Sleep Medicine 15 (2014) 913–917

Contents lists available at ScienceDirect

Sleep Medicine

journal homepage: www.elsevier.com/locate/sleep

Original Article

Attribution, cognition and psychopathology in persistent insomnia disorder: outcome and mediation analysis from a randomized placebo-controlled trial of online cognitive behavioural therapy

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ARTICLE INFO

Article history:
Received 20 January 2014
Received in revised form 28 February 2014
Accepted 3 March 2014
Available online 12 March 2014

Keywords:
Insomnia
Sleep
Treatment
Psychological intervention
Placebo
Internet

ABSTRACT

Objectives: Insomnia patients complain that mental events keep them awake. This study investigates how cognitive behavioural therapy (CBT) affects such events and considers how attributional, cognitive and psychopathological symptoms may mediate sleep improvement.
Method: A pragmatic, parallel-group randomized controlled trial of 164 adults (120 F: (mean 49 years (18–78 years)) meeting Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) criteria for insomnia disorder, assigned to CBT (n = 55; 40 F), imagery relief therapy (IRT placebo; n = 55; 42 F), or treatment as usual (TAU; n = 54; 38 F), was conducted. CBT/IRT comprised six online sessions delivered by an animated therapist, with automated web/e-mail 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-week 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 vs. IRT: d = 0.76 for 'trying too hard'). CBT was also superior to IRT on the GCTI (e.g., 'rehearsal and planning', d = 0.62; 'sleep and sleeplessness', d = 0.74). CBT vs. TAU comparisons yielded larger effects, whereas placebo effects (IRT vs. 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.

1. 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 behaviour, a 'racing mind' and trying too hard to sleep are features. The latter nosology, in particular, implies that cognitive behavioural 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 upon not only the impact of CBT on sleep but also its impact on a

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http://dx.doi.org/10.1016/j.sleep.2014.03.001
1389-9457/

range of secondary outcomes that are likely maintaining factors, such as attribution, cognition and psychopathological status. The objectives of this secondary analysis were: (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 (SDQ)) [8], night-time thought content (measured with the Glasgow Content of Thoughts Inventory (GCTI)) [9,10], and stress, depression and anxiety (measured with the Depression, Anxiety and Stress Scales (DASS)) [11]; and (b) to evaluate their potential meditational role in insomnia CBT outcomes.

2. Methods

2.1. Design and participants

This was a pragmatic, parallel-group randomized controlled trial (RCT) comprising online CBT, online imagery relief therapy (IRT: placebo) and treatment as usual (TAU). Major assessments were at baseline, post treatment and 8-week follow-up. Detailed methodology, including study criteria, recruitment and participant flow and assessment and treatment protocol information, is available [7] and the link 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 49 years (18–78 years)) meeting Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) criteria for insomnia disorder were assigned (CBT (n = 55; 40 F), IRT (n = 55; 42 F) and TAU (n = 54; 38 F)). People with unstable mental/physical health problems, and suspected pf (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 the groups.

2.2. Measures

An online *Sleep Diary* yielded 'sleep efficiency' data (SE, %) calculated as {[1-(SOL + WASO/TIB)] × 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 the proportion of TIB spent asleep. The *Sleep Condition Indicator* (SCI) is a brief (eight-item) patient-reported outcome measure, based upon DSM-5 insomnia disorder criteria. Scores range from 0 to 10; higher values reflect sleep, that is, in 'better condition'. It was derived from large field studies ($\underline{n}$ = 30,000+), and it has excellent reliability (α = 0.89) and good concurrent validity [12,13].

The *SDQ* [8] 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' and 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) and '*I get too "worked up" at not sleeping*' (trying too hard)). Data from the present study demonstrate satisfactory reliability (α = 0.82) and moderate intercorrelation between subscales (average r = 0.40). The *GCTI* [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' and 3 'always': α = 0.87 for full scale). In this study, the GCTI was reduced to nine items following regression modeling (α = 0.79; average r = 0.38) (i.e., '*what happened today and what I've got on tomorro*', '*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 (α = 0.88), DASSanx (α = 0.82), DASSstress (α = 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*' and 3 '*applied to me very much, or most of the time*').

SE and SCI scores are 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.

2.3. Treatment groups

CBT participants received six 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 e-mail 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 and Borkovec [14] 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 that completed measures but received no additional help for their insomnia.

2.4. 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 three-group analysis of variance (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 $p < 0.05$ 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 (0.05/n of comparisons). Mediational 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 the hierarchical regression models to evaluate potential mediation of sleep change.

3. Results

3.1. Baseline characteristics

Of the four SDQ domains, the highest baseline value was for 'mental arousal' (mean (M) = 9.15, standard deviation (SD) = 2.75)