

Reducing Lung Cancer Survivors' Anxiety and Dyspnea (RELAX)

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Background & Significance

- With new screening recommendations, numbers of early-stage lung cancer survivors will increase. Essential to address survivorship issues in this group.
- Anxiety is common (20-30%) in this group and persists after treatment ends.
- Dyspnea is also common after treatment (regardless of disease stage) too and is worsened by anxiety and distress.
- These enduring symptoms cause functional impairment and diminished quality of life in this patient group.
- The proposed breathing intervention – the Resperate® device – is relatively inexpensive, simple to use, and highly acceptable to patients.

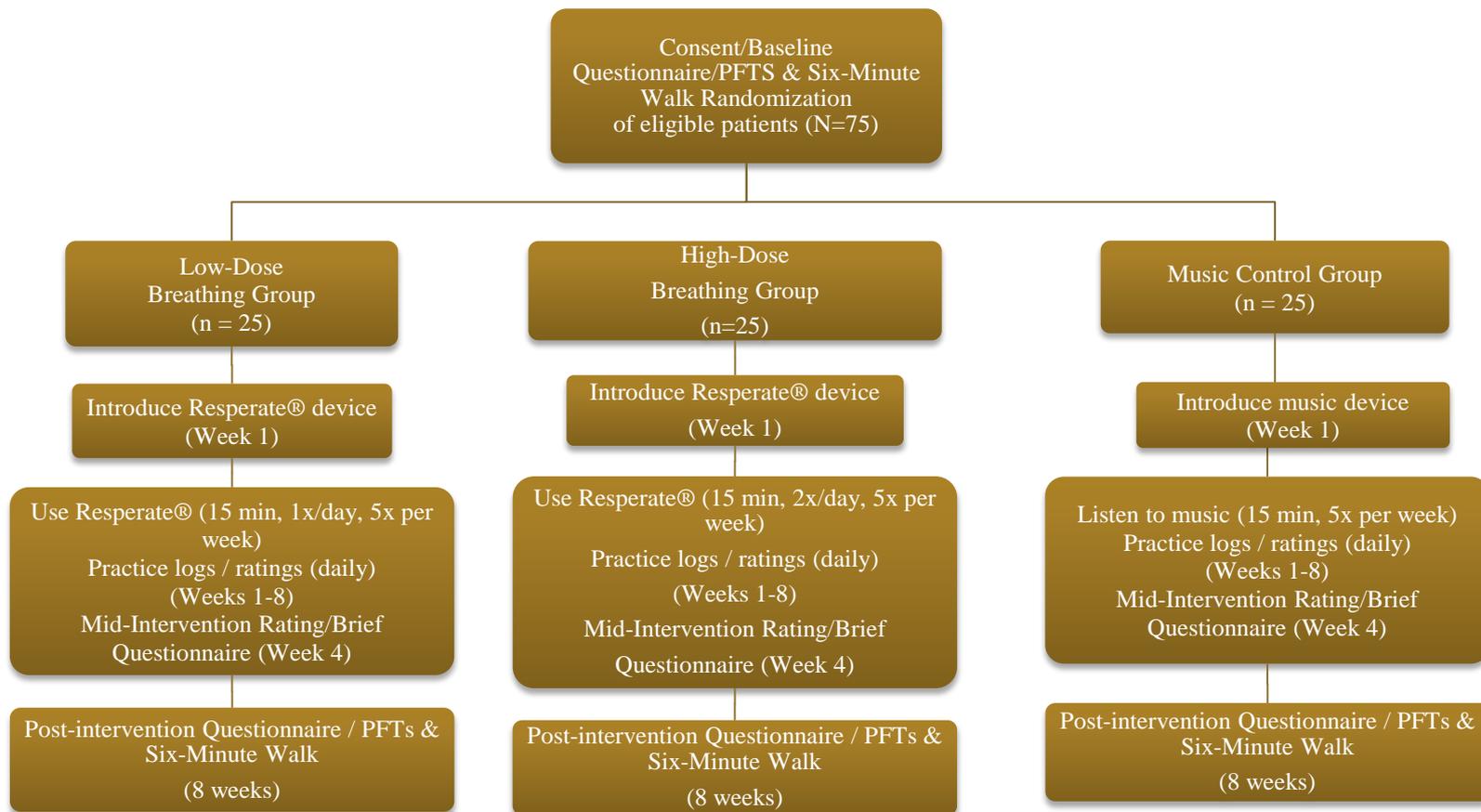
Study Objectives

- Aim 1: To assess feasibility (accrual, participation, adherence, retention) of a randomized study comparing device-guided breathing to music in 75 post-treatment lung cancer survivors with clinically meaningful anxiety symptoms.
- Aim 2: To obtain preliminary data on the variability and efficacy of two doses of a device-guided breathing intervention versus a music control group for reducing anxiety and dyspnea and improving respiratory functioning (pulmonary/functional fitness).

Resperate® Breathing Intervention



Study Schema



Eligibility Criteria

Inclusion Criteria

- ≥ 18 yrs of age
- Histologic or cytologic diagnosis of primary non-small cell Stage 0-II lung cancer
- 2-24 months post-completion of surgery, RT and/or chemotherapy with no further planned treatment during 8-week study
- Score ≥ 8 on anxiety subscale of the HADS
- ECOG performance status 0-2
- Hemoglobin ≥ 9.5
- Smoking status anticipated to be stable during course of this study
- Agrees to attend brief introduction session and home practice requirement (15 minutes 1x or 2x per day, 5 days per week)

Exclusion Criteria

- Does not read/understand English
- Active lung infection
- Radiation pneumonitis currently treated with oral steroids
- Unstable angina
- Pulmonary embolism in past 6 months
- Progressive cancer (must be NED/stable)
- Any change in psychotropic medications in past month
- Hearing loss that would preclude participating in interventions

Study Measures

Measures	Baseline	Weeks 1-8	Week 4	Week 8
HADS (Anxiety/Depression)	X		X	X
Cancer Dyspnea Scale	X		X	X
Pulmonary Function Tests (FEV1 / Diffusion Capacity)	X			X
Six-Minute Walk	X			X
GAD-7 (measure of Generalized Anxiety Disorder symptoms)	X			X
Visual Analogue Scales for Distress, Anxiety, and Dyspnea / Intervention Logs		To be completed 5 days/week		
Respiration Rate		For breathing groups, recorded on device		
Expectations of Benefit	X			X
Intervention Evaluation				X

Study Status

- Grant was submitted to NCI in February 2013. Scored in the 6th percentile on first submission.
- Accrual goal: 75 patients
- Anticipated start date: Early 2014
- Currently planned as limited-access study. Open to considering other sites that anticipate strong ability to accrue ESLC survivors.

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Questions, Discussion, and Feedback

(Please feel free to send questions or feedback to danhauer@wakehealth.edu.)