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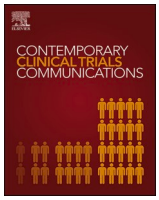

Rationale and usability findings of an e-health intervention to improve oral anticancer adherence among breast cancer survivors: The My Journey mindfulness study

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ABSTRACT

Background: Approximately 80% of breast cancer survivors are prescribed oral endocrine therapy (ET) medication for 5–10 years following primary treatment, making adherence to ET a critical aspect of cancer survivorship care. Despite the benefits of ET, non-adherence is problematic, and up to half of breast cancer survivors ave been documented to discontinue ET early. Our team developed *My Journey*, an online, mindfulness-based program designed to improve adherence to ET. This manuscript describes the usability testing of *My Journey* and the protocol development for the *My Journey* randomized feasibility trial.

Methods: Usability participants were women ($N = 15$) with a diagnosis of hormone receptor-positive non-metastatic breast cancer who had initiated ET. Participant impressions and feedback were collected qualitatively and quantitatively using items on usefulness, satisfaction, and ease of use. Participants in the 8-week feasibility trial ($N = 80$) will be randomized to receive the web-based *My Journey* intervention or a health education comparison condition.

Results: Quantitative feedback on the usability trial was favorable, with a mean overall usability score of 106.3 ($SD = 7.7$; *Range*: 83–115) indicating above average usability. Qualitative data showed that participants found several strengths in the initial design of the *My Journey* online tool and that participants liked the layout of *My Journey*.

Conclusions: Findings indicate that the *My Journey* online tool is useable. The program's feasibility is being evaluated in a randomized trial.

1. Introduction

Breast cancer is the most common cancer among women in the United States [1], and more than 80% of breast cancers are hormone receptor-positive (HR+) [2]. For HR + breast cancer, adjuvant endocrine therapy (ET) is typically prescribed daily for 5–10 years following primary treatment. Endocrine therapies such as tamoxifen and aromatase inhibitors are highly effective; five years of ET adherence (i.e., >80% adherence) is associated with 50% reduced risk for breast cancer recurrence and 30% reduced risk for breast cancer mortality [3,4]. Continued use of ET for up to 10 years reduces the risk of breast cancer recurrence and mortality in the second decade after diagnosis by 30% and 50%, respectively [5–8]. Thus, post-treatment adherence to ET is a critical aspect of continued breast cancer clinical care.

Despite the therapeutic benefits of ET, non-adherence to ET is problematic. Studies have found that, on average, 61% of patients took their doses of ET as prescribed after 3 years and 50% of patients took their ET doses as prescribed after 4 years [9,10]. Other studies have confirmed that up to half of breast cancer survivors discontinue ET before completing the recommended treatment course [5,11,12]. One of

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the most common predictors of ET non-adherence is the experience of side effects [13], as the overwhelming majority of women taking ET experience at least one side effect [14–17], and side effects can persist for years [18]. Common side effects include mood changes, fatigue, menopausal symptoms such as hot flashes, vaginal dryness, loss of sexual desire, joint and muscle pain, and bone loss [5,14–17,19]. In order to improve ET adherence, it is critical to effectively manage and reduce the burden of ET side effects.

Mindfulness-based interventions (MBIs) offer a potential solution to ET non-adherence. MBIs are self-management practices that guide participants in cultivating mindfulness, or non-judgmental awareness of one's present moment experiences [20,21]. Jon Kabat-Zinn, the creator of Mindfulness Based Stress Reduction (MBSR), encourages individuals to cultivate a greater sense of self-awareness [22]. MBIs have shown promise in the context of cancer. For example, MBIs for cancer patients have focused on reducing pain and distress and improving general functioning by increasing awareness and acceptance of side effects [23–25]. In studies among cancer patients, including those with breast cancer, participation in MBIs was associated with reduced side effects (e.g., pain, hot flashes), stress, and depressive symptoms, as well as improved health-related quality of life (HRQoL) [26–31]. Recent work has also demonstrated the efficacy of MBIs when delivered via web-based platforms [32], which may be particularly important for patients with chronic illnesses who might prefer to access interventions from the convenience of their homes. It is possible that MBIs could enhance breast cancer survivors' ability to manage burdensome ET side effects, which in turn could improve ET adherence (see Fig. 1). However, studies have not yet tested this.

To investigate these potential relationships, we developed the *My Journey* intervention. *My Journey* is a web-based intervention that incorporates an online, group-based MBI program designed to improve the management of ET side effects and ET adherence for women with HR + non-metastatic breast cancer. In Phase 1 of *My Journey*, we conducted usability testing of the *My Journey* website to verify ease of use and initial satisfaction with the content. Phase 2 involves testing *My Journey* in a randomized feasibility trial for acceptability, demand, and intended preliminary effects. This manuscript describes the procedures and findings from the Phase 1 usability testing and the protocol for the ongoing Phase 2 randomized feasibility trial.

2. Phase 1: usability testing

Through an NCCIH-funded pilot project (R34AT009447), we completed usability testing of the *My Journey*website: the first phase of our study. The study was registered on ClinicalTrials.gov, NCT03849573, on February 21, 2019. The goal of usability testing was to gather feedback from the intervention's target population (i.e., HR + breast cancer survivors taking ET) with the purpose of refining the *My Journey* website and study protocol prior to launching the feasibility trial. To increase the likelihood of finding user-centered problems, we completed usability testing with 15 participants [33]. Usability testing was conducted on a prototype of the *My Journey* website.

2.1. Materials and methods

2.1.1. Participants

Participants were: 1) female; 2) at least 18 years old; 3) able to speak and read English; 4) diagnosed with HR + breast cancer stage; 5) finished cancer treatment (i.e., surgery, radiation, chemotherapy) with the exception of ET; 6) prescribed ET within past 6 months; 7) no prior breast cancer diagnoses; and 8) free of visual, hearing, voice, motor, and psychiatric impairment that would interfere with study participation. We specifically focused on women who recently initiated ET because women who have already made the decision to discontinue ET may be less likely to enroll in a study for women taking ET, which would result in a missed opportunity to enroll women in need of interventions to improve adherence.

2.1.2. Procedures

All usability testing procedures were reviewed and approved by Northwestern University's Institutional Review Board. A trained research coordinator identified potential participants with assistance from staff in Northwestern University's Breast Clinic and then screened breast cancer survivors' electronic medical records for minimal information to determine eligibility. The research coordinator called eligible breast cancer survivors to describe the study, allow time for questions about the study, and determine interest in participating. Eligible and interested breast cancer survivors provided informed consent prior to participating in any study activities. Individual usability testing sessions were conducted at our laboratory space and audio recorded. During usability testing, participants were introduced to a prototype of the *My Journey* website that contained information on ET. While using the prototype, participants were instructed to provide feedback on the following categories: branding, aesthetic, accessibility, and intervention content. The study research assistant recorded the participants' responses in each category, and responses were then entered into an Excel spreadsheet for tracking. Usability testing sessions lasted approximately 1 hour, and participants were compensated $100 for their time. See Figs. 2–4 for images of *My Journey*.

2.1.3. Measures

Participants completed a modified version of the Usefulness, Satisfaction, and Ease of Use (USE) questionnaire [33]. The scale focuses on usefulness, ease of use, ease of learning, and satisfaction with mobile

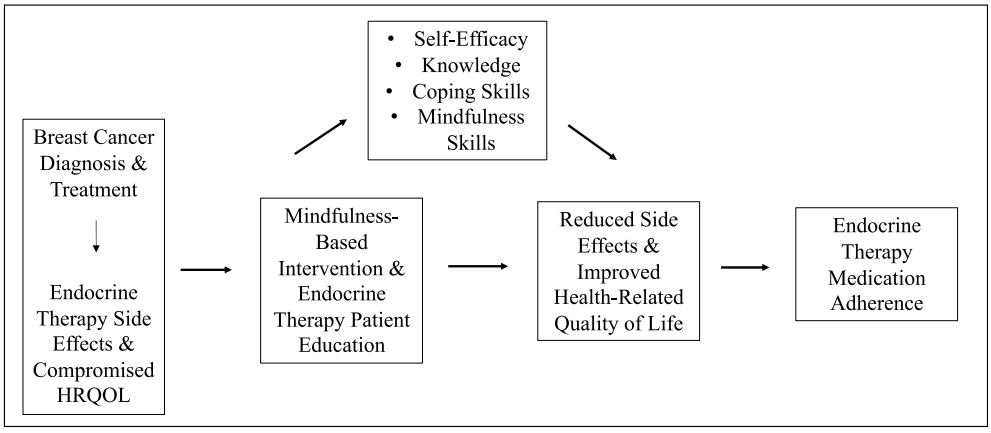

Fig. 1. Conceptual model of endocrine therapy adherence.

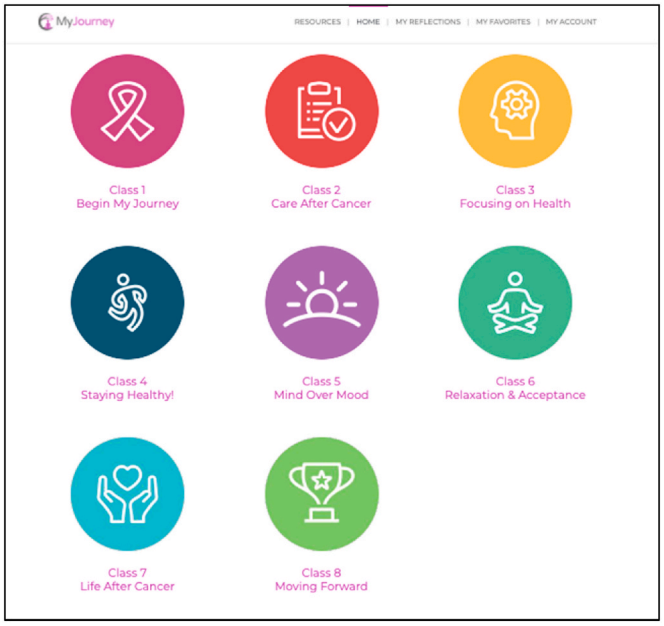

Fig. 2. My journey home page.

applications. Response options are on a five-point scale from 1 (agree) to 5 (disagree), and items were appropriately reverse scored and summed so that higher scores reflect more favorable usability.

2.1.4. *My Journey online tool*

Content in the *My Journey* Online Tool was informed by the Health Belief Model and Kabat' Zinn's MBSR program [34,35]. As seen in Tables 1 and 2, each session focuses on mindfulness skills, information about ET, and strategies for adherence to ET. Mindfulness skills included meditation, mindful non-reaction, present moment focus, and body scan. ET education included standard of care educational content about ET, the importance and benefits of medication adherence over time, and strategies for managing ET side effects. Content related to ET was adapted from the National Cancer Institute website, American Cancer Society website, and American Society of Clinical Oncology website [36–38]. Usability testing was conducted with a prototype of the *My Journey* website to evaluate the online platform. Once finalized, the *My Journey* enhanced care condition will require weekly group session attendance. Additionally, participants in this condition will have access to the *My Journey* website, which will contain interactive mindfulness-based activities for patients to engage with between sessions, as well as additional written information about managing ET side effects. In addition to attending the weekly group sessions, participants will be encouraged to access the website and practice mindfulness skills for at least 30 min a week. Because usability testing was conducted with a prototype of the *My Journey* website , no group sessions occurred during usability testing. User engagement features such as the virtual reinforcement awards (e.g., ribbons, trophies) were not available during usability testing but will be available during the randomized trial.

2.1.5. *Statistical considerations*

Descriptive statistics (e.g., means, standard deviations, ranges, frequencies, percentages) were used to characterize participants with regards to demographic and clinical characteristics. In addition, descriptive statistics were used to summarize usability using individual USE items and the overall USE score.

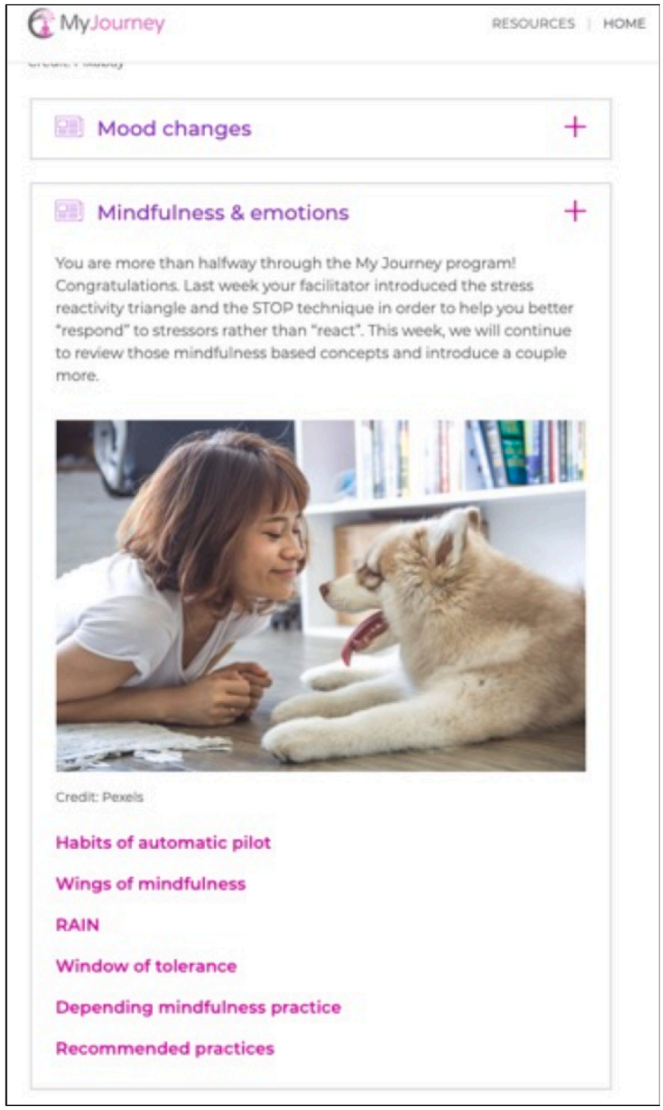

Fig. 3. *My Journey* mindfulness and emotions.

2.2. *Results*

2.2.1. *Participant characteristics*

Table 3 summarizes participants' demographic and medical characteristics. Participants ($N = 15$) were an average of 49.3 years old ($SD = 11.1$) and predominately White (53%) and married or partnered (60%). Most participants (60%) reported that they were able to maintain normal activities without symptoms. Approximately half of participants (53%) reported ever speaking with a mental health professional about their experience with cancer (e.g., a psychologist, counselor, religious leader, or social worker), whereas fewer participants (13%) had ever attended a cancer support group.

2.2.2. *Usability: quantitative results*

Usability feedback collected with the USE questionnaire was largely positive, with a mean total usability score of 106.3 ($SD = 7.7$, range 83–115) out of a maximum possible 115 (Table 4). Notably, all participants agreed with the statement that it is easy to remember how to use *My Journey*, and all participants disagreed with the statements that *My Journey* is cumbersome to use and requires learning a lot of things before beginning to use the program. One item, *"I think that I would like to use this system frequently,"* had a slightly lower rating than other items. Because usability testing was done with a prototype of the website, user

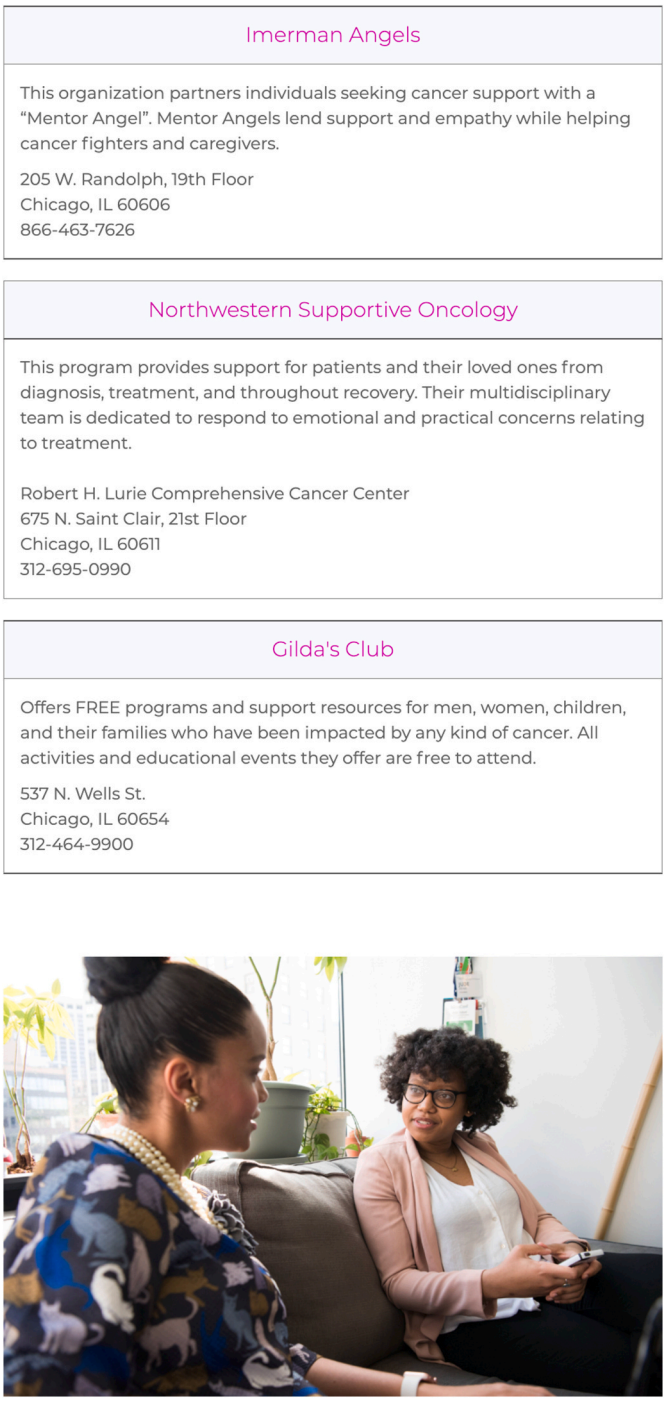

Fig. 4. Resources section of *My Journey*.

engagement features such as the virtual reinforcement awards (e.g., ribbons, trophies) were not yet available during usability testing, which may explain the lower score on this item.

2.2.3. Usability: qualitative results

Participants noted several strengths related to branding, aesthetics, accessibility, and content, as well as ways to refine the online and intervention content. As shown in Table 5, we made modifications to *My Journey* in direct response to participant feedback. This allowed us to refine the *My Journey* website prior to the next phase of testing.

Table 1
My Journey mindfulness content by week.

MBSR Components	Description
Week 1: Cultivating Mindfulness	This section introduces mindfulness, the concept of engaging the senses to redirect attention back to the present moment, and how it can assist in coping for breast cancer survivors.
Week 2: Attention and Perception	This section discusses mindful thinking vs. automatic pilot thinking. The role of perception and curiosity in increasing awareness and cultivating behavioral change is also examined.
Week 3: Embracing Pleasant Events	This section asks participants to reflect on pleasant events. Strategies are explored for noticing and appreciating positive events in daily life.
Week 4: Mindful Responses to Discomfort	This section employs mindfulness strategies as a way of coping with ET side effects, physical pain, and stress.
Week 5: Coping with Sadness and Depression	This section explores tangible skills for working with lower energy states. This section also introduces the Two Wings of Mindfulness (Compassion and Objective Observer).
Week 6: Coping with Worry and Anxiety	This section highlights how emotions, such as anxiety, often manifest themselves as physical sensations and how awareness of these sensations can prevent catastrophizing.
Week 7: Sexuality: Self Compassion and Kindness	This section explores compassionately acknowledging changes in one's appearance, feelings of sexual desire, and sexual functioning following breast cancer treatment.
Week 8: Keeping Mindfulness Alive	This section reviews mindfulness skills and incorporation of mindfulness into daily life.

Table 2
My Journey endocrine therapy content by week.

Endocrine Therapy (ET) Components	Description
Week 1: Breast Cancer Basics	This section discusses what breast cancer is, the different types of breast cancer treatments, and how these treatments impact survivors.
Week 2: ET Basics	This section explores how ET works and why it is prescribed.
Week 3: Adherence to ET	This section highlights ET benefits, the importance of adherence, and strategies for remembering to take medication.
Week 4: Side Effects of ET	This section introduces the array of ET side effects and how they can have a variable impact on breast cancer survivors.
Week 5: Breast Cancer and Depression	This section normalizes the emotional side effects of breast cancer diagnoses and taking ET.
Week 6: Breast Cancer and Anxiety	This section examines how stress can impact those coping with a breast cancer diagnosis and ET treatment.
Week 7: Body Image, Sex, and Sexuality	This section highlights how breast cancer and ET can change one's experiences with sexuality and intimacy.
Week 8: Review of ET Education	This section reviews breast cancer treatments, with special emphasis on ET, and considers ways to stay healthy during and after treatment.

3. Phase 2: randomized feasibility trial

After refining and finalizing *My Journey* in Phase 1, we began preparations for Phase 2, the randomized feasibility trial. The goal of this trial is to test the feasibility of *My Journey* relative to a health education comparison condition.

3.1. Materials and methods

3.1.1. Participants

Participants ($N = 80$) will be recruited from the Robert H. Lurie Comprehensive Cancer Center at Northwestern Memorial Hospital and various community-based support groups for cancer survivors, including the Dr. Susan Love Research Foundation's Army of Women [39]. Similar

Table 3
Demographic and medical characteristics of phase 1 usability participants.

Variable	Statistic
Age, *M* (*range*)	49.3 (36–69)
Race & Ethnicity, *n (%)*	
Black/African American	1 (7)
Hispanic	5 (33)
Non-Hispanic White	8 (53)
Asian	1 (7)
Marital status, *n (%)*	
Single	2 (13)
Married/partnered	9 (60)
Divorced	4 (27)
Education, n (%)	
Some high school	1 (7)
High school graduate or equivalent	1 (7)
Some college	1 (7)
College graduate	6 (40)
Some graduate school or more	6 (40)
Employment status, *n (%)*	
Employed	9 (60)
Not employed, looking for work	2 (13)
Not employed, not looking for work	1 (7)
Retired	2 (13)
Homemaker	1 (7)
Stopped working because of cancer, *n (%)*	
No	11 (73)
Yes	3 (20)
Not applicable	1 (7)
Income, *n (%)*	
$11,000-$25,000	1 (7)
$25,000-$50,000	1 (7)
$50,000-$75,000	2 (13)
≥$75,000	11 (73)
Activity level, *n (%)*	
Normal activity without symptoms	9 (60)
Some symptoms, bed rest not required during waking day	5 (33)
Bed rest required for <50% of waking day	1 (7)
Ever attended a cancer support group, *n (%)*	
No	13 (87)
Yes	2 (13)
Still attending a cancer support group, *n (%)*	
No	2 (13)
Yes	0 (–)
Not applicable	13 (87)
Ever talked with a mental health professional about cancer, *n (%)*	
No	7 (47)
Yes	8 (53)
Still talking with a mental health professional about cancer, *n* (%)	
No	5 (33)
Yes	3 (20)
Not applicable	7 (47)

to Phase 1, eligibility criteria include: 1) female sex; 2) at least 18 years old; 3) able to speak and read English; 4) diagnosed with HR + breast cancer stage I-III; 5) finished cancer treatment with the exception of ET; 6) prescribed to start taking ET within past 6 months; 7) free of prior breast cancer diagnoses; and 8) free of visual, hearing, voice, motor, and psychiatric impairment that would interfere with study participation. Participants in the randomized feasibility trial must also 9) be willing to be randomized to one of the study conditions and 10) have access to a computer or tablet with Internet capabilities.

3.1.2. Procedures

All randomized feasibility trial procedures were reviewed and approved by Northwestern University's Institutional Review Board. Consented participants will be randomized 1:1 to the 8-week *My Journey* enhanced care condition or an 8-week *Health Education* comparison condition. During the 8-week intervention time frame, participants will complete weekly classes based on assigned study condition. Participants will complete follow-up questionnaires of the theorized primary intervention outcomes and intervention targets at 4 weeks post baseline, 8 weeks post baseline, and 6 and 12 months post baseline. In addition, participants will complete a brief exit interview to assess satisfaction with and usability of the study online tool. Participants will be compensated $300 for completing the study.

Table 4
Usability results.

	M	SD	Range
Total usability score	106.3	7.7	83–115
Individual items			
It is useful	4.9	0.3	1–2
It gives me more control over the activities in my life	4.2	0.8	1–3
It meets my needs	4.4	0.6	1–3
It does everything I would expect it to do	4.1	1.1	1–5
I can recover from mistakes quickly and easily	4.6	1.1	1–5
I can use it successfully every time	4.9	0.3	1–2
I learned to use it quickly	4.9	0.4	1–2
I easily remember how to use it	5.0	0.0	–
It is easy to learn to use it	4.9	0.4	1–2
I am satisfied with it	3.9	1.4	1–5
I would recommend it to a friend	4.7	0.7	1–3
It is fun to use	4.3	0.8	1–3
It works the way I want it to work	4.6	0.7	1–3
I think that I would like to use this system frequently	4.1	1.2	1–5
I found the system unnecessarily complex	4.4	1.5	1–5
I thought the system was easy to use	4.7	1.1	1–5
I think that I would need the support of a technical person to be able to use this system	4.7	1.1	1–5
I found the various functions in this system were well integrated	4.4	1.2	1–5
I thought there was too much inconsistency in this system	4.6	1.1	1–5
I would imagine that most people would learn to use this system very quickly	4.9	0.3	1–2
I found the system very cumbersome to use	5.0	0.0	–
I felt very confident using the system	4.9	0.3	1–2
I needed to learn a lot of things before I could get going with this system	5.0	0.0	–

Notes. Total usability score is a sum of individual items. Possible item responses range from 1 (disagree) to 5 (agree) and possible total scores range from 23 to 115.

Table 5
Example qualitative quotes.

Theme	Summary of Participant Feedback	Resulting Modifications
Branding	• Original website name (*OncoTool*) was "harsh," "technical," and "like a clinical term" • The term "journey" is more acceptable.	• Website title changed to *My Journey*
Aesthetic	• Preference for a "bright" color scheme to "symbolize positivity" • Preference for "colors more associated with breast cancer such as pink" • Text should be "bigger," "bolder," and darker" to make it easier to read	• Color scheme changed to shades of pink • Text was made larger and darker
Accessibility	• Program should be accessible for women of different ages, backgrounds, and health statuses • Example: using the section title "healthy at every age" instead of "any age"	• Section titles were modified to be more inclusive
Content	• Existing content was relevant •Requested information about menopause, sexual side effects of ET, changes in body image, and fertility preservation	• Information on menopause, sexual side effects, changes in body image, and fertility preservation have been included in *My Journey*.

3.1.3. Study conditions and delivery

Participants will be randomized to one of two study conditions, which are the *My Journey* website or the *Health Education* comparison website condition. Both study conditions will include an 8-week intervention delivered over videoconference in a group format of 4–8 participants. Weekly group sessions across both conditions will last approximately 90 min. *Health Education* facilitators will be graduate-level trained members of the study team, and *My Journey* facilitators will be graduate-level, certified mindfulness instructors.

3.1.3.1. Health education comparison condition. The *Health Education* comparison condition focuses on information related to improving overall health. Importantly, it does not contain any of the mindfulness content from the *My Journey* enhanced care condition. We sought to provide a more rigorous design by incorporating a patient education control to determine whether an MBI would lead to improved outcomes beyond the effects seen in a typical patient education condition. Therefore, the *Health Education* comparison condition does contain the same information related to ET and managing ET side effects. The overlapping ET content between conditions is appropriate, as this information is the standard of care for breast cancer survivors experiencing side effects of ET [13]. In addition, the *Health Education* comparison condition includes health and lifestyle content related to diet, nutrition, types of physical activities, common chronic illnesses in older age such as heart disease, and healthy living. This content was developed from the National Cancer Institute and the National Heart, Lung, and Blood Institute guidelines [37,40]. Notably, participation in the *Health Education* comparison condition is strictly didactic. In addition to attending weekly, 90-min group sessions, participants have access to online written information about managing ET side effects and other health promotion topics. Participants will be encouraged to review the information in the *Health Education* website for approximately 30 min each week.

3.1.3.2. Patient engagement. Both *My Journey* and the *Health Education* will contain three levels of behavioral reinforcement. After using the website for 30 min, participants will be awarded a virtual ribbon. After using the website for 30 min and completing two interactive activities, participants will be awarded a virtual medal. Finally, after using the online tool for 30 min and completing five interactive activities, participants will be awarded a virtual trophy. Behavioral reinforcements reset each week so that participants can incrementally earn 8 ribbons, 8 medals, and 8 trophies over the course of the 8-week intervention timeframe. Earned awards will be displayed on the participants' dashboards within the online tools.

3.1.3.3. Fidelity. Adherence to the intervention protocol will be conducted by an author-constructed checklist focusing on adherence to the specified content in each condition. The fidelity checklist will cover a list of topics for the weekly session as well as whether any additional content, not in the manual, was introduced by the facilitator. Eighty percent of intervention topics covered will be considered and will be coded by an independent member of the research team. To avoid cross-contamination of intervention content, separate interventionists will be used for each condition of the study. In addition to providing training on intervention content delivery, the study PI will review the first 10% of group sessions to provide feedback to the therapists.

3.1.4. Outcomes

All participant-reported questionnaires will be administered and stored via Research Electronic Data Capture (REDCap) [41]: A secure web-based research data management system hosted at Northwestern University. Consistent with Bowen and colleagues [42], the primary outcome of this trial is feasibility, which we will assess using four markers: acceptability, demand, and intended preliminary effects.

3.1.4.1. Acceptability. We will assess acceptability with author-constructed questions which ask participants to rate how much they enjoyed the information presented in the weekly group sessions and how much they liked the weekly online groups in general [43–46]. Items are rated on a 5-point scale ranging from 1 (a lot) to 5 (did not review). Lower scores reflect better satisfaction with the program.

3.1.4.2. Demand. We will assess demand with rates of study recruitment, retention, and attendance as well as participants' use of their assigned website (e.g., frequency of logins, time spent on the online tool, click data, content accessed). The following rates will be deemed acceptable based on prior studies of oncology patients: 60% of eligible patients will be enrolled in the study, 70% of enrolled participants will remain in the study through the final assessment, and 70% of participants will attend all (8/8) sessions [47–49]. We will also assess the completion rate of the study assessments, including patterns, if any, in missing data as well as percentage of missing data for each participant.

3.1.4.3. Intended preliminary effects. We will assess the intended preliminary effects of *My Journey* on the theorized primary intervention outcomes (i.e., improved HRQoL and ET adherence) relative to the comparison condition. *My Journey* intervention targets are breast cancer knowledge [50], beliefs about ET [51], cancer- and medication-related self-efficacy [52,53], anxiety [54], fear of cancer recurrence [55], coping skills [56], social support [57], and mindfulness skills [58–60].

ET Adherence. Participants will self-report ET adherence using the 14-item Adherence to Refills and Medications Scale (ARMS) questionnaire [61]. The ARMS assesses barriers to medication adherence and adherence-related behavior on a 5-point scale ranging from 1 (none of the time) to 5 (all of the time). Lower scores indicate better medication adherence and fewer barriers to medication adherence. We will electronically verify ET adherence using medication event monitoring systems (MEMS) cap devices [62]. A MEMS cap is an electronic bottle cap that tracks when participants open a medication bottle. We will provide each participant with a MEMS cap and instruct them to use it with their ET medication throughout the course of the study. This will allow us to quantify the proportion of days those participants adhere to taking their ET medication (i.e., proportion of days they open their ET medication bottle). Finally, we will extract information from participants' medical and pharmaceutical charts to compute the proportion of days covered (PDC) ratio, which is the number of days in which a medication is available to a patient (e.g., days covered by a filled prescription) divided by the total number of days in the observation period [63–68]. The PDC is one of the most widely used methods to assess medication adherence. Adherence will be measured using a composite score that will include objective and subjective methods. Participants will be categorized as being adherent to hormonal therapy if their pharmaceutical records indicates that the number of days in which a medication is available to the patient divided by the total number of days in the data analysis period (i.e., proportion of days covered; PDC) is $\geq$ 80%, electronic monitoring registers an opened bottle cap at least 80% of prescribed days in the study, and 11 out of 14 items on the ARMS are endorsed as not having any struggles with endocrine therapy [69,70].

HRQoL. HRQoL will be assessed with the 46-item Functional Assessment of Cancer Therapy-Endocrine Symptoms (FACT-ES) [71]. The FACT-ES assesses HRQoL in the last seven days among breast cancer survivors taking ET. The FACT-ES yields a total HRQoL score as well as subscale scores reflecting physical well-being, emotional well-being, social well-being, functional well-being, and endocrine symptoms. To avoid overlap, only the subscales, as opposed to the total scale, will be scored, and interpreted. The primary HRQoL outcome will be the endocrine symptoms subscale and all other FACT subscales will be considered secondary HRQoL outcomes. Items are rated on a 5-point scale ranging from 0 (not at all) to 4 (very much). After appropriate reverse scoring, items are summed so that higher scores reflect better

HRQoL. Participants will also complete the PROMIS Depression CAT [54]. Items are rated on a 5-point scale ranging from 0 (never) to 5 (always) and converted to t-scores with a mean of 50, a standard deviation of 10, and higher scores indicating more depressive symptoms.

Breast cancer knowledge. Knowledge about Breast Cancer is a questionnaire of 16 statements about breast cancer treatment [50]. Participants respond by indicating whether a given statement is 'true' or 'false,' and the proportion of correct responses is calculated to reflect overall breast cancer knowledge.

Beliefs about ET. Beliefs About Medicines is an 11-item questionnaire that assesses perceptions of the cost-benefit analysis of taking ET, which can provide insight as to how adherent a patient may be [51]. Participants will rate their agreement with statements that other patients taking ET have said about their ET medication. Items are rated on a 5-point scale ranging from 0 (strongly agree) to 5 (strongly disagree), with higher scores indicating stronger perceived benefits of taking medications.

Cancer-related self-efficacy. The Communication and Attitudinal Self-Efficacy scale for cancer (CASE-cancer) is a 4-item questionnaire that assesses participants' confidence in their ability to understand and participate in their care, maintain a positive attitude, and seek and obtain information [52]. Items are rated on a 4-point scale ranging from 1 (strongly disagree) to 4 (strongly agree), with higher scores indicating better cancer-related self-efficacy.

Medication-related self-efficacy. We will assess medication-related self-efficacy with the Patient-Reported Outcomes Measurement Information System (PROMIS) Self Efficacy for Managing Symptoms computer adaptive test (CAT) [53]. The PROMIS Self Efficacy for Managing Symptoms CAT assesses how confident participants are in their ability to manage symptoms and side effects. Items are rated on a 5-point scale ranging from 1 (I am not at all confident) to 5 (I am very confident) and converted to t-scores with a mean of 50, a standard deviation of 10, and higher scores indicating better medication-related self-efficacy.

Anxiety. The PROMIS Short Form v1.0-Anxiety 4a is a fixed 4-item questionnaire that assesses symptoms of anxiety [54]. Items are rated on a 5-point scale ranging from 1 (never) to 5 (always). The PROMIS data is interpreted by applying a standard metric that is representative of the responses collected from the public.

Fear of cancer recurrence. The Concerns About Recurrence Scale (CARS) is a 4-item questionnaire that assesses participants' preoccupation with fears about the possibility of cancer recurrence [55]. Items are rated on a 6-point scale ranging from 1 (I don't think about it at all) to 6 (I think about it all the time), with lower scores reflecting less fear of cancer recurrence.

Coping skills. The Brief COPE is a 20-item questionnaire that assesses the frequency of using various coping skills to cope with cancer [56]. Items are rated on a 4-point scale ranging from 1 (I haven't been doing this at all) to 4 (I've been doing this a lot) and higher score reflect better coping.

Social support. The Emotional/Information Support subscale of the Social Support questionnaire is a 9-item questionnaire that assesses a participants' availability to various types of social support [57]. Items are rated on a 5-point scale ranging from 1 (none of the time) to 5 (all of the time), with higher scores indicating greater availability of social support.

Mindfulness skills. The author-constructed Mindfulness Follow-Up Survey assesses mindfulness skills using a combination of Likert-type and open-ended items [58]. The 21 Likert-type items assess how participants incorporate mindfulness practices into their daily lives. Items are rated on a 5-point scale ranging from 0 (not at all) to 4 (very much), with higher scores indicating a greater incorporation of mindfulness practices into daily life. Intolerance of Uncertainty is a 12-item questionnaire that assesses how participants cope with unpredictability [60]. Items are rated on a 5-point scale ranging from 1 (not at all characteristic of me) to 5 (entirely characteristic of me), and items are averaged with lower scores indicating a greater ability to cope with uncertainty and live in the present moment. Rumination Questionnaire is a 12-item questionnaire which assesses how likely a participant is to dwell on past experiences [59]. Items are rated on a 5-point scale ranging from 0 (strongly agree) to 4 (strongly disagree), with higher scores reflecting greater rumination.

3.1.5. Analytic plan

Power was calculated using PROC POWER in SAS version 9.4 [72]. To allow for typical study attrition, we aim to recruit 40 participants per condition (N = 80 total). Because this is a feasibility study with a small sample size, we will focus on descriptive statistics and within condition tests. Therefore, our analytic plan will calculate descriptive statistics, confidence intervals, and within group pre-post changes, as these are the most appropriate analyses for a feasibility study with our sample size. We will use summary statistics to characterize the sample and to examine the feasibility outcomes. To examine preliminary intended effects, we will calculate change scores pre- and post-intervention for each of the outcomes, and p values of less than .05 will be considered statistically significant. Within group comparisons will be evaluated using changes of half a standard deviation on PROMIS scales (i.e., 5 points) and two points on FACT subscales will be considered minimally important differences. Missing data will be handled using pairwise deletion.

4. Discussion

The purpose of this manuscript was to describe the rationale, protocol, and usability findings for an online, group-based MBI program called *My Journey*. This program was designed to enhance adherence to ET via MBI-associated improvements in ET side effects and HRQoL. Usability data were collected as part of a randomized feasibility trial, which is currently underway.

The quantitative usability feedback was generally positive, indicating above average usability. In addition, the qualitative analyses revealed that there were several strengths noted in the initial design of *My Journey*. Participants generally liked the layout and found the information to be relevant. Using feedback from the participants in the usability study, we were able to modify the branding, aesthetic, accessibility, and content for *My Journey*.

This study has several notable strengths. First, this study will establish the usability and feasibility of a novel and scalable website to deliver a behavioral intervention in the context of breast cancer ET adherence. The online delivery of this intervention is notable, as participants can engage in the intervention from the convenience of their homes. Second, although one study has demonstrated the efficacy of MBI for improving ET-related quality of life [73], our study sets the stage for a full-scale trial to establish the efficacy of an MBI program to improve adherence to ET. Third, unlike previous studies that have solely relied on one method of assessing medication adherence, our study's approach to measuring ET adherence through one subjective method (i.e., self-report) and two objective methods (e.g., electronic monitoring and pharmaceutical records) is innovative and will advance the literature on medication adherence among breast cancer survivors.

This study also has limitations worth noting. First, the scope of work is limited to establishing usability and feasibility as opposed to efficacy. Second, the study is limited to patients who have access to the internet and therefore may limit generalizability. However, it has been our experience from previous studies [44,74] that the most patients have access to the internet through computers and/or tablets with data plans. Finally, most of the data collection will take place within one geographic area and is only available in English. Considering the limited budget associated with feasibility studies and high costs of subcontracts and translations, we limited the scope of this feasibility project to one language with plans to translate into Spanish if our feasibility trial yields successful results. Finally, it is also important to note that our usability study sample is representative of the patients that seek care at our

comprehensive cancer center and not necessarily the general breast cancer population in the US., which is the first step in establishing the acceptability and usability of our online intervention. We have discussed several strategies to enhance generalizability and uptake, including making all written information in *My Journey* both audio and video accessible in future trials and translating to Spanish. Future directions should include additional considerations for enhancing generalizability and scalability.

In conclusion, results from the initial development and testing phase demonstrated the usability of a web-based MBI for breast cancer survivors prescribed ET. The feasibility and preliminary efficacy of *My Journey* is currently being investigated in a pilot randomized trial. If efficacious, there may be the potential to implement this program with patients diagnosed with other chronic conditions where medication regimens lead to side effects that reduce optimal adherence.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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