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Effective Recruitment of Rural Breast Cancer Survivors into a Lifestyle Intervention

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Abstract

- Lifestyle interventions may be effective for enhancing quality of life and prognosis among breast cancer survivors, but expanding their reach to underserved rural communities presents some unique challenges.
- Recruitment for this lifestyle intervention trial among rural breast cancer survivors was carried out by developing local partnerships with rural oncology practices and hospitals who were members of regional community oncology organizations.
- Recruitment strategies included mailing a tailored study brochure accompanied by a cover letter from providers and an opt-in/opt-out postcard, media coverage, clinic-based oncologist referrals, and community outreach.
- Mailing the tailored study brochure with the opt-in postcard yielded the highest number of survivors who enrolled in the lifestyle intervention trial.
- Oncologist referrals yielded a small number of participants but had the highest enrollment rate, and thus appear to play an important role in motivating some patients.

Lifestyle interventions targeting exercise and weight control in cancer survivors have become increasingly common due to the strong associations with improvements in function, quality of life, and cancer prognosis [1]. One of the most challenging aspects of conducting these trials is recruitment, especially for underserved populations. Rural residents who represent 20% of the U.S. population experience many of the same disparities as other minority groups including poorer lifestyle behaviors [2] and higher obesity rates [3]. Rural cancer survivors have less access to survivorship care, poorer mental health and quality of life [4, 5] and limited access to lifestyle intervention [6]. Geographic isolation and travel requirements pose additional barriers, however, little has been written about successful recruitment of this group.

This paper describes the recruitment of rural breast cancer survivors into a randomized trial investigating the effects of an 18-month intensive lifestyle intervention. We describe a

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CONFLICT OF INTEREST STATEMENT

None of the authors have a conflict of interest to report.

variety of recruitment methods and data on participant yield by different recruitment strategies.

METHODS

The Rural Women Connecting for Better Health study is examining two distance-based strategies for delivering a weight loss maintenance intervention subsequent to successful weight loss among rural women with a body mass index (BMI) 27–45 kg/m² and diagnosed with Stage 0-III breast cancer within the past 10 years. In brief, all participants receive a 6-month weight loss intervention with weekly group sessions delivered by phone via conference calls. At month 6, participants who are retained through Phase I are randomized to one of two weight loss maintenance conditions: continued bi-monthly group conference calls or bi-monthly mailed newsletters. The primary endpoint is weight loss maintenance from months 6 to 18 with secondary endpoints for quality of life and serum biomarkers. Participants were enrolled in 8 cohorts from 11 local cancer centers located across Kansas, Nebraska, and Iowa.

Partnerships with Oncology Practices

Recruitment was accomplished by developing partnerships with oncology practices serving a large percentage of rural patients, with support from two umbrella organizations. *The Midwest Cancer Alliance (MCA)* provides community oncologists with access to clinical trials, evidence-based prevention and survivorship resources, and continuing education. Currently, 15 cancer centers in the region are members of the MCA. Of these, 7 are located in rural counties, 5 of which partnered on the current study. *The NCI Community Cancer Centers Program (NCCCP)* was initiated in 2007 in rural and inner-city communities to enhance clinical trial participation and quality of care in medically underserved populations. Of the 21 hospitals in 16 states funded through NCCCP, 3 hospitals located in Nebraska and Iowa collaborated on this study.

To solidify the partnerships, we obtained a signed Memorandum of Understanding. We then submitted our Institutional Review Board (IRB) approved study protocol to IRBs at each site, even when not required in order to increase buy-in. Communication about the benefits of partnering focused on clinical trial participation, patient-centered care, and added value to the community. Our request from each site included assistance from the registrar with obtaining patient names and providing space and a phlebotomist for data collection. By conducting data collection visits on-site, their role in the research was highlighted.

Recruitment Strategies

Brochure Development—Our recruitment brochure was developed with input from rural breast cancer survivors who were previous program participants [7]. The brochure included information about the scientific rationale, details about program components, participant testimonials, and the most common reasons for exclusion. We held a focus group with 8 rural breast cancer survivors to elicit feedback on content and graphics. Each of the partnering sites approved the brochure and provided their hospital logo to be included.

Mailings—Each of the sites deferred to our HIPAA waiver and released names and addresses of all living female patients treated for breast cancer in the last 10 years. Patients were not pre-screened for weight status. Study staff prepared the mailing for patients with rural zip codes. The brochure was accompanied by a cover letter signed by the provider on their letterhead and an opt-in/opt-out postcard with a pre-paid postage return envelope. The number of mailings per site ranged from 493 to 2,192.

Direct Physician Referrals—Local oncologists at all sites were informed about the study and encouraged to refer their patients. Direct physician referrals came from 4 of the 12 sites.

Media Coverage and Advertisements—Paid newspaper advertisements were created for communities surrounding three sites. Due to low response, we did not pursue this approach with the remaining cohorts. Three different sites received radio and newspaper exposure which included interviews with the primary investigator and a local oncologist. On two occasions, participants were interviewed by local newspapers about their weight loss success. Finally, two Kansas state-wide reports were published in a rural health education newsletter and Kansas Public Radio on-line.

Community Outreach—The study was advertised at multiple community events including walks, health fairs, support groups, and patient seminars. Study investigators also gave four community presentations and six continuing medical education talks to increase awareness of the study throughout the region.

RESULTS

Table 1 describes the number of participants contacted, screened, eligible, consented, and enrolled by the different recruitment methods. The direct mailing yielded 84% of screened participants, whereas the other recruitment methods each yielded less than 5% of the screening sample. For the mailing, a total of 7101 invitations were sent, 6720 (95%) were successfully delivered, and among these 913 (13.6%) responded and 605 (9.0%) completed screening. Contact yield from the mailing across sites ranged from 7.4% to 20.5%. Among the mailing respondents, 25.1% inquired by phone, 50.3% opted-in by postcard, and 24.6% opted-out by postcard.

Of those screened, 35.6% ($n = 257$) were eligible as confirmed by chart review, and 29.1% ($n = 210$) were enrolled and randomized. The enrollment rate (% of those screened) within each recruitment method varied from 23.1% among those recruited from media coverage/advertisements to 48.4% among those referred by their provider. The opt-in card method had the highest overall yield of participants but among the lowest enrollment rate. Comparing across mailing respondents who called versus sent the opt-in card, those who called had a higher eligibility rate (40.4% vs. 32.0%) and enrollment rate (33.7% vs. 25.4%).

Participant characteristics for those screened, eligible, and randomized are presented in Table 2. There were no differences between those eligible and those enrolled in age, BMI, degree of rurality, or breast cancer stage.

CONCLUSIONS

Recruitment of geographically isolated cancer survivors presents some unique challenges that we were able to overcome by developing local partnerships with oncology practices with the help of regional and national community cancer organizations. Local partners were able to meet their own goals toward accreditation standards and highlight the study as a value added opportunity to deliver patient-centered care. Our most effective recruitment strategy was mailing the study brochure in partnership with local registrars. This allowed us to include a personal touch by using provider-signed cover letters and to avoid obstacles with obtaining provider waivers required for direct mailings from state cancer registries. Our undeliverable rate was 5%, and our response rate was 13.6% with 9.0% completing screening. This compares favorably to a 24% undeliverable rate and a 10.7% response rate with 6.0% completing screening using state registries [8]. The time spent on the mailing, including compiling, printing, and addressing envelopes, was approximately 600 hours, or 30% effort for a staff person.

The opt-in postcard yielded the greatest number of participants. This method of responding to the study invitation is more passive than calling, and not surprisingly it had a lower enrollment rate. Nevertheless, we believe based on the overall yield from this method that it is worth the additional screening effort required.

Oncologists at several sites referred patients, however this remained one of the lowest sources of recruitment. Given that long-term survivors typically have only one annual visit with their oncologist compared to four visits with their primary care physician [9], relying on oncology offices is not an effective way to reach a large number of long-term survivors. However, provider referrals appear to have an important role in motivating patients, many of whom may not otherwise respond to study brochures. Consistent with this, participants who were referred during a clinic visit had the highest enrollment rate across all of our recruitment methods.

Our overall enrollment rate among women screened was 29%. Enrollment rates in other lifestyle trials among long-term cancer survivors have varied greatly from 4% to 70% due to a variety of factors including how extensive the eligibility criteria are, how intensive the intervention is, and whether potential participants are prescreened for select criteria such as cancer stage. Rock et al. have an on-going large multi-site weight control trial among breast cancer survivors with similar eligibility criteria and intervention intensity as our current trial [10]. Using similar methods of recruitment, they experienced an enrollment rate of 14% excluding those pre-screened as ineligible based on cancer stage and time since diagnosis.

In summary our recruitment results demonstrate the feasibility of recruiting geographically dispersed rural breast cancer survivors treated at community cancer centers into an intensive weight control intervention. Consistent with the literature on strategies for recruiting minority participants, we found that mass mailings with a personalized letter was the most effective recruitment strategy, and that personal provider referrals resulted in the highest enrollment rate among those screened.

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Table 1

Participant Yield by Recruitment Methods

	Total	Mailing response by phone	Mailing response by opt-in card	Provider referral	Media coverage/ advertis- ements	Communit- y outreach	Other ^b
# Contacted the study team	832	229	459	33	44	16	51
# Screened for eligibility	721	208	397	31	26	13	46
# Eligible ^a	257 (35.6%)	84 (40.4%)	127 (32.0%)	16 (51.6%)	6 (23.1%)	7 (53.8%)	17 (37.0%)
# Attended consent visit ^a	216 (30.0%)	75 (36.1%)	102 (25.7%)	15 (48.4%)	6 (23.1%)	5 (38.5%)	13 (28.3%)
# Enrolled ^a	210 (29.1%)	70 (33.7%)	101 (25.4%)	15 (48.4%)	6 (23.1%)	5 (38.5%)	13 (28.3%)

^a % of number screened within each recruitment method

^b Friend referrals, [Clinicaltrials.gov](https://clinicaltrials.gov), Pilot database

Table 2

Characteristics of Screened, Eligible, and Randomized Participants

	Screened ^a (n=721)	Eligible (n = 257)	Randomized (n =210)
	M (SD) or n (%)	M (SD) or n (%)	M (SD) or n (%)
Age	58.2 (9.2)	58.0 (8.1)	58.0 (8.2)
BMI, self-report	32.7 (6.1)	33.1 (4.3)	33.3 (4.2)
Rurality ^b	687 (95.8)		
Urban	42 (5.8)	--	--
Large rural/Other rural	321 (44.6)	122 (47.4)	98 (46.7)
Small/Isolated rural	356 (49.5)	136 (52.5)	112 (53.3)
Time Since Diagnosis, years	4.6 (3.8)	4.0 (2.5)	3.9 (2.5)
Stage, self-report			
0	82 (11.6)	16 (6.2)	13 (6.2)
I-IIIc	523 (74.3)	216 (84.0)	175 (83.3)
IV	14 (2.0)	0 (0)	0 (0)
Unknown	85 (12.1)	25 (9.7)	22 (10.5)

BMI = body mass index in kg/m²;^aUp to 2% of values are missing for characteristics of screened participants due to not all information being collected at the initial screening call.^bBased on Rural-Urban Commuting Area Codes.