Title: Design and implementation of the Exercise for Health trial – a pragmatic exercise intervention for women with breast cancer.

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Abstract

Background Exercise for Health was a pragmatic, randomised, controlled trial comparing the effect of an eight-month exercise intervention on function, treatment-related side effects and quality of life following breast cancer, compared with usual care. The intervention commenced six weeks post-surgery, and two modes of delivering the same intervention was compared with usual care. The purpose of this paper is to describe the study design, along with outcomes related to recruitment, retention and representativeness, and intervention participation.

Methods: Women newly diagnosed with breast cancer and residing in a major metropolitan city of Queensland, Australia, were eligible to participate. Consenting women were randomised to a face-to-face-delivered exercise group (*FtF*, n=67), telephone-delivered exercise group (*Tel*, n=67) or usual care group (*UC*, n=60) and were assessed pre-intervention (5-weeks post-surgery), mid-intervention (6 months post-surgery) and 10 weeks post-intervention (12 months post-surgery). Each intervention arm entailed 16 sessions with an Exercise Physiologist.

Results: Of 318 potentially eligible women, 63% (n=200) agreed to participate, with a 12-month retention rate of 93%. Participants were similar to the Queensland breast cancer population with respect to disease characteristics, and the randomisation procedure was mostly successful at attaining group balance, with the few minor imbalances observed unlikely to influence intervention effects given balance in other related characteristics. Median participation was 14 (min, max: 0, 16) and 13 (min, max: 3, 16) intervention sessions for the *FtF* and *Tel*, respectively, with 68% of those in *Tel* and 82% in *FtF* participating in at least 75% of sessions.

Discussion: Participation in both intervention arms during and following treatment for breast cancer was feasible and acceptable to women. Future work, designed to inform translation into practice, will evaluate the quality of life, clinical, psychosocial and behavioural outcomes associated with each mode of delivery.

Keywords: Breast cancer, Exercise, Rehabilitation, Randomised controlled trial, Physical activity

1. Introduction

As survival rates following breast cancer have improved [1], so too has our understanding of the diverse physical and psychosocial side-effects that occur during and following treatment. Findings from studies on women following a diagnosis of breast cancer highlight that treatment-related side-effects are common, especially fatigue, pain and upper-body morbidity [2-5], and are highest during active treatment periods, which is completed for the majority of women by 6 months post-diagnosis [4] . However, side-effects also persist well beyond the treatment period [6-8], despite overall improvements in quality of life (QoL) [9, 10]. Safe and effective evidence-based strategies are needed to prevent or attenuate treatment-related sequelae and to optimise the recovery of breast cancer survivors.

Evidence to support the effectiveness of exercise programs in reducing symptoms and improving QoL after a cancer diagnosis comes from over 80 exercise intervention studies involving cancer survivors, particularly those with breast cancer. Synthesised in systematic reviews [11-18] and meta-analyses [19-22], results suggest that physical activity interventions implemented during and following treatment can prevent decline or improve cardio-respiratory fitness, body composition, skeletal health, immune function, strength and flexibility, body image, self-esteem, mood, and chemotherapy completion rates. These interventions have also been associated with reductions in hospitalisation duration, stress, depression, anxiety and the number and severity of side-effects, including nausea, fatigue and pain. Evidence from cohort studies also suggests a survival benefit among those who remain or become physically active following their diagnosis [23-25].

However, despite these benefits, the majority of breast cancer survivors remain or become insufficiently active following a breast cancer diagnosis [26-30]. Thus, we need to better understand how to assist women to become and stay appropriately active during and following breast cancer treatment. The majority of exercise intervention trials among women with breast cancer have evaluated interventions delivered in supervised, clinic-based settings, often in a group format [31]. While these have provided strong evidence of efficacy in controlled trials with selected volunteer samples, they tell us less about the extent to which such interventions might generalise to the very broad and heterogeneous population of women with breast cancer, or about the extent to which they could be integrated into clinical care [32].

Exercise for Health (EfH) is a pragmatic trial that evaluates feasibility and effectiveness of two modes of exercise intervention delivery that, if successful, could be integrated within clinical practice. The eight-month intervention was designed to assist women during active treatment periods (up to 6 months post-diagnosis), to more quickly and fully recover following treatment, and to develop the skills and confidence to become and stay physically active for the longer term. The purpose of this paper is to describe the design and methods of the EfH trial and to evaluate the feasibility of implementation (recruitment and retention), the generalisability of findings (representativeness of sample) and to describe intervention participation.

2. Trial Design

EfH was a randomised controlled trial, evaluating an eight-month exercise intervention delivered either face-to-face or over the telephone by tertiary-qualified Exercise Physiologists/Kinesiologists, commencing six weeks post-surgery for newly

diagnosed breast cancer patients. The trial (ACT RN: 012606000233527) was reviewed and approved by the Institutional Review Board (ie, Ethics Committee) at Queensland University of Technology and at each of the participating hospitals.

2.1. Eligibility criteria

Women with a first diagnosis of invasive breast cancer between October 2006 and June 2008, aged 20 to 69 years, and treated at one of four Brisbane hospitals were eligible for participation. These hospitals were purposely chosen as they represent the private and public Queensland hospitals with the highest caseloads, together treating 28.4% of those diagnosed with breast cancer in Queensland in 2007. To be eligible, women also had to reside within 30 km of the Brisbane central business district to enable participation in the face-to-face intervention group. Exclusions were made for women who were pregnant or lactating, were not willing to accept random assignment, had plans for additional surgery (e.g., breast reconstruction) during the study period, had poor understanding of written or spoken English, or had a medical condition that would prohibit participation in the exercise intervention (e.g., unstable hypertension).

2.2. Recruitment process

Breast Care Nurses and Physiotherapists at the participating hospitals were asked to introduce the trial to all women receiving surgery for breast cancer and to ascertain consent for contact details to be passed to researchers. This typically occurred while patients were in hospital for breast surgery or during the first surgical follow-up visit. Researchers then contacted potential participants 3-4 weeks post-surgery to discuss the trial in more detail and to obtain informed consent. Eligibility criteria were confirmed during a screening telephone interview, and information relevant to the implementation of an exercise intervention was collected, including future treatment plans, the status of pre-existing co-morbid conditions (e.g. heart conditions, diabetes, asthma, arthritis), current medications and exercise history prior to diagnosis. Baseline assessment was scheduled during this call.

2.3. Randomisation

Following baseline assessment, women were randomised individually via a computer-generated, unblocked, sequence of random numbers to obtain similar numbers of women in the face-to-face-delivered exercise intervention group (*FtF*), telephone-delivered exercise intervention group (*Tel*) and usual-care group (*UC*).

2.4. Exercise intervention

The intervention was implemented by Tertiary-trained Exercise Physiologists who are allied health professionals with skills and experience in exercise science. The Exercise Physiologists who worked on this study also underwent a 2-week training program, devised and developed by chief investigators, to ensure all staff had the required specialist skills for working with women with breast cancer and to ensure that program delivery was implemented in a standardised manner required for research.

The eight-month exercise intervention encouraged women to exercise at least four days per week, accumulating at least 45 minutes of moderate-intensity physical activity on these days (Table 1). Aerobic-based exercise was to be included in each session, while strength-based exercise was encouraged at least twice per week. To

arrive at this goal, intervention participants had 16 sessions scheduled with their designated Exercise Physiologist, during which time the intervention was gradually progressed by incorporating different exercise types and by increasing exercise intensity and duration (Table 1). While the overall goal of the program was the same for each participant, the exercise starting parameters and rate of progression towards the goal was individualised to account for the participant's baseline functional capacity, the presence and severity of treatment-related side-effects, exercise preferences and previous exercise history.

The Exercise Physiologists used a patient-centred approach by following the Chronic Disease Self-Management Intervention Model (CDSM) adapted from our previous work [33] to guide each session. The CDSM emphasises collaborative interactions, with the Exercise Physiologist offering support and guidance for increasing physical activity, while acknowledging the participant's expertise in knowing what works best for her in the context of her life. Each session assessed exercise progression during the previous period and ascertained participant-report of presence or change in treatment-related symptoms. In the instance that symptoms were adversely progressing, the participant was referred back to their breast care nurse, who then managed the participant according to usual care, which may have entailed referral to the treating clinician and/or physiotherapist. No participants were stopped from participating in this trial though as a consequence of presence or change in symptoms. During the sessions with the Exercise Physiologist, exercise achievements in the previous period were acknowledged, barriers resolved, subsequent exercise goals discussed and necessary follow-up support identified, with all session details recorded in the participant's case management folder. The responsibility for progress towards or maintenance of study goals was driven by the Exercise Physiologist during the first third of the eight-month intervention, shared by the participant and Exercise Physiologist during the second third, and the responsibility of the participant during the final third of the program. This approach allowed for women to be guided by the Exercise Physiologist during active treatment periods, when treatment-associated symptoms were most likely changing in type and/or severity. It allowed participants to develop exercise knowledge and confidence during the first part of the intervention, so that by the end, participants were aware of what and how much exercise they should be doing as well as what strategies they needed to optimise activity. Reduced reliance on the Exercise Physiologist was also facilitated by tapering the frequency of Exercise Physiologist contact over the eight-month period (once/week for 2 months, once/fortnight for 2 months and once/month for 4 months), and for those in the *FtF* by delivering the final two contacts by telephone. Of note, the exercise intervention was the same for those in the *FtF* and *Tel* group, with only the mode of intervention delivery being different. Caseloads for each Exercise Physiologist were also balanced with respect to *FtF* and *Tel* participants.

Study workbook and exercise tracker

Prior to intervention commencement, those in the exercise groups were mailed background information and a photograph of their assigned Exercise Physiologist (to help establish rapport between the Exercise Physiologist and the participant, particularly for those in the *Tel* group who never met their Exercise Physiologist face-to-face), an exercise workbook and an exercise tracker and pen. The workbook and exercise tracker were mailed to all *UC* participants following study completion.

The exercise workbook (available on request) was developed by the study investigators with expertise in breast cancer, exercise science and behavioural science, and was used to supplement intervention sessions with the Exercise Physiologist. The workbook contained information on a range of topics, including treatment-related side-effects, reasons for being active during treatment, exercise safety, types of activity and how much to do, exercise intensity and how to progress exercise. These topics were discussed during the first month of the program and were revisited as needed throughout the intervention. The workbook also contained a series of strength and flexibility-based exercises that were performed during face-to-face sessions or were talked through over the telephone. The exercise tracker was used by participants to plan and self-monitor weekly physical activity, but its use was not a compulsory component of the intervention.

2.5 Usual care

Those allocated to the usual care group participated in all data collection assessments (as described below) but did not receive any study exercise-intervention related material until study completion. They may have received ad hoc information related to exercise following breast cancer from their treating hospital, breast cancer support group or other source. If the usual care group questioned study assessors about exercise, they referred participants back to their breast cancer nurse for advice.

2.6. Data collection: timing and outcomes assessed

Three assessments were scheduled at: baseline/five weeks post-surgery (pre-intervention); six months post-surgery (mid-intervention and following the period of more regular contact with the Exercise Physiologist for those in the exercise groups), and 12 months post-surgery (approximately two months post-intervention) (Figure 1). In this manner, we are able to compare study outcomes of those in this sample with those from representative, prospective cohort studies with similar 6- and 12-months post-diagnosis endpoints, while also being able to evaluate whether the intervention reduces treatment-related side-effects, optimises recovery and leads to longer-term behaviour change. Study outcome data were collected via clinical assessment and by completion of participant-administered and interviewer-administered surveys using previously validated protocols and instruments. The primary outcome for the study is QoL[34], while secondary outcomes include physical activity levels[35], functional capacity[36, 37], and presence and severity of treatment-related symptoms such as fatigue[38], pain[39] and lymphoedema[4]. All clinical assessments were conducted by an Exercise Physiologist blinded to participant study group, and participants were instructed to not reveal their allocation. Information relating to participant characteristics (potential confounding variables) including personal (age, body mass index, socioeconomic status, number of children, working status, treating hospital), disease (type, tumour size and grade, stage and lymph node, oestrogen, progesterone and herceptin status) and treatment (chemotherapy, radiation therapy, hormone therapy and extent and laterality of surgery) characteristics was collected at baseline only via medical chart review or the participant-administered questionnaire.

2.7. Sample size calculations

A priori sample size calculations were based on the primary outcome, QoL, as measured by the Functional Assessment of Cancer Therapy, Breast (FACT-B+4) questionnaire [34]. Specifically, to detect a clinically important difference in overall QoL between groups or change over time of 8 units (standard deviation of change in

FACT-B+4 over 12 months = 10 units) [34]., with 90% power and 5% type I error (two tailed), a minimum of 40 women per group was required. However, sample size was inflated by 20% to allow for attrition, and an additional 20% for multivariable modelling, yielding our target sample size of approximately 60 women per group.

2.8. Statistical analysis

Recruitment rates represent the number of consenting and participating women divided by the number of eligible women approached to participate. Retention rates were calculated by dividing the number of participants who completed follow-up testing by the number who completed baseline testing. Participant characteristics were compared with data from the Queensland Cancer Registry to determine potential generalisability of study findings. Baseline characteristics for those assigned to the intervention and usual care groups were compared to determine success or otherwise of the randomisation process. Characteristics were described using mean and standard deviation for Normally-distributed, continuous outcomes; median, minimum and maximum for non-parametric continuous data; and proportions for categorical outcomes. *A priori*, absolute baseline differences of approximately 10% for all personal, treatment and disease characteristics were considered clinically relevant. Intervention participation was calculated by describing the level of participation in the scheduled intervention sessions with the Exercise Physiologist using the median (minimum, maximum). We considered *a priori*, that participation in at least 75% of these sessions was considered adequate exposure with an Exercise Physiologist to observe an intervention effect.

Future analyses of intervention impact on primary and secondary outcomes will proceed according to intention-to-treat principles (n=194). That is, participants will remain flagged according to their treatment allocation at baseline. Missing data will not be imputed as they are unlikely to be missing at random. Multivariate, repeated-measures models will consider group, time, and group by time interaction effects, adjusting for the influence of established and other identified confounders. Depending on how well assumptions are met, we anticipate using a generalised estimating equations framework for these analyses.

3. Results

3.1. Recruitment and retention

Of the 402 names of potentially eligible participants received from the Breast Care Nurses at the treating hospitals (Figure 2), 21% were excluded due to not meeting the inclusion criteria. Of the remaining 318 women, 63% were eligible and agreed to participate (n=200), 34% declined, and the remaining 3% could not be contacted (the proportion of ineligibles within the group who declined to participate or who could not be contacted is unknown). Of the 200 women who gave informed consent, six women withdrew prior to baseline assessment, thus were not randomised. The randomisation schedule led to 67, 67 and 60 women in the *FtF*, *Tel* and *UC*, respectively. Fourteen additional women withdrew consent after baseline testing and randomisation (6, 4 and 4 in the *FtF*, *Tel* and *UC*, respectively), with 12 of these women withdrawing prior to or within the first 6 weeks of commencing the intervention. Consequently, the overall (12-month) study retention rate was 93%. Women who withdrew (n=14) were of similar age, socioeconomic status (as defined by yearly income and education level) and had similar disease and treatment characteristics, including type of surgery, stage of disease, number of nodes examined

and number of positive nodes (data not shown), compared with those who maintained study participation through to final assessment. Study participants were on average 7 years younger than the Queensland breast cancer population, with slightly larger tumour sizes (22mm compared with 20mm); however, disease type and number of nodes examined and number of positive nodes were similar (Table 2).

3.2. Baseline characteristics

On average, participants were aged 52.4 years (SD=8.5) and were overweight (mean body mass index=26.6±5.2kg/m^2). The majority (71.1%) were diagnosed with infiltrating ductal carcinoma, and 30.4% and 61.9% were classified as having Stage I and II+ disease, respectively (4.1% were classified as stage 0 and 3.6% were unknown). Personal and diagnostic characteristics including age, BMI, socioeconomic status and type and stage of disease, were similar for participants in the *FtF*, *Tel* and *UC* groups (Table 3). However, those in the *Tel* were more likely to be treated at a private hospital and to have oestrogen/progesterone-receptor-positive disease when compared with those in the *UC*. Also, on average, the *FtF* were less likely to have HER2-positive breast cancer than the *Tel* and *UC*, the *Tel* was less likely to have a mastectomy than the *FtF* and *UC*, and the *UC* was less likely to be treated on the left side.

3.3. Intervention participation

Those in the *FtF* participated in a median of 14 sessions (min, max: 0, 16) with their Exercise Physiologist, with 82% participating in at least 75% of the schedule sessions. Those in the *Tel* participated in a median of 13 sessions (min, max: 3, 16) and 68% participated in 75% or more of the scheduled sessions.

4. Discussion

Substantial evidence derived from efficacy trials [20, 40] supports the integration of exercise during and following treatment for breast cancer. The EfH trial extends this work by evaluating two modes of delivering an evidence-based exercise intervention, along with an approach for recruitment and intervention implementation that could readily be taken up into practice. Existing hospital-based Breast Care Nurses and Physiotherapists introduced the trial to women immediately following breast surgery, and the intervention was delivered by tertiary-qualified Exercise Physiologists in a way that could be government-funded within the existing health care system of Australia. Further, in contrast to rigid intervention goals, the responsibility for planning, monitoring, and identifying and overcoming barriers to participation in regular exercise progressively shifted from the Exercise Physiologist to the participant during the eight-month intervention period. This approach acknowledges the need for professional guidance when exercising during active treatment periods, but the need for participant buy-in to sustain behaviour change and subsequent benefits in the longer term.

A recent review of 65 exercise intervention trials of 1-26 weeks duration (mostly 6-12 weeks duration) for people with cancer, during or following treatment, found that the median uptake and completion rates were 63% (33-80%) and 87% (80-97%), respectively [41]. Despite approaching women during a period of intense emotional turmoil (within 4 weeks of breast surgery) and asking women to partake in an eight-month intervention, we achieved similar recruitment (63%) and retention (93%) rates, indicating that the intervention was acceptable to and feasible for most. Nonetheless

our experiences have highlighted the need for support from the health care team, specifically physician recommendation and Breast Care Nurse follow-up, in making exercise a priority in the lives of women with breast cancer, in particular women who do not have a history of participating in regular exercise. Further, our experiences suggest that while introducing exercise early following a breast cancer diagnosis is a particularly sensitive challenge, it does have advantages. Specifically, capturing the necessary health history for participation in an exercise intervention allows the participant to freely disclose information in a non-threatening environment and initiates rapport-building between participant and Exercise Physiologist. Additionally, exercising during active adjuvant therapy may minimise treatment-associated symptoms [42, 43], and allows participants to develop confidence in their ability to exercise no matter what challenges they face.

Our inclusion criteria were broad, with study feasibility and safety dictating a need for only a few exclusion criteria, specifically age, health and residence. Compared with the Queensland breast cancer population, the EfH sample was, on average, seven years younger and had slightly larger tumours (on average 2mm larger). However, these differences were considered minor, particularly since disease type, number of nodes examined and number of positive nodes were similar, suggesting future outcome findings will likely be generalisable to the wider urban breast cancer community. Although not quantifiable, it is likely that the women who enrolled in the trial were more receptive to becoming or staying physically active compared with those who refused to take part. If correct, then our ability to influence behaviour in the *FtF* and *TG* will be reduced, and those in the *UC* may be more likely to initiate or maintain physical activity on their own. Both factors may bias the trial in the conservative direction by making it more difficult to observe change over time and differences between groups. In that case, any positive results attributed to the exercise interventions will represent underestimates of true effect sizes. We will be able to address this more directly when interview data regarding history of physical activity and tracking data become available.

An important and novel aspect of the EfH trial is our ability to determine whether the mode of intervention delivery influences intervention effect. The telephone-support intervention has the advantage of reaching women independent of place of residence and has possible cost advantages compared with face-to-face delivery of an exercise intervention. However, the magnitude of effect may be stronger when the intervention is delivered face-to-face, as the provision of support during exercise sessions may influence intensity and type of exercise undertaken. It is also possible that participant characteristics (e.g., age, disease severity, treatment status) will influence outcomes, perhaps interacting with mode of delivery. Evaluation of moderators of outcome will be the subject of future analyses.

Our ability to evaluate effect of mode of delivery will be influenced by the success of randomisation and balance in intervention participation between the intervention groups. Groups were not perfectly balanced in numbers (67, 67, 60 in the *FtF*, *Tel* and *UC*, respectively); in retrospect block randomisation may have improved this balance. However, there were only a few minor imbalances with respect to group characteristics, and these are unlikely to influence intervention effects given balance in other related characteristics. For example, while the *Tel* group was more likely to be treated at a private hospital and less likely to receive a mastectomy compared with

the *FtF* and *UC*, rates for stage of disease, extent of axillary dissection and receipt of adjuvant therapy were similar between the groups. Nonetheless, in future analyses we will assess the relationships between patient characteristics and outcomes of interest, and adjust for potential confounding as necessary. From a group perspective, there was no clinical difference in intervention participation between those in the *FtF* and *Tel* groups, with a median of 14 and 13 sessions undertaken, respectively. However, 82% of those in the *FtF*, compared with 68% of those in the *Tel* group, received the predefined adequate intervention dose, with these rates being in line with those reported in other efficacy trials [41].

In summary, the EfH trial was successful at recruiting a large sample that is mostly representative of the wider breast cancer population and will subsequently inform whether the mode of intervention delivery influences the outcomes under study. Key strengths to the trial include the use of a real-world approach with high-quality study design characteristics, including intention-to-treat principles, assessors blinded to group allocation, translational recruitment and intervention features, and an adequate sample size. The evidence-based exercise intervention under evaluation has exercise prescription features consistent with national physical activity guidelines [28], which also have been adopted by the Cancer Council Australia and the American Cancer Society. The recruitment, retention and intervention participation results provide clear evidence of the potential interest women with breast cancer have in pursuing activities that may optimise their lives during and following treatment. Subsequent analyses will explore the effect that EfH has on survivorship issues, including quality of life. It seems plausible that exercise may soon be viewed as a form of cancer treatment in its own right (e.g., may have an independent effect on survival [24, 44, 45]) as well as a form of adjuvant therapy that optimises the success of treatment (e.g., may enhance chemotherapy compliance [46]). Demonstrating an ability to deliver a translational and pragmatic exercise intervention to a generalisable sample of women with breast cancer will contribute significantly to the evidence base, supporting the integration of exercise into the care of women with breast cancer.

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Table 1: Exercise parameters of the Exercise for Health intervention

Frequency of exercise:	4+ times/week All sessions included upper- and lower-body range of motion exercises as part of a warm-up and cool-down			
	Type	*Intensity*	*Duration*	*Frequency of sessions with Exercise Physiologist*
Weeks 1-4/month 1	Aerobic	Low to moderate	20-30 minutes	Once/week
Weeks 5-8/month 2	Aerobic with strength introduced	Moderate	30-45 minutes	Once/week
Weeks 9-16/month 3-8	Aerobic and strength	Moderate to high	45+ minutes	Once/fortnight
Weeks 17+/month 5-8	Aerobic and strength	Moderate to high	45+ minutes	Once/ month

Table 2: Baseline demographic and disease characteristics of Exercise for Health study participants (n=194) diagnosed between 2006 and 2008 compared with Queensland Cancer Registry data for breast cancers diagnosed among women in 2007 (n=2469)

Characteristic	Study participants Median (min, max)	Cancer Registry Median (min, max)
Age at diagnosis (years)	52.0 (28, 69)	59 (24, 103)
Breast cancer size (mm)	22.0 (0.1, 100)	20.0 (0, 185
Number of nodes examined	7 (0, 29)	8 (0, 51)
Number of positive nodes	0 (0, 21)	0 (0, 44)
	n (%)	n (%)
Histologic type		
Infiltrating ductal	138 (71.1)	1757 (71.2)
Infiltrating lobular	18 (9.3)	265 (10.7)
Other	38 (19.6)	447 (18.1)

Source: Queensland Cancer Registry Data Collection, extracted 02-08-10.

Table 3: Baseline characteristics of randomised participants in the Exercise for Health trial by group allocation

Baseline characteristics*	Face to Face n=67 n (%)	Telephone n =67 n (%)	Control n= 60 n (%)
Personal characteristics			
Age (yrs) mean (SD)	51.2 (8.8)	52.2 (8.6)	53.9 (7.7)
BMI mean (SD)	26.6 (4.5)	26.6 (5.3)	26.5 (5.8)
Income			
< $52,000	17 (25.4)	21 (31.3)	19 (32.2)
$52,000 - $93,599	22 (32.8)	22 (32.8)	17 (28.8)
$93,600 - $130,000+	13 (19.4)	18 (26.9)	13 (22.0)
Missing	15 (22.4)	6 (9.0)	10 (16.9)
Children			
Yes	55 (82.1)	55 (82.1)	48 (80.0)
No	12 (17.9)	12 (17.9)	10 (16.7)
Missing			2 (3.3)
Currently working			
No	36 (53.7)	36 (53.7)	32 (53.3)
Full-time	16 (23.9)	19 (28.4)	13 (21.7)
Part-time/casual/other	15 (22.4)	7 (10.4)	13 (21.7)
Missing		5 (7.4)	2 (3.3)
Treating hospital			
Private Hospital	36 (53.7)	41 (61.2)	30 (50.0)
Public Hospital	31 (46.3)	26 (38.8)	30 (50.0)
Disease characteristics			
Type of Cancer			
Infiltrating ductal	48 (71.6)	48 (71.6)	42 (70.0)
Infiltrating lobular	5 (7.5)	6 (9.0)	7 (11.7)
Mixed ductal/lobular	5 (7.5)	4 (6.0)	4 (6.7)
Carcinoma In-situ	2 (3.0)	3 (4.5)	3 (5.0)
Other invasive carcinoma	3 (4.5)	5 (7.5)	3 (5.0)
Missing	4 (6.0)	1 (1.5)	1 (1.7)
Lymph Node Status			
Negative	34 (50.7)	38 (56.7)	33 (55.0)
Positive	29 (43.3)	29 (43.3)	23 (38.3)
None removed	3 (4.5)	0 (0.0)	4 (6.7)
Missing	1 (1.5)		
Tumour Size (mm)**			
Mean (SD)	27.7 (18.5)	26.2 (18.2)	24.1 (16.0)
Tumour Grading			
Overall Grade			
Grade 1	7 (10.4)	11 (16.4)	7 (11.7)
Grade 2	27 (40.3)	29 (43.3)	25 (41.7)
Grade 3	26 (38.8)	23 (34.3)	22 (36.7)
Missing/Not available	7 (10.4)	4 (6.0)	6 (10.0)
Stage			
0	2 (3.0)	3 (4.5)	3 (5.0)

I	23 (34.3)	18 (26.9)	18 (30.0)
II/III	38 (56.7)	45 (67.2)	37 (61.7)
Unknown	4 (6.0)	1 (1.5)	2 (3.3)
Oestrogen/Progesterone status			
Positive	42 (62.7)	48 (71.6)	32 (53.3)
Negative	13 (19.4)	8 (11.9)	8 (13.3)
Discordant	8 (11.9)	8 (11.9)	14 (23.3)
Unknown	4 (6.0)	3 (4.5)	6 (10.0)
HER2			
Positive	10 (14.9)	17 (25.4)	18 (30.0)
Negative	53 (79.1)	45 (67.2)	34 (56.7)
Not performed	1 (1.5)	3 (4.5)	7 (11.7)
Missing	3 (4.5)	2 (3.0)	1 (1.7)
Treatment characteristics			
Chemotherapy			
Yes	39 (58.2)	40 (59.7)	29 (49.2)
No	28 (41.8)	27 (40.3)	30 (50.8)
Radiotherapy			
Yes	11 (16.4)	8 (11.9)	7 (11.9)
No	56 (83.6)	59 (88.1)	52 (88.1)
Hormone Therapy			
Yes	6 (9.0)	4 (6.0)	3 (5.1)
No	61 (91.0)	63 (94.0)	56 (94.9)
Herceptin			
Yes	2 (3.0)	3 (4.5)	3 (5.1)
No	65 (97.0)	64 (95.5)	56 (94.9)
Most Extensive Surgery			
Lumpectomy	41 (61.2)	52 (77.6)	34 (56.7)
Mastectomy/Mod Rad Mastectomy	26 (38.8)	15 (22.4)	26 (43.3)
Laterality of Surgery			
Right	32 (47.8)	34 (50.7)	35 (58.3)
Left	31 (46.3)	32 (47.8)	20 (33.3)
Bilateral	4 (6.0)	1 (1.5)	5 (8.3)

* Baseline characteristics were assessed at 5 weeks post-surgery

Figure 1: Timeline of assessments and intervention for the Exercise for Health trial

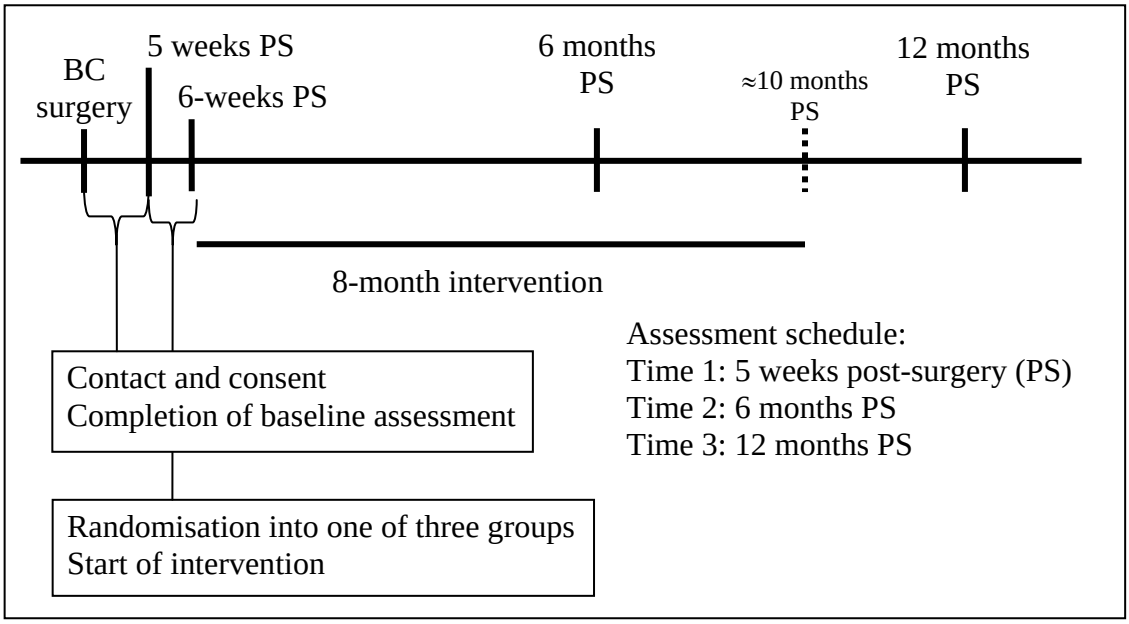

Figure 2: Flow chart of participant recruitment and retention