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Bright, Emma
Genung, Sarah
Stanton, Annette
et al.

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A Mixed-Methods Study of the Technical Feasibility and Patient Acceptability of a Real-Time Adherence Monitor in Breast Cancer Survivors Taking Adjuvant Endocrine Therapy

Emma E. Bright, Ph.D.[1], **Sarah R. Genung, B.A.**[1], **Annette L. Stanton, Ph.D.**[2,3,4], **Joanna J. Arch, Ph.D.**[1,5]

[1]Department of Psychology and Neuroscience, University of Colorado, Boulder, Boulder, Colorado

[2]Department of Psychology, University of California, Los Angeles, Los Angeles, California

[3]Jonsson Comprehensive Cancer Center, University of California, Los Angeles, Los Angeles, California

[4]Cousins Center for Psychoneuroimmunology and Department of Psychiatry and Biobehavioral Sciences, University of California, Los Angeles, Los Angeles, California

[5]Cancer Prevention and Control, University of Colorado Cancer Center, Aurora, Colorado

Abstract

Purpose: Oral anti-cancer medications are increasingly common and endocrine therapies represent the most common oral anti-cancer medications in breast cancer. Adjuvant endocrine therapies reduce the likelihood of recurrence and mortality in the approximately 80% of women diagnosed with hormone-receptor positive breast cancer, thus rendering adherence essential. Real-time medication adherence monitors, such as the Wisepill electronic pillbox, transmit adherence data remotely, allowing for early intervention for non-adherence. However, their feasibility and acceptability have yet to be examined among breast cancer survivors taking endocrine therapies.

Methods: This study presents quantitative patient-report and technical support data and qualitative patient acceptability data on Wisepill, a common real-time adherence monitor, among 88 breast cancer survivors prescribed adjuvant endocrine therapy.

Correspondence should be addressed to Emma E. Bright, Department of Psychology and Neuroscience, University of Colorado, Boulder, Box 345, Boulder, CO, 80309-0345, USA; emma.bright@colorado.edu.

Authors' contributions

All authors have made substantial contributions to the conception and design of the work, including the acquisition, analysis, and interpretation of data, as well as drafting the manuscript. All authors have approved the current version of manuscript and are accountable for all aspects of the work.

Conflicts of interest/Competing interests

The authors have no relevant financial or non-financial interests to disclose.

Ethics approval

University of Colorado Institutional Review Board approval was obtained for this study.

Consent to participate

Informed consent was obtained from all participants.

Availability of data and material

Upon reasonable request, the quantitative data analyzed in this study are available from the corresponding author in accordance with institutional policies. Qualitative data currently lack widely accepted de-identification standards.

Results: This mixed-methods study of a common real-time adherence monitor, among the first in breast cancer survivors taking adjuvant endocrine therapy, demonstrates its technical feasibility and patient acceptability.

Conclusion: The use of wireless medication monitors that transmit real-time adherence data are uniquely promising for maximizing the benefits of adjuvant endocrine therapy by allowing for continuous tracking, ongoing communication with oncologic or research teams, and early intervention. This study demonstrates the feasibility and patient acceptability of one such real-time adherence monitor.

Keywords

Breast cancer; medication adherence; endocrine therapy; real-time adherence monitor

Oral anti-cancer medications are increasingly common (1); however, medication adherence (i.e., taking the medication in the dose, frequency and duration as prescribed) among adults with cancer remains suboptimal (2-6). Nonadherence is associated with poor treatment efficacy, greater health care costs, and increased hospital utilization among patients with cancer (4). Medication adherence is a key pathway through which oncologic practice is translated into patient outcomes (5,7). A common class of oral anti-cancer medication is adjuvant endocrine therapy (AET), adjuvant medications that reduce recurrence and mortality among the approximately 80% of breast cancer survivors with hormone-receptor positive tumors (8-10). Recommendations suggest five to ten years of AET after primary treatment, making long-term adherence particularly challenging for breast cancer survivors (11). Despite the benefits of adherence, a systematic review revealed that AET adherence after 5 years ranged from 41-72% (2). The clear advantages of AET coupled with the challenges of adherence render the accurate assessment of adherence essential and early intervention for nonadherence necessary for optimizing medical outcomes among breast cancer survivors.

Current approaches for assessing medication adherence include indirect methods such as patient self-report on questionnaires and interviews, pill counts, prescription records, and more direct methods, such as serum detection and (12) electronic medication monitors (13). Electronic medication adherence monitors are precise and can track patterns in adherence over time without being subject to poor patient recall or social desirability. Advancements in electronic adherence monitors, such as the Wisepill real-time adherence monitor (Wisepill Technologies, Cape Town, South Africa), have eliminated the need for return visits to download device data and can remotely transmit adherence information in real time via wireless networks. Real-time adherence monitors allow for early intervention among patients who have discontinued their medications (14), as they detect lapses in adherence as they occur, providing novel opportunities to prevent treatment failure among breast cancer survivors taking AET.

In that real-time monitors represent the future of adherence assessment, it remains critical to evaluate their feasibility and acceptability in cancer populations that are commonly prescribed oral medication. Real-time monitoring of physical symptoms is well-established in many cancer care settings (15,16), however, real-time monitoring of medication adherence

is not. Despite widespread use of medication adherence monitoring among adults with HIV/AIDS (17,18), the feasibility and acceptability of real-time medication adherence monitors such as Wisepill are not yet established among breast cancer survivors prescribed AET. The current study provides the first known published report on the use of real-time medication adherence-monitoring devices in breast cancer survivors. This study uses mixed methods to evaluate patient and technical support perspectives on Wisepill, a real-time monitor. Our patient acceptability and feasibility goals were that: (1) patients would find the real-time medication adherence-monitoring devices acceptable on both quantitative and qualitative measures, (2) 95% of participants would complete the 30-day device feasibility baseline period and continue using it for the 6-month follow-up period, thus demonstrating patient feasibility of device use and (3) participants could successfully use the monitoring device throughout baseline and 6-month follow-up with minimal contact from the research team to resolve technical issues.

Methods

Participants

Patients who were prescreened as medically eligible by electronic chart review were recruited from Rocky Mountain Cancer Centers in Colorado to participate in a values-based clinical intervention trial to promote AET adherence (clinical trial identifier: NCT03980093) (19). The study eligibility criteria included: diagnosed with Stage 0 to III hormone receptor-positive breast cancer, completed primary cancer treatment, prescribed AET in the past 2.5 years with at least 1 year remaining, reported at least modest difficulty taking AET (see Screener), internet access to participate in the online intervention, and regular access to cell service to transmit Wisepill data. Of the 977 mailings that were sent to prescreened patients, 207 women responded, 99 were eligible, 11 women were not interested in participating after hearing more detail about the study, and 88 women enrolled. All participants provided informed consent and the University of Colorado Boulder Institutional Review Board approved the study.

Procedure

Participants were mailed a Wisepill device, a wireless electronic pillbox that sends real-time data when opened, along with instructions for its use. The device consists of a portable black rectangular box (4.33” long x 1.77” wide x .47” deep) that holds up to 30 large or 60 small pills (Figure 1). The instructions included visuals, basic written instructions, and troubleshooting tips printed on a 5 x 8” laminated card. After participants received the post-mailed package with the Wisepill and the instructions, a member of the research team called to confirm that the participants were able to set up and use the device. The devices were remotely monitored online by the research team several times per week to ensure proper functioning. Wisepill works by recording events (i.e., pill box openings) on the device and sending a report of those events to the Wisepill server via a SIM card. Participants with inconsistent cell service at home were asked to bring the device with them into a region with more consistent cell service (e.g., when getting groceries in town) at least once a week so that the adherence data stored on the device could be transmitted. The daily text reminder feature of Wisepill was disabled to focus on use of the device itself

and the values intervention content (i.e., the online intervention which focused on values as motivation for AET adherence; for values intervention details see Arch et al., 2022).

Measures

Screener.—Breast cancer survivors had to report missing 2 or more AET pills in the past month or at least one factor that made taking their medication moderately difficult to be eligible (19).

Feasibility.—Patient feasibility was assessed by examining the number of participants who successfully used the Wisepill device over the 30-day baseline period and the entirety of the seven-month study period.

Wisepill signal lapses greater than 48 hours (i.e., no adherence data transmitted over a 48-hour period) were briefly investigated by a member of the research team via the Wisepill generated online technical report. The research team could largely determine the cause of a signal lapse using the technical report and would follow up via telephone with the participant to resolve the technical difficulty. The nature of the technical issue and number of contacts needed to resolve it were recorded as a measure of technical feasibility.

Patient Acceptability.—Breast cancer survivors rated on a 5-point Likert-type scale (*1* not at all, *5* extremely) how helpful and convenient they found the Wisepill device, and how likely they were to recommend the device to another breast cancer survivor taking AET.

Qualitative information on patient acceptability of Wisepill was extracted from semi-structured phone exit interviews conducted with a subsample of participants ($n = 38$) by four post-baccalaureate interviewers Qualitative information on patient acceptability of Wisepill was extracted from semi-structured phone exit interviews conducted with a subsample of participants ($n = 38$) by four post-baccalaureate interviewers trained as either clinical interviewers or clinical psychology doctoral students with several years of clinical experience. Prior to conducting the qualitative interviews, the interviewers received additional instruction in active listening techniques and reflexive interviewing. Prepared prompts were used to guide the interviews and interviewers were also trained to respond in-the-moment to the participant and elicit relevant information (please see the Supplementary materials, Wisepill Qualitative Interview Guide, for the full interview prompts).

To ensure that the full range of experiences was represented in the interviews, 23 participants were randomly selected within satisfied, neutral, and dissatisfied strata based on their quantitative and qualitative responses to questions about their overall study satisfaction. As the responses to the values-based intervention were overwhelmingly positive, this approach resulted in oversampling negative responses; thus, 15 additional participants were randomly selected from the entire sample using a random number generator.

Interviews were transcribed and coded for both *a priori* and emergent codes regarding patient acceptability of Wisepill and suggestions for future Wisepill use. Codes for the qualitative patient acceptability data were informed by the widely-used Health Belief Model (20,21) by assessing perceived benefits, barriers, and cues to action. The research team

reviewed and revised the codes based on their clinical and research experience with breast cancer survivors taking AET. Example questions from the interviews include, “Did you experience any benefits in using the Wisepill box?” and “How convenient or inconvenient was it [Wisepill] to use?” Participants were also asked about how the monitoring function of the Wisepill may have affected their behavior and their recommendations for future use. All transcripts were coded in ATLAS.ti version 9.1 twice by 2 to 3 independent coders: once for broader themes and again for relevant sub-themes. After coding, the team met to establish consensus by resolving any conflicts through discussion.

Results

Sample characteristics

On average, participants were 58 years of age, 14 months from the end of primary treatment, and prescribed AET approximately 13 months prior to study entry (Table 1). Most participants were non-Latina white (92%) and prescribed aromatase inhibitors (63%). The average duration of the qualitative interviews was 36:57 (range = 17:30-55:09).

Feasibility: Completion—All participants (100%) completed a 30-day Wisepill monitoring baseline, exceeding the study’s 95% completion goal, and 98.86% (87/88) completed the 6-month Wisepill monitoring follow-up period.

Feasibility: Technical Difficulties—Over the 7-month study, 13.64% of participants (n = 12) experienced technical difficulties using Wisepill which required a total of 38 contacts to resolve, including losing connectivity (n = 9, contacts = 25), not registering pillbox openings (n = 1, contacts = 6), charging cable not working (n = 1, contacts = 4), and needing to reset the battery (n = 1, contacts = 3). These contacts were almost exclusively initiated by the research team, specifically all of those related to losing connectivity and not registering pill box openings were only research-team initiated.

Patient Acceptability: Quantitative Ratings—On a 5-point Likert-type scale, on average, participants found the Wisepill box to be moderately helpful (M = 3.15, SD = 1.31), moderately convenient (M = 3.66, SD = 1.36), and were somewhat likely (M = 3.40, SD = 1.49) to recommend the device to someone else taking AET. There were no statistically significant differences on any of the quantitative patient acceptability ratings by trial condition (p’s > 0.190).

Patient Acceptability: Qualitative Interviews

Patient Perceptions of Convenience.: Women responded to open-ended prompts about the acceptability of Wisepill and offered suggestions for future use. Most breast cancer survivors found Wisepill convenient to use (n = 27). For example, when asked about the convenience of the Wisepill, one participant stated:

> It was not at all inconvenient. It’s no different than a pill bottle to me in terms of use.
>
> (1056, prescribed an AI)

Patient Perceptions of Benefits.: Many women (n = 22) also found benefits in using the Wisepill. Breast cancer survivors found the real-time tracking features of the Wisepill to be a source of motivation, for example, one participant stated:

> I think the idea that someone was tracking you and that they were going to ask you about it…was a little more motivating to make sure I took it.
>
> (1046, prescribed tamoxifen)

The mere presence of the device was a helpful reminder and benefit for others:

> It made me aware of every day that I was taking my medications. And it helped me keep track of them.
>
> (1068, prescribed tamoxifen)

While others did not perceive any benefits from their use of Wisepill, they noted its ease of use:

> Did I experience any benefits in using it? No, [but] it was convenient to have. It was easy to open instead of opening a pill bottle, so that was kind of nice, you just kind of slid it flipped it open.
>
> (1073, prescribed an AI)

Patient Perceptions of Device-Influenced Behavior Change.: Many participants (n = 16) reported no changes in their behavior or motivation to take AET because their adherence was being monitored. For example, when asked whether knowing that her adherence data were being monitored had changed her behavior, one participant stated:

> I really don't think it affected it at all. Because yeah, I just don't think that that box motivated me in any way to take my medications. I take them because they're prescribed…
>
> (1066, prescribed tamoxifen)

Other participants (n = 9) reported positively changing their adherence behavior or feeling more motivated or committed to taking AET because of the knowledge that Wisepill was remotely transmitting their adherence data. One participant stated:

> I think occasionally like I said, I don't want to take it today. And then knowing that somebody was going to know whether I took it or not, okay fine I'll take it.
>
> (1037, prescribed an AI)

Participants were also asked for their recommendations for future use of the Wisepill device. Suggestions included daily access to an online Wisepill medication log (n = 10), a device-initiated reminder (alarm, blinking light, text message) to take their medication (n = 9), and a 7-day medication divider insert to track their medication (n =11; Table 2).

Discussion

Findings demonstrate that real-time wireless monitoring of AET adherence among breast cancer survivors is generally acceptable to patients and technically feasible. That 100% of

participants completed a 30-day Wisepill monitoring baseline and 99% completed a 6-month monitoring follow-up period also provides strong evidence of feasibility. The most common technical issue, lost wireless connectivity, delayed the transmission of data but still allowed for adherence information to be transmitted once the device reconnected. Although technical components of the device must be monitored to ensure proper functioning, serious technical issues were rare. These findings converge with previous research on the technical feasibility of Wisepill among patients with HIV/AIDS (17,22).

In addition, the devices were acceptable to patients, even with some of the more useful features, such as reminders, inactivated to focus on the use of the device itself. The device was rated as moderately helpful, convenient, and recommendable on quantitative measures. In qualitative exit interviews, many breast cancer survivors reported that the devices were convenient and beneficial for adherence. The accountability that comes from the devices being actively monitored by an outside team served as a cue to action for some participants, while others found the mere presence of the device to be a helpful reminder to take their medications. The ability of standard electronic adherence monitoring devices to serve as a visual reminder has been noted as a facilitator of medication adherence among patients with HIV/AIDS (23). While not all participants found benefits in the use of Wisepill as a reminder or otherwise, many still noted its convenience and ease of use.

The knowledge that their adherence was being tracked by others was cited as a facilitator for some participants, and may serves as a benefit in clinical settings, but lead to higher adherence rates in research settings. Implementing a baseline period of monitoring to allow participants to adjust to using the device as well as providing the device to all the experimental groups, as was done in the present trial, may mitigate the risk of inflated adherence.

While moderate difficulty taking their medication was an eligibility criterion, many women had high adherence during the study time period (19). On one hand, this renders it notable that breast cancer survivors still found the device to be moderately helpful, convenient, and recommendable even if they adhered to AET throughout the study period. On the other hand, high AET adherence rates may have inflated the feasibility estimates that showed very high Wisepill device use throughout the study period. Thus, future research examining feasibility among less AET adherent samples is essential.

Similar to studies in HIV/AIDS populations (24), the full capabilities of the Wisepill device, namely the daily reminder function, were not enabled in the present study, in order to focus exclusively on the device itself (and values intervention content). It is notable that participants still largely found the devices to be acceptable despite the absence of the reminder function. Research has shown some minimal benefit of electronic medication device reminders alone for promoting adherence among patients with non-cancer illnesses (25). Thus, future research examining the patient acceptability of real-time adherence devices with all features activated is warranted.

For future use, patients had consistent and feasible recommendations that included a daily pill log, daily reminders, and a 7-day pillbox divider, which could be incorporated

into future interventions or clinic policies to further promote adherence. Wisepill can be used with a 7-day pillbox divider and as noted, already supports a reminder function, as recommended by the current sample.

Despite variation with respect to socioeconomic status, this sample lacked racial and ethnic diversity, which requires caution in generalizing the findings to diverse groups. AET adherence differs among racial and ethnic groups, with lower AET adherence among women of other racial and ethnic groups compared to white women (26). The response rate to our mailing recruitment was high, nonetheless, recruitment by mail tends to over select for white participants and those with stable housing situations (27). Higher touch recruitment methods, such as clinic visits and partnering with community members and organizations are important areas for devoting more resources to collect more representative samples (28).

Research has shown that AET non-adherence predicts breast cancer recurrence and subsequent mortality (3,4,10,29). More accurate adherence monitoring, in combination with the potential for early intervention for non-adherence, would allow for prioritization of limited resources to promote adherence among breast cancer survivors at greatest risk for poor AET adherence or discontinuation. The use of wireless medication monitors that transmit real-time adherence data are uniquely promising for maximizing the benefits of AET by allowing for continuous tracking, ongoing communication with oncologic or research teams, and early intervention. Future research examining the long-term use of such devices with all features activated among diverse populations is an important next step for furthering our understanding of their utility for women prescribed AET. The present study is the first to our knowledge to demonstrate the technical feasibility and patient acceptability of a real-time wireless medication adherence monitor among breast cancer survivors taking AET, thus establishing a foundation for further use and investigation of these promising devices in this population.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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References

1. Weingart SN, Brown E, Bach PB, et al. NCCN Task Force Report: Oral Chemotherapy. JNCCN. 2008;6(S3):S-1–S-14.
2. Murphy CC, Bartholomew LK, Carpentier MY, Bluethmann SM, Vernon SW. Adherence to adjuvant hormonal therapy among breast cancer survivors in clinical practice: a systematic review. Breast Cancer Res Treat. 2012;134(2):459–478. [PubMed: 22689091]
3. Ruddy K, Mayer E, Partridge A. Patient adherence and persistence with oral anticancer treatment. CA: A Cancer Journal for Clinicians. 2009;59(1):56–66. [PubMed: 19147869]
4. Partridge AH, Avorn J, Wang PS, Winer EP. Adherence to therapy with oral antineoplastic agents. J Natl Cancer Inst. 2002;94(9):652–661. [PubMed: 11983753]

5. Greer JA, Amoyal N, Nisotel L, et al. A systematic review of adherence to oral antineoplastic therapies. The oncologist. 2016;21(3):354–376. [PubMed: 26921292]
6. Kaptein AA, Schoones JW, van der Meer PB, et al. Psychosocial determinants of adherence with oral anticancer treatment:'we don't need no education'. Acta Oncologica. 2021;60(1):87–95. [PubMed: 33151764]
7. Kravitz RL, Melnikow J. Medical adherence research: time for a change in direction? Med Care. 2004;42(3):197–199. [PubMed: 15076818]
8. Dunnwald LK, Rossing MA, Li CI. Hormone receptor status, tumor characteristics, and prognosis: a prospective cohort of breast cancer patients. Breast Cancer Res. 2007;9(1):R6. [PubMed: 17239243]
9. Makubate B, Donnan PT, Dewar JA, Thompson AM, McCowan C. Cohort study of adherence to adjuvant endocrine therapy, breast cancer recurrence and mortality. Br J Cancer. 2013;108(7):1515–1524. [PubMed: 23519057]
10. Hershman DL, Kushi LH, Shao T, et al. Early discontinuation and nonadherence to adjuvant hormonal therapy in a cohort of 8,769 early-stage breast cancer patients. J Clin Oncol. 2010;28(27):4120–4128. [PubMed: 20585090]
11. Burstein HJ, Temin S, Anderson H, et al. Adjuvant endocrine therapy for women with hormone receptor-positive breast cancer: American society of clinical oncology clinical practice guideline focused update. J Clin Oncol. 2014;32(21):2255–2269. [PubMed: 24868023]
12. Pistilli B, Paci A, Ferreira AR, et al. Serum Detection of Nonadherence to Adjuvant Tamoxifen and Breast Cancer Recurrence Risk. J Clin Oncol. 2020;38(24):2762–2772. [PubMed: 32568632]
13. Osterberg L, Blaschke T. Adherence to medication. NEJM. 2005;353(5):487–497. [PubMed: 16079372]
14. Haberer JE. Actionable adherence monitoring to optimise intervention. Lancet HIV. 2017;4(1):e5–e6. [PubMed: 27864001]
15. Kofoed S, Breen S, Gough K, Aranda S. Benefits of remote real-time side-effect monitoring systems for patients receiving cancer treatment. Oncol Rev. 2012;6(1):e7. [PubMed: 25992209]
16. Warrington L, Absolom K, Conner M, et al. Electronic systems for patients to report and manage side effects of cancer treatment: systematic review. J Med Internet Res. 2019;21(1):e10875. [PubMed: 30679145]
17. Haberer JE, Kahane J, Kigozi I, et al. Real-time adherence monitoring for HIV antiretroviral therapy. AIDS Behav. 2010;14(6):1340–1346. [PubMed: 20809380]
18. Evans D, Berhanu R, Moyo F, Nguweneza A, Long L, Fox MP. Can short-term use of electronic patient adherence monitoring devices improve adherence in patients failing second-line antiretroviral therapy? Evidence from a pilot study in Johannesburg, South Africa. AIDS Behav. 2016;20(11):2717–2728. [PubMed: 27146828]
19. Arch JJ, Crespi CM, Levin ME, et al. Randomized Controlled Pilot Trial of a Low-Touch Remotely-Delivered Values Intervention to Promote Adherence to Adjuvant Endocrine Therapy Among Breast Cancer Survivors. Ann Behav Med. 2022.
20. Haynes RB, Sackett DL. Compliance in Health Care. Baltimore, MD: Johns Hopkins University Press; 1979.
21. Carpenter CJ. A meta-analysis of the effectiveness of health belief model variables in predicting behavior. Health communication. 2010;25(8):661–669. [PubMed: 21153982]
22. Bachman DeSilva M, Gifford AL, Keyi X, et al. Feasibility and acceptability of a real-time adherence device among HIV-positive IDU patients in China. AIDS research and treatment. 2013;2013.
23. Wendel CS, Mohler MJ, Kroesen K, Ampel NM, Gifford AL, Coons SJ. Barriers to Use of Electronic Adherence Monitoring in an HIV Clinic. Annals of Pharmacotherapy. 2001;35(9):1010–1015. [PubMed: 11573846]
24. Stringer KL, Azuero A, Ott C, et al. Feasibility and acceptability of real-time antiretroviral adherence monitoring among depressed women living with HIV in the deep south of the US. AIDS Behav. 2019;23(5):1306–1314. [PubMed: 30377982]
25. Checchi KD, Huybrechts KF, Avorn J, Kesselheim AS. Electronic medication packaging devices and medication adherence: a systematic review. JAMA. 2014;312(12):1237–1247. [PubMed: 25247520]

26. Roberts MC, Wheeler SB, Reeder-Hayes K. Racial/ethnic and socioeconomic disparities in endocrine therapy adherence in breast cancer: a systematic review. American journal of public health. 2015;105(S3):e4–e15.

27. Nicholson LM, Schwirian PM, Groner JA. Recruitment and retention strategies in clinical studies with low-income and minority populations: progress from 2004–2014. Contemporary Clinical Trials. 2015;45:34–40. [PubMed: 26188163]

28. Kennedy BM, Kumanyika S, Ard JD, et al. Overall and minority-focused recruitment strategies in the PREMIER multicenter trial of lifestyle interventions for blood pressure control. Contemporary clinical trials. 2010;31(1):49–54. [PubMed: 19879377]

29. McCowan C, Shearer J, Donnan PT, et al. Cohort study examining tamoxifen adherence and its relationship to mortality in women with breast cancer. Br J Cancer. 2008;99(11):1763–1768. [PubMed: 18985046]

Figure 1.
An image of the Wisepill device with a sample values sticker

Table 1

Sample sociodemographic and medical characteristics

Sociodemographic characteristics	
Female	100.00% (88/88)
Age (in years, Range: 31-81)	*M*=58.34 (*SD*=10.37)
White/Caucasian & Non-Latina	92.05% (81/88)
Hispanic/Latina	3.41% (3/88)
Biracial	1.14% (1/88)
Native American/Alaskan Native	1.14% (1/88)
Black/African American	0.00% (0/88)
Other	2.27% (2/88)
Education	
High school diploma/some college	15.90% (14/88)
Associate's degree	11.40% (10/88)
Bachelor's degree	33.00% (29/88)
Graduate/Professional degree	39.80% (35/88)
Household Yearly Income	
Less than $30,000	11.40%
$31,000-$60,000	26.10%
$61,00-$90,000	19.30%
$91,000+	43.20%
Cancer treatment history	
Months from end of primary treatment (Range 1–36)	*M*=13.83 (*SD*=8.54)
Months prescribed endocrine therapy % who received:	*M*=13.11 (*SD*=8.29)
1)Surgery	1) 100.00% (88/88)
2)Chemotherapy	2) 34.09% (30/88)
3)Targeted Therapy	3) 10.23% (9/88)
4)Radiation	4) 68.18% (60/88)
Endocrine Therapy Type:	
1)Aromatase Inhibitors	1) 62.50% (55/88)
2)Tamoxifen	2) 37.50% (33/88)
Cancer stage	
0	5.68% (5/88)
I	71.59% (63/88)
II	18.18% (16/88)
III	4.55% (4/88)

Table 2

Patient suggestions from semi-structured exit interviews for Wisepill use

Suggestions for Future Use	Illustrative Quote	*n* (of 38)
Daily log Participants wanted access to an online or app-based daily medication log that they could check themselves as often as they wanted.	"It might also be beneficial if you could go online and, say you forget, gosh did I take my medication? When did I skip it, or when did I take it, kind of a thing? And if you could go online and get that data on a daily basis from the Wisepill that would be pretty handy."	10
Reminders Participants wanted a reminder (e.g., alarm, blinking light, text message) from the Wisepill to remind them to take their medication.	"If there was some mechanism that would say you haven't taken your pill within twenty-four hours…It would just be more of some type of reminder that yes, you have taken your pill or no you haven't."	9
Pillbox divider Participants wished that the Wisepill had a weekly divider with the days of the week separated to help them keep track of their medications.	"I think sometimes for people taking prescriptions, that it is helpful to have almost a Sunday, Monday, Tuesday, Wednesday, Thursday, Friday type container because at least for me, it's easy to forget once I've gotten up in the morning to get involved with something and then forget whether or not I've taken my medication."	11