Sleep and productivity benefits of digital Cognitive Behavioural Therapy for Insomnia: a randomised controlled trial conducted in the workplace environment

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Running title: Workplace trial of dCBT for insomnia

Conflicts of interest:

The dCBT intervention (www.sleepio.com) was provided to employees of the Fortune 500 company within which this RCT was based. For commercial reasons this company do not wished to be named, or to appear as co-authors, but have agreed to this paper being published. CE is a co-founder of and a shareholder in, Big Health (Sleepio) Ltd. SB receives a salary from Big Health. AIL is employed by the University of Oxford on funds provided to the University by Big Health.

Abstract

Objective: Evaluating digital Cognitive Behavioural Therapy (dCBT) for insomnia in a workplace environment.

Methods: Within a randomized controlled trial in a Fortune 500 company, we randomized 270 self-identified poor sleepers [180M/90F: mean age 33.6y (23-56y)] to dCBT (n=135) or waiting list (WL, n=135). dCBT comprised 6 online sessions delivered by an animated therapist. Major assessments were at baseline and post-treatment.

Results: Sleep Condition Indicator (SCI) scores were significantly higher for the dCBT group [interaction term: $F(1,485) = 15.63$, $p<.0001$], representing Cohen's *d* of 1.10 following dCBT (*d*=0.34 for WL). On the Work Productivity and Impairment questionnaire, 'presenteeism' demonstrated significant improvements following dCBT [$F(1,485)=10.99$, $p=0.001$: *d* =0.64 for dCBT, *d* =0.09 for WL]. Effects for 'abseenteeism' failed to reach statistical significance ($p=0.101$).

Conclusions: dCBT is effective in improving sleep and work-based productivity in adults with insomnia.

Key words: work; presenteeism; absenteeism; dCBT; treatment

Background

Insomnia disorder comprises a complaint of poor sleep, occurring ≥3 nights per week for ≥3 months, presenting with associated daytime effects [1]. Typically, insomnia is associated with fatigue, impaired work productivity, reduced quality of life and relationship satisfaction, and increased ill health [2-5]. Importantly, and despite the fact that many people with insomnia do not actively seek treatment, amongst those who do, such real life impacts serve as drivers of help-seeking [6, 7]. However, despite the importance of daytime factors, research has been conducted primarily in clinical environments, and on sleep outcomes.

Cognitive Behavioural Therapy (CBT) for insomnia has moderate to large, and durable, effects on sleep-onset latency (time taken to fall asleep), and wake-time after sleep-onset (time awake during the night), with smaller effects upon sleep duration [e.g 8,9], when recognised effect size criteria are applied [large (d = 0.8), moderate (d = 0.5), small (d = 0.3)] [35]. There is also preliminary evidence that CBT may yield health benefits [e.g. 10-13]. Less well established is the effect that CBT may have in the context of occupational wellbeing. This is surprising given that work performance is the second most-cited area of impairment in insomnia disorder [14], and that epidemiological study suggests that trouble sleeping is associated with lower productivity and attendance [15]. Reduced productivity could be due to cognitive deficits associated with insomnia such as lapses in attention and short-term memory [16], and/or low mood, reduced motivation and self-regulatory capacity [17]. Pharmaceutical studies have demonstrated some workplace benefit [18,19], but to our knowledge, this is the first workplace-based trial of CBT to evaluate impact on sleep and occupational function. It should be noted that the advantages and disadvantages of CBT relative to sleep medication in terms of efficacy and side-effects are discussed elsewhere [9].

Recently, digital CBT (dCBT) has widened access to therapy and several trials have reported moderate to large improvements in insomnia symptoms [20-26]. In the present study, we will use a dCBT programme that has been tested versus a placebo intervention [22].

Our hypotheses were that dCBT would improve both sleep and workplace performance by the end of treatment, compared to waiting list control (WL); and that when subsequently offered dCBT, the former WL group would exhibit similar improvements. We presumed that the most salient daytime sequelae of poor sleep in a workplace setting would be perceived work performance, which could be due to improvements in (for example) alertness, attention or cognitive performance. However, we did not plan this first study to assess formally the meditational relationship between sleep change and specific aspects of workplace functioning.

Figure 1

Methods

Setting and Participants

The study was conducted in a global 'Fortune 500' company, being one of foremost employers according to an annual list compiled and published by *Fortune* magazine, based upon the largest U.S. corporations by total revenue. Its workforce comprises predominantly office-based staff. The company concerned has comprehensive health insurance and employee wellbeing programmes, but at the time of the trial this did not extend to providing CBT for insomnia.

Participants were employees who had responded to a staff wellbeing email or attended a talk on the importance of sleep. They were asked if they wanted information about a sleep trial, and

were re-contacted if they left their email address for this purpose (n=484). They were then directed to the trial website. Unfortunately, in the interests of company confidentiality, we do not have access to information on the full denominator; that is the total number of employees who had responded to the email or attended a talk about sleep, over and above the 484 respondents. Consequently, we are unable to report the total number of employees who received information about the trial. Nevertheless, it is clear that there was considerable interest such that our sample size requirement (n=200, see below) was met within 24 hours; we enrolled all 270 people who gave their consent to participate and completed baseline assessment within 24 hours of opening recruitment.

The trial was promoted as suitable for people suffering from insomnia as defined by DSM-5. However, criteria were not formally evaluated; rather, participants self-identified as having poor sleep. All employees were 18 years or older, had reliable internet access and were able to read and understand English. Participants who took medication for sleep other health problems, were not excluded, providing they reported their health to be stable. Figure 1 illustrates the flow of participants and Table 1 provides demographic and clinical information.

Table 1

Research design

The study was a parallel group, randomised controlled trial comprising 2 arms: dCBT and Waiting List control (WL). After the controlled phase, WL participants entered a deferred dCBT arm, allowing treatment replication to be investigated. The original dCBT group completed a follow-up at 3 months. Major assessments for the RCT phase were at baseline (Week 0) and post-treatment (Week 8). Further assessments comprised a naturalistic follow-up of the dCBT

arm at Week 22 (3 months post-treatment), and post-treatment for the WL/ dCBT replication arm (their Week 16). The trial design is summarized in Figure 1. We used a simple online randomisation tool with an allocation ratio of 1:1, as recommended for large clinical trials [27]. Hence the research team were unable to influence randomisation, and had no access to future allocations. All assessment, treatment, and data-gathering procedures were conducted online, and all queries/enquiries managed electronically. These procedures ensured that the trial was genuinely an evaluation of a completely online CBT approach. Participants completed an explicit consent online. The study protocol was approved by a management team of the company.

Assessment measures

Our primary outcome measure was the Sleep Condition Indicator (SCI) [28]; a brief, patient-reported outcome based upon DSM-5 criteria. It comprises two quantitative items on sleep continuity, two qualitative items on sleep satisfaction/dissatisfaction, two quantitative items on severity, and two qualitative items on attributed daytime consequences. Psychometric studies demonstrate reliability (range of α -0.81 -0.89), temporal stability, and concurrent and discriminant validity [22, 29, 30]. The SCI generates a total score in range 0-32 but is re-calculated to an intuitive 0-10 format so that the maximum score '10' represents sleep that is in the best possible 'condition'.

Secondary outcomes related to workplace productivity, sleepiness, and mental health. The Work Productivity and Impairment questionnaire [31] yields two productivity metrics. 'Absenteeism' represents work time that is missed, whereas 'presenteeism' is defined as reduction in job effectiveness. Absenteeism is calculated as *(hours missed from work due to sleep problems/ (hours missed from work due to sleep problems + hours actually worked)*. Presenteeism is calculated as *how much poor sleep affected productivity at work/10*. Values were reported 'over the past 7 days'. Scores are

multiplied by 100 to obtain a percentage. The WPAI is sensitive to the daytime effects of insomnia [32]. Sleepiness was assessed by the question *"How likely is it that you would fall asleep during the daytime without intending to, or that you would struggle to stay awake while you were doing things?"* (0 'no chance', 1 'slight chance', 2 'moderate chance', 3' high chance') derived from the Epworth Sleepiness Scale [33]. Mental health was evaluated using the well-validated GAD-2 (Generalised Anxiety Disorder-2) [34] comprising two items from the GAD-7; and the Patient Health Questionnaire (PHQ-2) [35] derived from two items of the PHQ-9.

Other descriptive demographic and clinical information was collected at baseline (see Table 1). It should be noted that dCBT users were also invited to record daily sleep diaries, from which the program algorithm deployed sleep efficiency (the proportion of time in bed asleep, expressed a percentage: SE%), to titrate the delivery of therapy and to measure therapeutic progress. Diary data were based upon a single estimate at baseline, whereas daily diary data were collected from session 1 onwards. Diary data were not collected at all from the WL group at the start of the trial, therefore, it is not possible to make diary comparisons during the active RCT phase. However, WL participants who accepted subsequent re-allocation to dCBT then completed sleep diaries, making it possible to report uncontrolled data on SE outcomes for each group. SE was the primary outcome in our original placebo-controlled trial [22].

Treatment groups

Digital Cognitive Behavioural Therapy (dCBT) for insomnia

dCBT was delivered using an established program (www.sleepio.com and associated Sleepio App) [10, 22]. The programme is fully automated and highly interactive, with no human contact. In brief, content based on validated CBT manuals, is presented by an animated virtual therapist ('The Prof'), and tailored by the programme's algorithms to each individual's characteristics,

personal goals, sleep diary data and progress. Further support is provided by system-generated email/SMS prompts, access to a post-moderated online community.

Waiting List (WL)

Participants in the WL group did not receive any intervention or advice. They completed all major assessments for the trial and were offered dCBT upon completion of the post-treatment evaluation. In effect they were a deferred entry to treatment group. All participants in both groups received the program at no personal cost.

Data analysis and management

We wanted to have a sample large enough to test our secondary outcomes of work-related productivity, as well as our primary outcome of sleep improvement. Whereas the literature indicates that a large effect size [ES: d = (M1-M2/ δpooled)] of around 1.0 might be anticipated for sleep variables [8,22], we estimated a small to moderate ES would be more likely for a daytime variable. Consequently the study was planned with 80% power to detect an ES = 0.4, thus requiring a minimum sample of 200 (n=100 per group) at $p<.05$.

Data were analyzed using Linear Mixed Models using SPSS (IBM SPSS Statistics, Version 21, 2012), which includes a flexible and powerful procedure for fitting LMMs to longitudinal data sets. LMMs are regarded as offering several advantages over traditional repeated measures analyses of variance [36]. Fixed effects included group allocation, time (pre-, post-treatment), with particular interest in the group x time interaction, which we report here. Random effects were run to account for between-subject variation. We also conducted post hoc power calculations (*d)* [37].

Results

Participants were 270 adults (67%M) with an average age of 34 years, which was broadly representative of company demographics (Table 1). All participants were employed (mostly full-time) and the majority lived with a partner (60%). The sample was generally in good health. In relation to sleep, all participants self-identified as having a problem: difficulties with falling asleep (sleep-onset problem) and remaining asleep (sleep maintenance problem) were equally common (each sub-type occurring in 60% of the sample). Around one-third reported early morning awakening. These insomnia sub-types were not mutually exclusive; that is, all participants exhibited concerns in relation to falling asleep and/or remaining asleep and/or early morning awakening. Over 40% of participants reported having sleep problems for more than 1 year. Around one-quarter had asked their doctor for advice about sleep. There were no significant differences between the dCBT and WL groups on any of these characteristics, and baseline data in Table 2 confirm the groups were similar on the dependent variables of interest.

Table 2 summarizes our trial results for all variables, and Figure 2 illustrates our findings on the SCI.

Table 2

Randomised controlled trial

During the RCT phase, 98 of 135 dCBT participants (73%) and 116 of 135 (86%) WL participants completed post-treatment assessment (Figure 1). Of the dCBT participants 47% attended 4 or more sessions. Data, however, were analysed for all 270 participants. dCBT was associated with a significant improvement in sleep (1.66 points on the SCI, compared with 0.52 in the WL group). The group x time interaction term (the main statistic of interest) for this comparison was significant [$F(1,485) = 15.63$, $p<.0001$]. A large ES was observed for dCBT (d=1.10) and a small ES for WL (d=0.34). This confirmed our expectation that sleep would be improved following active intervention. There was some reduction in associated daytime sleepiness in the dCBT condition relative to WL [$F(1,483) = 4.13$, $p=.043$]. Although the mean score approximated a slight-moderate chance of daytime sleepiness at baseline, and post-dCBT score remained in this range, there was an ES change of d=0.40, compared to no change in the WL group.

Figure 2

On the WPAI 'presenteeism' scale, a 15.4% reduction in reports of poor sleep affecting productivity at work was observed following dCBT (2.4% following WL), representing a significant [$F(1,485) = 10.99$, $p=.001$], and medium effect in terms of Cohen's criteria (d=0.67). There was no significant change in the WL condition. On the 'absenteeism' scale, a small effect was associated with pre-post change after dCBT (d=0.32), with minimal effects after WL, but the interaction term was not significant [$F(1,484) = 2.70$, $p=.101$]. Looking specifically at the component '*hours missed from work due to the sleep problem'* in the past 7 days, the CBT baseline of 2.21 (SD 3.63) reduced by 1 hour to 1.07 (SD 2.70), with minimal change following WL [2.19

(SD3.82) to 2.21 (SD 4.06)]. This change again was not statistically significant [F(1,484) = 3.07, p=.080].

We did not observe any significant change associated with dCBT relative to WL on symptoms of anxiety [F(1,481) = 1.86, p=.173] or depression [F(1,481) = 0.38, p=.846]. However, despite symptom levels being low at baseline, a medium pre-post ES (*d*=0.50) was observed in the GAD-2.

Sleep diary data collected within the dCBT programme indicated that SE increased from 76% to 87% across the six weeks, and that 81% participants recorded sleep diaries for two weeks (or more), 67% for three weeks, 47% for four weeks and 32% for six weeks or more.

Replication phase

These data are presented on the right side of Table 2 for all variables, and in Figure 2 for the primary outcome (SCI).

Results may be summarised by saying that post-treatment mean scores, and baseline to post-treatment change scores for the WL group once re-allocated to dCBT are broadly comparable to outcomes obtained for the originally allocated dCBT condition.

More specifically, the WL to CBT group's magnitude of change on the SCI [1.76 (SD 1.78)] is comparable to that of the dCBT group [1.66 (SD 1.58)], and ES data are also similar (*d*=1.05 and 1.10 respectively). Likewise, sleepiness reduced by a similar amount (*d*=0.53). Replication effects are observed also for 'presenteeism', with if anything slightly stronger magnitude (*d*=0.74 compared with 0.64). A small effect emerged on the PHQ-2 following dCBT for the WL group (*d*=0.34). Importantly, no between group comparison made following active treatment was significant on any variable [range of F=.018-.452, range of p=.502-.893].

Sleep diary data from the WL participants who subsequently participated in dCBT suggest a similar improvement level to the original dCBT group. SE increased from 77% at week 1 to 87% at week 6.

Follow up

The original dCBT group transited into 3-month post-treatment follow-up. These data are uncontrolled, but consistently suggest maintenance of therapy gains. This can be seen in Figure 1 and Table 2 for the primary outcome of the SCI, and in Table 2 across all variables where baseline to post-treatment, and baseline to follow-up change scores and ES appear similar.

Sub-group analyses

Further analyses considered the possibility that outcomes might be associated with specific sub-populations (gender, age, civil status; health baseline; duration and subtype of insomnia, and use of medical services or medications) but were all statistically non-significant. Moreover, these factors did not predict adherence to the programme, based on diary weeks completed.

Discussion

Our results provide further confirmation that dCBT is effective in the treatment of persistent poor sleep; in this instance presenting in the context of worker health and wellbeing. Effects observed on the Sleep Condition Indicator were large in magnitude (d=1.10), similar in end-point to those obtained in a previous placebo-controlled RCT [22] and durable over time. A feature of the study was its replication design, following the controlled phase. Not only was this an ethical research paradigm, given that CBT is effective, the data from this reallocated group support the

direct impact of dCBT upon sleep, and to similar endpoints. Uncontrolled sleep diary data provide supportive evidence of sleep improvement. In our placebo-controlled trial [22], the primary outcome was sleep efficiency (SE), because this captured insomnia symptoms regardless of sleep-onset or sleep-maintenance subtype. In the present study is was encouraging therefore to observe a 10% increase in SE following dCBT, and that SE post-treatment of 87% was relatively high; 85% is commonly regarded as the clinical cut-off for poor sleep in insomnia samples.

However, given the nature of our participant group, we were particularly interested to see if dCBT would also be helpful with daytime functioning, and planned our study to have sufficient power to detect differences in these outcomes. Given that our participants were drawn specifically from an occupational setting (rather than for example from health care), the functional variable of greatest interest was how they felt they performed at work. Results were encouraging with demonstrable effects upon work-based productivity ('presenteeism': d=0.64). The WPAI is self-report – the extent to which (you believe) your productivity at work is impaired by poor sleep. Nevertheless, the magnitude of the absolute change (of some 15%) following dCBT was similar to the difference in presenteeism between good sleepers and insomnia sufferers reported in a previous workforce survey (13%) [32]. Previous investigation of non-sleep variables has indicated that CBT effects are not accounted for solely by placebo factors [e.g. 22,38-40]. We suggest our findings on presenteeism are worthy of further research investigation, especially since they were also replicated (d=0.77). In this regard it is noteworthy that mechanisms implicated in reduced productivity, during experimental sleep deprivation, include reductions in attention, working memory, innovative thinking, and multitasking [41-43] A greater tendency for 'cyberloafing' (non-work related internet activity) has also been reported following short sleep, which has been argued to be associated with a reduction in self-regulatory capacity [44]

We also obtained significant effects on sleepiness (moderate ES). This is interesting because people with insomnia do not typically complain of excessive sleepiness, as indeed our baseline data confirm. It may be that participants' construct of sleepiness was more focused than usual (i.e. at work) in which case these data may complement the notion of presenteeism. We must be cautious however, because we used only an unvalidated single-item proxy for the Epworth Sleepiness Scale.

No other LMM analyses achieved statistical significance. However, examination of 'absenteeism' data shows that these were (at d=0.3) below the threshold we set for detection of significant differences. It is also noteworthy that worker absence pre-treatment (4%) afforded limited room for improvement. For GAD-2, although a medium effect was observed following dCBT there was also a small effect of WL. This, coupled with low baseline values for GAD (and for PHQ-2), likely represents an unsatisfactory test in our mixed models analysis. Future studies exploring such variables might need either larger samples or to include more severe insomnia cases.

We acknowledge several important limitations to the study. First, we did not include formal screening of other disorders of sleep. It is possible that some participants may (also) have had sleep breathing or sleep motor problems. Second, the sleep diary is a staple tool of insomnia assessment. Whereas the dCBT group used diaries as part of their therapy programme, we did not gather such data from WL participants and were therefore unable to make comparisons using such data. We have added uncontrolled sleep diary information for sleep efficiency, however caution is advised for the interpretation of this data as diary data were based upon a single retrospective estimate at baseline, whereas daily diary data were collected prospectively from session 1 onwards. Other sleep-related measures, such as actigraphy, would also be useful to consider in future research. Third, on reflection a larger sample size may have enabled us to test whether or not statistically significant effects might be demonstrable across our full range of daytime outcomes, although floor effects were likely a factor in these relatively healthy

participants. Finally, these results, though based on a substantial sample, represent data form a single company and should not be taken to be generalizable at this point.

In conclusion, the results from this study are promising. They provide an early indication that dCBT for sleep problems may be readily accessed by staff participating in workplace wellbeing and occupational health programs, and that this approach may benefit people with insomnia in relation to their sleep and their productivity. It is important that future research with dCBT continues to explore the functional outcomes that are most salient to the environments in which people live and to the complaints of poor sleep that they present.

References

[1] American Psychiatric Association. *Diagnostic and statistical manual of mental disorders (5th ed.).* American Psychiatric Association, Washington; 2013.

[2] Roth T, Ancoli-Israel S. Daytime consequences of insomnia in the United States: Results of the 1991 National Sleep Foundation Survey II. *Sleep.* 1999;22:S354-S363.

[3] Kyle SD, Morgan K, Espie CA. Insomnia and health-related quality of life. *Sleep Med Rev.* 2010:14:69–82.

[4] Espie CA, Kyle SD, Hames P, et al. The daytime impact of DSM-5 insomnia disorder: comparative analysis of insomnia subtypes from the Great British Sleep Survey (n=11, 129). *J. Clin Psychiatry.* 2012:73:e1478–e1484.

[5] Kessler RC, Berglund PA, Coulouvrat C, et al. Insomnia and the performance of US workers: results from the America Insomnia Survey. *Sleep.* 2011:34:1161-1171.

[6] Stepanski E, Koshorek G, Zorick F, Glinn M, Roehrs T, Roth T. Characteristics of individuals who do or do not seek treatment for chronic insomnia. *Psychosomatics.* 1989:30:421–427.

[7] Morin CM, LeBlanc M, Daley M, Gregoire JP, Mérette C. Epidemiology of insomnia: Prevalence, self-help treatments, consultations, and determinants of help-seeking behaviors. *Sleep Med.* 2007:7:123-130.

[8] Riemann D, Perlis ML. The treatments of chronic insomnia: A review of benzodiazepine receptor agonists and psychological and behavioral therapies. *Sleep Med Rev.* 2009:13:205–214.

[9] Mitchell MD, Gehrman P, Perlis ML, Umscheid CA. Comparative effectiveness of cognitive behavioral therapy for insomnia: a systematic review. *BMC Fam Pract.* 2012:13:40.

[10] Espie CA, Kyle SD, Miller CB, Ong J, Hames P, Fleming L. Attribution, cognition and psychopathology in persistent insomnia disorder: outcome and mediation analysis from a randomized placebo-controlled trial of online cognitive behavioural therapy. *Sleep Med.* 2014:15:913-917.

[11] Pillai V, Anderson JR, Cheng P, et al. The Anxiolytic Effects of Cognitive Behavior Therapy for Insomnia: Preliminary Results from a Web-delivered Protocol. *J Sleep Med Disord.* 2015:2:1017.

[12] Manber R, Edinger JD, Gress JL, San Pedro-Salcedo MG, Kuo TF, Kalista, T. Cognitive behavioral therapy for insomnia enhances depression outcome in patients with comborbid major depressive disorder and insomnia. *Sleep.* 2008:31:489–495.

[13] Irwin MR, Olmstead R, Carrilo C, et al. Cognitive behavioral therapy vs. Tai Chi for late life insomnia and inflammatory risk: a randomized controlled comparative efficacy trial. *Sleep.* 2014:37:1543-1552.

[14] Kyle SD, Crawford MR, Morgan K, Spiegelhalder K, Clark AA, Espie CA. The Glasgow Sleep Impact Index (GSII): A novel patient-centred measure for assessing sleep-related quality of life impairment in Insomnia Disorder. *Sleep Med.* 2013:14:493-501.

[15] Hui SK, Grandner MA. Trouble sleeping associated with lower work performance and greater health care costs: longitudinal data from Kansas State Employee Wellness program. *J Occup Environ Med.* 2015:57:1031-1038.

[16] Fortier-Brochu E, Morin CM. Cognitive impairment in individuals with insomnia: clinical significance and correlates. *Sleep*. 2014:37:1787-1798.

[17] Barnes CM. Working in our sleep: sleep and self-regulation in organizations. *Organ Psychol Rev*. 2012:2:324-257.

[18] Walsh JK, Krystal AD, Amato DA, et al. Nightly treatment of primary insomnia with eszopiclone for six months: Effect on sleep, quality of life, and work limitations. *Sleep*. 2007:30:959-968.

[19] Erman M, Guiraud A, Joish VN, Lerner D. Zolpidem extended-release 12.5 mg associated with improvements in work performance in a 6-month randomized, placebo-controlled trial. *Sleep*. 2008:31:1371-1378.

[20] Ritterband LM, Thorndike, FP, Gonder-Frederick GA, et al. Efficacy of an Internet-based behavioral intervention for adults with insomnia. *Arch Gen Psychiatry*. 2009:66: 692–698.

[21] Vincent N, Lewycky S. Logging on for better sleep: RCT of the effectiveness of online treatment for insomnia. *Sleep*. 2009:32:807–815.

[22] Espie CA, Kyle SD, Williams C, et al. A Randomized, Placebo-Controlled Trial of Online Cognitive Behavioral Therapy for Chronic Insomnia Disorder Delivered via an Automated Media-Rich Web Application. *Sleep*. 2012:35:769-781.

[23] van Straten A, Emmelkamp J, de Wit J, et al. Guided Internet-delivered cognitive behavioural treatment for insomnia: a randomized trial. *Psychol Med*. 2014:44:1521-1532.

[24] Kaldo V, Jernelöv S, Blom K, et al. Guided internet cognitive behavioral therapy for insomnia compared to a control treatment - A randomized trial. *Behav Res Ther*. 2015:71: 90-100.

[25] Blom K, Tillgren TH, Wiklund T, et al. Internet-vs. group-delivered cognitive behavior therapy for insomnia: A randomized controlled non-inferiority trial. *Behav Res Ther.* 2015:70:47-55.

[26] Blom K, Jernelöv S, Kraepelien M, et al. Internet treatment addressing either insomnia or depression, for patients with both diagnoses: a randomized trial. *Sleep.* 2015:38:267-277.

[27] Hewitt CE, Torgerson DJ. Research methods: Is restricted randomisation necessary? *BMJ.* 2006:332:1506.

[28] Espie CA, Kyle SD, Hames P, Gardani M, Fleming L, Cape J. The Sleep Condition Indicator: a clinical screening tool to evaluate insomnia disorder. *BMJ open.* 2014:4:e004183.

[29] Voinescu B, Szentagotai A. Categorical and dimensional assessment of insomnia in the general population. J Cogn Behav Psychoth. 2013:13:197-209.

[30] Palagini L, Ragno G, Caccavale L, et al. Italian validation of the Sleep Condition Indicator: A clinical screening tool to evaluate Insomnia Disorder according to DSM-5 criteria. *Int J Psychophysiol.* 2015:98:435-440.

[31] Reilly MC, Zbrozek AS, Dukes EM. The validity and reproducibility of a work productivity and activity impairment instrument. *PharmacoEconomics.* 1993:4:353-365.

[32] Bolge SC, Doan JF, Kannan H, Baran RW. Association of insomnia with quality of life, work productivity, and activity impairment. *Qual Life Res.* 2009:18:415-422.

[33] Johns MW. Reliability and Factor-Analysis of the Epworth Sleepiness Scale. *Sleep.* 1992:15:376-381.

[34] Kroenke K, Spitzer RL, Williams JBW, Monaghan PO, Lowe B. Anxiety disorders in primary care: prevalence, impairment, comorbidity and detection. *Ann Intern Med.* 2007:146:317-325.

[35] Kroenke K, Spitzer RL, Williams JBW. The Patient Health Questionnaire-2: validity of a two-item depression screener. *Med Care.* 2003:41:1284-1292.

[36] West BT, Welsch KB, Galacki AT. *Linear Mixed Models: A Practical Guide Using Statistical Software.* Florida: Chapman Hall/CRC Press; 2007.

[37] Cohen J. *Statistical Power Analysis for the Behavioral Sciences (2nd ed.).* Hillsdale: Erlbaum; 1988.

[38] Edinger JD, Wohlgemuth WK, Radtke RA. Marsh GR Quillian RE. Cognitive behavioral therapy for treatment of chronic primary insomnia: A randomized controlled trial. *JAMA.* 2001:285:1856-1864.

[39] Jacobs GD, Pace-Schott EF, Stickgold, R, Otto MW. Cognitive behavior therapy and pharmacotherapy for insomnia: A randomized controlled trial and direct comparison. *Arch Intern Med.* 2004:164:1888-1896.

[40] Rybarczyk B, Stepanski E, Fogg L, Lopez M, Barry P, Davis A. A Placebo-Controlled Test of Cognitive-Behavioral Therapy for Comorbid Insomnia in Older Adults. *J Consult Clin Psychol.* 2005:73:1164-1174.

[41] Harrison Y, Horne JA. One night of sleep loss impairs innovative thinking and flexible decision making. *Organ Behav Hum Decis Process.* 1999:78:128-145.

[42] Lim J, Dinges DF. A meta-analysis of the impact of short-term sleep deprivation on cognitive variables. *Psychol Bull.* 2010:136:375-389.

[43] Haavisto ML, Porkka-Heiskanen T, Hublin C, Härmä M, Mutanen P, Müller K, Virkkala J, Sallinen M. Sleep restriction for the duration of a work week impairs multitasking performance. *J Sleep Res.* 2010:19:444-454.

[44] Wagner DT, Barnes CM, Lim VK, Ferris DL. Lost sleep and cyberloafing: Evidence from the laboratory and a daylight saving time quasi-experiment. *J Appl Psychol.* 2012:97:1068-1076.

Tables

Table 1 Demographic and clinical characteristics of the sample (n = 270)

Characteristic	**dCBT (n = 135)**	**WL (n = 135)**	**All (n = 270)**
Age, mean (SD), y	33.9 (6.41)	33.3 (5.59)	33.6 (6.01)
Gender, n (%)			
Female	47 (34.8)	43 (31.9)	90 (33.3)
Male	88 (65.2)	92 (68.1)	180 (66.7)
Occupation, n (%)			
Employed, Full-time	131 (97.0)	133 (98.5)	264 (97.8)
Employed, part-time	4 (3.0)	2 (1.5)	6 (2.2)
Civil status, n (%)			
Are you living with someone as a partner?			
Yes	76 (56.3)	87 (64.4)	163 (60.4)
No	59 (43.7)	48 (37.6)	107 (39.6)
Physical health			
Have you ever been diagnosed with…,? Yes (%)			
High blood pressure or heart disease	7 (5.2)	4 (3.0)	11 (4.1)
Diabetes	0	1 (0.7)	1 (0.4)
Stroke or other neurological problems	0	2 (1.5)	2 (0.7)
Cancer	1 (0.7)	0	1 (0.4)
Arthritis or other joint problems	5 (3.7)	0	5 (1.9)
Respiratory disorder (asthma, COPD, etc)	12 (8.9)	12 (8.9)	24 (8.9)
Digestive disorder (ulcers, IBS, etc)	3 (2.2)	14 (10.4)	17 (6.3)
Sleep apnea	3 (2.2)	4 (3.0)	7 (2.6)

Insomnia sub-type, Yes (%) *Over the past month have you had…?*			
Difficulty falling asleep	89 (65.9)	79 (58.5)	168 (62.2)
Difficulty staying asleep	83 (61.5)	82 (60.5)	165 (61.1)
Difficulty waking up too early	48 (35.6)	47 (34.8)	95 (35.2)
How long have you had a problem with your sleep?			
< 12 months	78 (57.8)	81 (60.0)	159 (58.9)
more than 1 year	57 (42.2)	54 (40.0)	111 (41.1)
Did you sleep well as a child? n (%)			
Yes	106 (78.5)	104 (77.0)	210 (77.8)
No	29 (21.5)	31 (23.0)	60 (22.2)
Chronotype *Are you more of a morning person ("early bird") or an evening person ("night owl")?*			
Definitively a morning person	10 (7.4)	16 (11.9)	26 (9.6)
More a morning than an evening type	23 (17.0)	26 (19.3)	49 (18.1)
Neither type	24 (17.8)	24 (17.8)	48 (17.8)
More an evening than a morning type	43 (31.9)	30 (22.2)	73 (27.0)
Definitively an evening type	35 (25.9)	39 (28.9)	74 (27.4)
Have you ever asked your doctor for advice about sleep? n (%)			
Yes	37 (27.4)	34 (25.2)	71 (26.3)
No	98 (72.6)	101 (74.8)	199 (73.7)
Do you take non-prescription sleep remedies? n (%)			
Yes	35 (25.9)	24 (17.8)	59 (21.9)
No	100 (74.1)	111 (82.2)	211 (78.1)

Table 2: Treatment outcomes for sleep and daytime measures. Baseline, post-treatment, and follow-up data are presented along with change scores and within group effect sizes (Cohen's *d*). The randomized part of the study is presented to the left of the central column. To the right, WL participants were allocated to active intervention. These data, therefore, represent follow-up for the original dCBT group, and post-treatment for original WL group following their re-allocation to dCBT.

Measure/ Treatment group	Baseline Mean (SE)	Post-treatment Mean (SE)	Change from Baseline to Post-Treatment Mean (SE)	*d*	WL re-allocated to dCBT	3-Mo Follow-up/Post-Treatment Mean (SE)	Change from Baseline to 3-Mo Follow-up/Post-Treatment Mean (SE)	*d*
SCI total								
dCBT	4.78 (0.14)	6.44 (0.16)	1.66 (0.16)	1.10		6.68 (0.18)	1.90 (0.19)	1.13
WL	4.72 (0.14)	5.24 (0.15)	0.52 (0.12)	0.34		6.48 (0.18)	1.76 (0.17)	1.05
Sleepiness								
dCBT	1.53 (0.06)	1.26 (0.07)	-0.27 (0.06)	0.40		1.21 (0.07)	-0.32 (0.07)	0.71
WL	1.51 (0.07)	1.50 (0.06)	-0.01 (0.07)	0.02		1.27 (0.07)	-0.24 (0.07)	0.53
WPAI: Presenteeism								
dCBT	43.6 (1.87)	28.2 (2.20)	-15.4 (2.40)	0.64		25.2 (2.26)	-18.4(2.98)	0.77
WL	40.9 (1.70)	38.5 (2.07)	-2.41 (2.06)	0.09		23.1 (2.34)	-17.8 (2.23)	0.74

WPAI: Absenteeism								
dCBT	4.16 (0.52)	2.05 (0.48)	-2.11 (0.54)	0.32		1.92 (0.46)	-2.24 (0.77)	0.31
WL	4.16 (0.62)	3.93 (0.60)	-0.23 (0.66)	0.05		2.48(0.59)	-1.68 (0.84)	0.23
GAD-2								
dCBT	2.32 (0.13)	1.59 (0.15)	-0.73 (0.16)	0.50		1.48 (0.17)	-0.84 (0.19)	0.50
WL	2.16 (0.13)	1.80 (0.14)	-0.36 (0.12)	0.25		1.46 (0.17)	-0.70 (0.17)	0.42
PHQ-2								
dCBT	1.57 (0.11)	1.38 (0.13)	-0.19 (0.14)	0.15		1.25 (0.14)	-0.32 (0.18)	0.21
WL	1.44 (0.12)	1.30 (0.12)	-0.14 (0.14)	0.11		0.92 (0.14)	-0.52 (0.15)	0.34

dCBT: digital Cognitive Behavioral Therapy; WL: Wait List; SCI: Sleep Condition Indicator; WPAI; Work Prductivity and Impairment questionnaire; GAD-2: Generalized Anxiety Disorder questionnaire (2-item); PHQ-2: Patient Health Questionnaire (2-item).

Figures

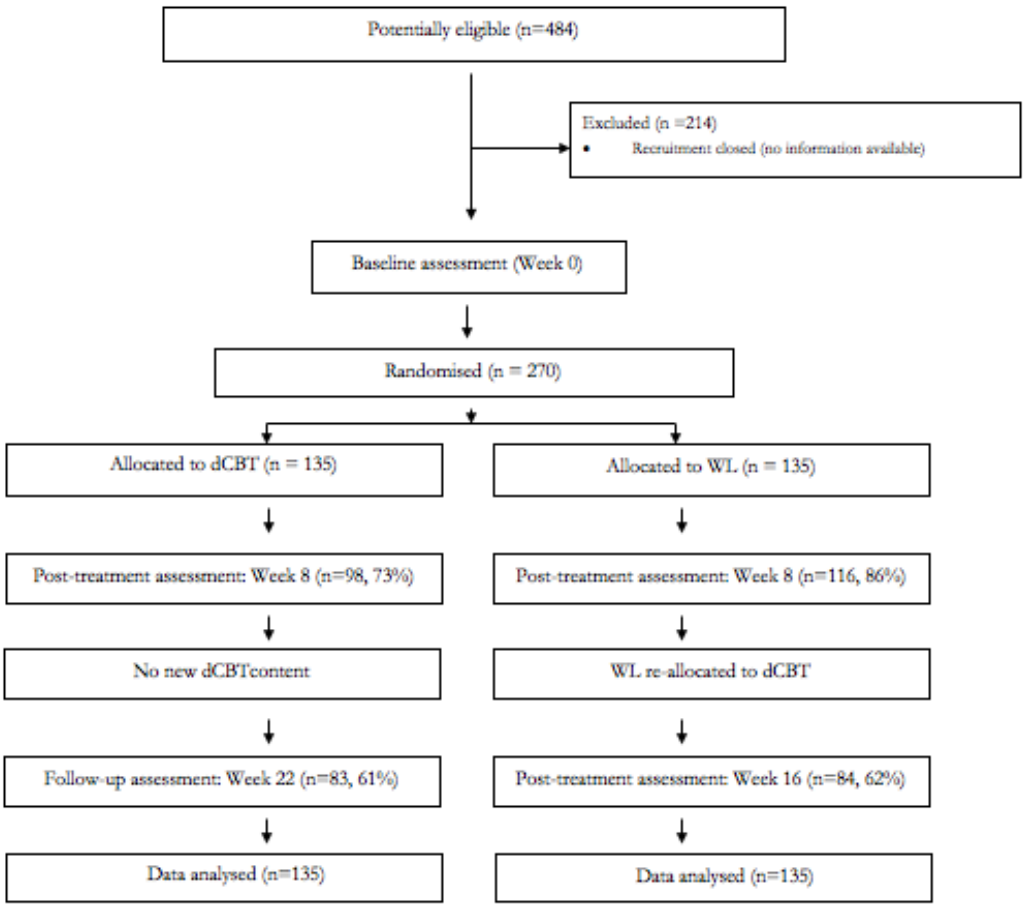


Figure 1: Trial design and flow of participants

[SCI: Sleep Condition Indicator; dCBT: digital Cognitive Behavioural Therapy for insomnia; WL: Waiting List]

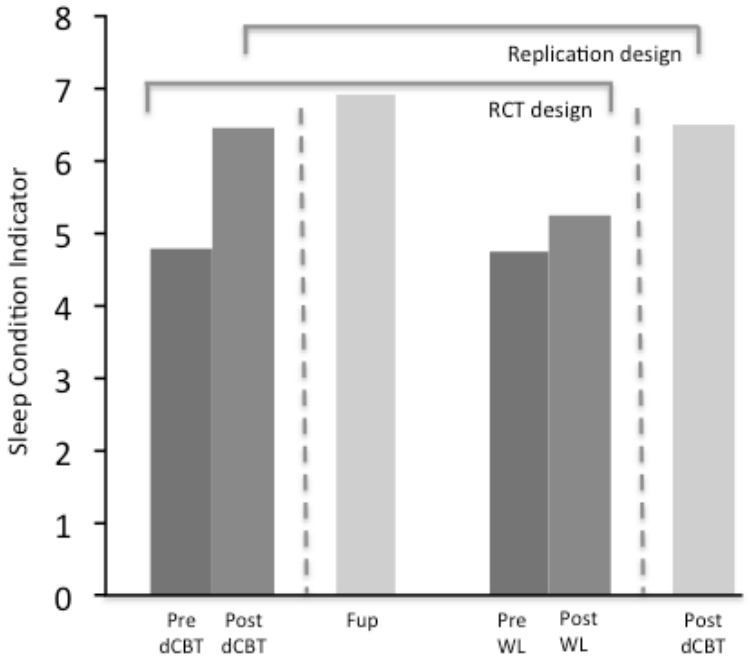


Figure 2: Treatment outcomes on the Sleep Condition Indicator for the dCBT and WL conditions. RCT comparisons are for pre- and post-treatment dCBT and WL data respectively. The WL group was then offered dCBT. The gap in the figure indicates a dysjunction here from the controlled element of the RCT design. The replication comparison of interest, therefore, is between the respective post-dCBT columns. Naturalistic follow-up data (3 mo) are presented for the orginal dCBT group only.

RCT: Randomised Clinical Trial; dCBT: digital Cognitive Behavioural Therapy for insomnia; WL; Waiting List