0501

DEVELOPMENT AND INITIAL EVALUATION OF WEB-BASED COGNITIVE BEHAVIORAL THERAPY FOR INSOMNIA "NITECAPP" IN RURAL DEMENTIA CAREGIVERS: A MIXED-METHODS STUDY

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Introduction: Informal caregivers (CGs) of persons with dementia frequently experience insomnia. The time consuming and unpredictable schedule of CGs, and associated emotional/physical exhaustion emphasize the need for brief, easily accessible interventions to treat insomnia. Internet-based behavioral insomnia interventions hold promise, particularly for rural CGs who have limited access to traditional in-person treatments. This study aimed to 1) translate an efficacious 4 session cognitive behavioral therapy for insomnia (CBT-I) to web-based "NiteCAPP" for dementia caregivers, and 2) conduct NiteCAPP usability testing/evaluate acceptability of content and features.
Methods: NiteCAPP is an online CBT-I that incorporates guided delivery through weekly therapist moderator feedback. A stepwise approach was implemented in order to explore user needs and validate NiteCAPP content in a focus group of rural dementia caregivers (n=5) and primary care providers (PCPs; n=5). Participants conducted usability testing and provided ratings of program content (1-least favorable to 5-most favorable) regarding ease of use, amount of information, website maintaining interest, adequate font size, videos maintaining interest/easy to understand/helpful. Participants also indicated whether they had at home internet access, method of internet access, and provided open ended feedback on NiteCAPP. Feedback transcripts were compiled and analyzed independently (C.S.M., A.F.C.) through deductive content analysis. Topics mentioned frequently were categorized and merged into common themes during consensus meeting, and NiteCAPP was subsequently adapted.
Results: Average ratings for NiteCAPP features were high, ranging from 4.1/5 to 4.7/5 across all items. All participants had access to internet through both phone and computer. No barriers to use identified. Feedback themes were largely positive (e.g., comprehensive written material, promotes independence, excellent visual tools for therapy moderator feedback, good pacing, use of visual contrast). Negative themes for improvement/adaptation included adding font size options, a light/dark mode, tab with all videos, reducing amount of scrolling, adding a glossary of terms.
Conclusion: Rural dementia CGs and PCPs evaluated NiteCAPP as easy to use with acceptable features and program content and no barriers to access. Improvement themes were used to adapt NiteCAPP. Next steps are to evaluate feasibility and preliminary efficacy of NiteCAPP in rural dementia CGs with insomnia.
Support: none

0502

SAFETY, TOLERABILITY, AND EFFICACY OF A NOVEL, HIGHLY POTENT AND SELECTIVE PARTIAL AGONIST FOR NOCICEPTIN/ORPHANIN-FQ PEPTIDE (NOP) RECEPTORS IN PATIENTS WITH INSOMNIA DISORDER

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Introduction: V117957 is a recently described investigational oral, potent, and selective nociceptin/orphanin-FQ peptide (NOP) receptor partial agonist which was previously evaluated in ~200 healthy subjects. Its satisfactory safety/tolerability profile has been established with the top doses at 30mg following a single oral administration and 10mg once daily for 2 weeks. V117957 demonstrated favorable drug-like properties for insomnia treatment, including oral bioavailability, fast absorption, and rapid elimination.
Methods: A total of 52 patients with insomnia disorder have been evaluated in two separate randomized, double-blind, crossover, placebo-controlled sleep studies. Insomnia disorder was confirmed by screening polysomnography (PSG). All subjects received orally, for two consecutive nights, either V117957 10mg or placebo in Study #1 or 0.5, 1, 3, 6mg or placebo in Study #2. Efficacy was measured via PSG for the primary endpoint of sleep efficiency (SE) and secondary endpoints of sleep onset (latency to persistent sleep [LPS]) and maintenance (wakefulness after sleep onset [WASO]). Efficacy also was measured by patient diary (subjective sleep latency [sSL], subjective total sleep time [sTST], sWASO). Pharmacodynamics (PD) on next-day residual effects were also measured, including cognitive, psychomotor and mood effects.
Results: V117957 showed statistically significant greater sleep efficiency and less WASO in a dose-dependent manner (0.5-10 mg) and a statistically significant reduction in LPS at 10mg, as compared to placebo. V117957 at 0.5mg and 1mg exhibited next-day residual effects similar to placebo. At doses of 3mg or higher, V117957 showed dose-dependent next-day residual effects. V117957 was safe and well-tolerated across all doses tested with no serious adverse events, with somnolence being the most frequent treatment-emergent adverse event. No concerning laboratory findings and no clinically significant findings on vital signs and electrocardiograms have been attributed to V117957 in these subjects.
Conclusion: V117957 was safe and well-tolerated in patients with insomnia disorder. These results demonstrated that NOP receptors represent a novel mechanistic treatment for insomnia disorder and support continued evaluation of V117957.
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0503

REDUCTIONS IN SLEEP AND DAILY RHYTHM VARIABILITY FOLLOWING BRIEF BEHAVIORAL TREATMENT FOR INSOMNIA

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Introduction: Brief behavioral treatment for insomnia (BBTI) is efficacious for insomnia symptoms. Here we examine whether BBTI reduces sleep and daily rhythm variability and whether reductions in variability result in improved functioning and quality of life.
Methods: Ninety-one Veterans with insomnia (49.3±18.7yrs; 18.7% female) were randomized to one of two treatment conditions: BBTI or progressive muscle relaxation training (PMRT; control condition). Variability was assessed using sleep diaries and actigraphy. The sleep diary outcome variables included bedtime variability, wake time variability, and total sleep time variability; actigraphy variables included interdaily stability, intradaily variability, and total sleep time variability. Functioning was assessed