Sleep to prevent evolving affecting disorders (SPREAD)

NCT02988375

Approved on March 8th 2016

1. PURPOSE: State in one or two sentences the purpose or objective of this project. The purpose of this study is to determine the effectiveness of Digital Cognitive Behavior Therapy for Insonmia (dCBTI) in preventing the incidence of depression among individuals with insomnia.

2. SPECIFIC AIMS: Number your aims so that the aims can be referred to in the Project Design and Data Analysis sections of this outline. Specific aim 1: to assess the efficacy of dCBTI for the prevention of incident depression among individuals with insomnia. Specific aim 2: to determine the moderating effects of health/SES disparities on the efficacy of the dCBTI intervention.

3. RATIONALE FOR THE PROJECT: a. State the rationale for the project and support it with background information about the project. Critically evaluate existing knowledge, and specifically identify the gaps in knowledge the project will fill. A growing body of research indicates that treatment for insomnia may also help prevent the onset of depression (Falussy, Balla & Frecska, 2014). However, CBTI, the current first-line treatment for insomnia, is under-utilized due to a shortage of providers, time- and cost-constraints, and the stigma associated with mental-health treatment (Fields, Schutte-Rodin, Perlis & Meyer, 2013). Digital, internet-delivered forms of CBTI (dCBTI) can overcome these obstacles to make access more widespread, reduce health-care costs, and serve as a sustainable population-level prophylactic treatment for depression. b. State the applicant's prior research and experience in this research area. Dr. Drake has a broad background in clinical psychology, with specific training and expertise in sleep medicine. He is an Associate Editor for the journal SLEEP and has authored over 100 peer-reviewed original articles, reviews, and chapters, focused on sleep. He recently served as Chairman of the National Sleep Foundation. Dr. Drake has been funded by the NIH to study vulnerability to insomnia and triggers of insomnia (i.e. life stressors). Dr. Drake is board certified in CBT-I Treatment to successfully treat insomnia with the long-term goal of preventing incident depression. His experience in this area will make it possible to recruit and retain participants for this research study focusing on insomniacs and depression prevention efforts.

4. SIGNIFICANCE: State concisely the importance of this project by relating the purpose to broader, long-range objectives. Depression is among the most prevelant mental health disorders and carries the heaviest burden of disability among the mentally ill, accounting for roughly 8% of all U.S. years lived with disability (Murray, Atkinson, Bhalla, et al., 2010). Thus, prevention efforts are a major public health concern. According to a recent meta-analysis of over 20-longitudinal studies, the risk of depressive onset among individuals with insomnia is nearly three times that for healthy sleepers (Baglioni, Battagliese, Feige, et al., 2011). Specifically, CBTI is recognized as an effective treatment for insomnia and has also been shown to improve comorbid depression (Manber, Bernert, Suh, Seibern & Ong, 2011; Wu, Appleman, Salazar & Ong, 2015). Combined, these results indicate that the early treatment for Insomnia via CBTI has strong potential for the prevention of depression (Falussy, Balla & Frecska, 2014). However, there are a number of barriers that hinder widespread access to CBTI. Two main problems include access to CBTI health care providers as well as the availability of enough health care providers to meet

he population demands for face-to-face therapy sessions. Thus, digital CBTI (dCBTI), which relies on web and mobile technology, can overcome these obstacles to widespread delivery, reduce patient load on current providers, and reduce health-care costs. Through dissemination of dCBTI, health care will have the potential to treat mental illness post-onset. Overall, this study will serve to determine the effectiveness of using an online CBT-I Treatment to successfully treat insomnia with the long-term goal of preventing incident depression.

5. SUBJECTS IN THE PROJECT: a. State the inclusion and exclusion criteria for enrollment of subjects. Inclusion factors for the patient group will be subjects who have Insomnia and have opted for behavioral treatment for insomnia as therapy at recruitment. Exclusion criteria for subject group includes the presence of unstable chronic medical conditions or mental health conditions that would interfere with the study protocol as well as the presence of moderate depression (QIDS > 15) at recruitment. The history of sleep disorders other than insomnia by self-report will be assessed and used as covariates in analyses; subjects presenting with a history consistent with obstructive sleep apnea (OSA) or restless leg syndrome (RLS) or other sleep disorders will be identified based on standardized questionnaires. b. Describe the control population (if utilized) and justify its selection. The control for this study will be an "information control" treatment group. Subjects will be emailed sleep tips and sleep-related information. c. Support the likelihood of recruiting the number of subjects required to complete the project. Relate this to other projects recruiting similar subjects. Participants will be recruited from several well-developed sources, including the HFHS Sleep Center Clinical database. We maintain a large and representative database (N=7608) of prior participants who have volunteered to be contacted for clinical trials. Preliminary analyses suggest that a large proportion of this database (N=2590) meets primary inclusion criteria for this proposal (current insomnia but no depression). These individuals will be contacted by phone and/or email for potential participation pending a screening assessment. We believe that based on the success we have seen in previous studies (IRB#5544 and #8447), we will be able to complete this protocol within two years following IRB approval.

6. PROJECT DESIGN AND PROTOCOL: a. Describe the experimental design/methodology. This is a randomized parallel group study with group 1 getting CBT-I treatment for insomnia by an online program (Sleepio) and group 2 getting information control sleep tips. Insomnia and other sleep-related symptoms will be assessed at pre treatment, post treatment and at 1-year follow-up. Sleepio can be accessed at www.sleepio.com. Click "Log In" at top right corner and enter email "test@sleepio.com" and password "password". b. Outline the protocol, corresponding it to the specific aims; identify the data or endpoints to be analyzed to reach the specific aims. Our primary aim is to maximize and/or improve sleep efficiency in patients (number of hours asleep over number of hours in bed) and to shorten sleep latency (amount of time taken to fall asleep). The primary aim will be to reduce the incidence of depression. Other secondary measures will be taken regarding aspects other than sleep in patients. These will be recorded through the surveys mentioned above and will measure symptom improvements in severity of depression and work productivity. c. Discuss potential limitations and difficulties in the protocol. We do not anticipate any limitations to the current protocol. d. Provide a tentative schedule for conducting and completing this project and, if applicable, the multicenter study. We plan on starting data collection between February 25 and March 1, pending IRB approval. e. Data collection: Submit a copy of the data collection tool or list the data fields to be collected (review IRB policy, Access to Medical Records for Research).Attached in appendix.

7. DATA ANALYSIS: Describe the analysis of the data and relate this to the specific aims in detail. Case reports and medical record reviews also require a description of the planned data analysis (ie. descriptive, observational). The Committee recommends free consultation with the Division of Biostatistics and Research Epidemiology before IRB submission. The following data analysis plan was developed in conjunction with Ed Peterson, biostatistics section. A logistic regression will be used to assess the association between treatment group and depression status at 1 year. This approach allows inclusion of covariates in the model. We plan on enrolling a total of 300 subjects per group. This results in the analysis having 85% power, with a two-sided alpha level of 0.05, to detect an odds ratio of 2.7 corresponding to rates of depression at 1 year of 10% and 4%. Stratified analysis assuming an equal split of the population, will have 85% power to detest an odds ratio of 10.0. This corresponds to a difference in rates from 10% to 1% which is what we anticipate.

8. JUSTIFICATION FOR NUMBER OF SUBJECTS OR DATA: a. State the number of subjects or data points to be analyzed in the project at this institution and the total number for multicenter studies. The Committee recommends consultation with the Division of Biostatistics and Research Epidemiology (313) 874-6360. The proposed sample size of 300 per group (n=600) will yield > 85% power to detect effects with a two-tailed 0.05 alpha level. b. Describe the statistical justification for this number of subjects or data points. The primary hypothesis i.e., risk of depression incidence in the dCBTI group relative to the control group will be analyzed using a multivariate logistic regression model. Group differences in continuous outcomes (e.g., SOL, TST, WASO; see STRATEGY section for a full list of quantitative measures) will be tested using ANCOVA models. Power. We anticipate a 14.6% rate of incident depression in the control group, compared to 6.7% in the treatment group.21 The proposed sample size of 300 per group (n=600) will yield > 85% power to detect effects with a two-tailed 0.05 alpha level.