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Comparing the Effects of Single and Multiple Component Therapies for Insomnia on Sleep Outcomes

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Abstract

Background: Single and multiple component therapies are recommended in professional guidelines for managing chronic insomnia. Systematic reviews point to insufficient evidence of the comparative effectiveness of these therapies, which is required for treatment decision making.

Purpose: To compare the effectiveness of three single component and one multiple component therapies on short-term sleep outcomes.

Methods: The data were obtained from 517 persons with chronic insomnia, enrolled in a partially randomized preference trial. They were allocated to the single component therapies: sleep education and hygiene (SEH), stimulus control therapy (SCT) and sleep restriction therapy (SRT), or the multiple component therapy (MCT). The outcomes, perceived insomnia severity and sleep parameters, were assessed with established measures at pre- and post-test. Repeated measure analysis of variance was used to compare the across therapy groups over time. The clinical relevance of the therapies' effects was evaluated by examining the effect size and remission rate.

Results: The four therapies differed in their effectiveness in reducing perceived insomnia severity and improving sleep outcomes. SEH was least effective. SCT, SRT and MCT were moderately effective. SCT and SRT demonstrated slightly higher remission rates than MCT for perceived insomnia severity and some sleep parameters.

Linking Evidence to Action: SCT and SRT are viable single component therapies that produce clinical benefits. Single component insomnia treatment may be more convenient to implement in the primary care setting due to the reduced number of treatment recommendations compared to MCT.

Keywords

Comparative effectiveness; behavioral therapy; insomnia; sleep hygiene education; stimulus control therapy; sleep restriction therapy; multi-component therapy; sleep outcomes; perceived insomnia severity; clinical benefits

Background and Significance

Single component therapies (e.g., stimulus control therapy) and multiple component therapies (e.g., the combination of stimulus control therapy and sleep restriction therapy) are recommended in professional guidelines (Riemann et al., 2017) to address the factors known to perpetuate chronic insomnia. Recent systematic reviews point to insufficient evidence on the effectiveness of single component therapies in improving sleep outcomes, raising questions about the appropriateness of recommending them as stand-alone therapies in practice. Ma et al. (2015) found that although the multi-component therapy (MCT) is well supported empirically, there is limited evidence of the efficacy of the single component therapies; in particular, sleep education and hygiene, stimulus control therapy, and sleep restriction therapy. Quassem et al. (2016) reached a similar conclusion in their review of evidence on the comparative effectiveness and safety of psychological and pharmacological treatments for chronic insomnia. In their review of 70 randomized clinical trials, Brasure et al. (2016) found that a small number (< 5) of trials examined the effects of single component therapies on sleep outcomes compared to inactive control conditions, and an even smaller number (< 2) of trials compared the effects of single component therapies to each other.

Evidence on the effectiveness of single component therapies and on their comparative effectiveness relative to MCT, which is recognized as first-line treatment for chronic insomnia (National Institutes of Health, 2005; Riemann et al., 2017), is required to inform treatment decision making. Persons with chronic insomnia and their health professionals need to understand, appraise, and weigh the benefits of single and multiple component therapies before selecting one (Stacey & Légaré, 2015).

This study extends the evidence on the effectiveness of single component therapies by comparing their impact on sleep outcomes, relative to each other and to MCT. Three single component therapies were investigated: Sleep education and hygiene (SEH), stimulus control therapy (SCT), and sleep restriction therapy (SRT). As a single component therapy, SEH represented treatment-as-usual. Further, SEH is viewed as foundational for other behavioral therapies because it provides basic information about sleep and insomnia that is necessary for participants to understand the rationale underlying the SCT and SRT (Bootzin & Epstein, 2011). Therefore, SEH was included in each of the therapies: SCT, SRT and MCT. The MCT consisted of SEH, SCT and SRT.

Purpose

The purpose of this study was twofold: (a) to compare the effectiveness of SEH, SCT, SRT and MCT in reducing perceived insomnia severity and in improving sleep parameters (i.e., number of naps, sleep onset latency, number of awakenings, time awake after sleep onset,

total sleep time, sleep efficiency and sleep quality); and (b) to evaluate the clinical relevance of the therapies' effects.

Methods

Design

The study design was aligned with recommendations of the Methodology Committee of the Patient-Centered Outcomes Research Institute (PCORI; 2012) for comparative effectiveness research. Specifically, broadly defined eligibility criteria were pre-set to enroll persons with chronic insomnia representative of the target population seen in primary care settings. Persons with primary or comorbid (i.e., associated with physical or mental conditions) chronic insomnia, regardless of whether or not they were taking sleep medications, were selected. The sleep outcomes were measured with self-report instruments as advocated for the assessment of patient-oriented outcomes (PCORI, 2012) such as insomnia (Buysse, Ancoli-Israel, Edinger, Lichstein, & Morin, 2006).

Allocation of participants to the therapies followed the schema used in partially randomized preference trials. Participants were assigned to therapy on the basis of chance or preference (Bradley-Gilbride & Bradley, 2010). Chance-based allocation involved randomizing participants to a therapy group as specified by the therapy code number written on a card that was enclosed in a sealed envelope. Preference-based allocation consisted of (a) having participants complete the Treatment Acceptability and Preference (TAP) scale (Sidani, Epstein, Bootzin, Moritz, & Miranda, 2009), which had a concluding question about participants' preferences for the therapies under evaluation; (b) randomly assigning participants indicating no preferences; and (c) allocating participants expressing preferences to the chosen therapy. The partially randomized preference trial has the advantages of improving enrollment rate and reducing attrition (Swift, Callahan, Ivanovic, & Kominiak, 2013) and is considered appropriate for comparative effectiveness research (Winter & Colditz, 2014). The limitation of this design is the possible non-comparability of participants assigned to the therapy groups on baseline variables, resulting from differences associated with preferences (Sidani, 2015); analysis of covariance was applied to control for these differences, if present. Outcome data were collected at pre-test (within 2 to 4 weeks prior to exposure to therapy) and at post-test (within 2 weeks of completing therapy).

Sample

Three strategies were used to recruit persons with chronic insomnia: (a) advertising in local newspapers and community newsletters, (b) distributing brochures to primary care and sleep clinics, and (c) making announcements on local TV or radio stations.

The study inclusion criteria were: (a) community-dwelling adults, 21 years of age or older; (b) ability to read and write English; (c) complaint of difficulty falling asleep or difficulty staying asleep of > 30 min per night, experienced on > 3 nights per week, and for > 3 months duration; and (d) report of impairment in daytime functioning. Persons were excluded if they had (a) a medical diagnosis of sleep apnea because its treatment interferes with the implementation of the behavioral therapies; and (b) cognitive impairment indicated

by a score < 24 on the Mini-Mental State Exam (Crum, Anthony, Bassett, & Folstein, 1993) because cognitive impairment interferes with understanding, processing and carrying out the treatment recommendations.

Sample size

A total of 517 persons with chronic insomnia completed the outcome measures at pre- and post-test. A larger number of participants were allocated to the MCT ($n = 262$) than the SEH ($n = 78$), SCT ($n = 95$) and SRT ($n = 82$), either through random or preference-based method. The sample size was adequate to detect small-moderate differences in the post-test outcomes, among the four therapy groups, setting power at .80 and $p < .05$ (Cohen, 1992).

Therapies for Chronic Insomnia

Sleep education and hygiene (SEH).—As a single component therapy, SEH was designed to mirror its implementation in primary care settings (Morin & Benca, 2012). SEH covered information on the factors that contribute to chronic insomnia and the set of behavioral (e.g., avoid caffeine and nicotine before bedtime) and environmental (e.g., have comfortable bedroom temperature) recommendations to promote a good night's sleep. The information was presented in a booklet. Participants were instructed to read the booklet at their convenience and to apply the recommendations on their own; they had no contact with the therapist.

Stimulus control therapy (SCT).—As a single component therapy, SCT consisted of six instructions that focused on re-associating the bed with sleep, such as go to bed only when sleepy; avoid activities other than sleep (e.g., reading) in bed; get out of bed if unable to sleep or fall back to sleep; and wake up at the same time every day (Bootzin & Epstein, 2011).

Sleep restriction therapy (SRT).—As a single component therapy, SRT focused on developing a consistent sleep-wake schedule that fits the individuals' sleep needs and lifestyle. The sleep needs are identified by reviewing the individual's sleep diary; in particular, his or her total sleep time. Participants worked out the sleep-wake schedule with the therapist in the first week of therapy and the bedtime was adjusted in subsequent sessions based on available guidelines (Manber et al., 2012).

Multi-component therapy (MCT).—The MCT included SEH, SCT and SRT, as described previously with one exception: The SCT instruction regarding going to bed was modified to accommodate the scheduled bedtime as per the SRT recommendation.

The SCT, SRT and MCT were implemented in the same mode and dose. They were given by professionals, prepared at the master's level, in four face-to-face group sessions followed by two individual sessions. The group sessions involved 8–10 participants and lasted 60 min, whereas the individual sessions were delivered via the telephone and were of 15–20 min duration. The sessions were offered once a week over a 6-week period. Initial sessions focused on clarifying the respective therapy recommendations, and subsequent ones

revolved around discussing challenges in carrying out the recommendations and strategies to address the challenges.

Variables and Measures

Screening variables.—Items, adapted from the Insomnia Interview Schedule (IIS), were used to assess difficulty falling asleep, difficulty staying asleep and early morning awakening (yes-no response format); the duration of sleep onset latency and time awake after sleep onset (in minutes); the duration of insomnia (in months or years); and self-reported diagnosis of sleep apnea. The IIS was developed and tested for content validity by Morin (1993). Impairment in daytime functioning was assessed with one item for rating the extent to which insomnia interfered with usual activities, using a numeric rating scale ranging from 1 to 10, with 10 quantifying the highest level of impairment. Cognitive impairment was measured with the Mini-Mental State Exam, which is an 11-item interview format questionnaire with established reliability and validity (Crum et al., 1993).

Demographic characteristics.—Standard questions were used to collect data on participants' age (in years), gender, marital status, education (years of formal schooling), employment status, and race.

Outcomes.—Perceived insomnia severity was measured with the Insomnia Severity Index (ISI) developed by Morin (1993). The ISI assesses distress with the sleep problem, using a five-point scale ranging from *not at all* (0) to *very much* (4). Total scale scores are interpreted as follows: 0–7: No clinically significant insomnia; 8–14: Sub-threshold insomnia; 15–21: Clinical insomnia of moderate severity; and 22–28: Clinically severe insomnia. The ISI has demonstrated good internal consistency reliability (Cronbach's $\alpha > .85$) and validity as evidenced by significant correlations with other subjective and objective measures of insomnia (Morin, Belleville, Blanger, & Ivers, 2011).

The sleep parameters were assessed with the Daily Sleep Diary (DSD)-Core Consensus items (Carney et al., 2012). The DSD is a self-administered log of naps taken during the day or evening, and nightly sleep behaviors including: Length of time it takes to fall asleep, number and duration of awakenings, wake-up time, and rating of sleep quality upon awakening. Participants completed the DSD upon awakening and returned the completed DSD by calling in their responses to a voice mail service, each morning in order to decrease retrospective estimates and recall bias. The DSD demonstrated test-retest reliability and validity; the sleep parameter estimates obtained with the DSD correlated with the respective estimates obtained with actigraphy (Buysee et al., 2006). In this study, the DSD was completed for 14 days before and 14 days after treatment. The sleep parameters were computed from pertinent DSD data and averaged across the 14 day period to quantify the pre-test and the post-test values of: (a) number of naps taken; (b) sleep onset latency (SOL), which is the amount of time (in minutes) it takes to fall asleep at the beginning of the night; (c) number of awakenings (excluding the final awakening); (d) wake after sleep onset (WASO), which is the amount of time (in minutes) spent awake, across all awakenings, during the night after the initial onset of sleep; (e) total sleep time, which is calculated as the time spent in bed minus the time awake; (f) sleep efficiency representing the percentage of

the total time in bed actually spent asleep; and (g) sleep quality which was rated as: 1 = *very restless*, 2 = *restless*, 3 = *average quality*, 4 = *sound*, 5 = *very sound*.

Ethical Approval

The study protocol was approved by the Research Ethics Board (REB # 13793) at the participating institution. All participants were informed of the research activities, risks and benefits prior to providing written consent.

Statistical Analysis

Descriptive statistics were used to characterize the sample on demographic characteristics and the experience of chronic insomnia. Between-group differences in the outcomes measured at pre-test were examined with one-way analysis of variance (ANOVA). For outcomes showing between-group differences at pre-test, analysis of covariance (ANCOVA) was applied to compare the effects of the SEH, SCT, SRT and MCT on the outcomes assessed at post-test, controlling for the respective outcomes measured at pre-test. The marginal mean scores, adjusted for pre-test scores, were computed for the post-test outcomes. For outcomes showing between-group comparability at pre-test, repeated measure analysis of variance (RM-ANOVA) was used to compare the effects of the four therapies over time.

The clinical significance of the therapies' effects was evaluated in two ways. First, the eta-squared (η^2) was calculated to quantify the size of the group, time, and group $\times$ time effects; η^2 values < .01 represent small, .06 moderate, and .14 large differences (Field, 2013). Second, the remission rate was computed for each therapy group using the criteria corresponding to "good sleep values" for the respective outcome. The criteria were: Post-test score on the ISI < 8 which indicates the absence of insomnia (Morin et al., 2011); post-test score on the SOL and WASO < 30 min (Buysee et al., 2006); and post-test score on sleep efficiency > 85% (Morin et al., 1999). The percentage of participants meeting or exceeding these scores is reported for each therapy group.

Results

Demographic Characteristics

On average, participants were middle aged (54.3 ± 15.7 ; range: 21 – 90 years) women (64.4%). Almost half (49.4%) of the participants were married; 24.9% were single, and the remaining (25.7%) were divorced or widowed. They had $15.9 (\pm 3.6)$ years of formal education. Participants were employed (57.3%), retired (32.2%) or unemployed (10.5%). They self-identified as White (84.2%), Asian (6.1%), Hispanic (4.1%), Black (3.1%) or other (2.5%).

Insomnia Experience

Participants experienced more than one symptom of insomnia, including difficulty falling asleep (70.7%), difficulty staying asleep (92.4%) and early morning awakening (75.8%). The mean duration of insomnia was $10.7 (\pm 11.5)$; range: 3 months-66 years).

Participants rated their insomnia as very bothersome, interfering with their daytime function (7.6 ± 1.7).

Outcome Comparison

The mean scores on the pre-test outcomes for the SEH, SCT, SRT and MCT are in Table 1. Statistically significant between-group differences were found for three outcomes at pre-test: Perceived insomnia severity (ISI), $F(3,487) = 3.30$, $p = .020$; sleep efficiency (SE), $F(3,511) = 6.07$, $p < .001$; and sleep quality, $F(3,511) = 8.93$, $p < .001$. The four therapy groups were comparable on the remaining outcomes measured at pre-test. The marginal mean scores for perceived insomnia severity, sleep efficiency and sleep quality, and the mean scores for the remaining outcomes measured at post-test are presented in Table 1. The results of the ANCOVA (group effect, adjusting for pre-test differences) and of the RM-ANOVA (group, time, group $\times$ time effects) are reported in Table 2. The remission rates for perceived insomnia severity, SOL, WASO and sleep efficiency are in Table 3.

Controlling for pre-test scores, there was a statistically significant between-group difference in perceived insomnia severity assessed at post-test. Participants who received the single component SRT had the lowest mean score at post-test. The difference was of a small size as indicated by the η^2 value (Table 2). The remission rates were higher for the SCT and SRT than the SEH and MCT (Table 3).

The time effect and the group $\times$ time interaction effect were statistically significant for number of naps, SOL, number of awakenings, and WASO (Table 2). The mean scores on these outcomes decreased from pre-test to post-test in all therapy groups; however, the post-test mean scores were lower in the SCT and SRT than the SEH and MCT groups. Overall, the time effect was moderate-to-large and the group $\times$ time interaction effect was small-to-moderate. In addition, the remission rates for SOL and WASO were higher in the SCT and SRT than the SEH and MCT groups (Table 3). Only the time effect was statistically significant for total sleep time and was of a large size. The mean scores increased in all therapy groups.

Results of ANCOVA showed statistically significant between-group differences in sleep efficiency; the difference was of a moderate size (Table 2). The mean post-test score was lowest in the SEH group. The remission rates were higher in the SCT and SRT than the SEH and MCT groups (Table 3). There were no between-group differences in sleep quality at post-test.

Study Limitations

The study findings should be interpreted with caution in light of two limitations. First, the number of participants was not well balanced across the four therapy groups. Second, the participants' perceptions of and adherence to the therapy could have contributed to inter-individual differences in the level of improvement in the outcomes.

Discussion

The study compared the effects of single and multiple component therapies for chronic insomnia on sleep outcomes, in a large sample representative of the target population. Although chance and preference-based methods were used for treatment allocation, participants in the therapy groups were comparable on most outcomes measured at pre-test; however, between-group differences in pre-test outcomes were controlled for statistically. Overall, the results of the statistical analysis and clinical relevance testing indicate that: (a) SEH is least effective in improving sleep outcomes; (b) SCT, SRT and MCT are moderately effective in reducing the perceived severity of chronic insomnia and enhancing sleep parameters (i.e., number of naps and awakenings, SOL, WASO, sleep efficiency) in adults experiencing primary or comorbid clinical insomnia of moderate severity, regardless of whether or not they reported taking sleep medications; and (c) SCT and SRT demonstrated slightly better outcomes that were clinically relevant as reflected in higher remission rates, than the MCT. Accordingly, the SCT and SRT are viable single component therapies that nurses can be trained to implement in primary care settings, as suggested by Espie (2009).

Consistent with previous findings, SEH is minimally effective, as a single component therapy, in improving sleep outcomes (Morin et al., 1999); yet, it is often used in primary care settings (Irish, Kline, Gunn, Buysse, & Hall, 2015; Morin & Benca, 2012). Participants allocated to SEH reviewed the booklet on their own, at their convenience, comparable to how SEH is provided in primary care. They may have selectively implemented the sleep hygiene recommendations they viewed as most relevant to their lifestyle (e.g., avoid nicotine for smokers), which may have contributed to the small changes in the sleep outcomes. At post-test, participants in the SEH group still reported taking more than one nap; their mean number of awakenings was comparable to that reported at pre-test; and their mean scores for SOL and WASO were close to 30 min, similar to the criteria used to determine eligibility for this study. Their mean sleep efficiency was less than 85%. In contrast, the mean ISI score at post-test reflected they had no insomnia but only 13.5% of participants were considered remitters. More than half of the participants met the remission criteria for SOL and WASO, whereas less than a third met those for sleep efficiency. Because some participants in the SEH group appear to have resolved their insomnia, it would be worthwhile to further investigate the effectiveness of SEH in future research while examining participants' implementation and adherence to the sleep hygiene recommendations, and the profile of participants who show improvement in sleep outcomes.

Participants who received the single component SCT demonstrated some improvement in most sleep outcomes. They reported taking fewer naps than at pre-test. Participants still had more than one awakening per night, with a mean WASO close to 30 min and sleep efficiency less than the 85% cut-off value for remission. However, their mean SOL was lower at post-test than pre-test, and the mean ISI score reflected they had no insomnia. The majority (> 80%) of participants in the SCT group achieved remission for SOL, about two-thirds met the remission criterion for WASO and sleep efficiency, but only one third were considered remitters according to the ISI criterion. These findings are consistent with those reported by Brasure et al. (2016) and Dautovich, McNamara, Williams, Cross, and McCrae, (2010), suggesting that SCT as a single component therapy, is small-to-moderately effective in

improving sleep outcomes. Additional research is needed to explore factors that may have contributed to the less-than-optimal improvement in sleep outcomes such as participants' characteristics which may have affected their implementation of the SCT instructions or moderated the effectiveness of SCT.

Participants who received SRT appeared to have benefited from this single component therapy. In fact, their post-test mean scores reflected the best outcomes comparable to those of good sleepers. These participants fell asleep in less than 20 min and were awake close to 20 min across all awakenings during the night. On average, their mean sleep efficiency exceeded the 85% cut-off score and their mean ISI score indicated they had no insomnia. The percentages of participants in the SRT group achieving remission for ISI, SOL, WASO and sleep efficiency, were comparable those found in the SCT group. These results support the effectiveness of SRT as a single component therapy, as also documented by Miller et al. (2014). Future investigation of the SRT could explore possible moderators of its effectiveness.

The mean post-test scores indicated improvement in most outcomes reported for participants in the MCT group. However, the percentages of participants in the MCT who met the criteria for remission on the ISI, SOL, WASO and sleep efficiency were lower than the respective percentages observed in the SCT and SRT groups. This finding is in line with the results of Epstein, Sidani, Bootzin, and Belyea's (2012) study. The less-than-optimal effectiveness of the MCT, compared to the single component SCT and SRT, contradicts the widespread assumption that integrating multiple components would produce additive, complementary and beneficial outcomes. This assumption was recently questioned, and researchers were encouraged to examine the main and interactive effects of the components (Collins, Dziak, Kugler, & Trail, 2014). The aim is to optimize therapy by incorporating the most effective components. The current study represents an attempt to dismantle the MCT into its components; the findings suggest that although the single component SCT and SRT are effective, combining them does not appear to yield additional benefits in improving sleep outcomes among persons experiencing insomnia of moderate severity for more than 10 years.

The factors that may have contributed to the lower remission rates in the MCT are unclear and should be explored in future research. We speculate two possible explanations. The first has to do with the complexity of the MCT, which is defined in terms of the number of components comprising this therapy, the number of treatment recommendations to carry out, and the effort required to initiate and adhere to these recommendations (Craig et al., 2013). The MCT included three components, each involving a set of recommendations: SEH had 12 recommendations; SCT had six instructions; and SRT required an often considerable change in the sleep-wake schedule. Implementing all these recommendations demands great efforts to initiate, integrate and sustain substantial yet simultaneous changes in sleep behaviors and environment (Brasure et al., 2016; Epstein & Bootzin, 2002). Accordingly, participants may have been overwhelmed with all the changes they had to make, and partially or inconsistently applied the sets of recommendations, jeopardizing the achievement of beneficial sleep outcomes. In contrast, the SCT and SRT had a relatively smaller number of recommendations to implement, which could have been perceived as

manageable. The second possible explanation relates to the method for therapy allocation used in this study. A larger proportion of participants were allocated to the SCT and SRT, compared to the MCT, on the basis of preference. Mounting evidence shows that matching therapy to participants' preferences reduces attrition, increases satisfaction with and adherence to treatment, and improves outcomes (Swift, Callahan, & Vollmer, 2011; Swift, Callahan, Ivanovic, et al., 2013; Sidani, 2015). Future studies could investigate the benefits of involving persons with chronic insomnia in the selection of therapy and providing them the preferred therapy, whether it consists of single or multiple components.

Implications for Research

More research is needed to generate additional evidence on the comparative effectiveness of single component therapies for managing chronic insomnia, while overcoming the limitations of this study. Studies could be designed to: (a) have a more balanced number of participants assigned to the therapies under evaluation; (b) examine the impact of the therapies on long term sleep outcomes (e.g., assessed at 3 to 12 month follow-up); (c) integrate qualitative methods for exploring participants' perceptions of the therapies and factors that may have contributed to the implementation of treatment recommendations; and (d) examine possible moderators of the therapies' effects on sleep outcomes. The rather large variance in the post-test outcomes observed in this study supports the need to examine moderators. Incorporating these design factors may help to answer the clinical question of who would most benefit from which therapy.

Linking Evidence to Action

- Sleep education and hygiene which is commonly used in practice, is minimally effective as a single component therapy for chronic insomnia.
- SCT and SRT are viable single component therapies that produce clinical benefits.
- Single component insomnia treatment may be more convenient to implement in the primary care setting due to the reduced number of treatment recommendations compared to MCT.
- SCT and SRT can be implemented by nurses in primary care practice.

Conclusions

The study findings indicate that the SCT and SRT are effective single component therapies and yield higher remission rates than the MCT. As single component therapies with fewer treatment recommendations to apply in daily life, the SCT and SRT may be more attractive and easier to implement and adhere to by persons with chronic insomnia, than the MCT. Additional research, using factorial designs, is needed to further examine the effects of individual and combined therapies, which has resource implications (Collins et al., 2014) for managing insomnia treatment in the clinical setting.

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References

- Bootzin RR, & Epstein DR (2011). Understanding and treating insomnia. *Annual Review of Clinical Psychology*, 7, 435–458. doi:10.1146/annurev.clinpsy.3.022806.091516
- Bradley-Gilbride J, & Bradley C (2010). Partially randomized preference trial design In Salkind NJ (Ed), *Encyclopedia of research design*. (Vol 2, pp. 1009–1015). USA: Sage.
- Brasure M, Fuchs E, MacDonald R, Nelson VA, Koffel E, Olson CM, ... Kane RL (2016). Psychological and behavioral interventions for managing insomnia disorder: An evidence report for a clinical practice guideline by the American College of Physicians. *Annals of Internal Medicine*, 165, 113–124. doi:10.7326/M15-1782 [PubMed: 27136619]
- Buysse DJ, Ancoli-Israel S, Edinger JD, Lichstein KL, & Morin CM (2006). Recommendations for a standard research assessment of insomnia. *Sleep*, 29(9), 1155–1173. [PubMed: 17040003]
- Carney CE, Buysse DJ, Ancoli-Israel S, Edinger JD, Krystal AD, Lichstein KL, & Morin CM (2012). The Consensus Sleep Diary: Standardizing prospective sleep self-monitoring. *Sleep*, 35, 287–302. doi:10.5665/sleep.1642 [PubMed: 22294820]
- Collins LM, Dziak JJ, Kugler KC, & Trail JB (2014). Factorial experiments: Efficient tools for evaluation of intervention components. *American Journal of Preventive Medicine*, 47(4), 498–504. doi: 10.1016/j.amepre.2014.06.021 [PubMed: 25092122]
- Cohen J (1992). A power primer. *Psychological Bulletin*, 112(1), 155–159. [PubMed: 19565683]
- Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, & Petticrew M (2013). Developing and evaluating complex interventions: The new Medical Research Council guidance. *International Journal of Nursing Studies*, 50(5), 587–92. doi:10.1016/j.ijnurstu.2012.09.010 [PubMed: 23159157]
- Crum RM, Anthony JC, Bassett S, & Folstein MF (1993). Population-based norms for the Mini-Mental State Examination by age and educational level. *Journal of the American Medical Association*, 269(18), 2386–2391. [PubMed: 8479064]
- Dautovich ND, McNamara J, Williams JM, Cross NJ, & McCrae CS (2010). Tackling sleeplessness: Psychological treatment options for insomnia. *Nature and Science of Sleep*, 2, 23–37.
- Epstein DR, & Bootzin RR (2002). Insomnia. *Nursing Clinics of North America*, 37, 611–631. [PubMed: 12587364]
- Epstein DR, Sidani S, Bootzin RR, & Belyea MJ (2012). Dismantling multicomponent behavioral treatment for insomnia in older adults: A randomized controlled trial. *Sleep*, 35, 797–805. doi: 10.5665/sleep.1878 [PubMed: 22654199]
- Espie CA (2009). “Stepped Care”: A health technology solution for delivering cognitive behavioral therapy as a first line insomnia treatment. *Sleep*, 32(12), 1549–1558. doi: 10.1093/sleep/32.12.1549 [PubMed: 20041590]
- Field A (2013). *Discovering statistics using IBM SPSS Statistics* (et al.). London, UK: Sage.
- Irish LA, Kline CE, Gunn HE, Buysse DJ, & Hall MH (2015). The role of sleep hygiene in promoting public health: A review of empirical evidence. *Sleep Medicine Reviews*, 22, 23–36. doi:10.1016/j.smrv.2014.10.001 [PubMed: 25454674]
- Ma Y, Dong M, Mita C, Sun S, Peng C-K, & Yang AC (2015). Publication analysis on insomnia: How much has been done in the past two decades? *Sleep Medicine*, 16, 820–826. doi: 10.1016/j.sleep.2014.12.028 [PubMed: 25979182]
- Manber R, Carney C, Edinger J, Epstein D, Friedman L, Haynes PL, ... Trockel M (2012). Dissemination of CBTi to the non-sleep specialist: Protocol development and training issues. *Journal of Clinical Sleep Medicine*, 8(2), 209–218. doi: 10.5664/jcsm.1786 [PubMed: 22505869]
- Methodology Committee of the Patient-Centered Outcomes Research Institute. (2012). Methodological standards and patient-centeredness in comparative effectiveness research. The PCORI perspective. *Journal of the American Medical Association*, 307(15), 1636–1640. doi: 10.1001/jama.2012.466 [PubMed: 22511692]

- Miller CB, Espie CA, Epstein DR, Friedman L, Morin CM, Pigeon WR, Spielman AJ, & Kyle SD (2014). The evidence base of sleep restriction therapy for treating insomnia disorder. *Sleep Medicine Review*, 18(5), 415–424. doi: 10.1016/j.smr.2014.01.006
- Morin CM (1993). *Insomnia: Psychological assessment and management*. New York, NY: Guilford.
- Morin CM, & Benca R (2012). Chronic insomnia. *The Lancet*. doi:10.1016/s0140-6736(11)60750-2
- Morin CM, Belleville G, Bélanger L, & Ivers H (2011). The Insomnia Severity Index: Psychometric indicators to detect insomnia cases and evaluate treatment response. *Sleep*, 34(5), 601–608. [PubMed: 21532953]
- Morin CM, Hauri PJ, Espie CA, Spielman AJ, Buysse DJ, & Bootzin RR (1999). Nonpharmacological treatment of chronic insomnia: An American Academy of Sleep Medicine review. *Sleep*, 22, 1134–1167. [PubMed: 10617176]
- National Institutes of Health. (2005). State of the science conference statement. Manifestations and management of chronic insomnia in adults. *Sleep*, 28(9), 1049–1057. [PubMed: 16268373]
- Quassem A, Kansagara D, Forciea MA, Cooke M, Denberg TD, for the Clinical Guidelines Committee of the American College of Physicians. (2016). Management of chronic insomnia disorder in adults: A clinical practice guideline from the American College of Physicians. *Annals of Internal Medicine*, 165, 125–133. doi: 10.7326/P16-9016 [PubMed: 27136449]
- Riemann D, Baglioni C, Bassetti C, Bjorvatn B, Dolenc Groselj L, Ellis JG, ... Spiegelhalder K (2017). European guideline for the diagnosis and treatment of insomnia. *Journal of Sleep Research*, 26, 675–700. doi:10.1111/jsr.12594 [PubMed: 28875581]
- Sidani S (2015). *Health intervention research: Advances in research design and methods*. London, UK: Sage.
- Sidani S, Epstein DR, Bootzin RR, Moritz P, & Miranda J (2009). Assessment of preferences for treatment: Validation of a measure. *Research in Nursing & Health*, 32, 419–431. doi:10.1002/nur.20329 [PubMed: 19434647]
- Stacey D, & Légaré F (2015). Engaging patients using an interprofessional approach to shared decision making. *Canadian Oncology Nursing Journal*, 24(4), 455–461.
- Swift JK, Callahan JL, & Vollmer BM (2011). Preferences. *Journal of Clinical Psychology: In Session*, 67(2), 155–165. doi: 10.1002/jclp.20759 [PubMed: 21120917]
- Swift JK, Callahan JL, Ivanovic M, & Kominiak N (2013). Further examination of the psychotherapy preference effect: A meta-regression analysis. *Journal of Psychotherapy Integration*, 23 (2), 134–145. doi:10.1037/a0031423
- Winter AC, & Colditz GA (2014). Clinical trial design in the era of comparative effectiveness research. *Open Access Journal of Clinical Trials*, 6, 101–110. doi:10.2147/OAJCT.S39758

Table 1.Mean (*SD*) Scores on the Outcomes Measured at Pre-Test and Post-Test, by Therapy Group

Outcome	SEH (<i>n</i> = 78)		SCT (<i>n</i> = 95)		SRT (<i>n</i> = 82)		MCT (<i>n</i> = 262)	
	Pre-test	Post-test	Pre-test	Post-test	Pre-test	Post-test	Pre-test	Post-test
Perceived insomnia severity (ISI score range: 1 to 28)	16.7 (4.4)	13.4 * (4.9)	17.0 (5.1)	10.6 * (5.0)	18.7 (5.0)	9.4 * (5.0)	17.6 (3.9)	11.5 * (4.8)
Sleep parameters Number of naps	1.6 (2.0)	1.4 (1.9)	1.7 (2.5)	0.9 (1.7)	1.6 (1.2)	0.9 (1.3)	1.9 (2.2)	1.5 (1.9)
SOL (minutes)	34.5 (25.1)	25.2 (16.0)	45.3 (40.6)	22.0 (24.1)	49.0 (41.7)	19.9 (16.9)	42.9 (30.7)	24.6 (22.2)
Number of awakenings	2.1 (1.5)	2.0 (2.4)	1.7 (0.8)	1.3 (1.0)	2.3 (2.2)	1.4 (1.2)	2.1 (1.2)	1.6 (1.0)
WASO (minutes)	45.5 (26.1)	32.2 (23.6)	48.4 (36.9)	26.8 (24.8)	56.1 (33.5)	22.7 (16.7)	54.4 (33.9)	28.8 (23.5)
Total sleep time (minutes)	363.9 (59.7)	393.6 (54.3)	350.8 (72.9)	389.9 (72.5)	336.2 (74.4)	368.8 (46.1)	346.9 (61.0)	376.9 (55.9)
Sleep efficiency (%)	73.4 (9.4)	79.1 * (8.6)	70.4 (13.4)	83.7 * (8.6)	65.8 (12.8)	86.8 * (8.5)	69.9 (10.4)	83.3 * (8.3)
Sleep quality (range: 1 – 5)	2.7 (0.4)	2.8 * (0.4)	2.4 (0.4)	3.0 * (0.4)	2.4 (0.5)	3.0 * (0.4)	2.6 (0.4)	3.0 * (0.4)

SD = standard deviation; SEH = sleep education and hygiene; SCT = stimulus control therapy; SRT = sleep restriction therapy; MCT = multi-component therapy; SOL = sleep onset latency; WASO = time awake after sleep onset;

* adjusted mean scores.

Table 2.

Results of Outcome Comparison by Therapy Group

Outcome	Group effect	Time effect	Group × time interaction effect
Perceived insomnia severity *	$F(3,465) = 9.23, p < .001, \eta^2 = .056$		
Sleep parameters Number of naps	$F(3,488) = 0.85, p = .465, \eta^2 = .005$	$F(1,488) = 43.15, p < .001, \eta^2 = .081$	$F(3,488) = 3.64, p = .013, \eta^2 = .022$
SOL	$F(3,488) = 0.60, p = .612, \eta^2 = .004$	$F(1,488) = 165.34, p < .001, \eta^2 = .25$	$F(3,488) = 5.88, p = .001, \eta^2 = .035$
Number of awakenings	$F(3,488) = 3.24, p = .022, \eta^2 = .020$	$F(1,488) = 34.46, p < .001, \eta^2 = .066$	$F(3,488) = 3.13, p = .025, \eta^2 = .019$
WASO	$F(3,488) = 1.22, p = .300, \eta^2 = .007$	$F(1,488) = 188.64, p < .001, \eta^2 = .278$	$F(3,488) = 5.51, p = .001, \eta^2 = .033$
Total sleep time	$F(3,488) = 3.98, p = .008, \eta^2 = .024$	$F(1,488) = 151.24, p < .001, \eta^2 = .236$	$F(3,488) = 0.77, p = .508, \eta^2 = .005$
Sleep efficiency *	$F(3,488) = 10.65, p < .001, \eta^2 = .061$		
Sleep quality *	$F(3,488) = 2.31, p = .075, \eta^2 = .014$		

* Outcome compared using ANCOVA – only group effect is reported.

Table 3.

Remission Rates (Percentage of Participants Meeting or Exceeding Criterion) on the Outcomes by Therapy Group

Outcome (criterion for remission)	SEH	SCT	SRT	MCT
Perceived insomnia severity (ISI score < 8)	13.5	33.0	27.8	23.3
SOL (score < 30 minutes)	68.9	83.5	82.1	74.4
WASO (score < 30 minutes)	56.8	67.0	71.8	61.9
Sleep efficiency (score > 85%)	29.7	60.4	62.8	48.1

SEH = sleep education and hygiene; SCT = stimulus control therapy; SRT = sleep restriction therapy; MCT = multi-component therapy; SOL = sleep onset latency; WASO = time awake after sleep onset.