat page

Papyrus – for people under 35 Call: 0800 068 41 41 Text: 07860 039967 Email: pat@papyrus-uk.org

SOS Silence of Suicide Call: 0300 1020 505 Email: support@sosilenceofsuicide.org

Information: Shout Crisis Text Line

Text "SHOUT" to 85258

APPENDIX F: AMENDMENT HISTORY

List details of all protocol amendments here whenever a new version of the protocol is produced.

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of changes made
1	1.20	05/05/2023	M Rockett, M Everson, W Hare, M Belete	2.3: change to pilot site. 2.3: clarification of who initially approaches participant 2.4: change to which participants complete GAD-7 & PHQ-8 questionnaires. 4.1: clarification of who initially approaches participant. 4.1: addition of a screening log. 5.1: clarification of who initially approaches participant. 5.2: amendment of which identifiable information collected. 5.7: change to which participants complete GAD-7 & PHQ-8 questionnaires. 6: amendment of safety reporting processes 8.6: clarification of how virtual consent will be stored. 8.7: clarification of how videos will be deidentified. 9.4: clarification of data controller and processor. App B: minor amendment to definitions. App C: Q48, amendment to which participants complete GAD-7 & PHQ-8 questionnaires. App E: addition of message sent to GP. General: References & Bibliography updated

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