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RESEARCH

Technology-based supportive care for metastatic breast cancer patients

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Abstract

Purpose Metastatic breast cancer (MBC) patients are living longer. However, symptom burden remains a significant issue. Technology-based interventions may assist. The purpose of this study was to test a virtual assistant for addressing symptoms in MBC using the Amazon Echo Show with Alexa.

Methods In this partial crossover randomized trial, the immediate treatment group was exposed to the intervention, called Nurse AMIE (Addressing Metastatic Individuals Everyday) for 6 months. The comparison group was unexposed for the first 3 months and then exposed for 3 months. The randomized controlled trial (RCT) during the first 3 months allowed for the evaluation of intervention effects on symptoms and function. The partial crossover maximized exposure to the intervention for evaluation of feasibility, usability, and satisfaction. RCT outcome data were collected at baseline and 3 months. Feasibility, usability, and satisfaction data were collected throughout the first 3 months of intervention exposure.

Results Forty-two MBC patients were randomized (1:1). Participants were 53 ± 11 years old and 4 ± 7 years from diagnosis with metastatic disease. No significant effects on psychosocial distress, pain, sleep disturbance, fatigue (vitality), quality of life, or chair stands were noted, despite high levels of acceptability (51%), feasibility (65%), and satisfaction (70%).

Conclusion A high level of participant acceptability, feasibility, usability, and satisfaction all suggest further research on this platform is warranted. The lack of statistically significant effects on symptoms, quality of life, and function may be the result of small sample size.

ClinicalTrials.gov registration number: NCT04673019 (registration date: December 17, 2020).

Keywords Metastatic breast cancer · Supportive care · Exercise · Artificial intelligence · Symptoms

Introduction

The number of women in the USA living with metastatic breast cancer (MBC) increased 17% from 2000 to 2010 and was expected to increase 31% from 2010 to 2020 [15]. Additionally, median survival times increased from 19.1 to 29.7 months for women diagnosed with MBC between ages 50 and 64, when comparing those diagnosed between the years of 1992 and 1994 to those diagnosed between 2005 and 2012 [15, 27]. Further, more than 11% of women diagnosed under age 64 between 2000 and 2004 survived 10 years or longer. The most likely cause of this increased life expectancy is earlier detection and improved treatment therapies. Although treatment of MBC is improving, side effects and symptoms associated with the disease and treatments remain a burden [27, 34]. These include pain, fatigue, emotional distress, impaired sleep, and decreased physical function

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greater than that experienced by women without MBC [6, 17, 18, 28]. These symptoms negatively affect quality of life [18, 34]. Women with MBC feel their needs are going unmet and have a desire to address these issues and improve their quality of life and well-being [14]. In fact, methods to cope with side effects and symptoms was highly rated by women diagnosed with MBC as an important informational need [16, 28]. For some women, living with the severe side effects of treatment reduces quality of life to a level that leads them to stop treatment and allow nature to take its course, with a high likelihood of mortality. In essence, mitigation of side effects may have a survival benefit.

Women with MBC may return to the clinic up to 36 times every 6 months [8, 32] for cancer treatments and acute medical care. Ideally, symptoms would be addressed by appropriately trained oncology nursing professionals. Unfortunately, there is scant time during these visits to address side effects and other quality of life-related concerns. Additionally, quality of life interventions that require study-related visits have had low adherence in this patient population [2]. Interventions are needed to improve the quality of life for these women without additional appointment burden.

Technology-based interventions have proven to be effective in promoting a variety of health behaviors in other patient populations, including increasing physical activity in adults with diabetes, improving diet among adults, and smoking cessation [4, 21, 23]. Previous studies have shown that technology-based exercise interventions are successful at increasing physical activity, physical function, and quality of life in women diagnosed with early-stage breast cancer [3, 7, 31]. Despite the success of technology, no previous studies have been identified that implement a technology-based supportive care intervention in women with MBC.

We recently developed Nurse AMIE, the first computer tablet-based supportive care software program of its kind [24, 25]. Results indicated that patients and their care teams found value in the tablet-based supportive care system; however, feedback indicated value to making two significant changes to the program [24]. First, the most common reason women declined participation was related to being intimidated by the computer tablet. As such, we wondered whether translation of the program into a virtual assistant with a conversational user interface would help women access this technology more easily. The conversational user interface in an Amazon Echo Show device with Alexa allows participants to operate the Nurse AMIE program by saying a few simple commands rather than navigate the buttons on a computer tablet. In addition, consistent feedback indicated that patients would value the addition of nutrition to the intervention offerings [20]. In this paper, we report on a study that tested the feasibility, acceptability, and initial efficacy of a supportive care intervention called Nurse AMIE, delivered by a virtual assistant using the Amazon Echo Show with Alexa.

Methods

Study design

This study used a partial crossover design (see Fig. 1). Patients were randomized to "immediate" or "delayed" treatment group. The immediate treatment group used the Nurse AMIE for Amazon Echo Show with Alexa for all 6 months of participation. The delayed treatment group received usual care for months 0–3 and then crossed over to the Nurse AMIE for Amazon Echo Show with Alexa during months 4–6.

This design had two advantages. First, it made recruitment easier (all participants received the intervention). Second, it gave the study team more feedback on the Nurse AMIE for the Amazon Echo Show with Alexa than would have been possible with a classic randomized controlled trial. The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Penn State Institutional Review Board. All participants provided written informed consent prior to any study-related activities. The trial was registered on ClinicalTrial.gov (NCT04673019).

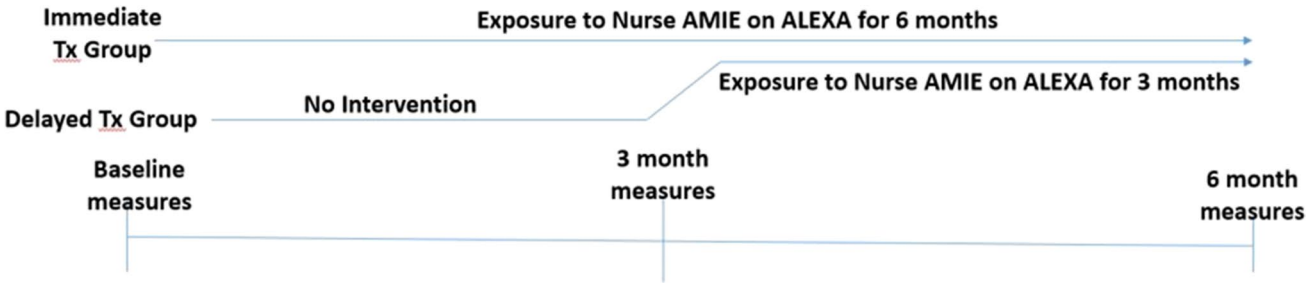

Fig. 1 Study design

Participants

Participants were women who were diagnosed with MBC, spoke English, and had sufficient vision and hearing to interact with the Amazon Echo Show with Alexa (or family support to help). Other eligibility criteria included not having any significant medical or psychiatric conditions outside of cancer and a life expectancy of 6 months or more (both clinician determined). Women participating in other behavioral intervention trials were excluded. To recruit patients, we reviewed the schedules of the two breast medical oncologists at Penn State who participated as investigators (MV and CT). Upon identifying potential participants, we obtained confirmation from the medical oncologist regarding eligibility and permission to approach their patient. Toward the end of recruitment, we also advertised the trial on social media (Twitter and Facebook). If a woman reached out with interest, we sought input from her oncologist prior to proceeding to consent. Consent was completed through video conferencing and either waiting to receive the signed consent in the mail or having the participant sign the consent electronically using Research Electronic Data Capture (REDCap), a secure and web-based software platform [10, 11].

Description of the intervention

To develop the virtual assistant, we used the application programming interface (API) provided by the Alexa ecosystem. The design and implementation of the virtual assistant have been described elsewhere [22]. For this study, we used Amazon Echo Show with Alexa, which includes a video screen, so that the visual elements of Nurse AMIE developed for the tablet could still be used (e.g., greetings, exercise videos). The Alexa version of Nurse AMIE begins with the participant saying "Alexa, Open Nurse AMIE." This opens a screen, with a picture of a nurse, and Alexa (as AMIE) greets the participant. There is a unique greeting for every day participants open Nurse AMIE. The greeting is followed by a nutrition tip and recipe, largely based on information that can be found on the American Institute for Cancer Research website. AMIE then asked the participant about their sleep, pain, fatigue, and distress and for step counts from the prior day. An algorithm developed by our team then led to an empathic response, ranging from "I'm so glad you are feeling so well" to "I am so sorry to learn you are suffering." If their pain or distress were rated 7 or higher (out of a possible 10), there was a reminder to "be sure to contact the clinical care team about your elevated symptoms." Further, elevated symptoms of pain or distress (7 or higher) were flagged by our study team to alert the oncology care team. Staff called and/or emailed the oncology care team with news of elevated symptoms so that appropriate medical interventions could be considered. Based on the symptom ratings, our algorithm then recommended an activity to help with those symptoms. The possible interventions on the tablet included soothing music, cognitive behavioral therapy lessons, guided relaxation, exercise videos (balance, strengthening, stretching), or audio messages to assist with symptom management [24, 25]. If the participant wanted, she could choose a different activity by pressing a pink ribbon to get to a menu of options. The interaction ended with a farewell, with unique farewells for each day of use. The use of the unique greetings, emphatic responses, and unique farewells were intentional, with a goal to personify Nurse AMIE for participants.

During the first 3 months that participants interacted with Nurse AMIE, we called weekly to check in. The content of the calls included general queries regarding well-being and symptom checks and to troubleshoot any technology issues. The immediate treatment group continued to use Nurse AMIE without these calls during months 4–6 of participation.

Measurements

Acceptability was defined as the proportion of eligible patients approached who agreed to participate. We defined an a priori threshold of 50% for acceptability of this intervention. Feasibility was defined as the number of days out of the first 90 days of exposure to Nurse AMIE for the Amazon Echo Show with Alexa that patients logged in. We defined an a priori threshold of 50% of patients logging in at least 30 days as "feasible."

Because this study was conducted during the height of the COVID-19 pandemic, all study activities, including measurements, were conducted online, using video conferencing. A physical function test (chair stands) was performed to discern the time required to stand and sit five times. The validity of objectively assessed physical function measured by video conference has been established [9].

Surveys included demographics, a quality of life survey (SF-36) [33], and patient-reported surveys. We also administered validated surveys focused on the four symptoms we asked about each day. Pain was measured by the brief pain inventory (range 0–10, 10 worst)) as well as the pain subscale of the SF-36 (0–100, 0 worst) [30, 33]. Sleep was measured by the Sleep Disturbance Scale (range 0–100, higher score indicates greater sleep disturbance) [35]. Fatigue was assessed using the vitality subscale of the SF-36 (range 0–100, 0 worst) [33]. Distress was assessed using the distress thermometer used clinically at Penn State Cancer Institute and included scales from 0 to 10 (10 worst) for practical problems, as well as family, emotional, spiritual, and physical problems. Surveys typically took 30 min or less to complete.

We also gathered data from the Nurse AMIE program on the Amazon Echo Show with Alexa, including a daily question about whether the most recent intervention was helpful to the patient. We assessed usability of the technology with the Client Satisfaction Questionnaire [13], the Credibility/

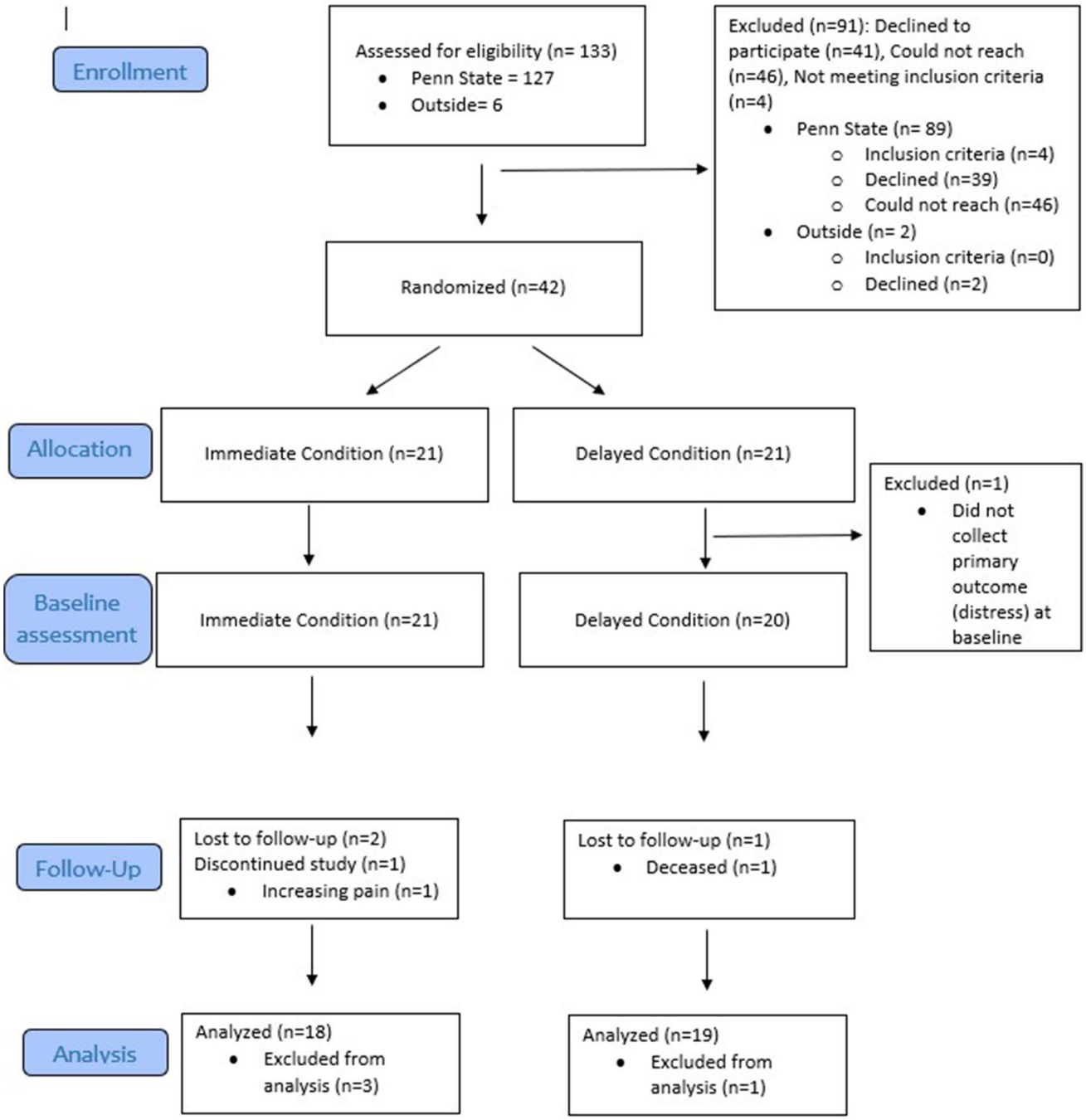

Fig. 2 Consort

Expectancy Questionnaire [5], and the User Version of the Mobile Application Rating Scale [29].

Statistical analysis

Descriptive analysis with means and standard deviations (SD) for continuous variables and frequencies and proportions for categorical variables were applied for demographics, usability data (including feasibility, satisfaction), and the consort features preceded further statistical activities. The normality assumption for continuous variables was checked based on Shapiro–Wilk tests. Two-group comparisons (immediate Tx vs delayed Tx) at baseline were performed based on two-sample *t*-tests or Wilcoxon rank sum tests for continuous variables and Pearson's Chi-square tests or Fisher exact tests for categorical variables, as appropriate. Further, paired *t*-tests (comparing the

Table 1 Demographics (mean (SE) or *N* (%))

Variable	All (*N* = 42)	Treatment (*N* = 21)	Control (*N* = 21)	*P*-value comparing groups
Age (years)	53.36 (10.97)	54.57 (9.80)	52.14 (7.95)	0.48
Time since BrCa diagnosis	8.46 (7.22)	8.95 (7.15)	7.95 (7.44)	0.66
Time since METS diagnosis	3.98 (2.63)	4.00 (2.85)	3.95 (2.46)	0.95
Marital status				0.59
Never married	3 (7.1)	2 (9.5)	1 (4.8)	
Currently married	34 (81.0)	16 (76.2)	18 (85.7)	
Divorced/separated	4 (9.5)	3 (14.3)	1 (4.8)	
Widowed	1 (2.4)	0	1 (4.8)	
Race				1.00
White	38 (90.5)	19 (90.5)	19 (90.5)	
Black	2 (4.8)	1 (4.8)	1 (4.8)	
Native Hawaiian	1 (2.4)	1 (4.8)	0	
Other	1 (2.4)	0	1 (4.8)	
Ethnicity				0.06
Hispanic/Latino	4 (9.5)	4 (19.1)	0	
Not Hispanic/Latino	35 (83.3)	15 (71.4)	20 (95.2)	
Unknown	3 (7.1)	2 (9.5)	1 (4.8)	
Education				0.59
High school	7 (16.7)	2 (9.5)	5 (23.8)	
Some college	11 (26.2)	7 (33.3)	4 (19.1)	
4-year degree or more	24 (57.1)	12 (57.2)	12 (57.1)	
Occupation				0.03
Full time	16 (38.1)	6 (28.6)	10 (47.6)	
Part time	4 (9.5)	0	4 (19.1)	
Unemployed	10 (23.8)	8 (38.1)	2 (9.5)	
Retired	12 (28.6)	7 (33.3)	5 (23.8)	

delayed treatment group during the period of intervention to the same patients during the period of no intervention) or Wilcoxon signed rank tests (comparing the immediate and delayed intervention groups over the first 3 months of participation) are properly applied for comparisons of intervention effects on function and symptoms. All analyses were accomplished using R version 4.2.0.

Results

Figure 2 provides the consort diagram. There were 133 patients assessed for eligibility between January and May 2021. Of these, the majority were identified by medical record review at Penn State clinics ($N = 127$). Six women contacted us based on social media, four of whom participated. We achieved an acceptability metric of 51%. Forty-one women declined participation. Reasons for declining participation included being too busy and feeling like they already had sufficient support. A total of 42 patients were randomized to immediate or delayed intervention.

As shown in Table 1, patients were, on average, 53 years old, diagnosed with breast cancer over 8 years prior to study and received a diagnosis of MBC approximately 4 years prior to study. Most (81%) were married, 90.5% reported White race, and 9.5% reported Hispanic ethnicity. The majority of the sample (83.3%) had attended at least some college, and 50% reported not currently working (71.4% in the immediate group and 33.3% in the delayed group, $p = 0.03$). Of participants who participated in the 90 days of the intervention ($n = 37$), 24 (64.9%) logged in at least 30 days. The use of the technology declined in months 4–6, after the weekly calls ended: 58%, 47%, and 29% logged in during months 4, 5, and 6.

Table 2 presents the effects of the intervention on four symptoms: distress, pain, sleep, and vitality/fatigue, as well as quality of life, physical function, and chair stands. Results are presented for baseline and 3-month changes for both groups, for the first 3 months of exposure to the intervention, as well as for the delayed intervention group during the "control" period of 0–3 months. Statistical analyses assessed the effects of 3 months of intervention for the first 3 months of the trial (the randomized controlled trial) as well as for the within-person comparisons

Table 2 Effects on function and symptoms (mean (SE))

	Immediate Tx		Delayed Tx		Control		*P*-value immediate vs control	P-value delayed vs control
	Baseline ($n=21$)	3-month change ($n=17$)	3-month value ($n=16$)	Change at 6 months ($n=15$)	Baseline ($n=21$)	3-month change ($n=16$)		
Distress (higher is worse)								
Practical (range 0–10)	2.76 (2.68)	−0.65 (3.00)	2.15 (2.70)	0.27 (3.10)	2.40 (2.72)	−0.25 (3.23)	0.7007	0.7443
Family problems (range 0–10)	2.9 (2.53)	−0.33 (2.91)	2.65 (2.72)	−0.73 (1.79)	2.30 (2.68)	0.35 (1.84)	0.4004	0.1352
Emotional problems (range 0–10)	2.86 (2.24)	−0.44 (2.09)	1.85 (2.06)	−0.13 (2.33)	2.40 (1.43)	−0.55 (1.76)	0.8682	0.8275
Spiritual religious problems (range 0–10)	0.48 (1.25)	−0.11 (1.60)	0.40 (0.99)	−0.27 (0.59)	0.15 (0.37)	0.25 (0.72)	0.3884	0.1038
Physical problems (range 0–10)	3.90 (2.41)	−0.67 (2.57)	3.10 (2.20)	−0.40 (2.69)	3.35 (2.23)	−0.25 (2.73	0.6308	0.5744
Pain (higher is worse)								
Pain severity (range 0–10)	3.57 (2.73)	0.33 (2.70)	3.35 (2.89)	−1.81 (2.68)	3.57 (2.93)	−0.10 (2.02)	0.5829	0.0204
Pain interference (range 0–10)	2.06 (2.17)	−0.60 (0.91)	1.44 (1.48)	1.40 (1.53)	2.49 (2.67)	−0.86 (2.46)	0.6713	0.0033
Sleep disturbance score (0–100 higher is worse)	53.12 (2.92)	0.17 (3.88)	52.89 (3.68)	−0.78 (3.54)	54.04 (3.53)	−0.96 (3.16)	0.3325	0.4077
SF-36 (range 0–100, higher is better)								
SF36_Vitality/fatigue	49.76 (21.12)	6.67 (12.83)	51.25 (17.61)	0.00 (16.80)	49.05 (18.41)	2.00 (17.35)	0.3494	1.0000
SF36_Physical functioning	71.67 (24.77)	8.06 (19.03)	70.75 (22.14)	−1.00 (14.29)	70.00 (22.14)	0.00 (10.39)	0.1230	0.7904
SF36_Role limitations due to physical health	45.24 (47.84)	6.94 (49.86)	60.00 (44.72)	3.33 (44.19)	57.14 (42.68)	0.00 (35.36)	0.6274	0.7744
SF36_Role limitations due to emotional problems	65.08 (45.31)	16.67 (56.30)	80.00 (33.16)	−8.89 (29.46)	80.95 (30.86)	−1.67 (41.48)	0.2332	0.2620
SF36_Emotional well-being	75.43 (10.30)	0.44 (12.72)	79.80 (11.50)	−2.13 (14.33)	78.48 (10.39)	0.40 (7.33)	0.9897	0.5734
SF36_Social functioning	79.17 (23.16)	1.39 (17.62)	82.50 (15.39)	−5.00 (21.55)	80.95 (17.95)	1.25 (13.99)	0.9789	0.3840
SF36_Pain	62.50 (22.30)	3.61 (19.18)	64.00 (22.69)	2.17 (14.20)	65.00 (22.05)	−2.00 (18.65)	0.3677	0.5640
SF36_General health	54.52 (19.03)	0.76 (11.98)	55.50 (17.98)	−1.67 (9.39)	54.76 (18.81)	−0.50 (12.97)	0.7567	0.5029
Chair stands (lower is better)	11.29 (3.85)	−1.16 (2.91)	11.06 (3.52)	−0.97 (3.50)	11.62 (3.82)	−0.58 (3.29)	0.5718	0.2998

Table 3 Usability survey scores after 3 months of use ($N=33$) (higher is better for all surveys)

	Mean (SD)
Client satisfaction questionnaire (range 8–32)	25.36 (4.87)
CEQ-scale	
How logical did it seem? (Range 1–10)	7.42 (1.62)
Help with symptoms? (Range 1–10)	5.76 (2.50)
Recommend to a friend? (Range 1–10)	7.24 (2.36)
Improvement in symptoms? (Range 1–100%)	47.81 (28.82)
System usability (Range 1–100)	86.14 (11.69)

of 3 to 6 months (receiving the intervention) to 0 to 3 months (not receiving the intervention) for the delayed treatment group. No statistically significant between-group differences were observed.

As shown in Table 3, the average rating for satisfaction with the intervention (Client Satisfaction Questionnaire) over 33 respondents was 25.36 on a scale of 8–32 (32 best). Patients indicated that Nurse AMIE seemed logical (7.42 on scale of 1–10, with 10 being best). When asked if Nurse AMIE helped with symptoms, the mean response was 5.76 on a scale of 0–10 (10 best). As to whether they would recommend Nurse AMIE to a friend, the mean response was 7.24 on a scale of 0–10 (10 best). As to the magnitude of improvement in symptoms experienced as a result of Nurse AMIE interventions, participants answered a mean of 47.81 on a percentage scale from 0 to 100 (100 best). Finally, the mean score on the System Usability Survey was 86.14 on a scale from 0 to 100 (100 best). Participants reported being satisfied with all interventions at a rate of 70% or higher (see Fig. 3). No adverse events were reported by any participants in this study.

Discussion

Metastatic breast cancer patients are living longer while withstanding ongoing treatments, their side effects, and the symptoms of the disease. Addressing symptoms and side effects is a desire of MBC patients, and ideally, these issues would be addressed by appropriately trained oncology nursing clinicians. However, appointment lengths are often insufficient to address all symptom issues, and adding clinic appointments may be burdensome to patients who are already seeing their care team frequently. As such, virtual assistant technology-based interventions to address symptoms and side effects of MBC may be attractive. In this trial, we translated a previously developed tablet-based supportive care intervention into a new setting: a virtual assistant using the Amazon Echo Show with Alexa. In combination with prior acceptability results of 55% and 68% and the current acceptability results of 51%, we conclude there is evidence that this intervention is acceptable to patients and their clinicians [24, 25]. Further, the intervention is feasible, as evidenced by nearly 65% of participants logging into the system at least 30 out of the 90-day intervention period. Participants also reported high levels of satisfaction with the interventions offered (reporting that the intervention was useful to them 70% of offered interventions).

Results from the usability surveys are highly promising. The average System Usability Scale (SUS) score is 85.14 (SD 11.69). Based on thresholds established in prior work [12], the SUS score indicates Nurse AMIE has "excellent" usability. Similarly, the average Client Satisfaction Questionnaire (CSQ) score is 25.36 (SD 4.87), which falls within the good to excellent range [1]. In other words, the users were highly satisfied with Nurse AMIE. The Credibility/Expectancy Questionnaire (CEQ) [5] survey shows that users were confident in recommending Nurse AMIE to a friend who experiences similar problems with an average score of 7.24 (SD 2.36). Users reported Nurse AMIE to be "somewhat useful' in reducing their symptoms (mean 5.76 (SD 2.50)). The average expected improvement in symptoms was 47.81% (SD 28.81). Users also found Nurse AMIE interactions to be highly logical with an average score of 7.42 (SD 1.62).

There were no significant effects observed on the symptom-based patient-reported outcomes, quality of life scales, or the objective physical performance measure. This could be the result of a small sample

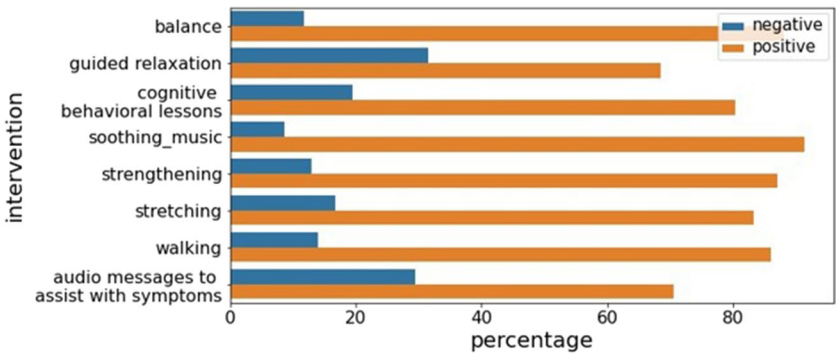

Fig. 3 Patient satisfaction with interventions

size or the type or duration of the intervention. There were several outcomes for which effects were promising and that may be expected to show statistical significance in a similar study with a larger sample size. These include the SF-36 physical functioning, which improved by 8 points in the intervention group during the first 3 months of the study (no change in control), and SF-36 vitality/fatigue, which increased nearly 7 points (2 points in control). In a trial with 160 MBC participants, these differences would be significant. The observed effects on these two outcomes are within range of minimally clinically important differences defined within other oncology populations [19].

There is one other technology-based supportive care platform for breast cancer we have identified. Young, Empowered, and Strong is a web-based education and supportive care intervention for young women across the care continuum. To date, this intervention has been piloted with 30 patients, including 10 with metastatic disease. Acceptability of this study was 75%; feasibility of the surveys included was 52% [26]. Offering technology-based support on a website is another option, though the question of whether this approach would be as acceptable to older patients remains unanswered. Ideally, a supportive care platform would be available by phone, website, tablet, and on the Amazon Echo Show with Alexa. Another consideration for future studies would be to integrate technology-based supportive care systems with human nursing care models to maximize patient outcomes.

Limitations of our study include the small sample size and the loss to follow-up, which limit inferential power. Though we retained 88% of patients for the RCT, there were dropouts due to death, loss to follow-up, and increasing pain. Another limitation is that Nurse AMIE could be expanded to address additional common symptoms such as nausea and bowel issues. Finally, we recognize that the sample for the trial lacked diversity. The study largely recruited at a hospital in central Pennsylvania, where the majority of the patients are white. Another requirement of study participation was to have Internet access at home, which may have further limited diversity of our sample. Future studies should work to expand access to technology-based interventions to more diverse patient populations. Finally, the use of the application declined after weekly calls ended, suggesting perhaps that the calls would be useful to continue longer term in future versions of this intervention. Strengths include having adapted the study activities to be entirely online during a global pandemic, allowing the work to continue unabated.

We conclude, on the basis of this study, combined with results from two prior studies [24, 25], that a virtual assistant technology-based supportive care intervention called Nurse AMIE is acceptable to MBC patients and their clinicians, feasible for these patients, and that patients find the intervention to be useful. Nevertheless, we cannot yet conclude that our intervention has meaningful effects on the symptoms we target, largely because of statistical power. We have obtained funding for a larger study of Nurse AMIE (NCT05221606) that will allow us to explore this issue further. Technology-based supportive care platforms show promise for addressing patient needs in the setting of metastatic breast cancer. Future studies could also address the potential to integrate technology-based supportive care with nursing interventions.

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Declarations

Conflict of interest The authors declare no competing interests.

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