A RANDOMIZED TRIAL OF COGNITIVE BEHAVIOR THERAPY AND ARMODAFINIL TO TREAT INSOMNIA AND DAYTIME SLEEPINESS IN CANCER SURVIVORS

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INTRODUCTION: Insomnia and fatigue are the most frequently reported side effects associated with cancer. Although cognitive behavioral therapy for insomnia (CBT-I) is effective in addressing difficulty initiating and maintaining sleep, it frequently results in (short-term) sleepiness and fatigue. This may make it difficult for cancer patients to adhere to treatment. This study examines whether a combination of CBT-I and a wake-promoting medication (armodafinil) results in greater overall improvement in insomnia and fatigue symptoms among cancer survivors.

METHODS: Eighty-eight patients were randomized to one of four treatment conditions: 1) CBT-I + placebo (CBT+P), 2) CBT-I + armodafinil (CBT+M), 3) Placebo only (P) and 4) armodafinil only (M). CBT-I was delivered in 7 weekly one-hour individual therapy sessions (3 in person, 4 via telephone). Pre-post findings on sleep diary-measured sleep latency (SL), wake after sleep onset (WASO), total sleep time (TST), and daytime sleepiness measured by the Epworth Sleepiness Scale (ESS), are reported.

RESULTS: The mean age of the group was 56yrs, 88% were female and the majority of patients (68%) had breast cancer. All analyses were adjusted for baseline severity. Compared to the placebo group, patients in the CBT+P and CBT+M groups reported a significant reduction in SL with effect sizes of 0.67 and 0.58, respectively. There was a significant reduction in WASO in the CBT+M group only (p=.02). TST increased in the M group, but not in the CBT+P or CBT+M groups. There were no statistically significant reductions in daytime sleepiness (ESS) observed for any of the groups.

CONCLUSION: CBT-I alone and in combination with armodafinil was able to produce statistically and clinically significant improvement in self-reported sleep. The addition of armodafinil did not appear to enhance the effect of CBT-I via a reduction in daytime sleepiness. Analyses are ongoing to examine the impact of armodafinil on CBT-I compliance.

Trainee Award Eligible