Study Title:
Reducing Lung Cancer Survivors' Anxiety (RELAX)

ClinicalTrials.gov: Reducing Lung Cancer Survivors' Anxiety and Dyspnea

For Clinical Research Sites interested in participating in this study, please contact Robin Rosdhal by e-mail (rosdhal@wakehealth.edu) or by phone (336.713.6519).

PURPOSE:

The purpose of this research study is to compare the effects of music and different levels of device-guided breathing on anxiety and shortness of breath in lung cancer survivors.

Study Type:

Interventional

Study Design:

- *Allocation*: Randomized
- *Endpoint Classification*: Efficacy Study
- *Intervention Model:*
- *Masking*: Open Label
- *Primary Purpose*: Supportive Care

Estimated Enrollment:	75
Study Start Date:	January 2015
Estimated Study Completion Date:	May 2016
Estimated Primary Completion Date:	January 2016 (Final data collection date for primary outcome measure)

Primary Outcome Measures:

- Change from baseline HADS-Anxiety assessed 4 weeks post-randomization:
  - The clinical endpoints are anxiety (primary outcome: HADS-Anxiety), dyspnea, and respiratory function at baseline and 4 weeks post-randomization.
  - *Time Frame*: 4 Weeks
  - *Designated as safety issue*: No

Secondary Outcome Measures:

- Change from 4 weeks HADS-Anxiety at 8 weeks:
  - The clinical endpoints are anxiety (primary outcome: HADS-Anxiety), dyspnea, and respiratory function at 8 weeks post-randomization.
  - *Time Frame*: 8 Weeks
  - *Designated as safety issue*: No

Detailed Description:

Objectives -

1. To assess feasibility (accrual, participation, adherence, retention) of a randomized study of device-guided breathing and music in 75 post-treatment ESLC survivors with significant anxiety.

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 (primary outcome) and for improving self-reported dyspnea and respiratory functioning (secondary outcomes) in post-treatment lung cancer survivors.

3. To select the optimal dose of the device-guided breathing intervention (15 minutes once/day or twice/day) for subsequent randomized study.

For more information, please follow the ClinicalTrials.gov link provided at the top of page 1