

BMJ Open Behaviours of older adults and caregivers preparing for elective surgery: a virtually conducted mixed-methods research protocol to improve surgical outcomes

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ABSTRACT

Introduction Older adults (age ≥65 years) are pursuing increasingly complex, elective surgeries; and, are at higher risk for intraoperative and postoperative complications. Patients and their caregivers frequently struggle with the postoperative recovery process at home, which may contribute to complications. We aim to identify opportunities to intervene during the preoperative period to improve postoperative outcomes by understanding the preparatory behaviours of older adults and their caregivers before a complex, elective surgery.

Methods and analysis As a result of the COVID-19 pandemic, we will conduct this study via telephone and videoconferencing. Using a multiphase mixed-methods research design, we will collect data on 10–15 patient–caregiver dyads from a pool of older adults (across a spectrum of cognitive abilities) scheduled for an elective colorectal surgery between 1 July 2020 and 30 May 2021. We will collect quantitative and qualitative data before (T1, T2) and after (T3, T4) surgery. Preoperatively, participants will each complete a cognitive assessment and a semi-structured qualitative interview that focuses on their preparatory behaviours (T1). They will then answer questionnaires about mood, self-efficacy and home environment (T2). Three weeks following hospital discharge, participants will complete another qualitative interview focusing on a comparison of preoperative and postoperative preparedness (T3). Researchers will also collect information about the patient's medical conditions, the postoperative complications and healthcare utilisation from the patient's chart 30 days following discharge (T4). We will code and conduct thematic analysis of the qualitative data to identify salient themes. Quantitative data will be analysed using basic descriptive statistics to characterise the participants. We will integrate the qualitative and quantitative findings using results from the quantitative scales to group participants and with use of joint display analysis.

Ethics and dissemination Ethics approval was obtained from the University of Michigan IRB. Study findings will be disseminated through peer-reviewed journals and presentations at conferences.

Strengths and limitations of this study

- This exploratory study is the first to interview complete pairs of older adults and caregivers regarding their preparatory behaviours before a complex, elective surgery that requires an inpatient hospitalisation.
- This study specifically includes patients with cognitive impairment, who are frequently excluded from research studies.
- In limiting this study to a specific type of surgery at one medical centre and in English-only speaking patients, we may be missing other important themes for patients and caregivers.
- Due to a small sample size, the quantitative results will not be generalisable to the larger population of older adults and caregivers, and we cannot draw definitive conclusions about the association between preoperative characteristics and postoperative outcomes.
- This study will demonstrate the feasibility of using telephone and videoconferencing for research in a population of older adults with cognitive impairment.

INTRODUCTION

Worldwide, adults ≥65 years represent the largest growing segment of the population. Older adults comprise 50% of surgical procedures and advances in surgical techniques, anaesthesia and intensive care management have expanded the number of complex, high-risk surgeries accessible to older adults.^{1 2} Older adults are at higher risk for postoperative morbidity and mortality than younger patients,^{3–6} likely attributable to a higher number of long-term conditions and impairments in cognition, mobility and function.^{7–9} Older adults often see multiple clinicians and experience frequent transitions in healthcare settings,¹⁰ both of which are associated with adverse events.^{10 11} Informal caregivers such as spouses and adult children

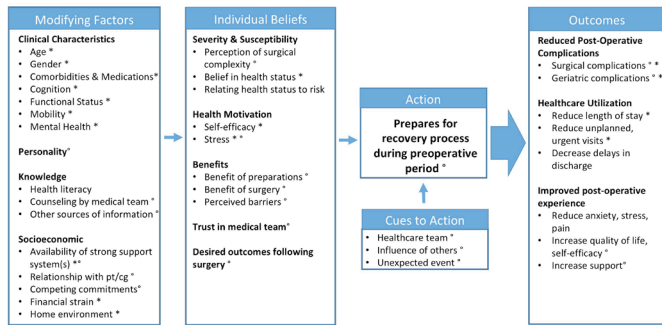


Figure 1 Our conceptual model for understanding the preparatory behaviours of older adult-caregiver dyads. This is adapted from the health belief model, which helps to explain and predict health-related behaviours. Understanding underlying individual beliefs and modifying factors is considered essential to developing effective behavior-change interventions. For the current protocol, variables that are measured quantitatively are marked with an asterisk (*), while constructs explored qualitatively are marked with a circle (°).

are often considered vital to a successful postoperative recovery.^{11–13} Unfortunately, patients and caregivers often cite feeling ill-prepared to manage at home following elective surgeries.

We present this protocol as a means for identifying opportunities to harness the period before a complex, elective surgery to better prepare older adults and their caregivers for the postoperative recovery. We will use a mixed-methods approach (qualitative interviews and quantitative assessments) to understand the preparatory behaviours of patient-caregiver dyads before surgery; identify the motivators for preparations and explore the relationship between preparations and the postoperative experience. Additionally, as the COVID-19 pandemic has forced many researchers to alternative data collection strategies, we present an example of a study of older adults using only telephone and videoconferencing.

Transitioning home

Older patients and caregivers report feeling rushed and overwhelmed by information, and admit that they sometimes are too distracted by the excitement of going home to engage with education delivered on day of discharge.^{14–18} Importantly, caregivers are not routinely included in the discharge process, potentially leading to informational gaps regarding postoperative instructions.^{11 12 15} This is especially problematic for older adults who may have difficulty in understanding postoperative instructions due to pre-existing cognitive impairment and/or postoperative delirium. COVID-19 visitor restrictions have introduced additional challenges in communication.

Once home, patients and caregivers cite challenges with managing surgical sites and medications, adapting to new limitations and coordinating care.^{13 17 19} They also report feeling unsupported by their medical team, being unaware of whom to contact or too embarrassed to ask questions.^{13 14 17 19 20} These challenges may contribute to postoperative complications (eg, infections, falls,

medication errors) and unplanned healthcare utilisation (eg, readmissions and Emergency Room visits).

Previous interventions

The time before elective surgery presents an opportunity to start preparing for the recovery process before hospitalisation. Interventions such as a preoperative comprehensive geriatric assessment (CGA), performed by a geriatrics-focused multidisciplinary team, are associated with improvements in length of stay, readmissions for medical conditions, mortality.^{21–23} The CGA, however, is resource intensive and requires adequate time before the day of surgery to conduct the assessment. Additionally, it is unclear which components of the CGA are most effective.²⁴ It is important to explore alternative methods for preoperative optimisation for care transitions.

To take advantage of the preoperative period to prepare patients and caregivers for the recovery process at home, it is imperative that we understand preoperative experiences of patients and caregivers. In particular, what are patients and caregivers doing between healthcare visits to prepare for surgery, what motivates their behaviour and how might preoperative preparations influence their postoperative experience? To date, there are no studies that specifically evaluate these preparatory behaviours longitudinally and through the eyes of patient-caregiver dyads.

Conceptual model

Using the Health Belief Model,²⁵ which posits that individual beliefs and modifying factors influence health-promoting behaviors, as a conceptual model for understanding the preparatory behaviours of patient-caregiver dyads before an elective surgery requiring an inpatient admission (figure 1). The target behaviour, ‘preparing for surgery’ encompasses many different behaviours such as modifying a living environment, arranging for social support or exercising. Qualitative findings from our study will explore common preparatory behaviours (the action) among older adults and caregivers, cues to action and how dyads relate their preoperative preparations with their postoperative experience. The qualitative and quantitative data together will help identify specific individual beliefs and modifying factors that influence preparatory behaviours. The quantitative analysis of postsurgical outcomes (ie, surgical and geriatric complications) and healthcare utilisation will also provide insight into participants’ post-operative experiences.

Adapting ‘virtual’ platforms

In response to the COVID-19 pandemic, many researchers are adapting their protocols to include ‘virtual’ platforms such as telephone and videoconferencing for both the informed consent process and data collection. Despite some concern about their ability to utilise virtual technology, there is evidence that older adults can utilise virtual platforms,^{26 27} and that participants and researchers find

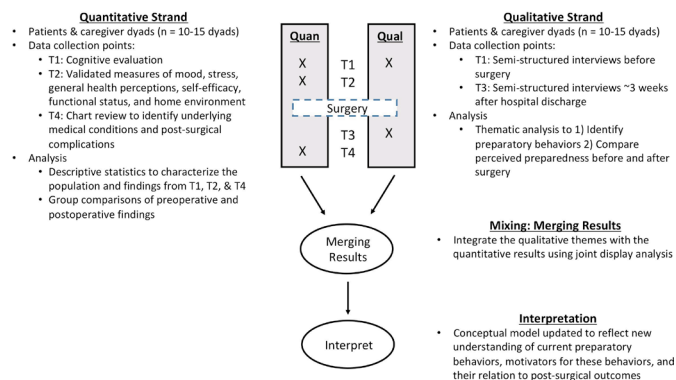


Figure 2 Summary of qualitative and quantitative components and how we will integrate the findings to create a new understanding of preparatory behaviours of older adults and their caregivers. T1–T4 indicate the points in time that data will be collected. T1 and T2 are before the surgery. T3 (21 days after discharge home) and T4 (30 days after discharge) are during the postoperative period.

virtual platforms to be feasible and acceptable methods for qualitative interviews.^{28–30} In order to reduce contact with potential participants, we adapted our original protocol to be entirely virtually. We present strategies for conducting a mixed-methods study virtually, which can be adapted across disciplines.

METHODS AND ANALYSIS

Overall study design

We will begin recruitment on 1 July 2020 and continue until 1 July 2021. This study will utilise a multiphase mixed-methods design³¹ that consists of qualitative and quantitative data collection and analysis before and after a scheduled surgery. The overall goal of our mixed-methods approach is to explore how patients and caregivers prepare for surgery, what influences their behaviour and how preoperative preparations influence their postoperative experience. The qualitative approach will provide details about patient and caregiver experiences preparing for surgery, recovering from surgery and how they relate their preoperative preparations to their postoperative experience. The quantitative approach will help characterise our sample and add information about the postoperative experience. Qualitative and quantitative findings will be integrated through comparison of the findings. We will collect data at four time points that span the preoperative and post-operative periods (figure 2).

In the preoperative period, the team will perform a cognitive assessment and conduct separate one-on-one semi-structured qualitative interviews of patients and their identified caregiver (T1). Following this, patients and caregivers will complete a series of validated questionnaires to characterise their current living situation and identify biopsychosocial factors that may influence preoperative preparatory behaviours (T2). We will then interview patients and caregivers again approximately 21 days following discharge (T3). We selected this time to

avoid overburdening patients and caregivers as they are recovering in the immediate postoperative period and to allow time for processing the postoperative experience. We will review the patient's electronic medical record (EMR) to identify preoperative medical comorbidities, postoperative complications and healthcare utilisation patterns (T4).

Sampling strategy, eligibility and recruitment

Sampling

We will use purposive sampling to identify community-dwelling older adults who are planned to undergo an elective colorectal surgery that requires an overnight admission at a large, academic university hospital. Purposive sampling will help us reach a goal of at least four patient–caregiver dyads where the patient has cognitive impairment.³² We prioritised cognitive impairment because of its importance in planning, prioritising, insight, judgement and learning, which we believe is important for preparatory behaviours. Colorectal surgery is used because of the high surgical complexity and transition across healthcare settings. Given diversity in the indication for colorectal surgery, we will also ensure we include those undergoing surgery for cancerous and non-cancerous reasons, and include patients who will have a new colostomy.

Sample size

Based on a qualitative approach, we will enrol at least 10 patient–caregiver dyads. This number was determined using prior studies that indicate in a homogeneous group (ie, one type of surgery, older adults, one institution), thematic saturation can be achieved in 6–12 interviews.³³ Given the additional heterogeneity introduced by including cognitively impaired older adults, differing patient–caregiver relationships and indications for surgery, we will recruit up to 15 patient–caregiver dyads as needed to produce meaningful and valid results from thematic analysis.

There are four points during recruitment where we will assess eligibility: during review of the patient's EMR; initial recruitment phone call; consenting process and first qualitative interview (figure 3).

Point 1

The team will review the schedule of the university's preoperative clinics twice weekly to identify potentially eligible patients. Patients eligible for recruitment will be ≥65 years old and scheduled to undergo an elective colorectal surgery within 3 months. Patients will be excluded if the EMR indicates they have severe cognitive impairment, are not fluent in English, are a patient of the Principal Investigator, live in a nursing home or a memory care assisted living facility or have a hearing impairment limiting their ability to communicate. We define severe cognitive impairment as having a chart diagnosis of 'severe memory impairment or severe dementia,' evidence that a person needs 24/7 supervision or Montreal Cognitive Assessment

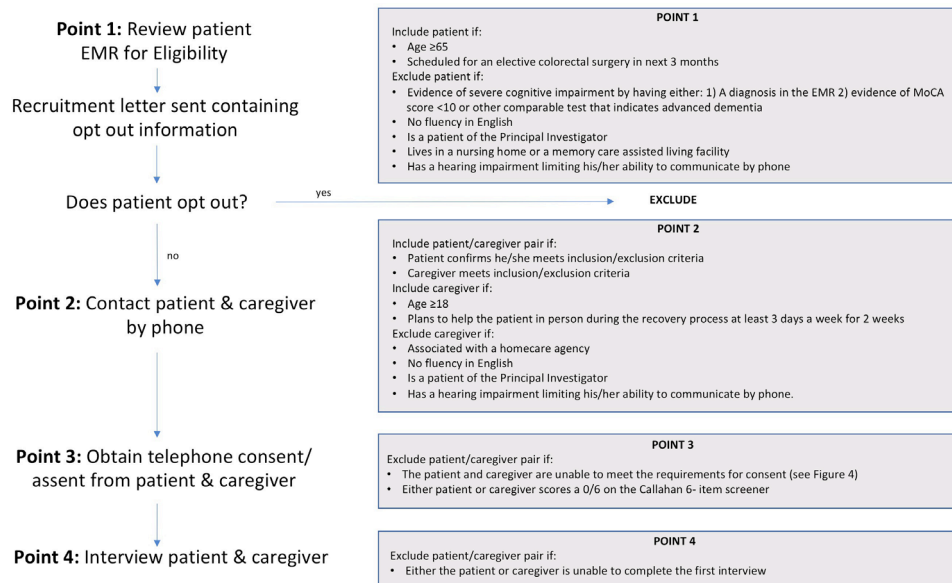


Figure 3 Flowchart indicating the four points in time during recruitment where we will assess eligibility. EMR, electronic medical record; MoCA, Montreal Cognitive Assessment.

score of ≤ 10 . This score has been used in other qualitative studies as it is the threshold for moderate dementia.³⁴ Patients meeting inclusion criteria will be sent a letter describing the study, a copy of the patient and caregiver consent forms and an ‘opt out’ postcard. If the patient does not return the postcard or contact us within 10 business days, we will then proceed with recruitment.

Nota bene: due to changes in scheduling of elective surgeries related to COVID-19, the study team will e-mail the patient our recruitment letter, consent forms and opt-out information if the patient’s surgery is scheduled within 10 days of identification on review of the preoperative schedule. If an email is unavailable, we will call the patient directly. We will either email or overnight-mail the patient the recruitment letter and consent form and schedule a time to review the study.

Point 2

We will call the patient to verify their eligibility. If the patient confirms that he or she meets all inclusion requirements and no exclusion requirements, we will then ask the patient to identify a caregiver. Eligible caregivers are ≥ 18 years old and plan to help the patient in-person during the recovery process ≥ 3 days per week for ≥ 2 weeks. The study team selected these requirements to verify that the caregiver is an active participant in the patient’s recovery process. We will exclude patients who are unable to identify a caregiver meeting these criteria; or if the caregiver is associated with a homecare agency; a patient of the principal investigator; does not have fluency in English or has a hearing impairment limiting their ability to participate in an interview. If the patient is interested in hearing more about the study and is able to identify a qualifying caregiver, we will then contact the caregiver to introduce the study and assess interest. If the caregiver is not interested in participating, we will

notify the patient that it appears that our study is not a good fit for the patient and caregiver. If the caregiver is interested in hearing more about the study, we will then confirm that he or she meets eligibility requirements. If so, we will contact the patient and begin the consenting process.

Point 3

During the consenting process, we will exclude the dyad if the participants are unable to meet the requirements for informed consent, which are discussed below. We will also exclude dyads if either the patient or caregiver scores a 0/6 on a screening tool to assess the ability to provide informed consent. This score would suggest that he or she may have severe cognitive impairment that would affect their ability to participate.

Point 4

We will exclude the dyad if either the patient or caregiver is unable to complete the first interview. This may be due to hearing impairments or severe cognitive impairment that limits the participant’s ability to engage in the interview. Examples of this would be an inability to answer simple questions or consistently providing 1–3 word answers.

Enrolment, consenting and ethical considerations for vulnerable research participants

We will begin the enrolment process over the telephone using a telephone script that accounts for differences in location and the ability to provide informed consent. If the patient and caregiver live in the same dwelling or can both be available at the time of the call, the study team will review the study and the consent forms with them together. If both participants wish to proceed, the researcher will begin the consenting process.

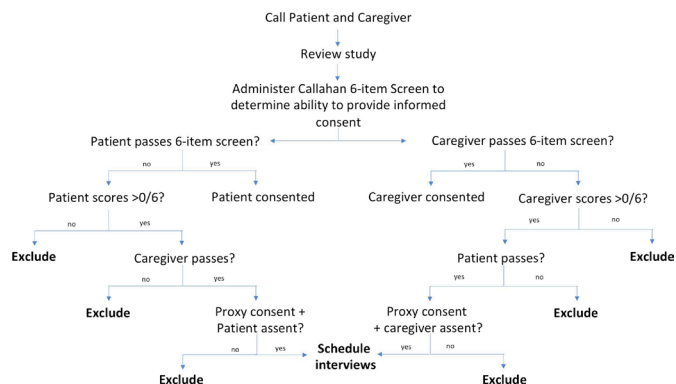


Figure 4 Consent flow diagram. This figure depicts how we will use the Callahan 6 Item Screen to determine competency to consent. Scores of 4–6 points are considered ‘passing’ and thereby indicate competency to consent.

We will obtain consent to participate in the study from both the patient and caregiver. To address potential ethical concerns regarding a participant’s ability to provide informed consent, we will utilise the Callahan 6-item screen³⁵ (figure 4), which is validated for research settings. We selected this tool based on the low-risk status of our study, the ability to administer over the phone and its simplicity. Scores on this screening tool range from 0 to 6 points, with lower scores indicating more impairment. Scores $\geq 4/6$ are considered ‘passing.’ Individuals scoring < 4 points will require a legal representative to provide telephone consent for the participant.

If both the patient and caregiver demonstrate competency to consent, they will be enrolled. If the patient fails the competency screen but the caregiver passes, we will ask the caregiver (as a legal representative) to provide telephone consent for the patient and confirm verbal assent from the patient. We will allow the patient to provide informed consent for the caregiver if the caregiver does not pass the competency screen. If both the patient and caregiver are not competent to consent, we will exclude the pair from the study. We will also exclude participants if they need a legal representative and the other participant is not their legal representative.

For instances where the caregiver is unavailable at the time of our initial call, we devised a protocol with three unique telephone scripts dependent on a patient or caregiver’s ability to provide informed consent.

The institutional review board (IRB) also approved a waiver to obtain written consent for this research study given the desire to limit face-to-face contact in the setting of a pandemic, patient characteristics (vision impairment) and technology factors (access to internet or scanner) that may make providing written consent over burdensome for this low-risk study. We will affirm participant assent to participate before each part of the study.

Incentives

Patients and caregivers will each receive \$30 for each part of data collection completed for a total of \$90 per person. In the event of disenrolment prior to completion of the

study, compensation will be made for the completed portions.

Semi-structured interviews

Interviews with patients and caregivers will occur before and after surgery; and they will be conducted separately to ensure both participants can speak openly about their experience. Qualitative interviews will use a semi-structured format that includes an interview guide while allowing the interviewers to ask follow-up and probing questions to gather more detail.³⁶ Preoperative interviews will focus on four domains: (1) knowledge of the planned surgery and expected postoperative recovery process; (2) preparations made in anticipation of the recovery process at home; (3) relationship with the patient or caregiver and (4) outcomes—beyond a successful surgery—valued by participants.

Postoperative interviews will focus on six domains: (1) general experience of recovering at home; (2) the degree of assistance from the caregiver; (3) changes in the patient–caregiver relationship; (4) comparison of the experience recovering at home to prior expectations; (5) utility of preparations and (6) suggestions to better prepare patients and caregivers for surgery.

Quantitative measures

Demographics

We will collect demographic information from the patient and caregiver during enrolment. Variables will include: age, gender, race and ethnicity.

Cognition (T1)

We will use the telephone (‘blind’) version of the Montreal Cognitive Assessment (t-MoCA) to measure cognition,³⁷ which was selected for its comparable sensitivity to detect mild cognitive impairment as longer tests (eg, Telephone Interview of Cognitive Status).³⁸ Scores below 18 or 19 points have been suggested to indicate possible cognitive impairment.^{37 38} To improve sensitivity, we selected ≤ 18 to indicate cognitive impairment.

Functional assessment (T2)

1. Katz Index of Independence in Activities of Daily Living:³⁹ This is a commonly used six-item yes–no scale to assess functional status. Respondents will indicate if they need supervision with bathing, dressing, toileting, transferring, continence or and feeding. Higher scores indicate more independence.
2. Lawton-Brody Instrumental Activities of Daily Living:⁴⁰ This eight-item scale measures the ability to manage more complex daily tasks such as shopping, transportation, managing medications and handling finances. Higher scores indicate more independence.
3. Surgery Survey for Older Adults:⁴¹ These questions are modified from the Vulnerable Elders Surgical Pathways and Outcomes Assessment tool, which assesses risk of postoperative complications based on a patient’s functional status, medical comorbidities, mobility, perceived ability to manage alone at home

and complexity of surgery. The full tool includes a visual assessment of gait and mobility, which we are unable to complete over the telephone. We will include information collected from chart-review and patient-report.

Perceptions and mood (T2)

1. General Self-Efficacy scale:⁴² This 10-item Likert scale (ranging from 'not confident' to 'very confident') measures a person's confidence in managing different situations, problems and events.
2. Perceived Stress:⁴³ This 10-item Likert scale (from 'never' to 'very often') assesses an individual's subjective experience of stress.
3. Financial Strain:⁴⁴ This is a single question about how hard (from 'very hard' to 'not very hard') has it been for the participant to pay for the very basics like food, housing, medical care and heating in the month prior.
4. Generalised Anxiety Disorder 7-item (GAD-7) scale:⁴⁵ This commonly used, 7-item Likert scale (from 'not at all' to 'nearly every day') assess symptoms of generalised anxiety and grades the severity.
5. Centre for Epidemiologic Studies Depression Scale (CES-D):⁴⁶ This 10-item Likert-scale (from 'rarely or none of the time' to 'all of the time') is commonly used to measure self-reported symptoms related to depression in research settings.
6. The Veterans RAND 12 Item Health Survey (VR-12):⁴⁷ This survey includes seven domains: general health perceptions, physical functioning, role limitations due to physical and emotional problems, bodily pain, energy/fatigue, social functioning and mental health and the answers will result in two summarised scores—physical component score and mental component score.
7. Modified Caregiver Strain Index:⁴⁸ This is a 13-item scale to measure caregiver burden. On a scale of 'no' to 'yes, on a regular basis', caregivers will report if they have experienced any symptoms seen with caregiver burden.

With consent from the patient to access their EMR, we will assess medical diagnoses and medications before surgery, prior surgical history, mobility, functional status, living environment and healthcare utilisation (eg, number of hospitalisations) in the year prior.

We will also review the patient's EMR to assess for common postoperative complications while hospitalised. These include complications as defined by the National Surgical Quality Improvement Programme (eg, wound infection, ventilator-associated-pneumonia)⁴⁹ and common geriatric complications (eg, functional decline, falls and delirium).⁴¹ We will also record discharge disposition and postoperative healthcare utilisation (use of skilled services on discharge, readmissions, ER utilisation and the number of communications with the healthcare team) from day of discharge to the 30-day post-operative visit.

Procedures

Two trained interviewers will conduct the one-on-one qualitative interviews using a cloud-based video conferencing platform called 'BlueJeans' (BlueJeans Network Inc.). We selected this platform because it allows video-conferencing, a call-in option and the ability to record only the audio-portion of the interview. There are other platforms with similar features.²⁸ Participants will be encouraged to use the video option as evidence suggests that this has comparable results to face-to-face interviews due to the ability to view subtle changes in facial expressions.^{30 50} Participants may use a password-protected conference call number if they experience trouble using videoconferencing. Interviewers will call participants if they have not joined within 5 minutes of the appointment time.

All participants will receive written instructions for accessing the application on their computer, tablet or phone. They will have a unique meeting ID, participant code and meeting link to enter the meeting, which will be sent by email or mail. Interviewers will ask participants to locate a quiet, private area in their home to conduct the interview. For additional safety, the interviewer will confirm the location and contact information for the participant in the event of an emergency during the interview.

At the start of the study (T1), the interviewer will first ask the participant to complete the t-MoCA. Following completion, the interviewer will then continue to the first semi-structured interview. This will be audio-recorded using BlueJeans and a backup audio-recorder.

Following the qualitative interview, we will e-mail or mail the participant a packet of quantitative measures to complete. These measures have been reformatted to simplify instructions and account for visual impairment in this population. Participants will be encouraged to complete these questionnaires prior to a telephone call from the research coordinator (T2), who will record their responses. As some of the questions are sensitive, the team devised a system where instead of providing full answers (eg, 'more than half the days') to a question, a participant will answer with a number that corresponds to a specific choice. For example, instead of answering 'more than half the days' for a question about anxiety, the participant would say 'My answer for question one is 'B'.

The postoperative qualitative interview (T3) will utilise the same procedures. We will also record the type of virtual platform each participant uses.

Analysis

Consistent with a qualitative approach, analysis will be an iterative process that begins concurrent with data collection. The team will meet regularly as the interviews are collected and transcribed. We will conduct a thematic analysis using MAXQDA 2020 (VERBI Software) to support data organisation and management.⁵¹ After the first two dyads complete the preoperative and postoperative interviews, we will begin to develop a

codebook through a process of open, descriptive coding. Open coding involves reading interview transcripts to gain a sense of the data and applying codes (ie, short text descriptors) to segments of text. The codes will be discussed among team members to develop a list of codes relevant to the research questions and definitions of each code. As more data are collected, the codebook may be modified by adding new codes or refining existing codes. All data will be coded by two team members using this codebook.

Coding will continue as two team members apply the codes to the remaining transcripts. To demonstrate interrater agreement, we will calculate an interrater correlation coefficient (kappa) using MaxQDA. Discrepancies will be discussed among the research team to ensure accurate application of the codes that reflect the meaning of each interview. Next, team members will meet to create code summaries and develop themes that represent salient ideas in the interviews.

In the quantitative portion, we will use descriptive statistics (eg, mean, median, SD, range) to characterise our population of patients and caregivers and further understand the postoperative experience. We will utilise descriptive statistics to describe the sample and exploratory inferential statistics to compare data between patients with and without cognitive impairment using Stata V.15 (StataCorp).

After analysing both portions, we will integrate the qualitative findings with the exploratory quantitative results guided by the seven steps of mixed-methods data analysis,⁵² including the use of joint display analysis.⁵³ Themes from the qualitative analysis will be compared with the statistical analysis from the quantitative to determine patterns in the data.

CONCLUSION

Our exploratory study is a first step in understanding preoperative preparations of older adults and their caregivers before a complex, elective surgery. It also presents a novel approach for conducting a mixed-methods study; and, in a population often excluded from studies due to concerns regarding their ability to utilise technology, provide informed consent, and respond to questions.

In using an innovative protocol, our study design has several limitations. Some include the potential for recall bias on postoperative interviews due to time delay and in evaluating the influence of preoperative preparations, and in limiting our sample size to 10–15 English-speaking patients undergoing colorectal surgery at a single medical centre. Results from our study will serve as a starting point to explore additional themes and future studies will need to include larger and more diverse populations.

Patient and public involvement

The Turner Clinic Patient Advisory Counsel for the Michigan Geriatrics Centre reviewed our protocol. Recommendations were incorporated into the final protocol.

Ethics and dissemination

Ethical approval for this study was obtained through the University of Michigan IRB (HUM00164220). Study findings will be disseminated through peer-reviewed journals and presentations at conferences. We will send participants the final manuscript, on request.

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Competing interests None declared.

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