



Published in final edited form as:

Psychooncology. 2019 August ; 28(8): 1774–1777. doi:10.1002/pon.5146.

Iterative adaptation process for eHealth Mindful Movement and Breathing to improve gynecologic cancer surgery outcomes

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Keywords

cancer; gynecologic surgical procedure; oncology; pain; yoga

1 | BACKGROUND

Women diagnosed with gynecologic cancers regularly face abdominal surgery and experience considerable pain that is often inadequately managed.¹ Acute perioperative pain is a risk factor for chronic pain.² Thus, interventions to reduce postoperative pain could prevent the transition of acute to chronic pain.

General guidelines for treating postoperative pain recommend a multimodal approach including nonpharmacologic interventions (eg, mind-body interventions),³ yet the multimodal approach in guidelines specific to gynecologic cancer surgery exclusively focuses on analgesic medications.⁴ Pain is one reason mind-body interventions such as yoga are commonly used in cancer patients, although limited evidence supports the efficacy of yoga for perioperative pain in this population.^{5,6} The multiple components of yoga (ie, mindfulness, movements, and breathing exercises) may also decrease the risk of postoperative deep venous thrombosis and pulmonary complications by facilitating mobility and deep slow breathing.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflict of interest to declare.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

The purpose of this study was to field-test the usability of a Mindful Movement and Breathing (MMB)⁶ yoga intervention adapted to eHealth (eMMB) and to finalize the intervention manual.

2 | METHODS

We conducted a mixed-methods one-arm study to refine eMMB implementation strategies (eg, video and videoconferencing) in women who underwent surgery for a suspected gynecologic malignancy ([ClinicalTrials.gov: NCT03379376](https://clinicaltrials.gov/ct2/show/study/NCT03379376)). We assessed usability in the applied setting (ie, field-test) because we aimed to evaluate modes of implementation. The primary study outcome was a manual for intervention implementation. Enrollment concluded when at least 10 participants were accrued and a consensus was reached on the manual. The Wake Forest School of Medicine's Institutional Review Board approved all study procedures (IRB: IRB00046462). We screened appointments and communicated with providers to identify adult females scheduled for an abdominal gynecological surgery to remove a suspected uterine or ovarian malignancy. Participation required ECOG performance status of 1, cognitive ability to complete assessments, and ability to understand, read, and write English. Patients were excluded if they had a diagnosis of schizophrenia, another psychotic disorder, or a sleep disorder.

2.1 | eHealth Mindful Movement and Breathing (eMMB)

Our previous study⁶ showed that an in-person MMB intervention was difficult to implement consistently before surgery. We therefore adapted MMB to eHealth (eMMB). We first refined eMMB⁶ by consulting with experts in mindfulness for pain reduction and the Krishnamacharya yoga tradition. We then incorporated qualitative feedback from stakeholders (ie, oncologist, nurse, mind-body experts, clinical informatics professional, research staff, and patients).

2.2 | Proposed Implementation Strategies

We gave participants a 20-minute eMMB video saved as a local file on an iPad with a written description of eMMB and asked participants to watch the video at least once before surgery. The yoga instructor called participants before surgery to invite guidance upon request and met with participants individually via videoconferencing, generally on postoperative day one. A study team member facilitated the videoconferencing session and had a second videoconferencing device and telephone available for backup. We asked participants to practice eMMB daily for 2 weeks after surgery. A study team member called participants to check in 2 days after the videoconference session.

2.3 | Measures

We asked participants to complete a usability questionnaire⁷ immediately following the videoconference session and to complete an interview 4 weeks after surgery. The interview guide probed for concepts in the Model of Supportive Accountability, which describes how providing human support may affect adherence to eHealth interventions by considering accountability, motivation, and the computer-mediated communication medium.⁸ Qualitative interviews were audio recorded and summarized. Other assessments took place before

surgery, and at 2 and 4 weeks after surgery, so the field-test would mimic our planned protocol. We reviewed medical records; other demographics were self-reported. We tracked recruitment, adherence to the videoconference session (target 70%), other communication with the interventionist, adverse events (Visual Analogue Scale assessments of pain and distress [0–100] immediately before and after the eMMB, all unexpected grade 4 and all grade 5 events reviewed), and assessment completion.

2.4 | Refinement Process

In the iterative process of finalizing the above-described implementation strategies, we used both informal and formal processes. We made minor changes to the protocol on an ongoing basis throughout the study based on feedback from study personnel. We also convened an expert panel twice (after each five participants were enrolled) to review qualitative and quantitative data and oversee all protocol changes until a consensus was reached on a final implementation manual.

3 | RESULTS

Participant characteristics are summarized in Table 1 (n=10 enrolled April-September 2018; see Figure S1 in the Supporting Information). Participants who completed the videoconference (n=7, 70%) reported high confidence in their ability to complete the intervention (71% strongly agreed, 29% agreed), satisfaction (71% strongly agreed, 29% agreed), and perceived helpfulness (86% very helpful, 14% somewhat helpful). Reasons for nonadherence to the videoconference session included feeling overwhelmed, surgical complications, and not interested.

These data, other qualitative feedback (n=7; mean [M] interview time=29 minutes) and implementation experiences informed modifications made to the eMMB manual related to usability and security. Usability modifications included (1) adding an option for providing the video link via email, (2) clarifying that the back-up phone call would be used if we were unable to complete the videoconference session in the clinical setting, (3) including an option to communicate via text messaging for scheduling, and (4) asking study staff to hold the iPad closer to participants during videoconferencing. Security modifications included (1) switching videoconferencing platforms because of an institutional Business Associate Agreement, (2) using single app mode on iPads to only allow access to the study video, (3) extending the time required by AirWatch before iPads needed to connect with the Medical Center's network to allow offline study video viewing, and (4) providing study cell phones to instructors to facilitate monitoring and privacy. Qualitative feedback validated that participants perceived support from the study team valuable⁸: "They were great. Really caring. That impressed me, being really concerned about everything going on with me."

All participants talked to an interventionist before surgery [M=6; range=1–14 days] and no participants initiated additional contact. Sixty percent of participants used a study iPad and 40% chose an emailed link. Five participants completed assessments at Weeks 2 and 4. No acute adverse events were reported. On average, pain (M=-21.3; SD=22.1) and distress (M=-3.2; SD=7.5) decreased immediately after the eMMB session. Trends were qualitatively supported including that the eMMB "definitely lowered my pain level" and "gave me a

sense of peace and helped me immensely.” One death occurred during the study unrelated to eMMB.

4 | CONCLUSIONS

Using an iterative process is recommended for developing and testing mind-body interventions⁹ and eHealth interventions.^{7,10} Results from the current study revealed opportunities to address usability and security concerns when finalizing the eMMB manual. We found the Model of Supportive Accountability⁸ helpful for guiding intervention implementation. For example, we decided to offer participants the option to use study iPads or an emailed link to view the video since options support intrinsic motivation. In addition, the increased communication bandwidth offered by videoconferencing allowed yoga instructors to see participants’ facial expressions, which we found relevant to enhancing human support and even more important than seeing participants’ movements.

In summary, this study supported usability of eMMB. We will determine the feasibility and acceptability of the eMMB intervention in the next study phase. The short-term decreases in pain and distress immediately following eMMB encourage further investigation.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

ACKNOWLEDGEMENTS

The authors wish to thank the study participants, Lynn Felder, Dr. Umit Topaloglu, and Dr. Samuel Lentz for their contributions. Research reported in this publication was supported by the National Center For Complementary and Integrative Health (R34AT009546) and the Wake Forest Baptist Comprehensive Cancer Center’s NCI Cancer Center Support Grant (P30CA012197) including use of the Qualitative and Patient-Reported Outcomes Developing Shared Resource. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Funding information

Wake Forest Baptist Comprehensive Cancer Center, Grant/Award Number: P30CA012197; National Center For Complementary and Integrative Health, Grant/Award Number: R34AT009546

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Key Points

- Improved management of acute pain among women undergoing surgery for suspected gynecologic malignancies may prevent chronic pain and other surgical complications.
- Practicing yoga may reduce pain and support usual care goals of encouraging mobility and deep breathing during the acute perioperative timeframe.
- We adapted a Mindful Movement and Breathing yoga intervention to an eHealth format.
- We then field-tested the usability of the adapted implementation strategies (N = 10).
- An expert panel reviewed data in two stages and oversaw adjustments to implementation strategies until the intervention manual was finalized.

TABLE 1

Demographic and clinical characteristics

Characteristics	N	%
Age		
Mean (SE)	58.2	14.4
Median (min, max)	55.5	44, 87
Ethnicity		
Hispanic/Latino	0	0%
Race		
Black/African American	1	10%
White	8	80%
More than one race	1	10%
Education		
8th-11th grades	1	10%
High school Graduate/Equivalent	3	30%
Some college	2	20%
College graduate	4	40%
Ability to pay monthly bills		
Very difficult	3	30%
Somewhat difficult	4	40%
Not very/Not at all difficult	3	30%
Internet access		
Yes	9	90%
Cancer type		
Ovarian	3	30%
Uterine/Endometrial	7	70%
Surgery type		
Robotic	6	60%
Laparotomy	4	40%