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Original Article

Oral self-management of palbociclib using mobile technology: Findings from a nurse-led randomized controlled trial

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ABSTRACT

Objective: Test the feasibility and effectiveness of a text message reminder intervention for the self-management of oral anticancer medication in patients with metastatic breast cancer.

Methods: Forty-three females initiating treatment with palbociclib participated in a two-armed prospective randomized clinical trial. Participants were randomized into the control ($n = 21$) and intervention groups ($n = 22$) from January 2020 to January 2023. Survey responses were collected at three-time points; (1) at consent, (2) end of treatment cycles, and (3) at a follow-up clinic visit. Surveys included a demographic questionnaire, the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire, post-study assessment, and the R-15 Participant Satisfaction Questionnaire. Nurse providers completed the Adaptation of Stamps Nurse Workload questionnaire.

Results: The COVID-19 pandemic and regulatory decisions supporting other CDK4/6 medications negatively influence recruitment; thus, a small sample for each arm only detected large differences between the two arms regarding effectiveness. Feasibility analysis was not conducted due to insufficient data, but the participants frequently used their smartphones for text messaging. Although the survey data were limited, participants provided anecdotal information supporting the use of text messaging as a positive method to remind them to take their medication, have their labs drawn, and attend MD visits. Participants would have liked text messages at the exact time they took their medications as a simple reminder.

Conclusions: Given the importance of cancer treatments and the difficulties patients experience during these treatments, text messages using smartphones can actively improve patients' engagement and their ability to manage their treatment regimens.

Trial registration: ClinicalTrials.gov; ID: NCT04216576.

Introduction

Medication self-management is a primary concern with oral anticancer therapy given that participants may fail to remember to take medications, complete laboratory tests, or attend doctor visits, which can lead to inappropriate dosing, inadequate laboratory monitoring, and failure to report side effects. Smartphones are ubiquitous forms of mobile technology that are increasingly being used for interventions in health care research. This study reports the findings of a nurse-led clinical trial using one-way text message reminders to help patients with metastatic

breast cancer (MBC) manage their cancer treatment. The original protocol details were previously published.[1]

MBC is a chronic, progressive condition where the goal of treatment is to minimize symptoms while controlling the spread of the disease.[2] Generally, palbociclib is a well-tolerated oral anticancer drug used to treat MBC in combination with letrozole or fulvestrant as initial treatment.[3,4] Consequently, participants may have different experiences and difficulties in self-administering multiple treatments and medication regimens. Text messaging interventions, which utilize customizable text messages sent from a clinician on the patient's smartphone, have been

explored in other studies and may be an alternatively feasible and effective intervention platform.[5–7] Related studies have suggested that mobile technology may improve participant-provider interactivity, strengthen medication reminder interventions, and ultimately improve the outcomes of the patient's care.[8,9] However, the reported literature identifies a gap in understanding the impact of text messaging on patients with MBC. This trial seeks to understand whether patients with MBC perceived that text message reminders help them take their medications as directed, attend clinic and lab appointments, and if using their smartphones effectively engaged and supported their ability to manage their cancer treatment regimen.

The purpose of this clinical trial was to evaluate the feasibility and effectiveness of a text messaging intervention for the self-management of oral anticancer medication in patients with MBC.

Secondary objectives include health-related quality of life (HRQoL), laboratory assessments, acceptability, usefulness of text messages, and satisfaction with the intervention by participants and nurses. The underlying hypothesis is that patients receiving text message reminders on their smartphones is a feasible and effective method to help self-manage their oral anticancer treatment regimens.

Methods

Study design

This study employed a 2-armed, randomly controlled clinical trial (RCT) design with an *intent-to-treat* analysis comparing the control arm and the experimental (intervention) arm. Participants were recruited from a comprehensive cancer center in the northeastern United States between January 1, 2020, and January 2023. The screening strategies involved organizational reports and referrals from medical oncologists and included all races and ethnic groups. All participants voluntarily provided written informed consent, which included the risks and benefits of the study, and they could withdraw from the study at any time. The consolidated standards of reporting trials (CONSORTs) guidelines were used in the reporting of this clinical trial.[10] (Supplemental Consort Checklist).

Patients meeting the following inclusion criteria were invited to participate: (1) Adults aged 18 years or older with MBC, (2) Read and write in English, (3) Initiating therapy on palbociclib, (4) using a smartphone, (5) downloading the study's text messaging application and receiving text message reminders, and (6) providing consent. Exclusion criteria: (1) Previous palbociclib treatment, (2) caregiver coordination of health care, or (3) ineligibility as designated by the inclusion or exclusion criteria. Nurses were sent the survey and may have completed multiple surveys due to the number of participants from their specific medical office practice who participated in this trial.

The original sample size of 200 participants (100 in each arm) was theoretically derived from data in the published literature and the number of participants treated with palbociclib (Ibrance®) during protocol development. The power analysis for the original study was estimated as the difference between the rates from the two groups at 40% of the pooled standard deviation and a power of 0.80 to detect such a difference at the 0.05 significance level. The study was then amended to address the decrease in recruitment due to the COVID-19 pandemic, regulatory changes of other CDK4/6 drugs, which included palbociclib, and changes in physician preferences for using palbociclib as the initial treatment for MBC. This resulted in a new reduced sample of 100 participants (50 in each arm). Consequently, the reduced target accrual was not reached with 43 patients enrolled in the two arms. Thus, an updated power assessment was calculated for the revised design. This revision was not a post-hoc assessment, but an updated power analysis based on actual accruals. Therefore, at a power of 0.73, we were able to detect a difference of 80% in pooled standard deviation between the rates of the two groups at a significance level of 0.05 for a two-sided, two-sample *t* test. However, using this power calculation, the actual sample size can only detect large differences between the two arms in terms of

effectiveness. Therefore, the reduced sample size no longer provided powerful comparisons between the two randomized groups.

Randomization

The clinical research coordinator (CRC) and principal investigator (PI) registered participant data into the organization's Clinical Randomization Data Base (CRDB). Randomization was accomplished using the random permuted blocks method and was stratified into three groups by age (≤ 45, 46–60, ≥ 60 years) and previous treatment regimens: (1) (CMF: cyclophosphamide, methotrexate, and docetaxel; (2) AC: Adriamycin (doxorubicin) and Cytoxan (cyclophosphamide), AC + paclitaxel (Taxol), and AC + docetaxel (Taxotere), and (3) other chemotherapy combinations.

Control and intervention arms

Self-Regulation Theory[11] guided this research and posits that health care experiences are unique to each participant whose participation and practice are critical for their health care outcomes. This study included criteria for intervention fidelity and quality assurance, study rigor, including validity and reliability, and data safety and monitoring procedures. For both groups, the standard of care treatment included bi-weekly laboratory testing for the first three cycles of therapy, medication dosing on a 28-day cycle, and monthly physician visits (Table 1). The *control group* received the standard of care and included teaching in the clinic or via telephone regarding medication administration, interval bloodwork, and follow-up visits. Upon initiating treatment, participants are provided a paper drug diary, medication calendar, and printed drug information. The *intervention group* includes the standard of care plus unidirectional text messages based on intervention time points, which are sent through a HIPAA-compliant messaging application downloaded to the participant's phone[12] (Supplementary Table S1).

Data collection

Self-reported surveys were administered to study participants at three time points: (1) Before Cycle 1; (2) at 12 weeks (after Cycle 3); and (3) at 24 weeks from baseline (end of study). An email link to the study's surveys was provided to participants and could be completed using a smartphone or personal computer. Participants had the option of completing paper surveys during their clinic visits, which were collected by the clinic team and sent to the CRC to upload into the study's REDcap database (Research Electronic Data Capture)[13,14] The CRC sent surveys to eligible nurses using the organization's email with a link to the study's database at the 12-week time point. To maintain the anonymity of nurse responses, demographic information was not collected.

Outcome measures

Participants were sent the Demographic Baseline Questionnaire (DBQ) which included the participant's demographics, use of technology, and treatment regimen. The primary outcomes were the feasibility and effectiveness[15,16] of the one-way text message reminders. The secondary variables included HRQoL,[17–19] nurses' satisfaction and workload,[20] laboratory tests, acceptability, and usefulness,[15,16] as well as the drop rate and side effects profiles. Additional documents included a drug diary, medication calendar, and text message chats. Details regarding the outcome variables and measures have also been previously published.[1] (Supplemental Table 2).

Data analysis

Patient characteristics were summarized using mean, median, interquartile range (IQR), and range for continuous variables, whereas frequency and percentage were used to describe categorical variables.

Table 1
Data and safety management, and quality assurance procedures.

Data management and safety monitoring plan	• The data and safety monitoring plans were approved by the National Cancer Institute (NCI) and were monitored by the organization's Office of Clinical Research. • The protocol was assessed for its level of risk degree of monitoring required and established the monitoring procedures identified in this report. • The research team was responsible for project compliance, data collection, abstraction, and entry, data reporting, regulatory monitoring, problem resolution and prioritization, and coordination of the activities of the protocol study team. • Participants were assigned unique identification numbers (IDs). All data were de-identified and entered REDcap (Research Electronic Data Capture), which is a password-protected database stored on a secure server. • Paper documents were destroyed after they were scanned by the participants' EMRs to serve as source documentation
Study rigor: Validity and reliability	• Scientific rigor was ensured based on the reliability, credibility, and safety of study measures and using standard reports for screening and data collection. • One of the four participating professional nurses obtained consent. • A rule-based quality assurance plan was developed to ensure quality and safety of the intervention, followed by quarterly review to ensure the consistency of the study methods. • All deviations from consistency, toxicities, and side effects occurring in the study participants were reported to the institutional review board (IRB). • Training manuals were developed for both the intervention and control arms and presented during unit-level staff meetings. • The research team attended detailed training to ensure fidelity of the intervention.
Intervention fidelity and quality assurance procedure	• The PI reviewed clinic schedules and study databases daily and identified participants who required text message reminders. • The PI, as well as the nurse researcher, does not provide direct care to participants. • Only the PI manually sends the text message. • If a participant replies with a text containing symptoms, the PI emails the medical oncologist's office practices and documents the response in the EMR. • CBC was collected on day 14 of the treatment cycle. Pending the results, medication may be dose-reduced or held. A text message is sent to the participant after the PI receives a verification email from the medical office practice.

PI, principal investigator; EMR, electronic medical records.

The primary aim of feasibility was calculated only for participants in the Intervention arm and was quantified as the percentage of participants who recommended text messages. The participants who provided answers to question No. 10 in the R15 Participant Satisfaction Questionnaire[15,16] at the 12-week time point, representing the completion of the first three cycles of treatment, were analyzed. Effectiveness was calculated as the number of days that accurately self-administered the medication divided by the number of days that the medication should have been taken.

The Wilcoxon rank-sum test was used to compare the secondary aims involving the accuracy rate of completed pill diaries, HRQoL, and laboratory values between the study arms. The *HRQoL*[17–19] was measured using three domains (function, symptoms, and global health status), with the mean score calculated per patient at each time point. *The laboratory values* (white blood cell [WBC] count, hemoglobin [HGB], hematocrit [HCT], platelets [PLT], and absolute neutrophil count [ANC]) were collected for each patient at three time points. *Nursing workload*[20] was measured using two subscale scores (task and autonomy) and was compared between arms using the clustered Wilcoxon rank sum test accounting for nurse ID.

The Clopper-Pearson Exact confidence interval was used to describe *the acceptability* and *dropout rates*. The *Dropout rate* was defined as the number of patients who did not complete the study divided by the number of patients who agreed to participate. *Acceptability* was defined as the proportion of patients who agreed to participate in the study. among those who were asked to participate. The frequency of grade 3+ *side effects* was tabulated for each arm using Fisher's Exact test. *Usefulness* was calculated for the intervention group only and was the sum of four questions that comprised domain EV3 from the Post Study Questionnaire.[15,16]

Results

Sample characteristics

Screening and recruitment were initiated at the New York campus and expanded to regional sites in New Jersey (Monmouth, Bergen, and Basking Ridge) and Long Island (Commack, Hauppauge, and Nassau). Six hundred records were screened (BAIC 270; Regionals 330), and 239 were assigned to other CDK4/6 Medications (40%), resulting in 78 eligible records with 68 participants who met the criteria for the study (21 declined; 47 consented to participate). Of the 47 participants, two provided consent but started medication before randomization, one withdrew, and one participant consented and was dropped because the consent documentation was incorrect (Fig. 1). The screening resulted in

43 female participants who were randomized into the Control (*n* = 21) and Intervention (*n* = 22) groups during the study time frame. Most participants were white, married or with a partner, and had graduate degrees or professional training (Table 2). Eighteen nurses received the STAMPS survey for the perceptions of tasks (10 responses) and autonomy (11 responses) and may have had multiple patients in each arm.

Participant perceptions and types of mobile technology

Overall, the participants in this study mostly used their smartphones. Laptops, tablets, iPads, and tablets were also frequently used (Table 3). Participants reported that they were very comfortable using smartphones, with the intervention group feeling more comfortable. Smartphones are reported to be the most frequently used technology by both groups. The frequency of texting was 59% in the control group was 59% compared to 47% in the intervention group but was not statistically significant (Table 4).

Primary aims

Although the original plan was to evaluate the feasibility of the mobile technology intervention (the percentage of participants who recommend text messages, i.e., question no. 10 in the R15 Participant Satisfaction Questionnaire at the 24-week timepoint), there were challenges in administering the questionnaire. Even at the 12-week time point, we only had six participants who answered this question (all said yes), while the remaining 16 participants did not answer. Thus, we chose not to conduct a pre-planned analysis or implement the decision rule when declaring feasibility due to insufficient data. Effectiveness results between the control and intervention groups were not significant.

Secondary aims

Secondary aims were collected to determine whether text messaging reminders influenced any of their treatment regimens. *Poststudy Health-Related Quality of Life*: No significant differences in European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30) domain scores were found between the control and intervention groups at any time point.

Nursing workload and satisfaction: Nurses did not report any changes in their workload (tasks and autonomy) related to text message reminders. *Laboratory values and standard of care activities*: No significant differences were found in the laboratory values (WBC, HGB, HCT, PLT, and ANC)
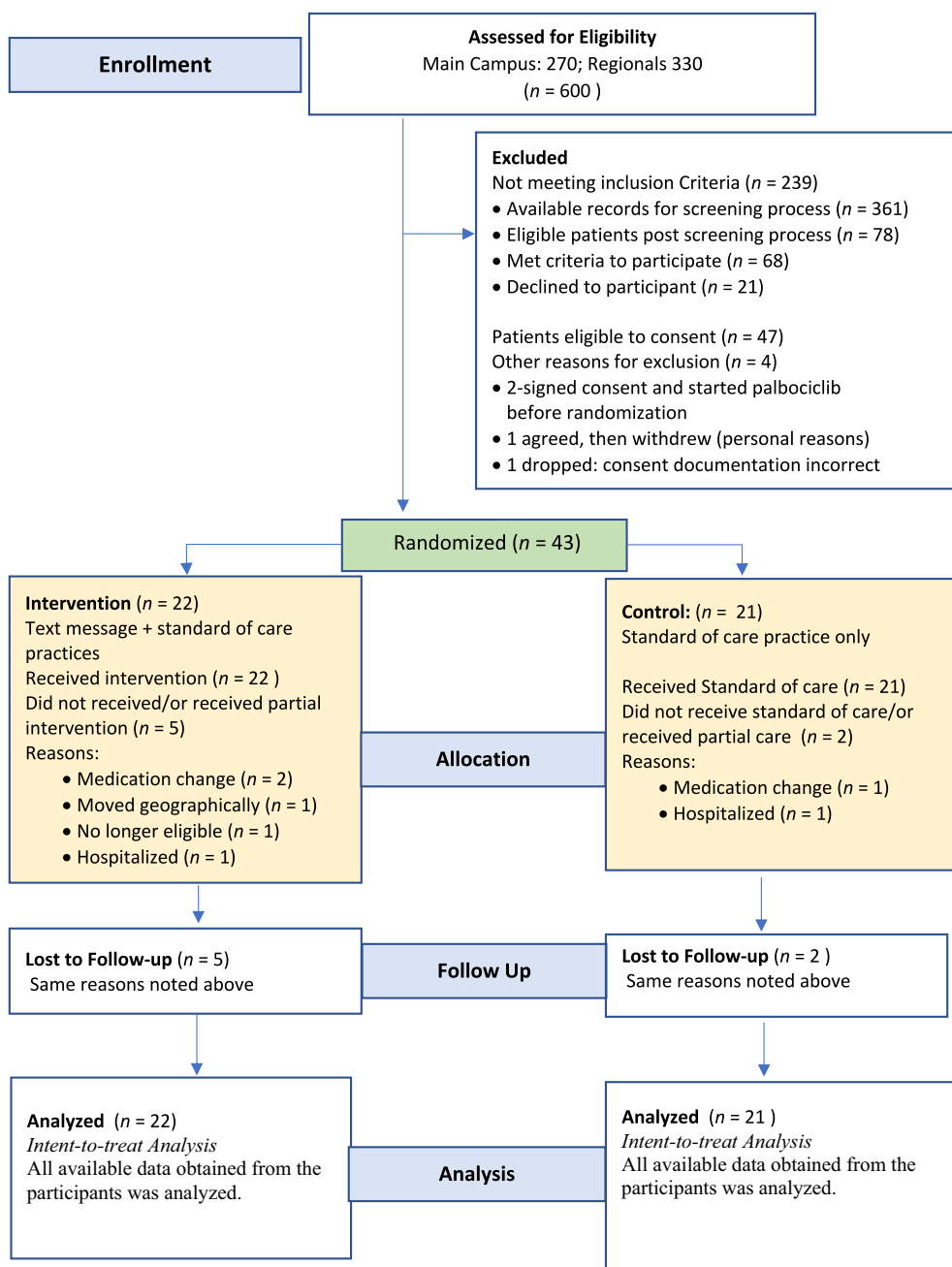
Fig. 1. CONSORT 2010 flowchart. CONSORT, consolidated standards of reporting trial.

between the control and intervention groups. *Acceptability:* There was good Acceptability for patients who participated in this study. Of the 68 patients who were asked to participate, 47 (69%, 95% CI: 57% to 80%) agreed. *Usefulness:* Participants in the Intervention group completed the Post Study Questionnaire to determine the usefulness of the text messaging they received. Fourteen participants did not complete the survey. Of the remaining eight participants who responded, the median score was 12.5 (IQR: 10.3, 14.5), and ranged (4.0, 16.0). *Side effects and dropout rates:* The standard of care for all patients undergoing chemotherapy regimens requires monitoring for side effects. The side effects and symptom profiles were summarized and did not reveal significant differences in the frequency of Grade 3+ side effects between the control and intervention groups. The participants who developed side effects were excluded from the study. The dropout rate of 9% was calculated for this study. Of the 47 participants who agreed to participate in the study, 4 (9%, 95% CI: 2% to 20%) did not complete the study.

Discussion

This nurse-led clinical trial assessed whether a text message reminder intervention can help patients self-manage their oral chemotherapeutic treatment regimens, not the outcomes of the medication (palbociclib). Integrating the patient's smartphone is supported in the literature as a viable method for improving self-management of medications and various interventions at home.[21–24] Despite the acceptance of eligible participants in this study, most participants completed the baseline surveys, but collecting surveys at additional time points was challenging. They consistently reported that their cancer diagnosis overwhelmed them, and they either could not be involved with any further activities or did not want to complete any surveys. These findings were not vastly different from those of other studies that presented mixed results, successes, and challenges.[21–24]

The study also explored participant demographics, HRQoL, laboratory testing, usability and acceptability of the text messaging

Table 2
Participant characteristics and demographics.

Characteristics	Overall n = 43[a]	Control group n = 21[a]	Intervention group n = 22[a]
Age (years)	58 (50, 65)	54 (49, 65)	58 (53, 65)
Race/Ethnicity			
White	17 (50%)	8 (47%)	9 (53%)
Asian/Pacific islander	2 (6%)	1 (6%)	1 (6%)
Black/African american	5 (15%)	4 (24%)	1 (6%)
Hispanic/Latino	9 (26%)	3 (18%)	6 (35%)
Mixed race	1 (3%)	1 (6%)	0 (0%)
Unknown	9	4	5
Marital status			
Married/Partnered	24 (71%)	10 (59%)	14 (82%)
Divorced/Separated	2 (6%)	1 (6%)	1 (6%)
Single	8 (24%)	6 (35%)	2 (12%)
Unknown	9	4	5
Education			
High school graduate/GED	3 (9%)	1 (6%)	2 (12%)
Some college or vocational training	4 (12%)	3 (18%)	1 (6%)
College graduate	7 (21%)	4 (24%)	3 (18%)
Graduate degree or professional training	20 (59%)	9 (53%)	11 (65%)
Unknown	9	4	5

[a] Median (IQR); *n* (%). GED, General Eucational Development; IQR, interquartile range.

Table 3
Types of mobile technology used by participants daily.

Characteristics	Overall n = 43[a]	Control group n = 21[a]	Intervention group n = 22[a]
Uses smartphone	34 (100%)	17 (100%)	17 (100%)
Unknown	9	4	5
Uses laptop	31 (91%)	15 (88%)	16 (94%)
Unknown	9	4	5
Uses iPad/tablet	18 (53%)	7 (41%)	11 (65%)
Unknown	9	4	5
Uses E-read	6 (18%)	2 (12%)	4 (24%)
Unknown	9	4	5
Uses flip-phone	1 (3%)	1 (6%)	0 (0%)
Unknown	9	4	5

[a] *n* (%).

Table 4
Participants' self-reported perceptions of using technology.

Characteristics	Overall n = 43[a]	Control group n = 21[a]	Intervention group n = 22[a]
How would you rate your comfort with mobile technology such as cell phones and smartphones?			
A little comfortable	3 (9%)	2 (12%)	1 (6%)
Neutral	1 (3%)	1 (6%)	0 (0%)
Very comfortable	20 (59%)	9 (53%)	11 (65%)
Extremely comfortable	10 (29%)	5 (29%)	5 (29%)
Unknown	9	4	5
How would you describe the frequency with that you use text messaging?			
Occasionally	3 (9%)	2 (12%)	1 (6%)
Regularly	13 (38%)	5 (29%)	8 (47%)
Frequently	18 (53%)	10 (59%)	8 (47%)
Unknown	9	4	5
Do you currently use any reminders to take your medication?			
Alarms	7 (21%)	3 (18%)	4 (24%)
Med calendar	1 (3%)	1 (6%)	0 (0%)
Mobile application	3 (9%)	3 (18%)	0 (0%)
None	16 (47%)	7 (41%)	9 (53%)
Other	3 (9%)	2 (12%)	1 (6%)
Pill box	4 (12%)	1 (6%)	3 (18%)
Unknown	9	4	5
Based on the information you have received from your health care team; how would you rate the level of complexity in managing your treatment?			
Easy	11 (32%)	5 (29%)	6 (35%)
Not complicated	18 (53%)	11 (65%)	7 (41%)
Somewhat complicated	5 (15%)	1 (6%)	4 (24%)
Unknown	9	4	5

[a] *n* (%).

intervention, and nurses' workload in caring for the study participants.

Although no differences were found between groups regarding how participants perceived the usefulness of text messaging and QOL, this finding was expected because both groups equally received standard-of-care practices. Participant narratives conveyed that fatigue was a major symptom as were the multiple lab visits, and side effects of the medication. These findings are consistent with another meta-analysis study on breast cancer patients.[25] The comparison of laboratory values did not detect differences between study groups despite the presence of text message reminders. However, in hindsight, we omitted asking individuals who received text messages whether this specific message improved the communication between the care team and self-administration of medications, or by sending a message to encourage patients to take the medication. Text messaging potentially prevented patients with low absolute neutrophil counts from developing further neutropenia symptoms and hospital admissions. Consistent findings from other mobile health clinical trials have shown mixed but promising results in engaging patients on oral chemo regimens at home.[26,27] However, despite the lack of significant findings in the study's statistical analysis, there were many positive and clinically significant outcomes from the anecdotal information of participants during their involvement in this study that must be underscored.

The intervention arm participants reported that receiving text message reminders was an acceptable and useful measure for self-managing their medication regimen, consistent with other studies indicating moderate benefits of text message reminders.[28] One patient reported that they disliked having text messages sent at limited time points and wanted the messages to be delivered daily and at the exact time they needed to take their medication. Other participants stated that they also kept a calendar and used phone alarms in addition to text messages. Most participants receiving text messages wanted the bi-directional ability to send text messages back to the sender. This option may be addressed in future work through an organization's Connected Care program using electronic patient-reported outcomes.

Pill diaries were used to determine the accuracy rate and thus effectiveness of text message reminders. Consequently, using either the paper or online option did not lead the participants to complete the diaries. When the PI called participants to reconcile the dates and times they took the medication, participants reported that they liked having phone calls, someone to talk to, and felt that the PI was their "*Buddy*" helping them through treatments. This was a significant clinical finding.

The control arm participants stated that they used multiple methods, including alarms on cell phones, smartwatches, and other self-managing methods, such as taking meds at the same time every day and placing the medications in the same spot as a medication reminder. The intervention arm participants maintained their treatment regimens and found the texts helpful. They voiced complaints about multiple clicks on encrypted text messages, which prompted the study team to create a text consent form for the message to be sent, similar to any personalized message.[29] Some participants requested customizing text to the exact time that they would take their medication, like an alarm, which may be a factor in improving the effectiveness of text messaging in future studies.

Nurses caring for patients in this study did not report any workload changes related to text message reminders between study arms. Not anticipated, the PI researcher may have become an unofficial adjunct to office practices in reporting changes in labs and as reminders to the office practice team about the patient's condition. Although not a significant finding, these results shed light on potential concerns regarding nursing workload, which were not specifically identified as a task in the nurses'

current workflow but may inform text message practices to patients in the future. The PI obtained anecdotal information from the patients and office practice nurses through emails between the PI and practice team. The text messages positively enhanced communication among the primary care teams. These results were consistent with other trials on breast cancer survivors and supported text messages as feasible, inexpensive, and acceptable for delivering health information about medical appointments.[27,30] Results and lessons learned from this research may inform modifications of future mobile technology studies.

Strengths, limitations, and implications for practice

The strengths of this study involved the multiple safety criteria included in this study to ensure that no message was unintentionally sent to the participants. Organizational standards require the protection of information, including messages that were initially encrypted. However, participant recommendations to modify the encryption were implemented and have facilitated participant experiences. Moreover, the narrative information from participants in both study groups demonstrated the clinical significance of patient-provider engagement and communication during chemotherapeutic treatment.

This study has limitations. There is bias in favor of participants who may be inclined to use technology. However, given the global use of mobile technology,[5,7] this study's intervention is potentially relevant to most individuals from various backgrounds. The study team recognizes that only English-speaking, reading, and writing individuals were included in this study. Finally, participants taking palbociclib alone as opposed to in combination with fulvestrant or letrozole are currently receiving treatment for MBC. A participant may initially be on a regimen of palbociclib and subsequently, letrozole may be added which may offer different experiences in using unidirectional text messaging intervention to support self-management. Low recruitment was influenced by the COVID-19 mandates implemented after the study opened in January 2020, whereby all research initiatives were suspended from March 2020 through August 2020. Physician practices decreased the use of palbociclib and increased the prescription of other CDK4 drugs. The Federal Drug Administration approved other CDK4 drugs for early breast cancers[31] and further limited the use of palbociclib for MBC. Further compounding the decrease in the use of palbociclib was the report of high medication co-pay costs, resulting in physician requirements to change treatment medication. The impact of these regulatory initiatives decreased the original sample of participants twice due to low enrollment. Despite robust recruitment practices, enrollment was closed in July 2022, and the study officially ended in January 2023, when the last participant completed the treatment cycles. Finally, the reduced sample size and recalculation of the power analysis did not provide powerful comparisons between the two randomized groups and limited the generalizability of the study findings. However, we are confident that our clinical findings, found in the participant narratives, can inform replication studies on text message reminders for participants in oncology practices globally. Given the importance of oral chemotherapy medications and the difficulties patients experience during treatment cycles, clinician-driven smartphone interventions actively engage patients in their care and help them self-manage treatment regimens, thereby minimizing the progression of their cancers.[7,23]

Conclusions

The participants in this clinical trial positively perceived this nurse-led, patient-centered intervention to improve their acceptability and ability to self-manage their chemotherapy regimens. Despite the limited statistical significance, the study findings provide strong clinical evidence related to the medication self-management of oral chemotherapy and insights gleaned from anecdotal data from women in the study to improve future web-based, technological, and supportive interventions.

CRediT authorship contribution statement

AM Mazzella-Ebstein [AMME] , M Barton-Burke, V Anthony, and Z Zhang were involved in protocol development. **A Smith and M Robson** were involved with protocol implementation, service staff, analysis, and review of this manuscript. **C White and Z Zhang** were the statisticians who analyzed this research. **AMME** drafted this manuscript, with review and editing by all authors. All authors had full access to all the data in the study, and the corresponding author had final responsibility for the decision to submit for publication. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Funding

Data availability statement

The data that support the findings of this study are available upon request from the corresponding author. The data are not publicly available because of privacy or ethical restrictions.

Ethics statement

Approval for this study followed the principles and guidlines of the Belmont Report and Common Rule Regulations. Ethical Approval was obtained through the Memorial Sloan Kettering Cancer Center's Institutional Review Board (MSK IRB: 19–458) in December 2019. Participation was voluntary, and participants could withdraw at any time. No incentives or reimbursements for medications were provided.

Declaration of generative AI and AI-assisted technologies in the writing process

No AI tools/services were used during the preparation of this work.

Declaration of competing interest

The authors declare no conflict of interest. Dr. Barton-Burke served as the Recipients of a Pfizer Grant supporting this research. Dr. Barton-Burke serves on the editorial board of the *Asia-Pacific Journal of Oncology Nursing*. The article underwent standard review procedures of the journal, with peer review conducted independently of Dr. Barton-Burke and their research groups.

Acknowledgments

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.apjon.2024.100604.

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