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Patient recruitment into a randomised controlled trial of supervised exercise therapy in sedentary women treated for breast cancer

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Abstract

Background: The purpose of this study was to determine the effectiveness of different recruitment strategies used to recruit patients into the Sheffield Exercise and Breast Cancer Trial (SHERBERT), which involved exercise as a therapy, in sedentary women treated for breast cancer. We also evaluated whether the routes of recruitment distinguished patients participating in the trial in terms of socio-economic characteristics, lifestyle behaviours, cancer treatment(s), treatment side effects, length of treatment and time since treatment was completed.
Methods: SHERBERT aimed to recruit at least 114 sedentary women, aged 18–65 years, who had been treated for breast cancer between 1 and 3 years previously, to receive exercise therapy, an equal contact exercise–placebo intervention or usual care. Potentially eligible patients were recruited by postal invitation letters from their treating clinician (i.e. oncologist/surgeon) or by a range of community strategies.
Results: We identified 572 potentially eligible patients via our various recruitment strategies. The response rate to clinician invitation letters was 39.3% (N=148/377), of patients who responded and remained available and interested (N=112) 46.4% (N=52) were eligible to be randomised. The community strategies derived a total of 195 interested responses, of these 66 patients (33.8%) were eligible to be randomised. On the basis of recruitment via clinician invitation letter we estimated the trial recruitment rate amongst eligible patients to be 28.6%. A total of 108 patients were eventually randomised. Responders to clinician invitation letters were more affluent compared to non-responders. Randomised patients recruited via different strategies did not vary significantly in terms of their socio-economic characteristics, lifestyle behaviours or variables related to cancer treatment.
Conclusions: The number of patients randomised was marginally lower than anticipated. We were able to identify and highlight valuable information for planning the recruitment of future trials involving similar populations.

Keywords: Recruitment; Breast cancer; Exercise

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1. Introduction

Breast cancer is the leading cancer amongst women in the United Kingdom (UK) [1]. In recent years there has been a growing interest in the effects of exercise interventions upon quality of life (QoL) in breast cancer patients and other cancer populations as demonstrated by recent systematic reviews and meta-analysis [2–5]; although detailed information about the effectiveness of the recruitment strategies in previous reports has been limited. Patient recruitment into randomised controlled trials (RCT) is recognised as one of the most difficult aspects of the study process since it can be costly and time consuming. It also has implications for the level of statistical power that can be demonstrated by trials and their subsequent value. To date, no study has documented recruitment into an exercise therapy RCT of women treated for breast cancer in the UK. Attributes of patients, including socio-economic and demographic characteristics, may influence willingness to participate in a RCT. Past research has failed to explore possible differences in the characteristics of breast cancer patients who respond and those who do not respond to the invitation to participate in an exercise trial, yet this information can be an important source of bias that must be considered when assessing the validity and generalisability of trial results. It is possible that patients randomised into trials who have been recruited by different methods may vary significantly in terms of socio-economic characteristics, lifestyle behaviours or type of cancer treatment. Specifically, cancer patients who respond to community advertisements to take part in a trial, particularly ones involving lifestyle and behavioural change interventions, may be more motivated, younger and potentially healthier, than cancer patients recruited from health service and hospital contexts.

The Sheffield Exercise and Breast Cancer Trial (SHERBERT) was a three group RCT designed to investigate the effects of an eight week supervised exercise therapy intervention, on QoL and associated measures, in sedentary women treated for breast cancer. SHERBERT included an equal contact exercise–placebo intervention ('body-conditioning') and a usual care group and is the first trial of its kind in the United Kingdom (UK).

The purpose of this study was to determine the effectiveness of different recruitment strategies used to recruit patients into SHERBERT. A further aim was to report on differences in the characteristics of responders and non-responders, to clinician postal invitations to participate in the trial. Most published exercise RCTs involving women treated for breast cancer have taken place in North America where the healthcare systems and possible avenues for recruitment may differ from those in Europe, including the UK. We also examine associations between trial recruitment routes and patient socio-demographic characteristics, lifestyle behaviours and breast cancer treatment regimens.

2. Methods

2.1. Trial design

Detailed information about SHERBERT has been reported previously [6] and will only be described briefly here. Women who had completed treatment for breast cancer were eligible and randomised to receive exercise therapy, an equal contact exercise–placebo intervention or usual care. The interventions lasted 8 weeks. Randomisation was stratified by hormonal therapy use (yes or no) and treatment by chemotherapy (yes or no) and was performed by an independent university clinical trials unit. Power calculations indicated that at least 114 women would need to be randomised into the three groups (at least $N=36$ per group). Recruitment for the trial began in January 2003 and finished in July 2005 (30 months). The South Sheffield Local Research Ethics Committee provided ethical approval for the trial.

2.2. Recruitment strategies and eligibility

2.2.1. Clinician invitation letters

The primary recruitment strategy was by postal invitation letter from patients' treating oncologist or surgeon (herein referred to as clinician invitation) who identified potentially eligible patients from hospital records. A trial information sheet was sent with the invitation letter. A total of four out of six oncologists and surgeons agreed to assist us with recruitment by writing to their eligible patients. Letters were personalised and for logistical reasons were sent in batches of approximately 15–30 throughout the trial recruitment period. Invitation letters were only sent to women aged 18–65 years who were 1 to 3 years post-treatment and had been treated at the main collaborating city hospital. Women with

metastases and inoperable or active loco-regional disease were ineligible and not invited to participate. No attempt was made to contact trial patients who did not respond to their clinician invitation letter.

2.2.2. Community strategies

Secondary recruitment strategies involved media (television, radio and newspapers) advertisements, presentations and trial awareness activities to cancer support groups, breast cancer nurses and by word of mouth. We provided eye-catching posters and leaflets that described the purpose of the trial and listed contact information that were placed in the community (e.g. supermarket checkouts, GP surgeries and libraries). Our launch press release led to local radio and newspaper publicity and several other articles based on interviews with the principal investigator about the study appeared in local and regional newspapers and magazines throughout the recruitment phase; these tended to appear in conjunction with other cancer events that were happening regionally and nationally, for example breast cancer awareness month and Race for Life events. A three-minute feature about the study was aired on regional BBC television news programmes on four occasions (including prime time) over one day, approximately half way through the trial recruitment period. Members of the trial team made presentations to regional breast cancer care support groups and organisations on five occasions throughout recruitment phase. Leaflets were also sent to breast cancer nurses at the start of the study requesting referral of potentially eligible patients. On two occasions, members of the trial team made presentations to breast cancer nurses attending information/training days and requested that they publicise the study to potentially eligible patients. All trial literature, presentations and advertisements specified that only sedentary women 18–65 years who were between 1–3 years post-treatment were eligible for the study. No other trial eligibility criteria were specified on the trial literature.

Patients recruited via community strategies verbally reported information about their age, diagnosis and cancer treatment eligibility as outlined above, letters to potential patients treating oncologist/surgeon confirmed this. All recruitment strategies ran concurrently. Therefore, patients may have been made aware of the study by more than one recruitment strategy, but we consider the primary strategy to be that reported by patients when they initially contacted the trial office to register their interest in participating. Women not treated at the main city hospital or seen by one of the oncologists/surgeons who did not agree to assist with recruitment would have only become aware of the study via our community activities. Regardless of this, all patients had to be residents within the trial ethical approval catchment areas to be eligible.

2.2.3. Further eligibility screening

For all recruitment routes, interested patients contacted the study team by calling a dedicated telephone line. Specifically, patients who were eligible according to age, diagnosis and treatment criteria were then screened for their current exercise behaviour; only sedentary women at the pre-contemplation, contemplation and preparation stages of change for exercise [7] were eligible. Patients also had to be willing to attend exercise sessions three times per week to be eligible for the trial. Potentially eligible patients were informed they had a 33% chance of being randomised to one of the three trial groups.

Patients still deemed eligible at this point were subsequently invited to attend a familiarisation session at the University centre where the trial took place, this also provided the opportunity for patients to meet with trial staff and to ask questions. During the familiarisation session potentially eligible patients were further screened for co-morbidities and contra-indications to exercise (e.g. uncontrolled hypertension) using the Physical Activity Readiness Questionnaire (PAR-Q) [8]; such patients were not automatically excluded at this point, but were asked to contact their general practitioner for approval to enter the trial. Women not wanting to be randomised to usual care or exercise–placebo intervention were also not eligible for the trial and were not randomised. Patients deemed both eligible and interested were asked to provide written informed consent after attending the familiarisation session and were then subsequently scheduled to visit the trial Centre for their baseline assessment of outcomes, after which patients were randomised to one of the trial conditions.

2.2.4. Recruitment incentives

As a recruitment incentive, patients were informed that if they were randomised to usual care they would be able to attend between three and five exercise sessions at the Centre free of charge after they had completed their final follow-up assessment of outcomes 6 months from baseline. We hoped this would encourage the usual care patient to remain sedentary throughout the trial period. We anticipated women who might wish to participate would need to organise their time around household and childcare responsibilities and the working week. Recruitment times and appointments

were therefore flexible and available throughout the day, including evenings and weekends. Patients who consented were reimbursed £2.50 in travel expenses for each visit to the centre, this included familiarisation, assessments and intervention visits. All randomised patients received a £20 sports shop voucher on completion of the intervention phase of the study.

2.2.5. Measures

At baseline all patients provided information concerning their medical history specific to their cancer diagnosis and treatment regimen, use and type of hormonal therapies and the presence of lymphoedema. Body mass index (BMI), percentage body fat (using bioelectrical impedance), aerobic exercise capacity (estimated VO_2max) and stage of change for exercise [9] were also recorded. Concerning recent behaviour of physical activity, the following question was asked: 'How often have you participated in one or more physical activities for 20 to 30 min per session during your free time in the last three months?' Patients were then asked to indicate one of a series of exercise frequencies: never, about once per month, about two or three times per month, about once per week, about twice per week, about three times per week and about four times or more per week. This method for assessing exercise behaviour was based on previous research [10,11]. The Index of Multiple Deprivation 2004 (IMD) rank score (based on residential postcode) was calculated for each patient [12]. This measure of deprivation encompasses seven domains: income, employment, health and disability, education, skills and training, barriers to housing and services, living environment and crime.

2.3. Data analyses and statistical methods

The randomisation yield by clinician invitation is based on the number of women interested and randomised divided by the number of letters sent. For all other recruitment routes randomisation yields are based on the number randomised, divided by the number of interested responses. The estimated recruitment rate of eligible patients (total randomised/number interested and eligible) was based on the assumption that the trial eligibility rate for responders and non-responders would be the same. Those who did not respond and those who withdrew their interest after their initial enquiry/were not further contactable are considered as a discrete group since these women did not demonstrate a firm interest and willingness to enter the trial.

Ranked data for IMD were converted to quartiles for analysis; quartile one representing the least deprived group and quartile four the most. For analysis purposes we combined the various community recruitment routes of cancer care support groups/breast cancer nurses, media advertisements and word of mouth into a single route of recruitment, herein referred to as community advert. Patients were categorised into one of four groups according to the frequency of exercise reported (never, ≤ 3 times per month, once per week and $\geq$ twice per week).

We explored whether responders and non-responders to clinician's invitation letters differed by age and IMD using independent *t*-tests and a chi-squared analysis respectively. A series of independent *t*-tests (continuous variables) or chi-squared tests (dichotomous variables) were used to examine differences in randomised patients' characteristics according to their route of recruitment (i.e. clinician invitation letter or community advert). Due to multiple testing, $p < 0.01$ was used to denote a significant difference between routes of recruitment and patients' characteristics.

3. Results

3.1. Response rates

We were able to identify 572 potentially eligible patients using all the trial recruitment strategies (See Fig. 1). The response rate to clinician invitations was 39.3% ($N = 148/377$), of these 24.3% ($N = 36/148$) withdrew their interest or were not reachable after initial contact with the trial office. Thus 112, who replied to clinician invitations, remained interested and potentially eligible in the trial. Our community recruitment strategies produced the following numbers of interested responses; cancer care support groups ($N = 22$); media adverts ($N = 159$); and word of mouth ($N = 14$). When combined, the total number of interested responses via our community strategies was 195; of these 22.6% ($N = 44$) withdrew their interest/were not reachable after their initial contact with trial office. A total of 151 patients identified from community strategies, remained interested and potentially eligible. Of patients interested in participating in the trial and recruited via oncologist invitation letter ($N = 112$), 52 were considered eligible. For community adverts, of interested patients ($N = 151$), 66 were considered eligible.

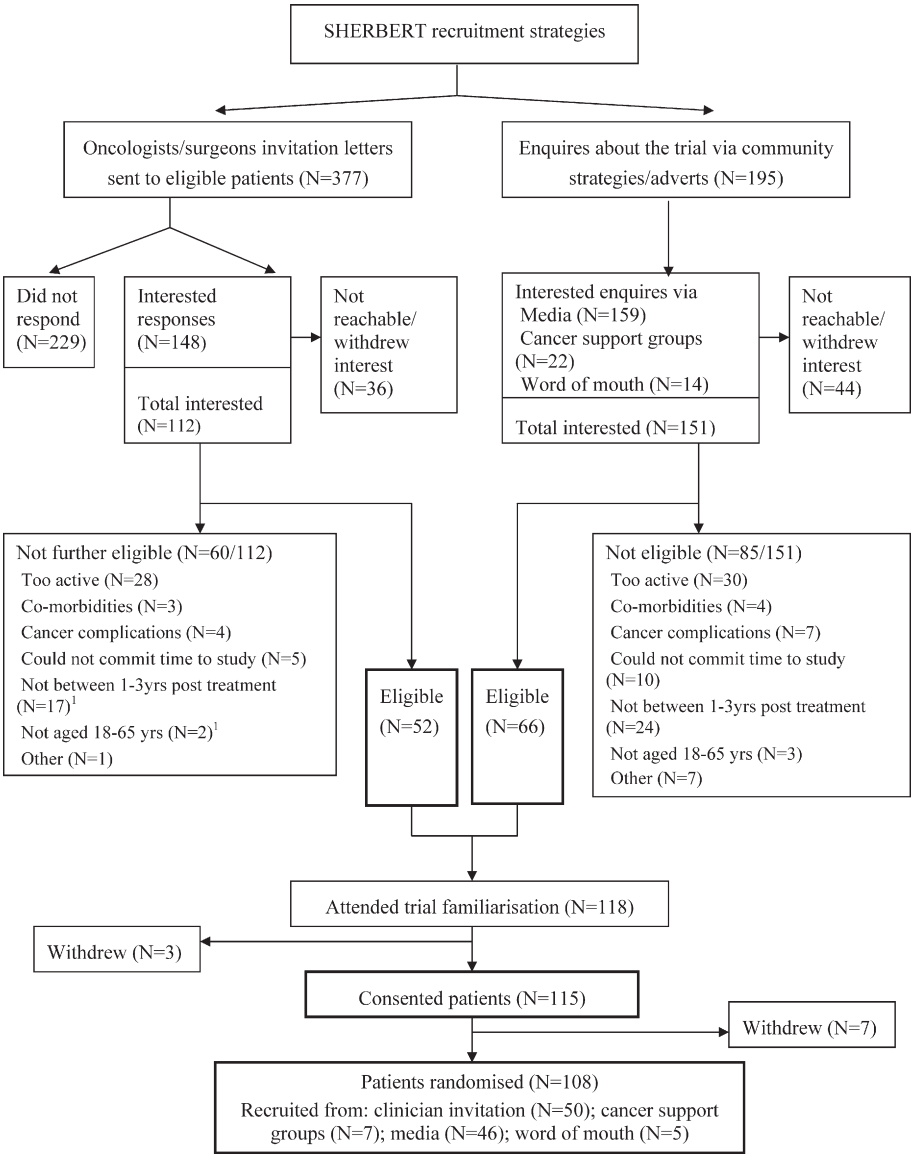

Fig. 1. Flow diagram of patient recruitment. (*Notes*: [1]Some women delayed responding to their oncologist/surgeon invitations and were then subsequently ineligible to take part.)

3.2. Reasons for ineligibility

The reasons for ineligibility across recruitment strategies, in order of prevalence, were: being too active ($N=58/572$, 10.1%), not 12–36 months post-treatment ($N=41/572$, 7.2%), not being able to commit to an exercise programme three times per week ($N=15/572$, 2.6%), cancer related medical complications ($N=11/572$, 1.9%), co-morbidities that contra-indicated exercise participation ($N=7/572$, 1.2%), not aged 18–65 years (5/572, <1%), other reasons (e.g. male) and not living in the areas covered by the ethics committee approvals (8/572, 1.4%).

3.2.1. Randomisation yields

The randomisation yield (total randomised/number of letters sent) for clinician invitation letters was 13.3% (50/377). Randomisation yield rates for community recruitment strategies (total randomised/number of enquires) were 31.8% (7/22) (cancer support groups), 28.9% (46/159) (media) and 35.7% (5/14) (word of mouth). When all the

Table 1
Socio-demographic status, lifestyle behaviours and breast cancer treatment regimens of randomised patients according to route of recruitment

	Clinician invitation letter ($N=50$)	Community adverts[a] ($N=58$)
	Mean (95% CI) or N (%)	Mean (95% CI) or N (%)
Age, years	51.2 (49.0–53.4)	50.9 (48.4–53.4)
Body mass index (kg/m^2)	29.0 (27.8–30.1)	28.2 (26.9–29.5)
Percentage body fat	40.8 (39.4–42.1)	40.0 (38.2–41.8)
Weight (kg) ($N=106$)	77.5 (73.2–80.3)	75.8 (71.6–78.0)
Maximal oxygen consumption[b] ($N=102$)	28.1 (27.6–29.9)	30.1 (28.6–31.9)
Smoking status		
Smoker	5 (10.2)	4 (6.9)
Non-smoker	44 (89.8)	54 (93.1)
Missing	1 (2.0)	0
Ethnicity		
White	50 (100)	56 (96.6)
Non-white	0	2 (3.4)
Index of multiple deprivation		
Quartile 1 (least deprived)	11 (22.0)	14 (24.1)
Quartile 2	15 (30.0)	16 (27.6)
Quartile 3	13 (26.0)	16 (27.6)
Quartile 4 (most deprived)	10 (20.0)	12 (20.7)
Missing	1 (2.0)	0
Stage of change for exercise		
Pre-contemplation and contemplation	29 (58.0)	29 (50.0)
Preparation	21 (42.0)	29 (50.0)
Physical activity		
Never	16 (32.0.)	14 (24.1)
$\leq$3 times per month	16 (32.0)	15 (25.9)
Once per week	12 (24.0)	17 (29.3)
$\geq$Twice per week	6 (12.0)	12 (20.7)
Employment status		
Employed	38 (76.0)	34 (58.6.)
Not employed	10 (20.8)	22 (37.9)
Missing	2 (4.0)	2 (3.4)
Education		
Secondary and A levels	19 (38.0)	28 (48.3)
Degree	12 (24.0)	12 (20.7)
Other/professional	16 (32.0)	15 (25.9)
Missing	3 (6.0)	3 (5.2)
Marital status		
Married/cohabitating	42 (84.0)	48 (82.8)
Single, widowed, divorced	8 (16.0)	10 (17.2)
Lymphoedema		
Yes	23 (46.0)	22 (37.9)
No	27 (54.0)	36 (62.1)
Number of children		
No children	5 (10.0)	7 (12.1)
Children	42 (84.0)	49 (84.5)
Missing	3 (6.0)	2 (3.4)
Using hormone therapy		
Yes	36 (72.0)	43 (74.1)
No	14 (28.0)	15 (25.9)
Treated with chemotherapy		
Yes	39 (68.2)	41 (70.7)
No	11 (31.8)	17 (29.3)
Treated with surgery		
Mastectomy	25 (50.0)	32 (55.2)
Breast conserving surgery	25 (50.0)	26 (44.8)

Table 1 (*continued*)

	Clinician invitation letter ($N=50$)	Community adverts[a] ($N=58$)
	Mean (95% CI) or *N* (%)	Mean (95% CI) or *N* (%)
Treated with radiotherapy		
Yes	41 (82.0)	43 (75.4)
No	9 (18.0)	14 (24.6)
Missing	0	1 (1.7)
Months post-treatment	18.4 (16.2–20.6)	16.6 (15.2–18.1)
Length of treatment (months)	7.8 (6.5–9.8)	8.1 (7.0–8.9)

[a] This category included women recruited by media activities, word of mouth and cancer support groups.
[b] ml/kg/min.

community strategies were combined into the single category of community advert, the overall randomisation yield was 29.7% (58/195). See Fig. 1.

3.2.2. Recruitment rate (clinician invitation letter)

Of patients ($N=112$) who responded and remained available and interested, 46.4% ($N=52$) were eligible to be randomised. If we assume a similar eligibility rate for non-responders and those not reachable after making initial contact with the trial office, it is estimated that 123/265 (i.e. 46.4%) of these patients would have been eligible had they been interested in taking part in the trial. Therefore a total of 175 patients were estimated to be eligible ($N=123$ non-responders/not reachable but estimated to be eligible plus $N=52$ eligible patients). Thus, on the basis that 175 ($N=123+52$) patients were eligible and 50 patients recruited by clinician invitation were eventually randomised, the estimated trial recruitment rate amongst eligible patients is 28.6% ($N=50/175$). Refer to Fig. 1.

3.2.3. Responders and non-responders (clinician invitation)

We found no significant differences in the age of responders ($N=129$, mean=52.4 years) and non-responders ($N=221$, mean=54.2 years) to clinician invitation letters. There was a trend for responders ($N=132$) to be more affluent than non-responders ($N=216$) ($\chi^2=9.80$, $p=0.02$). Numbers vary due to missing values.

3.2.4. Consenting and randomised patients

After completing telephone screening, a total of 118 patients were deemed fully eligible. Three patients withdrew from the study on completing the familiarisation session, resulting in 115 patients providing consent. Of consenting patients, a further seven withdrew prior to randomisation, therefore 108 patients (94% of consenting patients) were randomised over 30 months; this equates to 3–4 (mean=3.6) patients per month. Of randomised patients, 50 were recruited from clinician invitation letters, 7 from cancer care support groups, 46 from media activities and 5 from word of mouth (Fig. 1).

3.2.5. Associations between route of recruitment and randomised patient characteristics

Chi-squared tests were not performed for the variables ethnicity, smoking status and number of children as $\geq 25\%$ of cell frequencies were less than five (Table 1). No significant differences in socio-economic characteristics, lifestyle or variables related to cancer treatment were found between those patients recruited by clinician letter and those recruited by community adverts (Table 1).

4. Discussion

4.1. Response rates and eligibility

The response rate to clinician invitation letters (39%) was encouraging and suggests many breast cancer patients in the UK are reasonably motivated to participate in exercise trials. This also means that 61% of patients invited by their oncologist or surgeon to take part did not respond or were not reachable by the research team after the patient made initial contact. There may be a number of reasons why women declined to respond and it has been suggested that the physically demanding nature of exercise trials may make them less attractive to cancer patients compared to other types

of behavioural interventions [13]. It is possible that non-responders were already engaging in a physically active lifestyle and believed they had little to gain from participating in SHERBERT. Based on the number of responders excluded as being too active to benefit from the intervention ($N=28$) this certainly seems plausible for some women, although it is doubtful whether this explanation would account for the majority of non-responders since studies have consistently shown that physical activity levels reduce significantly after breast cancer diagnosis [14,15] and remains low years after treatment is completed [16]. Moreover, in the general population, rates of inactivity are high in women [17], so it seems plausible that many women who received an invitation to enter the trial from their treating clinician were indeed sedentary. Other reasons may have included fears about exercising after cancer diagnosis, post treatment fatigue, depression, social physique anxiety and medical complications limiting movement (e.g. lymphoedema and breast reconstruction). Acknowledging that fatigue may affect cancer patients for many years after treatment [18], another explanation may be related to the perception that 'rest is best' and therefore it is preferable to concentrate on conserving, rather than expending energy; participation in exercise may not be compatible with such health beliefs. To help relieve some of the concerns that breast cancer patients might have about engaging in exercise, future trials might benefit from including an informational leaflet that specifically addresses potential issues of concern when inviting patients by clinician invitation letter, as well as highlighting the potential benefits of exercise. Alternatively, providing a point of contact for women to talk to a health professional about their concerns and anxieties as they relate to exercise might also help with recruitment to such trials. For these reasons it could be that approaching patients during follow-up hospital clinic visits would result in higher recruitment figures than by clinician invitation letters because patients' fears about exercise could be addressed directly by clinicians during appointments. That said, recruiting patients in this way would be much more time consuming and costly, relative to clinician invitation letters.

4.2. Responders and non-responders

We initially thought it might be more difficult to recruit older and less affluent women because of the nature of the trial. However, we found no significant differences in the age of responders and non-responders to the clinician invitation letters. Our results suggest that level of deprivation may influence breast cancer patients' decisions to enter a RCT of exercise therapy; this is in broad agreement with evidence [19] that has reported socio-economically deprived individuals are less likely to engage in a physically active lifestyle.

4.3. Recruitment rate

Whilst our estimated recruitment rate of 28.6% by oncologist invitation letter was acceptable, this might also suggest that we have recruited a sample of atypical women. We do not believe this is the case for a number of reasons however. The sample population has similar characteristics to those reported in the breast cancer populations generally. For example, the highest age-specific incidence rates of breast cancer in the UK are in women 50–59 years [1], the mean age of trial participants was 51 years. We only recruited sedentary women; a typical health behaviour in women treated for breast cancer [14,15]. Our sample had high mean BMI and percentage body fat values and we have noted from previous reports [20,21] that women experience significant gains in weight after treatment for breast cancer. Related to this, recruitment to SHERBERT was affected by strict eligibility criteria. Most notably, many potential patients were excluded because they were too active. While contributing to our recruitment challenges, this restriction allowed for the assessment of the impact of exercise on trial outcomes in women who were not already benefiting from exercise.

Relatively few trials involving an exercise intervention with cancer patients have reported their recruitment rates but of those that have, less than 40% of eligible patients are typically recruited [22–25]. One exercise trial involving a mixed population of cancer survivors [26] has been able to recruit 80% of eligible patients although a control arm was not included. A recent exercise trial involving women undergoing treatment reported a recruitment rate of approximately 64% [27] but the intervention was home-based which is likely to have facilitated recruitment of eligible patients. A very high recruitment rate (94%) was recorded in a recent trial [28] conducted in Canada of the effects of an oncologist's recommendation to exercise in newly diagnosed breast cancer survivors upon self reported physical activity over 5 weeks from baseline. However, this study did not require patients to attend an exercise facility over several weeks or to be willing to commit to being physically active over the intervention period. The low commitment required of participants over a relatively short period of time is also likely to have facilitated the unusually high recruitment in this particular trial.

4.4. Route of recruitment and patient characteristics

We did not find that randomised patients recruited from different recruitment strategies varied significantly in terms of their socio-economic status, lifestyle behaviours, type of cancer treatment and treatment side effects. This is very promising since it suggests that any subsequent trial effects are unlikely to be influenced by the possibility that more motivated (and possibly healthier) women recruited via the community strategies responded differentially to those recruited via clinician invitation letter. It was very encouraging to note that women who were randomised were comparable across the different categories of deprivation. We did not want financial concerns to be a barrier to participation in the trial for less affluent women and we tried to minimise the potential for this issue to occur by offering all women reimbursement of their travel expenses and a £20 sports shop voucher on completing the intervention phase of the study; this may have helped to encourage a higher number of less affluent women to take part than would have been the case otherwise.

4.5. Strengths and weaknesses/future research directions

This report has several methodological weaknesses that should be considered when interpreting the findings and planning future research. The assumptions concerning the eligibility rate of non-responders may be considered by some as optimistic but given that oncologists and surgeons had already applied most of the key eligibility screening criteria prior to inviting patients, our assumptions seem reasonable. The trial was only concerned with recruiting women aged up to 65 years; therefore our recruitment data may not be applicable to older women who have been treated for breast cancer. We did not calculate the relative costs of our recruitment strategies but such information would have made a useful contribution in determining their effectiveness. As our trial recruitment strategies ran concurrently we must also consider that our estimated recruitment rate of 28.6% is in fact an underestimate. This is because some eligible women may have been made aware of the trial via one of the community routes prior to the date by which they would have been sent their clinician invitation and/or become eligible. Thus, it is possible such women would also have agreed to enter the trial on receiving their clinician letter of invitation, had they received this first. Future trials that use clinician invitations as the only method of patient recruitment may obtain a higher recruitment rate than documented here. We did not systematically log the socio-economic characteristics of women who enquired about the study via our community strategies and who were not eligible, this would have been useful data and future studies should allow sufficient costs in their recruitment budget to do this. We have noted that previous exercise trials [26,27,29] have recruited very small samples of Black and ethnic minority women; other exercise and cancer trials have not stated this information [22,23,28]. SHERBERT also recruited a low proportion of Black and ethnic minority women, further suggesting that recruitment of these populations of women into exercise trials is difficult. Greater efforts need to be made to actively engage these populations in future, perhaps by outreach activities to the target communities and by engaging community advocates/leaders from within ethnic minority communities. The production of trial adverts (and possibly clinician invitation letters where patients' ethnicity is known) in languages other than English might also prove useful. To ensure that fears about contact with men during exercise trials does not become a barrier to recruitment for women affiliated with particular religions/cultures, trial coordinators need to consider making female exercise instructors/leaders available at all times, and this information should be made explicitly clear in trial recruitment literature. Researchers should also consider that there might well be demographic and psychosocial determinants of physical activity experienced by ethnic minority women [30].

Our strengths are that we assessed the merits of a range of recruitment strategies, which previous trials have failed to report. We have also attempted to place our subsequent trial findings in context by assessing differences in responders and non-responders to clinician invitations. We also provide unique evidence about the associations between methods of recruitment of breast cancer patients randomised into an exercise trial, and their characteristics, lifestyle behaviours, treatment regimens and side effects, which previously has been an understudied area of research.

5. Conclusions

In conclusion, both clinician invitation letters and the community strategies contributed substantially to our recruitment process. It does seem that affluent women treated for breast cancer are more likely to respond to the invitation from their oncologist/surgeon than their less affluent counterparts. Method of recruitment in to SHERBERT

was not related to patients' characteristics. The trial recruitment rate was generally acceptable, yet likely to be a conservative estimate, which is encouraging. We were able to identify and highlight valuable information for the of planning recruitment to future exercise intervention trials involving breast cancer patients, but given recruitment was slower than had been anticipated with 108 eligible and randomised patients recruited, more information is needed to maximise the response and recruitment rates from various recruitment strategies, including those that were not assessed here.

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