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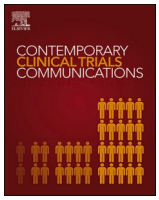

Comorbidities And Reducing InEquitieS (CARES): Feasibility of self-monitoring and community health worker support in management of comorbidities among Black breast and prostate cancer patients

Laura C. Schubel [a], Ana Barac [b], Michelle Magee [c,d], Mihriye Mete [a,e], Malinda Peeples [f], Mansur Shomali [f], Kristen E. Miller [a], Lauren R. Bangerter [a,g], Allan Fong [e], Christopher Gallagher [h], Jeanne Mandelblatt [i], Hannah Arem [a,j,*]

[a] Healthcare Delivery Research, MedStar Health Research Institute, Washington, DC, USA
[b] Heart and Vascular Institute Inova Health System, Falls Church, VA, USA
[c] School of Medicine, Georgetown University, Washington, DC, USA
[d] Diabetes Institute, MedStar Washington Hospital Center, Washington, DC, USA
[e] Center for Biostatistics, Informatics, and Data Science School of Medicine, Georgetown University, Washington, DC, USA
[f] WellDoc, Inc, Columbia, MD, USA
[g] Health Economics and Aging Research Institute, MedStar Health, Washington, DC, USA
[h] MedStar Washington Hospital Center, Washington, DC, USA
[i] Lombardi Comprehensive Cancer Center, Institute for Cancer and Aging REsearch (I-CARE), School of Medicine, Georgetown University, Washington, DC, USA
[j] Department of Oncology, Georgetown University, Washington, DC, USA

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ABSTRACT

Background: Black individuals with cancer have a higher prevalence of comorbidities and a worse cancer prognosis than other racial groups in the US. As part of a quality improvement project, we aimed to demonstrate feasibility of self-monitoring and community health worker (CHW) support among managing comorbidities for Black individuals with breast or prostate cancer.

Methods: In a single arm, pre-post study, we enrolled patients with diabetes and/or hypertension who identified as Black and were diagnosed with 1) stage 0-IV breast cancer, or 2) prostate cancer and on long-term androgen-deprivation therapy. Participants received a home-monitoring device linked to a mobile app and worked with a CHW over six months to track their blood pressure (BP) and/or blood glucose (BG). PROMIS surveys assessed support and self-efficacy.

Results: Between May 2021–December 2022, 61 patients with breast or prostate cancer comorbid with hypertension (79 %) or hypertension and diabetes (21 %) enrolled. Once weekly self-recording of BP and BG was achieved in 92 % of individuals (with hypertension) and 77 % of individuals (with diabetes and hypertension). Participants (n = 47) who reported ≥4 readings in Months 1 and 6 demonstrated improved BP control (mean reduction = 4.07 mmHg); too few BG readings were collected to assess change. We observed a slight decrease in PROMIS scores for informational (mean 3.2, sd 8.0) and instrumental support (mean 3.6, sd 8.3).

Conclusions: A self-monitoring and CHW intervention is a feasible approach to monitor hypertension among Black cancer patients. Modifications are needed to improve BG monitoring and patient reported outcomes.

1. Introduction[1]

Comorbidity at the time of a cancer diagnosis is common in the United States and can significantly impact patient outcomes [1–5]. Comorbidity may influence an individual's likelihood of being screened for cancer, influence cancer treatment choice and uptake, and result in

* Corresponding author. Healthcare Delivery Research, MedStar Health Research Institute, Washington, DC, USA.
E-mail address: Hannah.Arem@MedStar.net (H. Arem).

[1] **ADT:** Androgen deprivation therapy **CARES:** Comorbidities And Reducing InEquitieS (study title) **CHW:** Community Health Worker **EHR:** Electronic Health Record **FDA:** Food and Drug Administration **mHealth:** Mobile Health **PCP:** Primary Care Provider **PROMIS:** Patient-Reported Outcomes Measurement Information System **REDCap:** Research Electronic Data Capture **SBP:** Systolic Blood Pressure.

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lower reported quality of life [6–12]. Furthermore, comorbidity during and post-cancer treatment is associated with increased mortality [11–13]. Heart disease, for example, is the leading cause of death for women after completing breast cancer treatment and prostate cancer survivors on long-term androgen deprivation therapy (ADT) [14–16]. This indicates a pressing need for improved comorbidity control during and following cancer treatment, and fields such as onco-hypertension are emerging in response to the need to manage the complex inter-relations between these conditions [17,18].

Racial minorities and financially disadvantaged populations are disproportionately affected by chronic and comorbid conditions, due at large to greater disadvantages in their social determinants of health, and perpetuated and exacerbated by structural racism [19–23]. Furthermore, minoritized populations experience worse cancer outcomes than non-Hispanic White populations for the similar reasons [24,25]. Thus, it is important not only to recognize and manage comorbidities prior to and during cancer treatment, but to address the underlying social risk factors that may sustain disease management challenges [17,26–28].

A recent systematic review highlighted the importance of additional research on care coordination to address disparities among cancer survivors with comorbidities [29]. Community health workers (CHWs) have increasingly been leveraged to help with comorbidity management and patient navigation in oncology care. CHWs may share lived experiences including race or ethnicity, geographic community, and cultural backgrounds of the participating population to build trust between the patient and clinical teams and have been shown to be largely effective at addressing nonmedical needs that may in part impact an individual's ability to receive equitable care [30–33].

Similarly, home-based monitoring is another evidence-based strategy for comorbidity management [34–36]. Combined with medication and lifestyle reminders, some mobile apps have Food and Drug Administration (FDA) clearance for managing select conditions [37]. Previous work has suggested that staff support may be needed to best augment engagement with telehealth [38,39]. It is possible that CHW support may be able to fill this role and increase comorbidity management through home-based monitoring and patient navigation.

The goal of the current project was to investigate the feasibility, participant-reported acceptability, and preliminary efficacy of delivering a multi-component intervention including home-based self-monitoring, use of a mobile health (mHealth) app that provided comorbidity education and tracking capabilities, and CHW support to improve self-management of diabetes and/or hypertension among Black individuals with breast or prostate cancer.

2. Materials and methods

2.1. Study setting

This research was approved by the Georgetown University Institutional Review Board (STUDY00003543). Informed consent was obtained prior to all study procedures. The intervention was delivered between May 2021 to June 2023 at a cancer center in the Mid-Atlantic region. This study was registered with ClinicalTrials.gov Identifier: NCT04836221.

2.2. Recruitment

Eligibility criteria included patients who were identified as Black/African American in the electronic health record (EHR), had a documented diagnosis of Type 2 diabetes and/or hypertension prior to enrollment, and were either [1] diagnosed with stage 0-IV breast cancer within the prior six months, or [2] had a diagnosis of prostate cancer and were receiving long-term ADT (>six months). We selected these populations for distinct reasons: First, literature suggests that comorbidities are associated with less intense treatment, greater treatment toxicity, poorer quality of life, and higher risk of mortality in breast cancer [40]. We thus focused on the acute treatment period to target this critical window where guideline-concordant cancer treatment delivery is associated with better survival [40]. Second, previous research shows that long term ADT increases risk of metabolic syndrome, diabetes, and coronary artery disease [41]. Thus we anticipated that hypertension or diabetes control management skills and supports would be particularly relevant to these populations.

Participants were recruited via oncologist referral or identified by a clinical research coordinator through tumor board meetings. Potential participants were contacted by the research coordinator to discuss the study and to confirm interest and eligibility prior to obtaining written informed consent. Participants were compensated $50 upon completion of study questionnaires.

2.3. Intervention

The six-month intervention included key elements of the effective chronic care model, including self-management support, decision support, healthcare organization, and community resources [42,43]. Each participant was provided access to a comorbidity-specific app: The FDA-cleared BlueStar® (Welldoc, Inc) to manage diabetes and hypertension, or the BPStar® app (Welldoc, Inc) to manage hypertension [44–46]. Content for these apps was developed by medical experts and included the following features: blood pressure or blood glucose tracking, tailored education about disease management, and the ability to log medication adherence, meals, and exercise. Our intervention focused on engaging primarily with the blood pressure or blood glucose tracking. Other features were described to the participants but were not further facilitated. The app also generated data reports that could be sent to clinicians, printed, or displayed on a mobile device.

All participants received Bluetooth-enabled blood pressure cuffs that interfaced with the app; CHWs assisted participants in connecting the cuff to the app. Individuals were given a American Heart Association handout on how to take blood pressure which was reviewed with the CHW [47]. Participants with diabetes were not provided with a new monitor but rather were encouraged to use their monitor and strips provided by insurance. Clinical thresholds for referral were determined by a cardio-oncologist and endocrinologist. Referrals to the primary care provider (PCP) were made if median systolic blood pressure (SBP) was over 130 or median blood glucose was above 180.

Two Black female CHWs completed 100-h CHW trainings including modules on health equity, social determinants of health, data collection and documentation, health education, prevention, and wellness, outreach and advocacy, chronic disease and self-management, mental health, trauma-informed care, and substance use. CHWs spent a day shadowing in clinic with a cardiologist to learn more about hypertension management, met with the team's endocrinologist (MM) to learn about diabetes, and met with the team's medical oncologist (CG) to learn about cancer treatment. Further ongoing education included webinars, meeting with the clinical team and nurses, and coordinating with the oncology social workers. CHWs conducted weekly phone calls with participants to provide guidance in how to interpret normal readings vs. high readings, to help participants understand data tracking options within the app, and to facilitate medical appointment scheduling or transportation. CHWs also completed a social needs screening and referred participants to community resources. Weekly call duration, information discussed with participants, and medical events (e.g., emergency visits, surgery) were recorded.

2.4. Comorbidity monitoring

Participants were asked to log blood pressure and/or blood glucose at least three times weekly, which either synced with the app or was recorded manually. When there were technology challenges the CHW requested participant-reported readings by phone or text. CHWs created a note in the EHR when median weekly values exceeded the pre-

specified target.

2.5. Patient reported outcomes

Patient-reported outcome data were collected via electronic survey using REDCap (Research Electronic Data Capture) at baseline and at the end of the study [48,49]. The baseline surveys were administered during onboarding with the CHW and the end of study surveys were self-administered by the participant via an emailed link. If the participant did not feel comfortable self-administering the emailed survey (e.g., in the case of technical challenges), the clinical research coordinator conducted the survey in interview format with the participant. Both the baseline and end of study surveys contained the Patient-Reported Outcomes Measurement Information System (PROMIS) [50] 2.0 forms on emotional support (8-items), informational support (4-items), instrumental support (4-items), and social isolation (4-items), and PROMIS 1.0 forms on self-efficacy for managing emotions (4-items), self-efficacy for managing medications and treatment (4-items), and self-efficacy for managing social interactions (4-items). PROMIS scores are calculated as T-scores, whereby 50 indicates average [51]; for social support (including emotional, informational, and instrumental domains) and self-efficacy for managing chronic conditions, scores above 60 indicate better outcomes than average; for social isolation, scores above 60 indicate worse outcomes. The end of the study survey also contained open-ended questions on what participants liked most and least about components of the intervention (app and CHW support), as well as areas for improvement.

Clinical team members who referred patients to the study or received updates from their patients who participated (including 4 medical oncologists, one primary care provider, and 1 nurse navigator, and 1 licensed clinical social worker) were also asked by the study team to completed REDCap surveys using a validated survey to measure implementation outcomes of acceptability, appropriateness, and feasibility using a 4-item, 5-point Likert scale for each domain [52]. No incentive was offered to providers for completing the survey.

Prior to the study we set feasibility criteria as follows: accrual of >50 patients, >80 % reporting blood pressure or blood glucose 3+ times weekly, >80 % completion of CHW phone calls.

2.6. Statistical analysis

We used descriptive frequencies to compare demographics and medical history by cancer site, as well as achievement of pre-specified study feasibility criteria. In exploratory analyses, we compared mean blood pressure from baseline (month 1) to month six among those who reported at least four blood pressure or blood glucose readings at those time points. Paired t-tests were used to assess significance of mean change. We also examined differences in self-monitoring by participant comorbidity burden (hypertension only vs hypertension and diabetes) as they utilized different monitors and there was an additional burden on those being asked to track two comorbidities. We conducted patient reported outcome analyses for the overall population, and then separately by cancer site given differences in treatment stages (i.e., breast cancer participants were initiating treatment whereas prostate cancer participants had a wider range of time since diagnosis). Analyses were conducted using SAS® version 9.4 (SAS Institute Inc) and STATA® version 17 (StataCorp LLC). Significance was measured at the $\alpha = 0.05$ level. Open-ended end of study survey questions were thematically reviewed to understand key barriers and facilitators to mHealth use and engagement with CHWs. Qualitative results are quantified using the following descriptors: "few participants" refers to <20 % responses, "some" refers to 20-<45 %, "half" refers to 45-<55 %, "most" refers to 55%-<80 % and "nearly all" refers to 80+%.

3. Results

We recruited n = 61 individuals to the study (Table 1). Most participants were women with breast cancer (n = 42, 69 %), and the average age was 66 years (standard deviation (sd) 9.8). Two participants (3 %) self-reported their racial group as "other," specifying they felt limited in the provided demographic options. Breast cancer participants were largely early stage (31 % stage 0, 38 % stage 1, 24 % stage 2, 2 % stage 3, 5 % stage 4). All but one prostate cancer participant were in stage 4. All participants had hypertension; 13 (21 %) participants also had diabetes in addition to hypertension. All participants were able to access a smart phone. Fig. 1 depicts the number of individuals assessed for eligibility, recruited, enrolled, and lost to follow up. Four individuals dropped out of the trial prior to 16 weeks due to lack of interest (n = 2), competing priorities(n = 1), or health complications(n = 1). Those who dropped out before 15 weeks were not asked to complete the end of study forms. An additional six individuals completed more than half of the six-month trial (range 18–24 weeks) but had incomplete PROMIS data; the study team was unable to reach five individuals to complete end of study PROMIS forms and one had incomplete PROMIS baseline data. All individuals including dropouts were included in baseline analyses and in adherence reporting to evaluate protocol feasibility.

3.1. Completion of weekly calls and home-based self-monitoring

Of the total n = 61 participants at baseline, weekly phone or text contact with the CHW was reported across an average of 89 % weeks (Table 2), 85 % of which were by phone and 4 % by text message. Weekly calls lasted approximately 15 min. On average, n = 28/61 (46 %) of participants reported blood pressure 3+ times/week, 28/61 (46 %) reported 1–3 times/week, and 5/61 (8 %) reported blood pressure <1 time/week. Of the n = 13 participants with diabetes, only one (8 %) reported blood glucose 3+ times/week, nine (69 %) reported blood glucose 1–3 times/week, and three (23 %) reported blood glucose <1 time/week; the number of data points per week were highly variable, with some individuals reporting 5+ times in one week and not reporting in other weeks. While most participants utilized the Bluetooth

Table 1
Baseline characteristics of study population (n = 61).

Characteristics	Cancer Site	
	Breast N = 42	Prostate N = 19
	N (%)	N (%)
Age in years (mean, standard deviation)	66 (8.9)	67 (9.2)
Self-reported race of other	1 (2.3)	1 (5.3)
Cancer stage		
0	13 (30.9)	0
1	16 (38.0)	1 (5.3)
2	10 (23.8)	0
3	1 (2.3)	0
4	2 (4.6)	18 (94.7)
Time since most recent diagnosis		
5+ years	0	6 (31.6)
2-<5 years	0	2 (10.5)
1-<2 years	0	2 (10.5)
Six months – <1 year	2 (4.7)	6 (31.6)
Within the last six months	36 (85.7)	2 (10.5)
Within the last month	4 (9.5)	1 (5.3)
Comorbidity		
Hypertension only	31 (73.8)	17 (89.5)
Diabetes and hypertension	11 (26.1)	2 (10.5)
Primary care team		
Within healthcare system	30 (71.4)	17 (89.5)
External	11 (26.2)	2 (10.5)
Missing	1 (2.4)	0
Phone type		
Android	22 (52.4)	13 (68.4)
iPhone	20 (47.6)	6 (31.6)

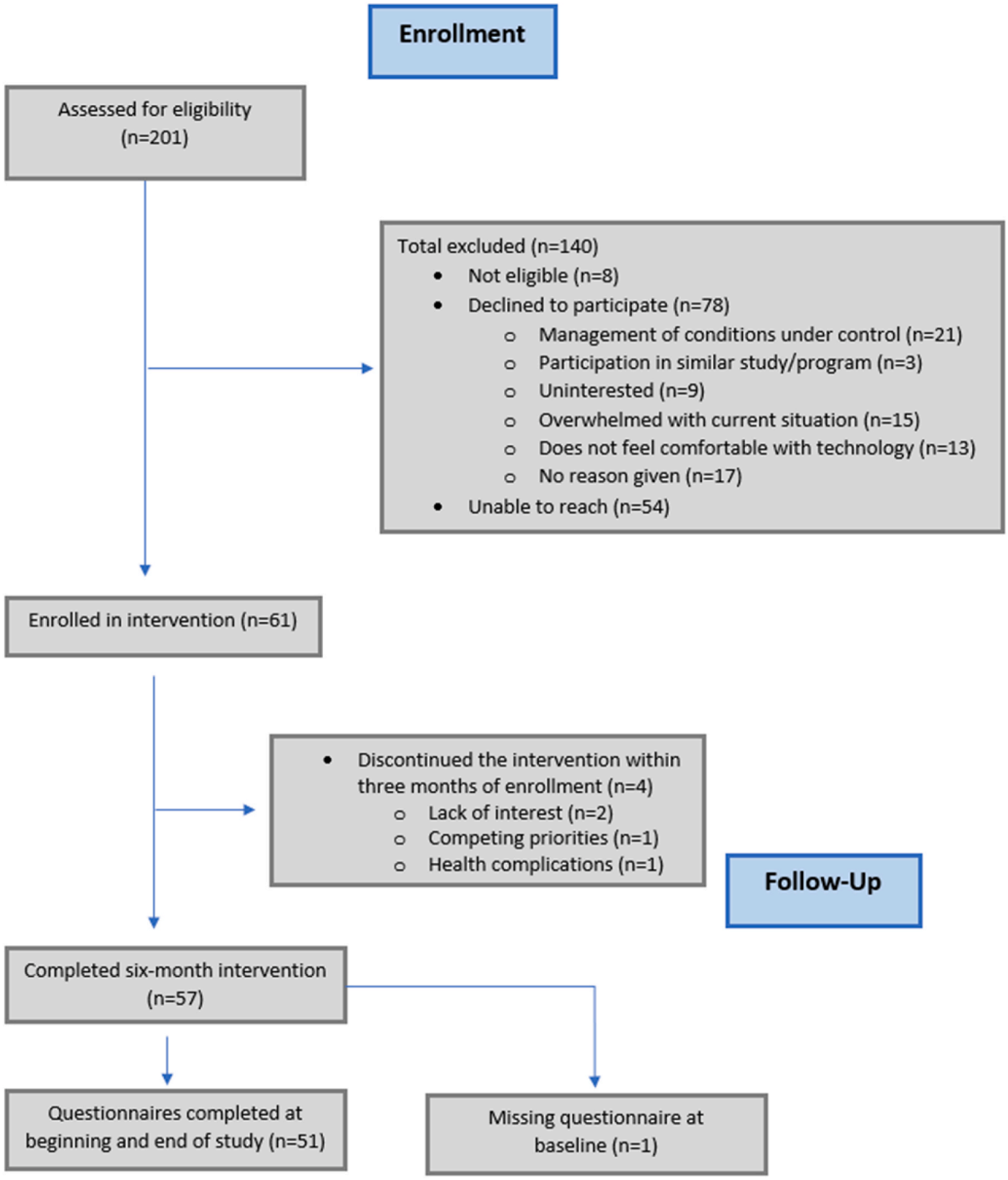

Fig. 1. Total number of individuals assessed for eligibility, reasons for declining enrollment, trial initiation, and trial completion.

connection, 18/61 (30 %) had trouble utilizing the technology and instead reported regularly (sent more than 14 days of data) to the CHW directly. Those n = 18 individuals who opted to send data directly to the CHW rather than use the app had a mean age of 70 years (sd 8.0). A greater percentage of those with comorbid diabetes and hypertension reported directly to the CHW (54 %, n = 7/13), while of those with hypertension 23 % (n = 11/48) reported directly. There was little difference in reporting directly to the CHW by sex/cancer site. Of participants with breast cancer, 29 % (n = 12/42) opted to send data to the CHW instead of the app, along with 32 % (n = 6/19) of those with prostate cancer. Data showed low engagement with other app features. Only 5–11 participants (range depended on the specific feature) utilized features to track carbs, exercise, weight, medication, height, and

Table 2
Achievement of feasibility benchmarks for study.

Pre-specified feasibility criteria	Results
Accrual of 50 patients	61 enrolled
>80 % recording blood pressure or blood glucose 3+ times per week	46 % reported blood pressure an average of 3+ times/week, 46 % reported 1-<3 times/week, and 8 % reported <1 time/week. 8 % reported blood glucose an average of 3+/week, 69 % reported 1-<3 times/week, and 23 % reported <1 time/week.
>80 % completion of weekly phone calls with community health workers	89 % of weekly phone calls completed

smoking at all, and only three engaged with these features regularly.

3.2. High readings and referrals

SBP exceeded the protocol threshold in 44 % of weekly reports. CHWs documented a referral to a PCP in 65 % of cases where readings exceeded the threshold. Among participants with diabetes, median blood glucose exceeded the threshold in 9 % of reported weeks. In 22 % of the weeks above threshold the CHW documented recommendation for scheduling a PCP appointment.

3.3. Exploratory trend analyses

Exploratory analyses are reported for the participants who had at least four blood pressure readings in month 1 and month 6 of the study (n = 47). Of the 47 participants analyzed, slightly more than half (n = 24, 51 %) started the study in month 1 with in target blood pressure. While n = 21 individuals stayed in target, three participants who started in target in month 1 moved out of target by month 6. Nine participants who were above the target range in month 1 achieved in target blood pressure by month 6. Overall, in month 6, 30 (70 %) participants reported in target blood pressure. The mean change in SBP for all 47 participants was a 4.07 mmHg improvement (95 % CI 1.32, 6.83) between month 1 and month 6 of the intervention (Fig. 2).

Among the n = 38 participants diagnosed with hypertension only and with at least four blood pressure readings reported in the first and last months, 18 (47 %) had in target blood pressure during month 1. Eight participants who started out of target achieved target blood pressure by month 6, while one participant who started in target in month 1 was out of target in month 6. Thus in month 6, 25/38 individuals (66 %) were in target. The mean change in SBP among these participants was 5.63 mmHg (95 % CI 3.01, 8.26) improvement in SBP. Of the nine people diagnosed with both diabetes and hypertension and with four or more blood pressure readings in month 1 and month 6, six (67 %) had in target blood pressure readings in month 1, decreasing to four (44 %) in month 6. Two participants who were in target in month 1 moved out of target by month 6, and one participant who was out of target in month 1 achieved target blood pressure by month 6. The mean change in SBP of this group with hypertension and diabetes was a 2.49 mmHg (95 % CI -11.93, 6.95) worsening in SBP between month 1 and 6. Only 4/13 (31 %) patients with diabetes reported blood glucose at least four times in months 1 and 6. Two participants had in target blood glucose readings their first month, increasing to four at month 6.

3.4. Patient reported outcomes

At baseline, participants reported overall emotional, informational, and instrumental support T-scores ranging from 60.3 to 62.1, suggesting that participants started with above average support (Table 3). Participants further reported lower social isolation than average (T-score = 40.4).

Among the 51/61 (84 %) participants who completed pre- and post-surveys, we found statistically significant changes for informational support (62.0–58.8; mean difference 3.2, 95 % CI 0.99, 5.47) and instrumental support (60.0–56.3; mean difference 3.6, 95 % CI 1.32, 5.97), where participants went from "high" to "average." Individuals maintained average or high scores for emotional support, social isolation, and for the three self-efficacy scales: managing emotions, medications and treatment, and social interactions, where there were no statistically significant differences over time.

When we separated outcomes by cancer site (Table 4), we found no changes over time among those with prostate cancer but worsening of scores among breast cancer participants for emotional support (61.2–57.7; mean difference 3.5, 95 % CI 0.99, 6.05), informational support (62.4–58.5; mean difference 4.0, 95 % CI 1.45, 6.46), or instrumental support (60.5–56.0; mean difference 4.5, 95 % CI 1.56, 7.44), as well as social isolation (40.5–43.7; mean difference −3.2, 95 % CI-6.41, 0.03). There were no changes in the three scales for self-efficacy for managing chronic conditions regardless of cancer site.

3.5. Participant feedback

In the end of study surveys, nearly all participants reported feeling positive about their connection with the CHW. Some participants suggested the CHW provided the motivation for self-monitoring. Almost all participants appreciated their connection with their CHW, and half of the participants reported that a weekly call was appropriate. When asked for challenges with the mHealth intervention, most participants

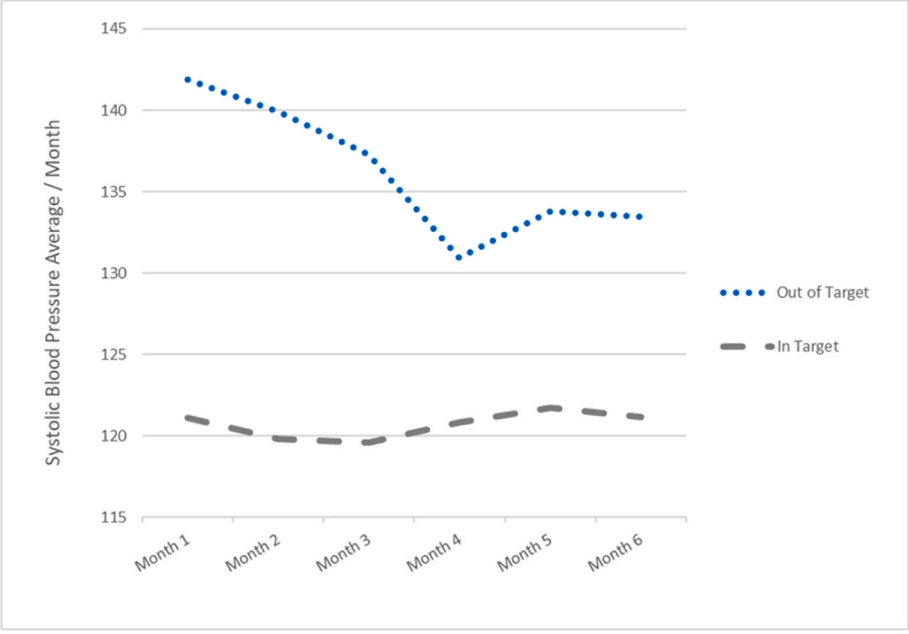

Fig. 2. In-target at baseline was defined as average systolic blood pressure <130 during the first month of the study and out-of-target was defined as average systolic blood pressure≥130.

Table 3
Pre-post mean (standard deviations) of patient-reported outcomes.

	Overall		Paired Comparisons			
	Baseline	Baseline measures among completers	Post-Intervention	Mean (sd) Difference	95 % CI for mean difference	p-value
	N = 60[c]	N = 51	N = 51			
Emotional Support[a]	60.3 (5.1)	60.0 (5.2)	58.1 (6.2)	2.0 (7.6)	[-0.17, 4.12]	0.07
Informational Support[a]	62.1 (5.4)	62.0 (5.6)	58.8 (6.8)	3.2 (8.0)	[0.99, 5.47]	0.01
Instrumental Support[a]	60.4 (5.8)	60.0 (6.2)	56.3 (8.0)	3.6 (8.3)	[1.32, 5.97]	0.003
Social Isolation[b]	40.4 (5.9)	40.5 (6.0)	42.8 (8.0)	−2.2 (8.7)	[-4.67, 0.21]	0.07
Self-Efficacy Managing Emotions[a]	66.3 (5.3)	66.2 (5.4)	67.1 (5.9)	−0.9 (6.3)	[-2.65, 0.90]	0.33
Self-Efficacy Managing Meds/ Treatment[a]	52.8 (6.7)	53.0 (6.7)	54.3 (5.6)	−1.2 (8.7)	[-3.66, 1.21]	0.32
Self-Efficacy Managing Social Interactions[a]	52.0 (6.6)	51.7 (6.6)	51.8 (6.9)	−0.2 (8.7)	[-2.60, 2.29]	0.90

[a] The overall population average T-score is 50, with higher numbers indicating better than average.
[b] The overall population average T-score is 50. For social isolation, higher scores indicate worse than average.
[c] One breast cancer participant had incomplete baseline PROMIS survey data and thus was not included in the PROMIS results.

Table 4
Pre-post comparisons of patient-reported outcomes by cancer site.

	Pre-intervention	Post-Intervention	Mean Difference	95 % CI for mean difference	p-value
Breast cancer (n = 37)					
Emotional Support[a]	61.2 (3.6)	57.7 (6.4)	3.5 (7.6)	[0.99, 6.05]	0.008
Informational Support[a]	62.4 (5.1)	58.5 (7.1)	4.0 (7.5)	[1.45, 6.46]	0.003
Instrumental Support[a]	60.5 (5.2)	56.0 (8.0)	4.5 (8.8)	[1.56, 7.44]	0.004
Social Isolation[b]	40.5 (6.2)	43.7 (8.4)	−3.2 (9.7)	[-6.41, 0.03]	0.052
Prostate cancer (n = 14)					
Emotional Support[a]	57.0 (7.4)	59.1 (5.6)	−2.1 (6.3)	[-5.73, 1.51]	0.23
Informational Support[a]	61.0 (6.9)	59.7 (6.3)	1.3 (9.1)	[-3.92, 6.55]	0.60
Instrumental Support[a]	58.7 (8.2)	57.3 (8.1)	1.4 (6.3)	[-2.26, 5.05]	0.43
Social Isolation[b]	40.5 (5.7)	40.2 (6.3)	0.3 (4.7)	[-2.42, 3.03]	0.81

[a] The overall population average T-score is 50, with higher numbers indicating better than average.
[b] The overall population average T-score is 50. For social isolation, higher scores indicate worse than average.

mentioned trouble operating the technology (blood pressure/glucose monitors and the mobile app) and trouble syncing the monitor to their app. Conversely, when asked what participants liked the most about the mHealth intervention, most participants appreciated tailored information on their data, counseling on wellness topics, and/or the ability to view and track self-monitoring trends, though some participants felt frustrated or overwhelmed with the responsibilities of cancer treatment and the research.

3.6. Clinical team member feedback

Four of seven (57 %) clinical team members responded to end of study surveys on acceptability, appropriateness, and feasibility. Of the three remaining clinical team members, all (one medical oncologist, one primary care physician, and one licensed clinical social worker) left the institution during the study. Thus respondents included three MDs and one RN. On average, participants reported 4.5/5 on acceptability and appropriateness, and 4.2/5 on feasibility of the intervention.

4. Discussion

This work describes a CHW and app-based intervention to support comorbidity education and tracking while improving self-management of diabetes and hypertension. This study has the following novel findings: 1) The 6-month, home-based mHealth intervention for self-management of hypertension and/or diabetes was feasible among Black women with breast cancer and Black men with prostate cancer; 2) At least once weekly self-recording of blood pressure and blood glucose values was achieved in 92 % of individuals (with hypertension) and 77 % individuals (with diabetes and hypertension); 3) Participants and providers largely reported positive feedback on the program, indicating acceptability of the intervention components. These findings suggest high potential for multi-pronged solutions within healthcare delivery and patient self-monitoring in this high-risk population.

There are limited studies focused on management of comorbidities such as hypertension during and after cancer treatment [17], and even fewer including significant percentages of racially minoritized participants. In response, there is a growing body of literature calling for increased patient-centered research and care in this area [53]. Given the lack of guidelines specific to this population, the present work did not follow an established protocol for frequency of monitoring comorbidities during cancer treatment, but rather deferred to general hypertension and diabetes management subject matter experts as well as digital health literature for setting the protocols around frequency of comorbidity management. Our finding that most participants monitored hypertension more than once a week but less than three times weekly should be interpreted within clinical recommendations. The appropriate recommendations for frequency of monitoring for specific cancer treatment regimens should also be further explored [54].

Team-based care (i.e., shared care, where the patient receives care from both a cancer specialist and a primary care provider or specialist) for cancer patients with comorbidities is a growing area of interest with limited evidence of health impact to date [29]. Several current studies [55–57] are now focused on exploring care models linking oncology to primary care given evidence that shared care leads to better comorbidity management among cancer patients. These ongoing studies focus on provider-level interventions and overall health management, as opposed to focusing on a specific comorbidity or pre-specified self-management plan. The ongoing studies further rely on nursing staff rather than CHW assistance. Our study thus differs from these ongoing studies by delivering a specific protocol for comorbidity self-management supported by a lay CHW. Still, like these ongoing studies we supported connection to

primary care visits to manage comorbidities by assisting patients in scheduling and attending regular appointments, as recommended in shared care models. Each of these models will provide evidence for supporting comorbidity management during cancer treatment [58].

Along with addressing health access barriers for the patients, the CHWs played a prominent role in contributing to improved clinical outcomes. Evidenced by the responses to the end of study surveys, the CHWs provided education and motivation around comorbidity tracking. A systematic review of health care delivery interventions for hypertension management among underserved populations found CHW involvement in patient care was associated with clinically meaningful improvements ranging from a 4.7–13.2 mmHg reduction in SBP across multiple studies [33]. In previous studies CHWs have shown successes in addressing nonmedical needs that impede successful comorbidity control such as transportation to medical appointments or affording medication copays [59]. CHWs in our study provided similar supports to participants but we lacked sufficient numbers to examine the impact of a specific type of social need support on outcomes. Still, participant success in self-monitoring and improvement in SBP demonstrate the potential role of CHWs in supporting patients in their care. This supports a body of research suggesting the potential for improvement through the utilization of CHWs to manage cancer care, address social determinants, and control chronic disease [60–64].

Both in combination and separately, mHealth apps have also been widely used to support chronic disease monitoring and providing education [65–67]. However, some studies in the general population have reported challenges with participant retention and attrition [68,69], particularly in older populations [70–72]. A previous study of hypertension control among African American individuals using an mHealth app and CHWs reported only a 38 % completion rate for educational modules and 44 % completion rate for the 10-week post-intervention assessment [73]. Our work had 84 % completion of the six-month assessment including PROMIS surveys; however, 30 % of participants throughout relied on manual tracking and sharing comorbidity data with the CHW, demonstrating the need for this work to employ alternative engagement strategies external to the mHealth platform. It is also possible that regular engagement with the CHWs in our work, in combination with an initial study referral from the patient's oncology provider, may have increased trust or connection, resulting in lasting engagement among participants [74–76].

We were unable to identify previous studies reporting on PROMIS domains of social support and self-efficacy among Black breast and prostate cancer patients. However, the validation study of these PROMIS measures included a sample that was 21 % Black/African American and among adults with chronic conditions [77]. One study on self-efficacy in Latina breast cancer survivors after treatment reported higher quality of life among those with higher self-efficacy after a smartphone based psychosocial intervention [78]. Another systematic review reported breast cancer self-efficacy was associated with goal-directed behaviors, although many studies were cross sectional [79]. A systematic review of self-management programs among prostate cancer patients suggested positive effects on quality of life and self-efficacy, but study designs and interventions included in the review were heterogeneous and thus hard to compare to our findings [80]. Our findings demonstrated a lack of or slightly worsening in informational and instrumental support and no statistically significant change in self-efficacy for managing chronic conditions. These results were somewhat expected because we recruited breast cancer patients at initiation of cancer treatment, which is accompanied by many physical, psychological, social, and emotional challenges. Thus, a slight worsening of these domains is not surprising and future research should assess support and self-efficacy across a longer time period. Of note, no change was reported among participating men with prostate cancer who were largely further from diagnosis.

Other work has explored the use of these PROMIS measures among a Chinese breast cancer population in Shanghai, finding that T-scores for instrumental support were average among this population, and T-scores for informational support were below average [81]. This population of Chinese women with breast cancer receiving chemotherapy showed differing trajectories based on education, income, employment, with those of a higher SES having better informational and instrumental support [82]. In another study among men with prostate cancer and receiving hormonal therapy in Shanghai an informational support program led to higher self-efficacy, but no difference with the control group for quality of life [83]. However, these populations are significantly different than the population included in this study in terms of race, healthcare system, timing of treatment, and the focus on comorbidity management. Still, it may be that informational support largely requires linguistic and cultural customization more so than other domains, as information needs may vary widely [84]. It is also possible that the timing of our data collection or the types of supports provided were inadequate to detect change. Our work also began in 2021 during the COVID-19 pandemic when there were still restrictions on visitors in place, which may explain some of the challenges in finding and utilizing support.

There are several limitations to this design. First, many individuals experienced challenges with syncing the monitor to the app. CHWs addressed these barriers by engaging a caregiver, conducting a home visit, or meeting participants at an in-clinic appointment. Among those who did not use the app, communicating blood pressure or glucose by phone may have led to some readings that were not reported or underreported. Furthermore, when high readings were not reported in real-time, PCP referrals were delayed or no longer relevant. These findings suggest that technology-based interventions for this population require added support. Also, while we initially planned to send app-generated reports to PCPs to improve information sharing prior to the patient's visit, EHR limitations with integrating reports and a large number of individuals with PCPs outside of the healthcare system lowered success of this approach. In response, the CHWs uploaded monitoring reports within our medical record but also taught patients how to print or display the monitoring reports to show PCPs during visits. Furthermore, primary care provider responses to blood pressure or glucose out of target were not standardized, which may have affected any expected change with medication titration. We also did not design this study to detect statistically and clinically significant changes in monitoring over time, but were rather focusing on acceptability and feasibility. Finally, while there is recent federal support for payment for navigation services which could encompass aspects of the CHWs role [85] at present, billing is still prohibitively complex and only supported by some payer. Thus many care coordination and social services supports are non-billable and thus supported by grants. This lack of funding limits the potential sustainability of such programs. New models of care are needed to show value of CHWs and associated billing systems in vulnerable patient populations, and for this evidence-base to inform future health policies and payment models that include CHWs.

5. Conclusion

This multi-component intervention for chronic disease management among Black breast and prostate cancer patients demonstrated feasibility through participant reporting, acceptability through qualitative findings, and preliminary efficacy through clinically meaningful changes in SBP. This work suggests that there may be benefits to interventions involving self-monitoring and CHW support in supporting management of comorbidities among high-risk and minoritized populations. Further research is needed to assess how CHWs may further support cancer patients with hypertension or diabetes to improve patient outcomes and support a future randomized control trial to measure impact on reducing racial disparities in outcomes.

CRediT authorship contribution statement

Laura C. Schubel: Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Formal analysis. **Ana Barac:** Writing – review & editing, Supervision, Conceptualization. **Michelle Magee:** Writing – review & editing, Supervision, Methodology. **Mihriye Mete:** Writing – review & editing, Formal analysis. **Malinda Peeples:** Writing – review & editing, Software. **Mansur Shomali:** Writing – review & editing, Software. **Kristen E. Miller:** Writing – review & editing. **Lauren R. Bangerter:** Writing – review & editing. **Allan Fong:** Writing – review & editing. **Christopher Gallagher:** Writing – review & editing, Project administration, Investigation. **Jeanne Mandelblatt:** Writing – review & editing. **Hannah Arem:** Writing – review & editing, Writing – original draft, Supervision, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization.

Trial registration

This study was registered with ClinicalTrials.gov Identifier: NCT04836221 on March 24, 2021.

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: The following conflicts of interest are noted in this work: Co-authors Malinda Peeples and Mansur Shomali are consultants for Welldoc, Inc., the home monitoring mHealth application used in this work. Co-author Christopher Gallagher is a member of the advisory boards for AstraZeneca/Daiichi Sankyo, Lilly Oncology, Pfizer, and Biotheranostics. The remaining authors declare that they have no competing interests related to the research, authorship, or publication of this paper.

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Data availability

Data will be made available on request.

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