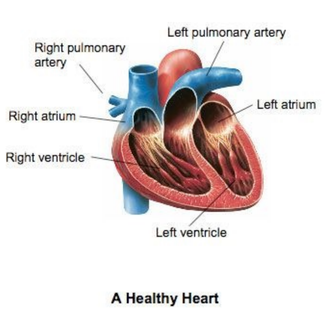
CBT-I and Light Therapy for Treating Insomnia

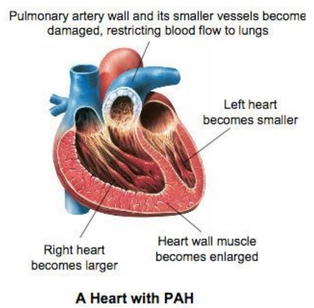
Michael Proano, P.I. Lea Ann Matura, PhD

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 roughly 2/3 of cases of PAH. Insomnia and poor sleep quality are common in pulmonary hypertension (PH) and are linked to depression, fatigue and overall lowered QOL.
- Fatigue is an overwhelming, sustained sense of exhaustion that increases the difficulty of carrying out daily activities. We found that more than 90% of subjects with PAH identify fatigue as interfering with their life.



A Healthy Heart



A Heart with PAH

Bright Light Therapy vs. CBT-I

- Bright Light Therapy has been used recently to treat sleep disorders such as insomnia, along with other circadian rhythm disorders. Light input given to photoreceptors in the eye decreases the secretion of melatonin, the hormone which controls the sleep-wake cycle. Bright Light Therapy is a safe, affordable, and relatively simple treatment option with only minor side effects.
- Bright Light Therapy has shown effectiveness in treating cancer-related fatigue, with previous studies finding a larger effect size on sleep efficiency as opposed to dim light.
- Cognitive Behavioral Therapy for Insomnia (CBT-I) involves behavioral and cognitive strategies which can help individuals alter beliefs that inhibit their sleeping ability. Behavioral interventions, including relaxation therapy, stimulus control, and sleep restriction, can result in better sleep habits.
- A literature review conducted to study the role of insomnia in other conditions identified CBT-I as improving insomnia along with other medical and psychological endpoints.
- Although CBT-I has been shown to be effective in combating insomnia, it is not as effective against the waking symptoms of fatigue. Additionally, evidence showing the impact of Bright Light Therapy on sleep and fatigue is largely inconclusive. Thus, there is a need to test the efficacy of CBT-I and Bright Light Therapy for treating specific conditions such as insomnia and fatigue.

Materials & Methods

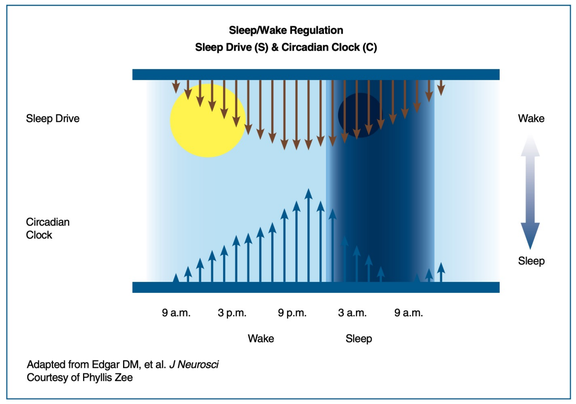
- The study consists of 3-arms: a group receiving Bright Light Therapy, a group receiving CBT-I, and a control group.
- Each subject remains in the study for approximately 10 weeks. Approximately 36 subjects will be enrolled after recruitment.
- In order to measure daytime activity and duration of sleep, 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
  - PROMIS Anxiety Questionnaire
  - Pittsburgh Sleep Quality Index (PSQI)
  - PROMIS Dyspnea Questionnaire
  - Pulmonary Arterial Hypertension Symptom Scale (PAHSS)
  - PROMIS 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.



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