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0634

TRAINED SLEEP PHYSICIANS CAN EFFECTIVELY ADMINISTER COGNITIVE BEHAVIORAL THERAPY FOR INSOMNIA (CBTI) IN THE CLINICAL SETTING

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Introduction: Psychologists typically conduct cognitive behavioral therapy for insomnia (CBTI). Few sleep physicians are formally trained and actively practice CBTI. The effectiveness and merits of CBTI as administered by a sleep physician in a community-based clinic is unknown.
Methods: A retrospective chart review was performed of 110 patients presenting with chronic insomnia from October 2013 to October 2014 who enrolled in CBTI with a formally trained sleep physician at a community-based clinic. The modified program consisted of 4 to 6 sessions lasting 30 to 60 minutes and emphasized sleep education, sleep consolidation, and relaxation training. Subjects were excluded if they did not attend at least 4 sessions, inadequately completed sleep logs, or if untreated sleep apnea interfered with compliance. The outcomes assessed included changes in sleep-onset latency, wakefulness after sleep onset, total sleep time, and sleep efficiency from baseline to conclusion of the program.
Results: Of the 110 subjects enrolled, 21 subjects were excluded (13 didn't attend at least 4 sessions, 4 inadequately completed sleep logs, and 4 had untreated known sleep apnea reducing compliance). The remaining 89 subjects were 65% women and 35% men. The average age was 60.69 years (ranging from 12 to 90 years). Sleeping pills were used at baseline in 74.2% (66 subjects) and obstructive sleep apnea (AHI > 5 on testing) was identified in 65.2% (58 subjects). Improvements were seen in all averaged measures from baseline to program conclusion: sleep-onset latency (55.5 to 22.5 minutes), wakefulness after sleep onset (45.17 to 25.21 minutes), total sleep time (6.22 to 6.25 hours), and sleep efficiency (74.0% to 85.5%).
Conclusion: CBTI is highly effective when administered by a trained sleep physician and can be successfully integrated into standard clinical practice. Physicians may be better equipped to taper sleeping pills and to identify and treat comorbid sleep conditions.

0635

INSOMNIA IN PEOPLE LIVING WITH HIV/AIDS SUCCESSFULLY TREATED BY COGNITIVE BEHAVIORAL TREATMENT

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Introduction: The triad insomnia-fatigue-depression affects 50 to 100% of people living with HIV/AIDS (PLWHA), with 1.2 million in the US. This study intends to establish the feasibility of allied-health personnel administered cognitive behavioral therapy for insomnia (CBTI) in PLWHA.
Methods: 27 HIV-seropositive subjects, 11.2% Caucasians and 85.2% African-Americans, including 8 females (29.6%), aged 43–59 years, with insomnia for at least 3 months and all currently taking HAART were enrolled. Screening process included the Duke Structured Interview for Sleep Disorders, to ascertain sleep disorder diagnoses. Last observation carried forward (LOCF) and T-test were utilized.
Results: There was no statistical difference between the treatment group (n = 15) and the placebo group (n = 12) for age, height, weight, gender and race/ethnicity distribution, therapist allocation. There was no statistically significant difference across both groups for sleep-diary derived sleep efficiency—SE (CBTI: 68.5% ± 12.0; Placebo: 62.7% ± 14.8; p = 0.29), and for the insomnia severity index—ISI (CBTI: 16.9 ± 4.6; Placebo: 16.3 ± 7.1; p = 0.8). Blinding was effective as perceived treatment by subjects was similar regardless of actual treatment allocation (Chi-squared = 0.675 with 1 df, two-tailed p = 0.41). Treatment was effective with a final SE of 85.0% ± 11.2 for the CBTI versus 71.8% ± 15.0 for the placebo group (p = 0.02) yielding a number needed to treat (NNT) of 8 and a Cohen's d effect size of 0.91; as well as a final ISI of 11.3 ± 6.9 for the CBTI versus 16.6 ± 5.6 for the placebo group (p = 0.036) yielding a NNT of 19 and an effect size of 0.78.
Conclusion: While insomnia is at least twice more prevalent in PLWHA than in the general population, we demonstrated that it can be effectively treated with a non-pharmacological therapy (CBTI), moreover when administered by allied-health personnel and over 4 weekly sessions.
Support (If Any): The Duke University Center for AIDS Research (CFAR), an NIH funded program (5P30AI064518)

0636

DUAL OREXIN RECEPTOR ANTAGONIST E2006 SHOWS EFFICACY ON SLEEP INITIATION AND MAINTENANCE ON SLEEP DIARY MEASURES IN PHASE 2 STUDY

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Introduction: Increasing attention has been paid to dual orexin receptor antagonists (DORA) to treat insomnia. This report presents Phase 2 sleep diary results with E2006, a novel DORA.
Methods: The study was a multicenter (US), randomized, double-blind, placebo-controlled, parallel group design, enrolling subjects with insomnia disorder per DSM-5. A Bayesian adaptive design tested 6 strengths of E2006 (1, 2.5, 5, 10, 15, 25 mg) or placebo administered for 15 nights (30 m before bedtime). Diaries were completed each morning. Safety was monitored via treatment-emergent adverse events (TEAEs), ECGs, vital signs, chemistries and morning assessments of residual sleepiness (in-clinic only). Sleep efficiency (SE), subjective Sleep Onset Latency (sSOL) and subjective Wake After Sleep Onset (sWASO) from sleep diaries were averaged for Baseline (BL) and during treatment (Days 1–7, 8–15).
Results: 616 screened, with 291 randomized (63.5% F, mean age 48 y). Mean (SD) BL Insomnia Severity Index was 20 ± 3 (moderate-severe). Demographics were similar between treatment groups. Overall mean (SD) BL values were SE: 65 ± 11%; sSOL: 59 ± 33 m; sWASO: 110 ± 48 m. 94.5% of E2006 and 91.1% of placebo subjects completed. During Days 1–7, the LS mean difference (E2006 vs placebo) for change from BL in SE was statistically significant for 5–25 mg, increasing 6–9.4% with overlapping confidence intervals. Except with 1 mg, sSOL decreased significantly, with median change from BL from −23 min (2.5 mg) to −26 min (25 mg); placebo −10 min. sWASO decreased in all treatment groups (significantly for 10 mg: LS mean difference: −29 min). Benefits seen for Days 1–7 were maintained for Days 8–15. TEAEs were more common with E2006. Somnolence was dose-related. There were 2 SAEs (one placebo; one 25 mg [discontinued study]). All TEAEs except the SAE at 25 mg were mild or moderate.
Conclusion: These data highlight the potential of E2006 to treat insomnia disorder. E2006 was well-tolerated in this study, with mild-moderate adverse events. Subject-reported efficacy was demonstrated for both sleep onset and sleep maintenance.