Trial in Progress: The Physical Activity Index (PAI) Feasibility Pilot Trial for Breast and Colon Cancer Survivors in North Carolina

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BACKGROUND

- An active lifestyle is recommended for cancer survivors' post-treatment, yet many fail to meet physical activity (PA) guidelines - especially breast cancer survivors (BCS) and colon cancer survivors (CCS) who often manage age-related conditions & cancer symptoms
- Avoiding sedentary behavior is advised to reduce treatment-related physical dysfunction
- Survivors frequently lack guidance from their medical team, and few validated tools exist to assess and counsel on PA and sedentary behavior
- Post-treatment is considered a 'teachable moment' for promoting healthy lifestyle changes (Figure 1)

Physical Activity Index (PAI):

- Combines performance measures for more accurate estimates of PA and its link to health outcomes than standard clinical tools
- Serves as a 'report card' showing survivors progress toward recommendations (Figure 2)

RATIONALE

Few validated tools exist to guide cancer survivors in adopting active lifestyles, making the post-treatment teachable moment an ideal time to test interventions that reduce sedentary behavior and promote PA

OBJECTIVES

Within middle aged and older BCS and CCS who have recently completed cancer treatment, we aim to:

- Assess the feasibility and acceptability of a PAI-based intervention at the teachable moment using screening, coaching, and self-monitoring tools (activity tracker + PAI 'report card')
- Estimate variability for moderate-to-vigorous physical activity (MVPA) and sedentary behavior for the study population

STUDY POPULATION

1. BCS or CCS (stages 0-III), within 3 years of diagnosis
2. Completed primary cancer treatment ≥ 3 months prior to enrollment
3. Male or female, ≥ 50 years old
4. Willing & able to comply to protocol & able to sign informed consent
5. Access to internet or cellular plan & camera for video calls
6. Able to read and speak English

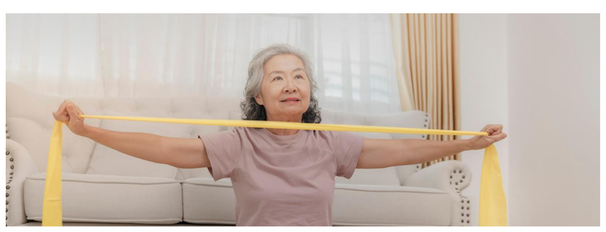
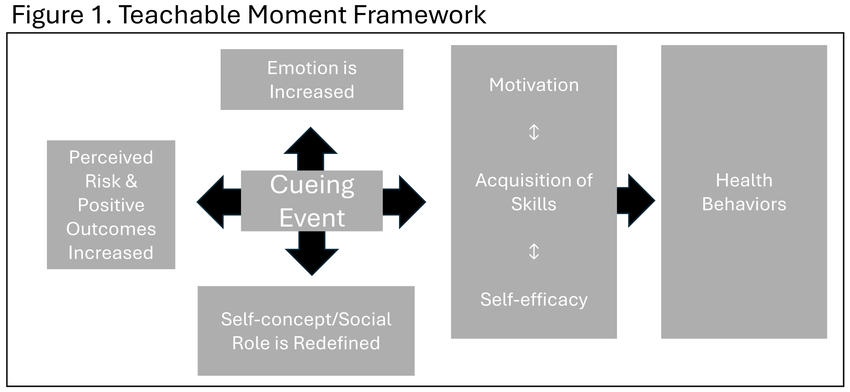


Figure 1. Teachable Moment Framework



METHODS

- Two-arm 1:1 randomized pilot trial (with waitlist control)
- Assessed 3 time points over 6 months, with 2 follow-up visits (12 months total)
- Participants provided with electronic exercise logs, Garmin VivoFit activity tracker, and resistance bands



Clinical Team:

- Interview: acceptability of the PAI intervention, related tools, and clinical experiences
- Focus group: perceptions about the value of PA to patient health

Physical Activity Index Output

This is a report on your physical activity, based on your answers and information from your doctor.

Moderate-vigorous intensity exercise or recreational activities			
No Activity Reported (0 Points)	Needs Improvement (1 Point)	Meets Recommendations (2 Points)	Exceeds Recommendations (3 Points)
		X	

Congratulations on making exercise a part of your routine! Currently, it is recommended that adults achieve at least 150 minutes of moderate-to-vigorous activity per week to help delay or prevent diseases like diabetes and heart disease. You may get additional health benefits from trying to increase the time you spend exercising or by increasing the intensity (working a little harder) each time you exercise.

Moderate-vigorous intensity exercise or recreational activities			
No Activity Reported (0 Points)	Needs Improvement (1 Point)	Meets Recommendations (2 Points)	Exceeds Recommendations (3 Points)
		X	

Great job! You are meeting the recommendation to do exercise to strengthen your muscles at least twice per week. Hopefully, you have noticed a difference in how you feel and move. Strength builds up over time, so maintaining a strength program is important. Some people prefer to do this with friends or as part of a group to make it part of a healthy lifestyle.

Moderate-vigorous intensity exercise or recreational activities			
No Activity Reported (0 Points)	Needs Improvement (1 Point)	Meets Recommendations (2 Points)	Exceeds Recommendations (3 Points)
	X		

You may be sitting and watching more television than you should (no more than three hours per day). Try to choose an active leisure time activity to replace television viewing. If you are not able to reduce your television viewing, try to stand up and take breaks during commercials, at least a couple of times per hour. Even on days when you exercise, small reductions in sitting activities can have additional benefits for your health.

Figure 2. Example of PAI Screener/'Report Card'

INTERVENTION



MEASURES

PA & Sedentary Behavior	PAI (MVPA Questions)*, Exercise Logs*, CHAMPS Activities Questionnaire, ActiGraph GTX3 *Collected during active intervention
Psychosocial Measures	Exercise Self-Efficacy Scale, Outcome Expectation for Exercise Scale, Geriatric Depression Scale
Health Status & Safety	Fall History, General Health (OARS), Self-Rated Health, Current Medications
Physical Function	400-Meter Walk

ANALYTIC PLAN

- Feasibility & Acceptability: Estimate participation, adherence, and retention rates with 95% CIs; compare to hypothesized rates using one-sample binomial tests
- Mixed Methods Analysis: Use RE-AIM QuEST framework and Mixed Methods Patient Reported Outcomes (QPRO)
- Descriptive Statistics: Summarize MVPA (PAI), sedentary behavior (exercise logs, accelerometer, PAI), & possible confounding variables (cancer type, treatment type, medications) measured to estimate SDs for use in future studies

DISCUSSION

This pilot will determine if the PAI intervention is feasible and acceptable and provide variability estimates to inform a future efficacy trial. Findings will guide refinement of PA counseling tools for survivorship care.



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