Protocol and Statistical Analysis Plan

Implementation of Brief Insomnia Treatments - Clinical Trial (NCT02724800)

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IRB Initial Approval: 3/11/2016

Amendments:

1	Approved	3/29/2016
2	Approved	5/31/2016
3	Approved	11/3/2016
4	Approved	11/21/2016
5	Withdrawn	1/6/2017
6	Approved	1/9/2017
7	Approved	2/7/2017
8	Approved	3/14/2017
9	Approved	5/22/2017
10	Approved	9/18/2017
11	Approved	10/18/2017
12	Approved	2/27/2018
13	Approved	3/27/2018
14	Approved	5/16/2018
15	Approved	7/3/2018
16	Approved	7/9/2018
17	Approved	7/31/2018
18	Approved	9/17/2018
19	Approved	2/8/2019
20	Approved	7/26/2019

Continuing Reviews:

2016	12/16/2016
2017	10/19/2017
2018	10/24/2018
2019	7/29/2019

Objective

The goal of this study is to test the non-inferiority of Brief Behavioral Treatment for Insomnia (BBTI) versus the current gold standard treatment for insomnia, Cognitive Behavioral Therapy for Insomnia (CBTI).

Design

This study is a prospective non-inferiority randomized clinical trial.

Hypotheses

1. Both BBTI and CBTI will significantly reduce insomnia symptoms, per the Insomnia Severity Index (ISI), from pre- to post-treatment.
2. BBTI will be non-inferior to CBTI based on ISI change score from pre- to post-treatment.

Methodology

Participants

Veterans with chronic insomnia were recruited. Eligible Veterans were ≥18 years, met Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5) criteria for insomnia disorder (First, Williams, Karg, & Spitzer, 2015), and had an ISI ≥15 (Bastien, Vallieres, & Morin, 2001).

Veterans were excluded if they had: current or past bipolar, psychotic, or seizure disorder; alcohol use disorder or substance use disorder in the past six months; other current, severe, and unstable and/or untreated psychiatric and/or medical disorders; been hospitalized, for any reason, in the past month; untreated sleep apnea and/or other untreated non-insomnia sleep disorders; moderate to severe cognitive impairment; homeless or unstable housing; shift workers; or if female, were pregnant.

This study was designed to enroll Veterans who would typically be eligible to engage in CBTI at a VAMC and was similar to the guidelines as part of the VA CBTI training program (Manber et al., 2014).

Procedures

All study procedures took place at VA Pittsburgh Healthcare System (VAPHS); recruitment, treatment, post-treatment, and 3-month follow-up took place May 2016 through June 2019, with 12-month follow-up through March 2020. Participants were recruited with advertisements, by invitation from practicing insomnia providers, and with postings on Craigslist.com.

Eligible Veterans, after a brief phone or in-person screen, were invited for an in-person appointment to sign informed consent and complete diagnostic interviews and self-report measures. Assessment of insomnia and other sleep disorders was conducted using the South Texas Research Organizational Network Guiding Studies on Trauma and Resilience (STRONG STAR) Clinical Interview for DSM-5 Sleep-Wake Disorders (Taylor et al., 2018). Risk for obstructive sleep apnea (OSA) was assessed using the STOP-BANG questionnaire (Chung et al., 2012); Veterans scoring ≥5 and/or had untreated OSA were excluded and referred to the Sleep Medicine Clinic. Cognitive impairment was assessed using the St. Louis University Mental Status Examination (SLUMS; Tariq, Tumosa, Chibnall, Perry 3rd, & Morley, 2006); Veterans with scores ≤20, indicative of serious cognitive impairment, were excluded. Finally,

psychiatric disorders were assessed using the Structured Clinical Interview for DSM-5, Research Version (SCID-5-RV; First et al., 2015).

Randomization and Sample Size

Veterans were randomized to BBTI or CBTI in a 1:1 manner, in random block sizes of 2, 4, or 6, stratified by age (18-64 or ≥65) and use of a prescription sedative-hypnotic medication (yes or no). Sequentially numbered envelopes were used to assign participants based on their strata with concealment until randomization. Participants were enrolled by the Principal Investigator with the randomization strategy developed by the study statistician using Stata v14 and group assignment by the study coordinator.

Sample size was calculated based on non-inferiority methods (Julious, 2004) and was further informed by the calculation of a non-inferiority margin (NIM), the pre-specified difference between treatments that demonstrates BBTI is not unacceptably worse than CBTI (Schumi & Wittes, 2011). The Reliable Change Index (RCI; Jacobson & Truax, 1991; Sloan, Marx, Lee, & Resick, 2018) measures change at post-treatment not due to error, and for this study was calculated for the "control" condition (CBTI) using VA rollout data (Trockel et al., 2014). The RCI equation uses a measure of reliability (internal consistency or test-retest reliability) for the outcome measure, in this case the ISI. The RCI for CBTI was calculated using both reliability metrics to create a range of NIMs. Using Cronbach's alpha (α=0.905; Morin, Belleville, Belanger, & Ivers, 2011) the RCI was 5.21 and using the test-retest reliability (r=0.78; Savard, Savard, Simard, & Ivers, 2005) the RCI was 3.43. We chose the NIM of 3.43. Accounting for 25% attrition, based on prior CBTI and BBTI studies (Buysse et al., 2011; Germain et al., 2014; Trockel et al., 2014) the target randomization goal was 56 participants (n=28/group) with 42 (n=21/group) completing post-treatment assessment to achieve 80% power.

Clinician Training

Study clinicians attended a half-day training by the Principal Investigator and study Co-Investigator; CBTI and BBTI trainings were separate and study clinicians only received one training. CBTI (Manber et al., 2014) was delivered in 5 in-person sessions, weekly or bi-weekly, with a goal of completing treatment in 8 weeks. The components included psychoeducation, sleep health education, stimulus control, sleep restriction, cognitive restructuring of maladaptive beliefs, and relaxation strategies as needed. Sleep diaries were completed daily throughout treatment, beginning with the baseline assessment. Increasing prescribed time in bed (TIB) occurred if sleep efficiency (SE) was ≥85%, in which case TIB was increased 15 minutes (if wanted by participant). CBTI was delivered by two licensed psychologists, one who delivered care in the Mental Health Clinic and another in Primary Care.

Interventions

BBTI (Troxel et al., 2012) includes one to two in-person sessions (session 1 and 3; week 3 is optional by phone) and two phone sessions (sessions 2 and 4) and will occur within 5 weeks.

- **Session 1 (45 minutes, in person).** Background information is provided about healthy sleep practices and the mechanisms of sleep regulation as well as the principles of stimulus control, sleep restriction, and sleep hygiene. Baseline sleep diaries will determine initial sleep parameters (e.g., bedtime, wake time, sleep onset latency, sleep efficiency). Lastly, the four "rules" are introduced and discussed.

- *Reduce your time in bed*. Sleep diaries will determine the prescribed bedtime, with the goal to match time in bed to time asleep (plus an additional 30 minutes to account for a normal amount of time spent awake at night). Reducing time in bed helps to increase the homeostatic sleep drive.
- *Wake up at the same time every day*. A consistent wake time is a) the most important cue for setting the biological clock, b) regulates exposure to morning light (another cue for the biological clock), and c) helps to increase the homeostatic sleep drive.
- *Do not go to bed unless sleepy.* By waiting until the sleep drive is at its peak, the likelihood of falling asleep is increased. The key is helping the Veteran understand the difference between sleepiness and fatigue/tiredness. The bedtime is restricted by the prescribed bedtime set by the sleep diaries as well as a state of sleepiness. Bedtime is not determined by when the Veteran "should" go to sleep.
- *Do not stay in bed unless asleep.* By saving the bed for sleep and sexual activity only, the association between the bed and sleep is strengthened. Staying in bed while awake perpetuates the cycle of wakefulness→frustration→arousal→wakefulness. This cycle is broken by staying out of bed if awake. The recommendation is to get out of bed if awake for longer than 30 minutes (self-estimation).

- **Session 2 (<20 minutes, phone call).** This is a check-in regarding changes in sleep/wake behaviors implemented in session 1. The clinician and Veteran will discuss the sleep diary from the past week, discuss adherence to the "rules," and problem-solve any adherence issues.
- **Session 3 (<30 minutes, in person or by phone).** The Veteran and clinician will review the past two weeks of sleep diaries and adjust the sleep schedule as needed. If SOL and WASO are <30 minutes for most nights during the previous two weeks, the Veteran can extend their sleep schedule by 15 minutes, either advancing the bedtime or delaying the wake time. If SOL/WASO is >30 minutes for most nights, sleep schedule is restricted by 15 minutes. Adherence to treatment recommendations is reinforced.
- **Session 4 (<20 minutes, phone call).** The final session, a phone call, addresses treatment difficulties, reviews the progress made, and covers relapse-prevention techniques. The concepts of stimulus control and sleep restriction are emphasized, as is the process of titrating sleep using the 30/30 rule.

CBTI (Manber et al., 2014) consists of five sessions, about 45-minutes each, and will occur within an 8-week period.

- **Session 1.** Basic sleep education, including a review of the predisposing, precipitating, and perpetuating factors of insomnia (3P model of insomnia). The homeostatic sleep drive and circadian drive are explained. Next, stimulus control, sleep restriction, and sleep hygiene are reviewed; these concepts provide the basic structure to improve insomnia.
    - *Wake-up and get out of bed at the same time every day.* A consistent wake time is a) the most important cue for setting the biological clock, b) regulates exposure to morning light, and c) helps to increase the homeostatic sleep drive for subsequent nights.
    - *Go to bed when you are sleepy, but not before a prescribed bedtime.* By waiting until the sleep drive is at its peak, the likelihood of falling asleep is increased.

- *Get up when you can't sleep.* Staying in bed while awake perpetuates the cycle of wakefulness à frustration à arousal à wakefulness. When unable to sleep, it is recommended to get out of bed and go to another room until sleepiness returns.
- *Use the bed only for sleeping.* By saving the bed for sleep and sexual activity only, the association between the bed and sleep is strengthened. Avoid TV, reading, work, etc., while in bed.
- *Avoid daytime napping, particularly in the late afternoon or early evening*. Sleep during the day can reduce the homeostatic sleep drive and make it more difficult to fall asleep at the desired bedtime.
- *Create a buffer zone*. This is a quiet time prior to bedtime that can help to reduce stress. It provides a transition between the goal-oriented activities of the day and the quiet more peaceful time of sleep.
- *Don't worry, plan, etc., in bed.* Avoid any stressful, worrisome, or stimulating activities in bed. Preoccupation with worries, problems, or planning can increase arousal and interfere with sleep.
- *Other helpful practices/sleep hygiene.* Recommendations include: turn the clock around, limit caffeine in the afternoon, limit alcohol within 3 hours of bedtime, exercise regularly but not close to bedtime, keep bedroom quiet, dark, and cool, avoid heavy meals close to bedtime but don't go to bed hungry.

- **Session 2.** Sleep diaries are reviewed, and prescribed bedtime is titrated based on sleep efficiency. If sleep efficiency <80%, time in bed is reduced by 15 minutes. If sleep efficiency ≥85%, time in bed is increased by 15 minutes. Problem-solving and motivational enhancement is used for any adherence issues. Additional handouts include information on what to do when awake (night and morning), enjoying your morning, and reasons for feeling tired.
- **Session 3-4.** Sessions 3 and 4 are focused on continued titration of the sleep schedule, monitoring adherence to treatment guidelines (1-8 above), and identifying and challenging dysfunctional beliefs about sleep (DBAS questionnaire), such as: "I need 8 hours of sleep per night" or "Insomnia has serious health consequences." Identifying and challenging automatic thoughts about sleep is can also be helpful. Lastly, relaxation (active or passive) may be introduced and practiced.
- **Session 5.** Continue titrating time in bed, cognitive restructuring, and relaxation as needed. If improvements have been appropriate, session 5 may focus on relapse prevention, summarizing gains, and discussing what was, or was not, helpful. Elements of relapse prevention include: keep a consistent wake time; go to bed only when sleepy, but not before the regular bedtime; and get out of bed if unable to sleep.

Measures

The primary outcome measure was the ISI (Bastien et al., 2001), administered at baseline, in-person treatment sessions, one-week post-treatment, and the 3-month and 12-month follow-up assessments.

The Consensus Sleep Diary (Carney et al., 2012) was used to collect data on sleep behaviors, including bedtimes, rise times, sleep onset latency (SOL), nighttime awakenings (NWAK), wake after sleep onset (WASO), time in bed (TIB), total sleep time (TST), total wake time (TWT), sleep efficiency (SE), and sleep

quality (SQ). Diaries were administered for two weeks of baseline, during treatment, two weeks after the post-treatment assessment, and the 3-month and 12-month assessments.

Additional sleep measures administered at baseline, post-treatment, 3-month and 12-month assessments included the Pittsburgh Sleep Quality Index (PSQI; Buysse, Reynolds, Monk, Berman, & Kupfer, 1989) as a measure of sleep quality, the Dysfunctional Beliefs and Attitudes about Sleep scale (DBAS; Morin, Vallieres, & Ivers, 2007) to assess sleep-disruptive cognitions, and the Epworth Sleepiness Scale (ESS; Johns, 1991) to assess daytime sleepiness.

Self-report measures of psychiatric symptoms included the Patient Health Questionnaire 9 (PHQ9; Kroenke, Spitzer, & Williams, 2001) to assess depression, the Generalized Anxiety Disorder 7 (GAD7; Spitzer, Kroenke, Williams, & Lowe, 2006) to assess anxiety, and the PTSD Checklist for DSM-5 (PCL5; Blevins, Weathers, Davis, Witte, & Domino, 2015) to assess symptoms of PTSD. Additional measures included the Patient Reported Outcome Measurement Information System (PROMIS) Fatigue Scale (Reeve et al., 2007) to assess fatigue and its impact on functioning and quality of life, a brief pain scale measuring pain intensity (P), interference with enjoyment of life (E), and interference with general activity (G [PEG]; Krebs et al., 2009), the PROMIS Global Health Scale (Hays, Bjorner, Revicki, Spritzer, & Cella, 2009) to measure the impact of physical health (QOL-PH) and mental health (QOL-MH) on quality of life, the Work and Social Adjustment Scale (WSAS; Mundt, Marks, Shear, & Greist, 2002) to measure psychosocial functioning impairment due to insomnia, and the Patient Global Impression of Change (PGIC; Hurst & Bolton, 2004). Psychiatric symptom and psychosocial measures were administered at baseline, post-treatment, and 3-month and 12-month assessments.

Summary of self-report measures

Measure	Items	Score Range	Desired Direction
ISI	7	0-28	↓
PSQI	18	0-21	↓
ESS	8	0-24	↓
DBAS‖	16	0-10	↓
PHQ9‡	8	0-24	↓
GAD7	7	0-21	↓
PCL5‡	19	0-76	↓
Fatigue†	6	33.4-76.8	↓
PEG	3	0-30	↓
QOL-PH†	4	16.2-67.7	↑
QOL-MH†	4	21.2-67.6	↑
WSAS	5	0-40	↓
PGIC	7	1-7	↑

Notes: ‖ average score; ‡ sleep item removed; † T scores
ISI, Insomnia Severity Index; PSQI, Pittsburgh Sleep Quality Index; ESS, Epworth Sleepiness Scale; DBAS, Dysfunctional Beliefs and Attitudes about Sleep; PHQ9, Patient Health Questionnaire; GAD7, Generalized Anxiety Disorder; PCL5, Posttraumatic Stress Disorder Checklist; PEG, pain intensity, interference with enjoyment of life, and interference with general activity; QOL-PH, Quality of Life – Physical Health; QOL-MH, Quality of Life – Mental Health; WSAS, Work and Social Adjustment Scale; PGIC, Patient Global Impression of Change.

Statistical Analysis Plan

Analyses were conducted with STATA v14. Baseline differences between CBTI and BBTI were analyzed using chi-square tests and t-tests.

To test treatment effectiveness, an intent-to-treat (ITT, n=63) and per-protocol (PP, n=24) approach were used. Consistent with ITT, all individuals randomized, regardless of their completion status, were encouraged to complete the post-treatment and follow-up assessments.

PP analyses were conducted on Veterans in each group that met strict criteria—attending all treatment sessions within the time frame defined *a priori* (BBTI: n=12, 4 sessions in 5 weeks; CBTI: n=12, 5 sessions in 8 weeks) and completing the one-week post-treatment assessment.

Linear mixed models (LMM) were used to test the main effects of treatment (CBTI vs. BBTI), time (baseline vs. post-treatment), and the interaction of treatment X time. Effect sizes were computed using Glass's Δ ($|M_{pre} - M_{post}|/SD_{pre}$; Morris, 2008).

Treatment response was an ISI reduction at post-treatment of ≥8 points (indicating a moderate response), and remission was a treatment response plus an ISI score ≤7 at post-treatment (indicating no clinically significant insomnia symptoms; Morin et al., 2011).

To establish BBTI as non-inferior to CBTI, the upper bound of the 95% confidence interval of the mean ΔISI from pre- to post-treatment ($\Delta ISI_{CBTI} - \Delta ISI_{BBTI}$) cannot exceed the NIM of 3.43. If the upper bound of the confidence interval exceeds the NIM, non-inferiority cannot be declared (inconclusive). If the lower bound of the confidence interval exceeds the NIM, BBTI will be declared inferior to CBTI. However, should the upper bound of the confidence interval not exceed zero, BBTI will be declared superior to CBTI (Aberegg, Hersh, & Samore, 2018).

References

Aberegg, S.K., Hersh, A.M., & Samore, M.H. (2018). Empirical consequences of current recommendations for the design and interpretation of noninferiority trials. *Journal of General Internal Medicine, 33*(1), 88–96. DOI: 10.1007/s11606-017-4161-4

Bastien, C.H., Vallieres, A., & Morin, C.M. (2001). Validation of the Insomnia Severity Index as an outcome measure for insomnia research. *Sleep Medicine, 2*(4), 297–307.

Blevins, C.A., Weathers, F.W., Davis, M.T., Witte, T.K., & Domino, J.L. (2015). The Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5): Development and initial psychometric evaluation. *Journal of Traumatic Stress, 28*(6), 489–498. DOI: 10.1002/jts.22059

Buysse, D.J., Germain, A., Moul, D.E., Franzen, P.L., Brar, L.K., Fletcher, M.E., … Monk, T.H. (2011). Efficacy of brief behavioral treatment for chronic insomnia in older adults. *Archives of Internal Medicine, 171*(10), 887–895. DOI: 10.1001/archinternmed.2010.535

Buysse, D.J., Reynolds 3rd, C.F., Monk, T.H., Berman, S.R., & Kupfer, D.J. (1989). The Pittsburgh Sleep Quality Index: A new instrument for psychiatric practice and research. *Psychiatry Research, 28*(2), 193–213. DOI: 10.1016/0165-1781(89)90047-4

Carney, C.E., Buysse, D.J., Ancoli-Israel, S., Edinger, J.D., Krystal, A.D., Lichstein, K.L., & Morin, C.M. (2012). The consensus sleep diary: Standardizing prospective sleep self-monitoring. *Sleep, 35*(2), 287–302. DOI: 10.5665/sleep.1642

Chung, F., Subramanyam, R., Liao, P., Sasaki, E., Shapiro, C., & Sun, Y. (2012). High STOP-Bang score indicates a high probability of obstructive sleep apnoea. *British Journal of Anaesthesia, 108*(5), 768–775.

First, M.B., Williams, J.B. W., Karg, R.S., & Spitzer, R.L. (2015). Structured Clinical Interview for DSM-5, Research Version. DOI: 10.1002/9781118625392.wbecp351

Germain, A., Richardson, R., Stocker, R., Mammen, O., Hall, M., Bramoweth, A.D., … Buysse, D.J. (2014). Treatment for insomnia in combat-exposed OEF/OIF/OND military veterans: Preliminary randomized controlled trial. *Behaviour Research and Therapy, 61*, 78–88. DOI: 10.1016/j.brat.2014.07.016

Hays, R.D., Bjorner, J.B., Revicki, D.A., Spritzer, K.L., & Cella, D. (2009). Development of physical and mental health summary scores from the patient-reported outcomes measurement information system (PROMIS) global items. *Quality of Life Research, 18*(7), 873–880. DOI: 10.1007/s11136-009-9496-9

Hurst, H., & Bolton, J. (2004). Assessing the clinical significance of change scores recorded on subjective outcome measures. *Journal of Manipulative and Physiological Therapeutics, 27*(1), 26–35. DOI: 10.1016/j.jmpt.2003.11.003

Jacobson, N.S., & Truax, P. (1991). Clinical significance: A statistical approach to defining meaningful change in psychotherapy research. *Journal of Consulting and Clinical Psychology, 59*(1), 12–19. DOI: 10.1037//0022-006x.59.1.12

Johns, M. (1991). A new method for measuring daytime sleepiness: The Epworth sleepiness scale. *Sleep, 14*(6), 540–545. DOI: 10.1093/sleep/14.6.540

Julious, S.A. (2004). Tutorial in biostatistics: Sample sizes for clinical trials with normal data. *Statistics in Medicine, 23*(12), 1921–1986. DOI: 10.1002/sim.1783

Krebs, E.E., Lorenz, K.A., Bair, M.J., Damush, T.M., Wu, J., Sutherland, J.M., … Kroenke, K. (2009). Development and initial validation of the PEG, a three-item scale assessing pain intensity and interference. *Journal of General Internal Medicine, 24*(6), 733–738. DOI: 10.1007/s11606-009-0981-1

Kroenke, K., Spitzer, R.L., & Williams, J.B. (2001). The PHQ-9: Validity of a brief depression severity measure. *Journal of General Internal Medicine, 16*(9), 606–613. DOI: 10.1046/j.1525-1497.2001.016009606.x

Manber, R., Friedman, L., Siebern, A.T., Carney, C., Edinger, J., Epstein, D., … Karlin, B.E. (2014). *Cognitive Behavioral Therapy for insomnia in Veterans: Therapist manual*. Washington, DC: U.S. Department of Veterans Affairs.

Morin, C.M., Belleville, G., Belanger, L., & Ivers, H. (2011). The Insomnia Severity Index: Psychometric indicators to detect insomnia cases and evaluate treatment response. *Sleep, 34*(5), 601–608.

Morin, C.M., Vallieres, A., & Ivers, H. (2007). Dysfunctional beliefs and attitudes about sleep (DBAS): Validation of a brief version (DBAS-16). *Sleep, 30*(11), 1547–1554. DOI: 10.1093/sleep/30.11.1547

Morris, S.B. (2008). Estimating effect sizes from pretest-posttest-control group designs. *Organizational Research Methods, 11*(2), 364–386. DOI: 10.1177/1094428106291059

Mundt, J.C., Marks, I.M., Shear, M.K., & Greist, J.H. (2002). The Work and Social Adjustment Scale: A simple measure of impairment in functioning. *The British Journal of Psychiatry, 180*, 461–464.

Reeve, B.B., Hays, R.D., Bjorner, J.B., Cook, K.F., Crane, P.K., Teresi, J.A., … PROMIS Cooperative Group. (2007). Psychometric evaluation and calibration of health-related quality of life item banks: Plans for the Patient-Reported Outcomes Measurement Information System (PROMIS). *Medical Care, 45*, S22-31.

Savard, M., Savard, J., Simard, S., & Ivers, H. (2005). Empirical validation of the Insomnia Severity Index in cancer patients. *Psycho-Oncology, 14*(6), 429–441. DOI: 10.1002/pon.860

Schumi, J., & Wittes, J. T. (2011). Through the looking glass: Understanding non-inferiority. *Trials, 12*(1), 106. DOI: 10.1186/1745-6215-12-106

Sloan, D.M., Marx, B.P., Lee, D.J., & Resick, P.A. (2018). A Brief Exposure-Based Treatment vs Cognitive Processing Therapy for Posttraumatic Stress Disorder: A Randomized Noninferiority Clinical Trial. *JAMA Psychiatry, 75*(3), 233. DOI: 10.1001/jamapsychiatry.2017.4249

Spitzer, R.L., Kroenke, K., Williams, J.B., & Lowe, B. (2006). A brief measure for assessing generalized anxiety disorder: The GAD-7. *Archives of Internal Medicine, 166*(10), 1092–1097.

Tariq, S.H., Tumosa, N., Chibnall, J.T., Perry 3rd, M.H., & Morley, J.E. (2006). Comparison of the Saint Louis University mental status examination and the mini-mental state examination for detecting dementia and mild neurocognitive disorder—A pilot study. Am*erican Journal of Geriatric Psychiatry, 14*(11), 900–910. DOI: 10.1097/01.JGP.0000221510.33817.86

Taylor, D.J., Wilkerson, A.K., Pruiksma, K.E., Williams, J.M., Ruggero, C.J., Hale, W., … STRONG STAR Consortium. (2018). Reliability of the Structured Clinical Interview for DSM-5 Sleep Disorders Module. *Journal of Clinical Sleep Medicine, 14*(3), 459–464. DOI: 10.5664/jcsm.7000

Trockel, M., Karlin, B.E., Taylor, C.B., & Manber, R. (2014). Cognitive behavioral therapy for insomnia with veterans: Evaluation of effectiveness and correlates of treatment outcomes. *Behaviour Research and Therapy, 53*, 41–46. DOI: 10.1016/j.brat.2013.11.006

Troxel, W M., Germain, A., & Buysse, D.J. (2012). Clinical Management of Insomnia with Brief Behavioral Treatment (BBTI). *Behavioral Sleep Medicine, 10*(4), 266–279. DOI: 10.1080/15402002.2011.607200