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Attribution, cognition and psychopathology in persistent Insomnia Disorder: outcome and mediation analysis from a randomized placebo-controlled trial of online Cognitive Behavioral Therapy

Colin A. Espie, PhD^{1,5}, Simon D. Kyle, PhD^{2*}, Christopher B. Miller, BSc³, Jason Ong, PhD⁴, Peter Hames, MA⁵, Leanne Fleming, PhD⁶

1. Sleep & Circadian Neuroscience Institute, University of Oxford
2. School of Psychological Sciences, University of Manchester
3. Woolcock Institute of Medical Research, University of Sydney
4. Rush University Medical Center
5. Sleepio Ltd.
6. University of the West of Scotland

***please address correspondence to:**

Simon D. Kyle, PhD
School of Psychological Sciences
University of Manchester
Zochonis Building, Brunswick Street
Manchester, M13 9PL
Email: simon.kyle@manchester.ac.uk

Abstract

Objectives: Insomnia patients complain that mental events keep them awake. This study investigates how cognitive behavioral therapy (CBT) affects such events, and considers how attributional, cognitive, and psychopathological symptoms may mediate sleep improvement.

Method: Pragmatic, parallel group randomized controlled trial of 164 adults (120 F: [mean 49y (18–78y)] meeting DSM-5 criteria for Insomnia Disorder, assigned to CBT (n=55; 40F), Imagery Relief Therapy (IRT placebo; n=55; 42F) or Treatment as Usual (TAU; n=54; 38F). CBT/IRT comprised 6 online sessions delivered by an animated therapist, with automated web/email support. CBT users had access to a moderated community. TAU comprised 'usual care'. Participants completed the Sleep Disturbance Questionnaire (SDQ), Glasgow Content of Thoughts Inventory (GCTI), Depression Anxiety and Stress Scales (DASS) and Sleep Condition Indicator (SCI) at baseline, post-treatment and 8 weeks follow-up.

Results: The sample was characterised by mental arousal, notably 'trying too hard' to sleep (SDQ), and by 'sleep and sleeplessness' and 'rehearsal and planning' thoughts (GCTI). Treatment effects were observed for all SDQ domains (e.g. CBT v. IRT: $d=.76$ for 'trying too hard'). CBT was also superior to IRT on the GCTI (e.g. 'rehearsal and planning', $d=.62$; 'sleep and sleeplessness', $d=.74$). CBT v. TAU comparisons yielded larger effects whereas placebo effects (IRT v. TAU) were small to moderate. Hierarchical regression demonstrated partial mediation of SCI improvement by attributional and cognitive factors ($R^2 =21-27%$) following CBT. Improvement in Sleep Efficiency appears to be independent of such factors.

Conclusion: Online CBT modifies sleep-related attributions, night-time thought content and psychopathology. This process partly mediates improvement in DSM-5 defined insomnia.

Keywords: Insomnia, sleep, treatment, psychological intervention, placebo, internet

Introduction

Insomnia Disorder comprises complaint of poor sleep, with significant daytime effects, occurring ≥ 3 nights per week for ≥ 3 months. (DSM-5, 2013).¹ The International Classification of Sleep Disorders (2nd ed.: ICSD-2)² refers to 'Psychophysiological Insomnia', where hyperarousal, maladaptive sleep behavior, a 'racing mind', and trying too hard to sleep are features. The latter nosology, in particular, implies that Cognitive Behavioral Therapy (CBT) could be an appropriate treatment. Indeed, studies (using both sets of criteria) demonstrate that CBT offers lasting benefit to both sleep-onset and sleep-maintenance insomnia.³ Recently, online CBT has shown promising results.⁴⁻⁶ We conducted the first randomized placebo controlled trial of online CBT demonstrating significant improvements in both sleep pattern and daytime functioning.⁷ Consistent with the formulation of insomnia as a psychophysiological condition, we feel it is important to reflect not only upon the impact of CBT on sleep, but also its impact on a range of secondary outcomes that are likely maintaining factors, such as attribution, cognition and psychopathological status. The objectives of this secondary analysis are: a) to evaluate the impact of CBT upon important cognitive and emotional correlates of insomnia, namely attributions for sleep disturbance (measured with the Sleep Disturbance Questionnaire)⁸, night-time thought content (measured with the Glasgow Content of Thoughts Inventory)^{9,10} and stress, depression and anxiety (measured with the Depression, Anxiety and Stress Scale)¹¹; and b) to evaluate their potential mediational role in insomnia CBT outcomes.

Methods

Design and participants

This was a pragmatic, parallel group RCT comprising online CBT, online Imagery Relief Therapy (IRT: placebo), and treatment as usual (TAU). Major assessments were at baseline, post-treatment, and follow-up 8 weeks later. Detailed methodology, including study criteria,

recruitment and participant flow, and assessment and treatment protocol information, is available⁷ and www.sleepio.com/research illustrates evaluation and intervention procedures. The study protocol was approved by the University of Glasgow, Faculty of Medicine Research Ethics Committee and all participants provided informed consent online. In brief, 164 participants [120 F: mean age 49y (18–78y)] with DSM-5 Insomnia Disorder were assigned [CBT (n=55; 40F), IRT (n=55; 42F), TAU (n=54; 38F)]. People with unstable mental/ physical health problems, suspected (other) disorders of sleep or heavy alcohol use, were excluded conservatively. The use of sleeping pills or other sleep aids was permitted and there were no baseline differences between groups.

Measures

An online *Sleep Diary* yielded ‘sleep efficiency’ data (SE, %) calculated as $\{[1 - (\text{SOL} + \text{WASO} / \text{TIB})] \times 100\}$. SOL refers to ‘sleep onset latency’ (time taken to fall sleep), WASO to ‘wake time after sleep-onset’ (total time awake resulting from awakenings in the night), and TIB to ‘time in bed’ (total time from retiring to rising). Thus, SE reflects proportion of TIB spent asleep. The *Sleep Condition Indicator* (SCI) is a brief (8-item) patient-reported outcome measure, based upon DSM-5 Insomnia Disorder criteria. Scores range from 0 – 10; higher values reflecting sleep that is in ‘better condition’. It was derived from large field studies (n=30,000+) has excellent reliability ($\alpha = 0.89$) and good concurrent validity.^{12,13}

The *Sleep Disturbance Questionnaire*⁸ (SDQ) profiles sleep beliefs, and aids tailoring and outcome evaluation. It comprises 12 items, rated for “typical nights when you don’t sleep well” (0 ‘never true’, 1 ‘seldom true’, 2 ‘sometimes true’, 3 ‘often true’, 4 ‘very often true’). Subscales reflect strength of attribution to underlying domains [e.g. ‘*My body is full of tension*’ (unable to relax), ‘*I am unable to empty my mind*’ (mental arousal), ‘*I can’t get my sleep pattern into a proper routine*’ (lack of routine), ‘*I get too “worked up” at not sleeping*’ (trying too hard)]. Data from the present study demonstrate satisfactory reliability ($\alpha = 0.82$) and moderate inter-

correlation between subscales (average $r = .40$). The *Glasgow Content of Thoughts Inventory*^{9,10} (GCTI: 25-items) asks “how often over the past 7 nights have the following thoughts kept you awake?” (rated 0 ‘never’, 1 ‘sometimes’, 2 ‘often’, 3 ‘always’: $\alpha = 0.87$ for full scale). In this study, the GCTI was reduced to 9 items following regression modelling ($\alpha = 0.79$; average $r = .38$) [i.e. ‘*what happened today and what I’ve got on tomorrow*’, ‘*things that have happened in the past and how they worked out*’, ‘*what the future might hold and what I should be doing for things to work out well*’, (rehearsal and planning); ‘*how long I’ve been lying awake*’, ‘*how I’m going to cope tomorrow if I don’t sleep well tonight*’, ‘*how out of control my sleep is and I don’t know what to do about it*’ (sleep and sleeplessness); ‘*noises I can hear in the house or from outside*’, ‘*my body feeling hot or cold; or my heart beat pounding in my head*’, ‘*trivial things of no importance that go through my mind*’ (heightened awareness)]. The *Depression, Anxiety, Stress, Scale*¹¹ (DASS: 21-items) comprises three reliable subscales [DASSdep ($\alpha = 0.88$), DASSanx ($\alpha = 0.82$), DASSstress ($\alpha = 0.90$)]. Items are rated “in relation to the past week” (0 ‘*did not apply to me at all*’, 1 ‘*applied to me to some degree, or some of the time*’, 2 ‘*applied to me to a considerable degree, or a good part of the time*’, 3 ‘*applied to me very much, or most of the time*’).

SE and SCI score were the primary sleep end-points in the RCT, and so are the dependent variables we use here to test the potential meditational effects of SDQ, GCTI and DASS measurements.

Treatment groups

CBT participants received 6 weekly sessions delivered by an animated ‘virtual therapist’ (The Prof). The programme comprised a fully automated media-rich web application, driven dynamically by baseline, adherence, performance and progress data, and including an online Wikipedia style sleep educational site, a social community of fellow users moderated by experts, and support, prompts and reminders sent by email and mobile SMS. CBT content was

consistent with the literature (details in Espie et al.).⁷ IRT was also delivered by 'The Prof' using the same application platform, and design and execution principles, but with no known active therapeutic ingredient. IRT was based on the established Steinmark & Borkovec¹⁴ quasi-desensitisation protocol. Insomnia patients often have concurrent physical and psychological symptoms, and concurrent treatments. Therefore, to reflect validity, and to permit generalizability, the protocol permitted continuation of usual health care for all participants. Aside from this, TAU alone participants comprised, effectively, a wait-list group who completed measures but received no additional help for their insomnia.

Data management and analysis

The study was designed to have 80% power to detect a medium effect size, consistent with published meta-analytic data,³ based upon a 3-group ANOVA model with fixed effects, main effects and interactions. Treatment effects were assessed using linear mixed effects models. For variables exhibiting between group differences at baseline, the baseline value was entered as a covariate. All comparisons were planned and tests were two-sided, with $p < .05$ considered to indicate statistical significance. Where appropriate, to control for multiple comparisons, a per family error rate was adopted to maintain the nominal error rate ($.05/n$ of comparisons). Mediation models evaluate mechanisms by which independent variables exert influence on a dependent variable. We examined standardized regression coefficients to determine the relationship of group allocation (following dummy variable coding) to change scores in SE/ SCI, and of group allocation to SDQ/ GCTI/ DASS change scores. We then applied hierarchical regression models to evaluate potential mediation of sleep change.

Results

Baseline characteristics

Of the four SDQ domains, the highest baseline value was for 'mental arousal' ($M = 9.15$, $SD = 2.75$) relative to 'trying too hard' ($M = 6.74$, $SD = 2.75$: $t(163) = 11.00$, $p < .001$), 'unable to relax' ($M = 6.14$, $SD = 2.38$: $t(163) = 14.81$, $p < .001$) and 'lack of routine' ($M = 5.89$, $SD = 2.34$: $t(163) = 14.30$, $p < .001$). Reports of 'trying to sleep' were also greater than 'lack of routine' ($t(163) = 4.10$, $p < .001$) and being 'unable to relax' ($t(163) = 2.93$, $p = .004$). SDQ domains inter-correlated very modestly ($r = .24-.49$), representing 6-24% of shared variance (R^2). On the GCTI, participants exhibited higher baseline scores for 'sleep and sleeplessness' ($M = 7.89$, $SD = 2.63$) and 'rehearsal and planning' thoughts ($M = 7.62$, $SD = 2.65$) compared to 'heightened awareness' thoughts ($M = 5.24$, $SD = 2.31$) [$t(163) = 12.83$, $p < .001$ and $t(163) = 10.74$ respectively, both $p < .001$]. There was no significant difference between rehearsal and planning and sleep thoughts, and the GCTI factors again moderately correlated ($r = .35-.43$, approximate $R^2 = 15\%$). Consistent with selection criteria, there was only modest baseline symptomatology on the DASS. Stress scores were significantly higher than depressive [$M = 7.80$, $SD = 3.70$ vs. $M = 5.05$, $SD = 3.01$; $t(163) = 11.1$, $p < .001$] or anxiety [$M = 2.70$, $SD = 2.20$, $t(163) = 21.0$, $p < .001$] scores, and depressive scores higher than anxiety scores [$t(163) = 11.5$, $p < .001$]. Between treatment group comparison revealed differences in pre-treatment scores for the SDQ variables 'unable to relax' [$F(2,161) = 4.34$, $p = .015$], 'mental arousal' [$F(2,161) = 3.84$, $p = .024$] and for 'heightened awareness' [$F(2,161) = 3.73$, $p = .026$] on the GCTI. Consequently, baseline values were introduced conservatively as covariates in subsequent hypothesis testing on these variables.

[Insert Table 1]

Impact of treatment on sleep-related attributions

Summary data comprising pre-treatment, post-treatment and follow-up mean (SE) values, change scores (with 95% CI) and within group effect sizes [ES: large ($d = 0.8$), moderate ($d =$

0.5), small ($d = 0.3$)] are presented in Table 1. In Table 2, relative ES are provided for each treatment comparison (CBT-TAU, IRT-TAU, CBT-IRT). For all SDQ variables, significant effects were observed, and remained highly significant when taking account of baseline values. The mixed effects model confirmed main effects for time [all $p < .001$] and for treatment \times time interactions. For 'unable to relax', comparison favored CBT at post-treatment [$F(4,263) = 3.12, p = .016$] relative to both TAU ($d = -0.72$) and IRT ($d = -0.56$) (Table 2). Effects were maintained at follow-up, with smaller standardized ES. For 'lack of routine', CBT was again superior [$F(4,266) = 4.30, p = .002$] to TAU and IRT (moderate to large ES) at post-treatment, and follow up. 'Mental arousal' [$F(4,270) = 4.65, p = .001$] and 'trying too hard' [$F(4,275) = 8.45, p < .001$] also exhibited significant interaction terms. For 'mental arousal', CBT was associated with stronger effects than TAU at post-treatment ($d = -0.90$) and follow-up ($d = -0.54$). The CBT-IRT comparison was also significant at each measurement point ($d = -0.64$ and $d = -0.19$). 'Trying too hard' reduced significantly following CBT compared with TAU ($d = -1.15$) and IRT ($d = -0.76$), and similar magnitude of effects were maintained at 8 weeks. These variables also exhibited a small placebo response (IRT-TAU) at follow-up ['mental arousal' ($d = -0.40$) and 'trying too hard' ($d = -0.35$)]. Following Bonferonni correction to maintain .05 error rate across SDQ variables (adjusted $p = .0125$) the interaction for 'unable to relax' was not significant.

[Insert Table 2 here]

Impact of treatment on night-time thinking

Main effects of time were observed for all variables [all $p < .001$]. The group \times time interaction was highly significant for thoughts about 'sleep and sleeplessness' [$F(4,266) = 10.92, p < .001$], associated with improvement in CBT relative to TAU after treatment and at 8 weeks (both $d \geq 1.00$); and by CBT relative to IRT ($d = -0.74$ and -0.56 respectively: Table 2). Superior outcomes were also demonstrated for CBT on 'rehearsal and planning' [$F(4,264) = 3.15, p = .015$] and

'heightened awareness' [$F(4,263) = 2.41, p = .049$]. Moderate effects for 'rehearsal and planning' thoughts relative to both groups were maintained at follow-up particularly for the CBT-TAU comparison. A similar pattern was observed for 'heightened awareness' with ES in the small to moderate range, however, the interaction term was no longer significant following conservative correction for multiple GCTI comparisons ($.05/3; p = .017$). Response to IRT, though inferior to CBT, was moderate for thoughts about 'sleep and sleeplessness' at post-treatment ($d = -0.42$) and follow-up ($d = -0.60$) relative to TAU. Small effects in favor of IRT relative to TAU were also obtained for the two other GCTI variables at follow-up.

Impact of treatment on symptoms of psychopathology

Main effects of time were obtained for DASSdep and DASSstress [both $p < .001$] with interaction effects also significant (respectively: [$F(4,322) = 5.91, p < .001$] and [$F(4,337) = 3.90, p = .004$]). Relative ES at post-treatment were generally small, favoring CBT over TAU and IRT (Table 2). At follow-up, ES had strengthened for the CBT-TAU and the IRT-TAU comparisons, with small additional benefits of CBT over IRT on DASSdep and DASSstress.

[Insert Table 3]

Mediation analysis

Standardized regression coefficients demonstrated significant effects on primary end-points at post-treatment (SCI: $\beta = .526$; SE: $\beta = .438$) and follow up ($\beta = .481$ and $.340$ respectively), and on potential mediators at post-treatment (SDQ: $\beta = -.469$; GCTI: $\beta = -.431$) and follow up (SDQ: $\beta = -.354$; GCTI: $\beta = -.431$; DASS: $\beta = -.359$). [All above: $p < .001$, excepting DASStotal at post-treatment ($\beta = -.169, p = .068$)]. None of the coefficients was significant for IRT.

Having further demonstrated these associations between CBT and our dependent and mediating variables (consistent with Tables 1 and 2), we focused upon post-treatment outcomes

and the influence of potential mediators. We did not find any significant mediating role of SDQ, GCTI or DASS scores or on SE outcomes ($R^2 = 0 - 3.7\%$; all $p > .20$). However, although SCI and SE change scores were moderately associated ($r = .448$, $p < .001$), there were significant findings for the SCI (Table 3). Reductions in SDQ total score explained 27% of variance in SCI outcome, with 'trying too hard' being the most predictive attribution ($R^2 = 24\%$). In a full mediation model it would be expected that adding intervention to the equation would have a non-significant effect. However, additional variance was explained [SDQ total: R^2 change = 12.8%, $F(\text{change})=13.38$, $p < .001$; SDQ 'trying too hard': R^2 change = 14.1%, $F(\text{change})=14.43$, $p < .001$]. Similarly, GCTI total score and thoughts about 'sleep and sleeplessness' demonstrated increases in variance in the combined models [GCTI total: R^2 change = 15.6%, $F(\text{change})=15.62$, $p < .001$; GCTI 'sleep and sleeplessness': R^2 change = 13.6%, $F(\text{change})=13.41$, $p < .001$]. These effects were also demonstrated in relation to psychopathological symptoms [DASS total: R^2 change = 17.1%, $F(\text{change})=20.93$, $p < .001$; DASSstress: R^2 change = 16.1%, $F(\text{change})=19.77$, $p < .001$].

It should be noted that effects on SDQ, GCTI and DASS were associated strongly with treatment (CBT: $\beta \geq .450$) compared with placebo (IRT: $\beta = .099 - .187$). 'Trying too hard' and thoughts about 'sleep and sleeplessness' were substantially inter-correlated ($r = .690$), and associations with DASS stress were more modest ($r = .374$ and $.275$ respectively). We decided, therefore, to conduct a final analysis, adding these three mediators on step one, which explained 33.2% variance. R^2 change was 10.4% on step two, again suggesting partial mediation associated with CBT ($\beta = .413$, $p < .001$). Mediation effects for IRT were not statistically significant ($\beta = .152$).

Discussion

Consistent with ICSD-2² criteria, our study confirms that people with insomnia attribute difficulty

sleeping to a racing mind and to trying too hard to sleep. They are commonly preoccupied with thoughts about sleep and sleeplessness, as well as rehearsing the day past and planning ahead. Cognitive strategies may pre-empt such mental arousal and/or obviate its effects. We observed significant effects on CBT-IRT comparisons, which, although small in magnitude (average $d = -0.32$), permit the conclusion that CBT impacted upon attribution and cognition beyond the effects of placebo. In comparison, CBT effects relative to TAU were moderate to large ($d = -0.65$). Trial methodologies do not permit conclusions to be drawn about *mechanisms* of treatment effect. However, regression modelling provided support for partial mediation of sleep improvement through cognitive change. The fact that we had a quasi-desensitization placebo arm, which did not demonstrate mediation effects, may offer greater confidence in this interpretation. Interestingly, our findings for CBT were limited to our index measure of sleep improvement. The SCI is DSM-5 based, with a score derived from quantitative items on sleep continuity, and sleep problem severity and duration; along with qualitative items on sleep satisfaction and attributed daytime consequences of poor sleep. We suggest, therefore, that cognitive therapeutic response may, at least in part, mediate the clinical experience of Insomnia Disorder. We did not find parallel mediation effects on sleep efficiency outcomes. We speculate that this may be because SE is a highly specific quantitative index of sleep pattern; indeed, one that is commonly used as a marker of behavioral dysregulation of sleep (both pattern and timing), and to quantify targets for behavioral aspects of CBT (notably stimulus control and sleep restriction therapies). Clearly further studies are required to investigate both cognitive and behavioral mediation possibilities, and importantly, other measures might be used to appraise constructs such as somatic arousal, dysfunctional beliefs and motivational state. Finally, it should be noted that we excluded participants with unstable or poor health. Our data on psychopathology were also limited, so the generalizability of our findings to people with comorbidities, or to non-Caucasian and non-UK populations, is uncertain.

References

1. Diagnostic and Statistical Manual of Mental Disorders, 4th ed (DSMIV). Washington: American Psychiatric Association; 1994.
2. International Classification of Sleep Disorders: Diagnostic and Coding Manual: 2nd ed. Westchester, IL: American Academy of Sleep Medicine; 2005.
3. 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.
4. van Straten A, Cuijpers P. Self-therapy for insomnia: A meta-analysis. *Sleep Med Rev* 2009;13: 61-71.
5. Cheng SK, Dizon J. Computerised cognitive behavioural therapy for insomnia: a systematic review and meta-analysis. *Psychother Psychosom* 2012; 81: 201-216.
6. Ritterband LM, Bailey ET, Thorndike FP, Lord HR, Farrell-Carnahan L, Baum LD. Initial evaluation of an internet intervention to improve the sleep of cancer survivors with insomnia. *Psycho-Oncology* 2012; 21: 695-705.
7. Espie CA, Kyle SD, Williams C, et al. A randomised, placebo-controlled trial of online cognitive behavioural therapy for chronic insomnia disorder delivered via an automated media-rich web application. *SLEEP* 2012; 35: 769-781.
8. Espie CA, Inglis SJ, Harvey L, Tessier S. Insomniacs' attributions: Psychometric properties of the Dysfunctional Beliefs and Attitudes about Sleep scale and the Sleep Disturbance Questionnaire. *J Psychosom Res* 2000; 48: 141-148.
9. Wicklow A, Espie CA. Intrusive thoughts and their relationship to actigraphic measurement of sleep: towards a cognitive model of insomnia. *Behav Res Ther* 2000; 38: 679-693.

10. Harvey KJ, Espie CA. Development and preliminary validation of the Glasgow Content of Thoughts Inventory (GCTI): a new measure for the assessment of pre-sleep cognitive activity. *Br J Clin Psychol*, 2004; 43: 409-420.
11. Henry JD, Crawford JR. The short-form version of the Depression Anxiety Stress Scales (DASS-21): Construct validity and normative data in a large non-clinical sample. *Br J Clin Psychol* 2005; 44: 227-239.
12. Espie CA, Kyle SD, Chylarova E, Hames P, Benzeval, M. The daytime impact of DSM-V insomnia disorder: comparative analysis of insomnia subtype from the Great British Sleep Survey (n=11,129). *J Clin Psych* 2012; 73: e1478-1484.
13. Espie CA, Kyle SD, Hames P, Gardani M, Fleming L, Cape J. The Sleep Condition Indicator (SCI): a clinical screening tool to evaluate Insomnia Disorder. *BMJ Open* in press
14. Steinmark SW, Borkovec TD. Active and placebo treatment effects on moderate insomnia under counterdemand and positive demand instructions. *J Abnorm Psychol* 1974;83: 157-63.

Table 1: Treatment outcomes for measures of attribution, thought content and psychopathology. Baseline, post-treatment and follow-up date [mean (SE)] are presented for each group along with change scores (95% CI) and within group effect sizes (Cohen's *d*). [SDQ: Sleep Disturbance Questionnaire, GCTI: Glasgow Content of Thoughts Inventory, DASS: Depression, Anxiety, Stress Scale]

Variable	Treatment Group	Baseline Mean (SE)	Post-treatment Mean (SE)	Change from Baseline to Post-Treatment (95% CI)	<i>d</i>	8-wk Follow-up Mean (SE)	Change from Baseline to Follow-up (95% CI)	<i>d</i>
SDQ - Unable to relax	CBT	5.45 (0.31)	3.60 (0.38)	-1.85 (-2.57 to -1.01)	-0.73	4.03 (0.41)	-1.42 (-2.45 to -0.60)	-0.49
	IRT	6.22 (0.31)	5.90 (0.40)	-0.32 (-1.17 to 0.27)	-0.14	5.64 (0.35)	-0.58 (-1.61 to 0.70)	-0.22
	TAU	6.76 (0.33)	6.62 (0.36)	-0.14 (-1.22 to -0.44)	-0.09	6.21 (0.41)	-0.55 (-1.31 to -0.50)	-0.26
SDQ - Mental arousal	CBT	8.38 (0.42)	6.05 (0.52)	-2.33 (-3.30 to -1.63)	-0.86	6.15 (0.53)	-2.23 (-3.44 to -1.36)	-0.69
	IRT	9.29 (0.35)	8.60 (0.44)	-0.69 (-1.61 to 0.16)	-0.25	7.72 (0.39)	-1.57 (-2.77 to -1.07)	-0.60
	TAU	9.80 (0.32)	9.38 (0.35)	-0.42 (-0.93 to -0.17)	-0.32	8.87 (0.43)	-0.93 (-1.49 to -0.50)	-0.55
SDQ - Lack of routine	CBT	5.65 (0.32)	3.74 (0.40)	-1.91 (-2.69 to -1.31)	-0.85	3.65 (0.38)	-2.00 (-2.71 to -1.34)	-0.93
	IRT	6.11 (0.34)	5.28 (0.34)	-0.83 (-1.51 to -0.18)	-0.40	4.74 (0.34)	-1.37 (-1.85 to -0.62)	-0.72

	TAU	5.91 (0.29)	5.49 (0.32)	-0.42 (-1.03 to 0.06)	-0.22	5.23 (0.36)	-0.68 (-1.28 to -0.81)	-0.33
SDQ – Trying too hard	CBT	6.25 (0.35)	3.67 (0.42)	-2.68 (-3.47 to -2.11)	-1.22	3.53 (0.45)	-2.72 (-3.66 to -2.09)	-1.11
	IRT	7.24 (0.33)	6.40 (0.43)	-0.84 (-1.82 to -0.27)	-0.34	5.90 (0.40)	-1.34 (-2.44 to -0.74)	-0.51
	TAU	6.74 (0.35)	6.11 (0.37)	-0.63 (-1.07 to -0.78)	-0.37	5.96 (0.39)	-0.78 (-1.32 to -0.24)	-0.43
GCTI – Rehearsal and planning	CBT	7.00 (0.39)	5.60 (0.44)	-1.40 (-2.39 to -0.86)	-0.56	5.43 (0.52)	-1.57 (-2.78 to -0.82)	-0.51
	IRT	7.78 (0.36)	7.35 (0.40)	-0.43 (-0.86 to 0.51)	-0.20	6.56 (0.42)	-1.22 (-1.96 to -0.87)	-0.42
	TAU	8.09 (0.32)	7.94 (0.37)	-0.15 (-0.84 to 0.08)	-0.10	7.89 (0.43)	-0.20 (-0.92 to 0.28)	-0.10
GCTI - Sleep and sleeplessness	CBT	7.53 (0.36)	4.65 (0.48)	-2.88 (-3.94 to -2.34)	-1.10	4.05 (0.49)	-3.48 (-4.62 to -2.68)	-1.14
	IRT	8.25 (0.33)	6.98 (0.41)	-1.27 (-2.07 to -0.58)	-0.55	6.23 (0.38)	-2.02 (-2.89 to -1.32)	-0.83
	TAU	7.89 (0.35)	7.47 (0.40)	-0.42 (-0.95 to 0.01)	-0.26	7.32 (0.42)	-0.57 (1.35 to 0.11)	-0.23

GCTI – Heightened awareness	CBT	4.69 (0.29)	3.42 (0.34)	-1.27 (-1.80 to -0.48)	-0.59	3.33 (0.34)	-1.36 (-2.02 to -0.57)	-0.60
	IRT	5.16 (0.29)	4.78 (0.37)	-0.38 (-1.06 to 0.21)	-0.19	4.00 (0.30)	-1.16 (-1.83 to -0.53)	-0.57
	TAU	5.87 (0.33)	5.81 (0.23)	-0.06 (-0.86 to 0.30)	-0.03	5.64 (0.22)	-0.23 (-1.01 to 0.21)	-0.11

DASS - Depression	CBT	4.98 (0.40)	3.38 (0.42)	-1.60 (-0.79 to -2.41)	-0.54	2.30 (0.35)	-2.68 (-1.08 to -3.55)	-0.85
	IRT	4.81 (0.41)	4.04 (0.43)	-0.77 (-0.12 to -1.42)	-0.33	3.81 (0.46)	-1.00 (-0.21 to -1.79)	-0.35
	TAU	5.53 (0.46)	4.53 (0.45)	-1.00 (-0.14 to -1.86)	-0.33	5.47 (0.64)	-0.06 (0.93 to -1.05)	-0.02
DASS – Anxiety	CBT	2.32 (0.27)	1.74 (0.31)	-0.58 (-0.19 to -0.98)	-0.40	1.34 (0.21)	-0.98 (-0.50 to -1.46)	-0.56
	IRT	2.63 (0.30)	2.48 (0.29)	-0.15 (0.36 to -0.67)	-0.08	2.04 (0.26)	-0.59 (-0.13 to -1.06)	-0.36
	TAU	3.29 (0.35)	2.98 (0.36)	-0.31 (0.32 to -0.95)	-0.14	2.92 (0.38)	-0.37 (0.22 to -0.96)	-0.18
DASS – Stress	CBT	7.25 (0.53)	5.04 (0.54)	-2.21 (-1.31 to -3.10)	-0.68	4.36 (0.47)	-2.89 (-1.97 to -3.80)	-0.87
	IRT	8.31 (0.51)	7.13 (0.48)	-1.17 (-0.45 to -1.89)	-0.46	6.85 (0.48)	-1.46 (-0.58 to -2.34)	-0.46
	TAU	8.08 (0.51)	7.27 (0.50)	-0.81 (0.12 to -1.73)	-0.25	7.45 (0.56)	-0.63 (0.27 to -1.52)	-0.20

Table 2: Relative effect sizes (Cohen's d) for each treatment group comparison (CBT-TAU, IRT-TAU, CBT-IRT) at post-treatment and follow-up for the SDQ (Sleep Disturbance Questionnaire), GCTI (Glasgow Content of Thoughts Inventory) and DASS (Depression, Anxiety, Stress Scale)

Variable	Relative effect size (d) Pre-treatment to post-treatment			Relative effect size (d) Pre-treatment to 8-wk Follow-up		
	CBT-TAU	IRT-TAU	CBT-IRT	CBT-TAU	IRT-TAU	CBT-IRT
SDQ						
Unable to relax	-0.72	-0.09	-0.56	-0.33	-0.04	-0.28
Mental arousal	-0.90	-0.07	-0.64	-0.54	-0.40	-0.19
Lack of routine	-0.73	-0.17	-0.53	-0.64	-0.27	-0.39
Trying too hard	-1.15	-0.23	-0.76	-0.96	-0.35	-0.51
GCTI						
Rehearsal and planning	-0.60	0.10	-0.62	-0.57	-0.28	-0.26
Sleep and sleeplessness	-1.23	-0.42	-0.74	-1.09	-0.60	-0.56
Heightened awareness	-0.42	-0.07	-0.34	-0.42	-0.34	-0.05
DASS						
Depression	-0.20	0.08	-0.31	-0.78	-0.56	-0.29
Anxiety	-0.14	0.08	-0.26	-0.31	-0.22	-0.12
Stress	-0.43	-0.13	-0.36	-0.69	-0.44	-0.26

Table 3: The mediating effects of changes in attribution, cognition and psychopathology [SDQ (Sleep Disturbance Questionnaire), GCTI (Glasgow Content of Thoughts Inventory), DASS (Depression, Anxiety, Stress Scale)] upon treatment outcome [on the Sleep Condition Indicator (SCI)]. First, the explanatory effects of each variable are presented; second, the additional effect of treatment allocation is presented (R^2 change); third β values demonstrate that mediation effects were associated with active intervention (CBT) rather than placebo (IRT).

Predictors of outcome on the SCI	R	R^2	R^2 change	β
SDQ total change	.520	.270		.353***
SDQ total change, treatment	.631	.398	.128***	
CBT				.466***
IRT				.181*
SDQ ‘trying too hard’ change	.493	.243		.323***
SDQ ‘trying too hard’ change, treatment	.620	.384	.141***	
CBT				.464***
IRT				.177*
GCTI total change	.462	.213		.293**
GCTI total change, treatment	.608	.369	.156***	
CBT				.484***
IRT				.187*
GCTI ‘sleep and sleeplessness’ change	.474	.225		.283**
GCTI ‘sleep and sleeplessness’ change, treatment	.601	.361	.136***	
CBT				.466***
IRT				.162*
DASS total change	.419	.176		.351***
DASS total change, treatment	.589	.347	.171***	
CBT				.466***
IRT				.119
DASS stress change	.434	.188		.355***
DASS stress change, treatment	.591	.349	.161***	
CBT				.450***
IRT				.099

*** $p < .001$, ** $p < .01$, * $p < .05$