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# BMJ Open

## Designing Mental Health Interventions for the Perioperative Period: Protocol for a Feasibility Trial

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## Designing Mental Health Interventions for the Perioperative Period: Protocol for a Feasibility Trial

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**ABSTRACT** (229/300 words)

**Introduction:** The perioperative period is high-risk for older adults. Depression and anxiety are common perioperative problems, frequently co-existing 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 rehospitalization. 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 demonstration study of a perioperative mental health intervention bundle comprised of behavioral activation and medication optimization within three older surgical patient populations (i.e., orthopedic, oncologic, and cardiac) to improve perioperative mental health, specifically depression and anxiety. The overarching goals of this study are two-fold: first, to adapt and refine the intervention bundle to meet the needs of older surgical patients; and second, to test the feasibility of study procedures and intervention bundle implementation. Quantitative data on clinical outcomes such as depression, anxiety, quality of life, delirium, falls, length of stay, hospitalization, and pain will be collected and tabulated for descriptive purposes. A hybrid inductive-deductive thematic approach will be employed to analyze qualitative 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 peer-reviewed journals, at professional conferences, and to our perioperative mental health advisory board.

**Strengths and limitations:**

- This perioperative mental health intervention bundle comprised of behavioral activation and medication optimization 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-centered perioperative mental health intervention bundle with psychological and pharmacological optimization components.
- Our approach will provide feasibility data on whether we can (i) enroll patients, (ii) collect and refine data collection methods, (iii) implement the intervention bundle within the perioperative

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3 context, (iv) tailor the intervention bundle for the three surgical cohorts, and (v) determine  
4 whether a future randomized effectiveness-implementation trial of the intervention bundle in the  
5 perioperative setting is feasible.  
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## 8 9 INTRODUCTION

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11 Americans undergo an average of nine surgeries in their lifetime.<sup>1</sup> Over 51 million surgeries are  
12 performed in the United States each year, and approximately half of all surgical patients are older than  
13 65.<sup>2</sup> The perioperative period - encompassing preoperative (before surgery), intraoperative (during  
14 surgery), and postoperative (after surgery) phases - is high-risk for older patients. Older patients are at  
15 increased risk for postoperative morbidity and mortality compared to younger adults.<sup>3-10</sup>  
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21 There have been efforts to reduce perioperative risks in older adults by optimizing physical health prior  
22 to surgery (prehabilitation), implementing protocolized pathways during the surgical hospitalization, and  
23 promoting postoperative rehabilitation (e.g., enhanced recovery). However, no corresponding  
24 perioperative interventions have been developed to address cognitive and mental health and well-being.  
25 We lack effective interventions tailored for older surgical patients, in spite of the high prevalence of  
26 depression and anxiety in this population,<sup>11</sup> frequent co-occurring cognitive impairment, and detrimental  
27 impact on surgical recovery.<sup>12</sup> Furthermore, anxiety and depression in older surgical patients increases  
28 the risk of postoperative complications, including short-term functional dependence and falls,<sup>13</sup>  
29 postoperative delirium,<sup>14</sup> opioid misuse,<sup>15,16</sup> decreased quality-of-life,<sup>17</sup> readmission, and mortality.<sup>8,18</sup>  
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38 We conducted a needs assessment study with older adults diagnosed with anxiety and depression who  
39 had undergone surgery and also interviewed clinicians who treat these patients.<sup>12</sup> Older surgical adults  
40 had varying care experiences, depending on their symptoms in the perioperative setting. Fear and  
41 uncertainty leading into the surgery, and poor management of their depression and anxiety medications  
42 post-operatively were of key concern. Clinicians treating this population observed that patients have a  
43 fear of surgery, experience acute pain, can suffer from postoperative neurocognitive disorders, and  
44 would benefit from more information about what to expect regarding surgery and recovery. Clinicians  
45 worried that central nervous system (CNS)-active medications could worsen outcomes, yet many  
46 patients reported taking these medications. Clinicians reported concerns that stopping these medications  
47 could lead to withdrawal symptoms, but maintaining them could worsen cognitive and mental health  
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3 impairment. Additionally, many were taking a sub-therapeutic dose of medications for mental health,  
4 suggesting a need to optimize their dosage.  
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7 Stakeholders emphasized the need for a perioperative intervention bundle to address these issues and -  
8 argued for a bundle encompassing psychological components that are behavioral, simple, interactive,  
9 and engaging, and pharmacotherapy components that can minimize the risk of psychiatric medication  
10 withdrawal symptoms and improper dosages during perioperative care. They also recommended that the  
11 mental health intervention bundle should start preoperatively to assist with preparation for surgery and  
12 continue postoperatively to enhance recovery after surgery.<sup>12</sup>  
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19 Researchers have examined the use of counseling, cognitive behavior therapy, and other psychological  
20 treatments (e.g., relaxation, mindfulness, supportive therapy) to promote the mental wellbeing of  
21 younger surgical patients.<sup>19-21</sup> For example, Li and colleagues<sup>20</sup> found that a psychological intervention  
22 provided to patients with cancer throughout the perioperative period was associated with decreased  
23 depressive symptoms and anxiety postoperatively. Similarly, research with patients undergoing  
24 orthopedic surgery suggests that perioperative psychological education and counseling improved both  
25 psychological function,<sup>21,22</sup> as well as physical function.<sup>21</sup> In addition, studies suggest that a combination  
26 of pharmacological and psychotherapy is more effective at treating anxiety and depression in older  
27 adults than monotherapy,<sup>23-28</sup> and may be considered more acceptable to older adults,<sup>25</sup> suggesting the  
28 need for an intervention bundle that combines psychotherapeutic and pharmacological elements. Older  
29 adults often take many medications, and in the perioperative period, there is heightened risk of adverse  
30 drug reactions and drug-drug interactions.<sup>29</sup> Perioperative medication optimization should focus on  
31 reduction or elimination of potentially inappropriate medications (such as benzodiazepines), in  
32 conjunction with appropriate antidepressant dosing and continuation throughout hospital transitions of  
33 care.  
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46 Our team has previously demonstrated the effectiveness of cognitive behavioral therapy (CBT) and  
47 behavioral activation for depression in medically ill populations,<sup>30-35</sup> and for anxious older adults with  
48 comorbid depression;<sup>28</sup> and also of medication optimization for older adults<sup>36</sup> in the perioperative  
49 setting.<sup>37</sup> Informed by our prior work (*see* Table 1 for features, clinical evidence, and rationale), we  
50 propose to adapt a perioperative mental health intervention bundle (*hereafter referred to as the*  
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*intervention bundle*) encompassing two integrated components - behavioral activation (psychotherapy), and medication optimization (pharmacotherapy) for older surgical patients with anxiety and depression.

**Table 1. Details on adapted perioperative mental health bundle components.**

<b>Intervention Bundle</b>	<b>Behavioral Activation</b>	<b>Medication Optimization</b>
Target	Patients	Clinicians and Patients
Interventionist	Perioperative Wellness Partner	Perioperative Wellness Partner follow an algorithm for medication optimization
Description	A behavioral intervention helping depressed and anxious patients by engaging them in reinforcing activities or activities that are meaningful and guided by their personal values. <sup>38</sup>	A pharmacologic intervention to adjust suboptimal doses of antidepressants, ensure continuation of antidepressants during transitions of care, and deprescribe medications that are harmful to older adults. <sup>39,40</sup>
Features	<p>Flexible component of CBT and standalone treatment in which the therapist helps a patient generate a list of pleasant, reinforcing activities, and co-creates action plans.</p> <p>Patient-centered treatment, in which the patient chooses the modality (i.e. which activities to engage in).</p>	Medication optimization 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 <sup>29,41,42</sup> Additionally, it involves a review of current medications (including OTC) for those that are eligible for deprescribing, including strong centrally-acting anticholinergic and antihistaminergic drugs and benzodiazepines.
Rationale for including	<p>Comparative efficacy and non-inferiority trials have shown that behavioral activation is about as effective as comprehensive CBT and it can be delivered by less highly-trained staff.</p> <p>Trials in medically ill patients have emphasized behavioral activation because it complements medically indicated physical activation and exercise goals, and it is feasible and acceptable<sup>43</sup></p>	<p>Medication optimization is a cardinal rule in treatment guidelines for depression.<sup>44</sup> Antidepressants are often prescribed at subtherapeutic doses and then not adjusted for response.<sup>45</sup> Suboptimal dosing is a main reason for these drugs' low effectiveness in the real world<sup>46</sup></p> <p>Strong centrally-acting anticholinergic and antihistaminergic drugs and benzodiazepines are "low-hanging fruit" for deprescribing as their harms outweigh benefits.<sup>47</sup> They are harmful perioperatively, increasing falls and delirium<sup>48-51</sup></p>
Core active components	<ul style="list-style-type: none"> <li>• Personalized Rationale Identification</li> <li>• Values and Goals Assessment</li> <li>• Activity Scheduling</li> <li>• Activity Monitoring</li> </ul>	<ul style="list-style-type: none"> <li>• Medication list reviewed by Wellness Partner on 1<sup>st</sup> visit prior to surgery</li> <li>• Determine the indication, duration of use, dose, and frequency of each medication</li> <li>• Evaluate each medication's eligibility for optimization or deprescription</li> <li>• Discuss with medication optimization team</li> </ul>

		<ul style="list-style-type: none"> <li>• Get buy-in to contact initial prescriber</li> <li>• Communicate recommendations to the patient</li> <li>• Weekly review of any new medications</li> <li>• Ensure that medication changes are reconciled during transitions of care and that the agreed-upon changes are implemented</li> </ul>
Modifiable components	<ul style="list-style-type: none"> <li>• Selected BA activities: depending on patient needs and preferences</li> <li>• Timing: Pre- and post-operative phases</li> <li>• Format: 1:1 session in-person/telephone/online</li> <li>• Duration: 20-30 minutes</li> <li>• Frequency: 1-4 (pre); 2-12 (post)</li> <li>• Setting: Home (telephone/online) and hospital</li> </ul>	<ul style="list-style-type: none"> <li>• Timing: Pre- and Post-operative phases (start as early as possible because medication changes have to be slow and deliberate). While in-hospital, the Wellness Partner 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</li> <li>• Format: 1:1 session in-person/telephone/online; then contact with the clinicians</li> <li>• Duration: 5 min</li> <li>• Frequency: 1-4 (pre); 2-12 (post)</li> <li>• Setting: Home (telephone/online) and hospital</li> </ul>

### Designing the Intervention Bundle: Adaptation Process

In preparation for this study, we organized an internal advisory board (IAB), comprised of patients, caregivers, clinicians and researchers, to propose initial adaptations to the intervention bundle, informed by a collaborative planning approach. This method integrates community-based participatory research with intervention mapping to guide intervention planning, implementation and evaluation.<sup>52,53</sup>

Intervention mapping is a step-by-step process that uses activities (e.g., group discussions) and tools (e.g., logic models) to develop a road map to inform the adaptation and implementation of interventions, and has been used in a range of interventions and health issues.<sup>54</sup> Together with the feedback from our advisory board, we proposed that 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 proposed intervention bundle; Appendices A and B for the detailed SOPs).



### ***Interventionists***

The interventionists are referred to as Perioperative Wellness Partners. They are Masters-level clinicians trained in Behavioral Activation using the material developed by Puspitasari and colleagues<sup>55</sup>. 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 licensed clinical social worker. Through their delivery of the intervention, they help to support the patients' health and well-being throughout the perioperative period, focusing on mental health and preparedness in the preoperative stage and mental health and maintenance in the postoperative stage to enhance the patient's surgical recovery.

### ***Initial Adaptations to Intervention Bundle***

#### **Behavioral Activation**

Figure 2 presents a model of behavioral activation for surgery. Behavioral activation as the core intervention allows for uniformity across participants from each cohort, yet enough flexibility for the actual components of behavioral activation to be individually adapted based on patient preferences. In addition to the core intervention of behavioral 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.<sup>56,57</sup>

#### **Medication Optimization**

Patient medications are reviewed by the Perioperative Wellness Partner, and based on the decision algorithm (see Appendix A for the MO SOP), the medications are *optimized* by our team of interventionists including a psychiatrist, psychologist, and pharmacists.

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

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3 Implementation Research (CFIR)<sup>58</sup> is a well-operationalized, multi-level determination framework  
4 derived from theory that will help us identify the determinants (i.e., barriers and facilitators) that affect  
5 the implementation process across the three settings and populations. The framework has 39 constructs  
6 across five domains: intervention characteristics, inner setting, outer setting, characteristics of  
7 individuals, and implementation process, which help elucidate the context and factors that affect  
8 implementation and intervention bundle evaluation. The Framework for Reporting Adaptations and  
9 Modifications-Expanded (FRAME)<sup>59</sup> will allow us to systematically track all adaptations to the flexible  
10 components of the intervention bundle to ensure the feasibility, fit and relevance in older surgical  
11 patients, without compromising its core components.  
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## 19 **Study Objectives**

20 The study objectives are summarized below:  
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- 22 1. Iteratively test and adapt the intervention bundle to make it patient-centered, in response to the  
23 needs/demands of older surgical patients with clinically significant symptoms of depression  
24 and/or anxiety.
- 25 2. Examine the feasibility of implementing a patient-centered intervention bundle for older surgical  
26 patients with clinically significant symptoms of depression and/or anxiety.
- 27 3. Identify multiple stakeholder perspectives and experiences with the intervention bundle with  
28 specific emphasis on its implementation barriers, enablers, and implementation strategies to  
29 ensure its reach, uptake and sustainability in perioperative settings.
- 30 4. Demonstrate the fidelity, acceptability and appropriateness of the intervention bundle delivery  
31 for older surgical patients with clinically significant symptoms of depression and/or anxiety
- 32 5. Assess the feasibility of study procedures including patient recruitment, screening, outcome  
33 assessments and intervention materials for older patients.  
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46 In this feasibility study, the intervention bundle components and their implementation plan will be  
47 iteratively adapted to meet the needs of older surgical patients along the preoperative and postoperative  
48 phases. Following this study, we will pilot test the adapted intervention bundle in a randomized  
49 controlled trial.  
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## 53 **METHODS**

### *Study participants and recruitment procedure*

The study will focus on older surgical patients receiving treatment within an adult teaching hospital, serving a catchment area including both urban and rural patients in a Midwest state in the US.

Participants are older adults undergoing cardiac, orthopedic or oncology surgical cohorts; additional stakeholders are their caregivers and clinicians, including physicians, nurses, advanced practice nurses, physician assistants, pharmacists, and social workers. Table 2 provides information about the expected enrollment numbers, inclusion criteria, and exclusion criteria for three types of participants.

**Table 2. Enrollment, inclusion criteria, and exclusion criteria by type of participant.**

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

Participant Type	Expected Enrollment	Inclusion Criteria	Exclusion Criteria
Patients	12-15 cardiac surgery patients 12-15 orthopedic surgery patients 12-15 oncologic surgery patients	<ul style="list-style-type: none"> <li>• <math>\geq 60</math> years of age on the day of surgery</li> <li>• Scheduled major orthopedic surgery, or major surgical resection of a thoracic or abdominal malignancy, or major cardiac procedure</li> <li>• Clinically significant depression or anxiety symptoms screened by the PHQ-ADS (Patient Health Questionnaire Anxiety and Depression Scale<sup>60</sup>) <math>\geq 10</math>*</li> </ul>	<ul style="list-style-type: none"> <li>• Estimated life expectancy &lt; 12 months</li> <li>• Unable to read, speak, and understand English</li> <li>• Current alcohol or other substance abuse</li> <li>• Severe cognitive impairment t screened by the SBT (Short Blessed Test) &gt;10</li> <li>• Acutely suicidal**</li> </ul>
Caregivers	25 caregivers will be recruited alongside patient participants	<ul style="list-style-type: none"> <li>• Identified by patient as a family member or friend who cares for the patient as needed to support health and safety</li> </ul>	
Clinicians	30 clinicians will be recruited via email (e.g., listserv) or word of mouth. Information sheets will be available for study team members to share with patient-facing staff that are involved in the care of our target patient population.	<ul style="list-style-type: none"> <li>• Affiliated with the clinical departments serving the study's target population</li> <li>• Includes clinicians responsible for surgical patient care delivery and management: physicians, nurses, advanced practice nurses, physician assistants, pharmacists, social workers</li> </ul>	

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3 Patient participants will be recruited via 3 paths: Epic Electronic Health Record (EHR) report, clinician  
4 referral, and self-referral. See Figure 3 for recruitment paths and participant flow.  
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### 7 ***Study design and approach***

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9 A mixed methods (Quant+Qual) approach supported by a parallel convergent study design will be used—  
10 where we will collect quantitative data on anxiety and depression, quality of life, in-hospital delirium  
11 incidence, post-discharge falls, medications, length of stay, all-cause rehospitalization, patient  
12 experience, and shared decision making. Qualitative surveys assess participants' feedback and  
13 experiences about their perceptions of barriers or facilitators affecting implementation and practicality of  
14 the bundle.  
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### 20 ***Assessment measures, outcomes, and timeline***

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22 At enrollment, a research coordinator will administer a battery of baseline assessments to characterize  
23 patient participants and their current condition.  
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#### 27 **Assessment measures**

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30 *Demographics:* The following characteristics will be collected: age, sex, race/ethnicity, education level,  
31 employment status, psychiatric diagnosis, substance use, and psychotropic medications.  
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35 *Medical history of comorbidities:* Patient medical history and comorbidities will also be collected.  
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38 *Pain:* Three questions from the Brief Pain Inventory (BPI) are used to assess pain, including whether the  
39 patient is diagnosed with chronic pain, whether they experience pain daily in the past 3 months, and if  
40 they have been experiencing pain in the past week related or unrelated to their surgery. The BPI is a  
41 well-validated 11-item measure of pain severity and interference in pain,<sup>61-66</sup> including after  
42 orthopedic,<sup>67</sup> oncologic,<sup>68</sup> and cardiac surgery<sup>69</sup>.  
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47 *SBT (Short Blessed Test):* The SBT, sometimes called the Orientation-Memory-Concentration Test, is a  
48 6-item scale frequently used to assess dementia within patients across 3 dimensions: orientation,  
49 registration, and attention. The SBT has demonstrated good test-retest reliability.<sup>70</sup>  
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53 *UB-CAM (Ultra-Brief Confusion Assessment Method):* This 2-item test for delirium<sup>71</sup> is used to screen  
54 for the use of the 3D-CAM.<sup>72</sup> The UB-CAM will be conducted during the postoperative hospital stay up  
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3 to twice daily for 3 days. If the Ultra-Brief CAM is positive, then the 3D-CAM will be used for further  
4 assessment. The CAM consists of a standardized, evidence-based interview that enables researchers and  
5 clinicians, following structured training, to reliably and reproducibly identify the four cardinal features  
6 of delirium. The Family Confusion Assessment (FAM-CAM) provides a method for informant-based  
7 assessment and can be used to evaluate for evidence of delirium based on observations from family  
8 members or caregivers.  
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14 *Medication list:* The Perioperative Wellness Partners will review the patients' medications at the initial  
15 intervention visit, capturing the medication name, dose, units, frequency, start date, stop date, and  
16 indication, where appropriate.  
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21 *Intervention fidelity:* Data related to intervention fidelity to examine the extent to which an intervention  
22 bundle is carried out by our Perioperative Wellness Partner as intended and consistently across different  
23 settings, and patients will be tracked as adherence to core components of the intervention bundle, quality  
24 of delivery, and participant responsiveness.<sup>73</sup> All sessions will be audio recorded and reviewed by the  
25 supervising and lead perioperative wellness partner (i.e., trained in intervention bundle and is fidelity  
26 certified). Additionally, at minimum 15-20% of the intervention sessions will be reviewed and rated for  
27 fidelity by another individual (licensed SW) with training in the intervention bundle. A research team  
28 member will also observe a sub-set of the intervention sessions to capture any deviations to the core  
29 components of the intervention. Written and/or verbal feedback will be shared with Wellness Partners.  
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37 *Adaptations to the intervention bundle and its implementation:* Adaptations are thoughtful and deliberate  
38 alterations to the flexible components of the intervention bundle, the format or delivery of the  
39 intervention bundle by perioperative wellness partners in order to improve its fit or effectiveness in a  
40 given context.<sup>59</sup> Other changes may happen to the delivery of the intervention. Data on such adaptations  
41 and modifications will be collected during (1) weekly case review intervention meetings where wellness  
42 partners will report on any changes they made to the intervention content, and delivery method and their  
43 underlying rationale to implement that change; and (2) periodic reflection meetings led by  
44 implementation scientists (at three time points: beginning, mid-point, conclusion of the project) with the  
45 wellness partners where they will be asked to reflect upon any modifications made deliberately and  
46 proactively, in response to unanticipated challenges in a given session or context.  
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*Feasibility of study procedures:* Data related to participant recruitment, retention, and assessments. This will help us ascertain if any modifications to the study procedures need to be made, to ensure power in subsequent randomized controlled trial studies.

A description of the primary and secondary outcomes and their timepoints are presented in Table 3.

**Table 3. Study primary and secondary outcomes.**

Patient-level Outcomes		Specific measure: description	Source	Timepoint
Primary (Clinical)	Anxiety and Depression	Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS) <sup>60</sup> : 16-item scale with components of the Patient Health Questionnaire-9 and Generalized Anxiety Disorder Scale	Questionnaire	Baseline; 1 mo; 3 mo
Primary (Target Engagement measure)	Anxiety and Depression / Target Engagement	Behavioral Activation for Depression Scale (BADs) <sup>74</sup> : 25-item questionnaire across 4 subscales: Activation, Avoidance/Rumination, Work/School Impairment, and Social Impairment. Frequently used to measure changes in behavioral activation levels following treatment.	Questionnaire	Baseline; 1 mo; 2 mo; 3 mo
Secondary (Clinical)	Quality of Life	The Veterans RAND 12 Item Health Survey (VR-12) <sup>75</sup> : 12-item scale frequently used to assess health-related quality of life <sup>76-79</sup> ( $\alpha = 0.7-0.8$ ) <sup>80</sup> .	Questionnaire	Baseline; 1 mo; 3 mo
	In-hospital delirium incidence	See description in Assessment section.	Interview	Baseline; In-Hospital / Postoperatively
	Post-discharge falls	Patient Reported Falls: 11-item questionnaire assessing whether and how frequently a patient has fallen in the past month. If the patient reports a fall-related injury limiting their activity, follow-up questions concern the circumstances of the fall, whether they sought medical help and any treatment involved.	Questionnaire	Baseline; 1 mo; 2 mo; 3 mo
	Medication optimized and adherence to medications	Data will be collected on the number of medications that are optimized, whether the patient is adhering to the medication recommendations, how many times a MO recommendation was made, and what was the	Interview	Baseline; 1 mo; 3 mo

		recommendation (increase vs. deprescribe)		
	Length of stay (both hospital and ICU)	The length of time elapsed between a patient's hospital admission and discharge	EHR	In-Hospital / Postoperatively
	All-cause rehospitalization	Any new admission to an acute care hospital within 30 days of discharge from the same or another acute care hospital	EHR	In-Hospital / Postoperatively; 1 mo; 3 mo
	Persistent postsurgical pain (PPSP)	Washington University PPSP Questionnaire <sup>81</sup> : Presence and intensity (at rest and on movement) of pain in the surgical area. <sup>82</sup> Pain interference with function, based on Brief Pain Inventory. <sup>83-85</sup>	Questionnaire	1 mo; 3 mo
Secondary (Process)	Patient experience	Modified-Consumer Assessment of Healthcare Providers and Systems (CAHPS). <sup>86</sup> 16 items adapted from the CAHPS Surgical Care Survey assessing patient experience prior to and following the intervention bundle.	Survey	End of Study
	Shared decision making	Shared decision-making process CollaboRATE modified <sup>87</sup> : 3-item survey modified to measure shared decision making, following encounters with study interventionists and perioperative wellness partners	Survey	End of Study
<b>System-level Implementation Outcomes</b>		<b>Specific measure: description</b>	<b>Data Source</b>	<b>Timepoint</b>
	Reach	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	EHR, Research data warehouse	End of Study
	Implementation-Potential	Acceptability, appropriateness and feasibility of the interventions: The Acceptability of Intervention Measure (AIM), the Intervention Appropriateness Measure (IAM), and the Feasibility of Intervention Measure (FIM). <sup>88</sup> Each survey has 4 items in a Likert scale ranging from completely disagree to completely agree. We will also capture the culture of each setting to understand potential determinants of successful	Surveys	End of Study



		implementation using Shortell et al. <sup>89</sup> measure.		
		CFIR-guided discussions with patients, caregivers, and clinicians to identify barriers and facilitators affecting the intervention bundle implementation process across all targeted settings and populations.	Interviews	End of Study

## Data management and analysis plan

### *Data management*

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

### *Data analysis*

Quantitative data will be tabulated for descriptive purposes and will report pre-post change and effect size with 95% confidence interval.

Observational data will be analyzed using open coding, and the FRAME analytic framework will be used to help track any adaptations to intervention bundle and delivery.<sup>59</sup> Interview data will be analyzed using an inductive-deductive thematic analysis.<sup>90</sup> After reading 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 sub-themes will be formed. Similar sub-themes 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 organized an internal advisory board with surgical patients, caregivers, clinicians (e.g., physicians, nurses, pharmacists, 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



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3 preoperative period, and enhances recovery during the postoperative period, coordinating and  
4 communicating with inpatient clinicians; and to evaluate whether the intervention methods are practical  
5 and appropriate for the patient populations and clinicians, without impacting perioperative workflow.  
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## 8 9 **ETHICS AND DISSEMINATION**

### 10 11 *Participant consents*

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13 Patients who meet all eligibility criteria and provide written informed consent will be enrolled into the  
14 study. Patient consent will be obtained via a paper collected by mail or in person, or by secure REDCap  
15 link to e-consent. Clinicians and caregivers (participating in semi-structured interviews via Zoom/Phone  
16 or in-person) will be consented verbally or with a written consent, depending on participant  
17 convenience.  
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### 23 24 *Harms*

25 This study involves minimal risk to subjects. Unlikely but potential risks include errors in medication  
26 recommendations, however, this risk is mitigated by the utilization of a multidisciplinary group of  
27 experts agreeing upon the recommendation and ongoing check points throughout the intervention  
28 process to ensure recommendations are correct and free from error. Additional risks include medication  
29 withdrawal symptoms as a result of the intervention recommendation, and breach of confidentiality. The  
30 risk of medication withdrawal (i.e., from benzodiazepines) is mitigated by slowly tapering rather than  
31 stopping these medications. If a participant endorses suicidal ideation, intent, or plan, the coordinator  
32 and Perioperative Wellness Partners are trained to follow an operationalized protocol (*see* Appendices A  
33 and B) that has been developed to manage high-risk participants in other studies of depressed  
34 participants potentially at risk for suicide. This protocol has already been used successfully by members  
35 of the research team to manage acutely suicidal patients. Patients will be encouraged to check with their  
36 physician if there is any question about the safety of any physical activities that are included in the  
37 behavioral activation plan. It is possible that the participant may feel uncomfortable completing the  
38 surveys or participating in the study sessions. The study sessions and interview can be discontinued at  
39 any time, and the patient may refuse to answer any questions that s/he does not wish to answer.  
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52 We will monitor for breaches of confidentiality and other adverse events on an ongoing basis. Once we  
53 become aware of a reportable adverse event, the event will be reported to Human Research Protection  
54 Office (HRPO) and Quality Assurance and Safety Monitoring Committee (QASMC) according to  
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3 institutional guidelines. This study does not require QASMC audit or submission of DSM reports.  
4 Should any unexpected serious adverse events occur, our study protocol will be modified to prevent  
5 other similar events.  
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### 8 9 ***Internal auditing for data quality***

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11 The research core team meets biweekly with the research coordinators and data manager to review the  
12 study report on study enrollment, recruitment, data quality and discuss the study progress and any issues  
13 raised by the participants.  
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### 16 17 ***Data safety and monitoring plan***

18  
19 The specific monitoring plan for this investigation is commensurate with the risks and the size and  
20 complexity of the studies planned. Given the nature of the protocol, the risks are likely limited to breach  
21 of confidentiality.  
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### 25 26 ***Dissemination***

27  
28 The feasibility study results will be disseminated at scientific meetings and peer-reviewed publications.  
29 Additionally, the results will be presented to our perioperative mental health internal and external  
30 advisory board consisting of patients, clinicians, nationally recognized researchers (psychiatry, health  
31 services, pain medicine), and hospital administrator stakeholder groups to determine which components  
32 of the intervention and its delivery to preserve, which adaptations to carry forward and how to advance  
33 with the randomized controlled trials. The Washington University Center for Perioperative Mental  
34 Health website (<https://perioperativewellness.wustl.edu/>) will be used to introduce the intervention  
35 bundle to patients and clinicians alike. To accelerate the dissemination efforts, the Center will use online  
36 communication channels including the Center's webpage, popular news media, social media, webinars,  
37 and patient and family community networks. As per the National Institute of Mental Health sponsor  
38 guidelines, we will also be sharing the de-identified data to ClinicalTrials.gov.  
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### 47 48 ***Trial status***

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50 This study is registered in Clinical Trials Registry NCT05110690. Recruitment commenced during the  
51 last week of November 2021, and we currently have ten patients enrolled in this feasibility study. The  
52 study is expected to conclude in November 2022.  
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## DISCUSSION & CONCLUSIONS

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, multi-morbidity with co-occurring cognitive and physical impairments, and polypharmacy that can also impact their mental health and well-being.<sup>13,91</sup>

The study protocol will adapt and test the intervention bundle comprised of behavioral activation and medication optimization 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 behavioral activation and medication optimization, 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 elements of our intervention bundle and its delivery mechanism that can be common across the three different surgical populations, and also elements 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 finalize modifications to our initial “in-progress” intervention bundle, resulting in a more patient-centered 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-centered 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

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2  
3 maintaining the core components of the bundle – leading to a higher potential for scalability and  
4 sustainability in the long term. Use of the implementation science frameworks offers us the lens  
5 to examine the feasibility and acceptability of the intervention bundle ahead of time, in order to  
6 accelerate the translation of the intervention bundle to usual care. *Lastly*, the study will inform the  
7 design and conduct of the planned randomized controlled trials in the three surgical cohorts. Before  
8 beginning these, the feasibility study provides us with an opportunity to identify and address  
9 unanticipated challenges with our study procedures including recruitment methods, engagement  
10 strategies, study design flaws, and outcome measurement challenges.

11  
12 This study comes with several limitations, similar to other feasibility trials. *First*, the sample sizes will  
13 be small as the proposed study focuses only on the evaluation of feasibility and implementation of the  
14 intervention bundle, thereby limiting the ability to detect changes in outcomes. *Second*, the study does  
15 not include a control condition, and hence we will not be making any conclusions about the intervention  
16 bundle effectiveness. *Third*, results from this study are specific to our study setting and population at an  
17 academic medical center and may not be generalized to other non-academic settings. Nevertheless, the  
18 study is an initial step to determine the impact of the intervention bundle on our primary outcomes  
19 (anxiety and depression). Our mixed-methods approach will elucidate whether the intervention bundle  
20 can practically be tested for the management of depression and anxiety in older surgical patients.  
21 Furthermore, this study will demonstrate whether it is feasible to (i) recruit, (ii) implement the  
22 intervention bundle in the perioperative period, and (iii) track the outcomes of interest, prior to  
23 conducting an RCT with a comparison group that will determine the efficacy of patient-centered  
24 intervention bundle in the three different surgical populations.

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7  
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17  
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## 48 **Figure Legend**

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51 Figure 1 - Adaptation process of the perioperative mental health (PMH) intervention bundle.  
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54 Figure 2 - Behavioral activation model for the perioperative setting.  
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3 Figure 3 - Patient recruitment paths.  
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For peer review only

- Patients
- Caregivers
- 1 Clinicians
- 2 Researchers
- 3
- 4



1. Understand needs, experiences, and preferences of older adults with anxiety and depression during the perioperative period
2. Suggest adaptations to intervention components to meet their needs

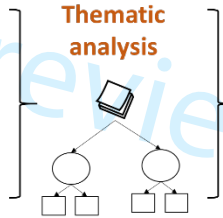
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Weekly intervention refinement meetings

- 6 Social workers
- 7 Pharmacists
- 8 Psychiatrists
- 9 Behavioral scientists
- 10
- 11



1. Discuss the application of the intervention with perioperative patients and adapt as needed
2. Ensure that core components are maintained



Intervention bundle

Patient preparedness for surgery:

Enhancing patient recovery:

Preoperative

In-hospital

Postoperative

Surgery scheduled

Day 90 post-op: intervention ends



8 Fig. 2a. Behavioral activation – symptom  
9 cycles

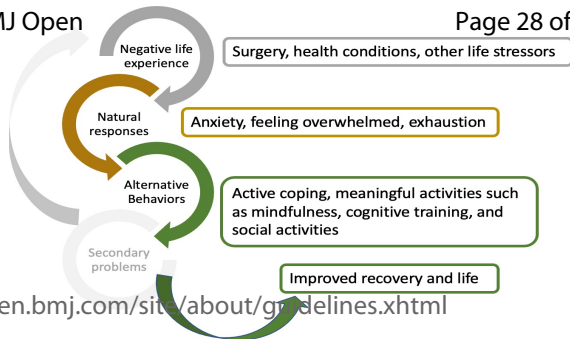
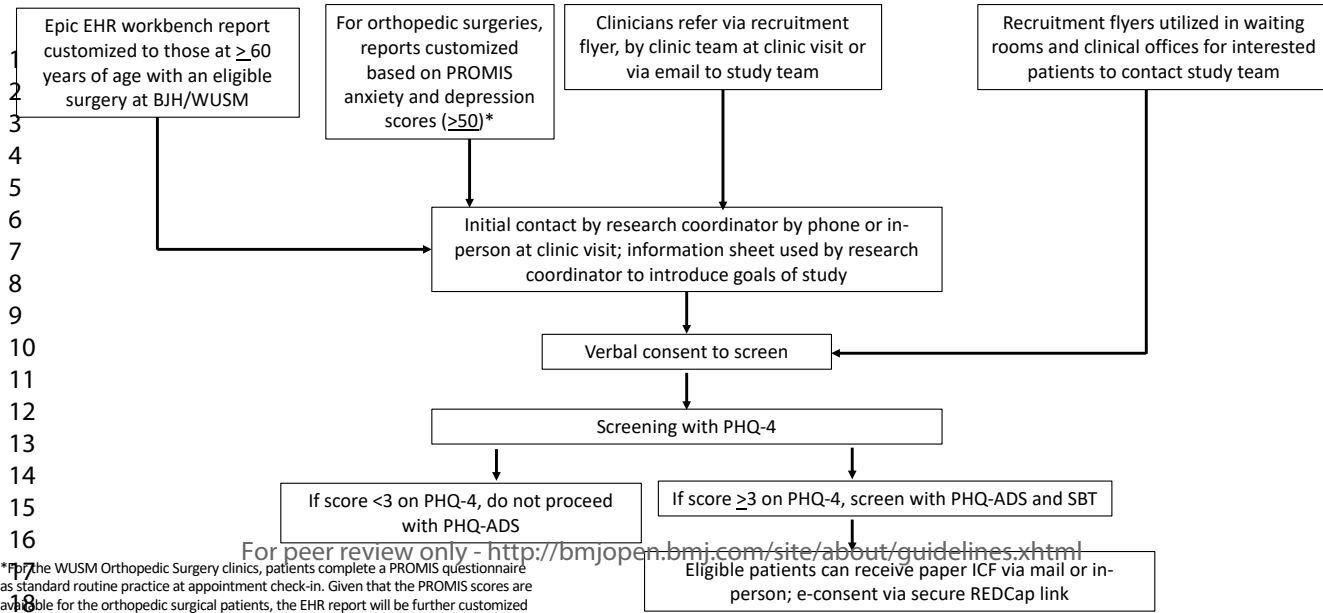


Fig. 2b. Behavioral activation – Interrupting symptom cycles

1. Epic Electronic Health Record Report

2. Clinician Referral

3. Self-referral



\* For the WUSM Orthopedic Surgery clinics, patients complete a PROMIS questionnaire as standard routine practice at appointment check-in. Given that the PROMIS scores are available for the orthopedic surgical patients, the EHR report will be further customized as needed based on PROMIS scores.

## APPENDIX A Medication Optimization Standard Operating Procedure (SOP)

### Center for Perioperative Mental Health Intervention: Medication Optimization

#### 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.

<b>MEDICATIONS WITH ANTICHOLINERGIC PROPERTIES: typically, these can be stopped abruptly</b>	
<b>Generic</b>	<b>Brand</b>
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, Levid, Levsin, Levsinex, NuLev
Imipramine	Tofranil
Meclizine	Antivert, Bonine
Orphenadrine	Norflex
Oxybutynin	Ditropan, Oxytrol
Prochlorperazine	Compazine
Promethazine	Phenergan
Pseudoephedrine HCl/Tripolidine HCl	Aprodine
Scopolamine	Transderm Scop
Tolterodine	Detrol
<b>SEDATIVES – BENZODIAZEPINES: may need tapering unless low-dose/intermittent</b>	



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

1 medication?]" "I will discuss with the medication optimization team and let you know what they  
2 recommend. Is it ok with you if we contact your doctor to discuss these changes?"  
3  
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5 **Step 5:** If the patient is taking an antidepressant eligible for dose escalation: (a) Explain that the dose of  
6 their medication may be more helpful for improving their mood and anxiety if taken at a higher dose. (b)  
7 Ask if they have ever tried taking it at a higher dose and whether they had any side effects or  
8 improvements. (c) Ask if they would have any concerns with increasing the dose. (e) Tell the patient  
9 you will discuss with the medication optimization team and return with official recommendations.(f) Get  
10 buy-in to contact the patient's PCP (and/or the prescriber of the medication).  
11

12 "I see that you are taking 75mg of venlafaxine each day, and continue to have anxiety and a low  
13 mood. Venlafaxine works better to manage those symptoms when it is taken at a higher dose,  
14 150mg. Have you ever taken venlafaxine at a dose higher than 75mg? Would you have any  
15 concerns with trying a higher dose to provide better management of your mood and anxiety? I  
16 will discuss with the medication optimization team and let you know what they recommend. Is it  
17 ok with you if we contact your doctor to discuss these changes?"  
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23 **Step 6:** Email medication list to the medication optimization contact (regardless of whether the patient  
24 appears to have any medications that are eligible for optimizing). Give any necessary details about  
25 patient experience, issues with medication compliance, resistance to stopping certain meds, perceived  
26 effectiveness, etc. Note any differences from their medication list in Epic.  
27  
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29 **Step 7:** Upon receiving instructions from the medication optimization contact, contact the patient's  
30 relevant physician (PCP in most cases) via Epic. For providers outside the WU/BJC Epic instance, a  
31 letter will be sent via fax with a call to the office to confirm receipt.  
32  
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34 **Step 8:** Communicate recommendations for medication optimization to the patient:  
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- 38 1) "As we discussed, your medications can have a huge impact on your energy, fall risk, and brain  
39 function. Our expert in medications in older adults has reviewed your list of medications and  
40 recommends stopping the Oxybutynin because it causes problems in older people. If you stop it,  
41 you will think more clearly, have more energy, and have better balance. We contacted your  
42 doctor and they are on board with this plan"  
43  
44
- 45 2) "You told me that you don't think the Oxybutynin is helping very much anyway, so you can just  
46 stop it immediately. If you notice bladder problems after stopping it, you can try taking a non-  
47 toxic alternative."  
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- 50 3) "Does this plan make sense to you? Do you have any questions?"  
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- 53 4) "Great, stopping the Oxybutynin will definitely help your energy and thinking. That'll help you  
54 towards your goal of going on evening walks with your wife."  
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## **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:

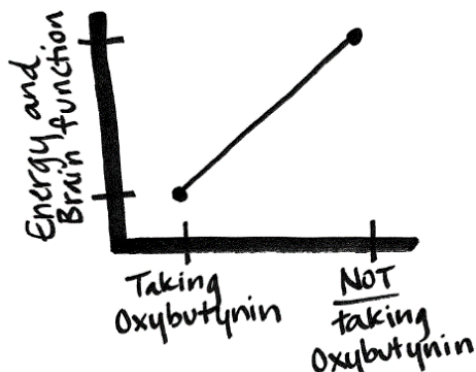
- Home visits are not required, but if they occur, they provide a good opportunity to compare the medication list to the actual medication bottles the patient has at home. Confirm that our original list is correct.
- If there are changes, check new meds against the list of medications eligible for medication 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.



1  
2 **Part C: Post-operative Check for Resuming Antidepressant Treatment**  
3

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

### Center for Perioperative Mental Health Intervention: Behavioral Activation

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 pre-operative 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 post-operative, 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 <b>negative life experiences</b> (including the upcoming surgery, and any other difficult circumstances). For context and to build upon strengths, assess and discuss <b>positive life experiences</b> (what's been going well lately).
2. Assess and discuss <b>emotional and behavioral responses</b> (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. <b>Validate</b> emotional and behavioral responses as natural, normal, common.
4. Discuss <b>symptom cycles</b> 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: <b>activation as an alternative</b> 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	1. <b>Values and long term goals:</b> find out what matters to the patient, what their aspirations are.
2	
3	2. <b>Targets for meaningful activities:</b>
4	Typically in BA, reinforcing activities – ones that are rewarding, pleasurable, meaningful and/or that
5	provide a sense of productivity or accomplishment. Another way to identify target activities is to ask
6	about personally important activities that the patient has discontinued or is doing less frequently than in
7	the past. These targets may be applicable in the perioperative setting. Targets for activities that may
8	be particularly helpful in the perioperative setting include:
9	- Activities that bring a sense of normalcy and help restore sense of identity
10	- Activities that distract from unproductive worry or rumination
11	- Activities that help with physically preparing or recovering from surgery
12	- Activities that promote social connection
13	- Activities that are cognitively engaging
14	3. <b>How activities affect mood:</b> gathering details on how the patient's real-life day-to-day activities
15	impact their mood.
16	4. <b>Avoidance:</b> assessing whether there are things the patient has been avoiding; and whether there are
17	activities that serve as an escape or distraction from difficult feelings or activities.
18	5. <b>Routine and routine disruptions:</b> learning about the patient's current and ideal daily routine
19	(sleep-wake, hygiene, eating habits, physical activity, work and/or chores) and any disruptions
20	affecting their normal routines and the reasons for disruptions. Even in the absence of routine
21	disruption pre-operatively, it is helpful to revisit post-operatively to assist in returning to healthy
22	daily routines.
23	6. <b>Current psychosocial stressors:</b> assess whether there are major current psychosocial stressors
24	impacting patient's recovery, function, and ability to carry out activity scheduling goals (e.g., acute
25	grief, financial difficulties, problematic living situation, fraught relationship with primary
26	caregiver). Always maintain focus on actions the patient can take even in difficult circumstances.
27	Activity Scheduling: collaborative process between the patient and Perioperative Wellness Partner to
28	plan for helpful activities. Activity scheduling is concrete and considers the difficulty of the task in the
29	context of the patient's life, including any acute or chronic physical limitations.
30	1. Collaboratively <b>identify activities</b> to work on
31	2. <b>Consider difficulty</b> of activity in the current context and break tasks into smaller parts if
32	needed
33	3. <b>Schedule at least one activity concretely</b> (what, where, when, with whom)
34	4. <b>Problem solve</b> any obstacles to activity completion
35	Pre-Operative Period: Ideally, both Behavioral Activation and Medication Optimization will begin
36	before surgery. This time can be used for assessment and learning the process of activity scheduling.
37	1. <b>Assess emotional and behavioral responses</b>
38	2. <b>Validate</b> emotional and behavioral responses as natural, normal, common
39	3. Assess patient's <b>primary concern</b> and goals
40	4. <b>Activity scheduling:</b> They should be actions that are the most important for the patient right
41	now, not something extra or additional. Activity scheduling can include a blend of activities
42	that focus on:
43	- Feeling prepared for surgery



<ul style="list-style-type: none"> <li>- Improving physical or emotional well-being</li> <li>- Coping with anxiety and uncertainty</li> <li>- Establishing habits to continue after surgery.</li> </ul>	
5. Assist with <b>problem-solving</b> and helping patients communicate with medical team as needed	
Operative Period: Hospitalization for surgery is very disruptive for patients and their families. BA during this period should continue to be concrete, realistic, and take into account the patient's current circumstances.	
1. <b>Assess emotional and behavioral responses</b>	
2. <b>Validate</b> emotional and behavioral responses as natural, normal, common	
3. Assess patient's <b>primary concern</b> and goals	
4. Assist with problem-solving with the patient and family and assist in communicating with their inpatient and transitional provider team if needed	
5. <b>Activity scheduling:</b> should be compatible 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, not something extra or additional.	
Post-Operative Period: Behavioral Activation at this time should assist the patient in their individual recovery, returning to meaningful activities, and in restoring their sense of self. The interventionist should be aware of the patient's discharge instructions, restrictions, and need for follow-up care.	
1. <b>Assess emotional and behavioral responses</b>	
2. <b>Validate</b> emotional and behavioral responses as natural, normal, common.	
3. Assess patient's <b>primary concern</b> and goals	
4. If there are <b>treatment goals from other disciplines</b> 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: <ul style="list-style-type: none"> <li>- Assess and problem-solve barriers</li> <li>- Clarify misunderstandings</li> <li>- Frame the importance of the treatment in the context of the patient's long-term goals and values.</li> </ul>	
5. <b>Activity scheduling:</b> should continue to be collaborative and focused on the patient's long-term goals and values. Activity scheduling can include a blend of activities that focus on: <ul style="list-style-type: none"> <li>- physical recovery</li> <li>- returning to previous functioning</li> <li>- promotion of psychological well-being.</li> </ul>	
Addressing Barriers: Through the duration of the intervention, the Perioperative Wellness Partner should assist the patient in anticipating and responding to barriers. Below is a listing of types of barriers and potential solutions.	
Barrier Type	Potential Solutions
<b>Antecedent failure</b> Not remembering at all, or not remembering at the right place and time.	<ul style="list-style-type: none"> <li>- Reminders</li> <li>- Arranging the environment</li> </ul>
<b>Skills deficit</b> Lacking the skills or knowledge that are needed to enact the behavior	<ul style="list-style-type: none"> <li>- Facilitate learning experiences for needed skills. Schedule and monitor the learning activities.</li> <li>- If problem-solving presents as a skills deficit, structured problem-solving can be done in session.</li> </ul>
<b>Social skills deficit</b> Lacking social or communication skills that are needed to enact the behavior	BA sessions can incorporate social skills training, including instruction, modeling, role-playing, and assigning real-world practice.

<p><b>Extrinsic contingency issue</b> Occurs when the desired behavior is not reinforcing, perhaps because of the behavior itself or the patient's environment.</p>	<ul style="list-style-type: none"> <li>- Premack's Principle: Reinforce a less rewarding behavior by engaging in a more enjoyable behavior afterwards.</li> <li>- In the short term, an arbitrary reward can be used.</li> </ul>
<p><b>Intrinsic contingency issue</b> Occurs when the patient avoids the desired behavior because of the emotions that it causes.</p>	<ul style="list-style-type: none"> <li>- Assist to identify avoidance triggers and patterns.</li> <li>- Validate the emotional response and avoidance as normal.</li> <li>- 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.</li> <li>- Connect the activity to the patient's goals and values.</li> <li>- Schedule concretely and break task down into manageable chunks.</li> </ul>
<p><b>Pain and/or fatigue</b> Physical pain and fatigue are common in medically ill surgical patients. Pain and fatigue may be caused the surgery, anesthesia, and co-morbid medical conditions. Anxiety, depression, and stress 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.</p>	<ul style="list-style-type: none"> <li>- Discuss pain and fatigue symptom cycles as they relate to the patient's experience.</li> <li>- Discuss activity - rest cycle (pacing) as an alternative: alternating planned activity with regular rest periods. Keep track of activity and rest periods and the impact on pain and fatigue levels.</li> </ul>
<p><b>Intervention Conclusion:</b> The study intervention is time-limited, and ends after approximately 90 days post-operatively.</p>	
<p>1. Assist the patient in identifying other supports and resources that will continue past the study period.</p>	
<p>2. Review progress and discuss what practices the patient would like to 'keep,' and address any barriers to doing so.</p>	
<p>3. Assess need for ongoing mental health treatment and assist with referrals.</p>	



# BMJ Open

## A Perioperative Mental Health Intervention Bundle for Older Surgical Patients: Protocol for an Intervention Development and Feasibility Study

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# A Perioperative Mental Health Intervention Bundle for Older Surgical Patients: Protocol for an Intervention Development and Feasibility Study

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## ABSTRACT

**Introduction:** The perioperative period is high-risk for older adults. Depression and anxiety are common perioperative problems, frequently co-existing 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 rehospitalization. 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 two-fold: first, to adapt and refine an intervention bundle comprised of behavioral activation and medication optimization to meet the needs of older adults within three surgical patient populations (i.e., orthopedic, oncologic, and cardiac); and second, to test the feasibility of study procedures and intervention bundle implementation. Quantitative data on clinical outcomes such as depression, anxiety, quality of life, delirium, falls, length of stay, hospitalization, and pain will be collected and tabulated for descriptive purposes. A hybrid inductive-deductive thematic approach will be employed to analyze qualitative 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 peer-reviewed journals, at professional conferences, and to our perioperative mental health advisory board.

### **Strengths and limitations:**

- This perioperative mental health intervention bundle comprised of behavioral activation and medication optimization 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-centered perioperative mental health intervention bundle with psychological and pharmacological optimization components.
- Our approach will provide feasibility data on whether we can (i) enroll patients, (ii) collect and refine data collection methods, (iii) implement the intervention bundle within the perioperative

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3 context, (iv) tailor the intervention bundle for the three surgical cohorts, and (v) determine  
4 whether a future randomized effectiveness-implementation trial of the intervention bundle in the  
5 perioperative setting is feasible.  
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## 8 9 **INTRODUCTION**

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11 Americans undergo an average of nine surgeries in their lifetime.<sup>1</sup> Over 51 million surgeries are  
12 performed in the United States each year, with older adults representing approximately half of all  
13 surgical patients.<sup>2</sup> The perioperative period - encompassing preoperative (before surgery), intraoperative  
14 (during surgery), and postoperative (after surgery) phases - is a high-risk and vulnerable time for older  
15 patients. Older patients are at increased risk for postoperative morbidity and mortality compared to  
16 younger adults.<sup>3-10</sup> Anxiety and depression in older surgical patients increase the risk of postoperative  
17 complications, including short-term functional dependence and falls,<sup>11</sup> postoperative delirium,<sup>12</sup> opioid  
18 misuse,<sup>13,14</sup> decreased quality-of-life,<sup>15</sup> and readmission. A meta-analysis of over 200,000 patients  
19 undergoing cardiac surgery revealed significantly increased mortality risk among individuals with  
20 perioperative depression and anxiety.<sup>16</sup>  
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30 There have been efforts to reduce perioperative risks in older adults by optimizing physical health prior  
31 to surgery (prehabilitation), implementing protocolized pathways during the surgical hospitalization, and  
32 also promoting postoperative rehabilitation (e.g., enhanced recovery). However, no corresponding  
33 perioperative interventions have been developed to address cognitive and mental health and well-being.  
34 In other words, we lack effective interventions tailored for older surgical patients, in spite of the high  
35 prevalence of depression and anxiety in this population,<sup>17</sup> frequent co-occurring cognitive impairment,  
36 and detrimental impact on surgical recovery.<sup>18</sup>  
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43 In our prior needs assessment interview study with older surgical adults diagnosed with anxiety and  
44 depression and their treating clinicians,<sup>18</sup> we found that older surgical patients had varying care  
45 experiences, depending on their symptoms in the perioperative setting. Fear and uncertainty leading into  
46 the surgery, and poor management of their depression and anxiety medications postoperatively were of  
47 key concern. Clinicians treating this population similarly noted that patients have a fear of surgery,  
48 experience acute pain, can suffer from postoperative neurocognitive disorders. They were also worried  
49 that central nervous system (CNS)-active medications could worsen outcomes, yet many patients  
50 reported taking these medications at a sub-therapeutic dose of medications for mental health, suggesting  
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3 a need to optimize their dosage. However, clinicians reported concerns that stopping these medications  
4 could lead to withdrawal symptoms, but maintaining them could worsen their cognitive and mental  
5 health impairment.  
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9 Patients and clinician stakeholders emphasized the need for a perioperative intervention bundle to  
10 address these issues and argued for a bundle encompassing psychological components that are  
11 behavioral, simple, interactive, and engaging, and pharmacotherapy components that can minimize the  
12 risk of psychiatric medication withdrawal symptoms and improper dosages during perioperative care.  
13 They also recommended that such a mental health intervention bundle would be effective if it started  
14 preoperatively to assist with preparation for surgery and continued postoperatively to enhance recovery  
15 after surgery.<sup>18</sup>  
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19 Researchers have examined the use of counseling, cognitive behavior therapy, and other psychological  
20 treatments (e.g., relaxation, mindfulness, supportive therapy) to promote the mental wellbeing of  
21 younger surgical patients.<sup>19-21</sup> For example, Li and colleagues<sup>20</sup> found that a psychological intervention  
22 provided to patients with cancer throughout the perioperative period was associated with decreased  
23 depressive symptoms and anxiety postoperatively. Similarly, research with patients undergoing  
24 orthopedic surgery suggests that perioperative psychological education and counseling improved both  
25 psychological function,<sup>21,22</sup> as well as physical function.<sup>21</sup> In addition, studies suggest that a combination  
26 of pharmacological and psychotherapy is more effective at treating anxiety and depression in older  
27 adults than monotherapy,<sup>23-28</sup> and may be considered more acceptable to older adults,<sup>25</sup> suggesting the  
28 need for an intervention bundle that combines psychotherapeutic and pharmacological treatment. Older  
29 adults often take many medications, and in the perioperative period, there is heightened risk of adverse  
30 drug reactions and drug-drug interactions.<sup>29</sup> Medication optimization and deprescription can help with  
31 reduction or elimination of potentially inappropriate medications (such as benzodiazepines), in  
32 conjunction with appropriate antidepressant dosing and continuation across outpatient and inpatient care  
33 transitions.  
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49 Our team has previously demonstrated the effectiveness of cognitive behavioral therapy (CBT) and  
50 behavioral activation for depression in medically ill populations,<sup>30-35</sup> and for anxious older adults with  
51 comorbid depression,<sup>28</sup> and also of medication optimization and deprescription for older adults<sup>36</sup> in the  
52 perioperative setting.<sup>37</sup> Informed by our prior work (*see* Table 1 for features, clinical evidence, and  
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rationale), we propose to develop a perioperative mental health intervention bundle (*hereafter referred to as the intervention bundle*) encompassing two integrated components - behavioral activation (psychotherapy), and medication optimization 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 organized 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.<sup>38,39</sup> Intervention mapping is a step-by-step process that uses activities (e.g., group discussions) and tools (e.g., 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.<sup>40</sup> 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 behavioral 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 analyzed to inform our pre-implementation adaptations to ensure effectiveness, feasibility, acceptability and overall satisfaction of the intervention bundle.

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, medication optimization was suggested for the

pharmacological component. *Third*, the term, perioperative wellness partner was formulated to refer to interventionists.

**[Insert Figure 1: Adaptation process of the perioperative mental health (PMH) intervention bundle]**

### ***Interventionists***

The interventionists, referred to as perioperative wellness partners are Masters-level clinicians trained in Behavioral Activation using the material developed by Puspitasari and colleagues.<sup>41</sup> 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 licensed clinical social worker.

**Table 1. Details on adapted perioperative mental health bundle components.**

<b>Intervention Bundle</b>	<b>Behavioral Activation</b>	<b>Medication Optimization</b>
Target	Patients	Clinicians and Patients
Interventionist	Perioperative wellness partner	Perioperative wellness partner follows an algorithm for medication optimization and works alongside with pharmacists and a geriatric psychiatrist
Description	A behavioral intervention helping depressed and anxious patients by engaging them in reinforcing activities or activities that are meaningful and guided by their personal values. <sup>42</sup>	A pharmacologic intervention to adjust suboptimal doses of antidepressants, ensure continuation of antidepressants during transitions of care, and deprescribe medications that are harmful to older adults. <sup>43,44</sup>
Features	Flexible component of cognitive behavior therapy (CBT) and standalone treatment in which the therapist helps a patient generate a list of pleasant, reinforcing activities, and co-creates action plans.  Patient-centered treatment, in which the patient chooses the modality (i.e. which activities to engage in).	Medication optimization 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 <sup>29,45,46</sup> 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 behavioral activation is about as effective as comprehensive CBT and it	Medication optimization is a cardinal rule in treatment guidelines for depression. <sup>48</sup> Antidepressants are often prescribed at subtherapeutic doses and then not adjusted for response. <sup>49</sup> Suboptimal dosing is a main



	<p>can be delivered by less highly-trained staff.</p> <p>Trials in medically ill patients have emphasized behavioral activation because it complements medically indicated physical activation and exercise goals, and it is feasible and acceptable<sup>47</sup></p>	<p>reason for these drugs' low effectiveness in the real world<sup>50</sup></p> <p>Strong centrally-acting anticholinergic and antihistaminergic drugs and benzodiazepines are "low-hanging fruit" for deprescribing as their harms outweigh benefits.<sup>51</sup> They are harmful perioperatively, increasing falls and delirium<sup>52-55</sup></p>
Core active components	<ul style="list-style-type: none"> <li>• Personalized Rationale Identification</li> <li>• Values and Goals Assessment</li> <li>• Activity Scheduling</li> <li>• Activity Monitoring</li> </ul>	<ul style="list-style-type: none"> <li>• Review of medication list by wellness partner on 1<sup>st</sup> visit prior to surgery</li> <li>• Determine the indication, duration of use, dose, and frequency of the medications of interest</li> <li>• Evaluate each medication's eligibility for optimization or deprescription</li> <li>• Discuss with medication optimization team</li> <li>• Get buy-in from patient to contact initial prescriber</li> <li>• Communicate recommendations to the patient</li> <li>• Weekly review of any new medications</li> <li>• Ensure that any medication optimization changes are reconciled during transitions of care and that the agreed-upon changes are implemented both pre-operatively and post-operatively</li> </ul>
Modifiable components	<ul style="list-style-type: none"> <li>• Selected behavioral activation activities: depending on patient needs and preferences</li> <li>• Timing: Preoperative and postoperative phases</li> <li>• Format: 1:1 session in-person/telephone/online</li> <li>• Duration: 20-30 minutes</li> <li>• Frequency: 1-4 (presurgery); 2-12 (postsurgery)</li> <li>• Setting: Home (telephone/online) and hospital</li> </ul>	<ul style="list-style-type: none"> <li>• 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</li> <li>• Format: 1:1 session in-person/telephone/online; then contact with the clinicians</li> <li>• Duration: 5 min</li> <li>• Frequency: 1-4 (pre); 2-12 (post)</li> <li>• Setting: Home (telephone/online) and hospital</li> </ul>

### ***Components of the Intervention Bundle***

#### **Behavioral Activation**

Figure 2 presents a model of behavioral activation for surgery. Behavioral activation will be practiced according to Kanter's *Behavioral Activation for Depression*.<sup>56</sup> Behavioral activation as the core intervention allows for uniformity across participants, yet enough flexibility for the actual components of behavioral activation to be individually adapted based on patient preferences. In addition to the core components of behavioral 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.<sup>57,58</sup> The behavioral activation process will be guided by the BA SOP (Appendix A) which will be adapted and calibrated as needed during the feasibility study.

**[Insert Figure 2: Behavioral activation model for the perioperative setting.]**

#### **Medication Optimization**

Patient antidepressant medications will be reviewed with the patient by the perioperative wellness partner, and based on the decision algorithm, are *optimized* by our study team of interventionists including a psychiatrist, psychologist, and pharmacists. The medication optimization process will be guided by the MO SOP (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, oncologic and orthopedic surgeries at a large academic medical center. Towards this end, we will use frameworks from implementation science to capture 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)<sup>59</sup> is a well-operationalized, multi-level determination framework derived from theory that will help us identify the determinants (i.e., 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

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3 Modifications-Expanded (FRAME)<sup>60</sup> will allow us to systematically track all adaptations to the flexible  
4 components of the intervention bundle to ensure the feasibility, fit and relevance in older surgical  
5 patients, without compromising its core components.  
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## 8 9 **Study Objectives**

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11 The study objectives are summarized below:  
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14 1. Examine the feasibility of implementing a patient-centered intervention bundle for older surgical  
15 patients with clinically significant symptoms of depression and/or anxiety.  
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- 17 2. Iteratively test and adapt the intervention bundle and the implementation plan to make it patient-  
18 centered, in response to the needs/demands of older surgical patients with clinically significant  
19 symptoms of depression and/or anxiety along the preoperative and postoperative phases.  
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- 21 3. Identify multiple stakeholder perspectives and experiences with the intervention bundle with  
22 specific emphasis on its implementation barriers, enablers, and implementation strategies to  
23 ensure its reach, uptake and sustainability in perioperative settings.  
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- 25 4. Demonstrate the fidelity, acceptability and appropriateness of the intervention bundle delivery  
26 for older surgical patients with clinically significant symptoms of depression and/or anxiety.  
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- 28 5. Assess the feasibility of study procedures including patient recruitment, screening, outcome  
29 assessments and intervention materials for older patients.  
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36 Following this study, we will evaluate the effectiveness and implementation potential of our adapted  
37 intervention bundle using a randomized controlled trial.  
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## 39 40 **METHODS**

### 41 42 *Study design and approach*

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44 A mixed methods (Quant+Qual) approach supported by a parallel convergent study design will be  
45 followed- this will allow us to collect quantitative and qualitative data simultaneously and merge the  
46 data in order to compare and interpret together.<sup>61</sup> Quantitative data on anxiety and depression, quality of  
47 life, in-hospital delirium incidence, post-discharge falls, medications, length of stay, all-cause  
48 rehospitalization, pain, patient experience, and shared decision-making will be collected. Qualitative  
49 surveys and interviews will help us to assess participants' feedback and experiences about factors  
50 affecting implementation and use of the bundle.  
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### *Study participants and recruitment procedure*

Patient participants include older adults undergoing cardiac, orthopedic 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 US. We will also invite their caregivers to participate in this study. Table 2 provides information about the expected enrollment numbers, inclusion criteria, and exclusion criteria of participants.

**Table 2. Enrollment, inclusion criteria, and exclusion criteria by type of participant.**

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

Participant Type	Expected Enrollment	Inclusion Criteria	Exclusion Criteria**
Patients	8-10 cardiac surgery patients	<ul style="list-style-type: none"> <li>• <math>\geq 60</math> years of age on the day of surgery</li> <li>• Scheduled major orthopedic surgery, or major surgical resection of a thoracic or abdominal malignancy, or major cardiac procedure</li> <li>• Clinically significant depression or anxiety symptoms screened by the Patient Health Questionnaire Anxiety and Depression Scale<sup>62</sup> <math>\geq 10^*</math></li> </ul>	<ul style="list-style-type: none"> <li>• Estimated life expectancy &lt; 12 months</li> <li>• Unable to read, speak, and understand English</li> <li>• Current alcohol or other substance abuse</li> <li>• Severe cognitive impairment screened by the Short Blessed Test &gt;10</li> <li>• Acutely suicidal</li> </ul>
	8-10 orthopedic surgery patients		
	8-10 oncologic surgery patients		
Caregivers	24-30 caregivers will be recruited alongside patient participants	<ul style="list-style-type: none"> <li>• Identified by patient as a family member or friend who cares for the patient as needed to support health and safety</li> </ul>	<ul style="list-style-type: none"> <li>• Age <math>\leq 18</math> years</li> </ul>

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

**[Insert Figure 3: Patient recruitment paths.]**

With the patients' consent, caregiver participants will be recruited via 2 paths: patient referral to either contact the study team or if share the caregiver's phone number such that the study team will contact caregivers by phone, or mail and invite them.

### *Assessment measures*

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3 At enrollment, a research coordinator will administer a battery of assessments to characterize patient  
4 participants and their current condition.  
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#### 7 Patient baseline measures

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10 *Demographics:* The following characteristics will be collected: age, sex, race/ethnicity, education level,  
11 employment status, psychiatric diagnosis, substance use, and psychotropic medications.  
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14 *Medical history of comorbidities:* Patient medical history and comorbidities will also be collected.  
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17 *Pain:* The Brief Pain Inventory (BPI) is a well-validated 11-item measure of pain severity and  
18 interference in pain,<sup>63-68</sup> including after orthopedic,<sup>69</sup> oncologic,<sup>70</sup> and cardiac surgery.<sup>71</sup> Three questions  
19 from the BPI will be used to assess pain, including whether the patient is diagnosed with chronic pain,  
20 whether they experience pain daily in the past 3 months, and if they have been experiencing pain in the  
21 past week related or unrelated to their surgery.  
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27 *SBT (Short Blessed Test):* The SBT, sometimes called the Orientation-Memory-Concentration Test, is a  
28 6-item scale frequently used to assess dementia within patients across 3 dimensions: orientation,  
29 registration, and attention. The SBT has demonstrated good test-retest reliability.<sup>72</sup>  
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33 *UB-CAM (Ultra-Brief Confusion Assessment Method):* This 2-item test<sup>73</sup> is used for a quick assessment  
34 of delirium using items from the 3D-CAM (3-minute diagnostic interview for confusion assessment  
35 method).<sup>74</sup> Patients are asked to state the day of the week and months of the year backwards.  
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39 *Medication list:* The perioperative wellness partner will review the patients' medications from the EHR  
40 and confirmed with the patient at the initial intervention visit, capturing the medication name, dose,  
41 units, frequency, start date, stop date, and indication, where appropriate.  
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#### 45 Intervention adaptation measures

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47 *Intervention fidelity:* Data related to intervention fidelity to examine the extent to which an intervention  
48 bundle is carried out by our perioperative wellness partner as intended and consistently across different  
49 settings, and patients will be tracked as adherence to core components of the intervention bundle, quality  
50 of delivery, and participant responsiveness.<sup>75</sup> All sessions will be audio recorded and reviewed by the  
51 supervising perioperative wellness partner (i.e., trained in intervention bundle and is fidelity certified).  
52 Additionally, all intervention sessions will be reviewed and rated for fidelity by a team of researchers  
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with training in the intervention bundle (licensed SW 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.<sup>60</sup> 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) a periodic reflection meeting led by implementation scientists with the wellness partners where they will be asked to reflect upon any modifications made deliberately and proactively, in response to unanticipated challenges in a given session or context.

The Behavioral Activation for Depression Scale,<sup>76</sup> or BADS, is our measure of target engagement. The BADS is a 25-item questionnaire across 4 subscales: Activation, Avoidance/Rumination, Work/School Impairment, and Social Impairment. It is frequently used to measure changes in behavioral 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 (i.e., primary outcome), the feasibility of collecting depression and anxiety outcome planned for our randomized control trial (i.e., secondary outcome) and implementation-potential of intervention bundle and other outcomes such as quality of life, readmissions (i.e., 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 randomized controlled trial studies.

**Table 3. Feasibility study outcomes and potential study primary and secondary outcomes for planned RCT.** Note: The surveys and questionnaires will be administered via email or research coordinators over the telephone.

Outcomes	Specific measure: description	Source	Timepoint
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1 2 3 4 5 6 7 8 9 10	Reach ( <i>Primary</i> )	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, Research data warehouse	End of Study
11 12 13 14 15 16 17 18	Completeness of planned RCT primary outcome data collection at specified timepoints ( <i>Secondary</i> )	Defined as a percentage of instrument or data fields completed for- Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS) <sup>62</sup> : 16-item scale with components of the Patient Health Questionnaire-9 and Generalized Anxiety Disorder Scale (collected at baseline; 1 mo; 3 mo)	Research data warehouse	End of Study
19 20 21 22 23 24 25 26 27 28 29 30	Implementation-Potential ( <i>Exploratory</i> )	Acceptability, appropriateness and feasibility of the interventions: The Acceptability of Intervention Measure (AIM), the Intervention Appropriateness Measure (IAM), and the Feasibility of Intervention Measure (FIM). <sup>77</sup> Each survey has 4 items in a Likert scale ranging from completely disagree to completely agree. We will also capture the culture of each setting to understand potential determinants of successful implementation using Shortell et al. <sup>78</sup> measure.	Surveys	End of Study
31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54	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: <ul style="list-style-type: none"> <li>• Quality of Life (collected at baseline; 1 mo; 3 mo)</li> <li>• In-hospital delirium incidence (collected at baseline; in-hospital/postoperatively)</li> <li>• Post-discharge falls (collected at baseline; 1 mo; 2 mo; 3 mo)</li> <li>• Medication optimized and adherence to medications(collected at baseline; 1 mo; 3 mo)</li> <li>• Length of stay (both hospital and ICU)</li> <li>• All-cause rehospitalization (collected in the hospital/postoperatively; 1 mo; 3 mo)</li> <li>• Persistent postsurgical pain (collected at 1 mo; 3 mo)</li> <li>• Patient experience (collected at end of study)</li> <li>• Shared decision making (collected at end of study)</li> </ul>	Research data warehouse	End of Study



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3 To obtain participant perspectives on the intervention bundle, we will conduct semi-structured  
4 interviews with patients and caregivers and the topics of discussions will be guided by the CFIR  
5 constructs. The interviews will explore the participants' perceptions, attitudes, and experiences with the  
6 intervention bundle, intervention bundle acceptability and detailed accounts of participants' experiences  
7 after the intervention has been stopped with regards to intervention sustainability and maintenance.  
8 These insights will inform whether the intervention bundle needs to be changed or adapted before our  
9 future trials. Interviews will be conducted via Zoom or telephone and will be digitally recorded and  
10 transcribed verbatim.  
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## 17 **Data management and analysis plan**

### 18 ***Data management***

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20 This study will be conducted under appropriate Washington University Institutional Review Board  
21 (IRB) guidance, and use only IRB-approved study procedures and instruments. A unique patient number  
22 (UPN) will be assigned at enrollment and used wherever possible on the case report forms (CRF) to  
23 identify data, minimizing use of patients' names or personal identifiers in data.  
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### 30 ***Data analysis***

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32 Quantitative data collected for the outcome measures for the feasibility study will be tallied and  
33 summarized using descriptive statistics. Completion of data collection will be described as a percentage  
34 of the instruments completed. The primary outcome of anxiety and depression for the planned RCT will  
35 be tabulated for descriptive purposes.  
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40 Fidelity and adaptation data will be analyzed using open coding, and the FRAME analytic framework to  
41 help track any adaptations to intervention bundle and delivery.<sup>60</sup> Interview data will be analyzed using  
42 an inductive-deductive thematic analysis.<sup>79</sup> After reading transcripts multiple times for familiarity,  
43 research team members will openly code using data-driven codes and then using CFIR-driven codes.  
44 Codes will be compared across the data to identify repeated and interrelated concepts and categories,  
45 and sub-themes will be formed. Similar sub-themes will be grouped over multiple rounds of review to  
46 generate overarching themes out of significant patterns between interviews.  
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### 53 ***Patient and public involvement***

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3 In preparation for this study, we organized an internal advisory board with surgical patients, caregivers,  
4 clinicians (e.g., physicians, nurses, pharmacists, social workers), and institutional leaders focused on  
5 patient experience to adapt our intervention bundle. Through the internal advisory board meetings, we  
6 sought to ensure that the intervention bundle facilitates patient preparedness for surgery during the  
7 preoperative period, and enhances recovery during the postoperative period, coordinating and  
8 communicating with inpatient clinicians; and to evaluate whether the intervention methods are practical  
9 and appropriate for the patient populations and clinicians, without affecting perioperative workflow.  
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## 16 **ETHICS AND DISSEMINATION**

### 17 *Participant consents*

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19 Patients who meet all eligibility criteria and provide written informed consent will be enrolled into the  
20 study. Patient consent will be obtained via a paper collected by mail or in person, or by secure REDCap  
21 link to e-consent. Caregivers (participating in semi-structured interviews via Zoom/Phone or in-person)  
22 will be consented verbally or with a written consent, depending on participant convenience.  
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### 28 *Harms*

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30 This study involves minimal risk to subjects. Unlikely but potential risks include errors in medication  
31 recommendations, however, this risk is mitigated by the utilization of a multidisciplinary group of  
32 experts agreeing upon the recommendation and ongoing check points throughout the intervention  
33 process to ensure recommendations are correct and free from error. Additional risks include medication  
34 withdrawal symptoms as a result of the intervention recommendation, and breach of confidentiality. The  
35 risk of medication withdrawal (i.e., from benzodiazepines) is mitigated by slowly tapering rather than  
36 stopping these medications. If a participant endorses suicidal ideation, intent, or plan, the coordinator  
37 and perioperative wellness partners are trained to follow an operationalized protocol (*see* Appendices A  
38 and B) that has been developed to manage high-risk participants in other studies of depressed  
39 participants potentially at risk for suicide. This protocol has already been used successfully by members  
40 of the research team to manage acutely suicidal patients. Patients will be encouraged to check with their  
41 physician if there is any question about the safety of any physical activities that are included in the  
42 behavioral activation plan. It is possible that the participant may feel uncomfortable completing the  
43 surveys or participating in the study sessions. The study sessions and interview can be discontinued at  
44 any time, and the patient may refuse to answer any questions that s/he does not wish to answer.  
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3 We will monitor for breaches of confidentiality and other adverse events on an ongoing basis. Once we  
4 become aware of a reportable adverse event, the event will be reported to Human Research Protection  
5 Office (HRPO) and Quality Assurance and Safety Monitoring Committee (QASMC) according to  
6 institutional guidelines. This study does not require QASMC audit or submission of DSM reports.  
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8 Should any unexpected serious adverse events occur, our study protocol will be modified to prevent  
9 other similar events.  
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### 13 14 ***Internal auditing for data quality***

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16 The methodology core team meets biweekly with the research coordinators and data manager to review  
17 the study report on study enrollment, recruitment, monitor data quality and discuss the study progress  
18 and any issues raised by the participants.  
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### 22 23 ***Data safety and monitoring plan***

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25 The specific monitoring plan for this investigation is commensurate with the risks and the size and  
26 complexity of the studies planned. Given the nature of the protocol, the risks are likely limited to breach  
27 of confidentiality.  
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### 31 32 ***Dissemination***

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34 The feasibility study results will be disseminated at scientific meetings and peer-reviewed publications.  
35 Additionally, the results will be presented to our perioperative mental health internal and external  
36 advisory board consisting of patients, clinicians, nationally recognized researchers (psychiatry, health  
37 services, pain medicine), and hospital administrator stakeholder groups to determine which components  
38 of the intervention and its delivery to preserve, which adaptations to carry forward and how to advance  
39 with the randomized controlled trials. The Washington University Center for Perioperative Mental  
40 Health website (<https://perioperativewellness.wustl.edu/>) will be used to introduce the intervention  
41 bundle to patients and clinicians alike. To accelerate the dissemination efforts, the Center will use online  
42 communication channels including the Center's webpage, popular news media, social media, webinars,  
43 and patient and family community networks. As per the National Institute of Mental Health sponsor  
44 guidelines, we will also be sharing the de-identified data to ClinicalTrials.gov.  
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### 53 54 ***Trial status***

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3 This study is registered in Clinical Trials Registry NCT05110690. Recruitment commenced during the  
4 last week of November 2021 and the enrollment is expected to conclude in November 2022.  
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## 7 **DISCUSSION**

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10 To our knowledge, the proposed perioperative mental health bundle will be the first of its kind to assist  
11 older surgical patients in managing their perioperative mental health. Current interventions need to be  
12 adapted and tested for older surgical patients – who face additional unique challenges such as frailty,  
13 multi-morbidity with co-occurring cognitive and physical impairments, and polypharmacy that can also  
14 impact their mental health and well-being.<sup>11,80</sup>  
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19 The study protocol will adapt the intervention bundle comprised of behavioral activation and medication  
20 optimization and provide evidence on the feasibility of testing the bundle as a potential intervention for  
21 anxiety and depression in older surgical patients. In addition, this study will provide feasibility data on  
22 implementing the bundle successfully within perioperative settings. Despite the empirical evidence  
23 available on behavioral activation and medication optimization, there are unique challenges to using and  
24 implementing these interventions for the perioperative population of older adults, in perioperative  
25 settings notable for their complexity. To the best of our knowledge, the protocol is the first to adapt and  
26 examine the feasibility of the intervention bundle within the perioperative setting for older surgical  
27 patients. We will identify components of our intervention bundle and its delivery mechanism that can be  
28 common across the three different surgical populations, and also components that are unique for a  
29 particular population, and further for a particular patient, based on their surgical pathways.  
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39 Results from this mixed method study will inform the following: *First*, findings related to experiences in  
40 participating in the intervention bundle, along with intervention fidelity and adaptation tracking will  
41 allow us to finalize modifications to our initial “in-progress” intervention bundle, resulting in a more  
42 patient-centered bundle that meets the needs and preferences of our diverse patients. *Second*, findings  
43 will determine if the components of the intervention bundle are feasible to be delivered in three very  
44 different settings in terms of dose, timing and duration of intervention. *Third*, findings will lead to an  
45 adapted intervention standard of procedure (SOP) that can guide the delivery of the intervention bundle  
46 by perioperative wellness partners, and one that can be tested for fidelity in our future effectiveness-  
47 implementation RCT. *Fourth*, findings will offer an initial roadmap for adapting and implementing  
48 patient-centered mental health interventions that are likely to be accepted and used by multiple  
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3 stakeholders in the future. The intervention bundle adaptations performed in this study can be flexible  
4 enough and tailored based on patient needs/surgical conditions in diverse surgical settings while also  
5 maintaining the core components of the bundle – leading to a higher potential for scalability and  
6 sustainability in the long term. Use of the implementation science frameworks offers us the lens  
7 to examine the feasibility and acceptability of the intervention bundle ahead of time, in order to  
8 accelerate the translation of the intervention bundle to usual care. *Lastly*, the study will inform the  
9 design and conduct of the planned randomized controlled trials in the three surgical cohorts. This study  
10 provides us with an opportunity to identify and address unanticipated challenges with our study  
11 procedures including recruitment methods, engagement strategies, study design flaws, and outcome  
12 measurement challenges.  
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21 This study comes with several limitations, similar to other feasibility trials. *First*, the sample sizes will  
22 be small as the proposed study focuses only on the evaluation of feasibility and implementation-  
23 potential of the intervention bundle, thereby limiting the ability to detect changes in outcomes. *Second*,  
24 the study does not include a control condition, and hence we will not be making any conclusions about  
25 the intervention bundle effectiveness. *Third*, results from this study are specific to our study setting and  
26 population at an academic medical center and may not be generalized to other non-academic settings.  
27 Nevertheless, this study will demonstrate whether it is feasible to (i) recruit, (ii) implement the  
28 intervention bundle in the perioperative period, and (iii) track the outcomes of interest, prior to  
29 conducting an RCT with a comparison group that will determine the efficacy of patient-centered  
30 intervention bundle in the three different surgical populations.  
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2  
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4 intervention bundle and their constructive feedback.  
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7  
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10 the protocol and approved the final version of the protocol submission.  
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24

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## 21 **Figure Legend**

22 Figure 1 - Adaptation process of the perioperative mental health (PMH) intervention bundle.  
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24 Figure 2 - Behavioral activation model for the perioperative setting.  
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27 Figure 3 - Patient recruitment paths.  
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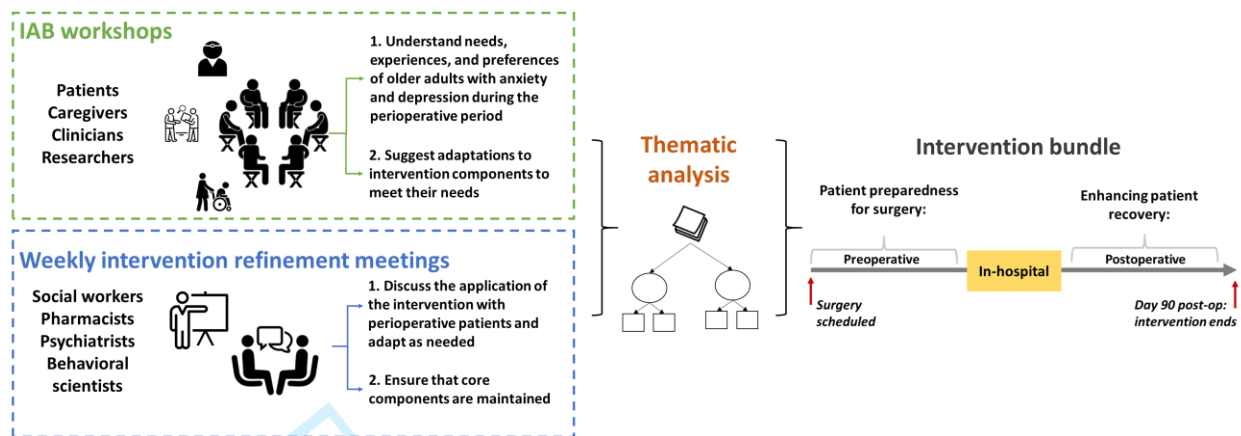




Fig. 2a. Behavioral activation – symptom cycles



Fig. 2b. Behavioral activation – Interrupting symptom cycles

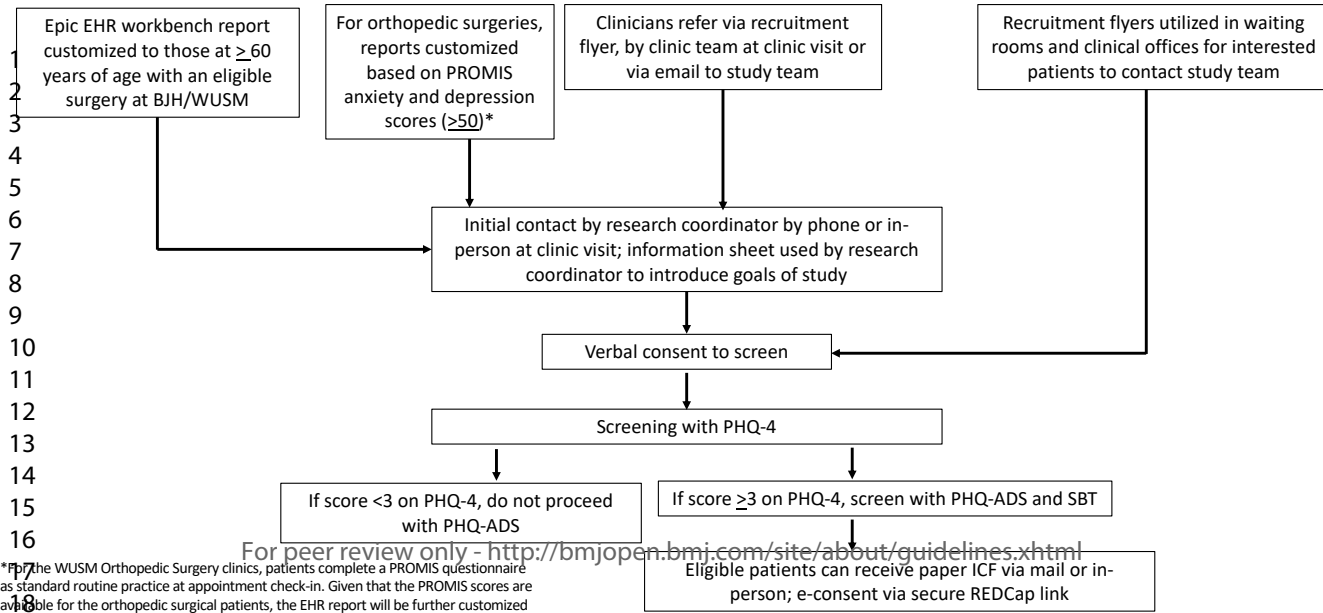
For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>



Recruitment Paths  
BMJ Open  
2. Clinician Referral

1. Epic Electronic Health Record Report

3. Self-referral



For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>

\* For the WUSM Orthopedic Surgery clinics, patients complete a PROMIS questionnaire as standard routine practice at appointment check-in. Given that the PROMIS scores are available for the orthopedic surgical patients, the EHR report will be further customized as needed based on PROMIS scores.

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## APPENDIX A Behavioral Activation Standard Operating Procedure (SOP)

### Center for Perioperative Mental Health Intervention: Behavioral Activation

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 pre-operative 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 post-operative, 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 <b>negative life experiences</b> (including the upcoming surgery, and any other difficult circumstances). For context and to build upon strengths, assess and discuss <b>positive life experiences</b> (what's been going well lately).
2. Assess and discuss <b>emotional and behavioral responses</b> (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. <b>Validate</b> emotional and behavioral responses as natural, normal, common.
4. Discuss <b>symptom cycles</b> 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: <b>activation as an alternative</b> 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	1. <b>Values and long term goals:</b> find out what matters to the patient, what their aspirations are.
2	
3	2. <b>Targets for meaningful activities:</b>
4	Typically in BA, reinforcing activities – ones that are rewarding, pleasurable, meaningful and/or that
5	provide a sense of productivity or accomplishment. Another way to identify target activities is to ask
6	about personally important activities that the patient has discontinued or is doing less frequently than in
7	the past. These targets may be applicable in the perioperative setting. Targets for activities that may
8	be particularly helpful in the perioperative setting include:
9	- Activities that bring a sense of normalcy and help restore sense of identity
10	- Activities that distract from unproductive worry or rumination
11	- Activities that help with physically preparing or recovering from surgery
12	- Activities that promote social connection
13	- Activities that are cognitively engaging
14	3. <b>How activities affect mood:</b> gathering details on how the patient's real-life day-to-day activities
15	impact their mood.
16	4. <b>Avoidance:</b> assessing whether there are things the patient has been avoiding; and whether there are
17	activities that serve as an escape or distraction from difficult feelings or activities.
18	5. <b>Routine and routine disruptions:</b> learning about the patient's current and ideal daily routine
19	(sleep-wake, hygiene, eating habits, physical activity, work and/or chores) and any disruptions
20	affecting their normal routines and the reasons for disruptions. Even in the absence of routine
21	disruption pre-operatively, it is helpful to revisit post-operatively to assist in returning to healthy
22	daily routines.
23	6. <b>Current psychosocial stressors:</b> assess whether there are major current psychosocial stressors
24	impacting patient's recovery, function, and ability to carry out activity scheduling goals (e.g., acute
25	grief, financial difficulties, problematic living situation, fraught relationship with primary
26	caregiver). Always maintain focus on actions the patient can take even in difficult circumstances.
27	Activity Scheduling: collaborative process between the patient and Perioperative Wellness Partner to
28	plan for helpful activities. Activity scheduling is concrete and considers the difficulty of the task in the
29	context of the patient's life, including any acute or chronic physical limitations.
30	1. Collaboratively <b>identify activities</b> to work on
31	2. <b>Consider difficulty</b> of activity in the current context and break tasks into smaller parts if
32	needed
33	3. <b>Schedule at least one activity concretely</b> (what, where, when, with whom)
34	4. <b>Problem solve</b> any obstacles to activity completion
35	Pre-Operative Period: Ideally, both Behavioral Activation and Medication Optimization will begin
36	before surgery. This time can be used for assessment and learning the process of activity scheduling.
37	1. <b>Assess emotional and behavioral responses</b>
38	2. <b>Validate</b> emotional and behavioral responses as natural, normal, common
39	3. Assess patient's <b>primary concern</b> and goals
40	4. <b>Activity scheduling:</b> They should be actions that are the most important for the patient right
41	now, not something extra or additional. Activity scheduling can include a blend of activities
42	that focus on:
43	- Feeling prepared for surgery

<ul style="list-style-type: none"> <li>- Improving physical or emotional well-being</li> <li>- Coping with anxiety and uncertainty</li> <li>- Establishing habits to continue after surgery.</li> </ul>	
5. Assist with <b>problem-solving</b> and helping patients communicate with medical team as needed	
Operative Period: Hospitalization for surgery is very disruptive for patients and their families. BA during this period should continue to be concrete, realistic, and take into account the patient's current circumstances.	
1. <b>Assess emotional and behavioral responses</b>	
2. <b>Validate</b> emotional and behavioral responses as natural, normal, common	
3. Assess patient's <b>primary concern</b> and goals	
4. Assist with problem-solving with the patient and family and assist in communicating with their inpatient and transitional provider team if needed	
5. <b>Activity scheduling:</b> should be compatible 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, not something extra or additional.	
Post-Operative Period: Behavioral Activation at this time should assist the patient in their individual recovery, returning to meaningful activities, and in restoring their sense of self. The interventionist should be aware of the patient's discharge instructions, restrictions, and need for follow-up care.	
1. <b>Assess emotional and behavioral responses</b>	
2. <b>Validate</b> emotional and behavioral responses as natural, normal, common.	
3. Assess patient's <b>primary concern</b> and goals	
4. If there are <b>treatment goals from other disciplines</b> 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: <ul style="list-style-type: none"> <li>- Assess and problem-solve barriers</li> <li>- Clarify misunderstandings</li> <li>- Frame the importance of the treatment in the context of the patient's long-term goals and values.</li> </ul>	
5. <b>Activity scheduling:</b> should continue to be collaborative and focused on the patient's long-term goals and values. Activity scheduling can include a blend of activities that focus on: <ul style="list-style-type: none"> <li>- physical recovery</li> <li>- returning to previous functioning</li> <li>- promotion of psychological well-being.</li> </ul>	
Addressing Barriers: Through the duration of the intervention, the Perioperative Wellness Partner should assist the patient in anticipating and responding to barriers. Below is a listing of types of barriers and potential solutions.	
Barrier Type	Potential Solutions
<b>Antecedent failure</b> Not remembering at all, or not remembering at the right place and time.	<ul style="list-style-type: none"> <li>- Reminders</li> <li>- Arranging the environment</li> </ul>
<b>Skills deficit</b> Lacking the skills or knowledge that are needed to enact the behavior	<ul style="list-style-type: none"> <li>- Facilitate learning experiences for needed skills. Schedule and monitor the learning activities.</li> <li>- If problem-solving presents as a skills deficit, structured problem-solving can be done in session.</li> </ul>
<b>Social skills deficit</b> Lacking social or communication skills that are needed to enact the behavior	BA sessions can incorporate social skills training, including instruction, modeling, role-playing, and assigning real-world practice.

<p><b>Extrinsic contingency issue</b> Occurs when the desired behavior is not reinforcing, perhaps because of the behavior itself or the patient's environment.</p>	<ul style="list-style-type: none"> <li>- Premack's Principle: Reinforce a less rewarding behavior by engaging in a more enjoyable behavior afterwards.</li> <li>- In the short term, an arbitrary reward can be used.</li> </ul>
<p><b>Intrinsic contingency issue</b> Occurs when the patient avoids the desired behavior because of the emotions that it causes.</p>	<ul style="list-style-type: none"> <li>- Assist to identify avoidance triggers and patterns.</li> <li>- Validate the emotional response and avoidance as normal.</li> <li>- 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.</li> <li>- Connect the activity to the patient's goals and values.</li> <li>- Schedule concretely and break task down into manageable chunks.</li> </ul>
<p><b>Pain and/or fatigue</b> Physical pain and fatigue are common in medically ill surgical patients. Pain and fatigue may be caused the surgery, anesthesia, and co-morbid medical conditions. Anxiety, depression, and stress 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.</p>	<ul style="list-style-type: none"> <li>- Discuss pain and fatigue symptom cycles as they relate to the patient's experience.</li> <li>- Discuss activity - rest cycle (pacing) as an alternative: alternating planned activity with regular rest periods. Keep track of activity and rest periods and the impact on pain and fatigue levels.</li> </ul>
<p><b>Intervention Conclusion:</b> The study intervention is time-limited, and ends after approximately 90 days post-operatively.</p>	
<p>1. Assist the patient in identifying other supports and resources that will continue past the study period.</p>	
<p>2. Review progress and discuss what practices the patient would like to 'keep,' and address any barriers to doing so.</p>	
<p>3. Assess need for ongoing mental health treatment and assist with referrals.</p>	

## APPENDIX B Medication Optimization Standard Operating Procedure (SOP)

### Center for Perioperative Mental Health Intervention: Medication Optimization

#### 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.

<b>MEDICATIONS WITH ANTICHOLINERGIC PROPERTIES: typically, these can be stopped abruptly</b>	
<b>Generic</b>	<b>Brand</b>
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, Levsin, Levsinex, NuLev
Imipramine	Tofranil
Meclizine	Antivert, Bonine
Orphenadrine	Norflex
Oxybutynin	Ditropan, Oxytrol
Prochlorperazine	Compazine
Promethazine	Phenergan
Pseudoephedrine HCl/Tripolidine HCl	Aprodine
Scopolamine	Transderm Scop
Tolterodine	Detrol
<b>SEDATIVES – BENZODIAZEPINES: may need tapering unless low-dose/intermittent</b>	

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



1 medication?]" "I will discuss with the medication optimization team and let you know what they  
2 recommend. Is it ok with you if we contact your doctor to discuss these changes?"  
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5 **Step 5:** If the patient is taking an antidepressant eligible for dose escalation: (a) Explain that the dose of  
6 their medication may be more helpful for improving their mood and anxiety if taken at a higher dose. (b)  
7 Ask if they have ever tried taking it at a higher dose and whether they had any side effects or  
8 improvements. (c) Ask if they would have any concerns with increasing the dose. (e) Tell the patient  
9 you will discuss with the medication optimization team and return with official recommendations.(f) Get  
10 buy-in to contact the patient's PCP (and/or the prescriber of the medication).  
11

12 "I see that you are taking 75mg of venlafaxine each day, and continue to have anxiety and a low  
13 mood. Venlafaxine works better to manage those symptoms when it is taken at a higher dose,  
14 150mg. Have you ever taken venlafaxine at a dose higher than 75mg? Would you have any  
15 concerns with trying a higher dose to provide better management of your mood and anxiety? I  
16 will discuss with the medication optimization team and let you know what they recommend. Is it  
17 ok with you if we contact your doctor to discuss these changes?"  
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23 **Step 6:** Email medication list to the medication optimization contact (regardless of whether the patient  
24 appears to have any medications that are eligible for optimizing). Give any necessary details about  
25 patient experience, issues with medication compliance, resistance to stopping certain meds, perceived  
26 effectiveness, etc. Note any differences from their medication list in Epic.  
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29 **Step 7:** Upon receiving instructions from the medication optimization contact, contact the patient's  
30 relevant physician (PCP in most cases) via Epic. For providers outside the WU/BJC Epic instance, a  
31 letter will be sent via fax with a call to the office to confirm receipt.  
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34 **Step 8:** Communicate recommendations for medication optimization to the patient:  
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- 38 1) "As we discussed, your medications can have a huge impact on your energy, fall risk, and brain  
39 function. Our expert in medications in older adults has reviewed your list of medications and  
40 recommends stopping the Oxybutynin because it causes problems in older people. If you stop it,  
41 you will think more clearly, have more energy, and have better balance. We contacted your  
42 doctor and they are on board with this plan"  
43  
44
- 45 2) "You told me that you don't think the Oxybutynin is helping very much anyway, so you can just  
46 stop it immediately. If you notice bladder problems after stopping it, you can try taking a non-  
47 toxic alternative."  
48  
49
- 50 3) "Does this plan make sense to you? Do you have any questions?"  
51  
52
- 53 4) "Great, stopping the Oxybutynin will definitely help your energy and thinking. That'll help you  
54 towards your goal of going on evening walks with your wife."  
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## **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:

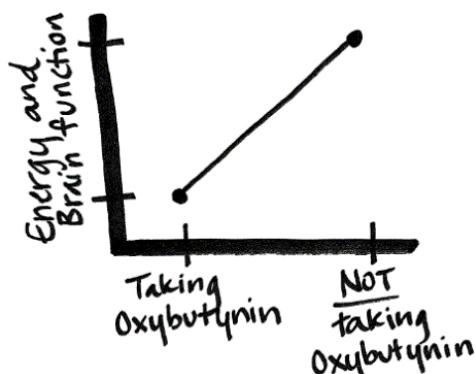
- Home visits are not required, but if they occur, they provide a good opportunity to compare the medication list to the actual medication bottles the patient has at home. Confirm that our original list is correct.
- If there are changes, check new meds against the list of medications eligible for medication 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.



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2 **Part C: Post-operative Check for Resuming Antidepressant Treatment**  
3

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

## A Perioperative Mental Health Intervention Bundle for Older Surgical Patients: Protocol for an Intervention Development and Feasibility Study

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# A Perioperative Mental Health Intervention Bundle for Older Surgical Patients: Protocol for an Intervention Development and Feasibility Study

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## ABSTRACT

**Introduction:** The perioperative period is high-risk for older adults. Depression and anxiety are common perioperative problems, frequently co-existing 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 rehospitalization. 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 two-fold: first, to adapt and refine an intervention bundle comprised of behavioral activation and medication optimization to meet the needs of older adults within three surgical patient populations (i.e., orthopedic, oncologic, and cardiac); and second, to test the feasibility of study procedures and intervention bundle implementation. Quantitative data on clinical outcomes such as depression, anxiety, quality of life, delirium, falls, length of stay, hospitalization, and pain will be collected and tabulated for descriptive purposes. A hybrid inductive-deductive thematic approach will be employed to analyze qualitative 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 peer-reviewed journals, at professional conferences, and to our perioperative mental health advisory board.

### **Strengths and limitations:**

- This perioperative mental health intervention bundle comprised of behavioral activation and medication optimization 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-centered perioperative mental health intervention bundle with psychological and pharmacological optimization components.
- Our approach will provide feasibility data on whether we can (i) enroll patients, (ii) collect and refine data collection methods, (iii) implement the intervention bundle within the perioperative

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3 context, (iv) tailor the intervention bundle for the three surgical cohorts, and (v) determine  
4 whether a future randomized effectiveness-implementation trial of the intervention bundle in the  
5 perioperative setting is feasible.  
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9 **Trial Registration number:** NCT05110690  
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For peer review only



## INTRODUCTION

Americans undergo an average of nine surgeries in their lifetime.<sup>1</sup> Over 51 million surgeries are performed in the United States each year, with older adults representing approximately half of all surgical patients.<sup>2</sup> The perioperative period - encompassing preoperative (before surgery), intraoperative (during surgery), and postoperative (after surgery) phases - is a high-risk and vulnerable time for older patients. Older patients are at increased risk for postoperative morbidity and mortality compared to younger adults.<sup>3-10</sup> Anxiety and depression in older surgical patients increase the risk of postoperative complications, including short-term functional dependence and falls,<sup>11</sup> postoperative delirium,<sup>12</sup> opioid misuse,<sup>13,14</sup> decreased quality-of-life,<sup>15</sup> 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.<sup>16</sup>

There have been efforts to reduce perioperative risks in older adults by optimizing physical health prior to surgery (prehabilitation), implementing protocolized pathways during the surgical hospitalization, and also promoting postoperative rehabilitation (e.g., 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,<sup>17</sup> frequent co-occurring cognitive impairment, and detrimental impact on surgical recovery.<sup>18</sup>

In our prior needs assessment interview study with older surgical adults diagnosed with anxiety and depression and their treating clinicians,<sup>18</sup> 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, can suffer from postoperative neurocognitive disorders. They were also worried that central nervous system (CNS)-active medications could worsen outcomes, yet many patients reported taking these medications at a sub-therapeutic dose of medications for mental health, suggesting a need to optimize 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.

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3 Patients and clinician stakeholders emphasized the need for a perioperative intervention bundle to  
4 address these issues and argued for a bundle encompassing psychological components that are  
5 behavioral, simple, interactive, and engaging, and pharmacotherapy components that can minimize the  
6 risk of psychiatric medication withdrawal symptoms and improper dosages during perioperative care.  
7 They also recommended that such a mental health intervention bundle would be effective if it started  
8 preoperatively to assist with preparation for surgery and continued postoperatively to enhance recovery  
9 after surgery.<sup>18</sup>  
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16 Researchers have examined the use of counseling, cognitive behavior therapy, and other psychological  
17 treatments (e.g., relaxation, mindfulness, supportive therapy) to promote the mental wellbeing of  
18 younger surgical patients.<sup>19-21</sup> For example, Li and colleagues<sup>20</sup> found that a psychological intervention  
19 provided to patients with cancer throughout the perioperative period was associated with decreased  
20 depressive symptoms and anxiety postoperatively. Similarly, research with patients undergoing  
21 orthopedic surgery suggests that perioperative psychological education and counseling improved both  
22 psychological function,<sup>21,22</sup> as well as physical function.<sup>21</sup> In addition, studies suggest that a combination  
23 of pharmacological and psychotherapy is more effective at treating anxiety and depression in older  
24 adults than monotherapy,<sup>23-28</sup> and may be considered more acceptable to older adults,<sup>25</sup> suggesting the  
25 need for an intervention bundle that combines psychotherapeutic and pharmacological treatment. Older  
26 adults often take many medications, and in the perioperative period, there is heightened risk of adverse  
27 drug reactions and drug-drug interactions.<sup>29</sup> Medication optimization and deprescription can help with  
28 reduction or elimination of potentially inappropriate medications (such as benzodiazepines), in  
29 conjunction with appropriate antidepressant dosing and continuation across outpatient and inpatient care  
30 transitions.  
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43 Our team has previously demonstrated the effectiveness of cognitive behavioral therapy (CBT) and  
44 behavioral activation for depression in medically ill populations,<sup>30-35</sup> and for anxious older adults with  
45 comorbid depression,<sup>28</sup> and also of medication optimization and deprescription for older adults<sup>36</sup> in the  
46 perioperative setting.<sup>37</sup> Informed by our prior work (*see* Table 1 for features, clinical evidence, and  
47 rationale), we propose to develop a perioperative mental health intervention bundle (*hereafter referred*  
48 *to as the intervention bundle*) encompassing two integrated components - behavioral activation  
49 (psychotherapy), and medication optimization and deprescription (pharmacotherapy) for older surgical  
50 patients with anxiety and depression.  
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## Developing the Intervention Bundle: Adaptation Process Prior to Feasibility Evaluation

In preparation for this study, we organized 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.<sup>38,39</sup> Intervention mapping is a step-by-step process that uses activities (e.g., group discussions) and tools (e.g., 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.<sup>40</sup> 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 behavioral 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 analyzed to inform our pre-implementation adaptations to ensure effectiveness, feasibility, acceptability and overall satisfaction of the intervention bundle.

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

**[Insert Figure 1: Adaptation process of the perioperative mental health (PMH) intervention bundle]**

### *Interventionists*

The interventionists, referred to as perioperative wellness partners are Masters-level clinicians trained in Behavioral Activation using the material developed by Puspitasari and colleagues.<sup>41</sup> 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 licensed clinical social worker.

**Table 1. Details on adapted perioperative mental health bundle components.**

Intervention Bundle	Behavioral Activation	Medication Optimization
Target	Patients	Clinicians and Patients
Interventionist	Perioperative wellness partner	Perioperative wellness partner follows an algorithm for medication optimization and works alongside with pharmacists and a geriatric psychiatrist
Description	A behavioral intervention helping depressed and anxious patients by engaging them in reinforcing activities or activities that are meaningful and guided by their personal values. <sup>42</sup>	A pharmacologic intervention to adjust suboptimal doses of antidepressants, ensure continuation of antidepressants during transitions of care, and deprescribe medications that are harmful to older adults. <sup>43,44</sup>
Features	<p>Flexible component of cognitive behavior therapy (CBT) and standalone treatment in which the therapist helps a patient generate a list of pleasant, reinforcing activities, and co-creates action plans.</p> <p>Patient-centered treatment, in which the patient chooses the modality (i.e. which activities to engage in).</p>	Medication optimization 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 <sup>29,45,46</sup> 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	<p>Comparative efficacy and non-inferiority trials have shown that behavioral activation is about as effective as comprehensive CBT and it can be delivered by less highly-trained staff.</p> <p>Trials in medically ill patients have emphasized behavioral activation because it complements medically indicated physical activation and exercise goals, and it is feasible and acceptable<sup>47</sup></p>	Medication optimization is a cardinal rule in treatment guidelines for depression. <sup>48</sup> Antidepressants are often prescribed at subtherapeutic doses and then not adjusted for response. <sup>49</sup> Suboptimal dosing is a main reason for these drugs' low effectiveness in the real world <sup>50</sup> Strong centrally-acting anticholinergic and antihistaminergic drugs and benzodiazepines are "low-hanging fruit" for deprescribing as their harms outweigh benefits. <sup>51</sup> They are harmful perioperatively, increasing falls and delirium <sup>52-55</sup>

Core active components	<ul style="list-style-type: none"> <li>• Personalized Rationale Identification</li> <li>• Values and Goals Assessment</li> <li>• Activity Scheduling</li> <li>• Activity Monitoring</li> </ul>	<ul style="list-style-type: none"> <li>• Review of medication list by wellness partner on 1<sup>st</sup> visit prior to surgery</li> <li>• Determine the indication, duration of use, dose, and frequency of the medications of interest</li> <li>• Evaluate each medication's eligibility for optimization or deprescription</li> <li>• Discuss with medication optimization team</li> <li>• Get buy-in from patient to contact initial prescriber</li> <li>• Communicate recommendations to the patient</li> <li>• Weekly review of any new medications</li> <li>• Ensure that any medication optimization changes are reconciled during transitions of care and that the agreed-upon changes are implemented both pre-operatively and post-operatively</li> </ul>
Modifiable components	<ul style="list-style-type: none"> <li>• Selected behavioral activation activities: depending on patient needs and preferences</li> <li>• Timing: Preoperative and postoperative phases</li> <li>• Format: 1:1 session in-person/telephone/online</li> <li>• Duration: 20-30 minutes</li> <li>• Frequency: 1-4 (presurgery); 2-12 (postsurgery)</li> <li>• Setting: Home (telephone/online) and hospital</li> </ul>	<ul style="list-style-type: none"> <li>• 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</li> <li>• Format: 1:1 session in-person/telephone/online; then contact with the clinicians</li> <li>• Duration: 5 min</li> <li>• Frequency: 1-4 (pre); 2-12 (post)</li> <li>• Setting: Home (telephone/online) and hospital</li> </ul>

### ***Components of the Intervention Bundle***

#### **Behavioral Activation**

Figure 2 presents a model of behavioral activation for surgery. Behavioral activation will be practiced according to Kanter's *Behavioral Activation for Depression*.<sup>56</sup> Behavioral activation as the core

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3 intervention allows for uniformity across participants, yet enough flexibility for the actual components  
4 of behavioral activation to be individually adapted based on patient preferences. In addition to the core  
5 components of behavioral activation (Table 1), study participants in collaboration with their  
6 perioperative wellness partner will be able to adapt the intervention by choosing activities, per their  
7 preference, with demonstrated benefit in improving depression and anxiety symptoms in older surgical  
8 patients.<sup>57,58</sup> The behavioral activation process will be guided by the BA SOP (Appendix A) which will  
9 be adapted and calibrated as needed during the feasibility study.  
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16 **[Insert Figure 2: Behavioral activation model for the perioperative setting.]**  
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19 **Medication Optimization**  
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21 Patient antidepressant medications will be reviewed with the patient by the perioperative wellness  
22 partner, and based on the decision algorithm, are *optimized* by our study team of interventionists  
23 including a psychiatrist, psychologist, and pharmacists. The medication optimization process will be  
24 guided by the MO SOP (Appendix B) which will be adapted as needed during the feasibility study.  
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29 In this paper, we present a protocol for a prospective study to further adapt, and test the feasibility of  
30 implementing our intervention bundle to reduce anxiety and depressive symptoms in older surgical  
31 patients undergoing cardiac, oncologic and orthopedic surgeries at a large academic medical center.  
32 Towards this end, we will use frameworks from implementation science to capture the nuances and  
33 complexities unique to each patient population/setting that will inform our adaptation and  
34 implementation of the mental health intervention bundle. The Consolidated Framework for  
35 Implementation Research (CFIR)<sup>59</sup> is a well-operationalized, multi-level determination framework  
36 derived from theory that will help us identify the determinants (i.e., barriers and facilitators) that affect  
37 the implementation process across the three settings and populations. The framework has 39 constructs  
38 across five domains: intervention characteristics, inner setting, outer setting, characteristics of  
39 individuals, and implementation process, which help elucidate the context and factors that affect  
40 implementation and intervention bundle evaluation. The Framework for Reporting Adaptations and  
41 Modifications-Expanded (FRAME)<sup>60</sup> will allow us to systematically track all adaptations to the flexible  
42 components of the intervention bundle to ensure the feasibility, fit and relevance in older surgical  
43 patients, without compromising its core components.  
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56 **Study Objectives**  
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The study objectives are summarized below:

1. Examine the feasibility of implementing a patient-centered 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-centered, 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 randomized 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.<sup>61</sup> Quantitative data on anxiety and depression, quality of life, in-hospital delirium incidence, post-discharge falls, medications, length of stay, all-cause rehospitalization, 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, orthopedic 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 US. We will also invite their caregivers to participate in this study. Table 2



provides information about the expected enrollment numbers, inclusion criteria, and exclusion criteria of participants.

**Table 2. Enrollment, inclusion criteria, and exclusion criteria by type of participant.**

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

Participant Type	Expected Enrollment	Inclusion Criteria	Exclusion Criteria**
Patients	8-10 cardiac surgery patients 8-10 orthopedic surgery patients 8-10 oncologic surgery patients	<ul style="list-style-type: none"> <li>• <math>\geq 60</math> years of age on the day of surgery</li> <li>• Scheduled major orthopedic surgery, or major surgical resection of a thoracic or abdominal malignancy, or major cardiac procedure</li> <li>• Clinically significant depression or anxiety symptoms screened by the Patient Health Questionnaire Anxiety and Depression Scale<sup>62</sup> <math>\geq 10^*</math></li> </ul>	<ul style="list-style-type: none"> <li>• Estimated life expectancy &lt; 12 months</li> <li>• Unable to read, speak, and understand English</li> <li>• Current alcohol or other substance abuse</li> <li>• Severe cognitive impairment screened by the Short Blessed Test &gt;10</li> <li>• Acutely suicidal</li> </ul>
Caregivers	24-30 caregivers will be recruited alongside patient participants	<ul style="list-style-type: none"> <li>• Identified by patient as a family member or friend who cares for the patient as needed to support health and safety</li> </ul>	<ul style="list-style-type: none"> <li>• Age <math>\leq 18</math> years</li> </ul>

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

**[Insert Figure 3: Patient recruitment paths.]**

With the patients' consent, caregiver participants will be recruited via 2 paths: patient referral to either contact the study team or share the caregiver's phone number such that the study team will contact caregivers by phone, or mail and invite them.

***Assessment measures***

At enrollment, a research coordinator will administer a battery of assessments to characterize 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.

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3 *Medical history of comorbidities:* Patient medical history and comorbidities will also be collected.  
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6 *Pain:* The Brief Pain Inventory (BPI) is a well-validated 11-item measure of pain severity and  
7 interference in pain,<sup>63-68</sup> including after orthopedic,<sup>69</sup> oncologic,<sup>70</sup> and cardiac surgery.<sup>71</sup> Three questions  
8 from the BPI will be used to assess pain, including whether the patient is diagnosed with chronic pain,  
9 whether they experience pain daily in the past 3 months, and if they have been experiencing pain in the  
10 past week related or unrelated to their surgery.  
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15 *SBT (Short Blessed Test):* The SBT, sometimes called the Orientation-Memory-Concentration Test, is a  
16 6-item scale frequently used to assess dementia within patients across 3 dimensions: orientation,  
17 registration, and attention. The SBT has demonstrated good test-retest reliability.<sup>72</sup>  
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22 *UB-CAM (Ultra-Brief Confusion Assessment Method):* This 2-item test<sup>73</sup> is used for a quick assessment  
23 of delirium using items from the 3D-CAM (3-minute diagnostic interview for confusion assessment  
24 method).<sup>74</sup> Patients are asked to state the day of the week and months of the year backwards. If the UB-  
25 CAM is positive, the assessment continues with the full 3D-CAM.  
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30 *Medication list:* The research coordinator and perioperative wellness partner will review the patients'  
31 medications from the EHR and confirmed with the patient at the initial intervention visit, capturing the  
32 medication name, dose, units, frequency, start date, stop date, and indication, where appropriate.  
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### 36 Intervention adaptation measures

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38 *Intervention fidelity:* Data related to intervention fidelity to examine the extent to which an intervention  
39 bundle is carried out by our perioperative wellness partner as intended and consistently across different  
40 settings, and patients will be tracked as adherence to core components of the intervention bundle, quality  
41 of delivery, and participant responsiveness.<sup>75</sup> All sessions will be audio recorded and reviewed by the  
42 supervising perioperative wellness partner (i.e., trained in intervention bundle and is fidelity certified).  
43 Additionally, all intervention sessions will be reviewed and rated for fidelity by a team of researchers  
44 with training in the intervention bundle (licensed SW and research assistant). Written and/or verbal  
45 feedback will be shared with our wellness partners.  
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53 *Adaptations to the intervention bundle and its implementation:* Adaptations are thoughtful and deliberate  
54 alterations to the flexible components of the intervention bundle, the format or delivery of the  
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3 intervention bundle by perioperative wellness partners in order to improve its fit or effectiveness in a  
4 given context.<sup>60</sup> Other changes may happen to the delivery of the intervention. Data on such adaptations  
5 and modifications will be collected during (a) weekly case review intervention meetings where wellness  
6 partners will report on any changes they made to the intervention content, and delivery method and their  
7 underlying rationale to implement that change; and (b) periodic reflection meetings<sup>76</sup> led by  
8 implementation scientists with the wellness partners where they will be asked to reflect upon any  
9 modifications made deliberately and proactively, in response to unanticipated challenges in a given  
10 session or context.  
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18 The Behavioral Activation for Depression Scale – Short Form<sup>77</sup>, or BADS-SF, is our measure of target  
19 engagement. The BADS-SF is a 9-item questionnaire derived from the original BADS<sup>78</sup> questionnaire  
20 which consists of 25 items across 4 subscales: Activation, Avoidance/Rumination, Work/School  
21 Impairment, and Social Impairment. It is frequently used to measure changes in behavioral activation  
22 levels following treatment.  
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### 28 ***Outcome measures for feasibility study***

29 Outcomes for the feasibility study and their timepoints are provided in Table 3. We will be assessing the  
30 reach of our study and our intervention bundle (i.e., primary outcome), the feasibility of collecting  
31 depression and anxiety outcome planned for our randomized control trial (i.e., secondary outcome) and  
32 implementation-potential of intervention bundle and other outcomes such as quality of life, readmissions  
33 (i.e., exploratory outcomes).  
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39 Data related to participant recruitment, retention, and assessments will be collected to help us ascertain  
40 if any modifications to the study procedures need to be made, to inform sample size estimates and power  
41 calculations in subsequent randomized controlled trial studies.  
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45 **Table 3. Feasibility study outcomes and potential study primary and secondary outcomes for**  
46 **planned RCT.** Note: The surveys and questionnaires will be administered via email or research  
47 coordinators over the telephone.  
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49 Outcomes	50 Specific measure: description	51 Source	52 Timepoint
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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, 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 (PHQ-ADS) <sup>62</sup> : 16-item scale with components of the Patient Health Questionnaire-9 and Generalized Anxiety Disorder Scale (collected at baseline; 1 mo; 3 mo)	Research data warehouse	End of Study
Implementation-Potential (Exploratory)	Acceptability, appropriateness and feasibility of the interventions: The Acceptability of Intervention Measure (AIM), the Intervention Appropriateness Measure (IAM), and the Feasibility of Intervention Measure (FIM). <sup>79</sup> Each survey has 4 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 (Exploratory)	We will be measuring the completeness of data collection for the following potential secondary outcomes for the planned RCT secondary outcomes: <ul style="list-style-type: none"> <li>• Quality of Life (collected at baseline; 1 mo; 3 mo)</li> <li>• In-hospital delirium incidence (collected at baseline; in-hospital/postoperatively)</li> <li>• Post-discharge falls (collected at baseline; 1 mo; 2 mo; 3 mo)</li> <li>• Medication optimized and adherence to medications(collected at baseline; 1 mo; 3 mo)</li> <li>• Length of stay (both hospital and ICU)</li> <li>• All-cause rehospitalization (collected in the hospital/postoperatively; 1 mo; 3 mo)</li> <li>• Persistent postsurgical pain (collected at 1 mo; 3 mo)</li> <li>• Patient experience (collected at end of study)</li> <li>• Shared decision making (collected at end of study)</li> </ul>	Research data warehouse	End of Study

To obtain participant perspectives on the intervention bundle, we will conduct semi-structured 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

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3 intervention bundle, intervention bundle acceptability and detailed accounts of participants' experiences  
4 after the intervention has been stopped with regards to intervention sustainability and maintenance.  
5 These insights will inform whether the intervention bundle needs to be changed or adapted before our  
6 future trials. Interviews will be conducted via Zoom or telephone and will be digitally recorded and  
7 transcribed verbatim.  
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### 13 **Data management and analysis plan**

#### 14 ***Data management***

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17 This study will be conducted under appropriate Washington University Institutional Review Board  
18 (IRB) guidance, and use only IRB-approved study procedures and instruments. A unique patient number  
19 (UPN) will be assigned at enrollment and used wherever possible on the case report forms (CRF) to  
20 identify data, minimizing use of patients' names or personal identifiers in data.  
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#### 25 ***Data analysis***

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27 Quantitative data collected for the outcome measures for the feasibility study will be tallied and  
28 summarized using descriptive statistics. Completion of data collection will be described as a percentage  
29 of the instruments completed. The primary outcome of anxiety and depression for the planned RCT will  
30 be tabulated for descriptive purposes.  
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35 Fidelity and adaptation data will be analyzed using open coding, and the FRAME analytic framework to  
36 help track any adaptations to intervention bundle and delivery.<sup>60</sup> Interview data will be analyzed using  
37 an inductive-deductive thematic analysis.<sup>80</sup> After reading the transcripts multiple times for familiarity,  
38 research team members will openly code using data-driven codes and then using CFIR-driven codes.  
39 Codes will be compared across the data to identify repeated and interrelated concepts and categories,  
40 and sub-themes will be formed. Similar sub-themes will be grouped over multiple rounds of review to  
41 generate overarching themes out of significant patterns between interviews.  
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#### 48 ***Patient and public involvement***

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51 In preparation for this study, we organized an internal advisory board with surgical patients, caregivers,  
52 clinicians (e.g., physicians, nurses, pharmacists, social workers), and institutional leaders focused on  
53 patient experience to adapt our intervention bundle. Through the internal advisory board meetings, we  
54 sought to ensure that the intervention bundle facilitates patient preparedness for surgery during the  
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3 preoperative period, and enhances recovery during the postoperative period, coordinating and  
4 communicating with inpatient clinicians; and to evaluate whether the intervention methods are practical  
5 and appropriate for the patient populations and clinicians, without affecting perioperative workflow.  
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## 8 9 **ETHICS AND DISSEMINATION**

### 10 11 *Participant consents*

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13 Patients who meet all eligibility criteria and provide written informed consent will be enrolled into the  
14 study. Patient consent will be obtained via a paper collected by mail or in person, or by secure REDCap  
15 link to e-consent. Caregivers (participating in semi-structured interviews via Zoom/Phone or in-person)  
16 will be consented verbally or with a written consent, depending on participant convenience.  
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### 20 21 *Harms*

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23 This study involves minimal risk to subjects. Unlikely but potential risks include errors in medication  
24 recommendations, however, this risk is mitigated by the utilization of a multidisciplinary group of  
25 experts agreeing upon the recommendation and ongoing check points throughout the intervention  
26 process to ensure recommendations are correct and free from error. Additional risks include medication  
27 withdrawal symptoms as a result of the intervention recommendation, and breach of confidentiality. The  
28 risk of medication withdrawal (i.e., from benzodiazepines) is mitigated by slowly tapering rather than  
29 stopping these medications. If a participant endorses suicidal ideation, intent, or plan, the coordinator  
30 and perioperative wellness partners are trained to follow an operationalized protocol (*see* Appendices A  
31 and B) that has been developed to manage high-risk participants in other studies of depressed  
32 participants potentially at risk for suicide. This protocol has already been used successfully by members  
33 of the research team to manage acutely suicidal patients. Patients will be encouraged to check with their  
34 physician if there is any question about the safety of any physical activities that are included in the  
35 behavioral activation plan. It is possible that the participant may feel uncomfortable completing the  
36 surveys or participating in the study sessions. The study sessions and interview can be discontinued at  
37 any time, and the patient may refuse to answer any questions that s/he does not wish to answer.  
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50 We will monitor for breaches of confidentiality and other adverse events on an ongoing basis. Once we  
51 become aware of a reportable adverse event, the event will be reported to Human Research Protection  
52 Office (HRPO) and Quality Assurance and Safety Monitoring Committee (QASMC) according to  
53 institutional guidelines. This study does not require QASMC audit or submission of DSM reports.  
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3 Should any unexpected serious adverse events occur, our study protocol will be modified to prevent  
4 other similar events.  
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### 6 7 ***Internal auditing for data quality*** 8

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10 The methodology core team meets biweekly with the research coordinators and data manager to review  
11 the study report on study enrollment, recruitment, monitor data quality and discuss the study progress  
12 and any issues raised by the participants.  
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### 15 16 ***Data safety and monitoring plan*** 17

18 The specific monitoring plan for this investigation is commensurate with the risks and the size and  
19 complexity of the studies planned. Given the nature of the protocol, the risks are likely limited to breach  
20 of confidentiality.  
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### 23 24 ***Dissemination*** 25

26 The feasibility study results will be disseminated at scientific meetings and peer-reviewed publications.  
27 Additionally, the results will be presented to our perioperative mental health internal and external  
28 advisory board consisting of patients, clinicians, nationally recognized researchers (psychiatry, health  
29 services, pain medicine), and hospital administrator stakeholder groups to determine which components  
30 of the intervention and its delivery to preserve, which adaptations to carry forward and how to advance  
31 with the randomized controlled trials. The Washington University Center for Perioperative Mental  
32 Health website (<https://perioperativewellness.wustl.edu/>) will be used to introduce the intervention  
33 bundle to patients and clinicians alike. To accelerate the dissemination efforts, the Center will use online  
34 communication channels including the Center's webpage, popular news media, social media, webinars,  
35 and patient and family community networks. As per the National Institute of Mental Health sponsor  
36 guidelines, we will also be sharing the de-identified data to ClinicalTrials.gov.  
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### 46 47 ***Trial status*** 48

49 This study is registered in Clinical Trials Registry NCT05110690. Recruitment commenced during the  
50 last week of November 2021 and the enrollment is expected to conclude in March 2023.  
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## 52 53 **DISCUSSION** 54 55 56 57 58 59 60



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3 To our knowledge, the proposed perioperative mental health bundle will be the first of its kind to assist  
4 older surgical patients in managing their perioperative mental health. Current interventions need to be  
5 adapted and tested for older surgical patients – who face additional unique challenges such as frailty,  
6 multi-morbidity with co-occurring cognitive and physical impairments, and polypharmacy that can also  
7 impact their mental health and well-being.<sup>11,81</sup>  
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13 The study protocol will adapt the intervention bundle comprised of behavioral activation and medication  
14 optimization and provide evidence on the feasibility of testing the bundle as a potential intervention for  
15 anxiety and depression in older surgical patients. In addition, this study will provide feasibility data on  
16 implementing the bundle successfully within perioperative settings. Despite the empirical evidence  
17 available on behavioral activation and medication optimization, there are unique challenges to using and  
18 implementing these interventions for the perioperative population of older adults, in perioperative  
19 settings notable for their complexity. To the best of our knowledge, the protocol is the first to adapt and  
20 examine the feasibility of the intervention bundle within the perioperative setting for older surgical  
21 patients. We will identify components of our intervention bundle and its delivery mechanism that can be  
22 common across the three different surgical populations, and also components that are unique for a  
23 particular population, and further for a particular patient, based on their surgical pathways.  
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33 Results from this mixed method study will inform the following: *First*, findings related to experiences in  
34 participating in the intervention bundle, along with intervention fidelity and adaptation tracking will  
35 allow us to finalize modifications to our initial “in-progress” intervention bundle, resulting in a more  
36 patient-centered bundle that meets the needs and preferences of our diverse patients. *Second*, findings  
37 will determine if the components of the intervention bundle are feasible to be delivered in three very  
38 different settings in terms of dose, timing and duration of intervention. *Third*, findings will lead to an  
39 adapted intervention standard of procedure (SOP) that can guide the delivery of the intervention bundle  
40 by perioperative wellness partners, and one that can be tested for fidelity in our future effectiveness-  
41 implementation RCT. *Fourth*, findings will offer an initial roadmap for adapting and implementing  
42 patient-centered mental health interventions that are likely to be accepted and used by multiple  
43 stakeholders in the future. The intervention bundle adaptations performed in this study can be flexible  
44 enough and tailored based on patient needs/surgical conditions in diverse surgical settings while also  
45 maintaining the core components of the bundle – leading to a higher potential for scalability and  
46 sustainability in the long term. Use of the implementation science frameworks offers us the lens  
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3 to examine the feasibility and acceptability of the intervention bundle ahead of time, in order to  
4 accelerate the translation of the intervention bundle to usual care. *Lastly*, the study will inform the  
5 design and conduct of the planned randomized controlled trials in the three surgical cohorts. This study  
6 provides us with an opportunity to identify and address unanticipated challenges with our study  
7 procedures including recruitment methods, engagement strategies, study design flaws, and outcome  
8 measurement challenges.  
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14 This study comes with several limitations, similar to other feasibility trials. *First*, the sample sizes will  
15 be small as the proposed study focuses only on the evaluation of feasibility and implementation-  
16 potential of the intervention bundle, thereby limiting the ability to detect changes in outcomes. *Second*,  
17 the study does not include a control condition, and hence we will not be making any conclusions about  
18 the intervention bundle effectiveness. *Third*, results from this study are specific to our study setting and  
19 population at an academic medical center and may not be generalized to other non-academic settings.  
20 Nevertheless, this study will demonstrate whether it is feasible to (i) recruit, (ii) implement the  
21 intervention bundle in the perioperative period, and (iii) track the outcomes of interest, prior to  
22 conducting an RCT with a comparison group that will determine the efficacy of patient-centered  
23 intervention bundle in the three different surgical populations.  
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43 intervention bundle and their constructive feedback.  
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53 EL, KF, BP, RW, TC, AB, MP, MA participated in the adaptation of the intervention; all authors edited  
54 the protocol and approved the final version of the protocol submission.  
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## 41 **Figure Legend**

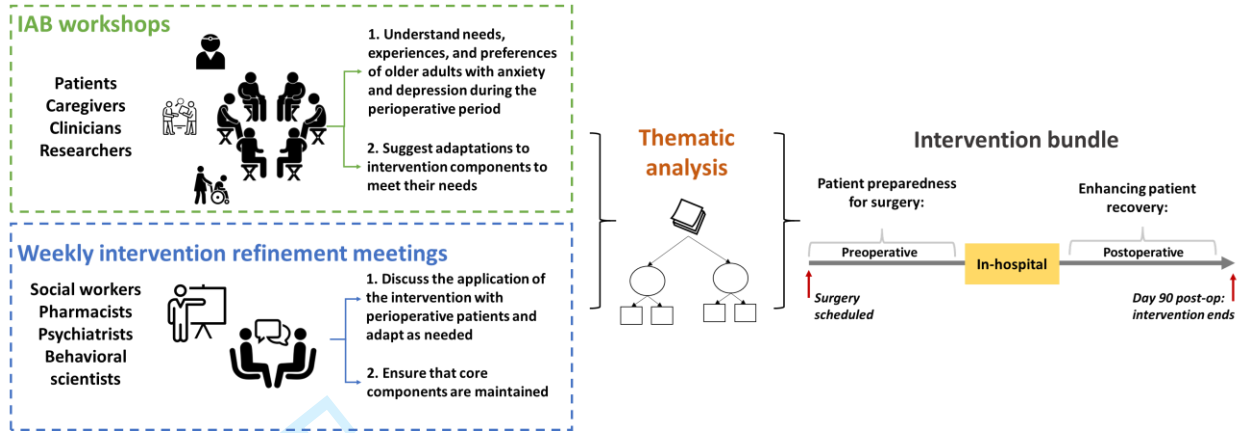
42 Figure 1 - Adaptation process of the perioperative mental health (PMH) intervention bundle.

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44 Figure 2 - Behavioral activation model for the perioperative setting.

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48 Figure 3 - Patient recruitment paths.  
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8 Fig. 2a. Behavioral activation – symptom  
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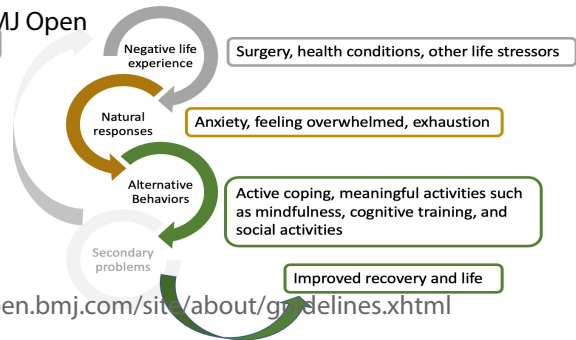


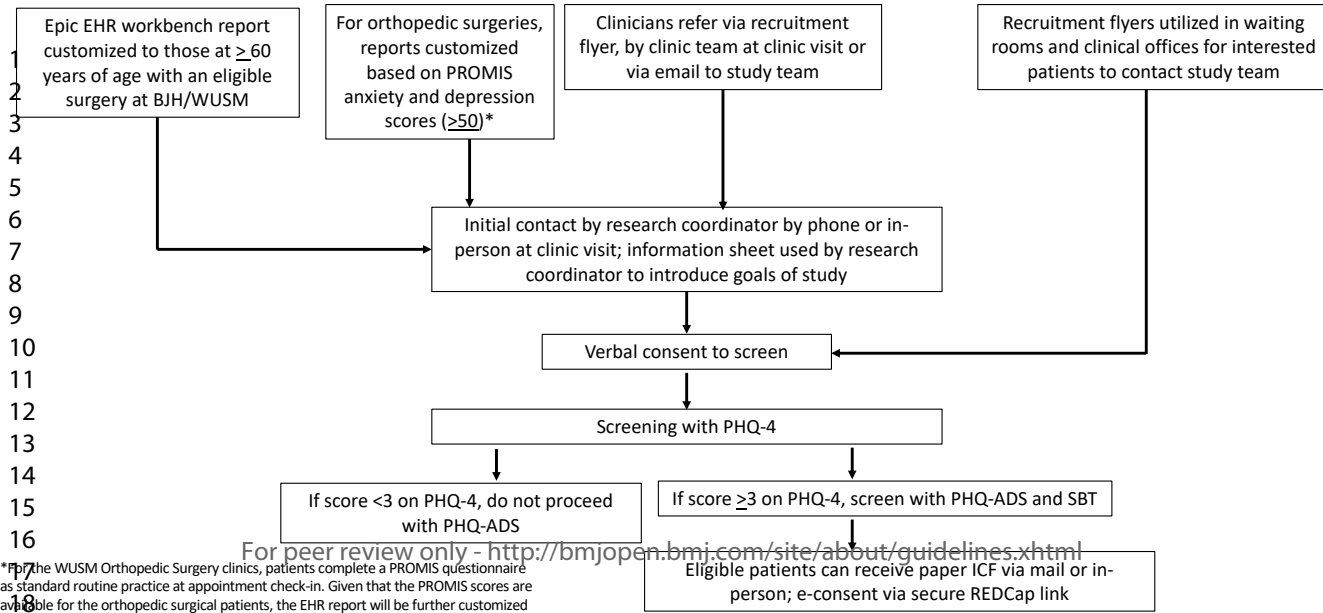
Fig. 2b. Behavioral activation – Interrupting symptom cycles

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Recruitment Paths  
BMJ Open  
2. Clinician Referral

1. Epic Electronic Health Record Report

3. Self-referral



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\*For the WUSM Orthopedic Surgery clinics, patients complete a PROMIS questionnaire as standard routine practice at appointment check-in. Given that the PROMIS scores are available for the orthopedic surgical patients, the EHR report will be further customized as needed based on PROMIS scores.

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## APPENDIX A Behavioral Activation Standard Operating Procedure (SOP)

### Center for Perioperative Mental Health Intervention: Behavioral Activation

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 pre-operative 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 post-operative, 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 <b>negative life experiences</b> (including the upcoming surgery, and any other difficult circumstances). For context and to build upon strengths, assess and discuss <b>positive life experiences</b> (what's been going well lately).
2. Assess and discuss <b>emotional and behavioral responses</b> (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. <b>Validate</b> emotional and behavioral responses as natural, normal, common.
4. Discuss <b>symptom cycles</b> 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: <b>activation as an alternative</b> 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	1. <b>Values and long term goals:</b> find out what matters to the patient, what their aspirations are.
2	
3	2. <b>Targets for meaningful activities:</b>
4	Typically in BA, reinforcing activities – ones that are rewarding, pleasurable, meaningful and/or that
5	provide a sense of productivity or accomplishment. Another way to identify target activities is to ask
6	about personally important activities that the patient has discontinued or is doing less frequently than in
7	the past. These targets may be applicable in the perioperative setting. Targets for activities that may
8	be particularly helpful in the perioperative setting include:
9	- Activities that bring a sense of normalcy and help restore sense of identity
10	- Activities that distract from unproductive worry or rumination
11	- Activities that help with physically preparing or recovering from surgery
12	- Activities that promote social connection
13	- Activities that are cognitively engaging
14	3. <b>How activities affect mood:</b> gathering details on how the patient's real-life day-to-day activities
15	impact their mood.
16	4. <b>Avoidance:</b> assessing whether there are things the patient has been avoiding; and whether there are
17	activities that serve as an escape or distraction from difficult feelings or activities.
18	5. <b>Routine and routine disruptions:</b> learning about the patient's current and ideal daily routine
19	(sleep-wake, hygiene, eating habits, physical activity, work and/or chores) and any disruptions
20	affecting their normal routines and the reasons for disruptions. Even in the absence of routine
21	disruption pre-operatively, it is helpful to revisit post-operatively to assist in returning to healthy
22	daily routines.
23	6. <b>Current psychosocial stressors:</b> assess whether there are major current psychosocial stressors
24	impacting patient's recovery, function, and ability to carry out activity scheduling goals (e.g., acute
25	grief, financial difficulties, problematic living situation, fraught relationship with primary
26	caregiver). Always maintain focus on actions the patient can take even in difficult circumstances.
27	Activity Scheduling: collaborative process between the patient and Perioperative Wellness Partner to
28	plan for helpful activities. Activity scheduling is concrete and considers the difficulty of the task in the
29	context of the patient's life, including any acute or chronic physical limitations.
30	1. Collaboratively <b>identify activities</b> to work on
31	2. <b>Consider difficulty</b> of activity in the current context and break tasks into smaller parts if
32	needed
33	3. <b>Schedule at least one activity concretely</b> (what, where, when, with whom)
34	4. <b>Problem solve</b> any obstacles to activity completion
35	Pre-Operative Period: Ideally, both Behavioral Activation and Medication Optimization will begin
36	before surgery. This time can be used for assessment and learning the process of activity scheduling.
37	1. <b>Assess emotional and behavioral responses</b>
38	2. <b>Validate</b> emotional and behavioral responses as natural, normal, common
39	3. Assess patient's <b>primary concern</b> and goals
40	4. <b>Activity scheduling:</b> They should be actions that are the most important for the patient right
41	now, not something extra or additional. Activity scheduling can include a blend of activities
42	that focus on:
43	- Feeling prepared for surgery

<ul style="list-style-type: none"> <li>- Improving physical or emotional well-being</li> <li>- Coping with anxiety and uncertainty</li> <li>- Establishing habits to continue after surgery.</li> </ul>	
5. Assist with <b>problem-solving</b> and helping patients communicate with medical team as needed	
Operative Period: Hospitalization for surgery is very disruptive for patients and their families. BA during this period should continue to be concrete, realistic, and take into account the patient's current circumstances.	
1. <b>Assess emotional and behavioral responses</b>	
2. <b>Validate</b> emotional and behavioral responses as natural, normal, common	
3. Assess patient's <b>primary concern</b> and goals	
4. Assist with problem-solving with the patient and family and assist in communicating with their inpatient and transitional provider team if needed	
5. <b>Activity scheduling:</b> should be compatible 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, not something extra or additional.	
Post-Operative Period: Behavioral Activation at this time should assist the patient in their individual recovery, returning to meaningful activities, and in restoring their sense of self. The interventionist should be aware of the patient's discharge instructions, restrictions, and need for follow-up care.	
1. <b>Assess emotional and behavioral responses</b>	
2. <b>Validate</b> emotional and behavioral responses as natural, normal, common.	
3. Assess patient's <b>primary concern</b> and goals	
4. If there are <b>treatment goals from other disciplines</b> 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: <ul style="list-style-type: none"> <li>- Assess and problem-solve barriers</li> <li>- Clarify misunderstandings</li> <li>- Frame the importance of the treatment in the context of the patient's long-term goals and values.</li> </ul>	
5. <b>Activity scheduling:</b> should continue to be collaborative and focused on the patient's long-term goals and values. Activity scheduling can include a blend of activities that focus on: <ul style="list-style-type: none"> <li>- physical recovery</li> <li>- returning to previous functioning</li> <li>- promotion of psychological well-being.</li> </ul>	
Addressing Barriers: Through the duration of the intervention, the Perioperative Wellness Partner should assist the patient in anticipating and responding to barriers. Below is a listing of types of barriers and potential solutions.	
Barrier Type	Potential Solutions
<b>Antecedent failure</b> Not remembering at all, or not remembering at the right place and time.	<ul style="list-style-type: none"> <li>- Reminders</li> <li>- Arranging the environment</li> </ul>
<b>Skills deficit</b> Lacking the skills or knowledge that are needed to enact the behavior	<ul style="list-style-type: none"> <li>- Facilitate learning experiences for needed skills. Schedule and monitor the learning activities.</li> <li>- If problem-solving presents as a skills deficit, structured problem-solving can be done in session.</li> </ul>
<b>Social skills deficit</b> Lacking social or communication skills that are needed to enact the behavior	BA sessions can incorporate social skills training, including instruction, modeling, role-playing, and assigning real-world practice.

<p><b>Extrinsic contingency issue</b> Occurs when the desired behavior is not reinforcing, perhaps because of the behavior itself or the patient's environment.</p>	<ul style="list-style-type: none"> <li>- Premack's Principle: Reinforce a less rewarding behavior by engaging in a more enjoyable behavior afterwards.</li> <li>- In the short term, an arbitrary reward can be used.</li> </ul>
<p><b>Intrinsic contingency issue</b> Occurs when the patient avoids the desired behavior because of the emotions that it causes.</p>	<ul style="list-style-type: none"> <li>- Assist to identify avoidance triggers and patterns.</li> <li>- Validate the emotional response and avoidance as normal.</li> <li>- 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.</li> <li>- Connect the activity to the patient's goals and values.</li> <li>- Schedule concretely and break task down into manageable chunks.</li> </ul>
<p><b>Pain and/or fatigue</b> Physical pain and fatigue are common in medically ill surgical patients. Pain and fatigue may be caused the surgery, anesthesia, and co-morbid medical conditions. Anxiety, depression, and stress 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.</p>	<ul style="list-style-type: none"> <li>- Discuss pain and fatigue symptom cycles as they relate to the patient's experience.</li> <li>- Discuss activity - rest cycle (pacing) as an alternative: alternating planned activity with regular rest periods. Keep track of activity and rest periods and the impact on pain and fatigue levels.</li> </ul>
<p><b>Intervention Conclusion:</b> The study intervention is time-limited, and ends after approximately 90 days post-operatively.</p>	
<p>1. Assist the patient in identifying other supports and resources that will continue past the study period.</p>	
<p>2. Review progress and discuss what practices the patient would like to 'keep,' and address any barriers to doing so.</p>	
<p>3. Assess need for ongoing mental health treatment and assist with referrals.</p>	

## APPENDIX B Medication Optimization Standard Operating Procedure (SOP)

### Center for Perioperative Mental Health Intervention: Medication Optimization

#### 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.

<b>MEDICATIONS WITH ANTICHOLINERGIC PROPERTIES: typically, these can be stopped abruptly</b>	
<b>Generic</b>	<b>Brand</b>
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, Levid, Levsin, Levsinex, NuLev
Imipramine	Tofranil
Meclizine	Antivert, Bonine
Orphenadrine	Norflex
Oxybutynin	Ditropan, Oxytrol
Prochlorperazine	Compazine
Promethazine	Phenergan
Pseudoephedrine HCl/Tripolidine HCl	Aprodine
Scopolamine	Transderm Scop
Tolterodine	Detrol
<b>SEDATIVES – BENZODIAZEPINES: may need tapering unless low-dose/intermittent</b>	

<b>Generic</b>	<b>Brand</b>
Alprazolam	Xanax
Chlordiazepoxide	Librium
Clonazepam	Klonopin
Diazepam	Valium
Estazolam	Prosom
Lorazepam	Ativan
Oxazepam	Serax
Triazolam	Halcion
Temazepam	Restoril, Normison, Planum, Tenox, Temaze
<b>NONBENZODIAZEPINE “Z-DRUGS” SEDATIVES: may need tapering unless low-dose/intermittent</b>	
<b>Generic</b>	<b>Brand</b>
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 below 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 antidepressant 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.

**Step 7:** 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.

**Step 8:** Communicate recommendations for medication optimization to the patient:

- 1) "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 non-toxic 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:

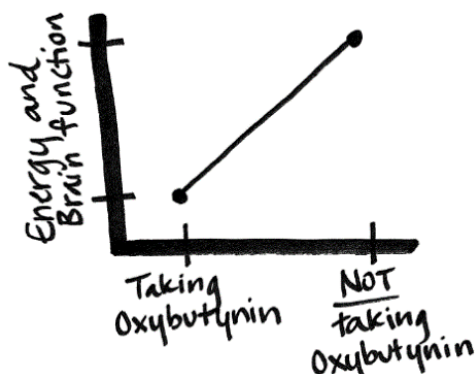
- Home visits are not required, but if they occur, they provide a good opportunity to compare the medication list to the actual medication bottles the patient has at home. Confirm that our original list is correct.
- If there are changes, check new meds against the list of medications eligible for medication 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.





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