Post-print Study on the Intervention Efficacy of Online Brief Behavioral Therapy for Insomnia Disorder

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Abstract

Background Insomnia disorder is a common psychiatric condition that brings serious negative impacts to patients' lives and health. Traditional Cognitive Behavioral Therapy for Insomnia (CBT-I) is an effective non-pharmacological treatment, but its complex operation, time-consuming nature, and low compliance limit its application in real-world settings. Brief Behavioral Therapy for Insomnia (BBT-I) is a simplified treatment based on CBT-I, with comparable efficacy to CBT-I but more suitable for real-world promotion. However, whether BBT-I is applicable to Chinese populations with insomnia disorder remains unclear, and research on BBT-I delivered through online modalities is particularly lacking.

Objective This study aims to investigate the efficacy of online BBT-I (eBBT-I) delivered via WeChat mini-programs in improving insomnia among Chinese patients with insomnia disorder, as well as its impact on patients' sleep-related beliefs and attitudes.

Methods This study employed a prospective non-randomized controlled design, with insomnia disorder patients from the Sleep Clinic of the Department of Psychiatry at the First Affiliated Hospital of Jinan University between February and November 2023 designated as the intervention group, and insomnia disorder volunteers recruited online and offline designated as the control group. The intervention group received a 2-week eBBT-I treatment, while the control group received a pseudo-intervention of mental health education. The Insomnia Severity Index (ISI) and the Brief Dysfunctional Beliefs and Attitudes about Sleep Scale (DBAS-16) were administered before and after the intervention to evaluate treatment efficacy.

Results The study ultimately included 35 patients in the intervention group and

30 in the control group. Primary outcome measures: Group and time showed a significant interaction effect on ISI scores (P<0.05); both group and time demonstrated significant main effects on ISI scores (P<0.05). Comparison of ISI scores between the two groups at 3 days before intervention (baseline) showed no statistically significant difference (P>0.05); at 14 days post-intervention, the intervention group had lower ISI scores than the control group (P<0.05); the intervention group' s ISI scores at 14 days post-intervention were lower than its baseline scores (P<0.05). Secondary outcome measures: No significant interaction effect between group and time on DBAS-16 scores (P>0.05); time showed a significant main effect on DBAS-16 scores (P<0.05); group showed no significant main effect on DBAS-16 scores (P>0.05). Comparison of DBAS-16 scores between the two groups at 3 days before intervention (baseline) and 14 days post-intervention showed no statistically significant difference (P>0.05); the intervention group' s DBAS-16 scores at 14 days post-intervention were higher than its baseline scores (P<0.05). These results indicate that eBBT-I effectively improved insomnia symptoms and negative impacts in patients with insomnia disorder, though its effect on improving sleep beliefs and attitudes remains to be enhanced.

Conclusion This study supports the feasibility and efficacy of eBBT-I in treating insomnia among Chinese patients with insomnia disorder, offering convenience for both patients and clinicians through more economical and efficient means, providing a new option for non-pharmacological treatment of insomnia disorder, and offering valuable exploration for the application of digital tools in the sleep field.

Full Text

The Effect of Online Brief Behavioral Therapy for Insomnia on Insomnia Disorders

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Abstract

Background: Insomnia disorder is a common mental health condition that significantly impacts patients'lives and well-being. Traditional cognitive-behavioral therapy for insomnia (CBT-I) is an effective non-pharmacological treatment method, but its complexity, time-consuming nature, and low compliance limit

its real-world application. Brief behavioral therapy for insomnia (BBT-I), based on CBT-I principles, offers comparable efficacy while being more suitable for real-world dissemination. However, the applicability of BBT-I to the Chinese population with insomnia disorder remains unclear, and research on BBT-I conducted online is lacking.

Objective: This study aims to investigate the efficacy of online e-aid brief behavioral therapy for insomnia (eBBT-I) delivered via WeChat Mini Program in improving insomnia symptoms among Chinese patients with insomnia disorder. Additionally, the study explores its impact on patients' sleep beliefs and attitudes.

Methods: This study employed a prospective non-randomized controlled design. Insomnia disorder patients from the Sleep Clinic at the First Affiliated Hospital of Jinan University between February and November 2023 were assigned to the intervention group. Insomnia disorder volunteers recruited online and offline were assigned to the control group. The intervention group received a 2-week eBBT-I treatment, while the control group received a sham intervention of mental health education. The severity of insomnia was assessed using the Insomnia Severity Index (ISI) and the Dysfunctional Beliefs and Attitudes about Sleep-16 (DBAS-16) questionnaire before and after the intervention to evaluate its effectiveness.

Results: The study ultimately included 35 patients in the intervention group and 30 patients in the control group. Key outcome measures: There was a significant interaction effect between group and time for Insomnia Severity Index (ISI) scores ($P<0.05$). Group and time separately had significant main effects on ISI scores ($P<0.05$). No statistically significant difference in ISI scores was observed between the two groups at baseline (pre-intervention) ($P>0.05$). After 14 days of intervention, the intervention group had lower ISI scores than the control group ($P<0.05$). Within the intervention group, ISI scores decreased after 14 days compared to baseline ($P<0.05$). Secondary outcome measures: There was no interaction effect between group and time for DBAS-16 scores ($P>0.05$). Time had a significant main effect on DBAS-16 scores ($P<0.05$). Group did not have a significant main effect on DBAS-16 scores ($P>0.05$). No statistically significant difference in DBAS-16 scores was found between the two groups at baseline or after 14 days ($P>0.05$). However, within the intervention group, DBAS-16 scores increased after 14 days compared to baseline ($P<0.05$). This indicates that eBBT-I effectively improved insomnia symptoms and negative impact in patients with insomnia disorder, but further improvement in sleep beliefs and attitudes is still needed.

Conclusion: This study supports the feasibility and effectiveness of eBBT-I in the treatment of insomnia disorder among Chinese patients. It provides a more economical and efficient approach for both healthcare providers and patients, offering a new non-pharmacological option for insomnia treatment. Additionally, it contributes to the exploration of digital tools in the field of sleep.

Keywords: Insomnia disorder; E-aid brief behavioral therapy for insomnia; Non-drug treatment for insomnia; Digital medical diagnostic and treatment tools; Insomnia Severity Index; Sleep beliefs and attitudes

Introduction

Insomnia disorder (ID) is a condition characterized by difficulty falling asleep, easy awakening, and early morning awakening [1]. The global prevalence of ID is 8%~18% [2], making it the second most prevalent mental illness worldwide [3]. Moreover, ID is highly correlated with cognitive dysfunction [4], anxiety disorders [5], depression [6], and diabetes [7], becoming an important clinical problem.

Treatment for insomnia disorder mainly includes conventional pharmacotherapy and non-pharmacological treatments represented by cognitive-behavioral therapy for insomnia (CBT-I). Among these, CBT-I is favored by clinical researchers due to its advantages of minimal adverse effects and durable efficacy [8]. However, traditional CBT-I comprises multiple treatment components including sleep restriction therapy, stimulus control therapy, sleep hygiene education, relaxation training, and cognitive restructuring, typically requiring 6-10 weeks [9]. This results in high training costs for practitioners and time/economic costs for patients, while also reducing patient compliance [10]. Notably, a meta-analysis on CBT-I adherence indicated that CBT-I conducted in real-world clinical settings has high dropout rates [11], reflecting the application challenges of CBT-I in real-world contexts.

Based on this clinical reality, Troxel et al. [12] extracted two core therapeutic components from CBT-I—stimulus control therapy and sleep restriction therapy —to develop brief behavioral treatment for insomnia (BBT-I). Stimulus control therapy requires patients to enter the bedroom only when feeling sleepy to establish a conditioned response with the bed, while sleep restriction therapy improves sleep efficiency by moderately limiting time in bed. The treatment course is reduced to half that of traditional CBT-I, yet demonstrates excellent improvement effects on insomnia symptoms. Furthermore, a non-inferiority study showed no significant difference in efficacy between CBT-I and BBT-I [13]. Therefore, BBT-I may be a more suitable non-pharmacological treatment for real-world implementation. However, existing BBT-I research has primarily focused on foreign populations, particularly veterans and elderly groups, lacking supporting evidence for treatment effects in the general Chinese population. Additionally, no studies have investigated BBT-I delivered through online treatment modalities.

Given that the effectiveness of online CBT-I has been confirmed in multiple studies [14], delivering BBT-I in an online format (e-aid BBT-I, eBBT-I) holds significant clinical importance. It can not only reduce learning costs for clinicians and time costs for patients with insomnia disorder, but also enable patients to review learning materials repeatedly to better grasp treatment essentials. There-

fore, this study aims to investigate the efficacy of eBBT-I for Chinese patients with insomnia disorder in real-world clinical practice through a prospective non-randomized controlled study.

Methods

Study Design and Inclusion/Exclusion Criteria

This study employed a prospective non-randomized controlled design. Participants were sourced from patients with insomnia disorder attending the Sleep Clinic of the Department of Psychiatry at the First Affiliated Hospital of Jinan University between February and November 2023, as well as through recruitment posters at the outpatient clinic and online advertisements. This study was approved by the Research Ethics Committee of the First Affiliated Hospital of Jinan University (Ethics Number: KY-2023-113).

Inclusion criteria: (1) Age 18-60 years; (2) Diagnosis of insomnia disorder according to the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) criteria, assessed by two attending physicians or higher; (3) No sleep-aid medication use for at least 7 days; (4) Junior high school education or higher and able to use a mobile phone to complete eBBT-I learning and intervention; (5) Provided informed consent.

Exclusion criteria: (1) Severe physical illness or mental disorders; (2) Sleep apnea syndrome or restless leg syndrome; (3) Shift or rotating shift workers; (4) Pregnant or lactating women; (5) Suicidal or self-harm tendencies; (6) Substance abuse or regular sedative-hypnotic medication use; (7) Non-compliance with eBBT-I requirements.

Patients were divided into an intervention group and a control group. The intervention group consisted of insomnia disorder patients from the hospital outpatient clinic, while the control group comprised insomnia disorder volunteers recruited through various platform advertisements and posters. The intervention group received eBBT-I intervention using the WeChat Mini Program "Online Sleep Management Platform" (hereinafter referred to as "the platform") developed by Pass Sleep Technology (Shenzhen) Co., Ltd., while the control group received a sham intervention consisting of mental health education videos.

Sample size was calculated using G*Power software for repeated measures ANOVA, with a medium effect size of f=0.25 and α=0.05. The calculation indicated that 66 participants were needed to achieve a statistical power of 0.8. In the final enrollment, 66 participants in the intervention group and 45 in the control group completed baseline data collection. The intervention period lasted 2 weeks, and in the post-intervention data collection after 2 weeks, 48 and 34 participants completed the assessment in the intervention and control groups, respectively. Among these, 6 participants in the intervention group took sleeping pills multiple times, 3 regularly napped and consumed alcohol, tobacco, or tea, and 4 voluntarily withdrew; 4 participants in the control group

received pharmacological treatment for insomnia disorder and were therefore excluded from data analysis. The final sample included 35 participants in the intervention group and 30 in the control group, with a completion rate of 53.03% and dropout rate of 46.97% in the intervention group, which is similar to dropout rates reported in eCBT-I studies [15].

Intervention Methods and Process

Questionnaire Administration

(1) General Information Questionnaire (including gender and age); (2) Dysfunctional Beliefs and Attitudes about Sleep-16 (DBAS-16) [16]; (3) Insomnia Severity Index (ISI) [17].

Intervention Procedure After enrollment, all participants accessed the Mini Program by scanning the QR code provided by the attending physician, completed registration by filling in basic personal information, and added the research team' s WeChat contact for subsequent intervention guidance. They were informed to suspend sleep-aid medication use during the 2-week study period.

Baseline Observation Period To observe participants' stable sleep patterns, no intervention was administered during days 1-3 of the study. During this period, participants were required to complete a series of research scales and fill out a "Sleep Diary" on the platform each morning upon awakening (Figure 1 [Figure 1: see original paper]A). The sleep diary recorded participants' time in bed, sleep onset time, awake time, and wake-up time, as well as daily emotional, mental, psychological, and physical status, and use of alcohol, tobacco, tea, and medications. The platform sent WeChat message reminders at 9:00 AM daily to prompt participants to complete their sleep diary.

Intervention Period Day 4 after enrollment marked the beginning of the intervention period, which lasted 14 days. (1) After obtaining participants' baseline data, the research team analyzed their sleep patterns and behavioral habits, identified unreasonable and improvable aspects via WeChat for the intervention group, and discussed personalized improvement plans. (2) At the start of the intervention period, the intervention group was required to complete "Sleep Prescription Setting" through the platform (Figure 1B). The sleep prescription, a core technique in eBBT-I' s sleep restriction therapy, gradually increases patients' sleep drive by moderately restricting time in bed, thereby improving sleep efficiency. The sleep prescription was determined based on participants' sleep diary data from the most recent 3-7 days, specifying daily total time in bed and sleep/wake times. Participants could set their preferred wake-up time, and the platform automatically calculated their required time in bed. The sleep prescription was updated during the second week of the intervention

to adjust according to participants' progress. (3) On day 4, the platform provided access to relevant learning videos. The intervention group watched videos on "Sleep Restriction Therapy" and "Stimulus Control Therapy," while the control group watched "Mental Health Education Videos." As previously described, sleep restriction therapy gradually adjusts patients' circadian rhythms by restricting sleep, thereby reducing sleep onset latency, improving sleep quality, and decreasing nighttime awakenings. Participants were required to strictly adhere to the sleep prescription and only go to bed when feeling sleepy. When awake in bed, they were instructed to leave the bedroom until feeling sleepy again. Stimulus control therapy required patients to refrain from any activities in bed other than sleep or sexual activity, such as using mobile phones or reading, to establish a conditioned response and psychological association with the bed, better control sleep-interfering factors, and accelerate sleep onset. (4) Both groups were required to complete daily sleep diaries throughout the intervention period, but the research team provided specific guidance only to the intervention group.

Post-test Assessment After the intervention period, participants in both groups completed the relevant research scales to measure changes in insomnia status during the study period.

Outcome Measures

Both groups underwent a 2-week study, with ISI and DBAS-16 scores recorded at 3 days pre-intervention and 14 days post-intervention initiation. The ISI served as the primary outcome measure to assess whether eBBT-I reduced the negative impact of insomnia on patients' lives and physical health. The DBAS-16 was used as a secondary outcome measure to evaluate whether eBBT-I effectively enhanced patients' rational beliefs and attitudes about sleep.

Statistical Methods

Data were analyzed using SPSS 22.0 statistical software. Normally distributed continuous variables were expressed as (mean $\pm$ standard deviation). Independent samples t-tests were used for between-group comparisons, paired samples t-tests for within-group comparisons, and repeated measures ANOVA for multi-timepoint observations. Categorical data were expressed as relative frequencies and compared between groups using ^{2} tests. All tests were two-tailed, with $P<0.05$ considered statistically significant.

Results

Comparison of Demographics and Baseline Data

Baseline data comparisons are presented in Table 1 . The control group comprised 30 participants (9 males, 21 females), while the intervention group in-

cluded 35 participants (7 males, 28 females). No significant differences were found between the two groups in gender, age, ISI scores, or DBAS-16 scores.

Comparison of Primary and Secondary Outcome Measures

Primary outcome measures: There was a significant interaction effect between group and time on ISI scores ($P<0.05$). Both group and time showed significant main effects on ISI scores ($P<0.05$). No statistically significant difference in ISI scores was observed between the two groups at 3 days pre-intervention ($P>0.05$). After 14 days of intervention, the intervention group had significantly lower ISI scores than the control group ($P<0.05$). Within-group comparison in the control group showed no significant difference in ISI scores before and after intervention ($P>0.05$). Within the intervention group, ISI scores at 14 days post-intervention were significantly lower than pre-intervention scores ($P<0.05$).

Secondary outcome measures: No significant interaction effect between group and time was found for DBAS-16 scores ($P>0.05$). Time showed a significant main effect on DBAS-16 scores ($P<0.05$), while group did not have a significant main effect ($P>0.05$). No statistically significant difference in DBAS-16 scores was observed between the two groups at 3 days pre-intervention or 14 days post-intervention ($P>0.05$). Within-group comparison in the control group showed no significant difference in DBAS-16 scores before and after intervention ($P>0.05$). Within the intervention group, DBAS-16 scores at 14 days post-intervention were significantly higher than pre-intervention scores ($P<0.05$), as shown in Table 2 .

Discussion

Intervention Effects

Against the backdrop of increasing academic [18] and social pressures [19], the prevalence of insomnia disorder remains high. Although the effectiveness of CBT-I has been confirmed by numerous studies, its implementation in practice faces numerous challenges. With the emergence and rise of digital tools and BBT-I, solutions to the application problems of CBT-I may be within reach. This study investigated the efficacy of eBBT-I for Chinese patients with insomnia disorder using a prospective non-randomized controlled design, administering 2-week eBBT-I and mental health education interventions to the intervention and control groups, respectively. ISI and DBAS-16 scales were assessed before and after intervention to evaluate changes in insomnia severity and sleep beliefs and attitudes.

The results demonstrated that ISI scores decreased significantly from baseline after eBBT-I treatment, indicating that eBBT-I improved insomnia symptoms and negative impacts in patients with insomnia disorder, while no significant changes were observed in the control group. Furthermore, the decline in ISI scores was significantly greater in the intervention group than in the control

group, suggesting that eBBT-I is an effective non-pharmacological treatment that better alleviates distress and improves quality of life compared to mental health education. These findings are consistent with previous research on BBT-I effects [20], indicating that eBBT-I shares similar core efficacy with CBT-I—adjusting patients' sleep habits and patterns through stimulus control and sleep restriction, enhancing their confidence and sense of control over sleep, thereby improving sleep quality.

Additionally, the results showed that DBAS-16 scores increased significantly from baseline after the 2-week eBBT-I treatment, indicating that eBBT-I changed patients' sleep beliefs and attitudes to become more rational and positive, whereas no significant changes were observed in the control group. This suggests that eBBT-I influences not only patients' sleep behaviors but also their sleep cognitions, thereby achieving more durable therapeutic effects. This result is also consistent with previous CBT-I research [21], demonstrating that eBBT-I can effectively impart sleep-related knowledge and skills, help patients eliminate erroneous or excessive expectations and worries about sleep, and enhance their self-efficacy and satisfaction regarding sleep.

However, the interaction effect between group and time on DBAS-16 scores was not significant, indicating that eBBT-I did not significantly improve sleep beliefs and attitudes compared to the control group, and the magnitude of score increase did not reach statistical significance. This may be because sleep beliefs are relatively stable and not easily changed. Additionally, one difference between eBBT-I and CBT-I is the absence of cognitive restructuring components, and particularly, current online BBT-I and CBT-I both lack face-to-face sessions, making it difficult to deeply and specifically understand patients' maladaptive sleep beliefs and thus effectively intervene in cognitive beliefs.

Real-World Clinical Application of eBBT-I

In terms of efficacy, as previously demonstrated, eBBT-I shows significant effects and can serve as a clinical treatment for insomnia disorder. Regarding adverse effects, the only potential negative impact of eBBT-I is mild daytime functioning impairment on the second day due to sleep restriction. In terms of acceptability and cost, this study utilized the Pass Sleep online management platform to deliver eBBT-I, eliminating the need for patients to attend face-to-face treatment at hospitals or clinics, thereby saving patients' time and economic costs while reducing psychological barriers and social stigma. Regarding implementation feasibility, the intervention duration and content of eBBT-I are generally half or less than those of CBT-I, relatively reducing training and operational costs for healthcare workers, as well as economic and time costs for patients, along with lower learning costs. Overall, eBBT-I is easier to implement and execute compared to CBT-I.

However, despite its numerous advantages, eBBT-I still faces some challenges in real-world application. First, compliance with remote eBBT-I intervention

is moderate, as establishing a therapeutic relationship between patients and therapists is more difficult in remote interventions compared to face-to-face sessions. Second, patients' awareness and acceptance of eBBT-I need improvement, as although cognitive-behavioral therapy is a clinically recommended first-line treatment, it remains a relatively novel concept for patients and carries some "psychotherapy" connotations. Finally, both BBT-I and CBT-I require a period of schedule adjustment to gradually improve insomnia symptoms, which may seem less efficient for patients accustomed to fast-acting sleeping pills.

Innovations, Limitations, and Future Directions

Innovations: First, this study applied eBBT-I to Chinese patients with general insomnia disorder, providing a new, effective, and convenient non-pharmacological treatment option for this population. Second, eBBT-I is delivered via a WeChat Mini Program, leveraging the popularity and convenience of WeChat in China, enabling patients to access eBBT-I learning and intervention anytime and anywhere. Finally, this study employed a prospective non-randomized controlled design that simulated real-world clinical environments, enhancing external validity and practicality, while providing a basis for the feasibility and necessity of future randomized controlled trials.

Limitations: First, this study lacked follow-up assessments, preventing evaluation of the long-term efficacy and stability of eBBT-I. Second, this study relied solely on self-report scales as evaluation indicators, lacking objective sleep monitoring and physiological measures, which limits comprehensive reflection of patients' sleep status and physiological changes.

Future directions: Future research should adopt randomized controlled trial designs with larger sample sizes and multi-center collaboration, conduct close follow-up with patients, introduce objective sleep monitoring and physiological indicators, and explore the long-term efficacy and mechanisms of eBBT-I, as well as its applicability and individualized differences for various types and severities of insomnia disorder, thereby providing stronger support and guidance for the prevention and treatment of insomnia disorder.

Conclusion

The results of this study demonstrate that eBBT-I can effectively improve insomnia symptoms and negative impacts in patients with insomnia disorder, though its effects on sleep beliefs and attitudes require further enhancement. This study supports the feasibility and effectiveness of eBBT-I in treating insomnia disorder among Chinese patients. It provides a more economical and efficient approach that offers convenience for both healthcare providers and patients, presents a new non-pharmacological option for insomnia disorder, and contributes valuable exploration to the application of digital tools in the sleep field.

Author Contributions

Chen Pengfei contributed to conceptualization and design, study protocol development, data collection, literature/material collection and organization, and manuscript writing. Professor Pan Jiyang provided guidance on research direction and overall quality control, and was responsible for participant diagnosis and education. Liu Yaxi, Wang Tuzhi, Zhang Guimei, and Cai Yixian provided input and guidance on the research protocol, participated in participant diagnosis and enrollment, critically reviewed the intellectual content, and contributed to quality control and manuscript revision. Chen Pengfei is responsible for the overall article.

Conflict of Interest

This article has no conflicts of interest.

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Note: Figure and Table captions referenced in the text:

Figure 1 Sleep diary and sleep prescription (A: Sleep diary interface; B: Sleep prescription interface)

Figure 2 WeChat reminders and video learning (A: WeChat chat interface reminder; B: Sleep management platform entry interface; C: Video learning and review interface)

Table 1 Comparison of baseline data between the two groups

Table 2 Comparison of ISI and DBAS-16 scores between the two groups before and after intervention

Note: Figure translations are in progress. See original paper for figures.