Introduction

- Pulmonary arterial hypertension (PAH) is a chronic disease which leads to right heart failure and death if left untreated. Individuals suffering from PAH can experience symptoms such as fatigue and sleep disturbance, which can greatly impair quality of life (QOL). Existing medications used to treat PAH and resulting symptoms are complex and no non-pharmacological treatments have been tested for PAH.
- Insomnia, defined as trouble initiating or maintaining sleep, is prevalent in PAH subjects with PAH identify fatigue as interfering with their life.
- PAH and resulting symptoms are complex and no non-pharmacological treatments have been tested for PAH.
- Cognitive Behavioral Therapy (CBT-I) involves behavioral and cognitive strategies which can help individuals alter beliefs that inhibit their sleep.
- Bright Light Therapy can greatly impair quality of life (QOL). Existing medications used to treat PAH.
- Bright Light Therapy has been shown to be effective in combating insomnia, it is not as effective against the waking symptoms of fatigue.

Materials & Methods

- The study consists of 3-arms: a group receiving Bright Light Therapy, a group receiving CBT-I, and a control group.
- Each subject remains in the study for approximately 10 weeks. Approximately 36 subjects will be enrolled after recruitment.
- In order to measure daytime activity and duration of sleep, an actigraphy will be worn by subjects on the wrist, at the first and last week of the study.
- Subjects will complete a sleep and activity diary throughout the study in order to collect data about their sleep/wake patterns.
- For the Bright Light Therapy component of the study, subjects utilize the Re-timer glasses device for 8 weeks daily, which emits blue-green 500 nm light.
- The CBT-I component of the study consists of 1 session every week for 8 weeks, provided by a trained professional. These sessions will involve discussion of sleep restriction, stimulus control and sleep hygiene.
- Subjects are instructed to complete the following questionnaires once they begin wearing the ActiGraph device:
  - Fatigue Severity Scale (FSS)
  - PROMS Sleep Disturbance
  - Insomnia Severity Index (ISI)
  - emphasis-10
  - CES-D
  - PROMS Anxiety Questionnaire
  - Pittsburgh Sleep Quality Index (PSQI)
  - PROMS Dyspnea Questionnaire
  - Pulmonary Arterial Hypertension Symptom Scale (PAHSS)
  - PROMS Physical Function Questionnaire

Results

- This study is still undergoing approval from the International Review Board (IRB). However, the following objectives are in place:
  - To assess the feasibility of CBT-I and Bright Light Therapy in patients with PAH.
  - To compare the effects of CBT-I and Bright Light Therapy on Standard of Care on primary (insomnia and fatigue severity) and secondary (wake after sleep onset and sleep onset latency) outcomes.
  - To examine the impacts of CBT-I and Bright Light Therapy to Standard of Care on the secondary outcome physical activity.
  - To examine the impacts of CBT— and Bright Light Therapy to Standard of Care on the secondary outcomes: PAH symptoms, depression, dyspnea and QOL.

Summary

- This study is a randomized control trial designed to test the effectiveness of Cognitive Behavioral Therapy and Bright Light Therapy for treating insomnia and fatigue seen in patients with pulmonary arterial hypertension.
- For 8 weeks, 12 subjects will receive Bright Light Therapy via the Re-timer device, while 12 other subjects will receive Cognitive Behavioral Therapy via a trained professional. The remaining 12 subjects will remain as a control group.

References

- van der Meer E, van der Meer M, Wilms C, et al. Circadian phase delay using the newly developed reLight Bright Light Therapy via the Re-timer device, while 12 other subjects will receive Cognitive Behavioral Therapy and Bright Light Therapy.