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BMJ Open Perioperative mental health intervention bundle for older surgical patients: protocol for an intervention development and feasibility study

Joanna Abraham ⁽ⁱ⁾, ¹ Katherine J Holzer, ¹ Emily M Lenard, ² Kenneth E Freedland, ³ Bethany R Tellor Pennington, ¹ Rachel C Wolfe, ⁴ Theresa A Cordner, ¹ Ana A Baumann, ⁵ Mary Politi, ⁵ Michael Simon Avidan, ¹ Eric Lenze²

ABSTRACT

Introduction The perioperative period is high risk for older adults. Depression and anxiety are common perioperative problems, frequently coexisting with cognitive impairment. Older patients with these conditions are more likely than younger patients to experience postoperative delirium, long hospital stays, poor quality of life and rehospitalisation. These experiences can, in turn, exacerbate anxiety and depressive symptoms. Despite these risks, little is known about how to treat perioperative anxiety and depression among older adults.

Methods and analysis We designed a feasibility study of a perioperative mental health intervention bundle to improve perioperative mental health, specifically depression and anxiety. The overarching goals of this study are twofold: first, to adapt and refine an intervention bundle comprised of behavioural activation and medication optimisation to meet the needs of older adults within three surgical patient populations (ie, orthopaedic, oncological and cardiac); and second, to test the feasibility of study procedures and intervention bundle implementation. Quantitative data on clinical outcomes such as depression. anxiety, guality of life, delirium, falls, length of stay, hospitalisation and pain will be collected and tabulated for descriptive purposes. A hybrid inductive-deductive thematic approach will be employed to analyse gualitative feedback from key stakeholders.

Ethics and dissemination The study received approval from the Washington University Institutional Review Board. Results of this study will be presented in peerreviewed journals, at professional conferences, and to our perioperative mental health advisory board. Trial registration number NCT05110690.

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For numbered affiliations see end of article.

Correspondence to Dr Joanna Abraham; Joannaa@wustl.edu

INTRODUCTION

Americans undergo an average of nine surgeries in their lifetime.¹ Over 51 million surgeries are performed in the USA each year, with older adults representing approximately half of all surgical patients.² The perioperative period—encompassing preoperative (before surgery), intraoperative (during surgery) and postoperative (after surgery)

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This perioperative mental health intervention bundle comprised of behavioural activation and medication optimisation will be the first of its kind focused on improving cognitive and mental health of older patients who undergo surgery and manage their symptoms of depression and anxiety along the perioperative continuum.
- ⇒ This study will iteratively adapt and test the feasibility of implementing a patient-centred perioperative mental health intervention bundle with psychological and pharmacological optimisation components.
- ⇒ Our approach will provide feasibility data on whether we can: (1) enrol patients, (2) collect and refine data collection methods, (3) implement the intervention bundle within the perioperative context, (4) tailor the intervention bundle for the three surgical cohorts and (5) determine whether a future randomised effectiveness-implementation trial of the intervention bundle in the perioperative setting is feasible.

phases—is a high-risk and vulnerable time for older patients. Older patients are at increased risk for postoperative morbidity and mortality compared with younger adults.^{3–10} Anxiety and depression in older surgical patients increase the risk of postoperative complications, including short-term functional dependence and falls,¹¹ postoperative delirium,¹² opioid misuse,^{13 14} decreased quality of life¹⁵ and readmission. A meta-analysis of over 200 000 patients undergoing cardiac surgery revealed significantly increased mortality risk among individuals with perioperative depression and anxiety.¹⁶

There have been efforts to reduce perioperative risks in older adults by optimising physical health prior to surgery (prehabilitation), implementing protocolised pathways during the surgical hospitalisation and also promoting postoperative rehabilitation (eg,

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enhanced recovery). However, no corresponding perioperative interventions have been developed to address cognitive and mental health and well-being. In other words, we lack effective interventions tailored for older surgical patients, in spite of the high prevalence of depression and anxiety in this population,¹⁷ frequent co-occurring cognitive impairment and detrimental impact on surgical recovery.¹⁸

In our prior needs assessment interview study with older surgical adults diagnosed with anxiety and depression and their treating clinicians,¹⁸ we found that older surgical patients had varying care experiences, depending on their symptoms in the perioperative setting. Fear and uncertainty leading into the surgery and poor management of their depression and anxiety medications postoperatively were of key concern. Clinicians treating this population similarly noted that patients have a fear of surgery, experience acute pain, and can suffer from postoperative neurocognitive disorders. They were also worried that central nervous system active medications could worsen outcomes, yet many patients reported taking these medications at a subtherapeutic dose of medications for mental health, suggesting a need to optimise their dosage. However, clinicians reported concerns that stopping these medications could lead to withdrawal symptoms, but maintaining them could worsen their cognitive and mental health impairment.

Patients and clinician stakeholders emphasised the need for a perioperative intervention bundle to address these issues and argued for a bundle encompassing psychological components that are behavioural, simple, interactive and engaging, and pharmacotherapy components that can minimise the risk of psychiatric medication withdrawal symptoms and improper dosages during perioperative care. They also recommended that such a mental health intervention bundle would be effective if it started preoperatively to assist with preparation for surgery and continued postoperatively to enhance recovery after surgery.¹⁸

Researchers have examined the use of counselling, cognitive-behavioral therapy (CBT), and other psychological treatments (eg, relaxation, mindfulness and supportive therapy) to promote the mental well-being of younger surgical patients.¹⁹⁻²¹ For example, Li and colleagues²⁰ found that a psychological intervention provided to patients with cancer throughout the perioperative period was associated with decreased depressive symptoms and anxiety postoperatively. Similarly, research with patients undergoing orthopaedic surgery suggests that perioperative psychological education and counselling improved both psychological function,^{21 22} as well as physical function.²¹ In addition, studies suggest that a combination of pharmacological and psychotherapy is more effective at treating anxiety and depression in older adults than monotherapy^{23–28} and may be considered more acceptable to older adults,²⁵ suggesting the need for an intervention bundle that combines psychotherapeutic and pharmacological treatment. Older adults

often take many medications, and in the perioperative period, there is heightened risk of adverse drug reactions and drug–drug interactions.²⁹ Medication optimisation and deprescription can help with reduction or elimination of potentially inappropriate medications (such as benzodiazepines), in conjunction with appropriate antidepressant dosing and continuation across outpatient and inpatient care transitions.

Our team has previously demonstrated the effectiveness of CBT and behavioural activation for depression in medically ill populations,^{30–35} and for anxious older adults with comorbid depression,²⁸ and also of medication optimisation and deprescription for older adults³⁶ in the perioperative setting.³⁷ Informed by our prior work (see table 1 for features, clinical evidence and rationale), we propose to develop a perioperative mental health intervention bundle (*hereafter referred to as the intervention bundle*) encompassing two integrated components: behavioural activation (psychotherapy) and medication optimisation and deprescription (pharmacotherapy) for older surgical patients with anxiety and depression.

Developing the intervention bundle: adaptation process prior to feasibility evaluation

In preparation for this study, we organised an internal advisory board (IAB), comprised of older surgical patients, their caregivers, clinicians and researchers, to propose initial adaptations to the intervention bundle, informed by a collaborative planning approach. This approach integrates community-based participatory research with intervention mapping to guide intervention planning, implementation and evaluation.^{38 39} Intervention mapping is a step-by-step process that uses activities (eg, group discussions) and tools (eg, logic models) to develop a roadmap to inform the adaptation and implementation of interventions and has been used in a range of interventions and health issues.⁴⁰ The IAB members participated in three workshop sessions, which provided us with an interactive forum to garner their perspectives and experiences with mental healthcare management and its impact on preparation before surgery and recovery after surgery. The sessions were moderated by an experienced qualitative researcher and focused on two key goals: (1) ascertain needs and design requirements for an intervention bundle to address the barriers associated with effective perioperative mental healthcare management and (2) suggest modifications to an intervention bundle to align with older surgical patient care pathways. We also held weekly meetings with interventionists including social workers, pharmacists, psychiatrists and behavioural scientists to refine and adapt the intervention bundle, based on the IAB input such that our bundle components integrates within the perioperative context and address needs of older adults. Transcripts of these sessions and the weekly meetings were thematically analysed to inform our preimplementation adaptations to ensure effectiveness, feasibility, acceptability and overall satisfaction of the intervention bundle.

Table 1 Details on adapted perioperative mental health bundle components		
Intervention bundle	Behavioural activation	Medication optimisation
Target Interventionist	Patients Perioperative wellness partner.	Clinicians and patients Perioperative wellness partner follows an algorithm for medication optimisation and works alongside with pharmacists and a geriatric psychiatrist.
Description	A behavioural intervention helping depressed and anxious patients by engaging them in reinforcing activities or activities that are meaningful and guided by their personal values. ⁶⁶	A pharmacological intervention to adjust suboptimal doses of antidepressants, ensure continuation of antidepressants during transitions of care and deprescribe medications that are harmful to older adults. ^{67 68}
Features	Flexible component of cognitive–behavioral therapy (CBT) and standalone treatment in which the therapist helps a patient generate a list of pleasant, reinforcing activities and cocreates action plans. Patient-centred treatment, in which the patient chooses the modality (ie, which activities to engage in).	Medication optimisation consists of a simple set of principles: identify the patient's likely need for a medication adjustment, advise their provider to make the adjustment, and assess response ^{29 69 70} Additionally, it involves a review of current medications (including over the counter) for those that are eligible for deprescribing, including strong centrally acting anticholinergic and antihistaminergic drugs and benzodiazepines.
Rationale for including	Comparative efficacy and non-inferiority trials have shown that behavioural activation is about as effective as comprehensive CBT, and it can be delivered by less highly trained staff. Trials in medically ill patients have emphasised behavioural activation because it complements medically indicated physical activation and exercise goals, and it is feasible and acceptable. ³¹	Medication optimisation is a cardinal rule in treatment guidelines for depression. ⁷¹ Antidepressants are often prescribed at subtherapeutic doses and then not adjusted for response. ⁷² Suboptimal dosing is a main reason for these drugs' low effectiveness in the real world. ⁷³ Strong centrally acting anticholinergic and antihistaminergic drugs and benzodiazepines are 'low-hanging fruit' for deprescribing as their harms outweigh benefits. ⁷⁴ They are harmful perioperatively, increasing falls and delirium. ⁷⁵⁻⁷⁸
Core active components	 Personalised rationale identification. Values and goals assessment. Activity scheduling. Activity monitoring. 	 Review of medication list by wellness partner on first visit prior to surgery. Determine the indication, duration of use, dose and frequency of the medications of interest. Evaluate each medication's eligibility for optimisation or deprescription. Discuss with medication optimisation team. Get buy-in from patient to contact initial prescriber. Communicate recommendations to the patient. Weekly review of any new medications. Ensure that any medication optimisation changes are reconciled during transitions of care and that the agreed-upon changes are implemented both preoperatively and postoperatively.
Modifiable components	 Selected behavioural activation activities: depending on patient needs and preferences. Timing: preoperative and postoperative phases. Format: 1:1 session in-person/telephone/online. Duration: 20–30 min. Frequency: 1–4 (presurgery); 2–12 (postsurgery). Setting: home (telephone/online) and hospital. 	 Timing: preoperative and postoperative phases (start as early as possible). While in-hospital, the pharmacy team coordinates with the hospital team to ensure that medication changes that were introduced preoperatively are maintained in-house and that no new inappropriate medications are initiated. Format: 1:1 session in-person/telephone/online; then contact with the clinicians. Duration: 5 min. Frequency: 1–4 (pre); 2–12 (post). Setting: home (telephone/online) and hospital.

Findings from this work pointed to three major design requirements and adaptations: first, the intervention bundle be initiated prior to surgery and continued after surgery to cover two phases (see figure 1): preoperative: focusing on *improving patient preparedness* for surgery, and postoperative: focusing on *enhancing recovery* (see section on components of the intervention bundle; appendices A and B for the detailed SOPs). Second, the term



Figure 1 Adaptation process of the perioperative mental health intervention bundle. IAB, internal advisory board.

medication optimisation was suggested for the pharmacological component. Third, the term, perioperative wellness partner was formulated to refer to interventionists.

Interventionists

The interventionists, referred to as perioperative wellness partners are masters-level clinicians trained in behavioural activation using the material developed by Puspitasari and colleagues.⁴¹ They will deliver the intervention bundle with oversight from study team members with knowledge in both medications and systems of care for perioperative management, including pharmacists, a psychologist, a geriatric psychiatrist and a licenced clinical social worker.

Components of the intervention bundle *Behavioural activation*

Figure 2 presents a model of behavioural activation for surgery. Behavioural activation will be practised according to Kanter's *Behavioral Activation for Depression.*⁴² Behavioural activation as the core intervention allows for uniformity across participants yet enough flexibility for the actual components of behavioural activation to be individually adapted based on patient preferences. In addition to the core components of behavioural activation (table 1), study participants in collaboration with their perioperative wellness partner will be able to adapt the intervention by choosing activities, per their preference, with demonstrated benefit in improving depression and anxiety symptoms in older surgical patients.^{43 44} The behavioural activation process will be guided by the Behavioural Activation Standard Operating Procedure (BA SOP) (online supplemental appendix A), which will be adapted and calibrated as needed during the feasibility study.

Medication optimisation

Patient antidepressant medications will be reviewed with the patient by the perioperative wellness partner, and based on the decision algorithm, are optimised by our study team of interventionists including a psychiatrist, psychologist and pharmacists. The medication optimisation process will be guided by the Medication Optimisation Standard Operating Procedure (MO SOP) (online supplemental appendix B), which will be adapted as needed during the feasibility study.

In this paper, we present a protocol for a prospective study to further adapt and test the feasibility of implementing our intervention bundle to reduce anxiety and depressive symptoms in older surgical patients undergoing cardiac, oncological and orthopaedic surgeries at a large academic medical centre. Towards this end, we will use frameworks from implementation science to capture



Figure 2 Behavioural activation model for the perioperative setting. (A) Behavioral activation – symptom cycles. (B) Behavioral activation – interrupting symptom cycles.

the nuances and complexities unique to each patient population/setting that will inform our adaptation and implementation of the mental health intervention bundle. The Consolidated Framework for Implementation Research (CFIR)⁴⁵ is a well-operationalised, multilevel determination framework derived from theory that will help us identify the determinants (ie, barriers and facilitators) that affect the implementation process across the three settings and populations. The framework has 39 constructs across five domains: intervention characteristics, inner setting, outer setting, characteristics of individuals and implementation process, which help elucidate the context and factors that affect implementation and intervention bundle evaluation. The Framework for Reporting Adaptations and Modifications-Expanded (FRAME)⁴⁶ will allow us to systematically track all adaptations to the flexible components of the intervention bundle to ensure the feasibility, fit and relevance in older surgical patients, without compromising its core components.

Study objectives

The study objectives are summarised below:

- 1. Examine the feasibility of implementing a patientcentred intervention bundle for older surgical patients with clinically significant symptoms of depression and/ or anxiety.
- 2. Iteratively test and adapt the intervention bundle and the implementation plan to make it patient centred, in response to the needs/demands of older surgical patients with clinically significant symptoms of depression and/or anxiety along the preoperative and postoperative phases.
- 3. Identify multiple stakeholder perspectives and experiences with the intervention bundle with specific emphasis on its implementation barriers, enablers and implementation strategies to ensure its reach, uptake and sustainability in perioperative settings.
- 4. Demonstrate the fidelity, acceptability and appropriateness of the intervention bundle delivery for older

surgical patients with clinically significant symptoms of depression and/or anxiety.

5. Assess the feasibility of study procedures including patient recruitment, screening, outcome assessments and intervention materials for older patients.

Following this study, we will evaluate the effectiveness and implementation potential of our adapted intervention bundle using a randomised controlled trial.

METHODS

Study design and approach

A mixed methods (quant+qual) approach supported by a parallel convergent study design will be followed; this will allow us to collect quantitative and qualitative data simultaneously) and merge the data in order to compare and interpret together.⁴⁷ Quantitative data on anxiety and depression, quality of life, in-hospital delirium incidence, postdischarge falls, medications, length of stay, all-cause rehospitalisation, pain, patient experience and shared decision making will be collected. Qualitative surveys and interviews will help us to assess participants' feedback and experiences about factors affecting implementation and use of the bundle.

Study participants and recruitment procedure

Patient participants include older adults undergoing cardiac, orthopaedic or oncology surgery receiving treatment at a large teaching hospital serving a catchment area including both urban and rural patients in a Midwest state in the USA. We will also invite their caregivers to participate in this study. Table 2 provides information about the expected enrolment numbers, inclusion criteria and exclusion criteria of participants.

Patient participants will be recruited via three paths: Epic Electronic Health Record (EHR) report, clinician referral and self-referral (figure 3).

With the patients' consent, caregiver participants will be recruited via two paths: patient referral to either contact the study team or share the caregiver's phone number

Table 2 Enrolment, inclusion criteria and exclusion criteria by type of participant			
Participant type	Expected enrolment	Inclusion criteria	Exclusion criteria*
Patients	 8–10 cardiac surgery patients. 8–10 orthopaedic surgery patients. 8–10 oncological surgery patients. 	 ≥60 years of age on the day of surgery. Scheduled major orthopaedic surgery, or major surgical resection of a thoracic or abdominal malignancy, or major cardiac procedure. Clinically significant depression or anxiety symptoms screened by the Patient Health Questionnaire Anxiety and Depression Scale⁷⁹ ≥10.† 	 Estimated life expectancy <12 months. Unable to read, speak and understand English. Current alcohol or other substance abuse. Severe cognitive impairment screened by the Short Blessed Test >10. Acutely suicidal.
Caregivers	24–30 caregivers will be recruited alongside patient participants.	 Identified by patient as a family member or friend who cares for the patient as needed to support health and safety. 	Age ≤18 years.

*Patients may meet any one or more of the exclusion criteria to become ineligible to participate. †Patients must meet all eligibility criteria to participate.



Figure 3 Patient recruitment paths.

such that the study team will contact caregivers by phone or mail and invite them.

Assessment measures

At enrolment, a research coordinator will administer a battery of assessments to characterise patient participants and their current condition.

Patient baseline measures

Demographics

The following characteristics will be collected: age, sex, race/ethnicity, education level, employment status, psychiatric diagnosis, substance use and psychotropic medications.

Medical history of comorbidities

Patient medical history and comorbidities will also be collected.

Pain

The Brief Pain Invento (BPI) is a well-validated 11-item measure of pain severity and interference in pain,^{48–53} including after orthopaedic,⁵⁴ oncological⁵⁵ and cardiac surgery.⁵⁶ Three questions from the BPI will be used to assess pain, including whether the patient is diagnosed with chronic pain, whether they experience pain daily in the past 3 months and if they have been experiencing pain in the past week related or unrelated to their surgery.

Short Blessed Test (SBT)

The SBT, sometimes called the Orientation-Memory-Concentration Test, is a six-item scale frequently used to assess dementia within patients across three dimensions: orientation, registration and attention. The SBT has demonstrated good test-retest reliability. $^{57}\,$

Ultra-Brief Confusion Assessment Method (UB-CAM)

This two-item test⁵⁸ is used for a quick assessment of delirium using items from the 3 min diagnostic interview for confusion assessment method (3D-CAM).⁵⁹ Patients are asked to state the day of the week and months of the year backwards. If the UB-CAM is positive, the assessment continues with the full 3D-CAM.

Medication list

The research coordinator and perioperative wellness partner will review the patients' medications from the EHR and confirmed with the patient at the initial intervention visit, capturing the medication name, dose, units, frequency, start date, stop date and indication, where appropriate.

Intervention adaptation measures Intervention fidelity

Data related to intervention fidelity to examine the extent to which an intervention bundle is carried out by our perioperative wellness partner as intended and consistently across different settings, and patients will be tracked as adherence to core components of the intervention bundle, quality of delivery and participant responsive-ness.⁶⁰ All sessions will be audio recorded and reviewed by the supervising perioperative wellness partner (ie, trained in intervention bundle and is fidelity certified). Additionally, all intervention sessions will be reviewed and rated for fidelity by a team of researchers with training in the

intervention bundle (licenced social worker and research assistant). Written and/or verbal feedback will be shared with our wellness partners.

Adaptations to the intervention bundle and its implementation

Adaptations are thoughtful and deliberate alterations to the flexible components of the intervention bundle, the format or delivery of the intervention bundle by perioperative wellness partners in order to improve its fit or effectiveness in a given context.⁴⁶ Other changes may happen to the delivery of the intervention. Data on such adaptations and modifications will be collected during: (A) weekly case review intervention meetings where wellness partners will report on any changes they made to the intervention content and delivery method and their underlying rationale to implement that change and (B) periodic reflection meetings⁶¹ led by implementation scientists with the wellness partners where they will be asked to reflect on any modifications made deliberately and proactively, in response to unanticipated challenges in a given session or context.

The Behavioral Activation for Depression Scale – Short Form,⁶² or BADS-SF, is our measure of target engagement. The BADS-SF is a nine-item questionnaire derived from the original BADS⁶³ questionnaire that consists of 25 items across four subscales: activation, avoidance/rumination, work/school impairment, and social impairment.

It is frequently used to measure changes in behavioural activation levels following treatment.

Outcome measures for feasibility study

Outcomes for the feasibility study and their timepoints are provided in table 3. We will be assessing the reach of our study and our intervention bundle (ie, primary outcome), the feasibility of collecting depression and anxiety outcome planned for our randomised control trial (ie, secondary outcome) and implementation potential of intervention bundle and other outcomes such as quality of life and readmissions (ie, exploratory outcomes).

Data related to participant recruitment, retention and assessments will be collected to help us ascertain if any modifications to the study procedures need to be made to inform sample size estimates and power calculations in subsequent randomised controlled trial studies.

To obtain participant perspectives on the intervention bundle, we will conduct semistructured interviews with patients and caregivers, and the topics of discussions will be guided by the CFIR constructs. The interviews will explore the participants' perceptions, attitudes and experiences with the intervention bundle, intervention bundle acceptability and detailed accounts of participants' experiences after the intervention has been stopped with regards to intervention sustainability and maintenance.

 Table 3
 Feasibility study outcomes and potential study primary and secondary outcomes for planned randomised controlled trial (RCT).

Outcomes	Specific measure: description	Source	Timepoint
Reach (primary)	Reach of the study: patients who agreed to participate in the study out of total eligible to participate. Reach of the intervention bundle: patients who completed the interventions out of patients who agreed to participate in the pilot.	Electronic health record and research data warehouse	End of study
Completeness of planned RCT primary outcome data collection at specified timepoints (secondary)	Defined as a percentage of instrument or data fields completed for: Patient Health Questionnaire Anxiety and Depression Scale ⁷⁹ : 16-item scale with components of the Patient Health Questionnaire-9 and Generalised Anxiety Disorder Scale (collected at baseline, 1 month, 3 months)	Research data warehouse	End of study
Implementation potential (exploratory)	Acceptability, appropriateness and feasibility of the interventions: the acceptability of intervention measure, the intervention appropriateness measure and the feasibility of intervention measure. ⁸⁰ Each survey has four items in a Likert scale ranging from completely disagree to completely agree.	Surveys	End of study
Completeness of planned RCT secondary outcomes data collection at specified timepoints (<i>exploratory</i>)	 We will be measuring the completeness of data collection for the following potential secondary outcomes for the planned RCT secondary outcomes: Quality of life (collected at baseline, 1 month, 3 months). In-hospital delirium incidence (collected at baseline, in-hospital/ postoperatively). Postdischarge falls (collected at baseline, 1 month, 2 months, 3 months). Medication optimised and adherence to medications (collected at baseline, 1 month, 3 months) Length of stay (both hospital and intensive care unit). All-cause rehospitalisation (collected at 1 month, 3 months). Persistent postsurgical pain (collected at 1 month, 3 months). Patient experience (collected at end of study). Shared decision making (collected at end of study). 	Research data warehouse	End of study

These insights will inform whether the intervention bundle needs to be changed or adapted before our future trials. Interviews will be conducted via Zoom or telephone and will be digitally recorded and transcribed verbatim.

Data management and analysis plan

Data management

This study will be conducted under appropriate Washington University Institutional Review Board guidance and use only Institutional Review Board-approved study procedures and instruments. A unique patient number will be assigned at enrolment and used wherever possible on the case report forms to identify data, minimising use of patients' names or personal identifiers in data.

Data analysis

Quantitative data collected for the outcome measures for the feasibility study will be tallied and summarised using descriptive statistics. Completion of data collection will be described as a percentage of the instruments completed. The primary outcome of anxiety and depression for the planned RCT will be tabulated for descriptive purposes.

Fidelity and adaptation data will be analysed using open coding and the FRAME analytic framework to help track any adaptations to intervention bundle and delivery.⁴⁶ Interview data will be analysed using an inductive–deductive thematic analysis.⁶⁴ After reading the transcripts multiple times for familiarity, research team members will openly code using data-driven codes and then using CFIR-driven codes. Codes will be compared across the data to identify repeated and interrelated concepts and categories, and subthemes will be formed. Similar subthemes will be grouped over multiple rounds of review to generate overarching themes out of significant patterns between interviews.

Patient and public involvement

In preparation for this study, we organised an internal advisory board with surgical patients, caregivers, clinicians (eg, physicians, nurses, pharmacists and social workers) and institutional leaders focused on patient experience to adapt our intervention bundle. Through the internal advisory board meetings, we sought to ensure that the intervention bundle facilitates patient preparedness for surgery during the preoperative period and enhances recovery during the postoperative period, coordinating and communicating with inpatient clinicians and to evaluate whether the intervention methods are practical and appropriate for the patient populations and clinicians, without affecting perioperative workflow.

ETHICS AND DISSEMINATION Participant consents

Patients who meet all eligibility criteria and provide written informed consent will be enrolled into the study. Patient consent will be obtained via a paper collected by mail or in person or by secure REDCap link to e-consent. Caregivers (participating in semistructured interviews via Zoom/phone or in-person) will be consented verbally or with a written consent, depending on participant convenience.

Harms

This study involves minimal risk to subjects. Unlikely but potential risks include errors in medication recommendations; however, this risk is mitigated by the utilisation of a multidisciplinary group of experts agreeing on the recommendation and ongoing check points throughout the intervention process to ensure recommendations are correct and free from error. Additional risks include medication withdrawal symptoms as a result of the intervention recommendation and breach of confidentiality. The risk of medication withdrawal (ie, from benzodiazepines) is mitigated by slowly tapering rather than stopping these medications. If a participant endorses suicidal ideation, intent or plan, the coordinator and perioperative wellness partners are trained to follow an operationalised protocol (see online supplemental appendices A and B) that has been developed to manage high-risk participants in other studies of depressed participants potentially at risk for suicide. This protocol has already been used successfully by members of the research team to manage acutely suicidal patients. Patients will be encouraged to check with their physician if there is any question about the safety of any physical activities that are included in the behavioural activation plan. It is possible that the participant may feel uncomfortable completing the surveys or participating in the study sessions. The study sessions and interview can be discontinued at any time, and the patient may refuse to answer any questions that he or she does not wish to answer.

We will monitor for breaches of confidentiality and other adverse events on an ongoing basis. Once we become aware of a reportable adverse event, the event will be reported to Human Research Protection Office and Quality Assurance and Safety Monitoring Committee (QASMC) according to institutional guidelines. This study does not require QASMC audit or submission of DSM reports. Should any unexpected serious adverse events occur, our study protocol will be modified to prevent other similar events.

Internal auditing for data quality

The methodology core team meets biweekly with the research coordinators and data manager to review the study report on study enrolment, recruitment, monitor data quality and discuss the study progress and any issues raised by the participants.

Data safety and monitoring plan

The specific monitoring plan for this investigation is commensurate with the risks and the size and complexity of the studies planned. Given the nature of the protocol, the risks are likely limited to breach of confidentiality.

DISSEMINATION

The feasibility study results will be disseminated at scientific meetings and peer-reviewed publications. Additionally, the results will be presented to our perioperative mental health internal and external advisory board consisting of patients, clinicians, nationally recognised researchers (psychiatry, health services and pain medicine) and hospital administrator stakeholder groups to determine which components of the intervention and its delivery to preserve, which adaptations to carry forward and how to advance with the randomised controlled trials. The Washington University Centre for Perioperative Mental website (https://perioperativewellness.wustl. Health edu/) will be used to introduce the intervention bundle to patients and clinicians alike. To accelerate the dissemination efforts, the Centre will use online communication channels including the Centre's webpage, popular news media, social media, webinars and patient and family community networks. As per the National Institute of Mental Health sponsor guidelines, we will also be sharing the deidentified data to ClinicalTrials.gov.

Trial status

This study is registered in Clinical Trials Registry NCT05110690. Recruitment commenced during the last week of November 2021, and the enrolment is expected to conclude in March 2023.

DISCUSSION

To our knowledge, the proposed perioperative mental health bundle will be the first of its kind to assist older surgical patients in managing their perioperative mental health. Current interventions need to be adapted and tested for older surgical patients, who face additional unique challenges such as frailty, multimorbidity with co-occurring cognitive and physical impairments, and polypharmacy that can also impact their mental health and well-being.¹¹⁶⁵

The study protocol will adapt the intervention bundle comprised of behavioural activation and medication optimisation and provide evidence on the feasibility of testing the bundle as a potential intervention for anxiety and depression in older surgical patients. In addition, this study will provide feasibility data on implementing the bundle successfully within perioperative settings. Despite the empirical evidence available on behavioural activation and medication optimisation, there are unique challenges to using and implementing these interventions for the perioperative population of older adults, in perioperative settings notable for their complexity. To the best of our knowledge, the protocol is the first to adapt and examine the feasibility of the intervention bundle within the perioperative setting for older surgical patients. We will identify components of our intervention bundle and its delivery mechanism that can be common across the three different surgical populations, and also

components that are unique for a particular population, and further for a particular patient based on their surgical pathways.

Results from this mixed method study will inform the following: first, findings related to experiences in participating in the intervention bundle, along with intervention fidelity and adaptation tracking, will allow us to finalise modifications to our initial 'in-progress' intervention bundle, resulting in a more patient-centred bundle that meets the needs and preferences of our diverse patients. Second, findings will determine if the components of the intervention bundle are feasible to be delivered in three very different settings in terms of dose, timing and duration of intervention. Third, findings will lead to an adapted intervention standard of procedure (SOP) that can guide the delivery of the intervention bundle by perioperative wellness partners and one that can be tested for fidelity in our future effectiveness-implementation RCT. Fourth, findings will offer an initial roadmap for adapting and implementing patient-centred mental health interventions that are likely to be accepted and used by multiple stakeholders in the future. The intervention bundle adaptations performed in this study can be flexible enough and tailored based on patient needs/surgical conditions in diverse surgical settings while also maintaining the core components of the bundle, leading to a higher potential for scalability and sustainability in the long term. Use of the implementation science frameworks offers us the lens to examine the feasibility and acceptability of the intervention bundle ahead of time, in order to accelerate the translation of the intervention bundle to usual care. Lastly, the study will inform the design and conduct of the planned randomised controlled trials in the three surgical cohorts. This study provides us with an opportunity to identify and address unanticipated challenges with our study procedures including recruitment methods, engagement strategies, study design flaws and outcome measurement challenges.

This study comes with several limitations, similar to other feasibility trials. First, the sample sizes will be small as the proposed study focuses only on the evaluation of feasibility and implementation potential of the intervention bundle, thereby limiting the ability to detect changes in outcomes. Second, the study does not include a control condition, and hence we will not be making any conclusions about the intervention bundle effectiveness. Third, results from this study are specific to our study setting and population at an academic medical centre and may not be generalised to other non-academic settings. Nevertheless, this study will demonstrate whether it is feasible to: (1) recruit, (2) implement the intervention bundle in the perioperative period and (3) track the outcomes of interest, prior to conducting an RCT with a comparison group that will determine the efficacy of patient-centred intervention bundle in the three different surgical populations.

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Author affiliations

¹Department of Anesthesiology, Washington University in St Louis School of Medicine, St Louis, Missouri, USA

²Department of Psychiatry, Washington University in St Louis School of Medicine, St Louis, Missouri, USA

³Department of Psychiatry, Washington University in St Louis, St Louis, Missouri, USA

⁴Department of Pharmacy, Barnes-Jewish Hospital, St Louis, Missouri, USA
 ⁵Department of Surgery, Washington University in St Louis School of Medicine, St Louis, Missouri, USA

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ORCID iD

Joanna Abraham http://orcid.org/0000-0002-3576-5279

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APPENDIX A Behavioral Activation Standard Operating Procedure (SOP)

<u>Center for Perioperative Mental Health Intervention:</u> <u>Behavioral Activation</u>

Behavioral Activation (BA) is a flexible, patient-centered treatment. The Perioperative Wellness Partner (study interventionist) supports the patient in engaging in activities of the patient's choice to promote their mental and physical wellness.

Behavioral Activation will be practiced according to *Behavioral Activation for Depression* by Jonathan W. Kanter et al, in Treatment of Depression in Adolescents and Adults, copyright 2011.

Sessions will occur via zoom, telephone, or in person, per patient preference. Location of sessions will be documented.

Sessions will begin no more than 30 days prior to scheduled surgery aiming for approximately 2 preoperative sessions. When the time between consent and surgery is less than 2 weeks, attempt 1 BA session or brief introductory contact prior to surgery. Sessions will conclude approximately 90 days postoperative, aiming for participants to receive approximately 8-10 BA sessions. Sessions will typically occur every two weeks but frequency can be increased to weekly to achieve 8-10 total sessions and per patient needs, preference, and treatment goals. The duration is anticipated to be approximately 40 minutes per session, but can be adjusted between 20 and 60 minutes depending on patient needs and treatment goals. Session duration will be documented.

Core components are summarized below:

Personalized Rationale: The Perioperative Wellness Partner will develop a personalized rationale to
ensure each patient understands how Behavioral Activation could be helpful for them:
1. Assess and discuss negative life experiences (including the upcoming surgery, and any other
difficult circumstances). For context and to build upon strengths, assess and discuss positive life
experiences (what's been going well lately).
2. Assess and discuss emotional and behavioral responses (what are they doing, not doing, doing
more of, doing less of in response to the negative life experiences? Are those responses causing
any problems?)
3. Validate emotional and behavioral responses as natural, normal, common.
4. Discuss symptom cycles and how behavioral responses can perpetuate problems. This is the idea
that our natural behavioral responses to a problem or symptom can sometimes make the problem
worse, or cause other problems.
5. Explain the goal of BA: activation as an alternative to the patient's behavioral responses.
Changing what we do can change how we feel and think, even in difficult circumstances.
6. Seek feedback and verify understanding of the intervention rationale
7. Discuss interventionist role to coach, guide, and help think of strategies, acknowledging that there
will be challenges.
8. Throughout - use the patient's language instead of jargon to discuss problems, responses, and
symptoms.
Assessment: conduct a concentrated, detailed assessment early in the treatment process.

1. Values and long term goals: find out what matters to the patient, what their aspirations are.

2. Targets for meaningful activities:

Typically in BA, reinforcing activities – ones that are rewarding, pleasurable, meaningful and/or that provide a sense of productivity or accomplishment. Another way to identify target activities is to ask about personally important activities that the patient has discontinued or is doing less frequently than in the past. These targets may be applicable in the perioperative setting. Targets for activities that may be particularly helpful in the perioperative setting include:

- Activities that bring a sense of normalcy and help restore sense of identity
- Activities that distract from unproductive worry or rumination
- Activities that help with physically preparing or recovering from surgery
- Activities that promote social connection
- Activities that are cognitively engaging
- 3. **How activities affect mood**: gathering details on how the patient's real-life day-to-day activities impact their mood.
- 4. Avoidance: assessing whether there are things the patient has been avoiding; and whether there are activities that serve as an escape or distraction from difficult feelings or activities.
- 5. **Routine and routine disruptions:** learning about the patient's current and ideal daily routine (sleep-wake, hygiene, eating habits, physical activity, work and/or chores) and any disruptions affecting their normal routines and the reasons for disruptions. Even in the absence of routine disruption pre-operatively, it is helpful to revisit post-operatively to assist in returning to healthy daily routines.
- 6. **Current psychosocial stressors**: assess whether there are major current psychosocial stressors impacting patient's recovery, function, and ability to carry out activity scheduling goals (e.g., acute grief, financial difficulties, problematic living situation, fraught relationship with primary current patients). A lyname maintain forms an activity are string to a string to be set in the set interval.

caregiver). Always maintain focus on actions the patient can take even in difficult circumstances. Activity Scheduling: collaborative process between the patient and Perioperative Wellness Partner to plan for helpful activities. Activity scheduling is concrete and considers the difficulty of the task in the context of the patient's life, including any acute or chronic physical limitations.

- 1. Collaboratively **identify activities** to work on
- 2. **Consider difficulty** of activity in the current context and break tasks into smaller parts if needed
- 3. Schedule at least one activity concretely (what, where, when, with whom)
- 4. Problem solve any obstacles to activity completion

Pre-Operative Period: Ideally, both Behavioral Activation and Medication Optimization will begin before surgery. This time can be used for assessment and learning the process of activity scheduling.

- 1. Assess emotional and behavioral responses
- 2. Validate emotional and behavioral responses as natural, normal, common
- 3. Assess patient's **primary concern** and goals
- 4. Activity scheduling: They should be actions that are the most important for the patient right now, not something extra or additional. Activity scheduling can include a blend of activities that focus on:
 - Feeling prepared for surgery

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- Improving physical or emotion	nal well-being	
- Coping with anxiety and uncer	rtainty	
 Establishing habits to continue 	e after surgery.	
5. Assist with problem-solving and help	ing patients communicate with medical team as needed	
Operative Period: Hospitalization for surgery i	s very disruptive for patients and their families. BA	
during this period should continue to be concre	ete, realistic, and take into account the patient's current	
circumstances.		
1. Assess emotional and behavioral res	ponses	
2. Validate emotional and behavioral res	ponses as natural, normal, common	
3. Assess patient's primary concern and	l goals	
4. Assist with problem-solving with the p	batient and family and assist in communicating with their	
inpatient and transitional provider tear	n if needed	
5. Activity scheduling: should be compa	tible with treatment goals from other disciplines and	
should be able to be safely performed	by the patient. They should be actions that are the most	
important for the patient right now, no	t something extra or additional.	
Post-Operative Period: Behavioral Activation a	at this time should assist the patient in their individual	
recovery, returning to meaningful activities, an	id in restoring their sense of self. The interventionist	
should be aware of the patient's discharge inst	ructions, restrictions, and need for follow-up care.	
1. Assess emotional and behavioral	responses	
2. Validate emotional and behaviora	l responses as natural, normal, common.	
3. Assess patient's primary concern	and goals	
4. If there are treatment goals from	other disciplines that are important for the patient's	
recovery but aren't being implemented by the patient (e.g., attending physical therapy), the		
interventionist should discuss this	with the patient:	
- Assess and problem-solve barriers		
- Clarify misunderstand	lings	
- Frame the importance	of the treatment in the context of the patient's long-term	
goals and values.		
5. Activity scheduling: should contin	nue to be collaborative and focused on the patient's long-	
term goals and values. Activity scl	neduling can include a blend of activities that focus on:	
- physical recovery		
- returning to previous	functioning	
- promotion of psycholo	ogical well-being.	
Addressing Barriers: Through the duration of t	he intervention, the Perioperative Wellness Partner	
should assist the patient in anticipating and res	ponding to barriers. Below is a listing of types of	
barriers and potential solutions.		
Barrier Type	Potential Solutions	
Antocodont foilure	Pamindars	
Not remembering at all or not remembering	- Reminders	
at the right place and time	- Analiging the environment	
Skills deficit	- Excilitate learning experiences for needed skills	
I acking the skills or knowledge that are	Schedule and monitor the learning activities	
needed to enact the behavior	- If problem-solving presents as a skills deficit	
hered to endet the bendvior	structured problem-solving can be done in session	
Social skills deficit	BA sessions can incorporate social skills training	
I acking social or communication skills that	including instruction modeling role-playing and	
are needed to enact the behavior	assigning real-world practice	
	Brear norra praemoor	

Extrinsic contingency issue	- Premack's Principle: Reinforce a less rewarding
Occurs when the desired behavior is not	behavior by engaging in a more enjoyable behavior
reinforcing, perhaps because of the behavior	afterwards.
itself or the patient's environment.	- In the short term, an arbitrary reward can be used.
Intrinsic contingency issue	- Assist to identify avoidance triggers and patterns.
Occurs when the patient avoids the desired	- Validate the emotional response and avoidance as
behavior because of the emotions that it	normal.
causes.	- Discuss that while negative emotions may make it
	harder to engage in the desired behavior, they
	probably don't make it impossible. Discuss acting,
	even while experiencing negative emotions.
	- Connect the activity to the patient's goals and
	values.
	- Schedule concretely and break task down into
	manageable chunks.
Pain and/or fatigue	- Discuss pain and fatigue symptom cycles as they
Physical pain and fatigue are common in	relate to the patient's experience.
medically ill surgical patients. Pain and	- Discuss activity - rest cycle (pacing) as an
fatigue may be caused the surgery,	alternative: alternating planned activity with
anesthesia, and co-morbid medical	regular rest periods. Keep track of activity and rest
conditions. Anxiety, depression, and stress	periods and the impact on pain and fatigue levels.
also contribute to pain and fatigue.	
Overexertion and inactivity can both	
exacerbate pain and fatigue, so achieving a	
balance of rest and activity is crucial.	
Intervention Conclusion: The study intervention	on is time-limited, and ends after approximately 90 days
post-operatively.	
1. Assist the patient in identifying other s	supports and resources that will continue past the study
period.	
2. Review progress and discuss what pra	ctices the patient would like to 'keep,' and address any
barriers to doing so.	
3. Assess need for ongoing mental health	treatment and assist with referrals.

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APPENDIX B Medication Optimization Standard Operating Procedure (SOP)

<u>Center for Perioperative Mental Health Intervention:</u> <u>Medication Optimization</u>

Part A: Initial Medication Review/Letter to Primary Provider

Step 1: Complete detailed review of patient's home medications: For each medication, determine the indication, the duration of use, the dose, and frequency. Ask follow-up questions as needed to: Confirm compliance of each medication. Assess history of any dose modifications and patient's perceived impact. Make sure to specifically ask for any over-the-counter medications or supplements, as well any as-needed medications.

Step 2: Evaluate the patient's home medications for any of the medications on the list below. Included on the list are medications that may be harmful for older adults and are therefore eligible for deprescribing. These medications can cause decreased energy, cognitive impairment, and increased fall risk.

MEDICATIONS WITH ANTICHOLINERGIC PROPERTIES: typically, these can be stopped	
abruptly	
<u>Generic</u>	Brand
Amitriptyline	Elavil
Atropine	
Benztropine	Cogentin
Chlorpheniramine*	Actifed, Allergy & Congestion Relief, Chlor-Trimeton, Codeprex, Efidac-24 Chlorpheniramine
Cimetidine	Tagamet
Cyclobenzaprine	Amrix, Fexmid, Flexeril
Cyproheptadine	Periactin
Dexchlorpheniramine	
Dicyclomine	Bentyl
Diphenhydramine*	Advil PM, Aleve PM, Bayer PM, Benadryl, Excedrin PM, Nytol, Simply Sleep, Sominex, Tylenol PM, Unisom
Diphenoxylate	Lomotil
Doxepin	Adapin, Silenor, Sinequan
Fesoterodine	Toviaz
Hydroxyzine	Atarax, Vistaril
Hyoscyamine	Anaspaz, Levbid, Levsin, Levsinex, NuLev
Imipramine	Tofranil
Meclizine	Antivert, Bonine
Orphenadrine	Norflex
Oxybutynin	Ditropan, Oxytrol
Prochlorperazine	Compazine
Promethazine	Phenergan
Pseudoephedrine	Aprodine
HCl/Triprolidine HCl	
Scopolamine	Transderm Scop
Tolterodine	Detrol
SEDATIVES – BENZODIAZEPINES: may need tapering unless low-dose/intermittent	

<u>Generic</u>	Brand
Alprazolam	Xanax
Chlordiazepoxide	Librium
Clonazepam	Klonopin
Diazepam	Valium
Estazolam	Prosom
Lorazepam	Ativan
Oxazepam	Serax
Triazolam	Halcion
Temazepam	Restoril, Normison, Planum, Tenox, Temaze
NONBENZODIAZEPINE "Z	-DRUGS" SEDATIVES: may need tapering unless low-
dose/intermittent	
Generic	Brand
Eszopiclone	Lunesta
Zolpidem	Ambien

* Almost all OTC sleep and cold/flu medications contain one of these. Patients will not likely know these ingredients. Find out if they take OTC sleep/cold medicine and recommend stopping it.

Step 3: Evaluate the patient's home medications for antidepressants eligible for dose escalation. Compare each antidepressant medication dosage to therapeutic dose ranges listed in the Lexicomp database. If a patient's medication dosage is <u>below</u> the therapeutic dose range, make a note on the patient's medication list. Common examples include:

- Citalopram: increase to 20mg if dose less than 20mg.
- Escitalopram: increase to 10mg if dose less than 10mg.
- Sertraline: increase to 50mg if dose less than 50mg.
- Fluoxetine: increase to 20mg if dose less than 20mg.
- Paroxetine: increase to 20mg if dose less than 20mg.
- Duloxetine: increase to 60mg if dose less than 60mg.
- Venlafaxine: increase to 150mg if dose less than 150mg.
- Vilazodone: titrate (by 10mg/week) to 40mg if dose less than 40mg.
- Bupropion: increase total daily dose to 300mg if total daily dose is less than 300mg.

Step 4: If the patient is taking a medication eligible for deprescribing: (a) explain why it may be harmful and get more clarification, if necessary, about reason for taking. (b) Find out (ask the patient) if they've noticed any problems with gait, cognition, or sedation or confusion. (c) Ask if the patient has any concerns about stopping the medication (e.g., benzodiazepines). (d) Get feedback from the patient (eg, willingness to stop). (e) Tell the patient you will discuss with the medication optimization team and return with official recommendations.(f) Find out who prescribes the medication and get buy-in to contact the patient's PCP (and/or the prescriber of the medication).

"Oxybutynin causes fatigue and cognitive problems in older people. Have you noticed any problems with your concentration, energy, or balance?" "You told me you take it for your bladder—do you think it's helping?" "You will think more clearly, have more energy, and have better balance if you stop it or switch to a different medication that isn't bad for your brain." "What do you think? [if in doubt, ask directly: "would you be willing to stop or switch this medication?]" "I will discuss with the medication optimization team and let you know what they recommend. Is it ok with you if we contact your doctor to discuss these changes?"

Step 5: If the patient is taking an antidepressants eligible for dose escalation: (a) Explain that the dose of their medication may be more helpful for improving their mood and anxiety if taken at a higher dose. (b) Ask if they have ever tried taking it at a higher dose and whether they had any side effects or improvements. (c) Ask if they would have any concerns with increasing the dose. (e) Tell the patient you will discuss with the medication optimization team and return with official recommendations.(f) Get buy-in to contact the patient's PCP (and/or the prescriber of the medication).

"I see that you are taking 75mg of venlafaxine each day, and continue to have anxiety and a low mood. Venlafaxine works better to manage those symptoms when it is taken at a higher dose, 150mg. Have you ever taken venlafaxine at a dose higher than 75mg? Would you have any concerns with trying a higher dose to provide better management of your mood and anxiety? I will discuss with the medication optimization team and let you know what they recommend. Is it ok with you if we contact your doctor to discuss these changes?"

Step 6: Email medication list to the medication optimization contact (regardless of whether the patient appears to have any medications that are eligible for optimizing). Give any necessary details about patient experience, issues with medication compliance, resistance to stopping certain meds, perceived effectiveness, etc. Note any differences from their medication list in Epic.

<u>Step 7</u>: Upon receiving instructions from the medication optimization contact, contact the patient's relevant physician (PCP in most cases) via Epic. For providers outside the WU/BJC Epic instance, a letter will be sent via fax with a call to the office to confirm receipt.

<u>Step 8</u>: Communicate recommendations for medication optimization to the patient:

- "As we discussed, your medications can have a huge impact on your energy, fall risk, and brain function. Our expert in medications in older adults has reviewed your list of medications and recommends stopping the Oxybutynin because it causes problems in older people. If you stop it, you will think more clearly, have more energy, and have better balance. We contacted your doctor and they are on board with this plan"
- 2) "You told me that you don't think the Oxybutynin is helping very much anyway, so you can just stop it immediately. If you notice bladder problems after stopping it, you can try taking a nontoxic alternative."
- 3) "Does this plan make sense to you? Do you have any questions?"
- 4) "Great, stopping the Oxybutynin will definitely help your energy and thinking. That'll help you towards your goal of going on evening walks with your wife."

Part B: Following Up with the Patient Throughout the CPMH Intervention

Phone calls:

- Use each phone call to keep an updated list of meds: "Have you had any changes to your medications since we spoke last?"
- If new meds have been added, check new meds against the list of medications eligible for medication optimization. If the patient is on a medication from the medication optimization list, then go through Step 3 above with the patient, then send update to Medication Optimization team.

Home visits:

- Home visits are not required, but if they occur, they provide a good opportunity to compare the medication list to the actual medication bottles the patient has at home. Confirm that our original list is correct.
- If there are changes, check new meds against the list of medications eligible for medication optimization. Send update to medication optimization team if necessary.
- Ask if they've noticed any changes since the medication was stopped.

"When you were in the hospital, you stopped taking oxybutynin because it causes fatigue and worsens memory. Since then, have you noticed any improvement in your energy or thinking?"

(If person responds yes, then make sure to respond positively and link this to their goals, eg "Great – your energy is improved! You're closer to your goal of taking walks with your wife in the evening!"

If the person responds no, then still say: "That's ok – people don't always notice these improvements. But I can guarantee you, since you stopped this medication, your brain is working better.")

• Also use a Progress Tracker graph to show the progress made by this medication optimization. See the example below.



Part C: Post-operative Check for Resuming Antidepressant Treatment

- Check the patient's MAR in Epic appx 24 hours post-operatively to assess whether the patient's antidepressant treatment was held for surgery. If it was held, check to see if it has been re-started.
- Current guidelines and practice indicate the discontinuation risks are worse and more likely than potential impact of SSRIs/SNRIs on bleeding. Patients whose antidepressants are not resumed risk relapse in depression within 2-6 weeks.
- In the event that a held antidepressant is not re-started post-operatively, CPMH pharmacists will contact the patient's unit pharmacist.