

Recruitment to the “Breast—Activity and Healthy Eating After Diagnosis” (B-AHEAD) Randomized Controlled Trial

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Abstract

Excess weight at breast cancer diagnosis and weight gain during treatment are linked to increased breast cancer specific and all-cause mortality. The Breast—Activity and Healthy Eating After Diagnosis (B-AHEAD) trial tested 2 weight loss diet and exercise programmes versus a control receiving standard written advice during adjuvant treatment. This article identifies differences in characteristics between patients recruited from the main trial site to those of the whole population from that site during the recruitment period and identifies barriers to recruitment. A total of 409 patients with operable breast cancer were recruited within 12 weeks of surgery. We compared demographic and treatment factors between women recruited from the main trial coordinating site ($n = 300$) to the whole breast cancer population in the center ($n = 532$). Uptake at the coordinating site was 42%, comparable to treatment trials in the unit (47%). Women recruited were younger (55.9 vs 61.2 years, $P < .001$), more likely to live in least deprived postcode areas (41.7% vs 31.6%, $P = .004$), and more likely to have screen-detected cancers (55.3% vs 48.7%, $P = .026$) than the whole breast cancer population. The good uptake highlights the interest in lifestyle change around the time of diagnosis, a challenging time in the patient pathway, and shows that recruitment at this time is feasible. Barriers to uptake among older women and women with a lower socioeconomic status should be understood and overcome in order to improve recruitment to future lifestyle intervention programs.

Keywords

breast cancer, lifestyle intervention, diet, exercise, recruitment

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Introduction

Observational studies associate excess weight at breast cancer (BC) diagnosis, and weight gain after diagnosis with increased BC specific and all cause mortality¹ and decreased quality of life.² These data suggest weight loss or preventing weight gain will improve the outcome for BC patients. Most previous diet and exercise trials have targeted behavior change after completion of adjuvant chemotherapy and radiotherapy.³ The American Society of Clinical Oncology guidelines recognize that many patients with different cancer types will gain weight during and after treatment and that some patients may feel able to instigate lifestyle change during treatment.⁴ However, although Survivorship Care Plans, which are popular in the United States, promote healthy lifestyles after diagnosis, only the minority include information on preventing weight gain during treatment.⁵ In the United Kingdom, the “Living With and Beyond Cancer”

initiative suggests promoting physical activity and weight management, but the focus is after treatment.⁶ Treatment-associated weight gain is currently seen in 70% of patients.⁷ Intervening at the time of diagnosis or early on during adjuvant treatment may provide a “teachable moment” when women may be responsive to making beneficial lifestyle

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changes. This timing provides an opportunity to prevent treatment-associated weight gain,^{8,9} which would otherwise be missed.

The Breast—Activity and Healthy Eating After Diagnosis (B-AHEAD) trial aimed to define a cost effective diet and exercise weight control intervention to be offered to patients at the time of diagnosis and implemented during adjuvant treatment. The intention was to prevent gains in body fat in healthy weight women, and achieve fat loss in overweight women. Patients were invited to the study around the time of surgery, and were asked to adhere to the programmes during adjuvant treatment and for 12 months after diagnosis.

Here we report uptake to the trial across the former Greater Manchester and Cheshire Cancer Research Network (GMCCRN), and the characteristics of patients recruited from the main trial site compared to those of the whole population from that site. These data describe the population to which the B-AHEAD trial outcomes, to be published in a future article, will be applicable. Data on uptake to weight control programmes at the time of diagnosis will help improve recruitment success in future clinical trials and programmes in clinical practice.

Materials and Methods

A total of 409 women from 9 hospitals in the GMCCRN were recruited over 29 months. Written informed consent was obtained from all individual participants included in the study. The trial was coordinated at the University Hospital of South Manchester (UHSM), which was also the main recruiting site (ISRCTN number 68576140).

Inclusion and exclusion criteria were as follows.

Inclusion Criteria

- Within 12 weeks of primary breast or axillary surgery for early BC (invasive or in situ)
- Any age
- Any weight (as the programs aimed to tackle existing weight problems and prevent weight gain that occurs in women of any weight)
- Able to understand written instructions

Exclusion Criteria

- Metastatic or inoperable disease
- Physical or mental health conditions: which recruiting staff decided either deemed subjects inappropriate to approach, or could impair compliance to the diet and exercise programs
- Regularly taking medication known to affect body composition, for example, daily glucocorticoids (2-3

days glucocorticoids with chemotherapy could be included)

- Women who have received neoadjuvant chemotherapy or neoadjuvant endocrine therapy

Women were made aware of the trial either before their surgery or at their initial postsurgery appointment by their breast surgeon or GMCCRN nurse.

Trial appointments at baseline, 6 and 12 months at UHSM measured the primary (weight, body fat [dual energy X-ray absorptiometry]) and secondary outcome measures (waist and hip circumference, insulin sensitivity, lipids, fitness [12-minute walk test on treadmill], and adherence [7-day food and activity diaries]). Participants were offered reimbursement for travel costs, for example, petrol, parking, public transport or taxi costs, and volunteer drivers were arranged if required.

Participants were randomized to one of the following:

1. Control group: standard written diet and exercise advice only (n = 138)
2. 12-week home-based diet and exercise program with fortnightly telephone calls and mailed information (n = 134)
3. 12-week supervised community-based programme with weekly classes held in 5 locations around Greater Manchester (n = 137)

Recruiting hospitals submitted monthly records on numbers of noneligible women, and eligible women declining entry, and the reasons for both. Uptake figures were most complete for UHSM, the main recruiting site. We compared demographic and treatment factors among women recruited to the B-AHEAD trial to the whole BC population at UHSM during the recruitment period to determine patterns of uptake. We were unable to directly compare those recruited with those who declined to enter the study as we were unable to collect data on women who did not consent to join the study. Data were analyzed by independent-samples *t* test, Pearson's chi-squared or Fisher's exact test using IBM SPSS version 20 (IBM, Armonk, NY, USA).

Results

During the 29-month recruitment phase at UHSM, 1116 women were screened, 410 did not meet the inclusion criteria (Table 1), 406 women declined to participate (Table 2), and 300 eligible women were recruited (42% of eligible women). The main reasons for exclusion were the presence of comorbidities (38.3%), or that patients had received neoadjuvant chemotherapy (31.2%). Unfortunately, 14.4% of women could not be contacted within the limit of 12 weeks after surgery.

Table 1. Reasons for UHSM Patients Being Deemed Not Eligible for the B-AHEAD Trial.

| Reason for Exclusion | n | % of Total |
|--|-----|------------|
| Breast cancer–related issues: | 160 | 39.0 |
| Neoadjuvant treatment | 128 | 31.2 |
| Metastases | 32 | 7.8 |
| Comorbidities: | 157 | 38.3 |
| Mental health conditions | 41 | 10.0 |
| Musculoskeletal diagnoses | 19 | 4.6 |
| Cardiac diagnoses | 18 | 4.4 |
| Diabetes on insulin | 5 | 1.2 |
| Digestive disorders (eg, IBD or Crohn's disease) | 3 | 0.7 |
| Respiratory diagnoses | 2 | 0.5 |
| Daily glucocorticoids | 1 | 0.2 |
| Other comorbidities | 68 | 16.6 |
| Recruitment issues: | 80 | 19.5 |
| Unable to contact patient within 12 weeks of surgery | 59 | 14.4 |
| Language barriers | 13 | 3.2 |
| Infection postoperation | 5 | 1.2 |
| Already recruited to another trial | 3 | 0.7 |
| Unknown reason | 13 | 0.3 |
| Total | | 410 |

Abbreviations: UHSM, University Hospital of South Manchester; B-AHEAD, Breast—Activity and Healthy Eating After Diagnosis; IBD, inflammatory bowel disease.

Almost 30% of eligible women did not wish to join the trial because of the extra hospital visits, blood samples or scans involved (Table 2). Another 12.8% were anxious or depressed around the time of diagnosis, or could not cope with having to make another decision. A significant number (7.4%) declined due to transport problems despite the offer of reimbursement of travel costs.

Patient, tumor, and treatment characteristics of the 300 women joining the trial from UHSM were compared with the 532 patients receiving surgery at UHSM during the middle year of trial recruitment (Table 3). Women recruited to B-AHEAD were younger, with significantly fewer women aged older than 70 years. They were more likely to have screen-detected cancers and breast conserving surgery and were more likely to live in the least deprived postcode areas. The distribution of ethnicities among women who joined the trial was similar to that of the wider UHSM population. Uptake was comparable across all body mass index (BMI) categories and among women scheduled to have chemotherapy. Distance from the hospital did not influence uptake.

Discussion

Our data do not support the previously highlighted concern cited among breast cancer health professionals that patients

Table 2. Reasons for Eligible UHSM Patients Declining Entry to the B-AHEAD Trial.

| Reason for Eligible Patients Declining Trial Entry | n | % of total |
|--|-----|------------|
| Factors related to trial recruitment soon after diagnosis | 173 | 42.6 |
| Doesn't want extra hospital visits, blood samples, or scans | 121 | 29.8 |
| Can't cope with making another decision at this time | 33 | 8.1 |
| Patient too anxious/depressed at this time | 19 | 4.7 |
| Trial related: | 129 | 31.8 |
| Has too many other commitments | 60 | 14.8 |
| Does not wish to take part in a research trial | 34 | 8.4 |
| Patient does not want to be randomized | 5 | 1.2 |
| Transport problems with attending additional trial appointments | 30 | 7.4 |
| Diet and/or exercise related: | 24 | 5.9 |
| Already has healthy lifestyle according to participant | 11 | 2.7 |
| Does not want to go on a diet/do exercise | 4 | 1.0 |
| Patient declined information about the trial/not interested in trial | 9 | 2.2 |
| Reason not disclosed | 80 | 19.7 |
| Total | | 406 |

Abbreviations: UHSM, University Hospital of South Manchester; B-AHEAD, Breast—Activity and Healthy Eating After Diagnosis.

would not welcome being approached regarding lifestyle interventions at the time of diagnosis.¹¹ The recruitment rate of 42% of eligible women is comparable to uptake to treatment trials in our unit (47%)¹² despite the fact that the diet and exercise trial required an additional commitment from patients to change behaviors and attend 3 trial assessment appointments. Thus, BC patients appear equally interested to join lifestyle and treatment interventions at the time of diagnosis and commencing adjuvant treatment. At the time of recruitment to the B-AHEAD trial, the main recruiting center had 13 other surgical and treatment trials also open to recruitment. Though not supported by data, these studies could have affected recruitment to the B-AHEAD trial, not because they precluded women from joining the study, but because clinicians may not have wished to overburden a patient to consider a lifestyle study as well as a treatment or surgical study. The good uptake may be consistent with the hypothesis that a BC diagnosis may be a “teachable moment” when women may be responsive to making beneficial lifestyle changes.^{8,9} Of 531 early stage breast cancer patients in a US survey, 57% indicated that they would welcome health promotion interventions “at diagnosis or soon after.”¹³

Table 3. B-AHEAD Population Compared With the Total UHSM BC Population.

| | B-AHEAD Population Recruited From UHSM 2009-2011 (N = 300) | Total UHSM Population 2010 Including Those Recruited (N = 532) | P ^a |
|--|--|--|-----------------|
| Age, years, at recruitment ^b | 55.9 (10.1) | 61.2 (12.8) | <.001 |
| Age >70 years ^c | 22 (7.3) | 118 (22.1) | <.001 |
| Distance: home to recruiting center (miles) ^b | 9.8 (7.0) | 10.3 (7.1) | .420 |
| BMI at recruitment (kg/m ²) ^b | 27.5 (5.5) | 27.1 (5.6) | .410 |
| Screen-detected BC ^c | 166 (55.3) | 259 (48.7) | .026 |
| Ethnicity ^d | | | |
| White—all types | 279 (93.3) | 461 (86.7) | .411 |
| Black—all types | 8 (2.7) | 9 (1.7) | |
| Asian—all types | 10 (3.3) | 25 (5.0) | |
| Mixed—all types | 1 (0.3) | 3 (0.6) | |
| Chinese | 0 (0.0) | 5 (0.9) | |
| Other | 1 (0.3) | 2 (0.4) | |
| Missing | 1 (0.3) | 27 (5.1) | |
| BMI category ^d | | | |
| Underweight (<18.5 kg/m ²) | 4 (1.3) | 9 (1.5) | .898 |
| Healthy weight (18.5-24.9 kg/m ²) | 108 (36) | 192 (36.2) | |
| Overweight (25-29.9 kg/m ²) | 105 (35) | 173 (32.5) | |
| Obese (≥30kg/m ²) | 83 (27.7) | 158 (29.8) | |
| Index of multiple deprivation ^{c,e} | | | |
| Greater Manchester quintiles | | | |
| 1 (least deprived) | 125 (41.7) | 168 (31.6) | .004 |
| 2 | 60 (20.0) | 94 (17.6) | |
| 3 | 42 (14.0) | 84 (15.8) | |
| 4 | 35 (11.7) | 70 (13.1) | |
| 5 (most deprived) | 38 (12.7) | 116 (21.8) | |
| Tumor type and grade ^c | | | |
| Invasive/in situ carcinoma | 256 (85.3) / 44 (14.7) | 444 (83.5) / 88 (16.5) | .447 |
| Grade 3 carcinoma | 73 (24.3) | 157 (29.5) | .170 |
| Estrogen receptor positive | 252 (83.9) | 431 (81.1) | .298 |
| Surgery type ^c | | | |
| Mastectomy | 95 (31.7) | 208 (39.1) | .032 |
| Axillary node clearance | 58 (19.3) | 112 (21.1) | .555 |
| Treatment ^c | | | |
| Chemotherapy | 88 (29.3) | 147 (27.6) | .601 |
| Radiotherapy | 213 (71.0) | 325 (61.1) | .004 |

Abbreviations: BMI, body mass index; BC, breast cancer; UHSM, University Hospital of South Manchester; B-AHEAD, Breast—Activity and Healthy Eating After Diagnosis.

^aP values in boldface indicate statistical significance ($P < .05$).

^bMean (SD), independent samples t test.

^cn (% of group), Pearson chi-squared.

^dn (% of group), Fisher's exact test.

^eIndices of Deprivation 2007 Layer Super Output Area Scores were identified from participant postcodes via Geoconvert.¹⁰

This article is one of the few to report uptake to weight control trials among BC patients during adjuvant treatment. Three diet and exercise trials among women scheduled to have adjuvant chemotherapy reported uptake figures of 45%,¹⁴ 65%,¹⁵ and 81%.¹⁶ However, these trials did not clarify whether they approached all eligible women within a certain time frame as we have done, or if they used a selective approach that would have given a higher level of

recruitment. Djuric et al¹⁷ recruited 56% of eligible women to their randomized diet and exercise trial during chemotherapy where recruitment was incentivized with a \$25 payment for each of the 3 study visits. Exercise-only trials during adjuvant treatment have reported uptakes of 63% in Australia,¹⁸ 47% in the United States,¹⁹ 44% in the Netherlands,²⁰ and 11% in the United Kingdom.²¹ Participants on the Australian exercise trial were on average

7 years younger than the general BC population, a finding similar to the B-AHEAD trial.

An important finding was the comparable uptake among women scheduled for chemotherapy versus those who were not. Weight gain is a particular problem for chemotherapy patients⁷ and one might perceive this group to be more reluctant to join such a trial due to higher anxiety levels and treatment burden.²² Factors affecting BC prognosis such as grade or tumor type did not influence uptake. We did, however, find a lower uptake among patients with a mastectomy, which was previously reported in the PACES study, an exercise study during adjuvant chemotherapy for breast cancer.²⁰

The lower average age of recruited patients in this trial and fewer women older than 70 years compared with the whole population is a concern and reflects previous data highlighting lower recruitment of older women to BC clinical trials.²³ This lower uptake may be because older women have declined entry or may reflect appropriate exclusion from the trial due to existing comorbidities. A review of recruitment to 985 breast cancer treatment trials in Canada found that older women were less likely to be eligible for trials, physicians were less likely to have a discussion around trials with older women, and even when meeting eligibility criteria older women were less likely to be recruited.²³ Conversely, a US study found that older breast cancer patients were equally likely to take part in treatment trials if they were eligible.²⁴ Strategies to maximize uptake of older women are important since around a third of newly diagnosed breast cancers in both the United States and England occur in women older than 70 years.^{25,26}

Our study population lived between 2 and 60 miles from the center, with a median distance of 8.6 miles. Distance from home to recruiting center was not cited as a factor for declining study participation. The BEST-Participation-Study, a randomized trial testing an exercise intervention during radiotherapy for breast cancer, which involved attending a central location for an exercise class twice weekly for 12 weeks, reported distance from the center as a significant factor in recruitment.²⁷ The difference between these trials is likely to reflect the fact we deliberately minimized the travel burden to trial participants by hosting the supervised diet and exercise classes in a number of venues proximal to participants' homes around the region. The reimbursement for transport costs in our study may have helped overcome difficulties with travel.

We sought to recruit women of any weight to the B-AHEAD trial and reported a comparable uptake between different BMI categories. This is consistent with an earlier small diet and exercise trial ($n = 9$).¹⁴ The remaining weight control trials among women of any weight have not reported whether there are any differences in uptake between these 2 groups.^{15,28} The BEST-Participation-Study focused on exercise to reduce fatigue and not weight control and also found

no difference in BMI between participants and nonparticipants.²⁷ Ethnicity also did not affect recruitment in this trial; however, our population of BC patients are mainly white Caucasian. Previous UK and US studies have reported reduced uptake among ethnic groups in truly multicultural settings.^{29,30}

We approached women across all levels of deprivation but found a lower uptake among the most deprived as seen in other BC treatment trials.³¹⁻³³ This difference may reflect higher rates of comorbidity thus lower eligibility among more deprived communities.³¹ The survey by Brown and Moyer³⁴ of more than 7000 adults in the United States found a lower understanding of clinical trials among patients with lower income and lower education levels, which may also have affected our recruitment seen here. It is recognized that increased deprivation levels are linked to poorer health behaviors, for example, lower levels of physical activity and higher rates of smoking,³⁵ and previous UK research has found poorer survival after BC among more deprived women.³⁶ Methods for improving engagement in clinical trials among more deprived women must be developed and implemented. There is some evidence from other cancer trials that effective initiatives could include improving readability of leaflets or using video presentations instead of written materials, improved communication skills of health care professionals, and using satellite clinics closer to patients' homes.³³ Schemes to offer financial assistance to reimburse the added cost of travel associated with cancer clinical trials have been shown to improve recruitment among patients with lower incomes and those living further away from the research center and this is an important area that all trials should consider to improve equality.³⁷ The greater uptake among women with screen-detected cancers may also reflect the greater uptake among women from more affluent areas who are more likely to attend screening,³⁸ are more motivated to engage in positive health behaviors and perhaps more interested in diet and exercise.^{39,40}

Previous research has reported that recommendation from the oncologist was an important factor for deciding to enter a trial.⁴¹ We did not collect data on the input of the oncologist within the different recruiting centers. However, future lifestyle trials should engage the support and enthusiasm of oncologists, in addition to the research nurses, to increase the likelihood that they promote the trial to potential participants. Adequate research staff levels are also crucial after patients have been initially approached. Five percent of women approached regarding B-AHEAD were unable to be recontacted within the 12-week time frame for recruitment due to inadequate levels of recruiting staff.

We were unable to produce a CONSORT diagram as we failed to obtain full uptake data in all recruiting centers. This problem has previously been highlighted with cancer exercise trials⁴² and BC treatment trials.⁴³ CONSORT

diagrams allow assessment of studies' generalizability and future studies should endeavor to collect and publish full recruitment data. A limitation of the present paper is that the conclusions we have made for the UHSM patients may not be applicable to the other recruiting centers with different patient populations.

Here we present UK data showing successful recruitment to a diet and exercise trial using the cancer research network, at a challenging time for BC patients soon after surgery, and among patients facing the prospect of chemotherapy. The data describe the population to which the outcomes of the B-AHEAD study, to be published in a future article, will be applicable. Future studies should aim to gather complete uptake data from all centers and explore ways to engage older and lower socioeconomic women in interventions.

Authors' Note

The views expressed are those of the authors and not necessarily those of the National Health Service, the National Institute for Health Research, or the Department of Health.

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Ethical Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The B-AHEAD trial was approved by North West 8 Research Ethics Committee—Greater Manchester East, reference 08/H1013/45.

Declaration of Conflicting Interests

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