The TeleHealth Resistance Exercise Intervention to Preserve Dose Intensity and Vitality in Elder Breast Cancer Patients (THRIVE-65) Trial

Schleicher E[1], Oppenheim J[2], Kemp W[2], Doerksen S[1], Diguglielmo K[2], West SM[1], Ahmed M[1], Binder J[1], Nguyen TL[2], Mills C[3], Tanasijevic A[2], Owusu C[3], Thomson CA[4], Basen-Engquist K[5], Ligibel JA[2], Schmitz KH[1]

[1]Division of Hematology Oncology, UPMC Hillman Cancer Center, School of Medicine, University of Pittsburgh, Pittsburgh, PA; [2]Department of Medical Oncology, Dana Farber Cancer Institute, Boston, MA; [3]Department of Medicine, Division of Hematology and Oncology, Case Western Reserve University, Cleveland, OH; [4]Department of Health Promotion Sciences, Mel and Enid Zuckerman College of Public Health, University of Arizona, Tucson, AZ; [5]Department of Health Disparities, The University of Texas MD Anderson Cancer Center, Houston, TX.

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As the number of **older women** with **breast cancer** rises, **optimizing treatment delivery**, **tolerance**, & **functional status** during **chemotherapy** is increasingly **relevant** to **clinical practice**

University of Pittsburgh

BACKGROUND



Age-related declines worsen chemotherapy treatment outcomes & reduce **received dose intensity (RDI)** in older breast cancer patients



Chemotherapy **RDI below 85%** is linked to increased recurrence & mortality risk



Exercise & a protein-rich diet may **improve RDI & survival**

PRIMARY AIM



Assess impact of an **exercise + protein support intervention (THRIVE-65)** vs. **Health Education & Support (HES)** control in women **age ≥ 65** with **breast cancer** receiving **chemotherapy** on **RDI**

SECONDARY AIMS

Evaluate the impact of the **THRIVE-65 intervention** vs. **HES control** in women **age ≥ 65** with **breast cancer** receiving **chemotherapy** on the following:



METHODS

RECRUITMENT

Four medical centers:

- Dana-Farber Cancer Institute
- Case Western Reserve University
- UPMC Hillman Cancer Center
- Mount Nittany Medical Center



270
Sample size goal



140
Older women randomized over 31 months

Table 1. Eligibility Criteria

Inclusion Criteria	Exclusion Criteria
Women age ≥ 65	Following a high protein diet or diet for co-morbid disease contradicting THRIVE-65
Stage I-III invasive breast cancer	Performing ≥ 2 weekly strength training for 3+ consecutive months in past year
BMI between 18-50 kg/m^2	Engaging in competitive aerobic activities
Beginning 10+ weeks of cytotoxic chemotherapy for curative intent	Medical conditions/medications that prohibits exercise
Ability to walk for 6 minutes or 2 blocks	Current use of weight-loss medication
Ability to provide informed consent	History of alcohol/substance abuse within past year
Ability to understand English	History of dementia

INTERVENTIONS



THRIVE-65
Exercise + Protein Support

- 2x weekly virtual supervised resistance exercise led by trained exercise physiologists
- 90 minutes/week of unsupervised aerobic exercise
- Diet counseling with a registered dietitian
  - 1.2 g/kg/day protein intake goal
- Fitbit



HES control
Health Education & Support

- Tablet with supportive programming
  - e.g., non-tailored nutrition, meditation, yoga
- Fitbit

STATISTICAL ANALYSIS

The primary analysis assumes 65-75% of the control group will achieve an RDI of 85% and hypothesizes that 82-89% of the THRIVE-65 group will achieve an RDI of 85% (80% power, two-sided 0.05 significance level).

MEASURES

Table 2. Overview of all participant measurements in the THRIVE-65 trial

Outcomes & measures	Instrument	Baseline	Each cycle	End of Study[d]
Primary Aim				
Received dose intensity	Electronic medical record	X	X	
Geriatric Assessment Components				
Functional status	6-Minute walk test	X		X
	Handgrip assessment	X		X
	Karnofsky performance status	X		X
	MOS SF-36	X		X
	Number of falls in last 6 months	X		X
	OARS MFAQ (IADL)	X		X
Cognitive impairment	Universal mini-cog scale	X		
Comorbidities	OARS physical health	X		X
Medication review	List of medications, herbs, or vitamins	X		X
Sleep disturbance	Pittsburgh sleep quality index	X		X
Psychological status, functioning & social support	Geriatric depression scale short form	X		X
	MOS social activity limitation scale	X		X
	MOS social support survey subscale	X		X
Additional Measures				
Socio-demographic data	Demographic survey	X		
Chemotoxicities	CARG-breast cancer		X	
	Electronic medical record		X	
	PRO-CTCAE[a]		X	
Injury/Illness	Adverse events questionnaire		X	
Lymphedema	Norman lymphedema survey[b]	X		X
Peripheral neuropathy	FACT-NTX-4	X		X
Anxiety	PROMIS anxiety short form 8a	X		X
Anthropometry	Body weight, height, waist circumference	X		X
Muscle mass	D3-creatine dilution test	X		X
Physical activity	ActiGraph accelerometry	X		X
	Fitbit		X	
	Morgenstern physical activity questionnaire	X		X
Hunger vital sign	Hunger vital sign survey	X		X
Dietary intake	24 Hour dietary recall	X		X
Protein intake	Protein checklist[c]		X	
Study tablet engagement	Tablet engagement questionnaire		X	
Healthcare utilization	Healthcare utilization survey			X

[a] Administered on Day 1 and Day 8 of the first and final cycles of chemotherapy
[b] Administered only to participants who have already completed breast surgery at the time of enrollment
[c] Thrive-65 intervention completes throughout the study; HES control completes at start of 3rd chemotherapy cycle
[d] Occurs at the end of chemotherapy treatment

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