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## Brief Report: Pilot Randomized Trial of a Couple-based Physical Activity Videoconference Intervention for Sedentary Cancer Survivors

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### Abstract

**Objective:** Including partners in interventions to increase physical activity (PA) could promote better adherence and longer term effects. In preparation for a future large-scale RCT, this randomized pilot trial tested the acceptability of a novel couple-based PA intervention for breast and prostate cancer survivors, and the feasibility of conducting an RCT testing the intervention.

**Methods:** Twenty cancer survivors (70% female; mean age=63.0 years, SD=8.9) and their partners (35% female; mean age=62.8 years, SD=7.7) were randomized to either the intervention or waitlist control. Couples in the intervention received four videoconference sessions including training in communication and support skills and behavior change techniques. Measures of PA and partner support for exercise were collected from survivors and partners before randomization and post-intervention. Survivors also completed a physical well-being measure, and intervention participants completed a treatment acceptability measure.

**Results:** Recruitment was challenging; approximately 18% of eligible survivors and their partners agreed to participate. 92% of randomized participants completed post-intervention surveys, and 78% of dyads randomized to the intervention arm completed all four sessions. Mean acceptability ratings were moderate to high. Mean difference scores suggested that participants in the intervention arm tended to report greater improvements in PA, partner support, and physical well-being than those in the control arm.

**Conclusions:** These preliminary findings suggest that the couple-based PA intervention was acceptable to survivors and their partners, and that a large scale RCT is likely to be feasible with

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modified recruitment strategies. Recommendations for improving recruitment and conducting a larger study are presented.

### **Keywords**

physical activity; cancer; dyads; intervention study

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## **Introduction**

Clinicians and researchers promote physical activity (PA) among cancer survivors to prevent cancer recurrence and improve physical function, psychological outcomes, and quality of life. (Fong et al., 2012) However, most survivors are not sufficiently active. (Blanchard, Courneya, & Stein, 2008) Interventions to increase PA among cancer survivors have had mixed success; many studies find that post-intervention improvements in PA are not sustained, and interventions often lack attention to psychosocial aspects of behavior change. (Bourke et al., 2014) Thus, more strategies are needed to help cancer survivors initiate and maintain PA.

Involving a partner in interventions to increase PA may provide important benefits including the ability to leverage partner social support for behavior change (Sher & Baucom, 2001) and the potential for a “two-for-one” effect, with increases in PA for both partners. To date, only one prior study has used a couple-based approach to increase PA for cancer survivors, finding that it led to improvements in PA and body strength among survivors and spouses. (Winters-Stone et al., 2016). While promising, the study was limited by a small sample size and intensive in-person format which required couples to attend two sessions per week for six months. In addition, the intervention did not include training in couple communication skills or communal coping strategies to enhance their ability to support each other’s exercise behavior.

We developed a novel home-based PA intervention which we delivered to cancer survivors together with their partners via videoconference. The intervention was guided by interdependence theory which describes how relational factors influence motivation for behavior change (Lewis et al., 2006) and a communal coping approach that emphasizes the importance of couples communicating, engaging in cooperative action, and providing each other with practical and emotional support to achieve their goals. (Lyons, Michelson, Sullivan, & Coyne, 1998) The primary aim of this pilot study was to assess the feasibility of recruiting and retaining couples, and the acceptability of the intervention. A secondary aim was to measure key outcome domains including survivor and partner PA, partner support for PA, and survivor physical well-being.

## **Methods**

### **Participants**

Survivors were eligible if they (a) had been treated for breast or prostate cancer at Duke Cancer Institute, (b) were married or in a committed relationship and cohabitating with their spouse/partner, and (c) reported a sedentary lifestyle (e.g., not undertaking dedicated PA on

3 days/week).(Bourke et al., 2014) We excluded survivors and/or partners if they were <18 years of age, not fluent in English, had metastatic disease, or were hearing impaired, too sick to participate, had a medical condition that prohibited prolonged walking, were participating in another research study that promotes PA, or could not provide consent.

Our initial inclusion criteria included that participants have smartphones which they could use to sync data from a smart activity tracker which we planned to use as an objective measure of PA. However, we found that we were excluding a significant number of survivors because they or their partner did not own smartphones. Thus, to increase the reach of the intervention, we decided to eliminate the requirement for this study.

## Procedures

All study procedures were approved by the Institutional Review Board at Duke University School of Medicine (Pro00060926). Participants were recruited between July, 2015 and September, 2016. Potentially eligible survivors were sent an introductory letter about the study by their oncologist. Study staff followed up by telephone to assess survivor and partner eligibility and interest. Eligible, interested dyads were scheduled for an in-person visit to complete informed consent and baseline measures. They were then randomly assigned with 1:1 allocation to either the intervention or waitlist control. Randomization was stratified by cancer type (breast vs. prostate). Randomization assignments were generated by REDCap and revealed to the couple by study staff after both partners completed baseline surveys. Couples assigned to the intervention were loaned tablet computers with 3G internet access to use for videoconferencing and instructed in their use. Two months following randomization, participants completed post-intervention measures. Each participant was paid \$40.

## Measures

Both members of the couple completed the following self-report questionnaires on REDCap at baseline and post-intervention except where noted. *Acceptability* was measured using three items which assessed the perceived helpfulness of the intervention in increasing PA and improving communication with their spouse, and the likelihood of recommending the program to other cancer survivors and partners. Items were rated on a scale from 1 (“not at all/definitely would not recommend”) to 5 (“extremely/definitely would recommend”). (Nguyen, Attkisson, & Stegner, 1983) An open-ended item assessed additional comments regarding the intervention. Couples in the intervention arm completed this at post-intervention only. *Physical activity* was assessed using the Godin Leisure-Time Exercise Questionnaire (Godin & Shephard, 1985), a 3-item measure assessing the frequency of mild, moderate, and strenuous bouts of exercise performed for at least 15 minutes in duration in a typical week. *Partner Support for Exercise* was assessed using a 15-item scale that measures the degree to which one’s partner provides instrumental and emotional support for exercise habits.(Sallis, Grossman, Pinski, Patterson, & Nader, 1985) *Physical well-being* was assessed using the FACT-G physical well-being subscale. (Cella et al., 1993) Only survivors completed this scale.

## Couple-based Physical Activity Intervention

The intervention consisted of four 60-minute intervention sessions conducted via videoconference. The first three sessions were conducted weekly, with a booster session one month later. The intervention was guided by interdependence theory (Lewis et al., 2006), and a communal coping approach. (Lyons et al., 1998) It included training in communication skills to help couples identify and use effective social support strategies, engage in joint decision making about goals and plans for increasing PA, and work through barriers to making these changes. The intervention also incorporated important behavior change techniques found to help people change their exercise behavior, such as goal setting, self-monitoring of behavior, and prompts for practice, adapting them to a communal coping approach. Detailed information about the content of the intervention can be found in the online Appendix.

## Statistical Analyses

This was an exploratory pilot study meant to assess preliminary feasibility and acceptability. (Whitehead, Sully, & Campbell, 2014) As such, a sample size calculation was not performed. We aimed for 20 couples as we felt this would be a large enough sample to inform the aims and realistic given the limitations of staffing for the study, including staff time available to recruit, administer assessments, and conduct the intervention. Feasibility was defined as the ability to recruit 20 couples in the approximately 10 months available for enrollment during the one-year funding period (e.g., 2 couples/month), and 75% attending all treatment sessions and providing post-intervention assessments. We measured key outcome domains for completion rates, estimates, and 95% confidence intervals between the control and intervention groups. As recommended by guidelines for pilot studies with small sample sizes, (Eldridge et al., 2016; Kraemer, Mintz, Noda, Tinklenberg, & Yesavage, 2006) we did not conduct statistical tests of group differences.

## Results

### Participant characteristics

Participants were 14 female and 6 male cancer survivors (mean age= 63.0 years, SD=8.9, range=47 to 76) and their partners (7 females and 13 males; mean age=62.8 years, SD=7.7, range=49 to 74). Two couples were same-sex. Couples had been married/partnered for average of 32.6 years (SD=15.0, range=7 to 54). 70% of survivors and partners were Caucasian. Additional participant characteristics can be found in the online Appendix.

### Feasibility and Acceptability

**Study Enrollment and Participation.**—Of 324 survivors screened, 192 (59%) were excluded because the survivor reported exercising three days per week, was no longer partnered, had a medical condition that precluded prolonged walking, or was unable to be contacted. 112 (35%) refused participation, primarily due to lack of survivor or partner interest or lack of time. Dyads who were initially deemed ineligible due to not having a smartphone were re-contacted after this criterion was removed to reassess eligibility and interest. 20 survivor-partner dyads enrolled into the study. Nine were randomized to

the intervention and 11 to waitlist control. Seven of nine (78%) dyads assigned to the intervention arm completed all four sessions; two dyads were unable to complete the sessions in the allotted time frame due to travel and work demands. 37 of 40 participants (92%) completed the post-intervention assessment. The CONSORT diagram can be found in the online Appendix.

**Acceptability.**—Mean acceptability ratings were all over 4.0 on the 5-point scale, with the exception of partner ratings of helpfulness of the intervention for increasing PA (mean=3.5). Most survivors and partners would recommend the program to others, with 67% and 78% reporting 4 or 5 on this item, respectively.

**Outcome domains.**—Means and 95% confidence intervals are shown in Table 1. Mean difference scores suggest that participants in the intervention arm tended to report greater improvements in PA, partner support, and physical well-being than those in the control arm.

## Discussion

The primary aim of this pilot study was to determine the acceptability of a novel couple-based PA intervention delivered via videoconference, and the feasibility of conducting an RCT testing the intervention among breast and prostate cancer survivors and their partners. Findings largely supported the feasibility of this approach. Retention was good with 92% of participants providing post-intervention data. Treatment completion rates were also good with 78% of dyads in the intervention arm completing all four sessions. The primary challenge to feasibility was recruitment. A large proportion of survivors were ineligible because they were unpartnered or were physically active. Among eligible dyads, approximately 18% agreed to participate. While recruitment in couple-based intervention studies in cancer is notoriously challenging, this uptake rate is somewhat lower than that in our previous studies,(L.S. Porter et al., 2017) and was likely influenced by the initial eligibility criteria of owning a smartphone, inadequate staffing for recruitment, and restriction of recruitment efforts to oncology clinics.

Survivors and partners rated the intervention as helpful in improving PA and communication, and most reported they would recommend it to others. In response to open-ended questions on the acceptability measure, couples noted that they enjoyed the experience of participating in the intervention together, and that they appreciated the brevity and the flexibility of the sessions. In addition, the pattern of the changes on key outcome domains was promising. However, due to the small sample size it is not possible to draw any conclusions about the intervention's effects.

Our intervention was novel for several reasons. First, it was home-based and delivered via videoconference. A home-based approach provides advantages of increasing reach and accessibility and promoting independent exercise behavior.(Pinto, Frierson, Rabin, Trunzo, & Marcus, 2005) Findings from this study add to those of prior research indicating that videoconferencing is a feasible and acceptable mode of intervention delivery.(L.S. Porter et al., 2017) Second, our intervention included a focus on dyadic communication skills and communal coping to enhance the couple's ability to work together to identify goals,

make plans, and overcome barriers for increasing PA, and to provide effective social support to each other for initiating and maintaining behavior change. Participants noted that communication skills training was helpful in understanding each other's point of view, finding ways to encourage each other in their PA goals, and problem-solving about ways to increase PA.

Limitations of the study include the small sample size, lack of long-term follow up, lack of observational measures of PA, limited number of outcome domains assessed, and recruitment from a tertiary care setting. Due to the small sample size, we presented descriptive summaries and confidence intervals of outcome data. In addition, the intervention focused primarily on increasing participants' aerobic exercise (e.g., walking) relative to their current level of PA, and did not specifically prescribe levels of aerobic activity and strength training that would meet current exercise guidelines. Nonetheless, these preliminary findings suggest that a couple-based intervention may be a promising approach to increasing PA in cancer survivors.

Lessons learned from this pilot study are being used to plan a definitive RCT to test the efficacy of the Move2Health intervention. A power analysis suggests that a sample of 220 couples (110 per arm) is necessary to detect an effect size of .35, accounting for 10% attrition, which equates to enrolling 4–5 couples per month over 48 months of recruitment. While this would not be feasible using the methods we employed in this pilot study, our previous experience recruiting dyads into large oncology trials suggests this target is feasible when funding is available to pay staff for recruitment (L.S. Porter et al., 2009; L. S. Porter et al., 2011). Lessons learned from this pilot study suggest the following strategies to improve recruitment in a larger trial: including survivors with additional cancer diagnoses which will substantially increase the pool of potential participants, assessing PA objectively to verify eligibility of patients who report being physically active, and recruiting from primary care providers, the community, and through social media in addition to oncology clinics. We will also utilize strategies that have been successful in prior studies including budgeting for adequate staff for recruitment, and training staff to utilize motivational interviewing techniques when discussing the study with potential participants. To improve rigor in a larger trial, we will stratify randomization based on baseline levels of PA, include an objective measure of PA that does not require participant use of a smartphone, and include 6- and 12-month follow up assessments. Finally, we will examine constructs derived from interdependence theory as potential mechanisms of treatment effects.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

## Acknowledgments

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**Table 1.**

Means and 95% Confidence Interval (CI) on study measures

	Patient			Partner		
	Intervention (N=9) †	Control (N=11)	Difference‡	Intervention (N=9)	Control (N=11)	Difference
	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)
<b>Acceptability</b>						
Helpful in increasing physical activity	4.1 (2.2, 5.1)	-	-	3.5 (2.3, 4.7)	-	-
Helpful in improving communication	4.1 (3.2, 5.1)	-	-	4.1 (3.3, 5.0)	-	-
Recommend to others	4.2 (3.3, 5.2)	-	-	4.5 (3.9, 5.1)	-	-
<b>Godin Exercise Questionnaire*</b>						
Baseline	17.9 (8.8, 26.9)	11.4 (4.2, 18.6)	1.3 (-12.2, 14.8)	26.8 (11.0, 42.5)	20.8 (12.4, 29.3)	10.8 (-3.6, 25.1)
Follow up	22.6 (7.2, 38.0)	13.1 (3.3, 23.0)		29.6 (11.0, 48.2)	14.9 (2.3, 27.6)	
<b>Partner Support</b>						
Baseline	2.6 (2.6, 3.0)	2.8 (2.4, 3.2)	0.8 (-0.0, 1.6)	2.8 (2.2, 3.4)	2.8 (2.3, 3.4)	0.8 (0.02, 1.6)
Follow-up	3.1 (2.6, 3.6)	2.5 (2.0, 3.0)		3.5 (3.2, 3.8)	2.6 (1.9, 3.4)	
<b>Physical well-being FACT-G</b>						
Baseline	0.7 (0.2, 1.2)	0.6 (0.2, 1.1)	-0.5 (-1.0, -0.1)	-	-	-
Follow-up	0.4 (0.1, 0.7)	0.8 (0.2, 1.4)		-	-	

† For acceptability, follow-up, and difference scores, N=8 for patients in the intervention group as one patient was lost to follow-up.

‡ This is the difference of Intervention versus Control on change score (follow-up minus baseline on study measures) where positive difference means indicate Intervention group improved more on measure than Control group.

\* Total score, including all physical activities.