Supplementary Material

Combined internet-based cognitive-behavioral and chronobiological intervention for insomnia: A randomized controlled trial.

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Supplementary Background

Insomnia Disorder is the second most common mental health problem, estimated to affect at least 7% of the population [1, 2]. The disorder is diagnosed when problems falling asleep or maintaining sleep, accompanied by subjectively impaired daytime functioning, occur three times or more each week for at least three months, and cannot be attributed to unfavorable sleeping conditions [3]. Insomnia is a major risk factor for other health problems, notably depression [4], reduces work productivity and increases healthcare consumption, thus imposing a large economic burden on patients and society [5]. The combination of high prevalence and high costs of insomnia makes it important to optimize affordable treatment.

Cognitive behavioral therapy for insomnia (CBTI) is the only non-pharmacological treatment supported by sufficient empirical evidence and is often preferable to pharmacotherapy because of its long-term effects [3, 6] and cost-effectiveness [7]. Internet-based CBTI (ICBTI) results in comparable improvements [8-11]. Unfortunately, neither face-to-face CBTI nor ICBTI have satisfying results for all individuals [2, 12]. Meta-analysis shows that it is not that common for ICBTI to improve sleep beyond the cutoff for normal sleep efficiency of 85% [11], thus leaving ample room for additional improvement.

A less studied type of intervention for insomnia is chronobiological treatment (CT). CT aims to enhance regularly timed input to the circadian system by addressing its interaction with bright light, physical activity or body warming [13]. Although the European Sleep Research Society does recommend light and exercise in the treatment of Insomnia Disorder [3], support for their effectiveness is much smaller than for CBTI [14]. The combination of CT and CBTI has been applied in one study, with promising results [15]. No prior study compared the effectiveness of CT, ICBTI and their combination in treating Insomnia Disorder.

The primary aims of the present study were to evaluate the initial and sustained separate, additive and interaction effects of CT and ICBTI on sleep efficiency in Insomnia Disorder.

Supplementary Methods

The detailed protocol of this study has been registered (trialregister.nl Trial ID: NTR4010) and published [16].

Participant Recruitment and Selection

Participants were recruited between November 2013 and August 2016 through the Netherlands Sleep Registry (NSR [17]), social media, newspaper advertisements and the website of Somnio, a company offering ICBTI. Interested people filled out an online screening questionnaire. Possibly eligible participants were contacted by phone to discuss the screening information they provided and to answer their possible questions. Inclusion criteria were: an age between 18 and 70 years and a

diagnosis of Insomnia Disorder according to ICSD3 and DSM-5 [3, 18, 19]. Exclusion criteria were daily use of sleep medication, shift work, a current diagnosis of a psychiatric or neurological disorder, eye disease, cardiovascular disease, and disabilities or restrictions with respect to physical activity. Participants incidentally using prescribed or over-the-counter sleep medication were only included after refraining from use one month prior to and throughout participation. All participants signed a written consent form. Of the 946 individuals who completed the online screening questionnaire, 175 enrolled in the study (see Supplementary Figure 1, CONSORT Diagram of Participant Flow).

Study Design, Sample Size, Statistical Power, Randomization and Blinding

Design. In a two by four factorial design (figure 1), participants were randomly assigned to ICBTI or not in week 1-4 (factor 1, two conditions) as well as to one of three chronobiological treatments or placebo in week 1-4 (factor 2, four conditions). Those that were not allocated to ICBTI in week 1-4, received it week 6-9, after the post assessment. All interventions and assessments took place at participants' homes. Assessments were conducted at baseline (T0, week 0), following completion of a 4-week treatment period (T1, week 5) and after completion of the second 4-week period (T2, week 10).

Sample size and estimated statistical power. The sample size required to have sufficient statistical power ($1-\beta = 0.80$ at a critical $\alpha = 0.05$) to detect small-to-medium effects were calculated for a mixed effect model that simultaneously estimated all treatment effects using repeated sleep efficiency values of 7 nights before and 7 nights after the intervention period [20]. According to conventions we considered d=0.2 a small effect and d=0.5 a medium effect. The range implicates that group means differ by 0.2 to 0.5 times the standard deviation. The a priori sample size calculation requires an estimate of the intraclass correlation coefficient (ICC) of repeated sleep efficiency values. At the time we designed the registered protocol including power calculations [16] we could take advantage of available subjective sleep efficiency from the 9-day sleep diaries that we recently assessed through the internet for 27 people suffering from insomnia and found an ICC of 0.2. Sample size calculations [20] indicated that 160 completers would provide, at a significance of alpha=0.05, sufficient power (1-beta=0.80) for minimal detectable differences of $d = 0.27$ (main effect ICBTI, n=80 vs. n=80), d=0.31 (main effect of any CT vs. II, n=120 vs. n=40), d=0.31 (main effect of a specific CT, n=40 vs. n=120), d=0.28 (interaction effect of ICBTI with any active CT, n=60 vs. n=100), and d=0.41 (interaction effect of ICBTI with a specific CT, n=20 vs. n=140). Expecting a dropout of about 10%, we initially aimed at staggered entry of 180 participants but stopped recruitment at n=175 due to time limitations.

Randomization and blinding. The first 20 participants were randomized using the *sample* function in R [21], which generated a random number between 1 and 8, each referring to one combination in the 2 by 4 design. Subsequent randomization was done using covariate-adaptive randomization [22, 23] scripted in R [21]. Covariates were: Insomnia Severity Index (ISI) score, sex, age, use of non-sleep medication and time of year of inclusion. Details on the covariate-adaptive randomization can be

found in the registered trial protocol [16]. Author TM ran the script and noted the allocated treatment group in the trial master file. Participants were only aware of their own assigned condition and blind to whether or not it was an active treatment and to the existence of parallel other conditions. KD was blinded to case information including treatment allocation while processing the data.

Interventions

Internet-guided Cognitive Behavior Therapy for Insomnia

Using the Somnio platform [somnio.eu, 24], CBTI with guidance of a therapist was implemented to be online accessed from a computer (not a smartphone). The behavioral and cognitive components included stimulus control, sleep restriction, sleep hygiene and education, relaxation exercises and cognitive restructuring according to the European Guideline for the Treatment of Insomnia [3]. The four-week intervention consisted of four online lessons with information and assignments that were introduced one by one every subsequent week. Within the online platform, the supervising therapist evaluated the sleep diaries, provided feedback, answered questions and adjusted assignments based on progress. The therapist tailored the assignments, for example bedtimes for sleep restriction, utilizing the information from the sleep diary data from the previous week. The therapist estimated to have invested on average 15 minutes for each individual per module, totaling one hour of guidance per participant.

Chronobiological Treatments

Participants were randomly allocated to one of four interventions, being either Bright Light (BL), Physical Activity (PA), Warm Baths (WB) or the placebo condition of an inactivated ionizer (II) [25]. All interventions were scheduled daily at a set time, attuned to participants' desired bed and wake-up times, and were instructed and verified to be applied exclusively during weeks 1-4. Enrolled participants were informed about their treatment allocation through email a week before baseline. That same week, they were mailed a package including elaborate information on the protocol and the assigned treatments, an actigraph, a treatment device if appropriate and log-in information for the NSR [17], the internet platform through which all questionnaires were online assessed. Participants received the required equipment (bright light, bath thermometer, inactivated ionizer) at the start of week 1 and handed it back in at the end of week 4 for use by others. They were instructed to apply the allocated CT exclusively during weeks 1-4. Compliance to these instructions was monitored daily using a diary kept from week 0 to week 11.

Bright Light. Participants allocated to the scheduled bright light CT condition were asked to sit facing a goLITE BLU light device (HF3220/01, Philips Consumer Lifestyle, Drachten, The Netherlands) each morning for half an hour, within an hour after a self-selected fixed desired wake-up time. Bright light entrains circadian rhythms [26] and has also been reported to improve sleep quality [27]. The blue LED light device has a peak wavelength of 470 nm (full width half-maximum 25 nm), and was

instructed to be used at an arms-length distance of 50 cm, positioned on a table at 45 degrees sideways. That use provides an irradiance of 1.0 Watt/m2 and a photopic illuminance of 100 lux at eye position, which is equivalent to a melanopic illuminance of 770 m-lux [28]. The device specifically targets melatonin-containing retinal ganglion cells in the eyes that project to the biological clock of the brain, and was shown to have a clinical efficacy in seasonal affective disorder that was not different from the use of bright white light treatment of 10 000 lux [29].

Physical Activity. Participants allocated to the scheduled Physical Activity CT condition were instructed to walk or bicycle daily for half an hour within the one-hour interval 3 to 2 hours prior to a self-selected fixed desired bedtime. Physical activity ameliorates insomnia complaints [30, 31].

Warm Baths. Participants allocated to the scheduled Warm Baths condition were instructed to take a daily warm bath for half an hour within the same one-hour interval 3 to 2 hours prior to a self-selected fixed desired bedtime. The increase in skin temperature induced by a warm bath at this time of day lasts into the sleep onset period and can promote sleep [32-34]. The timing of the warm baths may require some elaboration. As for the other interventions, warm baths were aimed at boosting the amplitude of physiological circadian rhythms. As we reviewed previously, well-timed whole body warming can effectively boost the amplitude of the diurnal rhythm in core body temperature with favorable effects on sleep [35]. Milder warming protocols utilizing foot baths may not affect the amplitude of the diurnal rhythm in core body temperature [36], although they have also been implemented to promote relaxation and sound sleep (see Haghayegh et al. 2019 [37]).

Because we could previously not confirm that people with insomnia benefitted of any of several foot warming methods that were effective in good sleepers [38] while two research groups did report favorable effects of whole body baths for insomnia, we chose to implement whole body warming.

In older females with a specific type of insomnia (only difficulties maintaining sleep) a preliminary report [39] and a full report [32] indicated sleep improvements after a warm bath between 20:00 to 20:30 hr, which was timed 2 to 1.5 hours prior to bedtime and 3 hours prior to lights out at 23:30 hr (see Figure 1, page 895 of Dorsey et al 1999 [32]). In older patients with insomnia and vascular dementia, a warm bath timed 2 to 1.5 hours prior to bedtime likewise improved sleep [40]. On the contrary, and as to be expected, an evening hot bath could not halt the sleep-disturbing effect of apneas in patients with obstructive sleep apnea [41]. No study in insomnia patients compared different times for bathing. To choose the optimal timing we therefore critically reviewed prior studies on the effect of timed hot baths in well-sleeping controls.

Bunnell et al [42] compared how sleep was affected by hot baths taken at different times of the day. As compared to times more distant from lights out, or closer to it, baths ending 4.5 hrs before lights out least elevated core body temperature at bedtime while most pronouncedly reducing nocturnal wakefulness and especially sleep onset latency (by 50%), two major problems of ID. In a study by Jordan et al [43], hot baths ending 4 hrs before lights out reduced disturbed sleep and enhanced slow wave sleep and REM sleep. Horne and Reid [44] heated participants until 17:30 hr which was more

than 5 hrs before lights out, and reported an increase in slow wave sleep but a decrease in REM sleep. Using less intense heating, Horne and Shackel [45] concluded that that as the time of the day of heating recedes from nighttime sleep, a larger "dose" of heating is required to produce the same effect. They moreover concluded that half an hour of heating 7-8 h before sleep has little effect, while if administered 2-3 hr before lights out, it enhances slow wave sleep, and finally, that about 2 hr has to elapse before body heating affects SWS. Indeed, a hot bath ending 0.5 hr prior to lights out did not improve nocturnal wakefulness or slow wave sleep in one study [46], although it did suppress nocturnal movements in another study [47]. Based on the careful review of these studies, and because we aimed to boost the circadian amplitude of the core body temperature rather than to interfere with its normal decline that reliably takes place 2 h prior to sleep onset [48], we instructed participants to bathe for half an hour immediately before this decline, i.e. between 3 to 2 hours prior to desired sleep onset.

Assessments

Diagnosis. To support the diagnosis of Insomnia Disorder [3, 18, 19] and to evaluate past and current health, participants completed an online version of the Duke Structured Interview for Sleep Disorders (DSISD [49]).

Diary. Throughout the protocol, participants kept an extended Dutch version of the Consensus Sleep Diary (CSD [50]). The primary outcome measure was the change in sleep efficiency (SE) as reported in the diary. Sleep efficiency is a common standard outcome measure for insomnia and has the advantage of covering all three of the diagnostically defining complaints about sleep quality: difficulties initiating sleep, difficulties maintaining sleep, and early morning awakening. We did not consider total sleep time, because sleep quality is the primary issue in insomnia, and a reduction of total sleep time may even be beneficial. Sleep efficiency is the most commonly reported primary outcome measure in recent meta-analyses on ICBI [10, 11], followed by the insomnia severity index (ISI), which would have been a viable alternative. In our registered trial protocol [16] we did prefer sleep efficiency, derived from the Consensus Sleep Diary [50], because it has the advantage that it utilizes assessments that are repeated day-after-day, while the insomnia severity index is a single retrospective evaluation of the past two weeks. A review on the accuracy of sleep assessment methods concluded that better accuracy of diaries than questionnaires because diaries record night-to-night variability of good and bad nights and are less sensitive to retrospective memory bias [51]. This advantage has also been noted by the consensus Recommendations for a Standard Research Assessment of Insomnia [52] which phrased it as follows: "*sleep diaries may yield a more representative sample of an individual's sleep than 1-time questionnaires*".

SE was calculated as the ratio of the subjective total sleep time (TST) relative to time in bed (TIB), expressed as percentage. TIB was defined as the time between lights-off and the moment after final awakening when no further attempt to sleep was made [53]. Secondary outcome measures obtained

from the diary were sleep onset latency (SOL), wake after sleep onset (WASO) which included possible time awake after final awakening still attempting to fall asleep; and TST. The sleep diary was extended with 3 questions to assess the major sleep complaints evaluated by the DSM-5 to diagnose Insomnia Disorder: difficulty initiating sleep (DIS), difficulty maintaining sleep (DMS) and early morning awakening with inability to return to sleep (EMA). Participants were asked to rate their night on these 3 complaints on a 7-point Likert scale ranging from 'very good' to 7 'very bad'.

To assess daytime functioning, we developed a dedicated diary with 18 items that queried all daytime impairments relevant to insomnia according to a British Association for Psychopharmacology consensus paper on ICSD, ICD-10 and DSM nosologies [54]. Participants were asked to rate their day on all 18 daytime impairments on a 7-point Likert scale, ranging from 'very bad' to 'very good'. These 18 domains were averaged per day for analyses.

Prior Expectations and Post-intervention Attribution. Prior to the interventions, a dedicated questionnaire was administered to assess expected effectiveness of the allocated treatments on a 7-point Likert scale ranging from 'very much deteriorate' to 'very much improve'. Using the same Likert scale answer options, we also asked for expected change in sleep if no treatment would be given, which provides insight in the patients' conception of expected recovery if their insomnia was left untreated. Finally, at T2, after the interventions, a 7-point Likert scale ranging from 'very much deteriorated' to 'very much improved' was used to assess the sleep changes subjectively attributed to the interventions.

Compliance. Compliance for each CT was assessed by a question on timing of compliance, added to the sleep diary. The number of compliant days was used for analysis. Compliance for the ICBTI sleep restriction part was monitored using the time in bed data from the sleep diary. Unlike sleep restriction, other CBTI lessons were not as suitable for daily quantitative assessment of compliance. However, the ICBTI was guided and the supervising clinical psychologist kept close track of whether participants had read the planned lessons and filled out the questions it contained. Participants were immediately reminded if they did not. One might state that adherence to reading the planned lessons and filling out the contained questions was thus guided to be complete. Nights were marked as non-compliant if time in bed was longer than the time set by the ICBTI sleep restriction. Again, the number of compliant nights was used for analysis.

Attrition. Participants were marked as drop-out if they (1) contacted us that they wanted to stop, (2) stopped filling out the diaries or showed no compliance to treatment and did not continue after being prompted to do so.

Actigraphy. During assessment weeks T0, T1 and T2, participants wore a wrist actigraph (Philips Actiwatch Spectrum, Philips Respironics, Murrysville, PA, USA) to estimate sleep. Outcome measures derived from the actigraphy data were SE, SOL, WASO, TST, average sleep bout duration and average wake bout duration.

Questionnaires. A comprehensive set of online questionnaires was assessed at T0, T1 and T2 consisted of: Insomnia Severity Index (ISI) [55], Dysfunctional Beliefs and Attitudes Scale [56], Glasgow Sleep Effort Scale [57], Sleep Locus Of Control scale [58] and Sleep Self-Efficacy Scale [59], Pre-Sleep Arousal Scale [60], Arousal Predisposition Scale [61], Hyper Arousal Scale [62] and Adult ADHD Self Rating Scale [63], Hospital Anxiety and Depression Scale [64], Positive Affect Negative Affect Scale [65] and Temporal Experience of Pleasure Scale [66], Short Form 36 [67] and Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness: TiC-P [68]. The data of the TiC-P however contained over 90% of zeroes, meaning that many participants reported no costs and had no production losses at all during the assessed weeks. Therefore, we were unable to analyze cost-effectiveness.

Statistical analyses

Immediate post-treatment effects (T1 relative to T0) and follow-up effects (T2 relative to T0) of ICBTI, CTs and their interactions on the primary outcome measure (SE) were estimated using mixed effect models (R software package 'lme4' [69]). This approach provides an intention to treat analysis by allowing inclusion of all observations of all participants, irrespective of missingness. Separate analyses first addressed specific effects of each individual CT and subsequently a possible generic effect of any active CT (irrespective of type BL, PA or WB) versus the placebo condition (II). Diary and actigraphy measures were analyzed with a 3-level mixed effect model with days *i*, nested within week *j*, nested within participant *k*. Questionnaire measures were likewise analyzed, but now using 2-level instead of 3-level mixed effect models since they were not assessed daily. Group differences in expected and attributed treatment effects and in compliance to treatment were analyzed with ANOVAs and t-tests. Group differences in post-intervention attributed effectiveness of treatment were analyzed with a paired-sample t-test. Group differences in attrition were evaluated with a chi-squared test. Treatment conditions were dummy coded with as reference no initial ICBTI (factor 1) and no active CT (i.e. the inactivated ionizer placebo). Analyses on secondary outcomes were considered exploratory and not corrected for multiple comparisons.

Supplementary Results

Participants

The mean (SD) age was 51.0 (11.2) years (range 20-70 years) and 79% was female. Education level was low (secondary education or less) in 36%, average (post-secondary education) in 35% and university level in 29%. The majority of participants was employed (fulltime 45%, part-time 32%) and lived with a partner (66%). About half (54%) presented a current comorbid somatic disorder. The mean (SD) duration of Insomnia Disorder was 9.3 (11.2) years. The severity of insomnia (ISI) at

baseline was 16.35 (3.98). The use of the Consensus Sleep Diary allowed us to calculate that the mean (SD) Mid Sleep time [70] at T0 was 3:31 (1:04) hr, indicating that the chronotype of our sample did not deviate from the distribution reported for their age in population-based epidemiological studies [71, 72]. Table 1 provides descriptive statistics.

Allocation to Interventions

ICBTI in week 1-4 was randomly assigned to 87 participants and was provided simultaneously with randomly assigned BL (n=21), PA (n=21), WB (n=24), or the inactive II placebo condition (n= 21). The same chronobiological and placebo conditions were randomly assigned in week 1-4, but without initial ICBTI, to 88 participants (BL: n=24, PA: n=24, WB: n=20, II: n=20). These 88 participants were given ICBTI in week 6-9.

T0-T1 Changes in Sleep Efficiency

Mixed effect models showed a 5.55% (95% CI: 0.95 – 10.15%, *P* =.02) increase in SE between T0 and T1, irrespective of ICBTI or CT condition (eFigure 1). SE increased by an additional 6.69% (95% CI: 0.34 – 13.03%, *P* = .04) in participants that completed ICBTI between T0 and T1. Changes in SE were not affected by any CT or CT by ICBTI interaction (all *P* > .15, Supplementary Table 5). A model that combined the three active CT's into a single 'any CT' condition did not show main or interaction effects either (*P* > .28, Table 2). The findings indicate that at T1, there was an effect ICBTI but not of any of the three active CTs beyond the CT placebo condition.

T0-T2 Changes in Sleep Efficiency

At T2 relative to T0, SE had increased by 13.44% (95% CI: 9.48 – 17.40%) in participants that had just received ICBTI from week 6 to 9, which was significantly more (*P* =.04) than in participants that had received ICBTI already in week 1 to 4, where the increase was 6.93% (95% CI: 2.32 – 11.54%). This difference indicates a gradual loss of the initial gain in SE that the latter group had initially reached immediately after completion of ICBTI.

Of particular relevance to maintenance of initial benefits, a noticeable effect of combining ICBTI with CT in week 1-4 appeared only at T2. At T2 relative to T0, SE had increased by 12.89% (95% CI: 10.06 – 15.71%) in participants that combined ICBTI in week 1 to 4 with any active CT, which was almost twice (*P* =.003, Table 3) the increase seen in participants that had received ICBTI in combination with placebo CT (6.90%, 95% CI: 2.76 – 11.04%). Figure 2 shows group means across T0 to T2 within the participants that received ICBTI during week 1-4, either with or without CT. Separate analyses on combining ICBTI with each of the three individual CTs showed highly similar improvements from T0 to T2 (BL: 13.83%, 95%CI: 10.05 – 17.61; PA: 13.28%, 95%CI: 7.22 – 19.36; WB: 11.38%, 95%CI: 6.66 – 16.10). Supplementary Table 6 shows that whole model-estimated effects are also similar. There was no difference in fit between the model with separate CTs

and the more parsimonious model that analyzed them as a combined 'any CT' condition (likelihood-ratio test $\chi^2 = 5.97$, $df = 8$, $P = .65$).

Prior Expectations and Post-intervention Attribution

Expected effects. Participants expected no significant sleep improvement in case they would not receive intervention (-0.05 ± 0.77, t(173) = -0.89, $P = .38$) and significantly more with the placebo or any active CT (0.97 ± 0.76, ~slightly improve , t(173) = 13.02, $P < .001$) and with ICBTI (1.33 ± 1.02, ~slightly improve, t(173) = 15.96, $P < .001$). Expectancies did not differ among the placebo or active CTs ($F_{3.170} = 0.55$, $P = .64$), but were overall lower for CT than for ICBTI (t(173) = 6.19, $P < .001$). Details can be found in Supplementary Table 4.

Post-intervention attribution of sleep changes to treatment. Assessed at T2, the effects attributed to CT interventions did not differ between groups randomized to the inactive or any of the active CT interventions ($F_{3.162} = 1.43$, $P = .23$). Similarly, the effects attributed to ICBTI was not different for participants that received ICBTI in week 1-4 and those that received ICBTI in week 6-9 ($F_{1.154} = 0.29$, $P = .59$). However, participants attributed a stronger effect to ICBTI than to CT (t (155) = 7.59, $P < .001$). Details can be found in Supplementary Table 4.

Compliance. Diaries confirmed adherence to the exclusive use of the allocated CT during the larger part of the days of weeks 1-4. The number of days of compliance differed between CTs ($F_{3,163} = 9.77$, $P < .001$). Compliance was better to II and BL than to PA and WB (Tukey, all $P < .01$). Paired t-tests showed that compliance to ICBTI was worse than compliance to II (t(39) = -5.24, $P < .001$) and BL (t(40) = -3.01, $P = .004$) but not different from compliance to PA (t(36) = -0.69, $P = .50$) and WB (t(41) = 0.90, $P = .37$). Details can be found in Supplementary Table 4.

Attrition. The CONSORT flowchart (Supplementary Figure 1) provides detailed information on the attrition. Interventions and assessments were completed by 167 (95%) of the participants at T1 and by 156 (89%) at T2 (Figure 1). Attrition was independent of assignment to CT condition ($\chi^2 = 7.08$, $df = 3$, $P = .07$) and timing of ICBTI ($\chi^2 = 0.89$, $df = 1$, $P = .34$).

T0-T1 Changes in Secondary Outcome Measures

Supplementary Table 2 shows the estimated effects of time and time by treatment between T0 and T1 for all outcome measures. Supplementary Tables 7 and 8 show group means (SD). A significant time by treatment effect indicated that ICBTI reduced subjectively reported TIB by 31.29 minutes (95% CI: -57.23 – -5.34 min., $P = .02$) and actigraphically estimated TST by 29.89 minutes (95% CI: -54.70 – -5.08 min., $P = .02$). None of the CTs showed any effect on the actigraphy or diary measures. Secondary outcomes assessed by questionnaires suggested that ICBTI induced improvements on the ISI, DBAS, GSES and PSAS-cognitive subscale, indicating reduced insomnia severity, arousal, dysfunctional thoughts and sleep effort (Supplementary Table 2 and 5).

T0-T2 Changes in Secondary Outcome Measures

Supplementary Table 3 shows the estimated effects of time and time by treatment outcome measures between T0 and T2. Supplementary Tables 7 and 8 show group means (SD). Effect estimates indicate that the late benefits on sleep efficiency gained by combining ICBTI with any CT in week 1-4 were also seen in subjective SOL, WASO, TST and complaints about early morning awakening and daytime functioning. To facilitate interpretation of the main and interaction effect coefficients, group mean changes were calculated. In participants that initially combined ICBTI with any active CT, SOL decreased by 23.60 minutes (95%CI: -33.94 – -13.27 min.), which was significantly more (P = .04) than in those who combined ICBTI in week 1-4 with the placebo CT (-0.49 min., 95%CI: -16.42 – 15.43 min.). In those who combined ICBTI with active CT, WASO decreased by 64.29 minutes (95%CI: -80.06 – -48.52 min.), which was significantly more (P = .005) than in those who combined ICBTI with placebo CT (-12.94 minutes, 95%CI: -44.89 – 19.01 min.). In those who combined ICBTI with active CT, TST increased by 49.87 minutes (95%CI: 37.08 – 62.66 min.), which again was significantly more (P = .01) than in those who combined ICBTI with placebo CT (17.38 minutes, 95%CI: -5.28 – 40.04 min.). None of the actigraphy outcome measures showed significant ICBTI by CT by time interaction effects. The secondary outcome measures that were assessed by questionnaires did not show ICBTI by CT by time interaction effects, although some measures showed strongly significant (P < .001) improvements between T0 and T2 for all participants, irrespective of treatment or timing (ISI, DBAS, GSES and Sleep Self-Efficacy Scale (SSES), see Table 3).

Supplementary Discussion

The present study is the first to evaluate, within a single design, the effects of CT, ICBTI and their interaction on sleep efficiency in Insomnia Disorder. ICBTI improved SE, whereas none of the active CTs did as compared to their placebo control condition. Adding CT to ICBTI did however have benefits that appeared only at follow-up. For participants that only received ICBTI, a part of the initial sleep efficiency improvement was lost during the month following completion of treatment. Those that received ICBTI in combination with any active CT better maintained their initial gain in sleep efficiency and moreover fell asleep more easily, slept longer and had less nocturnal wakefulness. Future studies on combined treatment could extend the follow-up period to evaluate the duration of the benefit.

Since SE indexes the time spent asleep during the time spent in bed, an increase does not necessarily indicate more, or better, sleep. SE increases equally with a mere reduction of TIB without change in time asleep. Immediate effects of ICBTI on SE are indeed at least partly driven by the reduced time in bed demanded by the sleep restriction intervention that is integral part of ICBTI. However, at T2, the participants that had combined ICBTI with CT in week 1-4 experienced more sleep and less wake

compared to those who only received ICBTI in week 1-4, while time in bed did not differ. Supported by additional benefits to subjective SOL, WASO, TST and complaints about early morning awakening and daytime functioning, the findings suggest that the addition of either Bright Light, Physical Activity or Warm Baths solidifies the sleep improvement induced by ICBTI.

It was unexpected that four weeks of stand-alone CT, without ICBTI, did not improve sleep efficiency or any of the other outcomes. Meta-analysis suggests the application of bright light to be moderately efficacious in the treatment of Insomnia Disorder [73]. Meta-analyses also suggested improvement in sleep [74] and insomnia complaints [31] with physical activity, although it might take a longer intervention to reach clinically relevant effects [30]. Slowly developing and delayed effects of chronobiological interventions have been noted before [27, 75] and may involve slow adaptation of the neuronal network of the suprachiasmatic nucleus (SCN [14]), the biological clock of the brain. Such a slow process, however, does not explain why late benefits were only found when CT was combined with ICBTI, not for CT without ICBTI. One possibility is that the presence of disturbed sleep interferes with adaptation of the neuronal network of the SCN [76, 77]. A hypothetical mechanism could be that the induction of a more consolidated sleep period by ICBTI might promote effectiveness of CT in slowly adapting the neuronal network of the SCN and promoting sound sleep. It should be noted that the fact that circadian disruption can generate insomnia complaints does not imply that it is the key underlying mechanism for the majority of cases with insomnia disorder. The chronotype of our sample did not deviate from the distribution reported for their age in population-based epidemiological studies [71, 72]. CTs may be more effective in themselves for insomnia complaints with an evident involvement of circadian disruption. Likewise, while ample human and animal studies demonstrated that the timed application of bright light, physical activity and warm baths can support a solid circadian rhythm, each of these three interventions can also have effects that do not involve the biological clock.

Actigraphic sleep estimates were not sensitive enough to pick up the subjectively experienced improvement in sleep efficiency. Whereas actigraphy is commonly used to estimate polysomnographic sleep measures, the estimates are not very accurate in people with Insomnia Disorder [78]. In fact, even the gold standard polysomnographic sleep measures do not reflect the subjective experience of people suffering from insomnia well [79, 80]. The conscious experience of wakefulness during sleep concerns complex interactions in brain activity that are insufficiently captured by polysomnography [81, 82]. Insomnia disorder is therefore diagnosed on subjective complaints, which are recommended for clinical investigations.

Limitations. A few limitations of our study should be mentioned. First, the intervention period of 4 weeks might not be long enough for effects of stand-alone CT to emerge. As mentioned above, some studies investigating chronobiology-based interventions reported slowly developing effects. Second, the strict exclusion of people diagnosed with psychological disorders, may have led to a sample with low baseline scores on secondary outcome measures related to complaints about mood, affect and

quality of life, thus leaving little room for improvement. It remains to be evaluated how our findings generalize to people with other disorders comorbid to Insomnia Disorder. Third, and related, the number of secondary outcome measures was large, and the few significant effects found would not survive adjustment for multiple comparisons. This finding suggests that there is no indication of overall widespread multivariate benefits of the interventions. A fourth limitation of the present study could be that we aimed to evaluate different chronobiological interventions side by side. As detailed in our registered trial protocol [16] the sample sizes were calculated for detecting small to medium effect sizes. The reason for evaluating individual chronobiological interventions next to each other, rather than combining them was based on a previous small uncontrolled open label study [15]. In that study, we did combine the three chronobiological interventions, and learned from participants that it was very taxing. We therefore considered it of both fundamental and clinical value to study the effects of the individual interventions: if effect sizes would differ considerably, future interventions could prioritize the most effective of the three. A direct comparison between the effectiveness of CBTI and the isolated CTs may not be completely fair, because CBTI is a multicomponent treatment. Although the combination of all three CT interventions may be demanding, future studies could investigate whether such a multicomponent CT would have stronger effects. A further limitation of the current study is that we cannot generalize the findings to people with insomnia that use sleep medication. The current study is the first to evaluate whether chronobiological treatment can compare to, and add to, the effects of ICBTI. The most commonly used sleep medications, benzodiazepines and melatonin, both have pronounced effects on the biological clock (for review see [83]), which could mask or interact in unpredictable ways with the nonpharmacological interventions we applied. To maintain a tractable sample size, it therefore seemed appropriate to start with a sample where such unpredictable masking and interaction effects would not increase heterogeneity and dilute effects. Future studies could evaluate added effects of chronobiological treatment in people with insomnia that use sleep medication.

Clinical Relevance. While there is no consensus on what minimal clinically important differences are, we facilitated interpretation by providing whole-sample means and standard deviations at onset and effect sizes *d* of interventions [84, 85]. With a (post-hoc assessed) overall between-subject standard deviation of 15.00 at onset, a small (d=0.2) effect implies a post-treatment group difference in sleep efficiency of 3%, and a medium (d=0.5) effect a post-treatment group difference of 7.5%.

Whereas our study is not directly comparable because it does not include long-term follow-up, some studies found slight decreases at follow-up of initial gains in sleep efficiency immediately after treatment [6, 86]. A previous meta-analysis reported a decrease in effect size (ES) of sleep-diary reported sleep efficiency benefits of face-to-face CBTI from immediately after treatment (ES=0.86) to 3-months (ES=0.81) and 12-months (ES=0.54) [87]. Meta-analysis specifically on ICBTI differ in their conclusion. While one found no indication of a decrease in (ES) of sleep efficiency benefits of CBTI from immediately after treatment (ES=0.58) to 1-4-months follow-up (ES=0.57) [10], another

meta-analysis reported that the 7.7% sleep efficiency benefit immediately following treatment reduced to a 4.4% benefit at 1-24 months follow-up [11]. Of note however, in these meta-analyses, the improvements in the control groups contribute to the waning group differences over time, which we also found in our study. Still, it has been noted that given the recurrent or persistent nature of insomnia, short-term treatment may not be completely sufficient and maintenance CBT booster sessions might optimize long-term outcomes [6]. In their comprehensive review on insomnia, Morin and Benca concluded that even patients who respond well to short-term therapy can be vulnerable to recurrent episodes of insomnia and that long-term maintenance therapies to prevent or minimize insomnia recurrence need to be developed and assessed [2]. Our motivation to evaluate the possible value of adding chronotherapeutic interventions was based on this need.

The initial sleep efficiency in our sample was 69.4%, which is at the lower range of the pooled baseline estimate reported in a meta-analysis on ICBTI (mean 72, 95% CI 69-75%) [11]. The ICBTI-induced improvements in our study were comparable to the pooled estimate for improvement of this meta-analysis (mean 7.2, 95% CI 5.1-9.3%) [11]. The meta-analysis shows that it is not that common for ICBTI to increase sleep efficiency to values well above 85%, which is commonly considered as the cutoff for a normal sleep efficiency [53]. A closer look into the studies reported in the meta-analysis revealed that a post-treatment sleep efficiency >85% was only found in 2 out of the 9 studies that reported sleep efficiency. In these two studies, the pre-treatment sleep efficiency was relatively high. Across studies, the post-treatment sleep efficiency showed a correlation of r=0.56 with the pre-treatment sleep efficiency, and age showed a correlation of r=-0.73 with pre-treatment sleep efficiency [11]. Efficiency is the sleep variable that shows the strongest decline with age, especially from 40 yrs on [88]. Therefore, a post-treatment sleep efficiency >85% may be especially hard to attain for older people and people with more severe insomnia.

Conclusion. The sleep efficiency of people suffering from Insomnia Disorder benefits from four weeks of ICBTI. Whereas this benefit would otherwise weaken over time, the addition of CT helps to maintain the effect on sleep efficiency and moreover improves sleep onset latency, total sleep time, nocturnal wakefulness and complaints about early morning awakening and daytime functioning. No benefit could be demonstrated for CT as stand-alone therapy. CT interventions are low in cost and risk, making them a promising addition to consolidate ICBTI effects on sleep in Insomnia Disorder.

Supplementary Statements

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Statement of Ethics

Participants signed informed consent. The study was approved by the Medical Ethical Committee of the VU University medical center.

Author Contributions

TB and TZ contributed equally to this manuscript. KD, JSB and TM carried out recruitment and data-collection and coordinated the RCT. EJWVS designed the study. KD, MF and EJWVS performed the data analyses. KD and EVS interpreted the results and drafted the manuscript. All authors contributed to and approved the manuscript.

Supplementary References

1 Wittchen HU, Jacobi F, Rehm J, Gustavsson A, Svensson M, Jonsson B, Olesen J, Allgulander C, Alonso J, Faravelli C, Fratiglioni L, Jennum P, Lieb R, Maercker A, van Os J, Preisig M, Salvador-Carulla L, Simon R, Steinhausen HC: The size and burden of mental disorders and other disorders of the brain in Europe 2010. Eur Neuropsychopharmacol 2011;21:655-679.

2 Morin CM, Benca R: Chronic insomnia. Lancet 2012;379:1129-1141.

3 Riemann D, Baglioni C, Bassetti C, Bjorvatn B, Dolenc Groselj L, Ellis JG, Espie CA, Garcia-Borreguero D, Gjerstad M, Gonçalves M, Hertenstein E, Jansson-Fröjmark M, Jennum PJ, Leger D, Nissen C, Parrino L, Paunio T, Pevernagie D, Verbraecken J, Weeß H-G, Wichniak A, Zavalko I, Arnardottir ES, Deleanu O-C, Strazisar B, Zoetmulder M, Spiegelhalder K: European guideline for the diagnosis and treatment of insomnia. J Sleep Res 2017;26:675-700.

4 Baglioni C, Battagliese G, Feige B, Spiegelhalder K, Nissen C, Voderholzer U, Lombardo C, Riemann D: Insomnia as a predictor of depression: A meta-analytic evaluation of longitudinal epidemiological studies. J Affect Disord 2011;135:10-19.

5 Daley M, Morin CM, LeBlanc M, Gregoire JP, Savard J: The economic burden of insomnia: direct and indirect costs for individuals with insomnia syndrome, insomnia symptoms, and good sleepers. Sleep 2009;32:55-64.

6 Morin CM, Vallieres A, Guay B, Ivers H, Savard J, Merette C, Bastien C, Baillargeon L: Cognitive behavioral therapy, singly and combined with medication, for persistent insomnia: a randomized controlled trial. JAMA 2009;301:2005-2015.

7 Wickwire EM, Shaya FT, Scharf SM: Health economics of insomnia treatments: The return on investment for a good night's sleep. Sleep Med Rev 2016;30:72-82.

8 Krystal AD, Prather AA: Should internet cognitive behavioral therapy for insomnia be the primary treatment option for insomnia? Toward getting more shuti. JAMA Psychiatry 2017;74:15-16.

9 Ritterband LM, Thorndike FP, Ingersoll KS, et al.: Effect of a web-based cognitive behavior therapy for insomnia intervention with 1-year follow-up: A randomized clinical trial. JAMA Psychiatry 2017;74:68-75.

10 Zachariae R, Lyby MS, Ritterband LM, O'Toole MS: Efficacy of internet-delivered cognitive-behavioral therapy for insomnia - A systematic review and meta-analysis of randomized controlled trials. Sleep Med Rev 2016;30:1-10.

11 Seyffert M, Lagisetty P, Landgraf J, Chopra V, Pfeiffer PN, Conte ML, Rogers MAM: Internet-delivered cognitive behavioral therapy to treat insomnia: A systematic review and meta-analysis. PLOS ONE 2016;11:e0149139.

12 Harvey AG, Tang NK: Cognitive behaviour therapy for primary insomnia: can we rest yet? Sleep Med Rev 2003;7:237-262.

13 Scheer FAJL, van Heijningen C, Van Someren EJW, Buijs RM: Environmental light and suprachiasmatic nucleus interact in the regulation of body temperature. Neurosci 2005;132:465-477.
14 Van Someren EJW, Riemersma RF: Live to the rhythm, slave to the rhythm. Sleep Med Rev 2007;11:465-484.
15 Van Der Werf YD, Altena E, van Dijk KD, Strijers RL, De Rijke W, Stam CJ, Van Someren EJW: Is disturbed intracortical excitability a stable trait of chronic insomnia? A study using transcranial magnetic stimulation before and after multimodal sleep therapy. Biol Psychiatry 2010;68:950-955.
16 Dekker K, Benjamins JS, Van Straten A, Hofman WF, Van Someren EJW: Effectiveness of internet-supported cognitive behavioral and chronobiological interventions and effect moderation by insomnia subtype: study protocol of a randomized controlled trial. Trials 2015;16:292.
17 Benjamins JS, Migliorati F, Dekker K, Wassing R, Moens S, Blanken TF, te Lindert BHW, Sjauw Mook J, Van Someren EJW: Insomnia heterogeneity: Characteristics to consider for data-driven multivariate subtyping. Sleep Med Rev 2017;36:71-81.
18 American Psychiatric Association: DSM-5: Diagnostic and Statistical Manual of Mental Disorders., ed 5th. Washington, DC, American Psychiatric Press, 2013.
19 Diagnostic Classification Steering Committee: ICSD3 - International classification of sleep disorders: Diagnostic and coding manual., ed 3rd edition. Rochester, Minnesota, American Sleep Disorders Association, 2014.
20 Twisk JWR: Applied longitudinal data analysis for epidemiology. Cambridge, Cambridge University Press, 2003.
21 R Core Team: R: A language and environment for statistical computing. Vienna, Austria, R Foundation for Statistical Computing, 2016,
22 Frane JW: A method of biased coin randomization, its implementation, and its validation. Drug Inf J 1998;32:423–432.
23 Kang M, Ragan BG, Park J-H: Issues in outcomes research: An overview of randomization techniques for clinical trials. J Athl Train 2008;43:215-221.
24 Hofman WF, Kumar A: Online treatment of insomnia using behavioral techniques. Sleep Diagn Ther 2010;5:28-32.
25 Flory R, Ametepe J, Bowers B: A randomized, placebo-controlled trial of bright light and high-density negative air ions for treatment of Seasonal Affective Disorder. Psychiatry Res 2010;177:101-108.
26 Czeisler CA, Kronauer RE, Allan JS, Duffy JF, Jewett M, Brown EN, Ronda JM: Bright light induction of strong (type 0) resetting of the human circadian pacemaker. Science 1989;244:1328-1333.

27 Riemersma-van der Lek R, Swaab DF, Twisk J, Hol EM, Hoogendijk WJG, Van Someren EJW: Effect of bright light and melatonin on cognitive and non-cognitive function in elderly residents of group care facilities: a randomized controlled trial. JAMA 2008;299:2642-2655.

28 Lucas RJ, Peirson SN, Berson DM, Brown TM, Cooper HM, Czeisler CA, Figueiro MG, Gamlin PD, Lockley SW, O'Hagan JB, Price LLA, Provencio I, Skene DJ, Brainard GC: Measuring and using light in the melanopsin age. TINS 2014;37:1-9.

29 Meesters Y, Winthorst WH, Duijzer WB, Hommes V: The effects of low-intensity narrow-band blue-light treatment compared to bright white-light treatment in sub-syndromal seasonal affective disorder. BMC Psychiatry 2016;16:27.

30 Hartescu I, Morgan K, Stevinson CD: Increased physical activity improves sleep and mood outcomes in inactive people with insomnia: a randomized controlled trial. J Sleep Res 2015;24:526-534.

31 Yang P-Y, Ho K-H, Chen H-C, Chien M-Y: Exercise training improves sleep quality in middle-aged and older adults with sleep problems: a systematic review. Journal of Physiotherapy 2012;58:157-163.

32 Dorsey CM, Teicher MH, Cohen-Zion M, Stefanovic L, Satlin A, Tartarini W, Harper D, Lukas SE: Core body temperature and sleep of older female insomniacs before and after passive body heating. Sleep 1999;22:891-898.

33 Raymann RJEM, Swaab DF, Van Someren EJW: Skin deep: cutaneous temperature determines sleep depth. Brain 2008;131:500-513.

34 Raymann RJEM, Van Someren EJW: Diminished capability to recognize the optimal temperature for sleep initiation may contribute to poor sleep in elderly people. Sleep 2008;31:1301-1309.

35 Te Lindert BHW, Van Someren EJW: Skin temperature, sleep, and vigilance; in Romanovsky AA (ed) Handbook of Clinical Neurology. San Diego, Elsevier, 2018, vol 156, pp 353-365.

36 Sung EJ, Tochihara Y, Kim JS: Effects of timing of bathing on sleep in winter; in Werner J, Hexamer M (eds): Proceedings of the IX conference on Environmental Ergonomics. Dortmund, 2000, pp 429 - 432.

37 Haghayegh S, Khoshnevis S, Smolensky MH, Diller KR, Castriotta RJ: Before-bedtime passive body heating by warm shower or bath to improve sleep: A systematic review and meta-analysis. Sleep Med Rev 2019;46:124-135.

38 Raymann RJEM, Swaab DF, Van Someren EJW: Skin temperature and sleep-onset latency: Changes with age and insomnia. Physiol Behav 2007;90:257-266.

39 Dorsey CM, Lukas SE, Teicher MH, Harper D, Winkelman JW, Cunningham SL, Satlin A: Effects of passive body heating on sleep of older female insomniacs. J Geriatr Psychiatry Neurol 1996;9:83-90.

40 Mishima Y, Hozumi S, Shimizu T, Hishikawa Y, Mishima K: Passive body heating ameliorates sleep disturbances in patients with vascular dementia without circadian phase-shifting. Am J Geriatr Psychiatry 2005;13:369-376.
41 Dowdell WT, Javaheri S: Lack of effect of external warming on sleep architecture in sleep apnea/hypopnea syndrome. Am Rev Resp Dis 1992;145:137-140.
42 Bunnell DE, Agnew JA, Horvath SM, Jopson L, Wills M: Passive body heating and sleep: influence of proximity to sleep. Sleep 1988;11:210-219.
43 Jordan J, Montgomery I, Trinder J: The effect of afternoon body heating on body temperature and slow wave sleep. Psychophysiol 1990;27:560-566.
44 Horne JA, Reid AJ: Night-time sleep EEG changes following body heating in a warm bath. Electroencephalogr Clin Neurophysiol 1985;60:154-157.
45 Horne JA, Shackell BS: Slow wave sleep elevations after body heating: proximity to sleep and effects of aspirin. Sleep 1987;10:383-392.
46 Sung EJ, Tochihara Y: Effects of bathing and hot footbath on sleep in winter. J Physiol Anthropol Appl Human Sci 2000;19:21-27.
47 Kanda K, Tochihara Y, Ohnaka T: Bathing before sleep in the young and in the elderly. Eur J Appl Physiol 1999;80:71-75.
48 Harding EC, Franks NP, Wisden W: The temperature dependence of sleep. Front Neurosci 2019;13
49 Edinger JD, Wyatt JK, Olsen MK, Stechuchak KM, Carney CE, Chiang A, Krystal AD, Lineberger MD, Means MK, Radtke RA: Reliability and validity of the Duke Structured Interview for Sleep Disorders for insomnia screening. Sleep 2009;32 (Suppl):A265-A265.
50 Carney CE, Buysse DJ, Ancoli-Israel S, Edinger JD, Krystal AD, Lichstein KL, Morin CM: The consensus sleep diary: standardizing prospective sleep self-monitoring. Sleep 2012;35:287-302.
51 Ibáñez V, Silva J, Cauli O: A survey on sleep assessment methods. PeerJ 2018;6:e4849.
52 Buysse DJ, Ancoli-Israel S, Edinger JD, Lichstein KL, Morin CM: Recommendations for a standard research assessment of insomnia. Sleep 2006;29:1155-1173.
53 Reed DL, Sacco WP: Measuring sleep efficiency: What should the denominator be? J Clin Sleep Med 2016;12:263-266.
54 Wilson SJ, Nutt DJ, Alford C, Argyropoulos SV, Baldwin DS, Bateson AN, Britton TC, Crowe C, Dijk DJ, Espie CA, Gringras P, Hajak G, Idzikowski C, Krystal AD, Nash JR, Selsick H, Sharpley AL, Wade AG: British Association for Psychopharmacology consensus statement on evidence-based treatment of insomnia, parasomnias and circadian rhythm disorders. J Psychopharmacol 2010;24:1577-1601.
55 Bastien CH, Vallieres A, Morin CM: Validation of the Insomnia Severity Index as an outcome measure for insomnia research. Sleep Med 2001;2:297-307.

56 Morin CM, Vallieres A, Ivers H: Dysfunctional beliefs and attitudes about sleep (DBAS): validation of a brief version (DBAS-16). Sleep 2007;30:1547-1554.

57 Broomfield NM, Espie CA: Towards a valid, reliable measure of sleep effort. J Sleep Res 2005;14:401-407.

58 Vincent N, Sande G, Read C, Giannuzzi T: Sleep locus of control: report on a new scale. Behav Sleep Med 2004;2:79-93.

59 Lacks P: Behavioral treatment for persistent insomnia. New York, Pergamon Press, 1987.

60 Nicassio PM, Mendlowitz DR, Fussell JJ, Petras L: The phenomenology of the pre-sleep state: the development of the pre-sleep arousal scale. Behav Res Ther 1985;23:263-271.

61 Coren S: Prediction of insomnia from arousability predisposition scores: scale development and cross-validation. Behav Res Ther 1988;26:415-420.

62 Pavlova M, Berg O, Gleason R, Walker F, Roberts S, Regestein Q: Self-reported hyperarousal traits among insomnia patients. J Psychosom Res 2001;51:435-441.

63 Kessler RC, Adler L, Ames M, Demler O, Faraone S, Hiripi E, Howes MJ, Jin R, Secnik K, Spencer T, Ustun TB, Walters EE: The World Health Organization adult ADHD self-report scale (ASRS): a short screening scale for use in the general population. Psychol Med 2005;35:245-256.

64 Zigmond AS, Snaith RP: The hospital anxiety and depression scale. Acta Psychiatr Scand 1983;67:361-370.

65 Watson D, Clark LA, Tellegen A: Development and validation of brief measures of positive and negative affect: the PANAS scales. J Pers Soc Psychol 1988;54:1063-1070.

66 Gard DE, Gard MG, Kring AM, John OP: Anticipatory and consummatory components of the experience of pleasure: a scale development study. J Res Personality 2006;40:1086-1102.

67 Ware JE, Sherbourne CD: A 36-item short-form health survey (SF-36): a conceptual framework and item selection. Med Care 1992;30:473-483.

68 Hakkaart-van Roijen L, Straten A, Tiemens B, C. H. Donker M: Manual Trimbos/iMTA Questionnaire for Costs Associated with Psychiatric Illness (TIC-P) (in Dutch). 2002.

69 Bates D, Machler M, Bolker BM, Walker SC: Fitting linear mixed-effects models using lme4. Journal of Statistical Software 2015;67:1-48.

70 Kantermann T, Burgess HJ: Average mid-sleep time as a proxy for circadian phase. PsyCh J 2017;6:290-291.

71 Fischer D, Lombardi DA, Marucci-Wellman H, Roenneberg T: Chronotypes in the US – Influence of age and sex. PLoS One 2017;12:e0178782.

72 Roenneberg T, Kuehnle T, Juda M, Kantermann T, Allebrandt K, Gordijn M, Merrow M: Epidemiology of the human circadian clock. Sleep Med Rev 2007;11:429-438.

73 van Maanen A, Meijer AM, van der Heijden KB, Oort FJ: The effects of light therapy on sleep problems: A systematic review and meta-analysis. Sleep Med Rev 2016;29:52-62.

74 Kredlow MA, Capozzoli MC, Hearon BA, Calkins AW, Otto MW: The effects of physical activity on sleep: a meta-analytic review. J Behav Med 2015;38:427-449.

75 Lieverse R, Van Someren EJW, Nielen MM, Uitdehaag BM, Smit JH, Hoogendijk WJ: Bright light treatment in elderly patients with nonseasonal major depressive disorder: a randomized placebo-controlled trial. Arch Gen Psychiatry 2011;68:61-70.

76 De Boer T, Detari L, Meijer JH: Long term effects of sleep deprivation on the mammalian circadian pacemaker. Sleep 2007;30:27-262.

77 De Boer T, Vansteensel MJ, Detari L, Meijer JH: Sleep states alter activity of suprachiasmatic nucleus neurons. Nat Neurosci 2003;6:1086-1090.

78 Hauri PJ, Wisbey J: Wrist actigraphy in insomnia. Sleep 1992;15:293-301.

79 Buysse DJ: Insomnia. JAMA 2013;309:706-716.

80 Edinger JD, Fins AI, Glenn DM, Sullivan Jr RJ, Bastian LA, Marsh GR, Dailey D, Hope TV, Young M, Shaw E, Vasilas D: Insomnia and the eye of the beholder: Are there clinical markers of objective sleep disturbances among adults with and without insomnia complaints? J Consult Clin Psychol 2000;68:586-593.

81 Tagliazucchi E, van Someren EJW: The large-scale functional connectivity correlates of consciousness and arousal during the healthy and pathological human sleep cycle. NeuroImage 2017;160:55-72.

82 Wassing R, Benjamins JS, Dekker K, Moens S, Spiegelhalder K, Feige B, Riemann D, van der Sluis S, Van Der Werf YD, Talamini LM, Walker MP, Schalkwijk F, Van Someren EJW: Slow dissolving of emotional distress contributes to hyperarousal. PNAS 2016;113:2538-2543.

83 Ramkisoensing A, Meijer JH: Synchronization of biological clock neurons by light and peripheral feedback systems promotes circadian rhythms and health. Front Neurol 2015;6:128.

84 Lemieux J, Beaton DE, Hogg-Johnson S, Bordeleau LJ, Goodwin PJ: Three methods for minimally important difference: no relationship was found with the net proportion of patients improving. J Clin Epidemiol 2007;60:448-455.

85 Page P: Beyond statistical significance: clinical interpretation of rehabilitation research literature. International journal of sports physical therapy 2014;9:726-736.

86 Kaldo V, Jernelöv S, Blom K, Ljótsson B, Brodin M, Jörgensen M, Kraepelien M, Rück C, Lindefors N: Guided internet cognitive behavioral therapy for insomnia compared to a control treatment – A randomized trial. Behav Res Ther 2015;71:90-100.

87 Okajima I, Komada Y, Inoue Y: A meta-analysis on the treatment effectiveness of cognitive behavioral therapy for primary insomnia. Sleep Biol Rhythms 2011;9:24-34.

88 Ohayon MM, Carskadon MA, Guilleminault C, Vitiello MV: Meta-analysis of quantitative sleep parameters from childhood to old age in healthy individuals: developing normative sleep values across the human lifespan. Sleep 2004;27:1255-1273.

Table 1. Sociodemographic and clinical characteristics of participants

Characteristic	week 1 - 4 / week 6 - 9	Inactive Ionizer ICBTI	Bright Light ICBTI	Physical Activity ICBTI	Warm Baths ICBTI	Inactive Ionizer + ICBTI	Bright Light + ICBTI	Physical Activity + ICBTI	Warm Baths + ICBTI	All	Test Statistic[a]	*P* Value
						no treatment						
N		20	24	24	20	21	21	21	24	175		
Age, mean (SD), y		51.3 (10.2)	47.8 (13.8)	50.8 (11.6)	53.2 (6.4)	52.3 (13.6)	50.4 (9.9)	50.7 (12.8)	51.7 (10.0)	51.0 (11.2)	$F_{7,167} = 0.45$	.87
Female, No. (%)		15 (75)	22 (92)	20 (83)	16 (80)	17 (81)	13 (62)	17 (81)	18 (75)	138 (79)	$\chi^2 = 6.79$	.45
Education Level, No. (%)												
Secondary education or less		7 (35)	9 (38)	8 (33)	4 (20)	9 (43)	9 (43)	11 (52)	6 (25)	63 (36)	$\chi^2 = 16.14$	.30
Post-secondary education		7 (35)	12 (50)	8 (33)	5 (25)	8 (38)	6 (29)	6 (29)	10 (42)	62 (35)		
University		6 (30)	3 (12)	8 (33)	11 (55)	4 (19)	6 (29)	4 (19)	8 (33)	50 (29)		
Occupation, No. (%)												
Employed fulltime		7 (35)	7 (29)	11 (46)	12 (60)	9 (43)	11 (52)	8 (38)	14 (58)	79 (45)	$\chi^2 = 12.40$	.57
Employed parttime		7 (35)	10 (42)	8 (33)	6 (30)	4 (19)	7 (33)	8 (38)	5 (21)	55 (32)		
Other[b]		6 (30)	7 (29)	5 (21)	2 (10)	8 (38)	3 (14)	5 (24)	5 (21)	41 (23)		
Marital Status, No. (%)												
With partner[c]		11 (55)	14 (58)	16 (67)	12 (60)	14 (66)	13 (62)	15 (71)	20 (83)	115 (66)	$\chi^2 = 5.65$	.58
Without partner[d]		9 (45)	10 (42)	8 (33)	8 (40)	7 (34)	8 (38)	6 (29)	4 (17)	60 (34)		
Health, No.(%)[e]												
Current Somatic Disorder[f]		14 (70)	10 (41)	17 (71)	7 (35)	15 (71)	10 (48)	10 (48)	12 (50)	95 (54)	$\chi^2 = 16.23$	.30
Past Somatic Disorder		4 (20)	9 (38)	3 (12)	7 (35)	4 (20)	8 (40)	6 (27)	9 (38)	50 (29)		
Insomnia duration, mean (SD), y[g]		7.2 (9.7)	9.9 (14.4)	12.5 (12.0)	8.6 (12.4)	8.0 (8.6)	9.7 (11.1)	7.1 (6.9)	10.6 (12.5)	9.3 (11.2)	$F_{7,155} = 0.58$	.78
ISI, mean (SD)		16.00 (4.74)	16.92 (3.20)	15.13 (4.61)	16.50 (3.44)	16.76 (4.31)	15.81 (3.30)	16.95 (3.92)	16.79 (4.23)	16.35 (3.98)	$F_{7,167} = 0.61$	.75

Abbreviations: ICBTI, Internet-based Cogntive Behavioral Therapy for Insomnisa; SD, Standard Deviation; ISI, Insomnia Severity Index.

[a] Significance test results are between group effects from ANOVA's for continues variables (F statistic) and chisquared tests for categorical variables (c2 statistic). All 8 combinations of the 2 by 4 factorial design are assessed as separate groups.

[b] including unemployed, homemaker and student

[c] married, legal partnership or legal cohabitation

[d] single, divorced, widowed

[e] If a participant had both a past and a current disorder, they had to indicate 'current'.

[f] Reported somatic disorders reported were high blood pressure, metabolic disorders, hearing loss, trombosis, appendicitis, urinal problem, skin infections, artrosis, bone fractures et cetera. If a somatic disorder was current, it was made sure it was not an exclusion criterium.

[g] Insomnia duration, derived from the Duke's Structured Interview for Sleeping Disorders (DSISD), was not correctly filled out by 12 participants

Table 2. Estimated effects of time and treatment by time interactions on all outcomes measures at T1 relative to T0

	T1 - T0			ICBTI x T1-T0			Any CT x T1-T0			ICBTI x Any CT x T1-T0		
Outcome measure	**β (SE)**	***d*[a]**	***P* Value**	**β (SE)**	***d*[a]**	***P* Value**	**β (SE)**	***d*[a]**	***P* Value**	**β (SE)**	***d*[a]**	***P* Value**
Sleep Diary												
Sleep Efficiency (%) (Primary)	5.55 (2.36)	0.34	**.02**	6.69 (3.25)	0.41	**.04**	-2.93 (2.69)	0.18	.28	3.42 (3.73)	0.21	.36
Time in Bed (min)	-8.08 (9.58)	0.13	.40	-31.29 (13.24)	0.52	**.02**	10.31 (10.92)	0.17	.35	1.99 (15.19)	0.03	.90
Sleep Onset Latency (min)	0.41 (8.70)	0.01	.96	-16.71 (12.03)	0.25	.17	-2.60 (9.93)	0.04	.79	-6.25 (13.81)	0.09	.65
Wake After Sleep Onset (min)[b]	-2.54 (16.95)	0.02	.88	-44.34 (23.43)	0.37	.06	-5.94 (19.34)	0.05	.76	-14.64 (26.89)	0.12	.59
Total Sleep Time (min)	16.65 (10.93)	0.19	.13	10.19 (15.08)	0.12	.50	-3.81 (12.47)	0.04	.76	17.03 (17.31)	0.19	.33
Average Daytime Functioning	0.16 (0.16)	0.26	.32	-0.14 (0.22)	0.23	.52	-0.10 (0.19)	0.16	.60	0.22 (0.26)	0.36	.39
Difficulty Initiating Sleep	-0.22 (0.24)	0.16	.36	-0.20 (0.34)	0.14	.55	0.07 (0.28)	0.05	.80	-0.05 (0.38)	0.04	.89
Difficulty Maintainting Sleep	-0.70 (0.19)	0.50	**<.001**	0.01 (0.26)	0.01	.96	0.16 (0.22)	0.11	.47	-0.29 (0.30)	0.21	.33
Early Morning Awakening	-0.54 (0.24)	0.38	**.03**	0.11 (0.33)	0.07	.75	-0.10 (0.27)	0.07	.71	-0.47 (0.38)	0.33	.22
Actigraphy												
Sleep Efficiency (%)	0.01 (1.45)	0.00	.99	1.56 (2.03)	0.19	.44	0.12 (1.69)	0.02	.94	0.76 (2.36)	0.09	.75
Sleep Onset Latency (min)	-0.47 (2.76)	0.03	.87	0.30 (3.87)	0.02	.94	2.66 (3.20)	0.16	.41	-3.52 (4.48)	0.21	.43
Wake After Sleep Onset (min)[b]	3.21 (5.29)	0.09	.54	-14.17 (7.42)	0.40	.06	-6.85 (6.16)	0.20	.27	9.25 (8.61)	0.26	.28
Total Sleep Time (min)	-4.16 (9.02)	0.07	.65	-29.89 (12.66)	0.51	**.02**	7.09 (10.51)	0.12	.50	4.78 (14.69)	0.08	.75
Average Sleep Bout Duration (min)	-0.36 (9.26)	0.01	.97	7.94 (12.97)	0.22	.54	15.21 (10.68)	0.41	.16	-20.40 (14.96)	0.56	.17
Average Wake Bout Duration (min)	-0.01 (0.05)	0.02	.90	0.00 (0.07)	0.01	.96	-0.05 (0.06)	0.14	.38	-0.01 (0.08)	0.03	.90
Sleep related surveys												
Insomnia Severity Index	-1.81 (0.90)	0.65	**.05**	-2.93 (1.25)	1.06	**.02**	1.08 (1.02)	0.39	.29	-1.66 (1.43)	0.60	.25
Dysfunctional Beliefs and Attitudes	-1.92 (1.99)	0.32	.34	-6.65 (2.74)	1.11	**.02**	0.78 (2.25)	0.13	.73	-2.83 (3.13)	0.47	.37
Glasgow Sleep Effort Scale	-0.88 (0.46)	-0.64	.06	-1.28 (0.63)	0.93	**.04**	0.69 (0.52)	0.50	.18	-0.04 (0.72)	0.03	.95
Sleep Locus Of Control	0.71 (0.93)	0.25	.44	-0.26 (1.30)	0.09	.84	-0.51 (1.06)	0.18	.63	2.81 (1.48)	0.98	.06
Sleep Self-Efficacy Scale	1.08 (1.18)	0.29	.36	2.10 (1.65)	0.57	.20	-0.89 (1.35)	0.24	.51	0.49 (1.89)	0.13	.80
Hyperarousal												
Pre-Sleep Arousal Scale - Somatic	1.15 (0.96)	0.46	.23	-0.76 (1.29)	0.30	.56	-0.86 (1.07)	0.34	.42	-0.18 (1.46)	0.07	.90
Pre-Sleep Arousal Scale - Cognitive	0.74 (1.57)	0.18	.64	-4.84 (2.13)	1.18	**.02**	-2.55 (1.76)	0.62	.15	4.83 (2.41)	1.17	**.05**
Arousal Predisposition Scale	-0.99 (1.11)	0.34	.37	1.60 (1.50)	0.55	.29	0.97 (1.24)	0.34	.44	-1.80 (1.70)	0.62	.29
Hyper Arousal Scale	-1.29 (1.13)	0.44	.26	1.83 (1.53)	0.62	.23	1.01 (1.27)	0.34	.43	-1.93 (1.73)	0.65	.27
Adult ADHD Self-Report Scale	-0.55 (0.81)	0.26	.50	0.52 (1.09)	0.25	.63	0.23 (0.90)	0.11	.80	-0.95 (1.24)	0.45	.44
Mood and Affect												
Anxiety (HADS)	-0.19 (0.52)	0.12	.71	-1.21 (0.72)	0.75	.10	0.48 (0.59)	0.30	.42	0.01 (0.83)	0.00	.99
Depression (HADS)	-0.12 (0.59)	0.07	.84	-1.11 (0.82)	0.61	.18	0.02 (0.67)	0.01	.97	0.24 (0.94)	0.13	.80
Positive Affect (PANAS)	1.18 (1.25)	0.30	.35	0.28 (1.75)	0.07	.87	-2.12 (1.43)	0.55	.14	2.25 (2.00)	0.58	.26
Negative Affect (PANAS)	-0.07 (0.97)	0.02	.95	-2.76 (1.36)	0.92	**.04**	0.84 (1.11)	0.28	.45	1.07 (1.55)	0.36	.49
Temporal Experience of Pleasure	3.03 (1.72)	0.57	.08	-3.19 (2.40)	0.60	.19	-3.56 (1.96)	0.67	.07	5.21 (2.75)	0.98	.06
Quality of Life SF36												
Physical Component Summary	-0.18 (1.26)	0.05	.89	0.36 (1.78)	0.09	.84	-0.26 (1.44)	0.07	.86	0.09 (2.03)	0.02	.96
Mental Component Summary	0.72 (1.77)	0.13	.68	2.57 (2.50)	0.47	.31	-1.40 (2.02)	0.26	.49	0.97 (2.85)	0.18	.73

The model intercept and main effects of ICBTI and any CT are not shown. Main effects for ICBTI and any CT were non significant, except for a significantly higher intercept for participants receiving any CT on Depression (HADS) (β (SE) = 2.00 (0.93), P = .03 and SF 36 Physical Component Summary (β (SE) = 3.09 (1.52), *P* = .04)

Abbreviations: SE, standard error of b; ICBTI, Internet-based Cognitive Behavioral Therapy for Insomnia; CT, Chronobiological Treatment; ISI, Insomnia Severity Index HADS, Hospital Anxiety and Depression Scale; PANAS, Positive Affect Negative Affect Scale; SF36, Short Form 36. Effect estimates were obtained from intent-to-treat mixed-effect regression analyses.

[a] Effect size is calculated by dividing the effect estimate (b) by the residual standard deviation of the model

[b] Wake After Sleep Onset includes the time awake after final awakening, but before Lights On

Table 3. Estimated effects of time and time by treatment interactions on all outcome measures at T2 relative to T0

	T2 - T0[a]			ICBTI first x T2-T0			Any CT x T2 -T0			ICBTI first x Any CT x T2-T0		
Outcome measure	**β (SE)**	***d*[a]**	***P* Value**	**β (SE)**	***d*[a]**	***P* Value**	**β (SE)**	***d*[a]**	***P* Value**	**β (SE)**	***d*[a]**	***P* Value**
Sleep Diary												
Sleep Efficiency (%) (Primary)	13.39 (2.26)	0.85	**<.001**	-6.48 (3.12)	0.41	**.04**	-5.08 (2.61)	0.32	.05	11.07 (3.61)	0.70	**.003**
Time in Bed (min)	-29.88 (8.92)	0.51	**.001**	7.56 (12.35)	0.13	.54	5.06 (10.29)	0.09	.62	1.76 (14.29)	0.03	.90
Sleep Onset Latency (min)	-18.40 (8.34)	0.30	**.03**	17.89 (11.53)	0.29	.12	4.04 (9.63)	0.07	.68	-27.21 (13.36)	0.44	**.04**
Wake After Sleep Onset (min)[b]	-58.53 (14.56)	0.54	**<.001**	45.70 (20.13)	0.42	**.02**	14.53 (16.82)	0.13	.39	-66.14 (23.33)	0.61	**.01**
Total Sleep Time (min)	35.34 (11.26)	0.41	**.002**	-17.95 (15.56)	0.21	.25	-14.43 (13.01)	0.17	.27	46.92 (18.04)	0.55	**.01**
Average Daytime Functioning	0.46 (0.17)	0.77	**.01**	-0.49 (0.23)	0.82	**.04**	-0.26 (0.19)	0.44	.18	0.54 (0.27)	0.90	**.05**
Difficulty Initiating Sleep	-0.35 (0.22)	0.25	.12	0.02 (0.31)	0.01	.96	0.03 (0.26)	0.02	.92	-0.12 (0.36)	0.09	.74
Difficulty Maintaining Sleep	-1.00 (0.24)	0.72	**<.001**	0.28 (0.33)	0.20	.40	0.27 (0.27)	0.19	.32	-0.47 (0.38)	0.34	.21
Early Morning Awakening	-1.05 (0.23)	0.75	**<.001**	0.37 (0.32)	0.27	.24	0.23 (0.27)	0.16	.40	-0.74 (0.37)	0.53	**.05**
Actigraphy												
Sleep Efficiency (%)	2.62 (1.47)	0.34	.08	-0.29 (2.10)	0.04	.89	-1.73 (1.74)	0.22	.32	0.88 (2.45)	0.11	.72
Sleep Onset Latency (min)	-2.73 (2.55)	0.16	.29	0.95 (3.66)	0.05	.80	4.13 (3.04)	0.24	.18	0.37 (4.28)	0.02	.93
Wake After Sleep Onset (min)[b]	-5.99 (5.45)	0.18	.27	-8.82 (7.80)	0.27	.26	0.91 (6.48)	0.03	.89	7.67 (9.13)	0.23	.40
Total Sleep Time (min)	-18.87 (9.06)	0.33	**.04**	5.02 (12.98)	0.09	.70	1.75 (10.78)	0.03	.87	-1.91 (15.19)	0.03	.90
Average Sleep Bout Duration (min)	0.98 (9.89)	0.03	.92	14.97 (13.97)	0.50	.28	-0.27 (11.56)	0.01	.98	-5.32 (16.22)	0.18	.74
Average Wake Bout Duration (min)	-0.04 (0.06)	0.10	.53	-0.11 (0.08)	0.30	.18	-0.01 (0.07)	0.02	.92	0.08 (0.10)	0.23	.38
Sleep related surveys												
Insomnia Severity Index	-5.06 (1.04)	1.64	**<.001**	-0.20 (1.42)	0.07	.89	-0.52 (1.19)	0.17	.66	0.58 (1.63)	0.19	.72
Dysfunctional Beliefs and Attitudes	-13.87 (2.57)	1.83	**<.001**	3.63 (3.51)	0.48	.30	2.45 (2.94)	0.32	.41	-4.11 (4.03)	0.54	.31
Glasgow Sleep Effort Scale	-1.92 (0.51)	1.27	**<.001**	-0.67 (0.70)	0.44	.34	0.23 (0.58)	0.15	.69	0.95 (0.80)	0.63	.24
Sleep Locus Of Control	3.12 (1.12)	0.94	**.01**	-3.04 (1.53)	0.92	**.05**	-1.28 (1.28)	0.39	.32	3.45 (1.76)	1.04	.05
Sleep Self-Efficacy Scale	5.23 (1.31)	1.35	**<.001**	-0.17 (1.79)	0.04	.93	-0.82 (1.49)	0.21	.59	-0.87 (2.06)	0.22	.67
Hyperarousal												
Pre-Sleep Arousal Scale - Somatic	-0.31 (1.14)	0.10	.79	1.19 (1.54)	0.40	.44	-0.21 (1.29)	0.07	.87	-1.53 (1.76)	0.52	.38
Pre-Sleep Arousal Scale - Cognitive	-0.90 (1.38)	0.25	.52	-0.48 (1.86)	0.13	.80	-1.69 (1.56)	0.47	.28	0.34 (2.13)	0.10	.87
Arousal Predisposition Scale	-2.98 (1.12)	1.03	**.01**	1.85 (1.52)	0.64	.22	2.73 (1.27)	0.94	**.03**	-2.25 (1.73)	0.77	.20
Hyper Arousal Scale	-0.20 (1.01)	0.08	.85	-0.36 (1.36)	0.14	.79	-0.82 (1.14)	0.32	.47	-0.07 (1.56)	0.03	.97
Adult ADHD Self-Report Scale	-0.32 (0.86)	0.14	.71	-0.71 (1.16)	0.32	.54	-0.37 (0.98)	0.16	.71	1.19 (1.33)	0.53	.37
Mood and Affect												
Anxiety (HADS)	-1.29 (0.60)	0.71	**.03**	-0.08 (0.84)	0.04	.92	0.63 (0.69)	0.35	.37	-0.20 (0.97)	0.11	.84
Depression (HADS)	-1.20 (0.69)	0.57	.09	0.14 (0.97)	0.07	.89	-0.02 (0.80)	0.01	.98	0.08 (1.12)	0.04	.94
Positive Affect (PANAS)	3.77 (1.45)	0.86	**.01**	-3.89 (2.02)	0.89	.06	-2.62 (1.66)	0.60	.12	5.51 (2.33)	1.26	**.02**
Negative Affect (PANAS)	-1.97 (1.08)	0.60	.07	-1.48 (1.51)	0.45	.33	1.68 (1.24)	0.51	.18	0.22 (1.74)	0.07	.90
Temporal Experience of Pleasure	5.26 (1.77)	0.98	**.003**	-4.94 (2.47)	0.92	**.05**	-3.84 (2.04)	0.72	.06	4.78 (2.85)	0.89	.10
Quality of Life SF36												
Physical component summary	0.25 (1.24)	0.07	.84	-1.61 (1.71)	0.43	.35	-0.14 (1.42)	0.04	.92	1.56 (1.97)	0.41	.43
Mental component summary	3.10 (1.65)	0.62	.06	0.67 (2.28)	0.13	.77	-1.28 (1.90)	0.26	.50	1.46 (2.64)	0.29	.58

The model intercept and main effects of ICBTI and any CT are not shown. Main effects for ICBTI and any CT were non significant, except for a significantly higher intercept for participants receiving any CT on Depression (HADS) (β (SE) = 1.92 (0.89), *P* = .03 and SF 36 Physical Component Summary (β (SE) = 3.09 (1.47), *P* = .04)

Abbreviations: SE, standard error of β; ICBTI, Internet-based Cognitive Behavioral Therapy for Insomnia; CT, Chronobiological Treatment; ISI, Insomnia Severity Index HADS, Hospital Anxiety and Depression Scale; PANAS, Positive Affect Negative Affect Scale; SF36, Short Form 36. Effect estimates were obtained from intent-to-treat mixed-effect regression analyses.

[a] Effect size is calculated by dividing the absolute effect estimate (β) by the residual standard deviation of the model

[b] Wake After Sleep Onset includes the time awake after first awakening, but before Lights On

Table 4. Prior Expectations, Post-intervention Attribution and Compliance

Characteristic	Inactive Ionizer	Bright Light	Physical Activity	Warm Baths	ICBTI week 1-4	ICBTI week 6-9
Expected treatment effect						
n	41	44	45	44	87	87
no treatment[a]	0.15 (0.73)	-0.14 (0.67)	-0.18 (0.89)	-0.02 (0.76)	-0.07 (0.90)	-0.03 (0.62)
CT[a]	0.50 (0.75)	0.49 (0.88)	0.68 (1.06)	0.29 (0.77)	0.57 (0.95)	0.40 (0.80)
ICBTI[a]	1.39 (0.80)	1.14 (0.80)	1.47 (0.79)	1.32 (0.93)	1.38 (0.81)	1.28 (0.86)
Post-intervention Attribution						
n	40	43	41	42	84	82
CT[a]	0.50 (0.75)	0.49 (0.88)	0.68 (1.06)	0.29 (0.77)	0.57 (0.95)	0.40 (0.80)
n	39	40	37	40	83	73
ICBTI[a]	1.49 (0.82)	1.15 (1.12)	1.00 (1.20)	1.20 (0.88)	1.25 (0.96)	1.16 (1.09)
Compliance						
n	40	43	42	42	84	83
CT	26.33 (2.40)	25.93 (5.10)	22.17 (5.82)	21.36 (6.63)	23.98 (5.91)	23.88 (5.43)
n	40	41	37	42	84	76
ICBTI[b]	21.68 (6.15)	22.46 (6.42)	21.97 (5.38)	22.45 (5.76)	22.92 (5.46)	21.30 (6.29)

Data are Mean (SD). Test statistics are between treatment effects. ICBTI = Internet-based Cognitive Behavioural Therapy for Insomnia.

Given sample sizes are of available data

[a] -3 = very much deteriorated, -2 = deteriorated, -1 = slightly deteriorated, 0 = no change, 1 = slightly improved, 2 = improved, 3 = very much

[b] Compliance for ICBTI is for sleep restriction

Table 5. Estimated effects of time and treatment by time interactions on all outcome measures at T1 relative to T0

	T1 - T0			ICBTI x T1-T0			Bright Light x T1-T0			Physical Activity x T1-T0			Warm Baths x T1-T0			ICBTI x Bright Light x T1-T0			ICBTI x Physical Activity x T1-T0			ICBTI x Warm Baths x T1-T0		
Outcome measure	**β (SE)**	***d*[a]**	***P* Value**	**β (SE)**	***d*[a]**	***P* Value**	**β (SE)**	***d*[a]**	***P* Value**	**β (SE)**	***d*[a]**	***P* Value**	**β (SE)**	***d*[a]**	***P* Value**	**β (SE)**	***d*[a]**	***P* Value**	**β (SE)**	***d*[a]**	***P* Value**	**β (SE)**	***d*[a]**	***P* Value**
Sleep Diary																								
Sleep Efficiency (%) (Primary)	5.55 (2.35)	0.34	**.02**	6.68 (3.24)	0.41	**.04**	-1.13 (3.20)	0.07	.72	-4.65 (3.23)	0.28	.15	-3.18 (3.28)	0.19	.34	0.41 (4.51)	0.02	.93	5.66 (4.55)	0.35	.22	4.28 (4.53)	0.26	.35
Time in Bed (min)	-8.03 (9.53)	0.13	.40	-31.35 (13.18)	0.52	**.02**	11.27 (12.98)	0.19	.39	16.35 (13.11)	0.27	.21	2.83 (13.36)	0.05	.83	0.04 (18.33)	0.00	1.00	-8.62 (18.48)	0.14	.64	14.74 (18.41)	0.24	.42
Sleep Onset Latency (min)	0.41 (8.67)	0.01	.96	-16.71 (11.99)	0.25	.17	-2.97 (11.83)	0.04	.80	-3.20 (11.94)	0.05	.79	-1.50 (12.17)	0.02	.90	1.77 (16.69)	0.03	.92	-10.59 (16.81)	0.16	.53	-9.87 (16.76)	0.15	.56
Wake After Sleep Onset (min)[b]	-2.54 (16.86)	0.02	.88	-44.35 (23.31)	0.37	.06	-17.07 (23.00)	0.14	.46	-7.92 (23.21)	0.07	.73	9.10 (23.66)	0.08	.70	7.79 (32.43)	0.06	.81	-14.94 (32.68)	0.12	.65	-37.63 (32.59)	0.31	.25
Total Sleep Time (min)	16.66 (10.92)	0.19	.13	10.19 (15.06)	0.12	.50	8.64 (14.90)	0.10	.56	-8.67 (15.07)	0.10	.57	-12.67 (15.29)	0.14	.41	-5.97 (20.99)	0.07	.78	22.17 (21.18)	0.25	.30	35.34 (21.06)	0.40	.09
Average Daytime Functioning	0.16 (0.16)	0.26	.31	-0.14 (0.22)	0.23	.52	0.11 (0.22)	0.18	.60	-0.15 (0.22)	0.25	.48	-0.27 (0.23)	0.44	.23	-0.09 (0.31)	0.15	.77	0.29 (0.31)	0.47	.35	0.48 (0.31)	0.77	.13
Difficulty Initiating Sleep	-0.22 (0.24)	0.16	.36	-0.20 (0.33)	0.14	.55	-0.01 (0.33)	0.01	.97	0.23 (0.33)	0.16	.49	0.00 (0.34)	0.00	1.00	0.09 (0.46)	0.06	.85	-0.30 (0.47)	0.21	.53	0.04 (0.47)	0.03	.93
Difficulty Maintaining Sleep	-0.70 (0.19)	0.50	**<.001**	0.01 (0.26)	0.01	.96	0.05 (0.26)	0.04	.84	0.33 (0.26)	0.23	.22	0.10 (0.27)	0.07	.71	-0.21 (0.37)	0.15	.56	-0.52 (0.37)	0.37	.16	-0.16 (0.37)	0.11	.67
Early Morning Awakening	-0.54 (0.24)	0.38	**.02**	0.11 (0.33)	0.08	.75	-0.37 (0.32)	0.26	.26	-0.04 (0.33)	0.03	.91	0.13 (0.33)	0.09	.70	-0.18 (0.45)	0.13	.69	-0.56 (0.46)	0.40	.22	-0.69 (0.46)	0.49	.14
Actigraphy																								
Sleep Efficiency (%)	0.01 (1.43)	0.00	.99	1.56 (2.00)	0.19	.44	-1.15 (2.02)	0.14	.57	0.12 (2.08)	0.02	.95	1.36 (2.05)	0.17	.51	0.47 (2.85)	0.06	.87	0.82 (2.89)	0.10	.78	0.94 (2.84)	0.12	.74
Sleep Onset Latency (min)	-0.47 (2.70)	0.03	.86	0.30 (3.79)	0.02	.94	0.93 (3.80)	0.05	.81	7.87 (3.91)	0.47	**.05**	-0.39 (3.87)	0.02	.92	0.06 (5.37)	0.00	.99	-11.89 (5.43)	0.70	**.03**	0.84 (5.37)	0.05	.88
Wake After Sleep Onset (min)[b]	3.20 (5.20)	0.09	.54	-14.15 (7.30)	0.40	.05	-3.10 (7.38)	0.09	.67	-5.32 (7.63)	0.15	.49	-11.88 (7.48)	0.34	.11	8.90 (10.40)	0.25	.39	12.15 (10.55)	0.35	.25	6.91 (10.38)	0.20	.51
Total Sleep Time (min)	-4.13 (8.96)	0.07	.65	-29.91 (12.57)	0.51	**.02**	6.86 (12.70)	0.12	.59	9.94 (13.13)	0.17	.45	5.39 (12.87)	0.09	.68	-2.82 (17.89)	0.05	.87	2.67 (18.16)	0.05	.88	13.42 (17.87)	0.23	.45
Average Sleep Bout Duration (min)	-0.36 (9.11)	0.01	.97	7.94 (12.75)	0.22	.53	-0.43 (12.69)	0.01	.97	25.15 (12.92)	0.68	.05	21.04 (13.00)	0.57	.11	0.43 (17.94)	0.01	.98	-28.96 (18.11)	0.79	.11	-32.35 (18.01)	0.88	.07
Average Wake Bout Duration (min)	-0.01 (0.05)	0.02	.90	0.00 (0.07)	0.01	.96	-0.09 (0.07)	0.24	.23	0.02 (0.07)	0.05	.82	-0.07 (0.07)	0.21	.30	-0.02 (0.10)	0.05	.85	-0.05 (0.10)	0.15	.60	0.03 (0.10)	0.08	.76
Sleep related surveys																								
Insomnia Severity Index	-1.81 (0.88)	0.66	**.04**	-2.93 (1.23)	1.07	**.02**	1.24 (1.21)	0.45	.31	1.73 (1.20)	0.63	.15	0.21 (1.24)	0.08	.86	-1.26 (1.71)	0.46	.46	-3.77 (1.72)	1.38	**.03**	0.00 (1.72)	0.00	1.00
Dysfunctional Beliefs and Attitudes	-1.91 (1.98)	0.32	.34	-6.65 (2.73)	1.12	**.02**	0.97 (2.69)	0.16	.72	1.29 (2.67)	0.22	.63	0.06 (2.73)	0.01	.98	-1.78 (3.76)	0.30	.64	-5.06 (3.79)	0.85	.18	-1.70 (3.79)	0.29	.65
Glasgow Sleep Effort Scale	-0.88 (0.45)	-0.65	.05	-1.28 (0.62)	0.94	**.04**	0.73 (0.62)	0.53	.24	0.28 (0.61)	0.21	.64	1.13 (0.63)	0.83	.07	0.25 (0.86)	0.18	.77	-0.06 (0.87)	0.04	.95	-0.40 (0.87)	0.29	.64
Sleep Locus Of Control	0.71 (0.93)	0.25	.44	-0.27 (1.29)	0.09	.84	-0.43 (1.28)	0.15	.74	-0.69 (1.26)	0.24	.58	-0.46 (1.30)	0.16	.72	2.36 (1.80)	0.83	.19	3.05 (1.81)	1.07	.09	3.03 (1.81)	1.06	.10
Sleep Self-Efficacy Scale	1.08 (1.18)	0.29	.36	2.10 (1.65)	0.58	.20	-1.31 (1.62)	0.36	.42	-0.94 (1.61)	0.26	.56	-0.48 (1.65)	0.13	.77	1.23 (2.28)	0.34	.59	1.22 (2.30)	0.33	.60	-0.89 (2.30)	0.24	.70
Hyperarousal																								
Pre-Sleep Arousal Scale - Somatic	1.15 (0.95)	0.46	.23	-0.76 (1.29)	0.31	.56	-0.50 (1.27)	0.20	.69	-1.07 (1.27)	0.43	.40	-0.98 (1.26)	0.39	.44	-0.35 (1.76)	0.14	.84	-0.08 (1.78)	0.03	.97	-0.15 (1.72)	0.06	.93
Pre-Sleep Arousal Scale - Cognitive	0.74 (1.55)	0.18	.64	-4.84 (2.10)	1.19	**.02**	-1.41 (2.07)	0.35	.50	-2.56 (2.07)	0.63	.22	-3.68 (2.06)	0.90	.08	4.17 (2.87)	1.02	.15	3.56 (2.91)	0.87	.22	6.46 (2.82)	1.58	**.02**
Arousal Predisposition Scale	-0.99 (1.09)	0.35	.36	1.60 (1.47)	0.57	.28	0.77 (1.45)	0.27	.60	2.64 (1.44)	0.94	.07	-0.45 (1.44)	0.16	.75	-1.58 (2.00)	0.56	.43	-2.90 (2.02)	1.03	.15	-0.84 (1.96)	0.30	.67
Hyper Arousal Scale	-1.29 (1.11)	0.45	.25	1.83 (1.51)	0.63	.23	1.94 (1.49)	0.67	.19	1.47 (1.48)	0.51	.32	-0.32 (1.47)	0.11	.83	-2.65 (2.05)	0.92	.20	-3.39 (2.08)	1.17	.11	-0.02 (2.01)	0.01	.99
Adult ADHD Self-Report Scale	-0.54 (0.79)	0.26	.49	0.53 (1.07)	0.26	.62	1.59 (1.05)	0.77	.13	-0.24 (1.05)	0.12	.82	-0.62 (1.05)	0.30	.55	-2.51 (1.46)	1.22	.09	-0.52 (1.47)	0.25	.73	0.09 (1.43)	0.04	.95
Mood and Affect																								
Anxiety (HADS)	-0.19 (0.51)	0.12	.71	-1.21 (0.71)	0.76	.09	0.81 (0.70)	0.51	.25	0.37 (0.70)	0.23	.60	0.24 (0.71)	0.15	.74	-0.27 (0.99)	0.17	.79	-0.70 (1.01)	0.44	.49	0.87 (0.99)	0.55	.38
Depression (HADS)	-0.12 (0.58)	0.07	.84	-1.11 (0.81)	0.62	.17	0.45 (0.79)	0.25	.57	-0.27 (0.80)	0.15	.74	-0.13 (0.81)	0.07	.87	0.07 (1.12)	0.04	.95	-0.19 (1.14)	0.10	.87	0.75 (1.13)	0.42	.51
Positive Affect (PANAS)	1.18 (1.25)	0.30	.35	0.28 (1.75)	0.07	.87	-1.99 (1.71)	0.51	.25	-1.98 (1.72)	0.51	.25	-2.38 (1.75)	0.61	.18	2.05 (2.41)	0.53	.40	2.87 (2.45)	0.74	.24	1.93 (2.43)	0.50	.43
Negative Affect (PANAS)	-0.07 (0.96)	0.02	.95	-2.76 (1.34)	0.93	**.04**	1.30 (1.31)	0.44	.32	1.45 (1.32)	0.49	.28	-0.28 (1.34)	0.10	.83	-0.28 (1.85)	0.10	.88	0.66 (1.88)	0.22	.73	2.90 (1.86)	0.98	.12
Temporal Experience of Pleasure	3.03 (1.70)	0.58	.08	-3.19 (2.38)	0.61	.18	-5.58 (2.32)	1.06	**.02**	-2.98 (2.34)	0.57	.20	-1.93 (2.38)	0.37	.42	6.31 (3.28)	1.20	.06	5.98 (3.34)	1.14	.07	3.29 (3.30)	0.62	.32
Quality of Life SF36																								
Physical Component Summary	-0.18 (1.26)	0.05	.89	0.36 (1.77)	0.09	.84	-0.53 (1.71)	0.14	.76	-0.65 (1.71)	0.17	.70	0.50 (1.76)	0.13	.77	0.14 (2.44)	0.04	.96	1.08 (2.46)	0.28	.66	-0.91 (2.47)	0.23	.71
Mental Component Summary	0.72 (1.74)	0.13	.68	2.57 (2.45)	0.48	.30	-3.46 (2.37)	0.64	.15	-1.50 (2.37)	0.28	.53	0.94 (2.43)	0.17	.70	1.90 (3.37)	0.35	.57	-0.25 (3.41)	0.05	.94	0.82 (3.41)	0.15	.81

The model intercept and main effects of ICBTI and any CT are not shown. Main effects for ICBTI and any CT were non significant, except for a significantly higher intercept for participants receiving ICBTI combined with Warm Baths on sleep diary WASO (β (SE) =88.12 (40.63), *P* = .03), a lower intercept for participants receiving Bright Light on Sleep Locus of Control (β (SE) = -3.48 (1.71), *P* = .04) and a higher intercept for participants receiving Physical Activity on Depression (HADS) (β (SE) = 2.48 (1.11), *P* = .03) and SF 36 Physical Component Summary (β (SE) = 3.61 (1.80), *P* = .05)

Abbreviations: SE, standard error of β; ICBTI, Internet-based Cognitive Behavioral Therapy for Insomnia; CT, Chronobiological Treatment; HADS, Hospital Anxiety and Depression Scale; PANAS, Positive Affect Negative Affect Scale; SF36, Short Form 36. Effect estimates were obtained from intent-to-treat mixed-effect regression analyses.

[a] Effect size is calculated by dividing the absolute effect estimate (β) by the residual standard deviation of the model

[b] Wake After Sleep Onset includes the time awake after final awakening, but before Lights On

Table 6. Estimated effects of time and treatment by time interactions on subjective and all outcome measures at T2 relative to T0

	T2 - T0			ICBTI x T2-T0			Bright Light x T2-T0			Physical Activity x T2-T0			Warm Baths x T2-T0			ICBTI x Bright Light x T2-T0			ICBTI x Physical Activity x T2-T0			ICBTI x Warm Baths x T2-T0		
Outcome measure	**β (SE)**	***d*[a]**	***P* Value**	**β (SE)**	***d*[a]**	***P* Value**	**β (SE)**	***d*[a]**	***P* Value**	**β (SE)**	***d*[a]**	***P* Value**	**β (SE)**	***d*[a]**	***P* Value**	**β (SE)**	***d*[a]**	***P* Value**	**β (SE)**	***d*[a]**	***P* Value**	**β (SE)**	***d*[a]**	***P* Value**
Sleep Diary																								
Sleep Efficiency (%) (Primary)	13.40 (2.25)	0.85	**<.001**	-6.48 (3.11)	0.41	**.04**	-4.06 (3.15)	0.26	.20	-6.38 (3.25)	0.40	.05	-5.10 (3.17)	0.32	.11	10.97 (4.37)	0.69	**.01**	12.85 (4.50)	0.81	**.005**	9.42 (4.43)	0.60	**.04**
Time in Bed (min)	-29.85 (8.83)	0.51	**.001**	7.52 (12.22)	0.13	.54	6.76 (12.31)	0.11	.58	9.85 (12.69)	0.17	.44	-0.75 (12.44)	0.01	.95	6.45 (17.15)	0.11	.71	-15.50 (17.60)	0.26	.38	13.71 (17.38)	0.23	.43
Sleep Onset Latency (min)	-18.40 (8.32)	0.30	**.03**	17.88 (11.51)	0.29	.12	6.09 (11.63)	0.10	.60	2.65 (12.01)	0.04	.83	3.29 (11.73)	0.05	.78	-27.75 (16.17)	0.45	.09	-31.18 (16.62)	0.51	.06	-22.16 (16.39)	0.36	.18
Wake After Sleep Onset (min)[b]	-58.53 (14.47)	0.54	**<.001**	45.70 (20.02)	0.42	**.02**	13.27 (20.25)	0.12	.51	1.47 (20.92)	0.01	.94	28.38 (20.39)	0.26	.17	-58.46 (28.13)	0.54	**.04**	-56.39 (28.92)	0.52	.05	-82.30 (28.51)	0.76	**.004**
Total Sleep Time (min)	35.34 (11.22)	0.41	**.002**	-17.95 (15.51)	0.21	.25	-7.39 (15.69)	0.09	.64	-16.01 (16.22)	0.19	.33	-20.68 (15.82)	0.24	.19	45.92 (21.80)	0.53	**.04**	42.27 (22.42)	0.49	.06	52.35 (22.11)	0.61	**.02**
Average Daytime Functioning	0.46 (0.16)	0.77	**.01**	-0.49 (0.23)	0.83	**.03**	-0.06 (0.23)	0.10	.80	-0.16 (0.24)	0.27	.49	-0.56 (0.23)	0.94	**.02**	0.26 (0.32)	0.43	.42	0.29 (0.33)	0.48	.39	1.05 (0.32)	1.76	**.001**
Difficulty Initiating Sleep	-0.35 (0.22)	0.25	.11	0.02 (0.30)	0.01	.95	-0.21 (0.31)	0.16	.48	0.22 (0.32)	0.16	.49	0.10 (0.31)	0.08	.74	0.06 (0.43)	0.05	.88	-0.51 (0.44)	0.37	.25	0.07 (0.43)	0.05	.88
Difficulty Maintaining Sleep	-1.00 (0.23)	0.72	**<.001**	0.28 (0.32)	0.20	.39	0.10 (0.32)	0.07	.77	0.14 (0.33)	0.10	.68	0.56 (0.33)	0.40	.09	-0.32 (0.45)	0.23	.48	-0.41 (0.46)	0.29	.38	-0.68 (0.46)	0.49	.14
Early Morning Awakening	-1.05 (0.23)	0.75	**<.001**	0.37 (0.32)	0.27	.24	-0.03 (0.32)	0.02	.92	0.14 (0.33)	0.10	.68	0.56 (0.32)	0.40	.08	-0.54 (0.44)	0.38	.22	-0.59 (0.45)	0.42	.19	-1.06 (0.45)	0.75	**.02**
Actigraphy																								
Sleep Efficiency (%)	2.62 (1.46)	0.34	.07	-0.28 (2.08)	0.04	.90	-1.59 (2.15)	0.20	.46	-0.45 (2.26)	0.06	.84	-2.88 (2.14)	0.37	.18	-0.23 (2.99)	0.03	.94	-0.41 (3.08)	0.05	.89	3.04 (3.00)	0.39	.31
Sleep Onset Latency (min)	-2.72 (2.55)	0.16	.29	0.94 (3.65)	0.05	.80	2.84 (3.76)	0.16	.45	5.23 (3.96)	0.30	.19	4.34 (3.75)	0.25	.25	0.73 (5.25)	0.04	.89	1.01 (5.40)	0.06	.85	-0.59 (5.26)	0.03	.91
Wake After Sleep Onset (min)[b]	-5.97 (5.45)	0.18	.28	-8.85 (7.80)	0.27	.26	3.69 (8.04)	0.11	.65	-1.16 (8.49)	0.04	.89	-0.07 (8.01)	0.00	.99	5.38 (11.22)	0.16	.63	9.19 (11.55)	0.28	.43	8.67 (11.24)	0.26	.44
Total Sleep Time (min)	-18.88 (8.96)	0.33	**.04**	5.10 (12.84)	0.09	.69	0.26 (13.25)	0.00	.98	12.46 (14.01)	0.22	.38	-4.53 (13.19)	0.08	.73	-1.53 (18.48)	0.03	.93	-20.23 (19.04)	0.36	.29	13.34 (18.51)	0.23	.47
Average Sleep Bout Duration (min)	0.98 (9.80)	0.03	.92	14.97 (13.85)	0.50	.28	1.72 (14.00)	0.06	.90	-1.61 (14.50)	0.05	.91	-0.58 (14.22)	0.02	.97	7.36 (19.67)	0.25	.71	-8.72 (20.06)	0.29	.66	-15.29 (19.81)	0.51	.44
Average Wake Bout Duration (min)	-0.04 (0.06)	0.10	.53	-0.11 (0.08)	0.30	.18	-0.06 (0.09)	0.16	.50	0.03 (0.09)	0.07	.78	0.02 (0.08)	0.04	.85	0.12 (0.12)	0.34	.30	0.08 (0.12)	0.21	.53	0.05 (0.12)	0.13	.69
Sleep related surveys																								
Insomnia Severity Index	-5.06 (1.01)	1.68	**<.001**	-0.20 (1.39)	0.07	.88	-1.96 (1.39)	0.65	.16	0.91 (1.44)	0.30	.53	-0.39 (1.39)	0.13	.78	1.91 (1.93)	0.64	.32	-2.18 (1.97)	0.72	.27	1.92 (1.93)	0.64	.32
Dysfunctional Beliefs and Attitudes	-13.88 (2.54)	1.85	**<.001**	3.63 (3.46)	0.49	.30	-0.02 (3.49)	0.00	.99	3.37 (3.62)	0.45	.35	4.13 (3.47)	0.55	.24	0.33 (4.82)	0.04	.94	-7.75 (4.95)	1.04	.12	-5.17 (4.83)	0.69	.29
Glasgow Sleep Effort Scale	-1.92 (0.50)	1.29	**<.001**	-0.67 (0.69)	0.45	.33	-0.01 (0.69)	0.01	.99	-0.16 (0.72)	0.11	.83	0.87 (0.69)	0.58	.21	1.23 (0.96)	0.83	.20	0.95 (0.98)	0.64	.34	0.69 (0.96)	0.46	.48
Sleep Locus Of Control	3.12 (1.12)	0.95	**.01**	-3.04 (1.52)	0.92	**.05**	-0.54 (1.53)	0.16	.73	-2.59 (1.59)	0.79	.11	-0.92 (1.53)	0.28	.55	2.50 (2.12)	0.76	.24	4.84 (2.18)	1.47	**.03**	3.18 (2.13)	0.97	.14
Sleep Self-Efficacy Scale	5.23 (1.26)	1.40	**<.001**	-0.16 (1.72)	0.04	.93	2.27 (1.73)	0.61	.19	-2.09 (1.79)	0.56	.25	-2.83 (1.73)	0.76	.10	-4.06 (2.40)	1.09	.09	0.84 (2.46)	0.22	.73	0.74 (2.40)	0.20	.76
Hyperarousal																								
Pre-Sleep Arousal Scale - Somatic	-0.30 (1.12)	0.10	.79	1.18 (1.52)	0.40	.44	-1.22 (1.50)	0.42	.41	0.73 (1.53)	0.25	.63	-0.01 (1.57)	0.00	1.00	-0.22 (2.04)	0.07	.92	-2.80 (2.16)	0.95	.20	-1.85 (2.12)	0.63	.39
Pre-Sleep Arousal Scale - Cognitive	-0.90 (1.35)	0.26	.51	-0.48 (1.83)	0.14	.79	-0.76 (1.80)	0.22	.67	-0.84 (1.85)	0.24	.65	-3.74 (1.88)	1.06	**.05**	-0.70 (2.46)	0.20	.78	-1.33 (2.60)	0.38	.61	3.19 (2.56)	0.91	.21
Arousal Predisposition Scale	-2.98 (1.10)	1.05	**.01**	1.86 (1.48)	0.65	.21	2.99 (1.46)	1.05	**.04**	3.50 (1.50)	1.23	**.02**	1.56 (1.53)	0.55	.31	-1.69 (1.99)	0.59	.40	-2.46 (2.11)	0.87	.24	-2.45 (2.07)	0.86	.24
Hyper Arousal Scale	-0.20 (1.00)	0.08	.84	-0.36 (1.35)	0.14	.79	-0.67 (1.33)	0.26	.61	-0.17 (1.36)	0.07	.90	-1.72 (1.39)	0.67	.22	0.23 (1.81)	0.09	.90	-0.99 (1.92)	0.38	.61	0.58 (1.89)	0.22	.76
Adult ADHD Self-Report Scale	-0.31 (0.85)	0.14	.71	-0.71 (1.15)	0.32	.54	0.24 (1.13)	0.11	.83	-0.57 (1.16)	0.26	.63	-0.90 (1.19)	0.40	.45	0.61 (1.55)	0.27	.70	0.62 (1.63)	0.28	.71	2.29 (1.61)	1.03	.16
Mood and Affect																								
Anxiety (HADS)	-1.29 (0.59)	0.72	**.03**	-0.08 (0.83)	0.05	.92	0.76 (0.83)	0.42	.36	0.37 (0.86)	0.21	.67	0.74 (0.82)	0.41	.37	-0.12 (1.16)	0.07	.92	-0.75 (1.21)	0.42	.53	0.18 (1.16)	0.10	.88
Depression (HADS)	-1.20 (0.69)	0.58	.08	0.14 (0.96)	0.07	.89	0.03 (0.95)	0.01	.98	0.13 (0.99)	0.06	.89	-0.15 (0.95)	0.07	.88	0.32 (1.34)	0.15	.81	-0.85 (1.40)	0.41	.54	0.57 (1.34)	0.28	.67
Positive Affect (PANAS)	3.77 (1.43)	0.87	**.01**	-3.89 (2.00)	0.90	.05	-1.77 (1.99)	0.41	.37	-2.21 (2.06)	0.51	.28	-3.67 (1.98)	0.85	.07	3.77 (2.79)	0.87	.18	6.74 (2.89)	1.55	**.02**	6.11 (2.79)	1.41	**.03**
Negative Affect (PANAS)	-1.97 (1.07)	0.61	.07	-1.48 (1.50)	0.46	.33	3.26 (1.49)	1.01	**.03**	0.53 (1.55)	0.16	.73	1.17 (1.48)	0.36	.43	-1.68 (2.09)	0.52	.42	1.66 (2.17)	0.51	.45	0.83 (2.09)	0.26	.69
Temporal Experience of Pleasure	5.26 (1.76)	0.99	**.003**	-4.94 (2.46)	0.93	.05	-3.21 (2.44)	0.60	.19	-3.86 (2.54)	0.73	.13	-4.36 (2.43)	0.82	.08	3.81 (3.42)	0.72	.27	6.47 (3.56)	1.22	.07	4.18 (3.43)	0.79	.22
Quality of Life SF36																								
Physical Component Summary	0.25 (1.23)	0.07	.84	-1.61 (1.70)	0.43	.34	0.16 (1.71)	0.04	.93	0.17 (1.77)	0.05	.92	-0.59 (1.70)	0.16	.73	2.10 (2.38)	0.56	.38	1.71 (2.44)	0.46	.48	0.76 (2.38)	0.20	.75
Mental Component Summary	3.10 (1.61)	0.64	.06	0.67 (2.22)	0.14	.76	-1.65 (2.24)	0.34	.46	-3.04 (2.33)	0.62	.19	0.37 (2.23)	0.08	.87	-0.73 (3.12)	0.15	.81	3.85 (3.20)	0.79	.23	1.71 (3.12)	0.35	.59

The model intercept and main effects of ICBTI and any CT are not shown. Main effects for ICBTI and any CT were non significant, except for a significantly higher intercept for participants receiving ICBTI in week 1-4 combined with Warm Baths on sleep diary WASO (b (SE) =88.64 (41.31), *P* = .03) and a higher intercept for participants receiving Physical Activity on Depression (HADS) (b (SE) = 2.25 (1.07), *P* = .04) and SF 36 Physical Component Summary (β (SE) = 3.62 (1.74), *P* = .04)

Abbreviations: SE, standard error of β; ICBTI, Internet-based Cognitive Behavioral Therapy for Insomnia; CT, Chronobiological Treatment; ISI, Insomnia Severity Index. Effect estimates were obtained from intent-to-treat mixed-effect regression analyses.

[a] Effect size is calculated by dividing the absolute effect estimate (β) by the residual standard deviation of the model

[b] Wake After Sleep Onset includes the time awake after final awakening, but before Lights On

Table 7. Means and Standard Deviations for Sleep Parameters[a]

	week 1 - 4	Inactive Ionizer		Bright Light		Physical Activiy		Warm Baths		Inactive Ionizer + ICBTI		Bright Light + ICBTI		Physical Activity + ICBTI		Warm Baths + ICBTI		All	
	week 6 - 9	ICBTI		ICBTI		ICBTI		ICBTI		no treatment									
Variable		n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
									Sleep Diary										
Sleep Efficiency (%) - Primary Outcome																			
T0		20	67.77 (15.00)	24	71.10 (11.66)	24	72.29 (12.14)	20	75.09 (11.39)	21	66.98 (11.96)	21	71.28 (10.64)	21	64.32 (24.02)	24	66.42 (17.81)	175	69.41 (15.00)
T1		19	73.79 (13.71)	22	76.99 (10.78)	22	73.01 (13.07)	20	77.32 (13.61)	21	79.32 (9.66)	21	83.15 (7.24)	20	79.16 (18.03)	22	78.58 (17.89)	167	77.68 (13.50)
T2		19	81.60 (11.11)	20	81.34 (9.12)	17	79.50 (8.56)	20	83.21 (8.31)	21	73.95 (14.58)	21	85.11 (5.81)	19	79.10 (17.71)	19	76.08 (19.90)	156	80.01 (12.93)
Time in Bed (min)																			
T0		20	479.24 (47.59)	24	483.75 (37.61)	24	471.06 (48.25)	20	470.20 (33.15)	21	482.22 (48.80)	21	458.11 (42.59)	21	485.58 (52.03)	24	473.98 (39.59)	175	475.57 (43.98)
T1		19	473.31 (45.68)	22	488.07 (57.00)	22	484.63 (63.56)	20	465.28 (39.81)	21	443.10 (39.71)	21	429.75 (41.33)	20	454.43 (40.15)	22	453.66 (42.21)	167	461.66 (50.02)
T2		19	451.80 (44.23)	20	460.50 (35.93)	17	452.12 (43.51)	20	438.84 (46.44)	21	460.14 (40.85)	21	448.93 (31.34)	19	455.85 (38.82)	19	465.52 (39.38)	156	454.19 (40.05)
Sleep Onset Latency (min)																			
T0		20	43.45 (36.96)	24	35.61 (27.55)	24	37.03 (48.86)	20	34.60 (33.11)	21	44.50 (27.54)	21	38.88 (34.06)	21	72.68 (78.98)	24	59.88 (104.91)	175	45.82 (56.90)
T1		19	44.21 (48.22)	22	33.90 (25.74)	22	35.54 (39.35)	20	33.50 (35.17)	21	28.20 (26.42)	21	21.46 (15.41)	20	37.73 (35.26)	22	34.32 (66.74)	167	33.47 (39.11)
T2		19	25.45 (27.30)	20	23.36 (19.09)	17	23.87 (23.56)	20	19.25 (17.34)	21	43.85 (41.00)	21	16.70 (11.16)	19	38.46 (41.87)	19	45.56 (95.27)	156	29.55 (42.80)
Wake After Sleep Onset (min)[b]																			
T0		20	129.40 (90.37)	24	111.35 (65.37)	24	123.59 (80.44)	20	89.56 (59.01)	21	116.20 (43.09)	21	108.44 (50.98)	21	157.24 (151.90)	24	165.51 (199.81)	175	125.77 (108.17)
T1		19	126.95 (100.89)	22	85.49 (53.67)	22	114.84 (73.21)	20	97.00 (79.95)	21	69.42 (38.56)	21	51.63 (27.91)	20	73.07 (91.55)	22	97.76 (126.42)	167	89.30 (81.61)
T2		19	71.05 (64.15)	20	62.23 (43.22)	17	71.13 (33.08)	20	60.32 (39.10)	21	103.47 (79.80)	21	50.41 (22.50)	19	75.11 (89.52)	19	114.89 (182.08)	156	75.97 (84.34)
Total Sleep Time (min)																			
T0		20	328.09 (79.03)	24	343.75 (60.47)	24	339.76 (55.49)	20	353.11 (52.24)	21	323.55 (59.65)	21	325.77 (56.82)	21	311.72 (113.57)	24	312.85 (87.94)	175	329.82 (73.10)
T1		19	348.27 (64.46)	22	376.82 (55.52)	22	351.83 (82.66)	20	356.64 (58.60)	21	351.17 (47.09)	21	356.49 (38.16)	20	359.62 (91.60)	22	358.64 (90.99)	167	357.63 (67.95)
T2		19	366.80 (45.85)	20	374.92 (45.03)	17	359.46 (53.98)	20	365.91 (54.83)	21	341.29 (82.68)	21	381.65 (38.82)	19	359.32 (80.17)	19	355.86 (96.56)	156	363.25 (64.88)
Average Daytime Functioning[c]																			
T0		20	4.54 (0.75)	24	4.35 (0.50)	24	4.57 (0.85)	20	4.55 (0.75)	21	4.63 (0.75)	21	4.77 (0.72)	21	4.79 (0.67)	24	4.43 (0.92)	175	4.57 (0.75)
T1		19	4.67 (0.90)	22	4.63 (0.75)	22	4.63 (0.86)	20	4.44 (0.74)	21	4.65 (0.78)	21	4.82 (0.84)	20	4.98 (0.79)	22	4.67 (0.86)	167	4.69 (0.81)
T2		19	4.97 (0.77)	20	4.78 (0.84)	17	5.05 (0.84)	20	4.46 (0.74)	21	4.59 (0.81)	21	4.93 (0.81)	19	4.94 (0.73)	19	4.89 (0.98)	156	4.82 (0.82)
Difficulty Initiating Sleep[d]																			
T0		20	3.26 (1.00)	24	3.56 (1.01)	24	3.10 (1.27)	20	3.17 (1.09)	21	3.60 (1.24)	21	3.32 (1.23)	21	3.50 (1.41)	24	3.20 (1.23)	175	3.34 (1.18)
T1		19	3.05 (0.86)	22	3.30 (1.04)	22	3.09 (1.26)	20	2.94 (0.91)	21	3.18 (1.11)	21	2.96 (0.96)	20	2.96 (1.20)	22	2.88 (0.98)	167	3.05 (1.04)
T2		19	2.90 (0.78)	20	2.94 (0.78)	17	2.82 (0.93)	20	2.90 (0.85)	21	3.27 (1.18)	21	2.84 (0.92)	19	2.82 (1.30)	19	3.06 (0.95)	156	2.95 (0.97)
Dificulty Maintaining Sleep[d]																			
T0		20	4.96 (0.77)	24	4.77 (1.30)	24	4.97 (0.94)	20	4.81 (0.73)	21	4.85 (0.87)	21	4.83 (1.03)	21	4.49 (1.28)	24	4.70 (1.16)	175	4.80 (1.03)
T1		19	4.20 (0.97)	22	4.06 (1.23)	22	4.52 (1.40)	20	4.22 (0.86)	21	4.17 (0.92)	21	4.01 (0.78)	20	3.62 (1.28)	22	4.05 (1.22)	167	4.11 (1.11)
T2		19	3.90 (0.89)	20	3.90 (1.30)	17	4.01 (1.16)	20	4.36 (0.99)	21	4.13 (1.29)	21	3.88 (0.82)	19	3.53 (1.37)	19	3.93 (1.01)	156	3.96 (1.12)
Early Morning Awakening[d]																			
T0		20	4.58 (0.96)	24	4.66 (1.21)	24	4.46 (1.08)	20	4.46 (0.95)	21	4.37 (1.25)	21	4.60 (1.11)	21	4.49 (1.18)	24	4.72 (1.08)	175	4.55 (1.09)
T1		19	4.05 (1.12)	22	3.68 (1.34)	22	3.81 (1.35)	20	4.05 (1.02)	21	3.94 (1.10)	21	3.61 (0.89)	20	3.42 (1.21)	22	3.84 (1.20)	167	3.80 (1.16)
T2		19	3.52 (0.85)	20	3.56 (0.92)	17	3.36 (0.85)	20	3.94 (1.06)	21	3.70 (1.26)	21	3.35 (1.04)	19	3.34 (1.15)	19	3.62 (1.21)	156	3.55 (1.05)

(continued)

Actigraphy																		
Sleep Efficiency (%)																		
T0	20	79.57 (5.48)	23	81.04 (8.37)	21	80.40 (5.73)	18	80.87 (4.49)	20	78.10 (8.23)	21	79.87 (6.62)	21	81.79 (7.54)	22	79.90 (5.56)	166	80.21 (6.62)
T1	19	79.42 (8.72)	19	80.00 (8.61)	19	80.86 (6.95)	20	82.30 (4.62)	21	79.81 (8.42)	21	81.70 (7.20)	18	84.93 (6.09)	22	84.10 (3.87)	159	81.65 (7.10)
T2	19	82.14 (7.52)	17	82.41 (8.76)	14	82.59 (7.21)	18	80.38 (8.17)	20	79.02 (10.29)	19	80.54 (8.72)	18	83.39 (5.95)	18	82.62 (4.09)	143	81.56 (7.78)
Sleep Onset Latency (min)																		
T0	20	10.10 (9.65)	23	10.00 (11.78)	21	10.90 (9.29)	18	12.39 (10.28)	20	15.64 (19.63)	21	8.54 (8.67)	21	13.48 (12.08)	22	9.72 (10.22)	166	11.28 (11.82)
T1	19	9.70 (7.11)	19	10.23 (8.67)	19	17.13 (16.43)	20	10.55 (9.75)	21	15.85 (11.98)	21	9.13 (5.13)	18	8.92 (6.26)	22	10.35 (6.89)	159	11.50 (9.88)
T2	19	7.49 (6.62)	17	9.28 (7.61)	14	13.46 (12.98)	18	13.92 (18.02)	20	16.62 (19.26)	19	10.70 (7.64)	18	18.40 (15.93)	18	12.77 (12.77)	143	12.86 (13.65)
Wake After Sleep Onset (min)[b]																		
T0	20	69.20 (29.48)	23	64.37 (24.04)	21	64.47 (25.92)	18	64.77 (16.92)	20	78.76 (34.78)	21	71.76 (28.17)	21	60.02 (26.60)	22	71.44 (26.13)	166	68.06 (26.95)
T1	19	73.32 (38.28)	19	67.42 (22.97)	19	60.87 (26.86)	20	56.11 (13.59)	21	67.27 (29.04)	21	61.46 (22.34)	18	53.25 (25.58)	22	53.41 (14.93)	159	61.57 (25.52)
T2	19	63.68 (32.48)	17	63.73 (30.09)	14	57.10 (20.51)	18	59.19 (23.50)	20	69.29 (33.45)	19	64.10 (34.59)	18	51.74 (21.05)	18	62.08 (20.88)	143	61.60 (27.77)
Total Sleep Time (min)																		
T0	20	409.33 (45.87)	23	419.08 (34.19)	21	398.09 (41.49)	18	403.64 (35.82)	20	404.64 (47.01)	21	397.30 (53.88)	21	419.45 (57.10)	22	406.12 (34.25)	166	407.41 (44.21)
T1	19	406.85 (52.08)	19	419.89 (60.23)	19	405.66 (36.72)	20	408.31 (38.19)	21	372.19 (45.01)	21	369.91 (38.28)	18	402.00 (40.12)	22	393.20 (39.82)	159	396.78 (46.49)
T2	19	392.93 (45.60)	17	400.28 (52.36)	14	392.71 (47.87)	18	377.91 (55.46)	20	383.51 (58.98)	19	382.01 (51.62)	18	396.70 (34.91)	18	401.05 (34.40)	143	390.55 (48.02)
Average Sleep Bout Duration (min)																		
T0	20	14.47 (4.79)	23	14.19 (4.90)	21	16.13 (14.23)	18	13.13 (3.02)	20	14.07 (3.75)	21	13.63 (4.36)	21	15.40 (5.55)	22	18.27 (19.51)	166	14.96 (9.48)
T1	19	14.12 (4.68)	19	13.30 (3.90)	19	40.96 (90.91)	20	33.83 (63.01)	21	21.61 (17.88)	21	21.32 (28.47)	18	19.20 (15.39)	22	14.55 (5.52)	159	22.32 (41.09)
T2	19	15.49 (5.61)	17	16.79 (16.52)	14	15.46 (4.78)	18	13.50 (3.32)	20	29.50 (49.16)	19	38.43 (106.24)	18	21.05 (16.94)	18	18.36 (23.41)	143	21.49 (44.40)
Average Wake Bout Duration (min)																		
T0	20	1.20 (0.27)	23	1.15 (0.31)	21	1.08 (0.25)	18	1.11 (0.28)	20	1.32 (0.53)	21	1.28 (0.68)	21	1.16 (0.48)	22	1.27 (0.36)	166	1.20 (0.42)
T1	19	1.19 (0.35)	19	1.09 (0.21)	19	1.11 (0.31)	20	1.01 (0.21)	21	1.31 (0.48)	21	1.05 (0.27)	18	1.06 (0.31)	22	1.17 (0.35)	159	1.13 (0.33)
T2	19	1.17 (0.29)	17	1.06 (0.17)	14	1.08 (0.17)	18	1.10 (0.38)	20	1.18 (0.27)	19	1.18 (0.71)	18	1.06 (0.32)	18	1.21 (0.33)	143	1.13 (0.37)
Sleep-related scales																		
Insomnia Severity Index																		
T0	20	16.00 (4.74)	24	16.92 (3.20)	24	15.13 (4.61)	20	16.50 (3.44)	21	16.76 (4.31)	21	15.81 (3.30)	21	16.95 (3.92)	24	16.79 (4.23)	175	16.35 (3.98)
T1	19	14.37 (4.68)	21	16.10 (3.60)	22	15.00 (4.96)	20	14.90 (4.22)	20	11.90 (5.10)	21	11.05 (4.61)	19	10.11 (4.32)	21	12.43 (4.48)	163	13.26 (4.86)
T2	17	10.94 (4.15)	19	9.63 (3.90)	16	10.38 (5.18)	20	11.05 (4.24)	20	11.40 (5.47)	20	10.40 (3.36)	19	10.37 (5.19)	19	13.26 (4.68)	150	10.94 (4.57)
Dysfunctional Beliefs and Attitudes about Sleep																		
T0	20	62.75 (13.06)	24	62.96 (14.60)	24	59.25 (15.48)	20	58.40 (12.60)	21	63.76 (15.00)	21	57.24 (9.63)	21	68.95 (13.34)	24	59.92 (15.37)	175	61.62 (14.01)
T1	18	61.67 (12.11)	21	61.67 (15.02)	22	58.91 (14.30)	20	56.55 (12.79)	20	55.35 (14.74)	21	47.86 (12.10)	19	55.95 (16.08)	21	50.62 (12.31)	162	55.99 (14.23)
T2	17	47.76 (15.30)	19	48.79 (15.95)	16	47.25 (15.50)	20	48.65 (11.97)	20	53.65 (13.89)	20	47.10 (12.12)	19	53.74 (17.88)	19	49.21 (11.48)	150	49.59 (14.23)
Glasgow Sleep Effort Scale																		
T0	20	5.15 (2.94)	24	4.58 (2.67)	24	5.25 (3.43)	20	3.70 (1.89)	21	5.19 (2.56)	21	4.14 (1.90)	21	4.95 (3.06)	24	4.83 (3.28)	175	4.74 (2.79)
T1	18	4.44 (2.68)	21	4.52 (2.60)	22	4.64 (3.08)	20	3.95 (2.56)	20	2.85 (2.62)	21	2.95 (2.06)	19	2.89 (1.79)	21	3.38 (3.04)	162	3.71 (2.64)
T2	17	3.06 (2.22)	19	2.89 (2.16)	16	2.44 (2.06)	20	2.65 (2.23)	20	2.45 (2.19)	20	2.75 (2.17)	19	3.05 (2.09)	19	3.84 (2.95)	150	2.89 (2.26)
Sleep Locus of Control																		
T0	20	24.10 (5.14)	24	20.63 (5.25)	24	24.75 (6.37)	20	23.65 (6.52)	21	22.86 (6.03)	21	23.76 (5.40)	21	22.67 (5.38)	24	22.38 (4.54)	175	23.06 (5.62)
T1	19	25.05 (5.46)	21	20.90 (5.37)	22	24.18 (5.53)	20	23.90 (5.75)	20	23.15 (7.19)	21	26.14 (5.96)	19	25.53 (6.82)	21	25.14 (5.53)	163	24.23 (6.05)
T2	17	27.24 (6.16)	19	23.00 (5.80)	16	24.25 (6.65)	20	25.85 (6.93)	20	22.80 (6.99)	20	25.80 (6.71)	19	25.05 (7.32)	19	24.79 (5.58)	150	24.83 (6.55)
Sleep Self-Efficacy Scale																		
T0	20	26.65 (6.91)	24	24.33 (4.93)	24	26.46 (6.37)	20	27.20 (5.33)	21	24.19 (6.20)	21	26.48 (4.82)	21	26.71 (5.20)	24	25.54 (5.77)	175	25.91 (5.71)
T1	19	27.68 (5.87)	21	24.10 (5.64)	22	26.41 (6.77)	20	27.80 (5.72)	20	27.20 (6.41)	21	29.57 (4.70)	19	30.21 (4.78)	21	26.90 (5.73)	163	27.44 (5.90)
T2	17	31.88 (5.77)	19	31.74 (6.89)	16	30.19 (5.14)	20	29.60 (5.62)	20	29.10 (6.77)	20	30.05 (4.51)	19	30.58 (4.82)	19	28.42 (6.22)	150	30.16 (5.76)

Abbreviations: ICBTI, Internet-based Cognitive Behavioral Therapy for Insomnia.

[a] Raw means (SDs) are presented.

[b] Wake After Sleep Onset includes time awake after final awakening, but before Lights On

[c] 1 = very poor, 2 = poor, 3 = somewhat poor, 4 = not good, not poor, 5 = somewhat good, 6 = good, 7 = very good

[d] 1 = very good, 2 = good, 3 = somewhat good, 4 = not good, not bad, 5 = somewhat bad, 6 = bad, 7 = very bad

Table 8. Means and Standard Deviations for Mood, Affect, Arousal and Quality of Life Parameters[a]

	week 1 - 4	Inactive Ionizer		Bright Light		Physical Activiy		Warm Baths		Inactive Ionizer + ICBTI		Bright Light + ICBTI		Physical Activity + ICBTI		Warm Baths + ICBTI			
	week 6 - 9	ICBTI		ICBTI		ICBTI		ICBTI		no treatment								All	
Parameter		n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
Mood and Affect																			
Anxiety (HADS)																			
T0		20	6.60 (3.52)	24	6.79 (3.64)	23	6.61 (3.17)	20	6.05 (1.99)	21	7.43 (3.60)	21	7.00 (3.30)	19	7.47 (2.74)	24	7.38 (3.49)	172	6.92 (3.21)
T1		19	6.47 (3.04)	22	7.50 (3.86)	22	6.73 (4.42)	20	6.10 (2.99)	20	6.20 (3.35)	21	6.14 (3.04)	19	5.89 (2.87)	22	7.18 (3.02)	165	6.55 (3.35)
T2		18	5.17 (2.92)	19	6.37 (3.83)	16	4.69 (1.99)	20	5.50 (3.20)	19	6.16 (4.06)	20	6.10 (2.88)	17	6.06 (3.03)	19	6.63 (2.83)	148	5.86 (3.15)
Depression (HADS)																			
T0		20	3.05 (2.95)	24	4.79 (3.40)	23	5.30 (4.76)	20	4.80 (4.36)	21	4.71 (3.55)	21	4.33 (3.54)	19	4.53 (3.85)	24	4.08 (3.23)	172	4.47 (3.72)
T1		19	3.05 (2.39)	22	5.00 (4.06)	22	4.59 (4.73)	20	4.55 (5.13)	20	3.40 (3.28)	21	3.62 (3.57)	19	2.79 (2.35)	22	3.55 (2.84)	165	3.85 (3.70)
T2		18	1.89 (2.47)	19	3.21 (2.99)	16	2.63 (2.96)	20	3.45 (4.63)	19	3.63 (3.53)	20	3.50 (3.22)	17	2.59 (2.37)	19	3.53 (3.01)	148	3.08 (3.22)
Positive Affect (PANAS)																			
T0		20	32.90 (7.68)	24	33.42 (6.22)	23	31.35 (8.45)	20	30.95 (7.53)	21	32.43 (7.39)	21	29.86 (5.43)	20	31.25 (5.76)	24	30.79 (7.03)	173	31.63 (6.96)
T1		19	33.79 (5.79)	22	33.09 (7.04)	22	31.41 (7.63)	20	29.75 (7.92)	20	33.70 (5.89)	21	31.38 (5.84)	19	33.79 (6.82)	22	32.41 (6.95)	165	32.39 (6.79)
T2		18	36.50 (6.80)	19	35.63 (5.57)	16	34.56 (7.83)	20	31.05 (7.41)	19	31.84 (5.86)	20	31.85 (6.49)	17	35.47 (6.21)	19	33.79 (6.92)	148	33.75 (6.78)
Negative Affect (PANAS)																			
T0		20	17.25 (4.84)	24	17.17 (6.32)	23	17.57 (6.83)	20	16.20 (4.67)	21	19.71 (8.65)	21	17.52 (6.07)	20	17.30 (4.77)	24	17.58 (5.84)	173	17.54 (6.10)
T1		19	17.32 (5.50)	22	18.41 (7.37)	22	18.64 (8.12)	20	15.85 (6.42)	20	17.15 (7.06)	21	15.71 (4.88)	19	16.32 (5.47)	22	17.59 (5.59)	165	17.16 (6.37)
T2		18	15.22 (4.83)	19	18.53 (6.87)	16	14.25 (4.51)	20	15.40 (7.34)	19	16.58 (6.95)	20	15.50 (5.85)	17	16.00 (4.91)	19	15.47 (3.69)	148	15.90 (5.79)
Temporal Experience of Pleasure																			
T0		20	75.85 (12.33)	24	77.29 (10.62)	23	75.13 (8.92)	20	74.30 (10.83)	21	73.43 (7.77)	21	75.62 (9.68)	20	76.00 (7.67)	24	76.29 (8.17)	173	75.53 (9.47)
T1		19	78.68 (11.04)	22	74.50 (11.75)	22	76.05 (9.14)	20	75.40 (15.26)	20	73.00 (8.52)	21	76.19 (9.82)	19	79.21 (7.12)	22	78.32 (8.40)	165	76.38 (10.37)
T2		18	80.72 (8.66)	19	79.00 (10.86)	16	77.25 (8.93)	20	75.20 (14.83)	19	73.53 (5.91)	20	76.35 (9.23)	17	78.76 (8.15)	19	76.95 (8.58)	148	77.16 (9.79)
Hyperarousal																			
Arousal Predisposition Scale																			
T0		16	36.56 (5.60)	22	35.95 (6.46)	20	36.85 (6.29)	18	35.11 (4.61)	20	36.10 (7.83)	20	34.40 (6.18)	19	36.42 (5.35)	21	37.38 (7.32)	156	36.10 (6.26)
T1		15	35.60 (5.83)	17	35.76 (5.40)	19	38.47 (6.84)	18	33.67 (5.24)	16	35.94 (9.14)	17	33.88 (5.82)	15	36.33 (6.50)	20	36.95 (5.86)	137	35.87 (6.42)
T2		14	33.64 (7.37)	17	36.00 (5.68)	16	36.13 (6.38)	14	33.71 (6.94)	16	33.56 (6.40)	19	34.47 (5.76)	13	35.69 (6.21)	17	35.65 (7.17)	126	34.88 (6.38)
Hyper Arousal Scale																			
T0		16	36.56 (6.57)	22	38.09 (7.46)	20	40.30 (6.95)	18	37.44 (5.01)	20	37.40 (8.09)	20	36.20 (6.68)	19	38.32 (5.61)	21	37.67 (6.99)	156	37.78 (6.72)
T1		15	35.33 (7.78)	17	38.47 (7.80)	19	40.00 (7.57)	18	35.83 (5.52)	16	37.31 (8.38)	17	36.06 (7.13)	15	37.33 (6.06)	20	37.90 (6.62)	137	37.35 (7.11)
T2		14	36.14 (7.30)	17	36.94 (9.34)	16	38.25 (7.43)	14	35.57 (6.85)	16	35.75 (7.30)	19	34.84 (6.09)	13	36.85 (5.47)	17	36.47 (8.06)	126	36.33 (7.22)
Adult ADHD Self-Report Scale																			
T0		16	9.94 (5.12)	22	10.14 (4.70)	20	10.05 (3.95)	18	11.00 (4.65)	20	9.90 (3.78)	20	9.55 (3.32)	19	9.63 (3.34)	21	9.67 (3.69)	156	9.97 (4.02)
T1		15	9.20 (4.84)	17	11.00 (4.89)	19	9.21 (3.49)	18	9.83 (4.94)	16	9.31 (3.96)	17	8.47 (3.48)	15	8.93 (3.17)	20	9.25 (4.58)	137	9.41 (4.18)
T2		14	9.29 (5.06)	17	9.88 (4.55)	16	8.50 (3.71)	14	10.14 (5.10)	16	8.38 (3.90)	19	9.21 (4.30)	13	8.92 (4.27)	17	9.88 (4.58)	126	9.28 (4.36)
Pre-Sleep Arousal Scale - Somatic																			
T0		16	16.69 (6.93)	22	15.41 (5.11)	20	15.70 (6.22)	18	14.56 (4.79)	20	16.10 (5.48)	20	15.30 (4.94)	19	15.16 (4.94)	21	14.95 (4.28)	156	15.46 (5.26)
T1		15	17.20 (5.83)	17	15.12 (4.17)	19	14.84 (5.38)	18	14.72 (5.48)	16	15.94 (6.53)	17	14.12 (3.55)	15	14.33 (4.03)	20	14.40 (3.27)	137	15.04 (4.83)
T2		14	15.71 (6.90)	17	13.06 (3.27)	16	14.56 (5.63)	14	14.50 (5.14)	16	16.50 (5.77)	19	14.58 (3.86)	13	14.08 (5.56)	17	14.18 (3.49)	126	14.63 (4.95)
Pre-Sleep Arousal Scale - Cognitive																			
T0		16	20.00 (7.21)	22	21.18 (7.64)	20	23.45 (8.25)	18	21.78 (6.54)	20	24.45 (7.34)	20	21.60 (6.86)	19	21.95 (7.67)	21	23.43 (6.91)	156	22.29 (7.29)
T1		15	21.67 (7.88)	17	19.65 (8.18)	19	21.47 (8.70)	18	18.83 (6.90)	16	20.25 (8.44)	17	19.88 (5.94)	15	18.73 (6.57)	20	22.15 (8.63)	137	20.38 (7.66)
T2		14	19.36 (6.33)	17	18.59 (6.95)	16	20.69 (8.48)	14	17.14 (6.33)	16	22.50 (7.87)	19	18.47 (6.41)	13	17.69 (6.21)	17	21.76 (7.45)	126	19.60 (7.11)
Quality of Life SF 36																			
Physical Component Summary																			
T0		20	44.16 (7.65)	24	47.22 (6.13)	24	47.78 (6.15)	20	46.66 (6.12)	21	46.79 (5.95)	21	46.16 (6.50)	21	47.70 (5.67)	24	48.89 (5.85)	175	46.99 (6.27)
T1		19	43.87 (7.41)	22	46.93 (4.85)	22	46.90 (6.99)	20	46.99 (5.84)	19	47.58 (4.38)	21	45.95 (6.61)	19	48.11 (4.83)	21	48.24 (4.98)	163	46.83 (5.86)
T2		18	44.71 (7.10)	19	47.84 (5.16)	16	47.42 (5.12)	20	46.32 (6.34)	20	45.91 (4.87)	20	47.57 (4.56)	19	48.00 (3.24)	19	47.45 (4.54)	151	46.90 (5.21)
Mental Component Summary																			
T0		20	47.84 (7.35)	24	44.14 (9.85)	24	44.23 (12.57)	20	45.36 (11.82)	21	44.98 (9.16)	21	47.99 (8.88)	21	45.31 (9.90)	24	42.30 (11.28)	175	45.17 (10.24)
T1		19	48.32 (7.35)	22	41.33 (11.84)	22	44.73 (10.80)	20	47.02 (9.04)	19	48.07 (9.40)	21	49.72 (7.80)	19	47.39 (11.85)	21	48.05 (9.62)	163	46.74 (9.99)
T2		18	50.81 (8.05)	19	46.36 (11.46)	16	47.97 (10.08)	20	48.82 (11.25)	20	48.89 (8.58)	20	49.60 (7.69)	19	50.46 (7.21)	19	49.00 (8.43)	151	49.00 (9.09)

Abbreviations: ICBTI, Internet-based Cognitive Behavioral Therapy for Insomnia; HADS, Hospital Anxiety and Depression Scale; PANAS, Positive Affect Negative Affect Scale; SF36, Short Form 36.

[a] Raw means (SDs) are presented.

Figure 1. CONSORT Diagram of Participant Flow

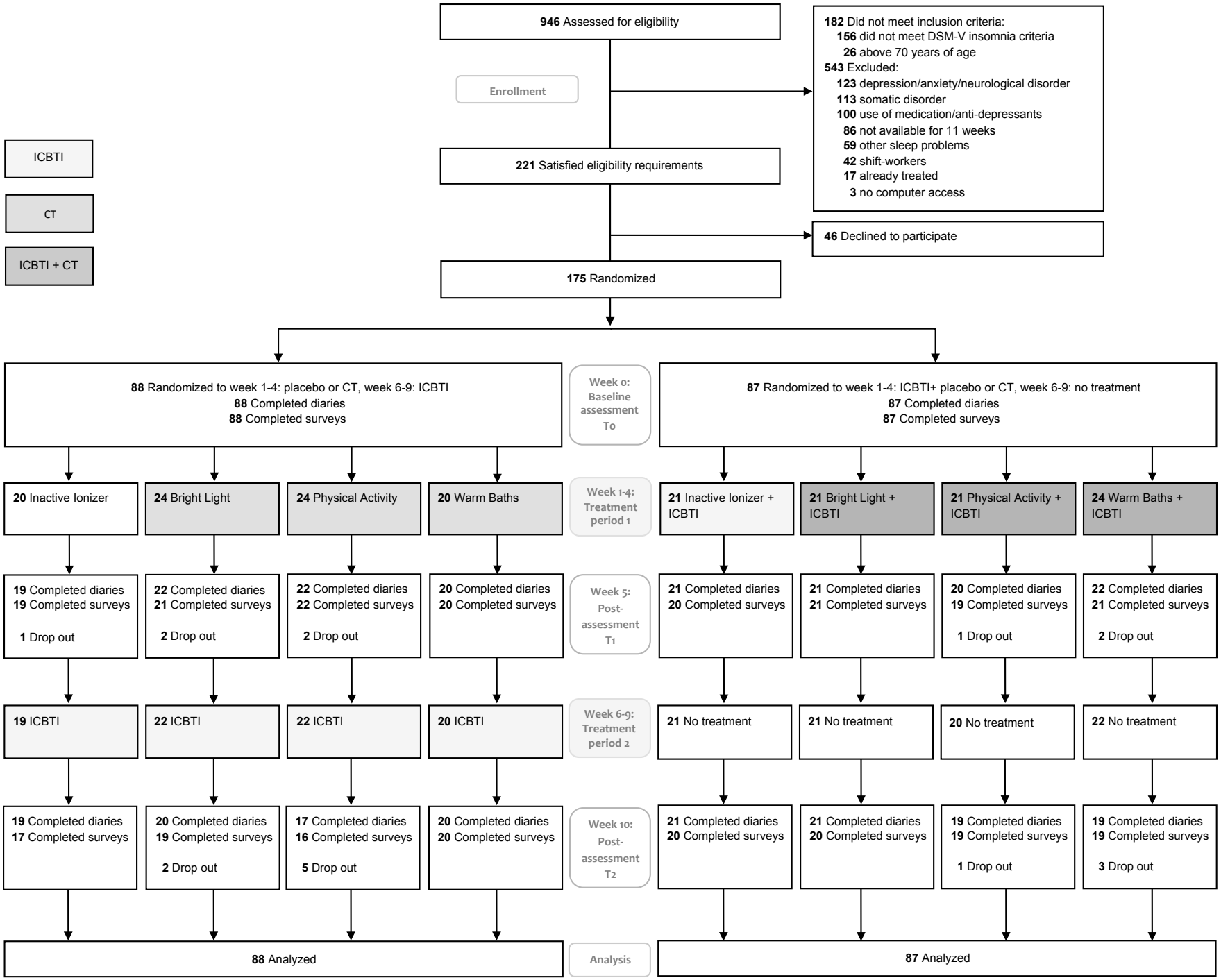
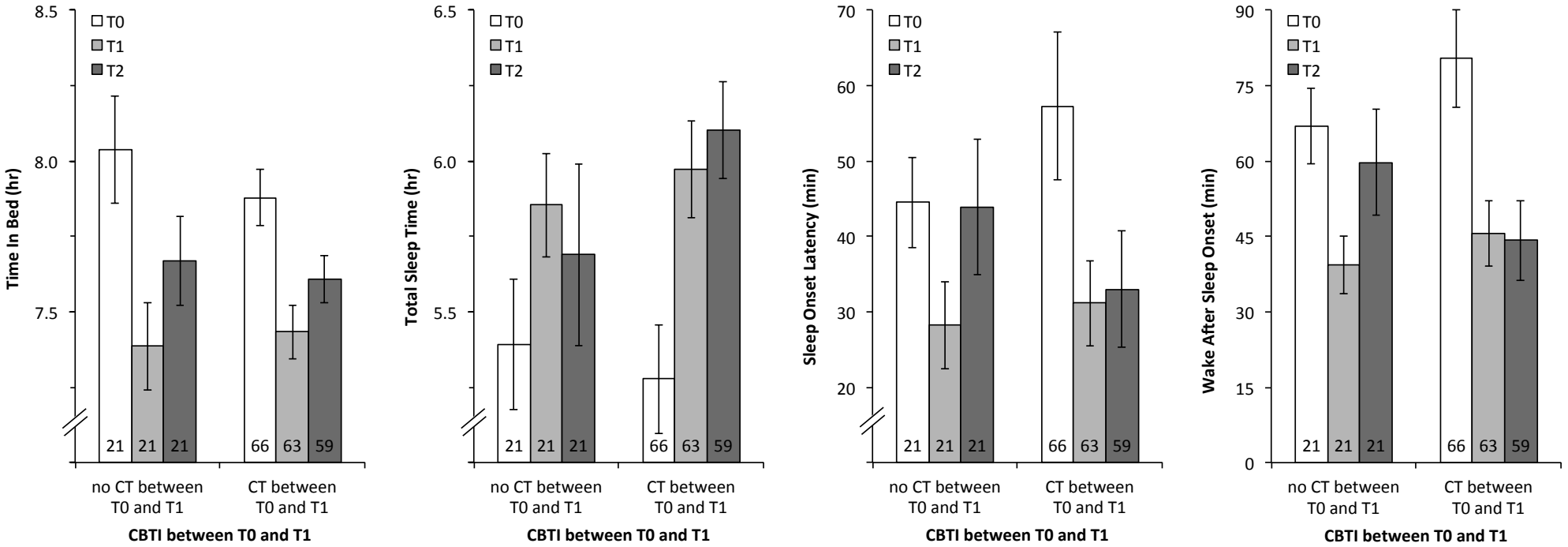


Figure 2. Secondary Sleep Outcomes.

From left to right, panels show the secondary outcome measures Time in Bed, Total Sleep Time, Sleep Onset Latency and Wake after Sleep Onset. Bars indicate baseline (T0, white), week 5 (T1, light grey) and week 10 (T2, dark gray) for the groups that received ICBTI in week 1-4 (between T0 and T1) either without CT (three bars on the left-hand side in each panel) or with CT (three bars on the right-hand side in each panel). Numbers in bars indicate the sample size of participants included at in each condition at each time point. Comparison of the light and dark grey bars shows little effect of adding CT on Total Sleep Time, Sleep Onset Latency and Wake after Sleep Onset immediately after CBTI. Only at follow-up it shows that adding CT has been of value, by promoting maintenance of the initial responses of these variables to ICBTI.



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomized trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2-4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	2, S4
	2b	Specific objectives or hypotheses	2, S4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	S5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	3, S4-5
	4b	Settings and locations where the data were collected	S5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	S6-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	2, S8-10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	S5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomization:			
Sequence generation	8a	Method used to generate the random allocation sequence	S5
	8b	Type of randomization; details of any restriction (such as blocking and block size)	S5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	S5-6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	S5-6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	S5-6
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	S10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	S10

Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	Suppl Fig 1& Results
	13b	For each group, losses and exclusions after randomization, together with reasons	Suppl Fig 1& Results
Recruitment	14a	Dates defining the periods of recruitment and follow-up	S4
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Suppl Table 1
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Suppl Tables 7 and 8
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Suppl Tables 2 and 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	S14-15
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	S14-15
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	S15-16
Other information			
Registration	23	Registration number and name of trial registry	S4
Protocol	24	Where the full trial protocol can be accessed, if available	S4
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	5