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Mechanisms of Change and Treatment Matching in Behavior Therapy, Cognitive Therapy and Cognitive Behavior Therapy for Chronic Insomnia

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Abstract

Objective—To examine the mediators and the potential of treatment matching to improve outcome for cognitive behavior therapy for insomnia (CBT).

Method—Participants were 188 adults (117 women; *M* age = 47.4 years, *SD* = 12.6) meeting DSM-IV-TR diagnostic criteria for chronic insomnia (*M* duration: 14.5 years, *SD*: 12.8). Participants were randomized to behavior therapy (BT; *n* = 63), cognitive therapy (CT; *n* = 65) or CBT (*n* = 60). The outcome measure was the Insomnia Severity Index (ISI). Hypothesized BT mediators were sleep incompatible behaviors, bedtime variability (BTv), risetime variability (RTv) and time in bed (TIB). Hypothesized CT mediators were worry, unhelpful beliefs and monitoring for sleep-related threat.

Results—The behavioral processes mediated outcome for BT but not CT. The cognitive processes mediated outcome in both BT and CT. The subgroup scoring high on both behavioral and cognitive processes had a marginally significant better outcome if they received CBT relative to BT or CT. The subgroup scoring relatively high on behavioral but low on cognitive processes and received BT or CBT did not differ from those who received CT. The subgroup scoring relatively high on cognitive but low on behavioral processes and received CT or CBT did not differ from those who received BT.

Conclusion—The behavioral mediators were specific to BT relative to CT. The cognitive mediators were significant for *both* BT and CT outcomes. Patients exhibiting high levels of both behavioral and cognitive processes achieve better outcome if they receive CBT relative to BT or CT alone.

Keywords

Insomnia; Cognitive-Behavior Therapy; Treatment Matching; Mediation

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Insomnia is the most prevalent of all sleep disorders (Ohayon & Reynolds, 2009). It is associated with significant daytime impairment, accidents and sickness (Daley et al., 2009; Sivertsen, Øverland, Bjorvatn, Mæland, & Mykletunb, 2009) as well as increased risk of developing a mental illness (Baglioni et al., 2011; Breslau, Roth, Rosenthal, & Andreski, 1996) or a physical health problem (Léger, Guilleminault, Bader, Lévy, & Paillard, 2002; Taylor et al., 2007). As such, insomnia is a significant and costly public health problem (Morin et al., 2014).

Research has clearly established the short and longer-term benefits of cognitive behaviour therapy (CBT) for the treatment of insomnia (e.g., Morin et al., 2006; Smith et al., 2002). CBT for insomnia is a multi-component treatment that includes behavior therapy (BT) elements (e.g., irregular sleep-wake schedules, unhelpful sleep habits, spending excessive time in bed, napping) and cognitive therapy (CT) elements (e.g., unhelpful beliefs about sleep, sleep-related worry, attentional bias) (Perlis, Aloia, & Kuhn, 2011). Despite the impressive outcomes associated with CBT for insomnia, there is room for improvement (Buysse, 2013; Espie, Inglis, & Harvey, 2001; Harvey & Tang, 2003; Morin, Culbert, & Schwartz, 1994). The present study pursues two pathways to improving treatment outcome.

First, we seek to identify mediators of treatment outcome. Research on mediators is valuable for improving knowledge of the elements of a treatment that lead to therapeutic change which, in turn, can be intensified and refined while inactive or redundant elements can be discarded (Kraemer & Robinson, 2005). Second, we seek to identify subgroups of patients who benefit differentially from specific treatment elements (BT elements versus CT elements). Indeed, at the heart of the personalized medicine approach (Insel, 2009a) is the hypothesis that matching the core pathology to the treatment will yield an optimized outcome. As such, this approach is consistent with efforts to ‘develop a personalized approach to the diverse needs and circumstances of people with mental illness’ (p. 128) (Insel, 2009b).

Schwartz and Carney (2012) provided a summary of the state-of-the-science on mediators of CBT for insomnia. Consistent with the cognitive and behavioral theories that underpin CBT for insomnia, Schwartz and Carney (2012) demonstrated the potential importance of both BT and CT elements. Specifically, reductions in time in bed, napping, bedtime and risetime variability, hyperarousal and unhelpful beliefs and attitudes about sleep as well as improvements in sleep-related self-efficacy and sleep locus of control were evident from before to after treatment and/or were reduced compared to a comparison group. Since the publication of this review, several other studies have identified mediators of outcome in CBT for insomnia delivered via bibliotherapy, the internet or in person including pre-sleep arousal (Sunnhed & Jansson-Fröjmark, 2015; Vincent & Walsh, 2013), time awake in bed (Vincent & Walsh, 2013), unhelpful beliefs (Ashworth et al., 2015; Norell-Clarke, Tillfors, Jansson-Fröjmark, Holländare, & Engström, 2014; Sunnhed & Jansson-Fröjmark, 2015), bedtime variability (Sunnhed & Jansson-Fröjmark, 2015), attributions, cognitive factors (Espie et al., 2014), perseverative cognitions, sleep effort (Ebert et al., 2015) and higher patient involvement (Kaldo, Ramnerö, & Jernelöv, 2015). However, Schwartz and Carney’s (2012) conclusion remains true; namely, considerable research is needed to clearly distinguish between mediators, moderators and outcome variables, and to identify which mediators are

important for CBT for insomnia. One way to address this gap is to examine mediators that are specific to BT vs. CT. Indeed, a requirement for establishing mediation is the demonstration of specificity in the association between treatment, potential mediator, and outcome (Kazdin, 2007).

The second pathway pursued to improving treatment outcome in the present study is derived from the patient homogeneity myth which is defined as 'the assumption that all patients with the same medical diagnosis are similar on all important variables' (p. 44) (Turk, 2005). Turk (2005) raised the possibility that subdividing, or splitting rather than lumping, is a potential pathway to improve treatment outcome. Indeed, promising findings have emerged from matching pathology to treatment type in chronic pain (Brennan et al., 2006), alcohol (Karno & Longabaugh, 2007), trauma (Weaver, Olin, & Wisdom, 2010) and cannabis use (Hendriks, van der Schee, & Blanken, 2012). We suggest that insomnia may be another prime candidate for improving treatment outcome by matching pathology to treatment type. Our rationale is that two of the building blocks for successful subgroup identification and treatment matching identified by Turk (2005) are features of the insomnia literature. First, the insomnia literature has developed distinct measures of the sub-elements of CBT; namely, behavioral processes and cognitive processes. Second, the insomnia literature has developed specific treatment elements that are hypothesized to treat maladaptive sleep-related behavior (i.e., BT) and cognitive (i.e., CT). If we apply Turk's arguments, made in the context of chronic pain, to insomnia we would reason that if the rationale for a treatment is that it addresses some underlying pathology, then patients who exhibit pathology related to behavior may benefit most from the BT elements, patients who exhibit pathology related to cognition may benefit from the CT elements and patients who exhibit pathology in both behavior and cognition would benefit from the combined CBT.

Using data from a large study evaluating the unique contribution of behavior therapy (BT) and cognitive therapy (CT) relative to full CBT (Harvey et al., 2014), the present study had two aims. Aim 1 was to evaluate the mediators contributing to improvement in BT and CT. It is hypothesized that change in behavioral processes (e.g., sleep incompatible activities) will mediate outcome in BT and that change in cognitive processes (e.g., dysfunctional beliefs) will mediate outcome in CT. To address this aim we first tested whether each of the proposed mediators was associated with treatment condition, and then tested whether the mediator interacts with treatment condition or has a main effect on the insomnia outcome. Aim 2 is to evaluate if the subgroup of patients who scored high on behavioral processes, high on cognitive processes versus high on both behavioral and cognitive processes exhibit differential outcome following BT versus CT versus CBT. We elected to use a categorical approach as it is inherent in the research question. Specifically, we would like to identify whether a group of patients who scored high on behavioral but low on cognitive processes at pre-treatment, would be helped by receiving a treatment that has a component of behavioral therapy (i.e., BT or CBT). The same goes for a group of patients who scored high on cognitive but low on behavioral processes, and a group of patients high on both processes. This is important to know as if a patient exhibits more behavioral processes, prioritizing the behavioral elements may quicken and maximize a positive treatment outcome. Same for CT. Three hypotheses were tested for Aim 2. First, the subgroup who scored high on dysfunctional behavioral processes are hypothesized to have a better outcome if they

received BT or CBT relative to CT. Second, the subgroup who scored high on dysfunctional cognitive processes will have a better outcome if they received CT or CBT relative to BT. Third, the subgroup who scored high on both behavioral and cognitive processes will have a better outcome if they received CBT relative to BT or CT. We grouped CBT with either CT or BT because it is important to know whether those high on behavioral and low on cognitive processes would have a better treatment outcome if they receive treatment that has a behavioral component. The same goes for CT or CBT vs. BT.

Method

For a more detailed description of the study design, treatment protocol and participant flow, see Harvey et al. (2014). In brief, 188 participants were randomized to BT (n=63), CT (n=65) or CBT (n=60). The overall attrition rate was 7.5% (14/188) during treatment and 10.6% (20/188) at the 6-month followup. Attrition was not significantly different across treatment groups at posttreatment (CBT = 3.3%, CT = 9.2%, BT = 9.5%, $p = .37$) or at 6-month followup (CBT = 5.0%, CT = 13.9%, BT = 12.7%, $p = .25$).

We note that the current report is different from a prior report (Eidelman et al., 2016) in two ways. First, in terms of the aims, this report is focused on determining mediators (with a focus on treatment specific mediators for CT vs. BT) and whether there is potential for enhancing treatment outcome by treatment matching. In contrast, Eidelman et al. (2016) conducted a ‘deep dive’ on the role of dysfunctional beliefs about sleep and one of the aims examines dysfunctional beliefs about sleep as a predictor of treatment outcome. Second, in terms of measures, this report examines three BT mediators and three CT mediators (one of the mediators examined was dysfunctional beliefs about sleep). In contrast, Eidelman et al. (2016) is focused on just dysfunctional beliefs about sleep as a predictor.

Participants

Patients were recruited from March, 2008 to November, 2011 through advertisements and referrals from health care practitioners. Participants were recruited from two sites: XX and XX. A telephone interview was completed to initially screen for eligibility. Eligible individuals were then invited to participate in an extensive diagnostic interview session.

Inclusion criteria were: (a) 25 years of age or older and (b) meeting criteria for persistent insomnia: (i) difficulty initiating and/or maintaining sleep, defined as a sleep onset latency and/or wake after sleep onset greater or equal to 30 min, with a corresponding sleep time of less than or equal to 6.5 hours per night, as ascertained by daily sleep diaries kept for a two-week baseline period; (ii) presence of insomnia more than 3 nights per week and for more than 6 months; (iii) the sleep disturbance (or associated daytime fatigue) causes significant distress or impairment in social, occupational, or other areas of functioning as measured by a rating of at least 2 on item no. 5 or 7 on the Insomnia Severity Index (Morin, 1993). This definition represents a combination of the Research Diagnostic Criteria (Edinger et al., 2004), the International Classification of Sleep Disorders’ criteria (ICSD; American Academy of Sleep Medicine, 2005) and the Diagnostic and Statistical Manual of Mental Disorders’ criteria (DSM-IV-TR; American Psychiatric Association, 2013) along with quantitative cutoffs typically used in insomnia research.

Exclusion criteria were: (a) presence of a progressive or unstable physical illness (e.g., cancer, acute pain) or neurological degenerative disease (e.g., dementia) directly related to the onset and course of insomnia, (b) use of hypnotics and other medications known to alter sleep (e.g., steroids, anxiolytics) (patients on SSRI for at least 3 months were included), (c) evidence of sleep apnea (apnea/hypopnea index > 15), restless legs or periodic limb movements during sleep (PLMS with arousal > 15 per hour), or a circadian-based sleep disorder (e.g., delayed or advanced sleep phase syndrome); or body mass index (BMI) of 35 or above, or BMI of 32 or above and reporting at least 3 symptoms of breathing-related sleep disorder on the Duke Structured Interview for Sleep Disorders (Edinger et al., 2009), (d) irregular sleep schedules, with usual bedtimes earlier than 9:00pm or later than 2:00am or rising time earlier than 5:00am or later than 10:00am, occurring more than twice/week or working on night or rotating shifts within the last year, (e) current or past psychological treatment of insomnia within the past 5 years, (f) individuals consuming more than two alcoholic beverages or more than four caffeinated beverages per day were required to reduce their intake below or equal to two and four respectively for the duration of the study or be excluded from the study, (g) a lifetime diagnosis of a psychotic or bipolar disorder or more than two lifetime episodes of major depressive disorder or an untreated current major depressive disorder or alcohol or drug abuse within the past year. When other comorbidities were present, we ensured that insomnia was the disorder currently most distressing and disabling (Di Nardo et al., 1993) or that participant were still suffering significant insomnia despite receiving treatment for the comorbid condition (e.g., major depression). Of the total 188 patients, 45 (23.9%) had at least one current comorbid Axis I disorder (ranging from 1 to 4 diagnoses, $M = 1.4$). Most frequent comorbid disorders were generalized anxiety disorder ($n = 18$), specific phobia ($n = 10$), adjustment disorder ($n = 5$), dysthymia ($n = 4$), obsessive-compulsive disorder ($n = 4$), social phobia ($n = 3$), panic disorder ($n = 3$), and major depressive disorder ($n = 3$). Of the total sample, 35.1% had used a prescribed hypnotic medication and 18.6% had used an over the counter product for sleep in the last month before the study. Recall that exclusion criteria (b) was the use of hypnotics and other medications known to alter sleep.

Study Design

A total of 188 adults with persistent insomnia were randomly assigned to one of three groups: (a) behavior therapy (BT; $n = 63$), (b) cognitive therapy (CT; $n = 65$), or (c) cognitive-behavior therapy (CBT; $n = 60$). Randomization was stratified by age (25–49 versus 50+) and presence of a comorbid psychiatric disorder (absence vs. depression, dysthymia, generalized anxiety disorder, social phobia, panic disorder, adjustment disorders). Group allocation concealment was achieved by sequentially numbered, opaque, sealed envelopes opened by the project coordinator at each study site. Treatment lasted 8 weeks for all three groups. Outcome measurements were taken pre-treatment, post-treatment and at 6-month follow-up. All participants provided written informed consent and received financial compensation to cover their travel expenses.

Assessment Measures

Diagnostic Measures—*Structured Clinical Interview for DSM-IV* (SCID; First, Spitzer, Gibbon, & Williams, 1995) is a semi-structured interview designed to assess *DSM-IV-TR*

diagnostic criteria for Axis I disorders. The SCID has good reliability. Trained psychology doctoral students and postdoctoral fellows administered the SCID to assess current and lifetime Axis I disorders.

Duke Structured Interview for Sleep Disorders (DSISD; Edinger, et al., 2004) is a semi-structured interview that assesses research diagnostic criteria for sleep disorders. The DSISD has good reliability and validity (Edinger, et al., 2009).

Primary Outcomes—*Insomnia Severity Index* (ISI; Bastien, Vallieres, & Morin, 2001; Morin, Belleville, Bélanger, & Ivers, 2011) is a 7-item scale assessing nighttime (difficulties falling asleep, staying asleep, early morning awakenings) and daytime variables (satisfaction with sleep, degree of impairment with daytime functioning, noticeability of impairments, distress or concern with sleep). Each item is rated on a 5-point scale and the total score ranges from 0 to 28. The ISI has adequate internal consistency (Cronbach's alpha =.91) and temporal stability (r = .80), and is sensitive to therapeutic changes (Morin et al., 2004; Morin, Beaulieu-Bonneau, LeBlanc, & Savard, 2005; Morin et al., 2009). The following interpretation guidelines are recommended: score of 0–7 (no clinical insomnia), 8–14 (sub threshold insomnia), 15–21 (insomnia of moderate severity), and 22–28 (severe insomnia). The total score was the primary outcome measure for this study.

Measures of Behavioral Processes—The dependent variables representing the behavioral elements were among those identified by Schwartz and Carney (2012) as possible mediators. Each were administered pre-treatment, session 4 (mid-way in treatment), post-treatment and 6-month follow-up.

Sleep Behavior Rating Scale (SBRS) (Kazarian, Howe, & Csapo, 1979): The frequency of sleep incompatible behaviors was measured with the SBRS. Patients rate which of a list of 20 sleep incompatible behaviors they engage in the bedroom or bed either during the day or around sleeping time (0 "Never" to 5 "Very often"). The items are summed to obtain a total score that ranges from 20 to 100, with a higher score indicating a higher level of sleep incompatible behaviors. The SBRS has high test-retest reliability (r = .88) and internal consistency.

Sleep Diary: Participants kept daily sleep diaries during a 2-week baseline period, the 8-week treatment phase, and for 2 weeks at the post-treatment and 6-month follow up assessments. The sleep diary has been shown to be a reliable estimate and is considered the gold standard subjective measure of sleep (Buysse, Ancoli-Israel, Edinger, Lichstein, & Morin, 2006). The effectiveness of stimulus control and sleep restriction, the essential elements of BT, are often measured by bedtime variability (BTv), risetime variability (RTv) and time in bed (TIB). As such, in the present study, BTv, RTv and TIB were considered as potential behavioral mediators. BTv and RTv were calculated as the individual standard deviation over 7-day sleep diary. We also considered including daytime naps, which stimulus control and sleep restriction recommends against, but the base rate of napping on the pre-treatment sleep diary was low.

Measures of Cognitive Processes—The dependent variables representing the cognitive elements were those identified by Schwartz and Carney (2012) as possible mediators and those implicated in cognitive models of insomnia (e.g., Espie, Broomfield, MacMahon, Macphee, & Taylor, 2006; Harvey, 2002; Jansson & Linton, 2007; Lundh, 2000; Morin, 1993). Each were administered pre-treatment, session 4 (mid-way in treatment), post-treatment and 6-month follow-up.

Anxiety and Preoccupation about Sleep Questionnaire (APSQ) (Tang & Harvey, 2004b) is a 10-item self-report measure that assesses sleep-related worry. The respondent is asked to rate, on a 10-point scale, how true each of the statements are for them over the past month (1 "Not true", 10 "Very true"). The items are summed to obtain a total score that ranges from 10 to 100, with a higher score indicating a higher level of anxiety and preoccupation about sleep. The APSQ has high internal consistency ($\alpha = 0.92$).

Dysfunctional Beliefs and Attitudes about Sleep (DBAS) (Morin, 1993) is a 30-item self-report scale that examines a broad range of sleep-related cognitions (beliefs, attitudes, expectations, and attributions) that are presumed to be instrumental in maintaining insomnia. Patients indicate the extent to which they agree/disagree with each statement on a 0 (strongly disagree) to 10 (strongly agree) Likert-type scale. Although there is no absolute right or wrong answer, their dysfunctional nature is suggested by the degree with which patients endorse a particular item, a higher score reflecting more dysfunctional beliefs. The psychometric properties of the original 30-item version of the DBAS are good, with evidence of adequate internal consistency (Cronbach's Alpha = 0.80) and temporal stability over a 2-week period, moderate item-total correlations (mean *rs* = 0.37), and acceptable convergent and discriminant validity (Espie, Inglis, Harvey, & Tessier, 2000; Morin, Stone, Trinkle, Mercer, & Remsberg, 1993; Smith & Trinder, 2001).

Monitoring for sleep-related threat: The *Sleep Associated Monitoring Index* (SAMI) (Neitzert Semler & Harvey, 2004) is a 30-item self-report measure that assesses attentional bias toward and monitoring for sleep-related threat. The respondent is asked to rate, on a 5-point scale, how true each of the statements is for them over the past month (1 "Not at all", 5 "All the time"). The items are summed to obtain a total score that ranges from 33 to 165, with a higher score indicating more monitoring. The SAMI has high internal consistency ($\alpha = 0.91$). The test-retest reliability is acceptable ($r = 0.82$), as is the discriminative validity and convergent validity (Neitzert Semler & Harvey, 2004).

Treatments

Treatments were provided in the context of eight weekly individual therapy sessions, with BT and CT sessions lasting 45–60 minutes and CBT sessions lasting 75 minutes long. Common treatment elements across all three arms included a generic overview of CBT within a self-management framework, the 3 P model of insomnia (Spielman & Glovinsky, 1991), keeping a daily sleep diary, setting treatment goals, and reviewing sleep hygiene information. The week-by-week content of sessions was published as an online supplement to the main study and can be found at http://europepmc.org/articles/PMC4185428;jsessionid_pfBi8HL2aa2rUZPa6ZeW.12.

Behavior therapy (BT): BT included a combination of stimulus control instructions (Bootzin, Epstein, & Wood, 1991) and sleep restriction procedures (Spielman, Saskin, & Thorpy, 1987), which involves curtailing time in bed to the actual time slept and gradually increasing it back to an optimal sleep time.

Cognitive Therapy (CT): CT was based on Beck's model (Beck, 1979; Beck, Emery, & Greenberg, 1985) and sought to reverse a broad range of cognitive maintaining mechanisms including unhelpful beliefs about sleep (Morin, Blais, & Savard, 2002), sleep-related or sleep-interfering worry (Tang & Harvey, 2004a), attentional bias and monitoring for sleep-related threat (Neitzert Semler & Harvey, 2005), use of safety behaviors (Ree & Harvey, 2004b) and misperception of sleep (Harvey & Tang, 2012). These treatment approaches are described elsewhere (Harvey, Sharpley, Ree, Stinson, & Clark, 2007; Morin, 1993; Perlis, et al., 2011). Second, CT included individually formulated experiments to test beliefs. A minimum of four experiments were conducted across the 8 sessions: a monitoring/ attentional bias experiment, the sleep survey experiment, the energy generating experiment and the fear of poor sleep experiment (Harvey, et al., 2007; Perlis, et al., 2011; Ree & Harvey, 2004a).

Cognitive-Behavior Therapy (CBT) consisted of a combination of both the BT and CT components delivered in an integrated fashion. A case formulation driven approach (Harvey, 2006; Persons, 2006) was used to determine the relative time and ordering of CT vs. BT. The formulation was guided by the symptoms that were present and the approach that elicited the most optimal response from the patient. For CBT to truly combine, and cover all elements of CT and BT, we elected to devote more time to CBT.

Therapists: All treatments were administered by licensed clinical psychologists or advanced graduate students in clinical psychology who had completed all of their clinical training requirements. Therapists had attended joint training workshops with the study principal investigators. Treatment manuals were also available to therapists and ongoing joint supervision from both study sites were provided during the course of the study.

Data Management and Analyses

Based on the power analysis conducted for the original grant application, this RCT was sufficiently powered with 80% of power to detect meaningful differences between groups. It is not recommended to do further post-hoc power analysis once the study is completed (Hoenig & Heisey, 2001).

All data were double-entered in an Access data warehouse (one per site) and missing or aberrant data were verified for maximal integrity of the database. Sleep diary variables were computed as nightly means averaged over the two-week (diary) for each assessment phase.

Analyses for the main hypotheses were performed using an intent-to-treat approach wherever possible, such that all randomized participants were included in the analyses. No data imputation was performed. Site and stratification variables (age and comorbidity) were included in all main analyses as fixed effects (Chow & Liu, 1998).

All data analysis was conducted using Stata 14 (StataCorp, 2015). Significance level of two-tailed $\alpha = 0.05$ was used throughout. Multilevel modeling (hierarchical linear modeling) was used to account for the repeated assessments nested within participants (Raudenbush & Bryk, 2002). Aim 1 evaluated the proposed mediators of treatments. As shown in Table 2, all mediators and outcome were assessed at pre-treatment, mid-treatment (session 4), post-treatment, and 6-month follow-up. By definition, mediators of treatment "measure an event or changes occurring during treatment" and "must correlate with the treatment, hence possibly be a result of treatment, and have either a main or interactive effect on the outcome" (Kraemer, Wilson, Fairburn, & Agras, 2002). We evaluated each potential mediator based on the following criteria proposed in Kraemer et al., 2002: 1) the mediator must measure an event or change after treatment occurs, 2) the mediator must correlate with treatment choice, and 3) the mediator must exhibit main effect or interaction with treatment on the outcome. All potential mediators evaluated in the current study meet the first criteria. For criteria 2, we tested whether treatment choice (BT vs. CT) significantly predicted changes in each of the potential mediators from pre-treatment through 6-month follow-up using multilevel modeling. We also examined whether there are significant changes from session 4 through 6-month follow-up in the potential mediators within each treatment choice. For criteria 3, we tested whether changes in mediators predict changes in the outcome from pre-treatment through 6-month follow-up using multilevel modeling. Note that additional criteria for testing mediators of intervention have been used in the literature, most notably including 1) the treatment, relative to the control, must exert significant effect on the outcome, and 2) the treatment effect is significantly reduced or eliminated when a mediator is controlled for (e.g., Stice, Presnell, Gau, & Shaw, 2007; Stice, Rohde, Seeley, & Gau, 2010). However, the current study tested three active treatment conditions with previously established effectiveness, namely CBT, CT, and BT, against each other, and no control group was included. Therefore, we were unable to test these additional criteria that typically require the treatment effect of an active treatment relative to a control condition. Although there was no control group, in the main paper (Harvey et al., 2014), large effects sizes (Cohen's $d = -1.94$ to -2.50) were reported during the treatment phase for all three active treatment groups. Given that the mediators were measured only once during treatment (at session 4), we were unable to calculate time to the occurrence of 0.5 SD change to evaluate whether changes in mediator occur before outcome (Stice, Presnell, Gau, & Shaw, 2007).

For Aim 2, subgroups that were high on behavioral processes, cognitive processes, and both behavioral and cognitive processes at pre-treatment were created using the following method: 1) raw scores at pre-treatment for all the relevant measures were first converted into z scores for all mediators, 2) composite scores were then generated for behavioral (i.e., SBRS, TIB, BTv and RTv) and cognitive processes (i.e., APSQ, DBAS, SAMI) respectively by taking the mean of the relevant z scores within each process, 3) binary group variables (i.e., high vs. low on behavior/cognitive process) were created by conducting median split on the composite score, and 4) an additional subgroup was created by taking participants who were in the high group on both behavior and cognitive processes. Subgroups that are relatively high on behavioral but low on cognitive processes, relatively high on cognitive but low on behavioral processes, and high on both processes at pre-treatment were used in for the Aim 2 analyses. There was no overlap between subgroups- participants can only be

placed in one subgroup. Multilevel modeling was then used to assess whether treatment choice (e.g., BT/CBT vs. CT) significantly predicted changes in the ISI score (outcome) from pre-treatment through FU6.

In other words, the median split method was applied to the behavioral and cognitive processes to create the three groups used in Aim 2 analyses: 1) the high behavioral low cognitive subgroup includes patients who scored in the upper 50% on the behavioral process but lower 50% on the cognitive process, 2) the high cognitive low behavioral subgroup includes patients who scored in the upper 50% on the cognitive process but lower 50% on the behavioral process, and 3) the high on both behavioral and cognitive processes subgroup includes patients who scored in the upper 50% on both processes. We then analyzed the effect of receiving "matched" treatment versus not on treatment outcome separately in each subgroup. Note that median split is acceptable because behavioral mediators were uncorrelated with cognitive mediators at pre-treatment (Iacobucci, Posavac, Kardes, Schneider, & Popovich, 2015). We did consider splitting into thirds so as to create bigger contrast, but we decided against this approach as the reduced sample size for each subgroup is a drawback particularly given the multilevel modeling analysis conducted for each subgroup.

Results

Participant Characteristics

There were no significant differences between groups at baseline on any demographic or outcomes variable (see Table 1 in Harvey, et al., 2014). Females constituted 53.3% of the CBT treatment arm, 69.2% of CT and 63.5% of BT. Mean age (in years) for CBT was 46.9 (*SD* = 11.3), 46.7 (*SD* = 12.8) for CT and 48.5 (*SD* = 13.6) for BT. Mean insomnia duration (in years) was 13.8 (*SD* = 11.9) for CBT, 14.8 (*SD* = 12.9) for CT and 14.8 (*SD* = 12.8) for BT. Insomnia Severity Index was 17.9 (*SD* = 3.4) for CBT, 17.6 (*SD* = 3.5) for CT and 18.3 (*SD* = 3.4) for BT. Table 1 presents the group differences for potential mediator variables and outcomes across treatment conditions and across assessment time points (pre-treatment, mid-treatment/session 4, post-treatment, and 6-month follow-up).

Aim 1

Table 2 presents the multilevel model results testing whether treatment conditions (BT vs. CT) were significantly associated with the hypothesized mediators. Receiving BT (vs. CT) significantly predicted more improvements from pre-treatment, session 4, post, to 6-month follow-up in all the hypothesized behavioral mediators (SBRS, TIB, BTv, RTv). Receiving CT (vs. BT) significantly predicted more improvements in all the hypothesized cognitive mediators (APSQ, DBAS, and SAMI) from pre-treatment, session 4, post, to 6-month follow-up. In addition, as shown in the supplemental material, in BT there were significant reductions in all behavioral and cognitive mediators from pre-treatment through post-treatment or 6-month follow-up. In CT, there were significant reductions in all cognitive mediators from pre-treatment through 6-month follow-up and only select behavioral mediators (i.e., BTv from pre-treatment to session 4 and TIB from pre- to post-treatment).

We then tested whether changes in the hypothesized mediators had a significant main effect or interaction with treatment condition on changes in the outcome from pre-treatment through 6-month follow-up. All potential behavioral and cognitive mediators tested had either a main effect or interaction on the outcome, providing evidence for significant mediation. The results are presented in Table 3.

For the behavioral mediators, there was a significant interaction for SBRS with treatment condition on ISI change. Further exploration of this interaction suggests a positive association (expected direction) between SBRS and ISI over time in BT ($B = 0.73$, $SE = 0.30$, $p = 0.02$) but a negative association (opposite direction) between SBRS and ISI over time in CT ($B = -0.71$, $SE = 0.33$, $p = 0.03$). For BTv and RTv, there was significant main effects on ISI change. While the main effects of BTv and RTv were only significant in BT but not CT, the interaction between BTv and RTv and treatment condition did not reach statistical significance. For TIB, there was a trend ($p = 0.10$) in the expected direction for an interaction with treatment condition on ISI changes. Although the interaction did not reach statistical significance, further exploration suggests that TIB only predicted ISI in BT ($B = 0.92$, $SE = 0.26$, $p < 0.001$) but not in CT ($B = 0.14$, $SE = 0.40$, $p = 0.72$).

For the cognitive processes, APSQ, DBAS, and SAMI all had significant main effects but not interactive effects on ISI, suggesting that these mediators were not specific to CT and were not particularly stronger in CT than BT.

Aim 2

Table 4 presents the descriptive statistics of ISI scores at pre-treatment, post-treatment and 6-month follow-up for participants who scored high on behavioral, cognitive, and both behavioral and cognitive processes at pre-treatment. As also shown in Table 4, multilevel modeling results suggest that among the participants who scored high on behavioral process but low on cognitive process at pre-treatment, those who received BT (i.e., BT or CBT) did not differ from those who did not receive BT (i.e., CT) in terms of the insomnia outcome from pre-treatment to post-treatment and 6-month follow-up. Similarly, among the participants who scored high on cognitive process but low on behavioral process at pre-treatment, those who received CT or CBT did not differ from those who received BT in terms of the insomnia outcome from pre-treatment to post-treatment and 6-month follow-up.

Among the participants who scored high on both behavioral and cognitive processes at pre-treatment, those who received CBT had a greater reduction in ISI scores from pre-treatment to post-treatment than those who received BT or CT alone ($B = -2.94$, $SE = 1.52$, $p = 0.053$). ISI changes from pre-treatment to 6-month follow-up or post-treatment to 6-month follow-up did not differ significantly comparing CBT vs. BT or CT for those who scored high on both processes process at pre-treatment.

Discussion

As expected, receiving BT (vs. CT) significantly predicted more improvement in all of the hypothesized behavioral mediators (SBRS, BTv, RTv and TIB) from pre-treatment, session 4, post-treatment, to 6-month follow-up, confirming an important role for targeting sleep

incompatible behaviors, greater variability in bedtime and risetime, and too much time in bed. Also, receiving CT (vs. BT) significantly predicted more improvement in all the hypothesized cognitive mediators (APSQ, DBAS, and SAMI) from pre-treatment, session 4, post-treatment, to 6-month follow-up, confirming an important role for targeting worry, unhelpful beliefs about sleep and monitoring for sleep-related threat. In addition, BT was associated with reductions in both behavioral and cognitive mediators from pre-treatment through post-treatment or 6-month follow-up, whereas CT was associated with reductions in all cognitive mediators from pre-treatment through 6-month follow-up and only select behavioral mediators (BTv and TIB) during treatment. These findings are consistent with prior research (e.g., Schwartz & Carney, 2012) and extend knowledge by pointing to the importance of two cognitive processes—worry and monitoring for sleep-related threat. To the best of our knowledge, this is the first analysis to examine worry and monitoring for sleep-related threat as predictors and mediators of insomnia treatment outcome. It is well documented that people with insomnia lie in bed worrying about a range of topics including not being able to get to sleep (Borkovec, 1982; Espie, 2002; Harvey, 2002; Lichstein & Rosenthal, 1980; Morin, 1993). In addition, multiple experimental studies show that ‘activating’ worry increases sleep problems and ‘deactivating’ worry reduces sleep problems (see Harvey, 2005 for review). Also, insomnia can be associated with narrowing of attention and selectively attending to or monitoring for sleep-related threats that might be internal stimuli (e.g., bodily sensations) and/or external stimuli (e.g., the environment for noise that might prevent sleep-onset) (Neitzert Semler & Harvey, 2004; Semler & Harvey, 2004).

All hypothesized behavioral and cognitive mediators had either a main effect or interaction on outcome. More specifically, and consistent with our hypothesis, sleep incompatible behaviors only mediated outcome in BT, and there was a significant treatment by mediator interaction discussed in detail below. BTv and RTv only mediated outcome in BT but not CT, although there was no significant treatment by mediator interaction to support that there was differential outcome through BTv and RTv comparing BT versus CT. TIB only mediated outcome in BT but not CT, and there was a marginally significant interaction suggesting that the relationship between TIB and insomnia outcome may be significantly stronger in BT relative to CT. Worry, unhelpful beliefs about sleep, and monitoring for sleep-related threat mediated outcome in CT and also mediated outcome in BT. The non-significant treatment by mediator interactions regarding cognitive mediators suggest that all cognitive mediators were equally related to outcome comparing BT versus CT (in another word, cognitive mediators are not significantly stronger mediators in CT relative to BT). Having said that, these findings were qualified by several significant interactions.

There was a curious treatment by mediator interaction involving sleep incompatible behaviors. There was a positive association (expected direction) between SBRS and ISI over time in BT, a finding that is consistent with our hypothesis. Surprisingly, there was a negative association (opposite direction) between SBRS and ISI over time in CT. In other words, reduced sleep incompatible behaviors was associated with worse outcome in CT. Perhaps cognitive changes, such as changes in beliefs about the utility of reducing sleep incompatible behaviors, may not have taken place yet. In other words, if participants stop engaging in sleep incompatible behaviors but do not really believe in the usefulness of this behavioral change, it might have a reverse effect on outcome. Future research is needed to

clarify this finding and determine if combining a focus on reducing sleep-incompatible behaviors and CT—as is done in CBT—are contraindicated.

For TIB, there was a trend for the interaction suggesting that TIB may be a mediator specific to BT and not CT. Together these findings accord with the proposed theoretical basis for stimulus control and sleep restriction (Bootzin, 1972; Spielman, Caruso, & Glovinsky, 1987) that both emphasize the importance of reducing non-sleep time in bed so as to reassociate the bed with sleep.

For the hypothesized cognitive mediators, change in APSQ, DBAS, SAMI mediated outcome in both BT and CT with comparable magnitude/strength. In other words, the hypothesized cognitive mediators were not specific to CT and were not particularly stronger in CT than BT. This is consistent with clinical observations that aspects of BT may operate via both cognitive and behavioral processes. Indeed, several clinical researchers have suggested that the BT components operate via a cognitive mechanism in that stimulus control may prevent people lying in bed worrying about not sleeping (Lichstein & Fisher, 1985) and relaxation may function by calming pre-sleep cognitive activity (Borkovec, 1982), reducing concern about the sleep disturbance, and fostering a more positive outlook (Espie, Lindsay, Brooks, Hood, & Turvey, 1989).

Moving on to our second aim, consistent with the hypothesis, among the participants who scored high on both behavioral and cognitive processes at pre-treatment, those who received CBT relative to BT or CT had marginally significant better outcome ($p = 0.53$), although note that the ISI mean value differences (Table 4) were large (e.g., group difference on ISI at posttreatment was 3.39, Cohen's $d = 0.79$) and thus may be of clinically significance. Also, the advantage to CBT was only significant during the active treatment phase. The latter finding is perhaps not surprising. There are many candidate processes that might influence outcome the post to follow-up such as memory for treatment recommendations (Harvey et al., 2016) and ability/motivation to continue to implement the recommendations without the support of a therapist. These results are important as improving outcome by matching to subgroup is presumably most relevant for the treatment period most proximal to when the measures were taken.

For those participants who scored relatively high on behavioral and low on cognitive process at pre-treatment, those who received BT or CBT did not differ from those who received CT in terms of the insomnia outcome from pre-treatment to post-treatment and 6-month follow-up. This result is contrary to our hypothesis. This result suggests that for those participants relatively high on behavioral process and low on cognitive process, whether or not the participants receive behavioral therapy did significantly predict the insomnia outcome.

Finally, among the subgroup of participants who scored relatively high on cognitive processes and low on behavioral process at pre-treatment, those who received CT or CBT did not differ from those who received BT in terms of the insomnia outcome from pre-treatment to post-treatment and 6-month follow-up. This result is contrary to our hypothesis. This finding suggests that those who score high on cognitive processes do well in BT, CT and CBT, providing further evidence that BT may target cognitive processes, an observation

that has been made by scholars in the field for some time (e.g., Borkovec, 1982; Espie, et al., 1989; Lichstein & Fisher, 1985). For example, a stimulus control recommendation is: if unable to fall to sleep after approximately 20 minutes, get up out of bed and go to another room until sleepy then return to bed. It is possible that the act of getting out of bed operates as a distraction, cutting into vicious cycles of worry and rumination. Also, sleep restriction involves the recommendation to reduce the amount of time in bed to the amount of time slept until sleep efficiency reaches 85%. This experience may serve as a behavioral experiment which corrects unhelpful beliefs about sleep such as 'I must get 8 hours of sleep every single night in order to cope'.

This discussion is offered in the context of several important limitations. First, there are several issues with regard to measures. We acknowledge the limitation that there are many other potential mediators of CBT such as sleep effort, sleep self-efficacy, locus of control and arousal (Schwartz & Carney, 2012) that were not measured in the present study. As such, it is possible that the mediators examined are not sufficiently sensitive. Future research should examine a broader range of mediators. There may be processes that are not easily assessed via self-report, particularly the cognitive processes which rely on participants being able to accurately introspect about and report on subtle often automatic processes. Future research should examine other methods to index such processes (e.g., MacMahon, Broomfield, & Espie, 2006). Also, we selected the total score on the ISI as it was the primary outcome. We didn't use remission/response because these variables are derived using ISI and using the continuous score of the ISI would result in greater statistical power and reduce the number of tests. Nonetheless, there is the potential to use other outcomes in future research. Another limitation regarding the measures is that the SBRS includes items that index sleep hygiene such as 'Talking on the phone around sleeping time' and 'Unpleasant conversation around sleeping time'. We note that all three treatment groups received basic sleep hygiene education. As such, the SBRS may be a less sensitive measure of behavioral processes. Second, although the presence of comorbidity was a stratification variable, it is possible that the severity and type of comorbidity may have impacted the results, particularly given the prevalence of anxiety disorders and the associated worry. Third, the present study does not address the temporal requirement for mediation (Kazdin, 2007). While it is encouraging to see that this need is starting to be addressed (Norell-Clarke et al., 2014), it remains an important domain for future research. Fourth, there are several issues related to generalizability. In the present study, CBT always started with BT before moving to CT. A worthwhile direction for future research would be to examine sequence effects such as if patients who are high on cognitive processes would benefit from receiving CT prior to BT in CBT. Fifth, as emphasized elsewhere (Harvey, et al., 2014), the CBT sessions were 75 minutes while BT and CT sessions were 45–60 minutes. This design feature raises a number of issues. We cannot exclude the possibility that duration of treatment sessions contributed to the advantage associated with CBT. Future research is needed to test the generalizability of the findings to service settings where the session time allowance is different. A question for future research is whether the results would be different is all three arms were 50 minutes. Also, we cannot know whether the enhanced version of CT employed in this study would yield different results relative to the CT traditionally added to CBT for insomnia. Relatedly, eight sessions of CT is shorter than

typical CT for insomnia and other disorders (Harvey, et al., 2014). Hence, we cannot exclude the possibility that an adequate initial dose of CT requires more than 8 sessions. Another challenge to the generalizability is our detailed exclusion criteria. This study was an efficacy study. Future research effectiveness studies are needed (e.g., Espie et al., 2008). Sixth, we did not check if there is variation in the percentage of time spent in BT or CT for the CBT condition. However, the case formulation approach was used to personalize within each treatment component included in the treatment manual (e.g., to work out what activities each patient would engage in during time out of bed in BT and to identify the thoughts to be examined in CT) so the time spent in BT and CT should be standard. Finally, it is likely to be impossible to truly isolate behavioral versus cognitive change since improvements in sleep through behavioral means may well improve cognitions and vice versa. Also, identifying individuals who are homogeneous in exhibiting either behavioral or cognitive processes is unlikely to be realistic. Indeed, the groups we created are relatively high on behavioral and relatively low on cognitive (and vise versa).

To summarize, to the best of our knowledge this is among the first examination of mediators of CBT that examines the specificity requirement for establishing mediation. The hypothesized BT mediators—sleep incompatible behaviors, time in bed, bedtime variability and waketime variability—exhibited specificity in mediating the outcome of BT not CT. In contrast, the CT mediators—worry, unhelpful beliefs about sleep and monitoring for sleep-related threat—mediated outcome of *both* BT and CT groups. Independent of matching there were main effects for every mediator except sleep incompatible behaviors. Sleep incompatible behaviors significantly predicted ISI reduction in BT but predicted worse outcome in CT. There was some evidence for the potential value of treatment matching. The subgroup who scored high on both behavioral and cognitive processes at pre-treatment exhibited better treatment outcome if they received the treatment that matched the processes present at pre-treatment. However, this was not the case for the subgroup who scored high on behavioral or cognitive processes at pre-treatment, who did well regardless of the treatment they received. To state the results another way: if an individual has relatively high levels of behavioral factors but relatively low levels of cognitive factors, any approach (BT, CT, or CBT) is likely to have a similar result; if an individual has relatively high levels of cognitive factors but relatively low levels of behavioral factors, again any approach (BT, CT, or CBT) is likely to have a similar result; and if an individual has relatively high levels of both behavioral and cognitive factors, CBT is likely to result in the best outcomes. Also, consistent with Harvey et al. (2014), at 6-month follow-up the treatments have similar outcome. Taken together, these findings suggest that the full CBT package will generally cover most patients. Cost-benefit analyses are needed to answer questions such as whether BT rather than CBT can cover most patients initially and then stepping up care for the group of patients who do not respond.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Public Health Significance

In behavior therapy for insomnia, sleep incompatible behaviors, bedtime variability, risetime variability and time in bed play a role in beneficial change. In both behavior therapy and cognitive therapy for insomnia, worry, unhelpful beliefs about sleep and monitoring for sleep-related threat play a role in beneficial change. Matching treatments to the processes present before treatment may be beneficial for patients who are high on both behavioral and cognitive processes before treatment. Patients who score relatively high on one process (behavioral or cognitive) but low on the other before treatment may do well regardless of the treatment they receive.

Table 1

Descriptive Statistics for Mediators and Outcome Variables in Each Condition

	CBT (*n* = 60)		CT (*n* = 65)		BT (*n* = 63)	
Mediator, outcome, and assessment	***M***	***SD***	***M***	***SD***	***M***	***SD***
SBRS						
Pre	43.39	11.44	40.97	9.01	39.87	10.98
S4	38.46	13.06	40.60	9.45	33.66	9.46
Post	35.28	10.30	39.19	10.52	33.61	10.62
FU6	36.02	10.37	38.94	10.83	35.15	10.64
Bedtime Variability						
Pre	0.75	0.33	0.89	0.36	0.75	0.37
S4	0.47	0.46	0.74	0.33	0.39	0.35
Post	0.56	0.28	0.83	0.41	0.50	0.30
FU6	0.66	0.31	0.83	0.28	0.72	0.35
Risetime Variability						
Pre	0.84	0.35	0.97	0.41	0.86	0.39
S4	0.48	0.33	0.91	0.52	0.46	0.34
Post	0.64	0.33	0.87	0.36	0.62	0.35
FU6	0.74	0.34	0.91	0.38	0.78	0.38
Time in Bed						
Pre	490.56	47.04	476.56	41.59	487.15	59.22
S4	404.25	50.71	473.91	50.91	390.45	47.77
Post	447.91	45.57	466.09	43.95	436.21	38.17
FU6	473.06	44.22	477.25	45.42	466.36	50.04
APSQ						
Pre	61.42	18.74	60.63	20.94	62.21	23.24
S4	46.33	18.95	41.87	17.93	51.90	20.27
Post	31.69	15.24	31.14	15.71	37.93	18.97
FU6	26.70	16.08	30.25	19.77	35.02	18.58
DBAS						
Pre	4.09	1.06	3.89	1.26	4.39	1.30

Mediator, outcome, and assessment	CBT (*n* = 60)		CT (*n* = 65)		BT (*n* = 63)	
	M	*SD*	*M*	*SD*	*M*	*SD*
S4	2.92	1.18	3.09	1.21	3.66	1.22
Post	1.98	1.18	2.08	1.06	2.86	1.31
FU6	1.94	1.15	2.30	1.35	2.67	1.26
SAMI						
Pre	2.70	0.56	2.68	0.62	2.76	0.56
S4	2.60	0.62	2.48	0.60	2.64	0.55
Post	2.02	0.55	2.03	0.55	2.43	0.57
FU6	1.99	0.47	1.99	0.62	2.29	0.59
ISI						
Pre	17.88	3.42	17.58	3.50	18.30	3.40
S4	12.05	3.42	13.10	4.32	12.07	3.61
Post	7.39	3.79	9.41	4.72	8.96	4.98
FU6	7.55	4.26	8.82	5.36	9.41	5.12

Note. TIB = time in bed. APSQ = Anxiety and Perception about Sleep Questionnaire. DBAS = Dysfunctional Beliefs and Attitudes about Sleep. SAMI = Monitoring for Sleep-Related Threat. Pre = Pre-treatment. S4 = Session 4. Post = Post-treatment. FU6 = 6-month follow-up.

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Table 2

Association between treatment condition (BT vs. CT) and mediators (measured at pre-treatment, session 4, post-treatment, and 6-month follow-up)

	Main Effects of Treatment Condition (BT vs. CT)		
Mediators (outcome)	***b***	***SE***	***p***
Behavioral Process			
SBRS	−4.57	1.45	0.002
BTv	−0.17	0.05	<0.001
RTv	−0.15	0.05	0.001
TIB	−28.49	7.10	< 0.001
Cognitive Process			
APSQ	5.80	2.51	0.021
DBAS	0.58	0.17	0.001
SAMI	0.20	0.08	0.011

Note. Regression coefficients are unstandardized. Treatment condition: BT vs. CT (BT=1, CT=0), excluding CBT. SBRS = Sleep Behavior Self-Rating Scale. BTv = Bedtime variability. RTv = Risetime variability. TIB = time in bed. APSQ = Anxiety and Perception about Sleep Questionnaire. DBAS = Dysfunctional Beliefs and Attitudes about Sleep. SAMI = Monitoring for Sleep-Related Threat. All models adjusted for time, age, site, and comorbidity.

Table 3

Association between mediators and treatment outcomes from pre-treatment to session 4, post-treatment, and 6-month follow-up

Outcome: ISI changes from pre to FU6	Treatment x Mediator interaction			Mediator main effect (regardless of treatment)			Mediator main effect in BT			Mediator main effect in CT		
	B	*SE*	*p*	*B*	*SE*	*p*	*B*	*SE*	*p*	*B*	*SE*	*p*
Behavioral Process												
SBRS	1.44	0.45	0.001	0.08	0.23	0.73	0.73	0.30	0.02	−0.71	0.33	0.03
BTv	0.43	1.10	0.32	0.80	0.22	<0.001	0.99	0.29	0.001	0.56	0.33	0.10
RTv	0.38	0.42	0.37	0.78	0.21	<0.001	0.97	0.30	0.001	0.58	0.30	0.052
TIB	0.77	0.47	0.10	0.69	0.22	< 0.001	0.92	0.26	< 0.001	0.14	0.40	0.72
Cognitive Process												
APSQ	−0.35	0.34	0.29	3.30	0.22	< 0.001	3.17	0.27	< 0.001	3.52	0.28	< 0.001
DBAS	−0.20	0.38	0.59	2.86	0.24	< 0.001	2.74	0.30	< 0.001	2.94	0.30	< 0.001
SAMI	−0.66	0.42	0.12	1.98	0.24	< 0.001	1.60	0.34	< 0.001	2.26	0.30	< 0.001

Note. Treatment = BT vs. CT (CBT excluded). All models adjusted for time, age, site, and comorbidity. ISI = Insomnia Severity Index. SBRS = Sleep Behavior Self-Rating Scale. BTv = Bedtime variability. RTv = Risetime variability. TIB = Time in Bed. APSQ = Anxiety and Preoccupation about Sleep Questionnaire. DBAS = Dysfunctional Beliefs and Attitudes about Sleep. SAMI = Monitoring for Sleep-Related Threat. All models adjusted for time, age, site, and comorbidity. All independent variables were standardized so that the regression coefficients indicate the ISI score change with 1 *SD* change in the independent variable. Mediator main effects in BT and CT were derived from the interaction model.

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Table 4

Mean ISI scores at pre-treatment, post-treatment, and 6-month follow-up for subgroups of interest and treatment effects on ISI changes from pre-treatment to 6-month follow-up

	High on Behavior & Low on Cognitive at Pre-Treatment (*N* = 40; 22%)							**Effect of Treatment on ISI changes**		
	CT			**BT or CBT**						
	N	***Mean***	***SD***	***N***	***Mean***	***SD***		***B***	***SE***	***p***
ISI Pre	16	16.88	4.03	24	15.88	2.97	Post vs. Pre	−1.43	1.47	0.33
ISI Post	16	9.19	4.65	22	6.86	2.80	FU6 vs. Pre	−0.64	1.59	0.69
ISI FU6	11	9.91	4.97	22	8.27	5.04	FU6 vs. Post	0.79	1.60	0.62
	High on Cognitive & Low on Behavior at Pre-Treatment (*N* = 40; 22%)							Effect of Treatment on ISI changes		
	BT			CT or CBT						
	N	*Mean*	*SD*	*N*	*Mean*	*SD*		*B*	*SE*	*p*
ISI Pre	15	19.33	3.20	25	18.88	2.88	Post vs. Pre	0.64	1.70	0.71
ISI Post	12	8.17	5.27	21	8.57	4.68	FU6 vs. Pre	−0.03	1.70	0.99
ISI FU6	13	9.08	4.48	22	8.42	4.62	FU6 vs. Post	−0.67	1.75	0.70
	High on Both Processes at Pre-Treatment (*N* = 53; 29%)							Effect of Treatment on ISI changes		
	BT and CT			CBT						
	N	*Mean*	*SD*	*N*	*Mean*	*SD*		*B*	*SE*	*p*
ISI Pre	39	19.41	3.20	14	19.07	2.30	Post vs. Pre	−2.94	1.52	0.053
ISI Post	38	10.24	4.97	13	6.85	3.44	FU6 vs. Pre	−0.01	1.54	1.00
ISI FU6	33	8.88	5.45	13	8.54	4.27	FU6 vs. Post	2.93	1.55	0.06

Note. Subgroups (high vs. low on each process) were created by median splitting the composite scores for behavior and cognitive processes using pre-treatment data. Pre = Pre-treatment. Post = Post-treatment. FU6 = 6-month follow-up.