Original Article

THRIVE intervention development: using participatory action research principles to guide a mHealth app-based intervention to improve oncology care

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Background: Women with hormone receptor-positive, early-stage breast cancer who adhere to adjuvant endocrine therapy (AET) reduce the risk of cancer recurrence and mortality. AET, however, is associated with adverse symptoms that often result in poor adherence. We applied participatory action research (PAR) principles to conduct focus groups and interviews to refine and enhance a web-enabled app intervention that facilitates patient-provider communication about AET-related symptoms and other barriers to adherence.

Methods: We conducted four focus groups with women with early-stage breast cancer on AET (N=28), stratified by race (Black and White) and length of time on AET (<6 months and >6 months), to determine preferences and refine the app-based intervention. A fifth mixed-race focus group was convened (N=6) to refine THRIVE app content using high-fidelity mock-ups and to develop new, tailored feedback messages. We also conducted interviews with oncology nurses (N=5) who participated in the THRIVE randomized controlled trial.

Results: Participants reported preferences for weekly reminder messages to use the THRIVE app, a free-text option to write in AET-related symptoms, and app aesthetics. Other requested app features included: a body map for identifying pain, sleep and dental problems on the symptom list, a dashboard, tailored feedback messages, and information about social support resources. Participants also developed new intervention messages, decided which messages to keep, and edited language for appropriateness and sensitivity. They also discussed the type of electronic pill monitor and incentive plan to be used in the intervention. Nurses reported THRIVE alerts integrated seamlessly into their clinical workflow and increased patient-provider communication, facilitating quicker response to patients' reported symptoms. Nurses reported no negative feedback or usability concerns with the app.

Conclusions: THRIVE app content reflects researchers' partnership with a racially diverse sample of breast cancer survivors and healthcare providers and adherence to participatory design by incorporating

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patient-requested app features, app aesthetics, and message content. The app has the potential to improve AET adherence and quality of life among breast cancer survivors and reduce disparities in mortality rates for Black women by facilitating communication with healthcare providers.

Keywords: mHealth; web-based intervention; participatory action research (PAR); breast cancer

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Introduction

Women with hormone receptor-positive (HR+) early-stage breast cancer (ESBC) are usually prescribed an adjuvant endocrine therapy (AET) medication after active treatment (e.g., breast surgery, chemotherapy, radiation) to reduce the risk of cancer recurrence and mortality (1,2). Despite its efficacy, AET nonadherence is common due, in part, to adverse side effects (3-5). Women on AET frequently report negative symptoms, such as pain, fatigue, hot flashes, sexual dysfunction and mental health challenges, all of which can negatively impact quality of life during survivorship (6-8). Adverse side effects significantly contribute to AET nonadherence for Black women, which may account for mortality disparities (9).

Clear, patient-centered communication between a woman with ESBC and members of her oncology care team is essential for timely identification and management of AET-related side effects (10,11). Effective patient-provider communication can reduce medication nonadherence and poor patient health outcomes for breast cancer survivors (12,13). However, communication challenges in the clinical oncology setting persist (14,15), highlighting the need for novel methods. mHealth technologies (e.g., web-enabled apps and devices) may offer innovative ways to improve healthcare service delivery and patient health outcomes.

mHealth apps have been employed to promote prevention, improve early detection, manage cancer care, and support cancer survivors (16,17). mHealth apps can also improve communication processes and information exchange between patients and providers (18). However, for mHealth interventions to have the potential to be effective at changing behavior and health outcomes, the app and its features must first engage users. Overall, a quarter of all apps downloaded to smart mobile devices are used only once (19). Engaging users/patients in the design process is critical for improving the likelihood of success of any mHealth intervention. To accomplish this, extensive formative work is recommended to test the interface and user experience among patients that would benefit from the intervention (19).

User-centered or participatory design, reflecting principles of participatory action research (PAR), is characterized by involving end users as co-developers in design phases and is recognized as an essential aspect of good mHealth design practice (19,20). mHealth interventions developed in accordance with PAR principles (e.g., patient empowerment, equitable, sustained participation by community stakeholders) increase relevance, appropriateness, rigor, validity and sustainability (21). Still, few studies have examined patient user preferences or solicited feedback from the healthcare team tasked with implementing the intervention. To avoid potential pitfalls from lack of stakeholder engagement in mHealth intervention development, we applied PAR principles in conducting focus groups and interviews to refine and enhance a web-enabled app-based intervention to improve symptom management and medication adherence for women with ESBC on AET. We present the following article in accordance with the MDAR reporting checklist (available at http://dx.doi.org/10.21037/jhmhp-20-103).

Description of the THRIVE intervention

The THRIVE intervention aims to facilitate timely and responsive symptom management and improve medication adherence by collecting and transmitting patient-reported symptoms and other potential adherence barriers to medical oncology care teams. The intervention is guided by the symptom management model (*Figure 1*), which describes the interrelatedness of three symptom management dimensions: symptom experience, management strategies, and health outcomes (23). The model is based on the assumptions that the patient's perception of symptoms is the gold-standard of measurement; troublesome symptoms

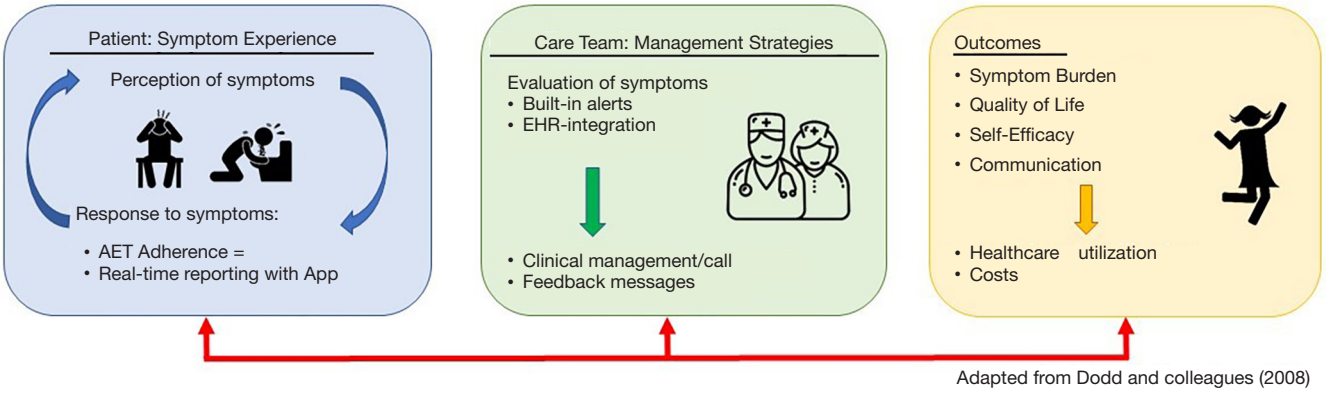


Figure 1 Conceptual framework guided by the symptom management model. Reprinted with permission from ref (22).

must be monitored and managed in a timely manner, and symptom management is dynamic (23).

In our pilot trial, we tested the feasibility of THRIVE among 44 women with HR+ ESBC and a new prescription for an AET medication. THRIVE uses a web-enabled app designed to improve patient-provider communication about AET adherence and related adverse symptoms outside of clinic visits. Intervention group participants received weekly reminders to report adherence in the last seven days and any new or changing adverse symptoms for eight weeks. Built-in, real-time alerts and electronic health record-integration allows any patient's report of AET nonadherence or adverse symptoms to be continually evaluated by the patient's oncology team and promptly address symptoms and other patient concerns, resulting in improved patient symptom experience and AET adherence. Participants randomized to receive weekly reminders to use the study app self-reported significantly higher AET adherence at eight weeks compared with controls (91% *vs.* 68%, P=0.02) (24). We are in the process of testing an updated version of the THRIVE intervention that builds on the success of the pilot study by: (I) engaging patients in the design and content of the app, text messages, and recruitment protocols-the focus of this paper; (II) including a larger sample, stratified by race, powered to test the intervention with and without tailed feedback messages; (III) expanding the intervention period from two to six months in order to capture later-onset adverse symptoms that might be slower to develop; and (IV) following participants for one to three years to test longer-term effects of the intervention on medication adherence and other outcomes. We are currently randomizing 300 patients initiating AET to one of three arms: (I) an "App" group (N=100) that receives weekly reminders to use the THRIVE study app; (II) an "App+Feedback" group (N=100) that receives weekly reminders and tailored feedback based on their use of the app; or (III) a "Usual Care" group (N=100) that receives usual care only (22). The primary outcome is medication adherence at 12 months, which is captured using an electronic monitoring pillbox.

Methods

The West Cancer Center and Research Institute (WCCRI), our partner for this study, provides a network of fully integrated cancer care at 9 clinic locations in Tennessee, Arkansas, and Mississippi. The WCCRI treats more than 1,200 patients with a new breast cancer diagnosis annually.

Patient focus groups

To update and refine the THRIVE intervention, including the web-enabled app, and ensure its relevance to the target audience, we conducted four focus groups involving women with ESBC on AET, stratified by race (Black and White) and length of time on AET (<6 and >6 months). Adult women (ages 18 years and older) with a diagnosis of HR+ ESBC and a prescription for an AET medication, including tamoxifen or aromatase inhibitor, were eligible. To recruit focus group participants, WCCRI physicians (LS and GV) identified potential participants from their patient rosters, and the study nurse (TJ) reviewed electronic health records. TJ contacted women by telephone, reviewed the study procedures, answered questions, and confirmed their eligibility.

Those who were interested in study participation were scheduled for a one-time focus group at the WCCRI

Table 1 THRIVE intervention self-affirmation messages

I am worth the effort I invest in my health
Everyday I become stronger and healthier
My body grows stronger every day
I am grateful to be alive. It is my joy and pleasure to live another wonderful day
I am beating breast cancer. I can take anything life throws at me
All of my interactions with medical personnel will be positive and pleasant
I honor my body by trusting the signals that it sends me
I am confident, beautiful and graceful
I allow my body to become an environment for health and healing
I feel great when I take care of myself
I love and respect my body

campus. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the University of Tennessee Health Science Center Institutional Review Board (17-05479-XP IAA) and informed consent was provided by all of the study participants. Demographic information (e.g., race, age, income, educational level) and cancer-related personal characteristics (e.g., staging at initial breast cancer diagnosis, family history, AET prescription) were collected from focus group participants via a brief questionnaire.

Focus groups were moderated by race-concordant moderators (JA and RK). Single-race focus groups were used to create opportunities for breast cancer survivors to engage in open dialogue with their peers in safe, nonjudgmental environments. Focus group participants were prompted to share their insights about patient-provider communication and technology in healthcare (14) and essential components and functional requirements of the THRIVE app, as well as to assess acceptability of app message content and frequency of reminder messages. Moderator guide used for these four focus groups included in Appendix 1.

A fifth mixed-race focus group was convened (N=6), comprised of participants from previous focus groups, to provide feedback on THRIVE app content using high-fidelity mock-ups and changes that would make the app more helpful and engaging. Participants were shown tailored feedback messages that focused on patient-reported AET adherence and symptoms, positive reinforcement, and motivational messages, and they were asked to provide feedback on messages that would lead to optimal adherence. The Moderator Guide used in this focus group is included in Appendix 2. Using a scale of 1–5, they evaluated each message for attention, motivation, personal relevance, appropriateness, and acceptability and decided which affirmations would be included in the intervention (*Table 1*). Lastly, participants were asked to select the electronic pill monitor to be used in the study and identify incentives that would facilitate participant retention. All focus group participants were compensated with a $40 gift card for each focus group in which they participated.

Nurse interviews

Semi-structured, in-person interviews were conducted with oncology nurses (N=5) charged with implementing the THRIVE intervention in clinical practice to qualitatively assess the impact of the THRIVE app on patient-provider communication, provider responsiveness to patients' adverse symptoms, clinical workflow, and initial challenges to app implementation. TJ recruited eligible nurses, and JA interviewed each nurse on the WCCRI campus. Interviews lasted approximately 20 minutes, and nurse participants were compensated with a $25 gift card. All nurse participants self-identified as female; three nurse participants were White and two were Black.

Data analysis

Focus group sessions were audio recorded and professionally transcribed verbatim. Transcripts were imported into NVivo 11Plus (QSR International Pty Ltd.). Researchers (JA and CG) read each transcript and conducted line-by-line coding independently. They engaged in an iterative process of developing codes for each focus group, discussing differences to clarify codes names and descriptions, and referencing transcript texts and audio recordings to resolve differences. Final analysis yielded themes as well as categories and sub-categories for themes. RK assessed internal validity and reliability by independently examining thematic analyses for clarity, consistency, credibility, and meaning (25,26).

Results

Twenty-eight women (average age: 64 years) took part in the focus groups. Most had stage I or stage II breast cancer at diagnosis (43% and 32%, respectively). Early AET users

Table 2 Focus group participants characteristics (N=28)

Characteristic	N	%
Race		
Black	13	46
White	15	54
Medication		
Anastrozole	24	86
Exemestane	3	11
Letrozole	1	4
Stage		
0	4	14
I	12	43
II	9	32
III	3	11
Number of months on AET (mean)	10.1	

averaged 2.63 months on their prescribed medication; late AET users averaged 16.55 months (*Table 2*). Participants in the four initial focus groups expressed their preferences for app features that would aid them in identifying and self-monitoring AET-related symptoms (i.e., body map, free-text option, patient dashboard, social support resources); content for tailored feedback messages and positive affirmations; and desired frequency of reminder messages to use the THRIVE app. Participants in the 5th focus group indicated their preference for an electronic pillbox and a loss-framed incentive plan to be used in the THRIVE intervention. Participants' responses about preferences for app content and features were compared to see if any race-based differences emerged; no substantive differences were found.

Nurses expressed favorable opinions of the THRIVE app, stating it improved patient-provider communication between patients and members of their oncology team. The app also improved providers' abilities to quickly address a patient's concerns about adverse symptoms and AET adherence challenges. Nurses reported the THRIVE app and alerts did not interrupt clinical workflow or increase work burden.

THRIVE app features

Body map

Most participants in the initial focus groups described experiencing pain; however, some shared that they often have difficulty describing multiple pain locations with varying severity levels. Participants reported wanting a way to delineate their specific pains beyond a numeric rating scale: "*Will we have something to list our type of pain we are having? Because this is just general, saying that I have pain, but you won't know what kind of pain I am having.*" To address participants' concerns about potential miscommunication with providers, a body map was added to the THRIVE app. The body map features anterior and posterior views of a female figure, and users can select any part of the body to indicate a pain site (*Figure 2*). Users are also able to rate the pain severity on a scale of 1–10 (10 being most severe). Participants in the 5th focus group reviewed the mock-up of the body map for the THRIVE app and gave it unanimously positive feedback. One participant said, "*It's awesome*," and another woman said, "*Yes! Because it is hard to tell someone exactly where you are talking about it hurts.*"

Free-text option

In three focus groups, participants discussed how AET medications can affect every woman differently, which prompted several women to seek clarification about the "other" response option. A few women explicitly asked if an open-response box would be included in the THRIVE app. One participant said, "*Is there something for you to fill out for yourself that is not on the list? Like if I have a side effect that is not on this list that would be 'other'?*" Another participant queried: "*If you hit 'other,' does it go to give you other reasons or give you a fill in box?*" Participants insisted it would be critical to their ability to describe symptoms and communicate with their provider accurately. Based on this feedback, the study team engaged our technology partner to ensure a free-text option would meet patient needs without creating unnecessary provider burden from uncategorizable—and potentially unactionable—patient-reported information. The free-text option was then placed at the end of the decision tree to ensure that information recorded in the free-text section included additional, unique information not recorded in previous steps (*Figure 3*). All participants in the fifth focus group positively rated the free-text option.

Patient dashboard

Several breast cancer survivors in the initial four focus groups shared that they use the electronic patient portal to track their lab results and monitor their treatment progress. One participant said, "*To always have those at your fingertips if I want to go back and see what my lab was on that day and how*

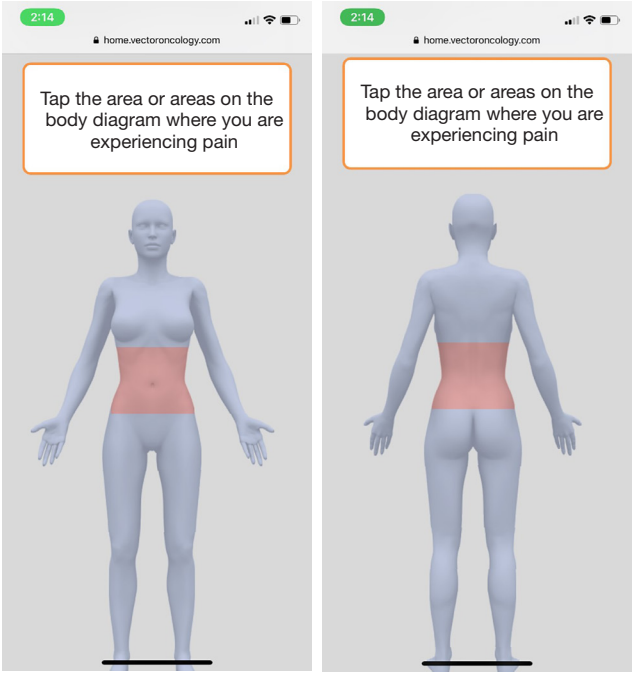


Figure 2 THRIVE app body map. Body map figures added for patients to note specific areas of pain: (A) shows front of body; (B) shows back of body. Reprinted with permission from ref (22).

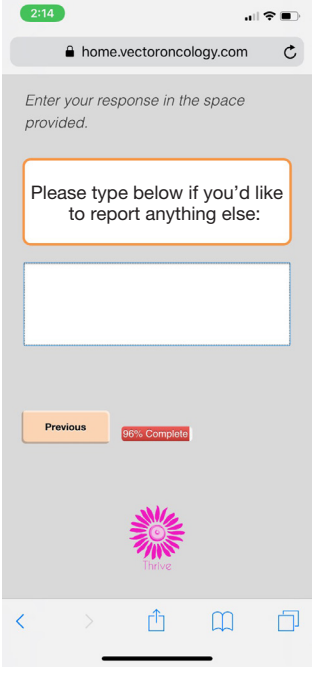


Figure 3 THRIVE app free-text feature.

this was or that was, that is good to have that." Participants indicated that it would be helpful to track AET-related symptoms on the app in a similar way: "*I think that it would also be helpful, at least for me, to know what days I have certain symptoms because maybe I am doing something on those days to make my symptoms worse. Give me an idea that maybe what I am eating or doing is aggravating this.*" To address this point, a dashboard feature displays dates when symptoms were reported, so patients can track their symptoms in real-time, see how symptoms change with time, and report trends to their oncology provider (*Figure 4*).

Social support resources

In each of the initial four focus groups, participants expressed the importance of providing within-app social support resources. Several participants acknowledged that patients receive written materials when they are first diagnosed with cancer, but if those resources are not readily accessible, then patients' social support needs may remain unmet. To address participants' suggestions, the THRIVE app features a hyperlink to the WCCRI website that contains a list of local and national support organizations.

Patient-friendly language

Focus group participants reported their desires for message wording to be both personal and professional. Participants expressed an understanding that the app would be used for medical purposes in a clinic setting; however, they reported wanting language that was "*a little bit more emotional, less like something that's just coming off of a computer.*" Additionally, participants wanted "cancer" removed from app messages. In one focus group, several participants brainstormed appropriate alternatives for "the C-word":

Participant A: I don't like having anti-hormonal cancer medicine said over again. I know that's what it is and I know that that's what the survey is, but couldn't we call it something else, something nice?

Participant B: Maybe like cancer medication?

Participant C: Hormone blocker? That's what I always call it just a hormone blocker.

Moderator: So that would be more positive language?

Participant C: Instead of throwing "cancer" in there every time.

Participant A: Yes, I know it's there.

Participant C: Yeah, we know it. We have all went

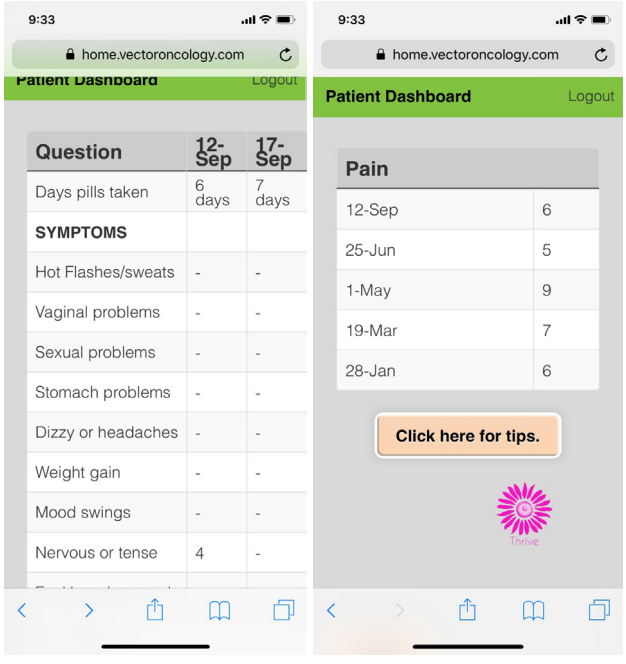


Figure 4 THRIVE app patient dashboard: (A) shows summary of symptoms reported using the app; (B) shows all previous reports of a specific symptom (e.g., pain) using the app.

Figure 5 THRIVE app aesthetics: (A) shows the logo developed with participant input for the THRIVE app; (B) shows an alternative version of the logo developed to be used in all study related communication with patients.

through it. Yeah, we know what it is.

This dialogue between focus group participants illustrates how breast cancer survivors find alternative medical words or phrases (e.g., medication, hormone blocker) for the word "cancer" to avoid frequent reminders about their diagnosis.

App aesthetics

A few participants openly shared their dislike of the THRIVE app's initial muted green color palette. One participant said, *"For me I like colorful things…colorful things kinda bring it out."* Another participant asked, "*Why don't we have pink?*" and indicated a preference for signature breast cancer pink to which other participants agreed. Based on this feedback, the THRIVE logo and icon app color scheme was changed to bold pink (*Figure 5*).

THRIVE intervention characteristics

Self-affirmation messages

Study team members generated a list of self-affirmations that patients in the "App" intervention group would receive weekly. Each self-affirmation message includes a link to the THRIVE app. Breast cancer survivors in the initial four focus groups reported positive perceptions of the statements: *"I get so tickled because I don't like apps, but I had to give all five stars because they are good. I think they was encouraging because some days I need it."*

Tailored feedback messages

Overall, focus group participants expressed positive views of the THRIVE app and its features, particularly the app's potential to improve patient-provider communication and AET adherence. One participant said, *"I like the idea that you can get messages back based on what you put into the survey, instead of feeling like sending information off into the air."* Another said, *"The personalized feedback gives you a feeling that you are connected instead of just 'here you are one month and then again six months later', so more interaction with your healthcare team."* Black and White women did not differ in their expressed desires for THRIVE app content and features; however, Black women in both single-race focus groups reported wanting an option for daily reminders to take their AET medication, especially for those with new prescriptions. One participant said, *"If every time I clicked on my phone and it say, 'Did you take your med?' then I say, 'Okay. Let me go take my medication.' I'm gonna stop and do that."* Black women also reported wanting timed medication messages (e.g., morning, afternoon, or evening) with graphics as personalized, visual reminders to adhere to their AET regimens. For instance, one participant said, *"Don't send no words just send a little pill bottle in that app, and then we*

will say, *'let's go twist that bottle*.'"

A pool of 126 tailored messages for study participants in the "App+Feedback" group were developed based on patient characteristics, including self-reported AET-related symptoms, lifestyle and preferred activities or hobbies, and religion/spirituality. Messages were also tailored to reflect the name of a patient's AET medication and provider. Several participants reported liking the potential just-in-time nature of tailored feedback messages, especially if they experience mental health challenges because of their cancer diagnosis or as a side effect of the AET medication. One participant said, "*You never know when you might just get that just at the right moment*. *You know*, *like*, *'Wow! That was a God thing*. *The Lord took care of that*.'" Additionally, focus group participants identified additional AET-related symptoms, specifically sleep disturbances/insomnia and dental health challenges (e.g., soft tooth enamel, tooth cracking, and tooth loss), which were subsequently added.

Participants in the fifth focus group worked in pairs to develop original feedback messages for the THRIVE intervention that highlighted the importance of adhering to one's AET regimen, engaging in open communication with healthcare providers, and maintaining an active, healthy lifestyle for one's self and others. At the end of the workshop session, each pair of survivors shared their feedback messages with the larger group. Participants engaged in back-and-forth dialogue to ensure the content of each new message was relevant to the objectives of the THRIVE intervention and spoke to the experiences of breast cancer survivors taking AET. Examples of survivor-generated messages that were included in the THRIVE intervention are: "AET doesn't work if you don't take it. Make it your goal this week to take your meds exactly how the doctor prescribed" and "Don't hesitate to report uncomfortable side effects. Your physician is not bothered by your calls." *Table 3* provides examples of tailored feedback messages. Focus group participants also reported liking messages with appropriate, related images; thus, tailored feedback messages with race-concordant graphics were added (*Figure 6*).

Reminder frequency

Focus group participants expressed belief that the THRIVE app and reminder messages would aid them in mindfulness about their cancer diagnosis and the importance of AET medication adherence. For instance, one participant said the THRIVE intervention would help women with breast cancer to "*remember to not just put your head in the sand and say*, *'I don't want to do this anymore*.'" Another participant said, "*I think that it helps you become more accountable and to do your part*. *If you are doing well*, *you don't just stuff it (cancer diagnosis) back*. *You'll remember that this is the reality of it*. *You are reminded to remember that this could re-occur so continue to do what you are doing even if it was several years back*."

In each of the first four focus groups, participants reported their preferences for reminder messages to use the THRIVE app. Participants expressed unanimous displeasure for daily reminder messages to use the app. Some indicated that, receiving reminder messages too frequently could cause "irritation" and prompt them to turn off app notifications. The majority of participants expressed a preference for weekly reminder messages. One participant said, "*I would say once a week*. *Don't bounce me every day*." Another participant said, "*So I won't remember if I'm supposed to do it every week and I only get a message once a month*." Focus group participants suggested that reminder message frequency should be adjusted to a patient's length of time on AET, such that patients with new prescriptions would receive reminder messages with greater frequency than those who had been on AET for longer periods. For instance, one participant said, "*I am thinking to begin with that weekly may be good but then once you have been on the medication for a while then weekly is going to seem like 'Oh my gosh*. *I just did this*, *and do I have to do it again!' So maybe monthly after that*, *a progressive schedule*." Unfortunately, researchers were unable to address this suggestion given limitations of the existing technology.

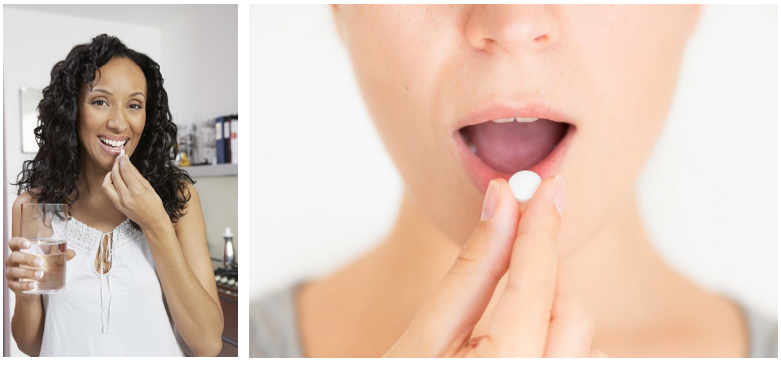
Electronic pill monitoring

A key component of the THRIVE intervention is using an electronic device to objectively evaluate the effect of the THRIVE app and messaging on breast cancer survivors' medication adherence. Participants in our fifth focus group were asked to identify their preference for an electronic pill monitor from two options. The first option was a pill bottle with an electronic cap that recorded each time the bottle was opened. This option required patients to own a smart phone and download an app (in addition to the THRIVE app) that captured and stored data from the electronic cap. The second option was a device (model RT2000) that resembled a pillbox developed by Wisepill. Data was captured each time the device was opened without patients having to download an additional app. Prior to selecting a preferred option, focus group participants asked about any negative effects of the electronic devices on the integrity of their AET medication, "*Do pills lose their strength in here?*"

Table 3 Select THRIVE intervention tailored feedback messages

Symptom messages
Hot flashes, cold sweats, and night sweats are common for women on (name of patient's AET medication). Wear loose, breathable clothing, and use light blankets and cotton sheets to stay cool
Feeling anxious? Consider reducing your caffeine consumption. Choose herbal teas or water instead of soft drinks and coffee. Try mineral water or club soda if you want some extra fizz!
Painful intercourse and decreased sexual desire are common side effects of (name of patient's AET medication). If you are experiencing decreased interest in sex or pain during intercourse, ask (name of patient's oncologist) or a counselor for ways to deal with sexual health changes
You had no symptoms to report last week. The THRIVE team celebrates your good health! Continue to take your (name of patient's AET medication) and practice healthy lifestyle habits
AET adherence messages
Many women with breast cancer live happy, fulfilling lives. The first step is taking your meds every day!
You did a great job taking your meds 7 times last week. Keep up the good work!
Last week you missed your (name of patient's AET medication) 4 times. Many people struggle to remember to take their medication. (name of patient's oncologist) or nurse will call you soon to talk about ways to help you take your meds exactly how your doctor prescribed
Exercise/healthy lifestyle messages
Make sure to eat lots of fruits and veggies, remain hydrated, and stay as active as you can to combat unwanted weight gain
Figure out your exercise style. Do you like doing the same thing every day, or do you like variety? Do you like to exercise by yourself, or do you love exercising with a group? If you don't know, try different activities until you find your passion
Have you tried art therapy? Aromatherapy? Reiki? Or tai chi? Mind-body practices may make a difference in physical side effects by improving mental health
Social support messages
Spend time exploring an online health community for women with breast cancer. You might find some useful information about managing symptoms
Social support is important. Ask your partner or a friend to come with you to your next appointment with (name of patient's oncologist)
There are many people who love and support you. Remind yourself of this whenever you feel discouraged today
Religion/spirituality messages
Peace I leave with you; my peace I give you. I do not give to you as the world gives. Do not let your hearts be troubled and do not be afraid. ~ John 14:27
Now, I ask not, "Why me?" Rather, I ask, "How shall I respond because it is me?" (Rabbi Doug Kahn)
Meditation on God is the medicine to cure millions of illnesses. My Tantra and Mantra is to meditate on God. Illnesses and pains are dispelled by meditating on Him. The fruits of the mind's desires are fulfilled. He is the Cause of causes, the All-powerful Merciful Lord. Contemplating on Him is the greatest of all treasures-Guru Granth Sahib Ji, 866
Patient-Provider Communication messages
Bring a notebook, a list of questions, and an open mind to your next appointment with (name of patient's oncologist)
Worried about a new or recurring symptom? Don't hesitate. Use the THRIVE app to report any side effects today
Use the THRIVE dashboard to track your pain levels. Make sure to discuss any concerns you have during your next clinic visit

and debated the pros and cons of each option. For instance, one participant said, "*The only thing I like about the bottle (option 1) is that you can put entire prescription in there and that you don't have to worry about refill your pill boxes because you have to remember to refill the pill boxes.*" One participant said she preferred the pillbox "*because that is what I do now.*"



Graphic for Black study participants

Graphic for White study participants

Figure 6 Example of a race-concordant graphic for the tailored feedback message (*taking THRIVE participant's AET medication name] regularly can help prevent cancer from coming back*) used with: (A) Black study participants; (B) White study participants."

Figure 7 THRIVE intervention electronic pill monitor-Wisepill model RT200.

There was not consensus among participants, yet the majority (4 out of 6) indicated a preference for the pillbox (i.e., second option) (*Figure* 7).

Incentive schedule for research participants

Participants in the fifth focus group were also asked to provide feedback on potential incentive plans for THRIVE intervention participants. Women in this focus group were presented with three options: two gain-framed plans and one loss-framed plan. The first option incentivized THRIVE intervention participants with a $5 monthly credit for study compliance (e.g., storing AET medication in the electronic pill monitor, keeping device charged); in the second option, study participants were given the same $5 monthly credit for study compliance plus one entry into a monthly lottery for a chance to earn an additional $20 or $300. The third option, the loss-framed plan, incentivized intervention participants with an initial $60 credit from which $5 monthly deductions would be taken for study noncompliance. One participant explained why she thought the gain-framed lottery option was unfair: "*That lottery thing, no. Because what if I am really good about doing mine and someone else is halfway doing theirs? You know, they might do it, but I'm just better and I take more time and I care more, but they're still up for the same incentive.*" Focus group participants unanimously selected the loss-framed incentive plan, as one participant said, "*Because you know it's there, and you gotta keep it.*"

Implementation feedback from WCCRI oncology nurses

Nurses reported favorable perceptions about the role of technology in healthcare service delivery. Several nurses said that technologies like web-enabled apps and patient portals give their patients more opportunities to share valuable information with healthcare providers who, in turn, are able to provide tailored, responsive feedback and better care. Yet, one nurse participant did express some reservations about technology, saying "*technology can be beneficial*" but may create additional barriers for older or low-income patients.

Every nurse participant reported initial reservations about the impact of the THRIVE app on clinical workflow and work burden. One nurse said, "*I have to say, initially I*

thought it was going to be a big burden. 'Oh my gosh! I don't want to get all this extra communication.'" However, all but one nurse reported THRIVE alerts did not increase work burden, and each nurse participant reported the app increased the potential for patient-provider communication. Specifically, nurses said the new free-text feature would be "*helpful*" because it increased the amount of information nurses had to address treatment issues. Nurses also reported that the THRIVE app gives patients more direct access to their oncologists and his/her care team, especially for patients who do not have direct contact with their nurse (e.g., personal email or cell phone). Additionally, nurses reported that patients often feel like they are bothering their providers if they contact them to report negative symptoms or challenges with medication adherence. They believe that since patients who use the THRIVE app are able to report their symptoms in real-time, nurses are able to intervene quickly when a patient is thinking about stopping AET medication because of adverse side effects. Nurse participants said THRIVE alerts can increase communication between the first AET prescription and 8-week follow-up visit, so patients' symptoms can be addressed quickly and "*patients don't have to suffer*." Nurses in this study reported no negative feedback or usability concerns with the THRIVE app. All nurses said they were comfortable with the intervention protocol and would recommend app-based interventions like THRIVE to other oncology nurses.

Discussion

Most women with ESBC on AET experience multiple adverse effects that can contribute to AET nonadherence, and they desire timely, patient-centered communication with oncology team members to manage AET-related symptoms and maintain their quality of life. This study describes development of the THRIVE intervention to demonstrate how an iterative, user-centered process, guided by PAR principles (21), can be employed to design a culturally and contextually relevant mHealth intervention that improves healthcare provision. Findings from this qualitative inquiry engaged patients and nurses to provide input on all key elements of the THRIVE intervention. We revised the THRIVE app content by incorporating patient-requested app features, app aesthetics, and message content. The app has the potential to improve AET adherence and quality of life among breast cancer survivors and reduce disparities in mortality rates for Black women by facilitating bidirectional communication with healthcare providers (27).

Black women face unique communication challenges related to side effects that contribute to AET nonadherence (14,28,29), which may account for mortality disparities. Thus, it was essential that we engaged in a culturally tailored approach to develop a mHelath intervention. We engaged Black breast cancer survivors in single- and mixed-race focus groups to better understand their unique needs and preferences for technology-facilitated patient-provider communication and healthcare provision. THRIVE app features (e.g., tailored feedback messages with race-concordant graphics and culturally appropriate language) are responsive to suggestions from our patient experts. Little is known about unique preferences among Black women with ESBC for technology "touches" (e.g., medication reminder messages) in app-based interventions, highlighting an additional area of mHealth research. Our participatory approach allowed us to go beyond a surface-level view of the scope and nature of Black breast cancer survivors' challenges and barriers to develop an mHealth solution that can circumvent issues that exacerbate health inequities (30).

Additionally, initial focus groups were stratified by duration of AET use to generate participant feedback that would better reflect the changing needs and experiences of women on AET. Recommendations that emerged from these discussions, such as providing links to WCCRI resources and support groups, may also help fill in support gaps experienced among many patients, following a period of decreased social support from patient support networks when compared to the primary phase of treatment (31,32). Given the trend of decreasing patient-provider interactions during the adjuvant treatment phase, enabling patients to utilize technology to report and seek recommendations for potentially severe AET-related side effects outside of the clinic visit may prevent early AET discontinuation.

In a recent study, healthcare providers reported favorable perceptions of telemedicine, particularly mobile apps, in oncology care for their abilities to improve patient-provider communication and facilitate patient reminders for medication intake (33). Yet, most breast cancer-focused mHealth apps lack healthcare professional involvement in development (34). The THRIVE intervention was developed in collaboration with WCCRI oncologists and nurses to ensure the app contains functionalities that would improve providers' abilities to address a patient's concern

in a timely manner without disrupting clinical workflow or adding to their work obligations. WCCRI nurses in our study reported one of the hallmarks of the THRIVE app is the ability for nursing staff to quickly respond to symptom alerts, thereby reducing the likelihood of patient AET nonadherence.

Despite the strengths of this study, there are some limitations worth mentioning. As with most qualitative methods, generalizability of this study's findings to other populations is limited by several factors. Given that our patient population is women with ESBC, these patient preferences might not be the same for other disease profiles of differing severity. Women with breast cancer metastases are likely to have different concerns and express different preferences for an app. More research is needed to understand how patients with later stages or greater disease burden perceive usability and benefit of the intervention. Furthermore, our sample was relatively small and also drawn from a single healthcare facility in the United States Midsouth; thus, certain factors (e.g., nurses' perceptions of work burden from app alerts) might vary as a function of existing staff workload and institutional infrastructure. Though our study captures the views of a diverse set of Black and White women with ESBC, preferences about app features and other intervention-related decisions (e.g., incentive scheme, pillbox preferences) might differ across more robust sociocultural, generational, geographic, and racial/ethnic backgrounds.

We are still in the process of testing the effectiveness of the THRIVE intervention on medication adherence and other key outcomes (22). This research adds to our understanding of how patients perceive and use a web-enabled app to further engage with their care team outside of clinic visits. Considering how ubiquitous web-enabled mobile devices have become, a successful intervention could be disseminated across health systems, conditions, and populations. Our results describe the process of applying PAR principles to tailor an interactive mHealth interventions. This process can be applied to other mHealth interventions to improve their effectiveness in delivering a low-cost and scalable intervention to improve outcomes across diverse patient populations and settings.

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from all the study participants.

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Appendix 1
UTHSC & WCCRI BC AET App Study
Focus Group Moderator Guide

Study Objective: *Improve symptom management and adjuvant endocrine therapy (AET) treatment adherence among women with breast cancer*

Good morning/afternoon and welcome to this focus group, sponsored by the West Cancer Center Research Institute (WCCRI) and UT Health Science Center. My name is (*name*), and I will serve as the moderator for today's conversation. This is (*name*), and she's here to take notes. We are here today to learn from you. Before we get started with the discussion, let's go around the room and have each person introduce herself.

1. Tell us your first name and your favorite restaurant in the city.

The moderator will instruct each woman to introduce herself as well as write her name on a table tent (name facing the group). The moderator will inform the group that pseudonyms are allowed to maintain anonymity.

Now that we've all become acquainted, I'd like to go over a few guidelines before we begin, so that we can really get the most out of our time together. This focus group session will be audiotaped for research purposes only. There will be no public broadcast of today's session. The audio recordings will only be used for the purposes outlined in the consent form each of you signed, so your identity and comments will remain confidential. Are there any questions? Let's begin. I am turning on the tape.

1. First, we are so excited to have you all here and really want to hear what everyone has to say. You can help us with that by speaking clearly and distinctly so we can all hear what you have to say; if I think that the audiotape won't pick up what you are saying, I will ask you to speak up because we want to capture your thoughts.

2. Second, we want to make sure that everyone can complete their thoughts and that we will be able to tell what you said on the audiotape. Whenever possible, please try to avoid interrupting or speaking while someone else is speaking.

3. Third, please let us know if you disagree with someone's opinion, but please do it in a respectful way.

4. Fourth, we value each person's opinions, so please contribute to the conversation. Don't just sit there quietly. If I notice that we haven't heard from you in a while, I will ask you whether you have anything to contribute, because sometimes it is hard to break into a conversation with so many ladies in one room.

5. On the other hand, please be aware and sensitive to the fact that everyone deserves an opportunity to be heard. Please make sure you're not the only one speaking.

6. In order to feel comfortable sharing with each other, we will all need to keep what is said in today's conversation confidential. Please feel free to mention that you participated in this focus group; however, please do not discuss any of the specifics about what any one person said, especially if it is of a sensitive nature.

Today, you will be asked to provide feedback about the enrollment process for a new study as well as your thoughts and suggestions for improving the content of a new web-based app used by patients at the West Cancer Center to improve communication about adjuvant endocrine therapy (AET) medication. Your honest feedback is important to the study team. Your thoughts and feelings about the content we are going to present to you will help improve the intervention, including the web app, for women with breast cancer.

You should have a small notebook and a packet in front of you. The notebook is yours to keep. Use it to jot down notes or questions or exchange information with other focus group members. The packet has five sheets, labeled Sheet A through Sheet G. You will be given instructions pertaining to these sheets throughout the discussion.

2. The overall purpose of the THRIVE study is improve patient-provider communication about AET medication through the use of web-based app. Sheet A provides examples of AETs, both generics and name brands.

What do you think the WCCRI team should know about women's physical/mental/emotional/spiritual needs when taking AETs?

*Probe #1: What recommendations would you make to the WCCRI team?

Now, I'd like to get your thoughts about the study enrollment process the team plans to implement.

(Moderator will read the short narrative about the general enrollment process)

A few days after being prescribed their first adjuvant endocrine therapy prescription, eligible women will receive a call from a research coordinator to tell them about the study and invite their participation. Interested individuals will schedule a time to

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meet in person with the research nurse shortly after picking up their AET pills. During this initial visit, women will be asked to bring in their AET pills and the nurse will (1) review the study consent form, (2) ask them to complete a brief, 10-minute survey, and (3) give them a new, electronic pill bottle monitor to be used with their AET prescription. The monitor looks just like a regular pill bottle. To compensate participants for their time and effort, they will receive $25 for each follow-up survey completed and pill bottle reading plus a $25 bonus for 100% completion for up to $200 for a year participation.

3. What do you think about the THRIVE enrollment process, as I have described it?

4. Think back to when you first received your AET prescription. When would have been the best time to approach you for participation in a study?

Thanks for your feedback on the study enrollment process. Now let's switch gears and think about how technology can impact communication in the medical setting.

5. How do you think use of technology, like the tablet used in the West Cancer Clinics, can increase communication between physicians and their patients?

*Probe #1: What topics would you most like to discuss via an app with your healthcare provider?

*Probe #2: Are there any topics you might feel MORE comfortable discussing electronically rather than face to face?

*Probe #3: Are there any topics that you might feel uncomfortable discussing with your healthcare provider in any format?

Please direct your attention to the packet. What I've given you are examples of a web-based app that has been developed to help providers improve communication with patients about taking their medications according to the prescribed regimen and side effects. For the next few minutes, I'd like you to provide feedback on the existing app. Feel free to write on the packet; the more, the better. As I describe each item, circle aspects you like, put Xs over aspects you don't like, and write any additional feedback you think is helpful.

Participants will receive reminders by email or text message to use the study app. Sheet B provides examples of those reminder messages.

6. Women are encouraged to use the app as much as possible, especially when they want to tell their doctor about new or changing symptoms. How frequently would you like to receive app reminders? How frequently is too frequently?

*Probe #1: Would you prefer a more personalized tailored message from your doctor? Would you delete the app? Turn off notifications?

Now, let's take a look at Sheet C. Here you will see an example of the flow of questions a person will receive through the app if she takes her AET medicine as prescribed and has no new symptoms to report.

Is the language in the questions clear? Do you like the layout of the app messages? Are there other symptoms that should be included? Feel free to mark up the packets. We are grateful for any feedback and recommendations you provide, so we can improve the existing app.

Now let's take a look at Sheet D. Here you will see an example of the flow of questions a person will receive if she does not take her AET medicine as prescribed or has new or changing symptoms to report. Again, provide feedback about the content of the app.

Now, let's take a look at Sheet E. Here are some examples of text messages patients may receive after using the app based on what they report.

(Moderator will read the directions. Moderator will also read each message to participants and direct them to provide feedback. Remind them to score each message.)

Finally, please look at Sheet F and G. Here are some examples of general messages, with and without graphics, patients may receive that are unrelated to what they report on the app.

Do you like these types of messages? Do you prefer graphic or no graphic? Why? How often would you like to receive these kinds of messages? Specifically, how often when you first receive an AET prescription, and how often once you've been on AET for a while?

(Moderator will read the directions. Moderator will also read each message to participants and direct them to provide feedback. Remind them to score each message.)

Sheet G instructions – circle the ones you like and cross out the ones you don't like.

7. What do you think of the sample messages? What other kind of content would be helpful in the messages a patient could receive through the app?

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7b. In addition to text-only feedback messages, would self-esteem/self-affirmations, photos, or video messages be effective? Why? Why not?

8. Thank you for your participation in that feedback. I'd like three or four volunteers to briefly describe what you liked best and least about this program you just viewed.

*Probe #1: How could this study/program be improved?

(If there is duplication in answers, the moderator should probe participants to provide new feedback/evaluations.)

(Notetaker will collect the packets from participants.)

9. How do you think real-time communication with a provider would impact how you take your medication and your health care?

*Probe #1: Do you think others would be completely honest in their answers knowing that their care team members are monitoring them? Why? Why not?

10. What are your thoughts about using this app?

*Probe#1: How do you feel about using this app on your own?

*Probe#2: Do you have family members or friends who are able to help you use the app?

11. Do you have data usage or privacy concerns? Would you worry about exceeding your data plan limit?

12. We have had a great discussion today about several important topics. Did I miss anything? Is there a topic or concern that you have that I didn't mention? Is there something that I should have asked but didn't? This is the open-format session of the conversation. Please feel free to add anything you think will help the WCCRI provide better care.

This concludes today's focus group session. Thank you so much for your time and great answers. Please leave your materials on the table. Please see the receptionist outside for your gift card incentive.

Appendix 2

THRIVE Study: Focus Group Moderator Guide

AET medication adherence message testing

THRIVE Study objective: Improve symptom management and adjuvant endocrine therapy (AET) treatment adherence among women with breast cancer

Good afternoon and welcome to another THRIVE study focus group, sponsored by the West Cancer Center and Research Institute (WCCRI) and UT Health Science Center. My name is Janeane Anderson, and I will serve as the moderator for today's conversation. Ilana Graetz and Ryan Blue are here to take notes.

Each of you were selected to participate in today's discussion because of your prior participation in a focus group. During that focus group, we discussed how web-based app technology can improve patient-provider communication and AET medication adherence among women with breast cancer. You provided feedback on some text-based and graphic messages. The THRIVE study team took your comments and suggestions and made changes to the app. Today, we would like to share some of those changes with you. We would also like your help in developing a new set of messages.

Before we get started with the discussion, let's go around the room and have each person introduce herself.

1. Tell us your first name and your favorite hobby or pastime.

The moderator will instruct each woman to introduce herself as well as write her name on a table tent (name facing the group). The moderator will inform the group that pseudonyms are allowed to maintain anonymity.

Now that we've all become acquainted, I'd like to go over a few rules before we begin.

1. First, please try to speak clearly and distinctly so we can all hear what you have to say; if I think that the audiotape won't pick up what you are saying, I will ask you to speak up because we want to capture your thoughts.

2. Second, please try to avoid interrupting or speaking while someone else is speaking. We want to make sure that everyone can complete their thoughts, and that we will be able to hear what you said in the audiotape.

3. Third, please let us know if you disagree with someone's opinion, but please do it in a respectful way.

4. Fourth, we value each person's opinions, so please contribute to the conversation. Don't just sit there quietly. If I notice that we haven't heard from you in a while, I will ask you whether you have anything to contribute, because sometimes it is hard to break into a conversation with so many ladies in one room.

5. On the other hand, please be aware and sensitive to the fact that everyone deserves an opportunity to be heard. Please

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make sure you're not the only one speaking.

6. Please feel free to mention that you participated in this focus group. However, please do not discuss any of the specifics about what any one person said, especially if it is of a sensitive nature. In order to feel comfortable sharing with each other, we will all need to keep what is said confidential.

This focus group session will be audiotaped for research purposes only. There will be no public broadcast of today's session. The audio recordings will only be used for the purposes outlined in the consent form each of you signed. Your identity and comments will remain confidential. Are there any questions? (Pause for questions). Let's begin. I am turning on the tape.

Today, you will be asked to provide additional, detailed feedback about the content of a web-based app used by the WCCRI. Specifically, you will be asked to review mock-ups of the app, evaluate the effectiveness of messaging for AET adherence, and help the THRIVE study team develop new messages for the app. As always, your honest feedback is important to the study team. Your thoughts and feelings about the content we are going to present to you will help improve the intervention, including the web app, for women with breast cancer.

You should have a coffee mug and a packet in front of you. The coffee mug is our gift to you. The packet has 12 sheets, labeled Sheet A through Sheet M. Later on in the focus group discussion, you will break out into small groups for an interactive activity.

2. To begin our discussion, I'd like you to visualize a woman like you on an AET medication, maybe even the medication you're currently taking. This woman has some difficulty following her doctor's prescription orders and does not take her pill daily. She also speaks of pretty severe side effects similar to ones you've experienced in the past (or may currently experience). This woman comes to you for advice. What do you tell her?

3. Keep this same woman in your mind. She also tells you that she is reluctant to talk to her doctor about her AET-related symptoms and side effects because she knows her doctor is going to lecture her about the dangers of not taking her pill exactly as she should. What advice could you give her about ways to improve communication with her oncology care team?

Probe #1: Has your oncologist said something to you that was particularly effective that helped you take your AET pill exactly as he or she prescribed? If so, what did your oncologist say to you?

4. What are your motivations for staying healthy?

Probe #1: How do you achieve your health goals?

Please direct your attention to the packet. What I've given you are examples of a web-based app that has been developed to help providers improve communication with patients about taking their medications exactly as the doctor prescribed and common side effects. For the next few minutes, I'd like you to provide feedback on the app updates.

(Moderator will solicit feedback for each of the app changes)

5. First, some changes were made to the overall aesthetic of the app. If you look at Sheet A, then you will notice the new THRIVE study logo and custom colors. This logo and color combination will appear several times as you navigate the app.

6. Participants from the first rounds of focus groups suggested a free text option for providing information about their AET-related symptoms and side effects. Sheet B is an example of this option.

7. Participants from the first rounds of focus groups also asked for a more precise way to report side effects. For instance, participants said they wanted a way to indicate where on their bodies they experienced pain. So, we now have a body map for app users. Sheet C is an example of this new option.

8. Please turn to Sheet D. Here you will find that a patient dashboard has been added to the app. The dashboard screen is designed to help patients better navigate the app, namely helping participants track their own symptoms and communicate them with their care team.

9. The importance of social support was a theme that came up in each of the first four focus groups. In order to address patients' social/emotional support needs, the app will feature a link to a list of social support organizations on the WCCRI website. What do you think about this new feature? Do you think patients will access the organizations via this link? Why or why not?

10. What additional medical educational information should be incorporated into the study app?

11. Do you think women like you would find non-medical general topics (e.g., jokes, Bible verses, inspirational quotes) appropriate for the study app? Why or why not?

Please turn to Sheets E-J. You may remember some of these messages from the focus group you participated in several

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months ago. Some of the messages are new to you. Today, I want you to take a careful look at the message content and think about whether the message meets your standards for Attention, Motivation, Personal relevance, Appropriateness, Attractiveness (graphic messages), and overall Acceptability. An explanation of each of those concepts is on an easel at the front and back of this room. For instance, after seeing a motivation message, how likely are you to adopt the practice or behavior?

(Moderator will review Sheets E-J with focus group participants and solicit written (ratings) and verbal feedback.)

12. Please turn to Sheets K-M. In addition to receiving only text-based messages, patients will also receive messages with graphics about relevant topics (e.g., AET medication reminders, tips for healthy living, affirmations). Examples of those images are on Sheets K-M. Please circle the "thumbs up" if you like the image and "thumbs down" if you do not.

Thank you for your detailed feedback on existing app messages. Now, you will be tasked with developing new text-based and graphic messages for the study app. Please divide yourselves in small groups of 2-3. For the next 25 minutes, each group should brainstorm as many messages as it can to encourage study participants to do three important things: (1) take their AET medication exactly how their doctor has prescribed; (2) communicate symptoms with their doctors; and (3) develop and maintain a happy, healthy lifestyle. The pieces of paper on the wall have been provided to help each group present their new ideas, so make sure you write the messages on these sheets of paper.

(Moderator sets a timer for 25 minutes. Moderator walks around each group to monitor progress and troubleshoot any challenges.)

Ok, ladies. Time is up! Each group should select a spokesperson to present her ideas to the larger group. When your group is not presenting, think about comments and suggestions you have for the new messages being offered by others. Who is the first volunteer?

(Participants present their ideas for new app messages and provide feedback.)

We have had a great discussion today about content and messaging for the THRIVE study app. Did I miss anything? Did any new message ideas come to your mind that you would like to share? Is there a topic or concern that you have that I didn't mention? Is there something that I should have asked but didn't? This is the open-format session of the conversation. Please feel free to add anything you think will help improve the study app and, ultimately, WCCRI patient care. (Pause for comments from participants).

This concludes today's focus group session. Thank you so much for your time and great answers. Please leave your materials on the table. Please see the receptionist outside for your gift card incentive.

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