Cognitive behavioral therapy for insomnia in stable heart failure: Protocol for a randomized controlled trial

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Abstract

Background: Chronic insomnia is associated with disabling symptoms and decrements in functional performance. It may contribute to the development of heart failure (HF) and incident mortality. In our previous work, cognitive-behavioral therapy for insomnia (CBT-I), compared to HF self-management education, provided as an attention control condition, was feasible, acceptable, and had large effects on insomnia and fatigue among HF patients.

Objectives: The purpose of this randomized controlled trial (RCT) is to evaluate the sustained effects of group CBT-I compared with HF self-management education (attention control) on insomnia severity, sleep characteristics, daytime symptoms, symptom clusters, functional performance, and health care utilization among patients with stable HF. We will estimate the cost-effectiveness of CBT-I and explore the effects of CBT-I on event-free survival (EFS).

Methods: Two hundred participants will be randomized in clusters to a single center parallel group (CBT-I vs. attention control) RCT. Wrist actigraphy and self-report will elicit insomnia, sleep characteristics, symptoms, and functional performance. We will use the psychomotor vigilance test to evaluate sleep loss effects and the Six Minute Walk Test to evaluate effects on daytime function. Medical record review and interviews will elicit health care utilization and EFS. Statistical methods will include general linear mixed models and latent transition analysis. Stochastic cost-effectiveness analysis with a competing risk approach will be employed to conduct the cost-effectiveness analysis.

Discussion: The results will be generalizable to HF patients with chronic comorbid insomnia and pave the way for future research focused on the dissemination and translation of CBT-I into HF settings.

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1. Introduction

Almost 75% of heart failure (HF) patients, a population of over five million Americans [1] who have poor function and high levels of morbidity and mortality, report poor sleep [2]. As many as 50% [3,4] report comorbid chronic insomnia (i.e., difficulty initiating or maintaining sleep, or waking early in the morning with associated non-restorative sleep that persists for at least a month [5]). Chronic insomnia is associated with disabling symptoms such as fatigue, dyspnea, anxiety, depression, excessive daytime sleepiness, and pain, and may contribute to the development of HF and incident mortality [6].

Despite the importance of insomnia to critical HF outcomes, HF patients report that health care professionals fail to address it [7]. Patients prefer behavioral approaches to hypnotic medications [7] that are associated with adverse events, such as daytime sleepiness, falls, and altered cognition, but little is known about the impact of behavioral treatment for chronic insomnia among HF patients.

Cognitive behavioral therapy for insomnia (CBT-I), a self-management intervention, focuses on dysfunctional behaviors and cognitions that perpetuate physical and psychological arousal and chronic insomnia [8]. The effects of CBT-I are more durable than hypnotic medications [8,9] without negative daytime effects [10].

In a pilot RCT, CBT-I improved chronic insomnia, sleep quality, sleep efficiency, and fatigue immediately after treatment in patients with...
Class II–III HF with chronic insomnia, compared with an attention control group who received HF self-management education alone [11]. Participants reported that it was highly acceptable and feasible. Both groups had stable HF at baseline (BL) and received evidence-based HF disease management. Evidence that chronic insomnia predicts incident HF and mortality [6] suggests the potential benefits of CBT-I to event-free survival (EFS), an outcome of critical importance to HF patients that has not been examined in relation to CBT-I. Although the benefits of CBT-I on sleep and insomnia have been widely documented, little is known about its effects on these important outcomes.

2. The organizing framework

The organizing framework is based on chronobiologic and homeostatic models of sleep regulation, the “3-p” model of insomnia [12], the Framework for Self- and Family Management of Chronic Conditions [13,14], and research on symptoms and symptom clusters [15]. Chronic insomnia occurs at least 3 nights/week for at least one month [16] and is associated with one or more of the following: non-restorative sleep, difficulty initiating sleep, maintaining sleep, and/or waking too early despite adequate sleep opportunity [5]. It is comorbid when it occurs with, but is not explained by, psychiatric, or medical disorders (e.g., HF). Insomnia often persists with optimal treatment of the comorbid condition [17]. The “3-p” model posits that biological, psychological, and social traits (predisposing factors); acute triggers, such as acute illness/treatment (precipitating factors); and maladaptive strategies (dysfunctional beliefs, attitudes, and behaviors) used to compensate for sleep loss (perpetuating factors) contribute to chronic insomnia through chronic somatic and/or psychological arousal – the “final common pathway” to chronic insomnia [17] (Fig. 1).

Predisposing and precipitating factors for insomnia are poorly understood, but they are likely multi-factorial. Aging and gender often predispose to insomnia, but among HF patients, age, gender [2,3], left ventricular ejection fraction (LVEF) [2], cardiac medications [18], and sleep apnea (SA) were not associated with chronic insomnia [3,19]. Because these factors and comorbidity may contribute to insomnia and other study outcomes, they will be explored as possible covariates (Fig. 1).

HF patients attributed awakening to modifiable factors such as increased time in bed awake [2], insufficient sleep, frequent napping [2], and use of TV as white noise at night [7]. Negative associations between sleep hygiene and sleep quality [19] and positive associations between insomnia severity and dysfunctional beliefs and attitudes about sleep, mental anxiety, and sleep effort underscore the contributions of perpetuating factors to chronic insomnia among HF patients.

The Framework for Self- and Family Management that explains the knowledge and skills to manage chronic conditions and related emotions and symptoms [13,14], is the conceptual basis for CBT-I and the attention control condition (HF self-management education) used in this study. CBT-I includes cognitive and behavioral strategies that address perpetuating factors for insomnia (Fig. 1, Table 1).

HF self-management includes behaviors needed to manage HF itself. Although self-care and self-management [20] and symptom clusters [15] have been associated with improved EFS in observational studies, estimates of the effects of self-management on EFS and health care resource utilization, are inconsistent [21,22]. The effects of CBT-I versus HF self-management education on EFS will be explored in this study.

CBT-I protocols vary in format (group vs. individual), the types of included elements, and session frequency, but consistently address perpetuating factors through behavioral, cognitive, and educational elements [8]. The components of our CBT-I intervention are described in Table 1.

CBT-I has consistent effects on chronic insomnia [17,23] and sleep efficiency [11,24,25], and improves some symptoms (e.g., fatigue, depression) in non-HF groups [26–28]. In our previous work, the observation of large effects of CBT-I on insomnia severity, remission rates, and fatigue [11], its effects on symptom clusters (patterns of severity of two or more symptoms), and its association with improved functional performance among HF patients supports the preliminary efficacy of CBT-I in HF patients, a group highly vulnerable to disabling symptoms. A symptom cluster, characterized by emotional distress, predicted cardiac events among patients with HF [15], and insomnia predicted incident HF, death from HF [6], health care resource utilization, and indirect costs [29,30], but to our knowledge, previous studies have not

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**Table 1**

<table>
<thead>
<tr>
<th>Components</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavioral</td>
<td>Re-associating the bed with sleep; maintaining a consistent sleep/wake schedule; arising at the same time each morning; going to bed only when sleepy; getting out of bed when unable to sleep; using bed only for sleep and sex; avoiding naps</td>
</tr>
<tr>
<td>Sleep restriction therapy</td>
<td>With therapist supervision, patient decreases time in bed to maximize sleep efficiency, and then gradually re-increases it until the optimum efficiency and duration is attained</td>
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<tr>
<td>Relaxation training</td>
<td>Reduction of somatic and cognitive arousal (e.g., progressive muscle relaxation; diaphragmatic breathing)</td>
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<tr>
<td>Cognitive therapy</td>
<td>Clarifies misperceptions/misattributions about insomnia/sleep; reframes unrealistic expectations; reduces performance anxiety; increases control over sleep</td>
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<tr>
<td>Educational</td>
<td>Focuses on managing lifestyle and environment: avoiding caffeine, tobacco and alcohol during evening hours; encouraging physical activity; avoiding naps; removing alarm clock from the bedroom; avoiding use of electronic devices/TV in the bedroom; use of blue screen filters; modification of sleep environment (comfortable bed, lighting, temperature, noise); information on normal sleep, age-associated changes, and potential interactions between heart failure, its treatment and sleep/insomnia</td>
</tr>
</tbody>
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**Fig. 1.** Organizing framework. Solid-lined boxes/arrow = outcomes; double lined box/arrow = intervention; broken boxes/arrows = factors likely to contribute to insomnia, healthcare resource utilization, symptoms, functional performance, and event-free survival (possible covariates); LVEF = Left ventricular ejection fraction; C-PAP = Continuous positive airway pressure.
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