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CHoosing Options for Insomnia in Cancer Effectively (CHOICE): Design of a patient centered comparative effectiveness trial of acupuncture and cognitive behavior therapy for insomnia

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ABSTRACT

Insomnia is a prevalent and persistent side effect of cancer, which if left unaddressed, can be unremitting and negatively influence physical and mental well-being. Acupuncture and Cognitive Behavioral Therapy (CBT) are commonly used non-pharmacological treatments that are efficacious for treating insomnia in cancer patients; however, little is known about the comparative effectiveness of these options. The goal of personalized medicine is to determine which treatments are most effective for which individuals, and patient preference for treatment is a particularly important contributor to adherence and outcomes. Here we describe the design of a clinical trial that begins to determine how best to personalize the treatment of insomnia for cancer survivors. This project is a randomized controlled comparative effectiveness trial with a nested qualitative study comparing acupuncture and CBT for insomnia and co-morbid symptoms in a heterogeneous sample of 160 cancer survivors. The primary aim is to determine which treatment is associated with the largest reduction in insomnia severity. The secondary aim is to examine the demographic, clinical, and psychological characteristics that predict and/or moderate treatment effect. Patients will receive ten treatments of acupuncture or 7 sessions of CBT over eight weeks and complete validated patient-reported outcome measures of sleep and co-morbid symptoms at baseline, mid-treatment, post-treatment, and at three-months to assess durability of effect. The results of the proposed study have the potential to improve healthcare outcomes by helping cancer survivors and their caregivers make informed and evidence-based decisions, leading to patient-centered and personalized care for cancer survivors with insomnia.

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1. Introduction

Sleep disturbance, primarily in the form of insomnia, is a frequently overlooked consequence of cancer diagnosis and treatment [1,2]. Several large-scale epidemiological studies demonstrate that close to 60% of people treated for cancer experience insomnia [3,4] which, if not appropriately treated, can become chronic [4]. Cancer-related sleep disturbances are particularly pernicious because of their relationship to impaired psychological health and physical well-being. More often than not, insomnia co-exists with pain, fatigue, depression, and anxiety, creating a positive feedback loop in which all symptoms are amplified and overall symptom burden is increased [5–7].

Acupuncture and Cognitive Behavioral Therapy (CBT) are both widely available and commonly used non-pharmacological treatments for insomnia and other co-morbid symptoms; however, there is a gap in the available evidence as to the comparative effectiveness of these options [8]. Some estimates suggest that up to one-third of cancer patients use acupuncture to help manage problematic cancer-related symptoms [9] and there is increasing evidence for the use and efficacy of acupuncture for the treatment of insomnia [10–12]. Acupuncture has been shown to be slightly more effective than benzodiazepines [13] and equally as effective as zolpidem for improving sleep in non-cancer populations [14]. Evidence also suggests that acupuncture has the potential to repair fragmented sleep architecture and increase time spent in slow wave sleep [15]. While evidence for the use of acupuncture for insomnia and comorbid symptoms is compelling, past research has also been criticized for having substantial poor methodologies such as small sample size, questionable randomization, poor reporting, and inappropriate analyses [16–18].

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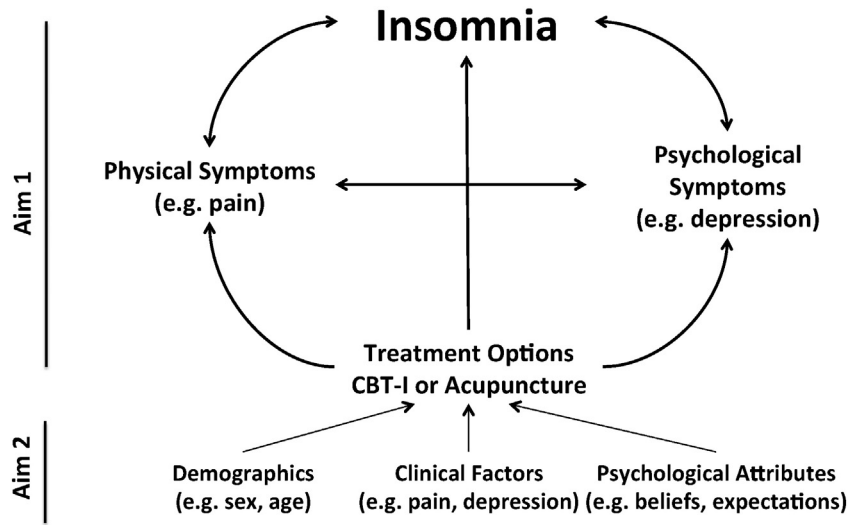E-mail address: maoj@mskcc.org (J.J. Mao).

Fig. 1. Conceptual model.

Cognitive Behavior Therapy for Insomnia (CBT-I) is a form of CBT specifically designed for insomnia. A systematic review and meta-analysis of randomized controlled trials of CBT-I in cancer patients concluded that CBT-I is a highly effective treatment for sleep disturbance and produces significant improvements in a variety of subjective sleep components [19]. Recent evidence also suggests that CBT-I is effective in reducing clinical levels of fatigue, anxiety, and depression related to cancer treatment [20,21]. Despite the evidence that CBT-I is an effective intervention, poor adherence is an issue [22], and there are still a significant proportion of individuals whose insomnia does not respond or remit after treatment [23].

Given that not all treatments are effective for every person, treatment decisions should be guided by person-level factors such as personal preference [24]. For interventions like acupuncture and CBT-I, which require a significant investment of time and active participation, patient preference for treatment is a particularly important contributor to patient adherence and outcomes [25,26]. Clearly, there is a need to better understand how patient preference should guide the choice of insomnia treatment options.

This study is the first rigorously designed comparative effectiveness study to examine the relative benefits of acupuncture and CBT-I. The primary aim is to determine which treatment is associated with the largest reduction in insomnia severity. The secondary aim is to examine the demographic, clinical, and psychological characteristics that predict and/or moderate treatment effect of both acupuncture and CBT-I (Fig. 1).

2. Material and methods

2.1. Study design

This project is a randomized controlled trial with a nested qualitative study to compare the effectiveness of acupuncture and CBT-I for insomnia and co-morbid symptoms in a heterogeneous sample of 160 cancer survivors who have finished primary treatment (Fig. 2). It is funded by the Patient Centered Outcomes Research Institute (PCORI) and the research team includes two patient co-investigators and a diverse group of patient advisors and community stakeholder groups. Eligible patients will be randomly assigned to acupuncture or CBT-I in a 1:1 ratio. In the acupuncture group, patients will receive ten treatments of acupuncture over eight weeks. In the CBT-I group, patients will receive seven sessions of CBT-I over eight weeks. Patients will complete validated patient-reported outcome measures of sleep and co-morbid symptoms at baseline, mid-treatment, post-treatment, and at a three-month follow-up to assess durability of effect.

To understand patient experience, we will conduct semi-structured interviews among 60 patients pre- and post-intervention to elicit their experience of their insomnia and cancer, their attitudes, beliefs, and
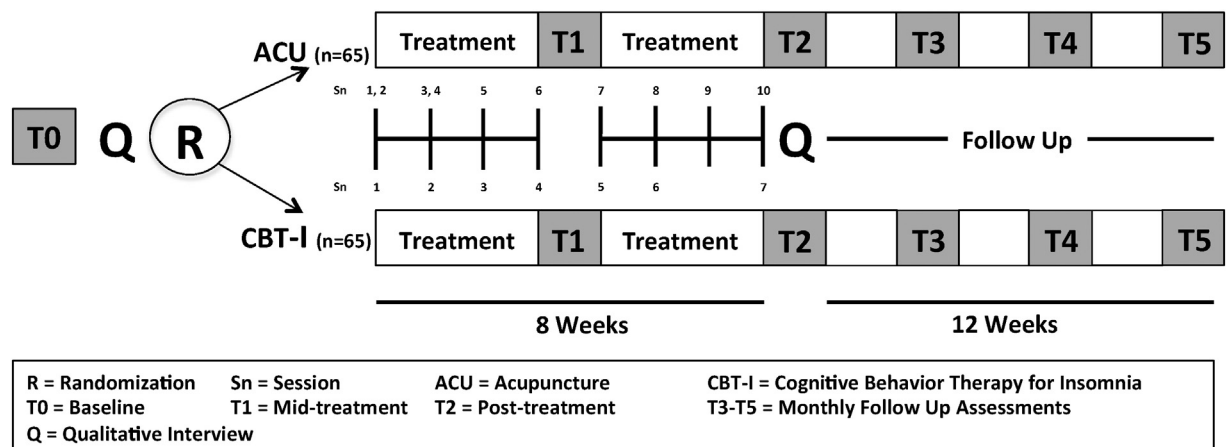

Fig. 2. Study timeline.