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A Hybrid Effectiveness-Implementation Trial of an Evidence-Based Exercise Intervention for Breast Cancer Survivors

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Background The primary aims of this hybrid Type 1 effectiveness-implementation trial were to quantitatively assess whether an evidence-based exercise intervention for breast cancer survivors, Strength After Breast Cancer, was safe and effective in a new setting and to qualitatively assess barriers to implementation.

Methods A cohort of 84 survivors completed measurements related to limb volume, muscle strength, and body image at baseline, 67 survivors completed measurements 12 months later. Qualitative methods were used to understand barriers to implementation experienced by referring oncology clinicians and physical therapists who delivered the program.

Results Similar to the efficacy trial, the revised intervention demonstrated safety with regard to lymphedema, and led to improvements in lymphedema symptoms, muscular strength, and body image. Comparison of effects in the effectiveness trial to effects in the efficacy trial revealed larger strength increases in the efficacy trial than in the effectiveness trial ($P < .04$), but few other differences were found. Qualitative implementation data suggested significant barriers around intervention characteristics, payment, eligibility criteria, the referral process, the need for champions (ie, advocates), and the need to adapt during implementation of the intervention, which should be considered in future dissemination and implementation efforts.

Conclusions This trial successfully demonstrated that a physical therapy led strength training program for breast cancer survivors can be implemented in a community setting while retaining the effectiveness and safety of the clinical trial. However, during the translation process, strategies to reduce barriers to implementation are required. This new program can inform larger scale dissemination and implementation efforts.

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Three major national organizations have published clinical guidelines recommending regular exercise for all women diagnosed with breast cancer (1–3). There has also been a call for exercise to become part of the standard of care for breast cancer survivors, given observational evidence of prevention of cancer recurrence/mortality (4) and experimental evidence that exercise improves adverse effects of cancer treatment, including lymphedema (5,6), physical functional decline (7), fatigue (8), and quality of life (9). Breast cancer survivors report wanting help with these impairments, but are often not referred to exercise programs (10). Coupled with evidence that exercise levels are reduced (11) and fitness levels are lower among breast cancer survivors (12), there is a need to translate evidence-based exercise interventions into community settings while maintaining safety and efficacy.

An efficacious exercise intervention for breast cancer survivors, Physical Activity and Lymphedema (PAL), was developed and tested in a randomized clinical trial (5,6,13,14). Given positive findings, the next step was to test the effectiveness and implementation of this evidence-based intervention. We examined contextual domains important to implementation nested in a hybrid effectiveness-implementation mixed-methods study (15,16). The primary aims of this hybrid Type 1 effectiveness-implementation trial (Strength After Breast Cancer; SABC) were to 1) quantitatively assess whether the PAL evidence-based exercise intervention for breast cancer survivors was still safe and effective when translated (ie, as the SABC intervention) into a community-based physical therapy (PT) setting, and 2) qualitatively assess barriers to implementation from the perspective of providers (ie, oncology clinicians and PTs). In this article, we report on primary outcomes from the trial (ie, safety and effectiveness) and implementation challenges.

Methods

All study activities were reviewed and approved by the University of Pennsylvania Institutional Review Board. All participants signed a written informed consent prior to study activities.

Safety and Effectiveness Assessment

Participants. Participants included breast cancer survivors, including those with and at risk for lymphedema, referred to the program

from oncology clinicians (physicians and nurse practitioners) and PTs at a National Cancer Institute (NCI) designated comprehensive cancer center and by self-referral. Survivors were eligible for referral into SABC if they had completed all curative treatments (except for hormonal therapies and trastuzumab) and if the referring clinician did not find any medical conditions that would preclude participation. Lymphedema status had no bearing on eligibility for referral, as weight lifting has benefits for breast cancer survivors beyond lymphedema related outcomes (1,5–7,14,17).

Data Collection. Measurements of all participants at baseline and 12 months were completed by trained staff using standardized methods. Demographic characteristics (age, education, race, and occupation) were self-reported. Cancer stage and treatment history were taken from electronic medical record. Anthropometry measures included height (baseline only) and weight. Physical activity outside of weight lifting was assessed using the College Alumnus Survey (18). Perometry was used to measure arm volumes at baseline and 12 months. The Optoelectronic Perometer (Juzo USA, Cuyahoga Falls, OH) is a state of the art reliable and valid tool to assess limb dimension and volume (19–21). For clinician-defined lymphedema onset or flare-ups requiring treatment, PTs (22) used a standardized clinical evaluation based on the Common Toxicity Criteria Adverse Events version 3.0 (23), including interlimb differences, changes in tissue tone or texture, and symptoms. Lymphedema-related symptom presence and severity were reported using a validated and reliable survey upon PT evaluation and re-assessment as needed (24). Muscular strength was assessed as the maximum amount of weight that can be lifted once (one repetition maximum = one-RM) for the bench press and leg press. One-RM tests, the standard for evaluating increases in muscular strength (25), are safe for most populations when properly supervised (25–27). Methods for the strength measurements have been reported elsewhere (13).

Implementation Assessment

Participants. Participants included referring clinicians working in a medical oncology setting (N = 39) and PTs (N = 32) who delivered the intervention as part of the effectiveness trial. All oncology clinicians referred at least one survivor. All PTs adopted the SABC program following training.

Data Collection. Qualitative data included semistructured interviews and direct observation. We developed a semistructured interview guide to elicit key stakeholders' perspectives on the intervention. Oncology clinicians and PTs were interviewed in groups and individually. In the oncology setting, direct observations were conducted in the waiting room of the cancer center and during tumor board meetings. In the PT setting, direct observations were conducted during staff meetings and during intervention provision with survivors. A research coordinator wrote detailed field notes following each direct observation session. Recruitment ceased when thematic saturation was reached with interviews or direct observations (28).

Intervention Description

We revised the PAL intervention (5,6) with the input of oncology clinicians, PTs, and survivors to improve the feasibility of implementation within a large NCI designated cancer center and associated PT clinic (see Table 1 for description and comparison of interventions). Revisions were intended to increase feasibility and reduce cost without adversely impacting safety or effectiveness. For example, the intervention within the clinical trial included 26 supervised small group training sessions over 13 weeks. It was felt that this would be prohibitively costly within the PT setting and might not be covered by insurance. Therefore SABC included four small group PT exercise sessions and an expectation that strength training exercises would be completed twice weekly at home. Further, based on feedback from survivors, the program was renamed (ie, SABC).

All women who completed the program were invited to repeat aspects of the program as they chose, only two women did so. Options for paying for the program included self-pay, third party payers, or a hybrid (eg insurance coverage for assessment and self-pay for intervention sessions; see Table 1 for further details). Participants were required to pay all coinsurance or copays according to specific insurance policies. There were no denials from third party payers for the PT assessment or intervention. Adjustable dumbbells (1–21 pounds) were donated for the study by Powerblock, Inc (Owatana, MN). In both the PAL and SABC interventions, women with lymphedema were required to wear a well-fitting compression sleeve and glove or gauntlet during exercise sessions. Participants were asked to call their PT for evaluation of possible onset or flare-ups upon report of a change in symptoms lasting one-week or longer, or if safety measurements at 3 or 6 months indicated a *change* in treated arm volume of greater than or equal to 5% and greater than or equal to 5% interlimb difference.

Data Analysis

Safety and Effectiveness Assessment. Continuous variables are summarized with means and standard deviations (or medians where noted). Categorical variables are summarized with rates and percentages (%). Changes in outcomes from pre- to post-intervention were assessed using paired *t*-tests. To compare study outcomes between the PAL efficacy (5,6,13,14) and SABC effectiveness trial, regression analysis was used to quantify the between-study differences in effects, adjusting for baseline values. Statistical tests were two-sided; $P < .05$ was the threshold for statistical significance. All statistical analyses were conducted with Stata 12.0 (College Station, TX).

Providers' Implementation Assessment. Each interview was audio recorded, professionally transcribed verbatim, and imported into NVivo 10.0 software for coding and analysis (QSR International, Melbourne, Australia). We used a modified grounded theory approach. Through a close reading of several interview transcripts and field notes from direct observation, the investigators developed and defined a set of codes that were applied to the data. We also used a set of a priori codes derived from our original research questions. The following themes emerged: intervention characteristics, payment, eligibility criteria, the referral process, the need for champions (ie, advocates) and the need for adaptation during implementation of the intervention (ie, flexibility regarding logistics).

Table 1. Comparison of intervention elements between efficacy and effectiveness interventions

Intervention elements	Physical Activity After Lymphedema efficacy trial (5,6)	Strength After Breast Cancer effectiveness trial
Referrals into program	Research recruitment through state cancer registries	From oncology physicians, nurse practitioners, physical therapists, and self-referral based on online and print materials
Pre-intervention assessments to ensure safety of participation	Signed permission from physician to enroll in study. Pre-intervention assessments by physical therapists for women with lymphedema, exercise professionals for women at risk for lymphedema	Physician referral required to undergo pre-intervention assessment. Physical therapists conducted assessments for all women regardless of lymphedema status
Lymphedema education session lecture based on National Lymphedema Network	Yes	Yes
Small group exercise sessions supervised by:	Exercise professionals	Physical therapists
Ratio of supervisor to survivors in small group sessions	One exercise professional to seven or fewer survivors	One physical therapist to seven or fewer survivors
Number of supervised small group exercise sessions	26 sessions over 13 weeks	Four sessions over 1–2 months (home exercise in between)
Ongoing safety assessments	Weekly by symptoms, monthly by arm circumferences, monitored by exercise professionals	Weekly by symptoms (self-monitoring), 3 and 6 months safety measurements by study staff
Method for follow-up if survivor needed help/assessment	Option for monthly personal training sessions and safety assessments with exercise professionals through 52 weeks	Option to repeat elements of the program or assessments with physical therapists
Setting for intervention	Community fitness facilities for all 52 weeks	Physical therapy clinic for four sessions, home exercise for all 52 weeks
Equipment used for weight lifting	Dumbbells, barbells, and fitness equipment as available in community fitness centers	Power blocks adjustable dumbbells (provided for free by a donation from the manufacturer)
Exercise adherence monitoring	Self-reported on exercise logs completed by survivors	Self-reported on exercise logs completed by survivors
Prescribed exercise sessions per week	2	2
Payment for the program	Free to study participants, paid for with grant funds	Self-pay (total $416.50), physical therapy copays, or a combination. Copays ranged from $0 to $80 per session. Many women had insurance cover the assessment with a copay, as it cost $229 for self-pay. Then each session thereafter was $37.50. If copay was greater than $37.50, women chose self-pay

Two team members coded each interview and field note independently, using the interrater reliability function in NVivo to evaluate percent agreement across coders. Discrepancies in coding were discussed until 95% agreement was reached. As data collection was ongoing, the constant comparative method was used [ie, the research team met bimonthly to compare newly collected data with themes that had previously emerged in order to guide further thematic development and refinement; (29)].

Results

Safety and Effectiveness Assessment. A total of 506 women were referred to the SABC program and 117 women participated between September 2011 and December 2012, during the period of study recruitment. Of these, 43 were referred by a PT, 31 by an oncology clinician, 7 by self-referral, and 3 women did not recall how they had been referred. Of these, 84 consented and participated in baseline measurements (note, 33 women completed the SABC program but opted not to complete research measurements). Of these, 67 completed measurements at 12 months (80% retention to 12 months). Of the 17 lost to follow-up, nine never completed the program, seven were lost to follow-up, and one became too ill to continue. Table 2 provides a description of participants in both the PAL efficacy and SABC effectiveness trials. Participants in the PAL efficacy trial completed 75.4 ± 28.7 weightlifting sessions over the year (ie, adherence = 72.5 ± 27.6%) whereas, participants in the SABC trial completed 50.7 ± 36.1 weightlifting sessions over the year (ie, adherence = 48.8% ± 34.7%). Lymphedema safety and effectiveness outcomes, muscular strength, and body image results from baseline and 12-month follow-up are presented in Table 3 for the 84 women who participated in SABC, as well as PAL participants. Table 4 presents a between-study comparison for lymphedema, strength, and body image results.

Findings from the SABC effectiveness trial were consistent with the PAL efficacy trial. At baseline, SABC participants reported more psychosocial concerns than PAL participants, including

Table 2. Baseline description of survivor participants from strength after breast cancer and physical activity after lymphedema trials*

Characteristic	Physical Activity After Lymphedema efficacy trial (5,6) (*n* = 131)	Strength After Breast Cancer effectiveness trial (*n* = 84)
Demographics		
Age, mean, (SD)	56.0 (8.2)	55.1 (10.5)
Education, n (%)		
High school grad or GED	17 (13%)	4 (5%)
Some college	45 (34%)	16 (19%)
≥College	69 (53%)	64 (76%)
Race/ethnicity (sum >100 due to rounding)		
White	80 (61%)	60 (83%)
Black	41 (31%)	10 (12%)
Other (Asian, unknown, multiracial)	10 (8%)	5 (6%)
Occupation		
Professional/technical	51 (39%)	46 (55%)
Clerical or sales	26 (20%)	10 (12%)
Manager/administrator	17 (13%)	5 (6%)
Homemaker, student, or unemployed	4 (3%)	11 (13%)
Other or unknown	8 (6%)	5 (6%)
Retired	25 (19%)	7 (8%)
Physical characteristics		
BMI	29.2 (5.9)	26.4 (5.1)
Cancer characteristics		
Months since cancer diagnosis, mean (SD)	57.7 (37.5)	27.5 (34.2)
Cancer stage		
Ductal carcinoma *in situ*	1 (<1%)	6 (7%)
1	61 (47%)	24 (29%)
2	3 (2%)	30 (36%)
3 or 4	41 (31%)	19 (23%)
Unknown	25 (19%)	5 (6%)
No. of nodes removed, mean (SD)	11.4 (7.8)	12.5 (10.1)
Chemotherapy	100 (76%)	60 (71%)
Radiation	105 (80%)	57 (68%)
Current receipt of drugs		
Tamoxifen	26 (20%)	24 (29%)
Aromatase inhibitors	1 (<1%)	27 (32%)
Arm volume difference, means SD median, (%)	7.2 (12.4)	0.67 (5.36)

* BMI = body mass index; GED = general equivalency diploma; SD = standard deviation.

Table 3. Safety and effectiveness assessment: lymphedema, muscular strength, and body image outcomes

	Strength After Breast Cancer effectiveness trial				Physical Activity After Lymphedema efficacy trial (5,6)			
	No. of Obs.	Baseline	12 months	*P*	No. of Obs.	Baseline	12 months	*P*
Lymphedema effectiveness outcomes								
Number of symptoms*	66	2.6 ± 2.6	1.7 ± 2.1	.002	131	3.3 ± 3.2	2.2 ± 2.6	<.001
Severity of symptoms*	66	1.6 ± 0.5	1.4 ± 0.5	.058	131	2.0 ± 0.7	1.6 ± 0.7	<.001
Arm volume (% interlimb difference)	48	0.68 ± 5.87	0.66 ± 5.07	.98	131	7.22 ± 12.40	6.84 ± 11.66	.40
Lymphedema safety outcomes								
New lymphedema onset†	49	—	4 (8%)	—	72	—	8 (11%)	—
Flare-up of existing lymphedema‡	27	—	5 (19%)	—	71	—	9 (14%)	—
Muscular strength outcomes								
Bench press, lbs.	34	45 ± 11	51 ± 13	<.001	115	42 ± 14	53 ± 15	<.001
Leg press, lbs.	37	190 ± 58	208 ± 54	.012	120	174 ± 55	222 ± 59	<.001
Body image and relationships								
Strength and health	66	34.2 ± 9.2	28.7 ± 9.3	<.001	120	33.8 ± 9.3	28.0 ± 8.8	<.001
Social barriers	64	19.8 ± 7.0	17.0 ± 6.3	.003	111	16.6 ± 6.5	14.8 ± 5.5	<.001
Appearance and sexuality	65	30.8 ± 6.7	27.7 ± 7.2	<.001	104	30.0 ± 8.0	27.0 ± 7.7	<.001
Total score	63	85.8 ± 19.9	74.0 ± 20.3	<.001	116	81.2 ± 20.2	70.0 ± 19.1	<.001

* Data were reported by patients for 14 symptoms: rings too tight, watch too tight, bracelets too tight, clothing too tight, puffiness, knuckles not visible, veins not visible, skin feels leathers, arm feel tired, pain, pitting, swelling after exercise, difficulty writing, or other. The change in severity of symptoms is the mean of the changes in severity for all 14 symptoms, with the possible severity score for each ranging from 0 (no symptom) to 4 (very severe).

† New lymphedema onset defined by a ≥5% increase in interlimb arm difference from baseline among women who entered the study with an interlimb arm volume difference <5% (interlimb volume difference: ((affected arm volume – unaffected arm volume)/unaffected arm volume).

‡ Flare-up of existing lymphedema defined by expert clinical evaluation among women who entered the study with an interlimb arm volume difference ≥5%.

Table 4. Between-study effects comparison of outcomes*

Lymphedema effectiveness outcomes	Cumulative incidence ratio or mean difference (95% CI) between SABC and efficacy RCT	*P*
Arm volume, % interlimb difference		
No. of symptoms	0.11 (−0.42 to 0.63)	.69
Severity of symptoms	0.04 (−0.21 to 0.29)	.76
Lymphedema safety outcomes		
New lymphedema onset	0.75 (0.24 to 1.38)	.63
Flare-up of existing lymphedema	1.37 (0.50 to 3.78)	.54
Muscular strength outcomes		
Bench press, lbs.	4.6 (0.2 to 9.0)	.04
Leg press, lbs.	26.7 (12.0 to 41.5)	<.001
Body image and relationships		
Strength and health	−0.49 (−2.66 to 1.67)	.65
Social barriers	−0.73 (−2.26 to 0.80)	.35
Appearance and sexuality	−0.16 (−1.93 to 1.61)	.86
Total score	−1.14 (−5.77 to 3.47)	.62

* CI = confidence interval; RCT = randomized controlled trial; SABC = Strength After Breast Cancer.

more concerns around strength and health, social barriers, and appearance and sexuality. In both studies, survivors demonstrated improvement in number and severity of upper body symptoms, improved strength, improved body image, and no changes in arm swelling. Participants in the PAL trial were more adherent than participants in the SABC trial. The only outcome for which there was a statistically significant difference of intervention efficacy was muscular strength. The PAL intervention resulted in greater strength improvements than the SABC intervention.

Providers' Implementation Assessment. A total of 19 providers were interviewed between July 2012 and December 2012. The providers included seven physicians, 10 PTs, and two nurse practitioners; 84% were female and 90% were Caucasian. A total of 17 direct observations were conducted. Table 5 includes illustrative quotes from the semistructured interviews and direct observations related to each domain.

Intervention Characteristics. PTs expressed that the group-based exercise intervention sessions were a challenge to implement in their setting given variability in individual survivor abilities.

Payment. Stakeholder perspectives on SABC program cost emerged as an important factor. Specifically, providers in the PT and oncology settings expressed that the program would need to be covered by insurance, or have a reasonable self-pay option to be sustainable.

Eligibility Criteria. Understanding the eligibility of women who could participate in the SABC program was complex for oncology providers and PTs. Specifically, oncology providers had difficulty identifying whether eligibility included only survivors with lymphedema vs any breast cancer survivor.

Referral Process. Oncology providers and PTs resided in two separate geographic locations and administrative entities which emerged as a barrier to referral. Oncology providers were required to complete a referral to PT through the electronic medical record system. A printed copy of the referral was given to the patient, who was then required to call the PT office to make an appointment. This process was labor intensive and confusing for both the clinician and survivor resulting in errors and missed referrals.

The Need for a Champion. A PT champion worked to gain acceptance for the SABC program, alter referral and training protocols, and orient PT staff. PTs reported that without this champion, implementation of SABC would not have been successful.

Adaptations. Adaptations to the core program were also necessary for the implementation process. We made three main adaptations. First, we met with PTs to help them understand how they could individualize the SABC program to each survivor. Second, given the referral challenges, we added a staff liaison in the oncology setting to assist with referrals. Third, the PT organization began to call survivors who received referrals which increased the proportion of women who scheduled the PT pre-program assessment from 39% to 65%.

Discussion

An effectiveness trial of the PT based rehabilitative exercise program, SABC, resulted in improvements in lymphedema, muscular strength, and body image outcomes similar to the PAL efficacy trial. Critically, after translation into the clinical setting, this intervention retained its safety and effectiveness. However, barriers to the implementation of SABC necessitate resolution before efforts to scale-up dissemination and implementation are initiated.

The findings from the effectiveness trial indicate that the adapted program was successful. When considering outcomes, it is necessary to compare samples. Comparisons between SABC and the PAL trials suggests that the samples are somewhat comparable, although survivors in the SABC trial reported lower frequency and less severity of symptoms of lymphedema, and demonstrated more muscular strength at baseline. A greater amount of muscle strength was gained in the PAL efficacy than the SABC effectiveness trial, as would be expected, given limits of progression of resistance in home- versus facility-based interventions. Lower adherence in the SABC cohort as compared with the PAL cohort may also have contributed to these differences. Survivors in the SABC trial reported more psychosocial concerns than those in the PAL trial, including

Table 5. Implementation: selected quotes from qualitative semistructured interviews and direct observations*

Theme	Quote	Participant type
Intervention characteristics	*If there is an 80-year-old woman and a 20-year-old woman, where they are completely performing different things, I can tell the 20-year-old's getting a little impatient*	Physical therapist
	At the beginning, there were five people in a class, it was insanity. I feel like that was a lot of people …I feel like the patients had so many questions and needed so many different adaptations that it was very hard to give the amount of attention that each person needed	Physical therapist
Payment	*I mean, the reality is that there are some financial constraints to this. And if I were referred to physical therapy, I would have no idea what my co-pay is, how much this is going to cost me. And maybe if there was some way to let patients know, or to give – and I know insurance companies vary widely, so maybe you don't have the resources to do that*	Oncology provider
	I think the largest barrier that I heard from women was the co-pay…the whole co-pay situation was very – I've got one woman, she had an $80 co-pay. And I tried to convince her. And we have so little control over that co-pay. I had never seen a co-pay that was more than $25…If we can't get enough participants to sign up for the classes on an ongoing basis, I think there's a financial hurdle to continuing to offer the class, despite our great desire to offer a wellness component	Physical therapist
Eligibility	*I can't actually remember the eligibility criteria…I know I should be thinking about patients to do [PAL]. I know – I recall that it has something to do with patients who have weight issues. But beyond that I can't keep it in my head. I need tools.*	Oncology provider
Referral	*So the job of who is going to do the selling [of PAL to the patients]? I think it has become clear that that it cannot fall on us [medical oncologists]… We can't do it. It is not going to happen at that course of the day when you are thinking about 79,000 other things. Selling this idea is going to have to be done by some external force and all we can do is cooperate and buy in and go along with it. It will be much more efficient I think*	Oncology provider
	Everything you refer in the health system, once that [referral] goes in, even for social work or physical therapy/occupational therapy after [the patient is] discharged, I put it in ahead of time and then that goes to somebody's inbox and that person calls [the patient]. It's gotten to the point if I put in an MRI thing and then try to call down to radiology to schedule on the phone, they're like 'Well, you already put it in we don't need you to call.' Most places once you put that in they know it's there, they'll get to it when they get to it	Oncology Provider
Champion	*If [champion's name] wasn't here, the physical therapy team would have said 'I can't, we can't, too many roadblocks' and would have given up much earlier on making this program happen*	Physical therapist
Adaptation	*The navigator position though, I think is… more for this issue of where do I send them? Figuring out the logistics of it. Am I sending them to this side or that side and what are the co-pay issues? You don't want to be dealing with all that. You don't have time to deal with all that*	Oncology providers
	I think just the level of communication with how the program was supposed to be run was difficult. Being a very research oriented facility, we thought there was a strict program that needed to be followed and that the program that had been given to us was the program we had to rigidly abide by… I don't think it was made clear that we had the flexibility to create our own program. And once we created our own program and implemented it, I think it's been much more smooth because we are all well trained in exercise science and physical therapy and when we made it our own, it became much more natural to teach	Physical therapist

* MRI = magnetic resonance imaging; PAL = Physical Activity and Lymphedema.

more concerns around strength and health, social barriers, and appearance and sexuality. These differences in the sample are likely representative of differences in inclusion and exclusion criteria in efficacy versus effectiveness trials (30). When benchmarking lymphedema, strength, and psychosocial outcomes at 12 months, it appears that both groups show similar patterns, which suggests the transportability of the intervention, particularly with regard to safety and effectiveness.

Despite the success of the program from a safety and effectiveness perspective, implementation challenges were identified (16). Fortunately, these barriers can be easily ameliorated in future efforts. First, PTs felt that the group format of the intervention detracted from their satisfaction with the experience of providing the intervention. In the efficacy trial, the intervention was delivered by exercise professionals in a group format. The PT setting may be less amenable to group interventions. Future efforts could use

an individual format or a tiered intervention by skill ability. Our adaptation to allow PTs to individualize the program (ie, flexibility within fidelity; 31) to each participant also seemed to address this barrier. Second, to sustain such a program, feasible payment options are needed including private insurance and self-pay. Stakeholders expressed that cost was a consideration for program uptake. Third party payers consistently covered this program during the effectiveness study and have continued to do so since the study was completed. Third, the need for a PT champion to assist with administrative barriers to implementation is important, and has been well-documented in the implementation science literature (32). Finally, it appears that when oncology clinicians make referrals to a rehabilitative exercise program, an active process (ie, follow-up phone calls) is needed.

A thornier challenge in survivorship care has to do with the well described issues regarding coordination of the complex health care needs of breast cancer survivors (33). Although we were able to demonstrate that the program was safe and effective, the inherent heterogeneity of the breast cancer survivorship population posed a major challenge for oncology clinicians to refer into SABC. The oncologists knew that the efficacy intervention had been particularly useful for lymphedema related outcomes among breast cancer survivors (5,6). Oncology clinicians vary with regard to their opinions regarding the level of risk for lymphedema based on clinical presentation of a given patient and this may have influenced interest in making referrals. Effort was made to clarify that clinicians could refer all breast cancer survivors and that the PTs would determine whether the program was appropriate, but as one physician said, "If they are all eligible, then we end up referring no one." Therefore, part of the confusion arose over decisions made by oncology clinicians regarding the relative benefits of the intervention for their patients. Well-validated criteria to help oncology clinicians quickly assess which survivors need referral to specialty care, including rehabilitative exercise, might be useful. In our study, we addressed this challenge by adding a staff liaison to assist physicians in the referral process, as has been done in other survivorship care efforts (34).

The findings from this hybrid Type 1 effectiveness-implementation trial provide support for the continuation of research on the dissemination and implementation of SABC. A number of future research questions necessitate further study. First, we conducted this trial in an exemplar setting (ie, an NCI Comprehensive Cancer Center connected to a major medical school), and it would be worthwhile to attempt implementation in a more community based setting (eg, local hospitals in different regions). When transporting the intervention to such a setting, information on safety and effectiveness are still needed. Second, a number of delivery variations are of interest. Future investigations can vary the most effective type of interventionist/setting (ie, PT, exercise professional), intervention cost options (self-pay and third party payer), and referral type (ie, self-referral, referral from oncology providers). Further, empirical assessment of survivor's willingness to pay for the program is warranted. Given the above noted challenges in coordinating health care needs for breast cancer survivors, future efforts might consider embedding this type of intervention within a holistic interdisciplinary approach, perhaps including it within a program that includes interventions for sleep, fatigue, cognitive impairment, or other common adverse treatment effects.

SABC is one exemplar of survivorship interventions for breast cancer that can be implemented in community settings. Such interventions have the potential to be disseminated and implemented through cancer centers throughout the United States to improve outcomes in all three million breast cancer survivors. We have successfully demonstrated that a group based strength-training exercise program can be implemented in a PT setting while retaining its safety and effectiveness, which can inform larger scale dissemination and implementation efforts. Continued attention to the translation of complex multicomponent interventions is warranted given that the mechanisms through which such interventions are implemented may be different than simple interventions such as implementation of hand washing or a new medication (35).

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