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Lifestyle Intervention for Seniors with Apnea (LISA)

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Real Life Pilot: Successes and Challenges

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Lifestyle Intervention for Seniors with Apnea- Pilot Study Goals

- The **overarching goal** of this study is to determine the *feasibility* and impact of a weight loss and exercise intervention on sleep apnea in older adults.
- **Specific Aim 1:** Determine the effect of the intervention on magnitude of improvement in sleep apnea
- **Specific Aim 2:** Determine whether changes in sleep apnea parameters are associated with changes in body composition and vascular parameters

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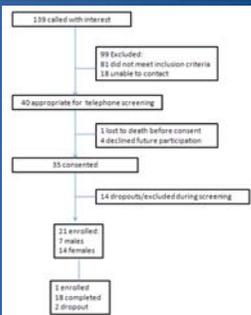
Background & Rationale

"Impetus" for the pilot project:

- Discussion with colleagues in Pulmonary Medicine ("Seed" for idea)
- Our data has demonstrated that cohorts with high likelihood of having sleep apnea had attenuated responses to exercise and weight loss interventions
- Sleep apnea is common and understudied in older adults; contribute to frailty indirectly through CVD

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Lifestyle Intervention for Seniors with Apnea- Consort Diagram



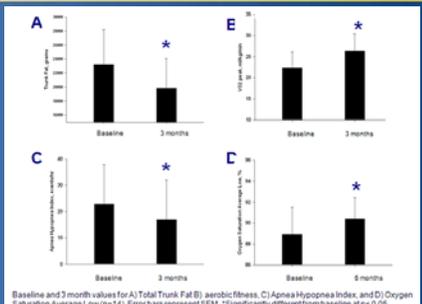
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Lifestyle Intervention for Seniors with Apnea -Study Design

- **Subjects:** Twenty adults (>60 years; BMI, 30-42 kg/m²) not currently being treated for sleep apnea
- **Protocol:** 3 month weight loss intervention consisting of AHA diet and ACSM guidelines driven comprehensive exercise program - "Proof of concept"
- **Outcomes:** Sleep outcomes, body composition, indices of vascular function

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Changes in Trunk Fat, Fitness and Sleep Outcomes



Baseline and 3 month values for A) Total Trunk Fat (B) aerobic fitness, C) Apnea Hypopnea Index, and D) Oxygen Saturation Average Low (n=14). Error bars represent SEM. *Significantly different from baseline at p<0.05.

Preliminary Conclusions



Following the 3 month intervention subjects lost weight (8.6%), total percent body fat (5.8%), improved fitness (15%), and had a mean reduction in AHI of 6 events per hour.

However, no relationship was observed between the change in AHI and the change in body weight or total body fat, suggesting that other factors account for the variance in AHI reduction.

An improvement in vascular stiffness was associated with improved OSA severity but not changes in body composition, thereby revealing a potential mechanism by which a weight loss diet and exercise reduce CVD burden in older adults with OSA.

Writing your proposal



- A small-scale test of the methods and procedures to be used on a larger scale if the pilot demonstrates their feasibility
 - Estimate adherence and retention rates
 - Investigate the acceptability of the interventions and assessments to participants
 - Investigate the variability of change in variables in order to make informed estimates of likely sample size required
 - Be careful of proposing a “feasibility” study

Conducting the Pilot Study: Successes and Challenges



Comments from a Reviewer



- If the hypothesis is that lifestyle intervention is effective in treating sleep apnea, which causes or exacerbates frailty, then the study design seems reasonable insofar as the primary outcome is AHI. However, this is not a particularly novel hypothesis as weight loss by diet and exercise are already standard of care for OSA and are effective means of reducing OSA severity.
- If the hypothesis is that lifestyle intervention is particularly effective or should be targeted to patients with sleep apnea, then there is no comparison group of obesity-matched patients without sleep apnea.

Choosing the right funding agency

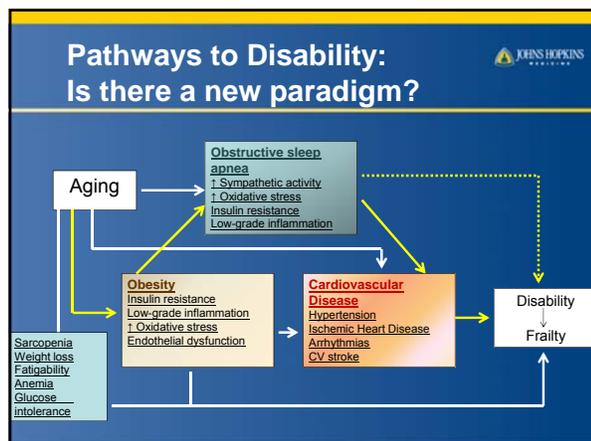


- Important to know the mission of the funding agency
 - The mission of the Hopkins OAIC is to identify causes and develop treatment for frailty. Mission also includes understanding preventative treatments for those at risk for frailty as this would have the broadest public health impact

Specific Aims and Significance



- Not definitive hypothesis testing but must be the goal that underpins the ultimate definitive study should have been made clearer
- Emphasize importance of area of inquiry
 - **A figure of a theoretical model may have illustrated goal of study**
 - **“A picture is worth a thousand words”**



Participant Burden & Approaches to Recruitment

- Participant burden
 - Use of novel technology to measure ventilation from sleep studies (See Figure)
- Approaches to recruitment
 - Allowed for the identification of most effective recruitment sources- Beacon Newspaper

Goals of the pilot- Selection of most appropriate outcome

- Apnea-hypopnea index (AHI) is an established clinical marker of sleep apnea severity, but:
 - Weight loss may account for only small percentage of variance in AHI reduction, suggesting other factors have significant role in treatment
 - Pilot allows one to explore other factors

Protocol Logistics- Issues to consider

- Baseline testing and methods
 - sleep study → fasting blood draw → vascular tests → breakfast
- Intervention
 - 3 days/wk exercise + 1 day/wk diet
- Structure of follow-up
 - When will blood be collected to reduce burden?

Test and Identify appropriate logistics

What did the pilot accomplish?

- Method Development
 - Use of ultrasound to assess abdominal fat
- Intervention Evaluation
 - Does weight loss treatment lead to improved sleep apnea in older group?
- Clinical Trials Preparation
 - We developed recruitment strategy and will estimate sample size based on preliminary data

Was I Too Ambitious?



- Data collection
 - There was a tendency to “bundle” a lot of assessments into project- aging, CV, sleep
 - This only becomes problem if it becomes a burden and distracts from the primary outcomes
- Study Design
 - The initial study design was abandoned in favor of a simpler, streamlined design

IRB approval



- Allow 3 months between typing first words to final approval
 - Award began on July 1; First subject consented in January
- Do not forget about ICTR approval
 - ICTR meets once per month

Inclusion of Pilot Data



- Yes
 - Helped to establish myself as having core competencies in relevant areas
 - I am not a sleep researcher but my colleagues are (would never work in RO1)
 - Highlighted the strengths of my co-investigators competent in area of inquiry

Successes



- Has helped to establish a multidisciplinary approach to an old problem
 - Aging, sleep, weight loss intervention
 - Met recruitment and retention goals in time of award

Meeting Challenges



- Sample size calculation
 - Important to meet the statistician BEFORE your proposal, 95% confidence interval approach was appropriate
- Budget
 - Use the resources available from ICTR and colleagues
 - Don't forget the parking passes for subjects

Successes



- Allowed for a platform to understand the flow/pace of data collection
 - Rate of referral and retention
 - Identified who, in this population, has this disorder
 - Aging, sleep, weight loss intervention

Words of Advice



- Be patient
- Trust your colleagues
- Use available resources
 - ICTR and OAIC cores

Acknowledgements



- Kerry Stewart
- Pulmonary Group
 - Alan Schwartz, Susheel Patil, Naresh Punjabi, Jason Kirkness
- OAIC
 - Jeremy Walston, Karen Bandeen-Roche, Gary Gerstenblith, Brian Buta, Steven Prior (U MD), Pepper Scholars
- Bayview CRU
 - Pam Ouyang, nursing staff, exercise staff and dietitians