Feasibility of Using Volunteer Research Staff to Deliver and Evaluate a Low-Fat Dietary Intervention: The American Cancer Society Breast Cancer Dietary Intervention Project

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Abstract

This report presents the results of a study to examine the feasibility of using volunteers as research staff for a randomized trial of whether reduction in dietary fat intake could prevent or delay breast cancer recurrence. We examined whether volunteers could be trained to recruit study participants, deliver a complex and intensive dietary intervention, and monitor intervention effectiveness. Volunteers, who were mostly employed nurses and dietitians, screened 521 women, of whom 293 were eligible and 144 were randomized. Participants were postmenopausal women under age 75, who had recently been diagnosed with breast cancer and treated with either mastectomy or lumpectomy. At 1 year postrandomization, 77% of intervention and 75% of control participants remained active in the study. Intervention effects (change in intervention group minus change in control group) at 3, 6, and 12 months postrandomization were 5.9, 8.4, and 7.2% energy from fat and 1.7, 3.0, and 3.5 kg body weight (all \( P < 0.001 \)). These results were similar to those from other studies that used paid, professional staff to deliver and monitor interventions. Results from this feasibility study suggest that volunteer-based health organizations can provide research opportunities for health practitioners and can conduct high-quality research at lower costs.

Introduction

Breast cancer is the second leading cause of cancer mortality in American women, with an incidence in 1991 of 325 per 100,000 women age 50 and over (1). Whether dietary change could reduce breast cancer risk remains an area of substantial scientific controversy (2, 3) and importance (4). There is a modest amount of evidence that dietary change, in particular fat and/or energy reduction, should be part of treatment for primary breast cancer (5–8). In one study, weight gain following treatment of breast cancer was associated with earlier recurrence (9). A proposed mechanism is that lower adipose mass and dietary fat reduction could reduce serum estradiol levels, which could lower risk of recurrence of estrogen receptor-positive disease (10). There are now at least two randomized, prospective clinical trials underway to test whether fat reduction in women treated for a primary breast cancer can prevent or delay cancer recurrence (11).

In 1992, the ACS proposed a study of whether dietary fat reduction and weight loss, in addition to adjuvant systemic therapy, could increase survival of women after surgical treatment of primary breast cancer. A unique aspect of this proposed trial was its design as a community-based effort using volunteers instead of paid research staff to perform most intervention- and evaluation-related activities. ACS divisions and local units were interested in participating in meaningful research projects, and using volunteers was viewed as a means to enhance community involvement and reduce research costs. Previous experience in the ACS Cancer Prevention Studies (12) showed that volunteers could successfully recruit participants for longitudinal studies that had relatively simple questionnaire-based data collection requirements. Previous work site- and community-based intervention studies using "community organization" strategies (13) to develop and deliver interventions have also successfully recruited volunteers to serve on community boards and to assist with intervention activities (14, 15). It was unknown, however, whether volunteers could deliver and monitor a complex and intensive dietary intervention. The ACS therefore funded a pilot or feasibility study, the BCDIP, designed to examine whether a randomized trial using community volunteers could recruit study participants, deliver and monitor the intervention, and achieve intervention goals. Results of this feasibility study can be used to both justify and better design trials using volunteers as research staff.

Received 10/8/96; revised 2/18/97; accepted 2/24/97.

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1 This study was funded by the American Cancer Society National Office, and was supported by the New York State and the Long Island Divisions of the American Cancer Society.

2 To whom requests for reprints should be addressed, at Cancer Prevention Research Program, Fred Hutchinson Cancer Research Center, 1100 Fairview Avenue North, P. O. Box 10924, Seattle, WA 98109-1024.


5 The abbreviations used are: ACS, American Cancer Society; BCDIP, Breast Cancer Dietary Intervention Project; COO, Central Operations Office; SNCC, Statistical and Nutrition Coordinating Center; VAR, volunteer adjunct researcher; WHT, Women's Health Trial; WINS, Women's Intervention Nutrition Study.
Materials and Methods

The BCDIP was a randomized clinical trial to test the feasibility of using volunteers to deliver and monitor a low-fat dietary intervention. Women who had been treated for breast cancer were randomized to receive either an intensive intervention to lower dietary fat to 15% of total energy or written materials on the ACS dietary guidelines (30% or less of total energy from fat). End points were dietary fat intake and change in body weight at 3, 6, and 12 months after randomization.

Organization. The BCDIP was a collaborative study for which the ACS central office in Atlanta provided funding and overall scientific leadership, the New York State ACS division headquarters established the COO in Glens Falls for nine local ACS unit offices throughout Upstate New York and Long Island, and the Cancer Prevention Research Program at the Fred Hutchinson Cancer Research Center in Seattle was the SNCC. The COO was responsible for volunteer recruitment and training, day-to-day study management, tracking of volunteer and participant activities, quality control of data collection forms, and data entry of 4-day food records. The SNCC was responsible for protocol and instrument development, intervention materials, professional staff training, data management and analysis, and overall quality control.

Professional and Volunteer Staffing. Professional, paid staff included principal investigators in Atlanta and Seattle, and Registered Dietitians in Seattle and Glens Falls. The principal investigator for the COO and principal investigators at each clinical site were volunteer oncology physicians, who promoted the study and assisted with patient recruitment. There were five groups of volunteer staff; called VARs: site coordinators, who were responsible for initial eligibility screening of potential participants, coordinating data flow to the COO, and local protocol adherence; assessment VARs, who were responsible for further eligibility screening and data collection for assessment of study end points; intervention VARs, who were divided into those who delivered either the individual or group dietary intervention sessions; and control VARs, who maintained contact with and encouraged continued participation of control women throughout the trial. Details of volunteer recruitment, characteristics, and performance will be published elsewhere. In brief, volunteers were recruited by the COO and local ACS units and trained by the BCDIP professional staff using standardized protocols. About half of the volunteers were recruited from existing ACS volunteer lists and half from local professional nursing and dietetic associations. Forty % of intervention VARs were registered dietitians, and assessment and control VARs were mostly registered nurses and other licensed professionals.

Participant Recruitment and Randomization. Participant recruitment activities occurred at local sites following volunteer recruitment and training. We identified potential participants primarily through local oncologists’ offices and secondarily through local advertising. The COO sent or delivered recruitment packets to oncology physicians. These packets included a letter to the physician explaining the study and eligibility criteria and informational brochures for potential participants. Media outreach was primarily through newspaper articles and television news. Interested women telephoned the toll-free study line or returned a short questionnaire to the local ACS office. Site coordinators contacted potential participants by telephone to conduct a brief screening interview. At initial screening, eligibility criteria included: diagnosis of breast cancer no earlier than 1991; age 75 years or younger; postmenopausal, defined as no menstrual period in the past year; no history of serious cardiovascular disease, other cancer (excluding nonmelanomatous skin or noninvasive cervical cancers), or insulin-dependent diabetes; 105% or greater of ideal body weight; willingness to be randomized into and participate in either the intensive intervention or the control group; and not already eating a very low-fat diet, estimated from a 10-item diet habits questionnaire modified from Kristal et al. (16).

Eligible women attended two prerandomization, run-in visits. At the first visit, an assessment VAR confirmed weight eligibility and taught participants how to keep a 4-day food record. At the second visit, the food record was reviewed for completeness and accuracy. To be eligible to continue, participants had to weigh 105% of ideal body weight at the first assessment visit and successfully complete the food record. Women also completed health history and psychosocial questionnaires and sent a medical eligibility questionnaire to their physicians. Women were medically eligible for randomization if they were diagnosed with adenocarcinoma in one breast only, had a tumor size of 1 or more cm in diameter with no nodal involvement or a smaller tumor with at least one but no more than nine positive auxiliary lymph nodes, had a mastectomy or lumpectomy (with radiation therapy), and received adjuvant chemo-hormonal therapy if needed. Randomization was blocked by study site, based on sequentially numbered sealed envelopes. On the day of each randomization, the COO sent completed, original, numbered randomization forms to the SNCC. These postmarked forms provided satisfactory confirmation that appropriate randomization procedures were followed.

Intervention Design and Delivery. The goal of the dietary intervention was to reduce fat intake to 15% or less of total energy. The intervention protocol was based on the program developed for the WHT, which targeted both nutrition education and behavior change skills and was based conceptually on social learning theory, cognitive-behavioral theory, and self-control theory (17). The WHT’s 18 highly structured, group classes were replaced with six 1-h, weekly, individual sessions, after which participants joined ongoing monthly, 1-h group sessions. There were 10 group sessions designed to provide social support and promote maintenance of new dietary habits. There was also a seventh individual session at 6 months post-randomization, when participants received feedback on their fat intake, the nutritional adequacy of their diet, and their success at weight reduction. This session also reinforced the importance of physical activity and allowed for one-on-one problem solving to maintain dietary goals. We used sequential individual followed by nonsequential group sessions because the number of participants at each study site was not large enough to support formation of groups for sequential delivery of the entire intervention. Using this mixed individual and group format, a participant could begin intervention as soon as she was randomized and then join an ongoing group as soon as individual intervention sessions were completed.

After randomization into the intervention arm, each participant was assigned to an individual intervention VAR, who was responsible for scheduling and delivering the weekly and the 6-month individual sessions. After completing the individual sessions, participants were then assigned to a group intervention VAR. The major learning objectives and activities for intervention sessions are given in Appendix I. The intervention sessions focused on three major content areas: eating patterns, dietary change skills, and behavioral skills. The majority of each session was spent on interactive activities and self-assessment, with little or no didactic presentation. Each intervention
participant received a comprehensive manual containing session information, self-assessment exercises related to the content of each session, and reference materials.

Volunteer Training and Certification. The COO and SNCC developed a comprehensive manual of operations, along with a detailed procedures manual for each type of VAR. All VARs attended at least a 1-day centralized training session conducted by COO and SNCC professional staff, which varied from 4 h for control VARs to 8 h or more for individual intervention VARs. The trainings were conducted separately for each type of volunteer (e.g., group intervention VAR training), but all of the trainings included background and research related to the BCDIP, an overview of study design and objectives, and the general roles of the different volunteer types. Each VAR received a manual of operations containing detailed procedures relevant to his or her particular functions in the study. The majority of the training time consisted of specific task-related training for each type of VAR. For example, assessment VARs practiced taking physical measures and collecting comprehensive food record data, and intervention VARs participated in role-playing situations. Assessment, individual intervention, and group intervention VARs also received additional reading and practice exercises, and these VARs completed certification procedures before contact with study participants.

After training and certification, the COO staff maintained oversight of VAR activities. A substantial part of the COO responsibility was to document VAR performance, focused especially on scheduled intervention and assessment contacts with participants. The BCDIP staff used volunteer activity logs, visit completion rates, bimonthly conference calls, and quality assurance site visits to monitor VAR and local study site activities. A description of maintenance activities and predictors of VAR retention will be discussed in detail in a separate article.

Intervention and End Point Monitoring. The study end points, dietary fat intake and body weight, were assessed at baseline and 3, 6, and 12 months postrandomization. Certified assessment VARs measured participants’ weight, in lightweight street clothes without shoes, using calibrated balance beam scales and standardized procedures. Dietary fat intake was assessed using 4-day food records. Participants kept records on 4 alternate days, recording portions in household units. At baseline, assessment VARs provided participants with detailed instructions and an instruction booklet on how to keep an accurate food record. Before the 3-, 6-, and 12-month follow-up visits, food record booklets and instructions were sent to each participant. An assessment VAR reviewed all food records with participants at each follow-up visit, and completed records were then sent to the COO for an additional review by a staff nutritionist. A trained COO staff member analyzed the food records using the Minnesota Nutrition Data System software (Food Database version 7a, Nutrient Database version 22) developed by the Nutrition Coordinating Center, University of Minnesota (Minneapolis, MN; Ref. 18). For quality control, a COO nutritionist independently coded a random 5% sample of all food records for comparison with standard data entry.

Statistical Methods. We used life table analysis to examine trends in participant dropout over time and to test whether study participation differed between intervention and control groups (19). We defined date of dropout as the earlier of either: (a) the date a participant informed the clinic that she no longer wished to be in the study or (b) the date of a follow-up visit that was never completed.

We defined the effects of dietary intervention, or the intervention effect, as

$$\text{Intervention effect} = \frac{\text{Fat(\%en)}_b - \text{Fat(\%en)}_f}{\text{Fat(\%en)}_b - \text{Fat(\%en)}_c}$$

where Fat (\%en) is the percentage of energy from dietary fat, the subscripts \(b\) and \(f\) refer to baseline and follow-up, and the subscripts \(I\) and \(C\) refer to intervention and control groups. The SD of the intervention effect is defined as

$$\sqrt{\text{VAR(Fat(\%en)}_b - \text{Fat(\%en)}_f + \text{VAR(Fat(\%en)}_b - \text{Fat(\%en)}_c}$$

where VAR refers to variance. We also examined trends in dietary intake and weight among the cohort of participants who remained active in the study through the 12-month follow-up visit.

Results

Between June 1993 and March 1995, 521 women completed the telephone screen and 293 were found initially eligible for the study based on age, breast cancer diagnosis, estimated fat intake, and willingness to be randomized. Of the 211 who attended the first clinic visit, 15 were found ineligible due to weight less than 105% of ideal, 43 did not have completed forms (primarily missing the physician’s medical eligibility form), 9 declined randomization, and 144 were randomized. There were no differences between intervention and control groups in baseline demographic, health behavior, and medical or psychosocial characteristics, and these are given for both treatment groups combined in Table 1. Most participants were married, between 50 and 64 years old, and employed outside the home. Almost 60% of all tumors were between 1 and 2 cm in diameter, and fewer than 7% were less than 1 cm in diameter. Participants practiced good health-related behavior; fewer than 8% smoked cigarettes, and almost 90% reported vigorous or moderate exercise for 20 min or more at least once per week. More than 75% reported that their overall health was good or excellent, their social ties with family and friends were strong, and they rarely or never used medications to relax.

There were marked differences in the numbers of participants that could be recruited from each of the nine study sites. The largest site was in Long Island, where 69 participants were randomized, and other sites randomized from 0 to 33 participants. Two clinical sites were closed midway through the trial, because recruitment of participants was too low to justify maintaining the volunteer staff. The one active participant in the closed sites was reassigned to an adjacent site. Three participants who did not meet eligibility requirements were randomized into the study: one whose surgery date was prior to January 1991, one who was premenopausal, and one who did not pass the diet screen. Because the principal purpose of this analysis is to evaluate the recruitment and intervention protocol, and not cancer end points, these participants are included in the results.

Fig. 1 shows the percentage of participants who remained active in the study from randomization through the final 12-month follow-up. One participant each, from both the intervention and control groups, dropped out of the study immediately after randomization. At 6 months, participation was slightly higher in the intervention group (85.1% intervention versus 78.9% control), but there were no differences in participation rates at the final 12-month follow-up (77.0% intervention versus 74.6% control). There were no significant differences in age, income, education, or tumor size between participants who dropped out and stayed active through the study. Smokers were
Table 1. Demographic, medical, health behavior, and psychosocial characteristics of participants at baseline (N = 144)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)a</td>
<td></td>
</tr>
<tr>
<td>35-49</td>
<td>14.6</td>
</tr>
<tr>
<td>50-64</td>
<td>68.1</td>
</tr>
<tr>
<td>65+</td>
<td>17.4</td>
</tr>
<tr>
<td>Income ($1000)</td>
<td></td>
</tr>
<tr>
<td>&lt;30</td>
<td>27.9</td>
</tr>
<tr>
<td>30-49</td>
<td>30.1</td>
</tr>
<tr>
<td>50+</td>
<td>41.9</td>
</tr>
<tr>
<td>Education (yr)</td>
<td></td>
</tr>
<tr>
<td>≤12</td>
<td>25.7</td>
</tr>
<tr>
<td>13-15</td>
<td>38.2</td>
</tr>
<tr>
<td>16</td>
<td>18.8</td>
</tr>
<tr>
<td>17+</td>
<td>17.4</td>
</tr>
<tr>
<td>Employment</td>
<td></td>
</tr>
<tr>
<td>Outside home</td>
<td>68.5</td>
</tr>
<tr>
<td>Retired</td>
<td>12.6</td>
</tr>
<tr>
<td>Other</td>
<td>18.9</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>68.1</td>
</tr>
<tr>
<td>Never married</td>
<td>3.5</td>
</tr>
<tr>
<td>Other</td>
<td>28.5</td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>97.2</td>
</tr>
<tr>
<td>African-American</td>
<td>2.1</td>
</tr>
<tr>
<td>Other</td>
<td>0.7</td>
</tr>
<tr>
<td>Time since breast cancer diagnosis (months)</td>
<td></td>
</tr>
<tr>
<td>&lt;6</td>
<td>15.3</td>
</tr>
<tr>
<td>6-12</td>
<td>26.4</td>
</tr>
<tr>
<td>12-17</td>
<td>24.3</td>
</tr>
<tr>
<td>18+</td>
<td>34.0</td>
</tr>
<tr>
<td>Size of largest tumor (cm)</td>
<td></td>
</tr>
<tr>
<td>&lt;0.5</td>
<td>2.3</td>
</tr>
<tr>
<td>0.5-0.9</td>
<td>4.7</td>
</tr>
<tr>
<td>1-1.4</td>
<td>29.5</td>
</tr>
<tr>
<td>1.5-2.0</td>
<td>29.5</td>
</tr>
<tr>
<td>&gt;2.0</td>
<td>34.1</td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
</tr>
<tr>
<td>Current</td>
<td>7.6</td>
</tr>
<tr>
<td>Quit</td>
<td>48.6</td>
</tr>
<tr>
<td>Never</td>
<td>43.8</td>
</tr>
<tr>
<td>Exercise (≥once per week)</td>
<td></td>
</tr>
<tr>
<td>Vigorous</td>
<td>46.5</td>
</tr>
<tr>
<td>Moderate</td>
<td>42.4</td>
</tr>
<tr>
<td>Light</td>
<td>3.5</td>
</tr>
<tr>
<td>None</td>
<td>7.6</td>
</tr>
<tr>
<td>Overall health (self-rated)</td>
<td></td>
</tr>
<tr>
<td>Excellent</td>
<td>29.9</td>
</tr>
<tr>
<td>Good</td>
<td>52.1</td>
</tr>
<tr>
<td>Average</td>
<td>16.0</td>
</tr>
<tr>
<td>Fair</td>
<td>2.1</td>
</tr>
<tr>
<td>Satisfaction with life</td>
<td></td>
</tr>
<tr>
<td>Extremely satisfied</td>
<td>13.2</td>
</tr>
<tr>
<td>Very satisfied</td>
<td>50.7</td>
</tr>
<tr>
<td>Somewhat satisfied</td>
<td>33.3</td>
</tr>
<tr>
<td>Slightly/Not satisfied</td>
<td>2.8</td>
</tr>
<tr>
<td>Social ties with family/friends</td>
<td></td>
</tr>
<tr>
<td>Extremely strong</td>
<td>31.9</td>
</tr>
<tr>
<td>Very strong</td>
<td>47.9</td>
</tr>
<tr>
<td>Somewhat strong</td>
<td>17.4</td>
</tr>
<tr>
<td>Slightly/Not strong</td>
<td>1.4</td>
</tr>
<tr>
<td>Take Medication to Relax</td>
<td></td>
</tr>
<tr>
<td>Every day</td>
<td>4.2</td>
</tr>
<tr>
<td>Few times per month</td>
<td>4.2</td>
</tr>
<tr>
<td>Rarely/Never</td>
<td>88.9</td>
</tr>
</tbody>
</table>

*Mean ± SD, 56.4 ± 7.3 years.

more likely to drop out than nonsmokers (45% versus 22%; P < 0.08). Participation in intervention activities was excellent for the seven individual sessions and only fair for the remaining 10 group sessions. Only three women (4%) did not complete all individual intervention sessions. Thirteen percent of women attended none of the group intervention sessions, 10% attended at least eight sessions, and the median number of group sessions attended was five.

Table 2 gives details on nutrient intake at baseline and 3, 6, and 12 months postrandomization. At baseline, there were no differences between intervention and control participants in macronutrient or micronutrient intakes. At all postrandomization follow-up time points, intervention participants consumed significantly less fat and more carbohydrate than controls, but there were no differences between intervention and control participants in total energy, protein, or alcohol intakes. Although the intervention group did not reach the goal of 15% energy from fat, mean fat intake remained below 20% energy from fat at all follow-up assessments. There was no evidence that intake of important micronutrients was compromised as a result of the dietary intervention. Postintervention intakes of β-carotene, vitamin C, and calcium were higher in intervention compared to control participants, although these differences were not always statistically significant. Intakes of α-tocopherol tended to decrease postrandomization in both treatment groups, and differences between treatment groups were small and not statistically significant.

Fig. 2 shows trends in percentage of energy from fat, percentage of energy from carbohydrate, and body weight for the cohort of 57 intervention and 53 control women who remained active through the study. Between baseline and 3 months postrandomization, there were significant decreases in percentage of energy from fat in both intervention and control groups. At 6 months, control group participants had increased their fat intake to near baseline levels, whereas there was no upward drift among intervention participants. The trend in percentage of energy from carbohydrate mirrored the drop in fat intake, with rises at 3 months postintervention that were sustained among intervention participants through the 1-year follow-up. There was a slight increase in weight among control participants, whereas among intervention participants, weight loss was substantial and sustained decrease in percentage of energy from fat with a corresponding increase in percentage of energy from carbohydrate due to the dietary intervention. The significant weight loss among intervention participants is objective evidence in support of these self-reported dietary changes.

Table 3 gives the intervention effects, defined as change in intervention group minus change in control group, for percentage energy from fat, total energy, and weight, at all postrandomization assessments. These results are similar to those based on the smaller cohort shown in Fig. 2. The intervention effect for percentage of energy from fat ranged from 6.1 to 9.0 percentage points (all P < 0.001). There were modest, nonsignificant differences in total energy. The intervention effects on weight increased from 1.7 kg at 3 months to 3.5 kg at 12 months postrandomization (all P < 0.001). We examined whether dietary change or weight loss in intervention participants differed by professional training of intervention VARs. In comparisons of registered dietitians, registered nurses, and volunteers with no health-related professional certification, there were no significant differences in dietary change or weight change at any time.
Discussion
This study demonstrated that it could be feasible to use community volunteers as research staff in a dietary intervention trial for the secondary prevention of breast cancer. Although there were problems with some operational aspects of the study, volunteers were reasonably successful with screening, determining eligibility, and randomizing participants following a standardized protocol. The most important finding from this study relates to the ability of volunteer staff, consisting of registered dietitians, registered nurses, and lay volunteers, to deliver and evaluate the dietary intervention. Volunteers, regardless of profession, were successful at delivering the intensive, low-fat dietary intervention. Although the intervention goal of 15% of energy from fat was not achieved, postrandomization assessments of mean fat intake were consistently under 20% of energy. There was also objective evidence that participants had adopted the low-fat diet, as weight loss in the intervention group was 1.5 kg at 3 months and 3.2 kg at 12 months. Nevertheless, the ACS chose not to fund a full-scale trial, due primarily to competing priorities for research funds.

There are two published studies that have examined the feasibility of a randomized controlled trial of low-fat diets in women: The WHT Feasibility and later expanded Vanguard Studies (20, 21), and the WINS (11). There are important differences between the BCDIP and these studies, which are important to consider before comparing study results. First, WHT participants were healthy women with a strong interest in point, nor were there nonsignificant differences that were consistent in direction across time points.

Table 2 Nutrient intake at baseline and 3, 6, and 12 months postrandomization, by treatment group

| Table 2 Nutrient intake at baseline and 3, 6, and 12 months postrandomization, by treatment group

<table>
<thead>
<tr>
<th>Baseline</th>
<th>3 months</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Energy (kcal)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>1739 (428)</td>
<td>1663 (374)</td>
<td>1474 (330)</td>
</tr>
<tr>
<td>Control</td>
<td>1663 (374)</td>
<td>1513 (370)</td>
<td>1445 (488)</td>
</tr>
<tr>
<td><strong>Fat</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>g</td>
<td>59.3 (22.5)</td>
<td>57.9 (21.7)</td>
<td>33.9 (17.7)</td>
</tr>
<tr>
<td>%en</td>
<td>29.8 (6.4)</td>
<td>30.7 (7.8)</td>
<td>19.9 (7.1)</td>
</tr>
<tr>
<td><strong>Carbohydrate</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>g</td>
<td>228.1 (65.4)</td>
<td>214.5 (58.0)</td>
<td>225.0 (58.4)</td>
</tr>
<tr>
<td>%en</td>
<td>53.0 (8.7)</td>
<td>52.3 (9.6)</td>
<td>61.5 (8.0)</td>
</tr>
<tr>
<td><strong>Protein</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>g</td>
<td>74.2 (17.8)</td>
<td>72.4 (19.0)</td>
<td>70.6 (16.1)</td>
</tr>
<tr>
<td>%en</td>
<td>17.7 (4.0)</td>
<td>17.7 (3.3)</td>
<td>19.6 (3.6)</td>
</tr>
<tr>
<td><strong>Alcohol</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>g</td>
<td>30.1</td>
<td>42.3</td>
<td>30.7</td>
</tr>
<tr>
<td>%en</td>
<td>6.7 (7.4)</td>
<td>6.0 (4.2)</td>
<td>5.0 (4.5)</td>
</tr>
<tr>
<td>%&lt;sup&gt;en&lt;/sup&gt;</td>
<td>4.8 (7.2)</td>
<td>3.0 (2.3)</td>
<td>3.1 (3.6)</td>
</tr>
<tr>
<td><strong>β-carotene (µg)</strong></td>
<td>4949 (4220)</td>
<td>4585 (4346)</td>
<td>4323 (3205)</td>
</tr>
<tr>
<td><strong>α-tocopherol (mg)</strong></td>
<td>7.6 (4.1)</td>
<td>7.1 (4.1)</td>
<td>5.0 (2.6)</td>
</tr>
<tr>
<td><strong>Vitamin C (mg)</strong></td>
<td>129.6 (59.4)</td>
<td>121.0 (60.1)</td>
<td>140.0 (75.2)</td>
</tr>
<tr>
<td><strong>Calcium (mg)</strong></td>
<td>738 (266)</td>
<td>688 (265)</td>
<td>749 (307.4)</td>
</tr>
</tbody>
</table>

*Mean (SD); %en, percentage of energy.
*<sup>a</sup> p < 0.01, intervention versus control.
*<sup>b</sup> p < 0.001, intervention versus control.
*<sup>c</sup> p < 0.05, intervention versus control.
*<sup>d</sup> Among those drinking.
diet and health, and both BCDIP and WINS participants had a previous diagnosis of breast cancer and thus may have been more highly motivated to comply with the intervention. The BCDIP and WINS interventions were also significantly modified from the WHT intervention. The WHT intervention was delivered in group sessions only, whereas both the BCDIP and WINS interventions combined individual and group sessions and had a more formal approach to integrating behavior skills with nutrition education. The most important difference, however, is that the WHT and WINS interventions were delivered by well-trained and paid registered dietitians. Nevertheless, the BCDIP low-fat dietary intervention resulted in dietary change and weight loss similar to those achieved in the WHT and WINS. In the WHT, intervention participants lowered their fat intakes to 20.9% of energy at 6 months and 21.6% of energy at 1 year, with corresponding weight losses of 3.2 kg and 3.0 kg (22). In the WINS trial, intervention participants at 3 months had lowered their fat intake to 20.3% of energy and their weight by approximately 1.5 kg, both of which were maintained for 24 months. Compared to the BCDIP, WHT participants were similar in age, education, income, marital status, and percentage currently smoking, and dropout rates were lower (77% of intervention and 82% of control women remained active at 24 months postrandomization), but participation in intervention

Table 3  Intervention effects* on percentage of energy from fat, energy, and weight, by time and follow-up

<table>
<thead>
<tr>
<th>Time from randomization</th>
<th>Fat (%en)±</th>
<th>Energy (kcal)±</th>
<th>Weight (kg)±</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 months</td>
<td>5.9 ± 1.4</td>
<td>81.1 ± 72.1</td>
<td>1.7 ± 0.6</td>
<td>62</td>
<td>59</td>
</tr>
<tr>
<td>6 months</td>
<td>8.4 ± 1.4</td>
<td>165.6 ± 95.5</td>
<td>3.0 ± 0.7</td>
<td>61</td>
<td>53</td>
</tr>
<tr>
<td>12 months</td>
<td>7.2 ± 1.5</td>
<td>38.1 ± 77.2</td>
<td>3.5 ± 0.7</td>
<td>56</td>
<td>53</td>
</tr>
</tbody>
</table>

* Change from baseline in intervention group minus change from baseline in controls.

* Mean ± SE; %en, percentage of energy.
activities was also lower (participants completed a median of only 6 of the 17 intervention sessions). Published data on the WINS are limited, and similar comparisons on demographic characteristics and study participation are not possible. Overall, these results suggest that the BCDIP intervention program is sufficiently well developed to be effective when delivered by trained volunteers to well-motivated participants.

Another result from this study is our finding that some of the operational aspects of running a clinical trial need to be modified when using volunteer research staff. It was difficult to recruit, train, and certify volunteer research staff while at the same time recruiting study participants. In certain sites, we had recruited and trained VARs before we began recruiting participants, and by the time we had participants ready for randomization, some of the certified VARs had lost interest or no longer had the time to commit. We also lost some eligible participants, because there were no certified VARs ready to begin intervention after participants had completed all prerandomization requirements. Thus, the trial was slow to begin, and a number of eligible participants and certified volunteers never participated in this study. There were other problems related specifically to volunteers’ performance. Although there was a formal study protocol and detailed manual of operations, three ineligible participants were randomized into the study. The reasons for ineligibility were minor deviations from the protocol, yet this demonstrates the importance of strict, centralized review of eligibility criteria before randomization. We also had to close two clinical sites after recruiting and training VARs. This was because the criteria for developing clinical sites were the commitment of the local ACS office and the participation of a local oncologist as principal investigator but did not include whether there was a feasible plan for recruiting from an adequate population base. Overall, these results suggest that future trials using volunteer scientific staff must carefully manage recruitment of clinical sites, volunteers, and participants and strictly monitor enrollment of study participants.

The results from this pilot study are a significant extension of the ACS experience in using community volunteers as research staff. Previous large ACS cohort studies have used volunteers in very limited ways, primarily to recruit participants and distribute self-administered questionnaires (12). In contrast, this dietary intervention study had a very complex protocol. We believe that several factors were important for the success of this project: (a) the volunteers were very interested in breast cancer research; (b) for the dietitians and nurses who were trained as intervention or assessment volunteers, participation in BCDIP was a way they could use their professional skills in a local research project in ways that were different from usual work activities. In particular, volunteers were exposed to research methods and trained in new approaches to dietary intervention; and (c) paid research staff were responsible for those activities essential to the scientific management of the project, including study design, intervention protocol, volunteer training and monitoring, and data management. Thus, there was a highly structured and professionally managed program within which volunteers could function as research staff.

There are several limitations to the conclusions one can draw from this study about using volunteers as research staff. One of the most important limitations to this study is that we did not use a randomized controlled trial to compare results using a volunteer research staff with those using a professional, paid staff. Historical comparisons with the WHT and WINS, as described above, are not without potential biases. In addition, we do not have sufficient data to estimate the cost-effectiveness of using volunteer compared to professional staff. We believe that using volunteer research staff could save money, because salaries for study personnel would be reduced. However, if using volunteers increases costs for training and quality control, increases dropouts, or results in a less effective intervention, using volunteer staff could increase the costs of research. All studies must train and supervise research staff, and the results on intervention effects suggest that volunteer delivery does not reduce effectiveness. The estimated total (direct plus indirect) 5-year costs of the BCDIP (following 2000 participants at eight clinical centers for 5 years) are approximately $12 million ($250,000/year for each clinical center, and $400,000/year for administrative, statistical, and nutrition coordination). The estimated first 5-year costs for the WINS are $15 million direct and $7.5 million indirect ($4,600 capitation per participant, $1.8 million nutrition coordination, $1.2 million for central administration, and the remainder shared among statistical and regional coordination), and these costs are expected to increase substantially. Although there are other differences in the designs of the WINS and BCDIP besides the use of volunteer staff, these cost estimates do suggest that there would be cost savings from the volunteer research staff design proposed by the BCDIP.

We conclude that it is feasible to develop research protocols that include complex dietary interventions delivered by volunteers research staff. Volunteers in this study, who were primarily professional nutritionists and nurses, achieved dietary and weight loss results equivalent to those of other intervention studies using paid, full-time registered dietitians. We believe that successful implementation of other studies involving volunteers would require modification of study protocols to provide training, careful oversight, and structure to volunteer activities. Studies using community volunteers would be attractive options for organizations such as the ACS, providing research opportunities for health professionals in the community while supporting high-quality research at lower costs.

Acknowledgments
The author of this study and principal investigator for the ACS national office was Dr. Daniel W. Nixon, the principal investigator for New York State activities was Dr. Robert W. Sponzo, and the principal investigator for the SNCC was Dr. Alan R. Kristal. BCDIP COO staff included Nancy Duhaime, M. S., R. D.; Pam Ladd; Nannette Oberhelman; and Joanne Swanson, R. N. SNCC staff included Drs. Deborah Bowen, Carrie Cheney, and Kay DeRoo, and Ann Shattuck, M. P. H., R.D. We are grateful to the volunteer researchers and participants at each site who gave their time to participate in this research project.

Appendix
Breast Cancer Dietary Intervention Project Intervention Sessions’ Objectives and Activities
All intervention sessions included the following activities:
• "Talking It Over: a brief discussion of experiences since the previous session, e.g., "Low-fat Shopping Skills: Where Are You Now?"
• "Making an Action Plan: to incorporate new strategies to decrease dietary fat, e.g., planning head for social situations.
• Food tasting of a variety of low-fat items (group sessions only)".

Individual Sessions
1. The Fats of Life
Objectives
• Increase awareness of where fat is in food
• Increase awareness that it is important to maintain/increase activity level
Activities
• "Where’s the Fat" demonstration
• Discussion: How to Eat Less Fat and More Food
• Using the "Added Fat Scan"
2. The Starting Line

Objectives
- Discuss ways to limit fats and oils
- Use self-monitoring to evaluate fat intake
- Distribute individual fat gram goals

Activities
- Using the “Fat Counter” to calculate “Fat Score”

3. S.O.S.: Seeking Out Support

Objectives
- Identify high-fat dairy foods currently used
- Discuss skills for selecting and using nonfat/low-fat dairy foods
- Identify eating partner’s influence on food

Activities
- Using the Dairy Fat Scan
- Identifying people who influence what you eat

4. Shopping Your Way to Low-Fat

Objectives
- Increase ability to understand nutrition labels and marketing techniques
- Help participant develop shopping skills
- Help participant recognize and use low-fat prepared foods

Activities
- Reading a nutrition information panel
- Guidelines for low-fat choices
- Acquiring low-fat shopping skills

5. The Main Event

Objectives
- Identify high-fat main dishes
- Discuss skills for selecting and preparing low-fat main dishes
- Identify strategies to accommodate home eating partners in low-fat eating plan

Activities
- Modifying main dish recipes
- Using the Main Dish Fat Scan

6. Goals for Tomorrow

Objectives
- Use of a shorter self-monitoring tool: Fat Scan
- Identify reasons for goal setting as a component of behavioral change

Activities
- Using the Fat Scan
- Guidelines for goal setting

Individual Session: Support for Change (6 months postintervention)

Objectives
- Discuss dietary changes made to date
- Evaluate nutritional adequacy of current diet
- Discuss ways of creating an energy deficit
- Identify potential compliance problems for long-term maintenance

Activities
- Discussion of previous months’ progress
- Discuss nutritional adequacy
- Review participant’s activity chart

Group Sessions

7. What’s Complex about Carbohydrates?

Objectives
- Identify sources of complex carbohydrates
- Discuss techniques for introducing low-fat meatless dishes to eating partners

Activities
- Increasing your intake of complex carbohydrates
- Family meals: dealing with concerns

8. Smart Snacking

Objectives
- Identify personal snacking habits
- Identify eating partners’ influences on snacking patterns
- List strategies to promote low-fat snacking

Activities
- Food availability and snacking: identifying challenges
- Using the Snack and Dessert Scan

9. Sweet Support

Objectives
- Discuss ways sweets are used as a reward
- Select low-fat dessert alternatives
- Identify social support strategies to deal with sweets and desserts

Activities
- Ways to reduce use of high-fat sweets and desserts
- How you will ask for and get the help that you need

10. Dining Out with Ease

Objectives
- Discuss skills and strategies for social eating
- Discuss skills and strategies for low-fat restaurant and special occasion eating

Activities
- Planning ahead for social eating situations
- Strategies for eating less fat at restaurants
- Menu selection using local restaurant menus

11. Roadblocks to Change

Objectives
- Identify situations that get in the way of change
- Learn to use problem-solving skills
- Learn fat-budgeting skills

Activities
- Problem solving for change: removing the roadblocks
- Fat Budgeting

12. Planning Ahead

Objectives
- Identify challenges of vacations and holidays
- Handle challenges by learning to plan ahead
- Learn ways to reduce the fat in home baking

Activities
- Planning ahead for vacation and holiday challenges
- Modifying a favorite baking recipe

13. Talking to Yourself

Objectives
- Explain how self-talk influences actions
- Identify negative thought patterns
- Replace negative self-talk with positive thoughts
- Identify low-fat lunch ideas

Activities
- Practice self-talk
- Identifying your negative thoughts
- Practice changing your mind

14. Saving Time in the Kitchen

Objectives
- Identify and discuss techniques to reduce time spent in meal preparation
- Identify ways to increase fish consumption

Activities
- Learning to save time in the kitchen
- Time management skills
- Making a shopping list

15. Relax for the Health of It

Objectives
- Identify sources of stress that interfere with the ability to change
- Demonstrate strategies to cope with stress
- Identify methods and recipes for quick meal preparation

Activities
- Making easy, quick meals in times of stress
- Using relaxation techniques

16. Staying on Track

Objectives
- Examine the events or emotions that trigger lapses, relapses and slippage
- Develop strategies to prevent lapses or relapses
- Reinforce ways to limit fats and oils

Activities
- Dealing with detours
- Preventing relapses
- Steps to staying on track

References


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