# Behavioral Treatment of Menopausal Insomnia; Sleep, Depression, Daytime (MENO)

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Insomnia is a key symptom of the menopausal transition with 40-50% of postmenopausal women (> 17 million) having insomnia. Insomnia associated with menopause has a pattern of sleep disturbance predominantly characterized by sleep maintenance difficulties including frequent awakenings and arousals, reduced sleep efficiency, and overall fragmented sleep. It has recently been demonstrated that this pattern of sleep disturbance, difficulty maintaining sleep, increases throughout the progression of menopause. We have recently found sleep maintenance problems in menopause are associated with reduced work performance, increased healthcare utilization, and impaired quality of life.

Cognitive-behavioral therapy for insomnia (CBT-I) yields equivalent short-term efficacy and superior long-term durability to pharmacological treatment of insomnia. However, the efficacy of cognitive behavioral therapy for insomnia comorbid with menopause, one of the primary focuses of the present proposal, has not been tested. Traditional CBT-I has disadvantages however, including the need for a trained therapist and significant time commitment on the part of the patient. Therefore, widespread availability of multicomponent CBT-I is limited by the relatively low number of CBT sleep specialists, complexity of therapy, and patient burden. Thus, another aim of this project is to test the acute and long-term efficacy of a single component behavioral therapy for menopausal-related insomnia. Given the significant daytime impairment present in insomnia comorbid with menopause including depression, quality of life, and fatigue, a final aim of this proposal is to determine the efficacy of CBT-I on these measures in women with menopausal-related insomnia.

Each patient who meets the criteria and opts for CBT-I as part of their standard clinical treatment for insomnia will be asked if they wish to participate in the study. Consented subjects will then receive CBT-I treatment for 4 weeks (2 face-to-face sessions and 2 phone contacts). The patients will maintain a sleep diary to measure sleep efficiency (number of hours asleep over number of hours in bed) and sleep latency (amount of time taken to fall asleep). This diary will be collected at each visit. The patients will fill out the following pre and post standardized surveys before and after the start of treatment: ISI, BAI, ESS, FSI, BDI-II, and SF-36 QoL, PSAS, DBAS. These surveys will measure secondary factors, such as, severity of insomnia, sleepiness, hyperarousal, fatigue, anxiety, depression, and quality of life (all included in the appendix). Our primary aim is to maximize and/or improve sleep efficieny in patients (number of hours asleep over number of hours in bed) and to shorten sleep latency (amount of taken to fall asleep). 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 improvement in severity of insomnia, sleepiness, depression, anxiety, dysfunctional beliefs and quality of life.

Each variable of interest (sleep diary measures and questionnaire assessments) will be compared between pre and post-treatment (the primary evaluation time points) using standard analysis of covariance, with the baseline demographics as covariates. Then the data on sleep efficiency, sleep latency, will be analyzed across all of the weekly time points using repeated measures analysis of covariance, with covariates included for the baseline levels of those variables along with age, BMI, and time since cancer development. The repeated measures modeling will primarily evaluate the main time effect. The repeated measures sphericity will be examined and an appropriate variance/covariance modeling structure will be used. If the analysis of variance assumption of distributional normality is violated, then an appropriate data transformation will be utilized.