

A Pilot Study of a Virtual Navigation Program to Improve Treatment Adherence Among Low-Income Breast Cancer Patients

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Background: Socioeconomic disparities negatively impact completion of adjuvant breast cancer treatment. Navigation programs may improve treatment completion but may not be accessible to all patients, especially in low-resource communities.

Objectives: A randomized trial was conducted to determine if access to a web-based navigation program improved adjuvant breast cancer treatment completion among low-income patients.

Methods: Patients (N = 101) were recruited, randomized to either web-based information access only (comparison arm) or to the web-based navigation program with nurse/social worker support (intervention arm) and were given a netbook computer, training, and Internet access. Adherence to recommended chemotherapy, radiation therapy, and/or initiation of hormone therapy was assessed by medical record review (available for 48 patients on each study arm). Baseline characteristics and results were compared by study arm using *t* test, chi-square test, Fisher's exact test, and Poisson regression analyses.

Results: The majority of participants were unemployed or on disability (68%) and were nonwhite (67%). Those randomized to the intervention had lower education levels and were slightly older than those on the comparison arm (*P* = .04). Two patients on the intervention arm refused part or all recommended treatments and 6 patients on the comparison arm refused some or all recommended treatments (*P*_{adj} = .08 for number of treatment refusals).

Discussion: Treatment completion was improved with navigator interaction compared with information access alone, but the difference was not statistically significant. Absolute benefit compared with usual care should be evaluated in a randomized trial.

Conclusion: Centralized virtual navigation is feasible for low-income populations and has the potential to improve treatment completion.

Completing complex breast cancer treatment is particularly challenging for the poor, who often have limited psychological support, face financial hardships, deal with multiple comorbidities, and are treated in low-resource settings.¹⁻¹² Patient navigation programs, most often used in the screening setting to improve time to diagnostic resolution, offer a potential solution to improve cancer outcomes by

overcoming disparities in the receipt and completion of treatment. However, few studies have rigorously examined the impact of navigation models beyond treatment initiation and specifically among low socioeconomic groups.¹³⁻¹⁶ The Patient Navigation Research Program, a network of 9 centers testing various lay navigator intervention models, followed cancer patients from diagnosis to treatment initiation, but

not beyond.¹⁷ Pooled data from 2 randomized clinical trials found no effect of navigation on time to completion of treatment among breast and colon cancer patients.¹⁸⁻²⁰ A trial among Hispanic patients diagnosed with breast and cervical cancer and treated in a public safety hospital noted a very high adherence overall with no difference associated with lay navigation.²¹

Interactive health communication is a burgeoning field, combining information with personal support to improve health outcomes. A review of Interactive Health Communication Applications (IHCAs) and their impact on patients with chronic disease demonstrated a positive effect on clinical and behavioral outcomes.²² However, the authors called for higher-quality studies to determine how best to deliver IHCAs and to establish their efficacy in improving health outcomes.²²

The aim of this pilot study was to assess the feasibility of an interdisciplinary centralized virtual navigation program to support treatment completion among newly diagnosed low-income patients with breast cancer. The virtual navigation program was comprised of 2 components: 1) an interactive web-based application, and 2) navigators. The usability of the program was assessed and treatment adherence was determined by review of the medical records.

The web-based application was developed with iterative input from low-income breast cancer patients who had little to no prior computer experience.²³ Simple, descriptive icons identified content areas with links to evidence-based information related to breast cancer treatment.

The navigators interacted with patients via telephone, videoconferencing, or internal messaging through the web-based application. To address the complex medical, psychological, and social needs of low-income patients, navigators were a nurse and social worker. Interactions were documented within the web-based application facilitating communication, coordination, and transparency between the navigators.

Methods

Study Design

A parallel-group randomized clinical trial was conducted comparing the web-based information-only component with the virtual navigation program (a combination of the web-based application and navigator support) for differences in treatment completion.

Patient Population

Eligible patients were English-speaking, newly diagnosed, stage 0 to III breast cancer patients whose treatment plans included adjuvant treatment beyond surgery

and who met low-income criteria as defined by the US Department of Housing and Urban Development guidelines.²⁴ Potential study participants were identified through 2 Maryland State Department of Health and Mental Hygiene breast cancer treatment insurance-type programs and by networking with oncology care providers across the state. Patients enrolled through the Department of Health and Mental Hygiene or through

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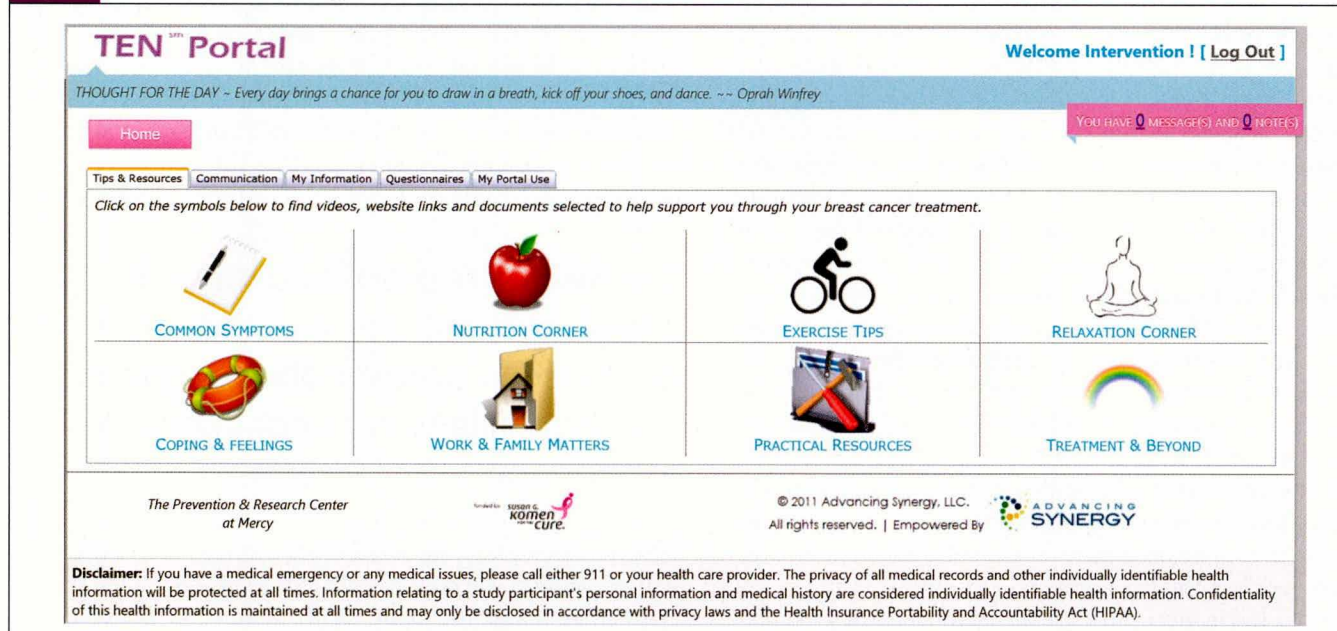
other practice sites were asked by the intake personnel to sign a consent granting permission to be contacted to learn more about the study. With permission from the patient, a study coordinator contacted interested individuals to determine eligibility, and, if eligible, schedule the consent and enrollment visit.

Enrollment visits took place in the patient's location of choice, with the majority conducted in their home. After obtaining informed consent, patients were randomized using a random permuted block design, with study investigators blinded to the size of the block. Random permuted blocks of a sequence of 8 participants were created. The treatment group assignments were placed in sealed opaque envelopes and opened after the informed consent was signed.

The Intervention

Detailed information on the development and usability of the interdisciplinary web-based navigation program are published elsewhere.²³ In brief, the web-based application was developed with iterative input from low-income breast cancer patients who had little to no prior computer experience. Content areas, identified by simple, descriptive icons, included common treatment-associated symptoms and their management, nutrition, exercise, relaxation techniques, coping and feelings, work and family matters, practical resources, and treatment and beyond (**Figure**). Each content area contained links to ad-free, institutional review board-approved vetted Internet sites providing evidence-based information related to breast cancer treatment. Baseline and follow-up questionnaires, as described below, were also embedded in the program. Additional elements of the web-based program in-

Figure Resources: Home Page



cluded a section to record contact information for their healthcare provider, breast cancer staging and pathology information, planned treatment, and a calendar. Patients randomized to the web-based information component only (comparison group) had access to the vetted websites but could not receive or access individually tailored information. Patients randomized to the virtual navigation program had access to

Medical records were abstracted to determine treatment completion, hormone initiation, unscheduled outpatient visits, ED visits, and hospitalizations.

vetted websites and videos and documents produced by the study team, and were contacted by their assigned navigator within 2 weeks of enrollment and approximately every 2 weeks thereafter during the 1-year intervention period. The primary method of contact was by phone; additional methods of contact included videoconferencing and messaging within the application and, on occasion, in-person contact. The navigators documented contact times, nature of the contact, and supporting details in the administrator-only section of the web-based application.

Patients were provided with a netbook computer, 1 year of wireless Internet access (up to 5 gigabytes per month), computer training, and hard copy instructions on using the netbook computer, connecting to the Internet, and navigating the web-based application. If the monthly data limit was exceeded, patients were informed and service was temporarily suspended until the following billing cycle.

Sample Size

Budgetary considerations, primarily due to the expense of wireless Internet access, constrained the sample size to approximately 100 patients. With 50 patients randomized to the virtual navigation program and 51 patients randomized to the web-based information component, we had 80% power to detect a 20% difference in completion rates at a 2-sided .05 significance level assuming a completion rate in the comparison group of 75% compared with 95% in the virtual navigation group.

Data Collection

Questionnaires, administered at baseline and at 12 months, included information on demographics, planned treatment, Functional Assessment of Cancer Therapy-Breast (FACT-B),²⁵ health history, Impact of Events Scale-Revised (IES-R),²⁶ and visual analog scales (VASs) for pain, mood, distress, and fatigue. Program usability was assessed at 3 months.²³ An open-ended comment section was available on each questionnaire.

Comments were summarized and apportioned as relevant to the navigator interactions or elements of the web-based program, such as “my information” section or “my schedule.”

Medical records were abstracted to determine treatment completion, hormone initiation, unscheduled outpatient visits, emergency department (ED) visits, and hospitalizations. Noncompletion of treatment was defined as refusal by the patient to complete part or all recommended treatment (surgery, chemotherapy, radiation therapy, or to initiate hormone therapy) as documented in the medical record. Hormone therapy initiation was examined since the intervention period was 12 months and therapy extends to 5 years and beyond.

Statistical Analyses

Baseline characteristics were compared between the 2 study arms using independent sample *t* tests for continuous measures and chi-square tests for categorical outcomes. Age and education were statistically significantly different between the study groups at baseline and, thus, were examined as potential confounders in multivariable analyses. Differences in the number of patients on each arm who refused all or part of an adjuvant form of therapy were assessed with Fisher's exact test and with logistic regression adjusting for potential confounders. Poisson regression with robust standard errors was used to compare the count of treatment refusals between the 2 study arms. Number of missed appointments, unscheduled visits, ED visits, and hospitalizations were compared between the 2 groups using chi-square tests; ordered logit was used to adjust for potential confounders. Generalized linear models were carried out for continuous measures, such as the FACT-B, IES-R, and VASs, adjusted for age, to assess changes from baseline. Repeated measures analysis of covariance was conducted to test differences in change scores between the 2 study groups (between baseline and 12-month follow-up) adjusting for age.

All *P* values are 2-sided. Analyses were conducted using Stata statistical software.

The trial was approved by the institutional review boards at Mercy Medical Center, Baltimore, MD, and the Maryland Department of Health and Mental Hygiene and was registered at ClinicalTrials.gov (NCT01596179).

Results

Of the 150 patients screened for eligibility, 102 were enrolled. Among those who did not enroll, 24 did not meet eligibility criteria, 9 stated they were not interested in joining a study, and the remainder could not be reached after agreeing to be contacted or canceled the

enrollment visit. One patient was enrolled as a “run-in” for a final test of the web-based application and is not included in the analysis. Of the 101 patients randomized, 51 were assigned to the intervention arm and 50 to the comparison arm. One patient assigned to the intervention arm was found to be ineligible shortly after randomization due to the presence of metastatic disease at diagnosis and was withdrawn from the study. Two patients, 1 on each study arm, withdrew immediately after randomization and before completing the baseline questionnaire, leaving 98 patients enrolled; 49 on each arm. Treatment completion beyond surgery could not be verified by medical records for 2 patients, 1 on each arm; thus, 48 patients on each arm remained in analyses related to hormone initiation and chemotherapy and radiation therapy completion rates. Eighty-six percent of pa-

At the 12-month follow-up, no statistically significant differences were observed in self-rated pain, distress, fatigue, mood, and quality-of-life scores.

tients on the navigator arm and 76% on the comparison arm completed the 12-month questionnaire; baseline characteristics did not differ between responders and nonresponders of the final questionnaire.

The baseline characteristics of participants are shown in **Table 1**. Patients randomized to the intervention arm were slightly older ($P = .04$) and less educated ($P = .04$) than those on the comparison arm. The stage distribution and assessments of quality of life and symptoms were similar between the 2 arms at baseline. The usability assessment of the web-based application obtained 3 months after enrollment was similar between the 2 groups, with approximately 75% reporting that they used the program frequently and that it was easy to use (data not shown).²³ Forty-three percent of patients on each study arm were from rural settings. Ninety-six percent of patients received their treatment in a community hospital setting; 2 in private practices. None of the patients had navigator services provided beyond initial diagnosis and surgery.

Treatment completion/refusals are shown in **Table 2**. All patients on the intervention arm completed recommended chemotherapy and initiated recommended hormone therapy. Two patients on the intervention arm did not complete radiation therapy; 1 patient refused all radiation treatment, and 1 patient partially completed recommended radiation treatment. Among those on the

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Table 1 Baseline Characteristics by Study Arm (N = 98)

Characteristic	Navigator Group (n = 49)	Comparison (n = 49)	P Value
Age at Baseline, years, mean (SD)	52.9 (9.9)	48.7 (10.0)	.04
Race (%)			
White	34.7	30.6	.79
Black	63.3	65.3	
Other	2.0	4.1	
Education (%)			
High school or less	57.1	36.7	.04
Greater than high school	42.9	63.3	
Marital Status (%)			
Married/partnered	24.5	24.5	.99
Single/divorced/separated/widowed	75.5	75.5	
Employment Status (%)			
Full time	24.5	38.8	.18
Disabled/medical leave	16.3	20.4	
Unemployed/other	59.2	40.8	
BMI, kg/m², mean (SD)	32.3 (7.1)	32.5 (8.5)	.88
Self-Reported Health (%)			
Excellent/very good	28.6	32.7	.90
Good	49.0	44.9	
Fair/poor	22.4	22.4	
Smoking Status (%)			
Current	20.4	18.4	.92
Former	30.6	28.6	
Never	49	53.1	
Tumor Stage (%)			
0/I	44.9	40.8	.68
II/III	55.1	59.2	
ER Status (%)			
Positive	73.5	65.3	.38
Negative	26.5	34.7	
HER2 Status (%)			
Positive	22.4	16.3	.31
Negative	69.4	79.6	
Equivocal	0.0	2.0	
Unknown	8.2	2.0	
Location			
Urban	57.1	57.1	.99
Rural	42.9	42.9	

Table 1 Baseline Characteristics by Study Arm (N = 98) *Continued*

Characteristic	Navigator Group (n = 49)	Comparison (n = 49)	P Value
Recommended Treatment (%)			
Radiation	63.3	73.5	.28
Combination chemotherapy	65.3	71.4	.52
Hormone therapy	72.9	61.2	.22
Self-Reported Health Conditions			
Median (min/max)	6 (0-19)	4 (0-17)	.35
FACT-B Total, mean (SD)	99.3 (24.9)	99.7 (24.2)	.93
Pain, mean (SD)	3.4 (3.4)	3.6 (2.8)	.99
Fatigue, mean (SD)	4.7 (3.2)	5.2 (3.1)	.54
Distress, mean (SD)	3.5 (3.5)	3.4 (3.1)	.84
Mood, mean (SD)	4.3 (3.2)	3.6 (3.0)	.37
IES-R, mean (SD)	27.7 (18.5)	26.4 (19.2)	.71

BMI indicates body mass index; ER, estrogen receptor; FACT-B, Functional Assessment of Cancer Therapy-Breast; IES-R, Impact of Events Scale-Revised; SD, standard deviation.

Table 2 Breast Cancer Adjuvant Treatment Refusals by Individual and by Treatment Type According to Study Arm

Adjuvant Treatment Completion by Individual		Navigator Group, n (%)		Comparison, n (%)	P Value*	P Value Adjusted†
No		2 (4.1)		6 (12.2)	.27	.24
Yes		46 (93.9)		42 (85.9)		
Missing		1 (2.0)		1 (2.0)		
Refusals by Adjuvant Treatment	n	No. of Refusals	n	No. of Refusals	P Value‡	P Value Adjusted‡
Chemotherapy	32	0	35	3	.04	.08
Radiation	31	2	36	3		
Hormone initiation	35	0	30	3		
Surgery	49	0	49	1		

*Fisher's exact test of proportions; †Binary logistic regression adjusting for age; ‡Poisson regression and Poisson regression adjusting for age.

comparison arm, 6 patients refused 10 recommended treatments. One of these patients did not complete definitive surgery and recommended radiation therapy and did not return for further follow-up. One patient completed only 2 of 6 recommended cycles of chemotherapy and refused radiation and hormone therapy. Two patients refused 2 forms of treatment and 3 patients refused 1 form of recommended treatment. Differences were not statistically significant after adjustment.

At the 12-month follow-up, no statistically significant differences were observed in self-rated pain, distress, fatigue, mood, and quality-of-life scores (data not shown).

In addition, there were no statistically significant differences between the 2 study groups in missed visits (1 or more missed visits: 6.1% for the intervention and 8.2% for the comparison group [$P = .85$]). Although a higher proportion of patients on the intervention arm had at least 1 ED visit (39% vs 29%) and hospitalization (43% vs 33%), these differences were not statistically significant ($P = .19$ and $P = .39$, respectively; data not shown).

Patients on the intervention arm were contacted an average of 29 times during the 12-month period. The median contact duration was 30 minutes (range, 2-140 minutes). Patients were good stewards of the equipment

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Table 3 Participant Comments on the Virtual Navigation Program Obtained from the 12-Month Questionnaire

Program Element	Group	Feedback Summary	Sample Comments
Information links	Comparison	Reliability, ease of use, sense of trust	<ul style="list-style-type: none"> • I really appreciate being directed to good sites and sources. When I have used Google search I have found unreliable sources, some of which are frightening. • After using the [application] I now understand more. • It [web-based application] was the best tool for me to learn and understand my breast cancer. • It answers so many questions and gives you some great resources. • I can easily look up information about breast cancer. • It's very informative and easy to use. • If I have any questions, I can get the answers at my fingertips. • It's easy to find information...without having to call the doctor every time you think of something you want to ask about. • It was my library of resources, and I could be prepared to ask doctors questions during visits.
Information links and documents	Navigator group	Reliability, ease of use, sense of trust	<ul style="list-style-type: none"> • I am so grateful...to have such knowledge at my fingertips and to know it is all real information. • It was very useful to get safe, more reliable information, and to get more tips and access to resources. • I feel comfortable and secure having this resource right with me at home to educate me on most concerns. • I prefer the information from this portal because I trust the information provided. • It's easy reading and has been very helpful to me. • I especially liked the nutrition information. • I have found all the information I needed...and...information I wanted to share with family and friends.
My information and calendar	Comparison	Information, organization, and consolidation	<ul style="list-style-type: none"> • Under healthcare provider section....It is nice to know I have one place I can go [to get that type of information]....I feel the same way with my schedule section. • ...everything I need in one place...it helps keep everything organized, which in turn takes a lot of stress off of me. • Scheduler...it keeps me organized. • I am happy to have something to help me remember appointments and especially contact information. • Schedule feature would have been more helpful if it was linked to the doctor's office so they could add in appointments.
My information messaging*	Navigator group	Communication, access to information	<ul style="list-style-type: none"> • I do like the idea....I can go here to access my information concerning my situation. • I like being able to send and receive messages....The messages...have been very encouraging.
Web-based application as a source of support	Comparison	Support system	<ul style="list-style-type: none"> • I am lucky to have the access and the opportunity to have "my mini support system" by my side. • My little...buddy has been like my sidekick of information. • I feel that the computer and the information on there was very useful for me because I am not the type of person who wants to go to support groups. • It helped to control anxiety after doctor's hours and also provided me an opportunity to be more active in the decision-making process for my care. • It has been very comforting to be able to use it when I'm feeling stressed by side effects. • I feel it was a support system in place for my recovery. • Very helpful when I'm nervous about something and my doctors can't quite answer my questions. • There have been three other ladies at my church who have been diagnosed with breast cancer....I have sent the various links...to use.

Table 3 Participant Comments on the Virtual Navigation Program Obtained from the 12-Month Questionnaire *Continued*

Program Element	Group	Feedback Summary	Sample Comments
Team-produced videos*	Navigator group	Relaxation, anxiety relief	<ul style="list-style-type: none"> • I used the relaxation link, and it was great....I could feel my body actually relaxing. • The meditation stuff you can use anytime, and it is very useful when going through scans and having anxiety – it is there for you 24/7.
Navigator access*	Navigator group	Reassurance, assistance, support	<ul style="list-style-type: none"> • Helpful is an understatement. She was excellent. She was there to help with my physical and mental needs. (social worker navigator) • My navigator answered a lot of questions about breast cancer and what I would be going through. • My nurse is the best. • It was nice having so much contact with someone who could give suggestions and reassurance. • [Navigator] has been very helpful to me when I was not able to get help from anyone else....She helped me to understand a lot of things....She was very considerate, more so than the people in other departments. • [Navigator] was a huge part of my recovery. I would call her in the early morning or at night when my doctor's office was closed with questions. • This program was indeed a blessing to me at a time when I felt hopeless and despair. • Helpful especially on my difficult days. • I don't feel I am lost in understanding what is going on...the study has made me positive and happy. • Without this [program] I wouldn't have much communication. I live alone, and no family or friends that are close to talk with.
Suggestions	Comparison, navigator group	Survivorship, community future steps	<ul style="list-style-type: none"> • More information on what to expect after treatment. • I enjoy using the computer. P.s. need more time to learn. (comparison group) • You need a chat room so us cancer patients can ask each other some questions. • More on survivorship...What to do once chemo and radiation treatments are over.

*Accessible to navigator group only.

with only 5 netbook computer replacements required. Seven patients on the navigator arm and 8 patients on the comparison arm exceeded the monthly cap at least once during the intervention and had temporary suspensions of service until the next billing cycle.

An open-ended comment section was included in the questionnaire, and comments, by subject matter and randomized group, are summarized in Table 3. They included comments on the information component of the application, specific components such as the “my information” section or “my schedule,” and sections specific to the intervention arm such as comments about the navigator or videos. The comparison group indicated receiving benefit and support from having readily accessible information they viewed as reliable, referring to the application as their “buddy” or “mini support” system. The information assisted them in formulating questions for their healthcare provider and aided in their deci-

sion-making. An additional benefit was having their personal information and healthcare provider information organized and accessible, although users commented that it would have been helpful to have a more direct

Few studies have rigorously examined the impact of navigation programs beyond treatment initiation, especially among low-income populations.

link to their doctor's scheduling system. For those on the intervention arm, the navigators received high praise, and the program was noted to help relieve stress and anxiety and give reassurance.

Discussion

The results from this pilot trial demonstrate the potential feasibility of using a centralized virtual navigator program to improve adherence to adjuvant breast cancer treatment among low-income breast cancer patients in urban and rural settings.

Patients in the intervention arm appreciated the access to both nurse and social worker navigators who could address their medical and psychosocial needs, respectively. More patients on the navigator intervention arm completed treatment compared with those with Internet access only, but this difference was not statistically significant.

The results of this study suggest a centralized navigation program may offer a solution to extend outreach to low-income patients in urban and rural settings.

No statistically significant differences were observed in hospitalizations and unscheduled outpatient or ED visits. The trial was designed to offer centralized support; the navigators were not embedded within practices and therefore were not in the direct line of care. It is possible that either embedding navigators who are healthcare providers within the practice or improving timing of navigator interactions to scheduled treatments may decrease ED visits and hospitalizations by helping patients avoid severe dehydration and other serious side effects through early intervention.

Few studies have rigorously examined the impact of navigation programs beyond treatment initiation, especially among low-income populations. The Patient Navigation Research Program found only a modest benefit of navigation on initiation of treatment, and only after 90 days from abnormal screening,¹⁶ and pooled data from 2 trials and a trial among Hispanic patients in a public safety hospital showed no difference in time to treatment completion.^{18,21} Similar to other studies, our results did not show a difference in quality of life, pain, fatigue, distress, or mood approximately 12 months after diagnosis between those having the information access alone and those with navigator support.^{20,27,28} A pooled analysis of 2 randomized navigation trials in breast and colorectal cancer patients, with the majority of patients having breast cancer, showed no difference in quality of life or distress at 3 months.^{18,20} Wagner et al reported on the impact on quality of life of a nurse navigation interven-

tion assessed in a cluster-randomized intervention trial conducted among breast, colorectal, and lung cancer patients enrolled in an integrated healthcare system (Group Health).²⁸ Patient experience was improved, but there was no difference in patient-reported quality of life. Nevertheless, patient experience may be the most relevant to completing treatment, and this aspect of care should be further explored.

Limitations of our study include lack of a usual care control arm and sample size. The patient advisors who assisted in the development of the program urged that all patients in the study be provided with computer access to the website. In addition, funding constraints prohibited a 3-armed trial and limited overall sample size.

The comparison arm likely experienced some benefit from having access to the vetted Internet sites via the computer application. The comments by those on the comparison arm indicated that access to information helped with decision-making and with physician communication, which likely affects adherence. Another potential limitation was that the navigators in our study were not embedded in the healthcare practice and thus could not always quickly intervene in matters of health, such as scheduling an urgent visit, which may help to decrease ED visits and hospitalizations. However, the independence of navigators may be helpful in instances where there is conflict between the patient and the healthcare provider or evidence of suboptimal care.

Navigator programs require an investment of time and money that may be beyond smaller practice settings. A centralized navigation program could provide a feasible solution for rural and small practice settings to provide navigation services. Providing wireless access was a major cost of the research grant. However, with the increasing availability of free wireless and lower wireless connectivity costs, virtual navigation services become increasingly feasible. We also estimated the patient load that 1 full-time equivalent nurse or social worker could carry, based on the contact attempts and successful contact and the average time per contact. These estimates are based on the low-income population included in our study that has complex concerns. Based on this study, we estimate that 1 full-time equivalent of a nurse and/or social worker could carry a patient load of 100 patients per year.

The findings suggest that a centralized web-based system with healthcare providers as navigators giving ongoing support may improve adherence to adjuvant cancer treatment compared with information access alone. Although navigators were not directly embedded in the healthcare practice, patients in the intervention arm appreciated the access to both nurse and social worker

navigators who could address their medical and psychosocial needs, respectively. Low-resource healthcare practices and communities may have difficulty offering navigation services due to small-volume practices and the costs involved. The results of this study suggest a centralized navigation program may offer a solution to extend outreach to low-income patients in urban and rural settings. Future studies should evaluate the program comparing a centralized virtual system to usual care. ✱

Study Sponsor

Susan G. Komen. Grant number KG110247.

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