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Cognitive behavioural therapy for insomnia as an early intervention of mood disorders with comorbid insomnia: A randomized controlled trial

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Abstract

Objective: To evaluate the effectiveness of small-group nurse-administered cognitive behavioural therapy for insomnia (CBTI) as an early intervention of mood disorders with comorbid insomnia.

Methods: A total of 200 patients with first-episode depressive or bipolar disorders and comorbid insomnia were randomized in a ratio of 1:1 to receiving 4-session CBTI or not in a routine psychiatric care setting. Primary outcome was Insomnia Severity Index. Secondary outcomes included response and remission status; daytime symptomatology and quality of life; medication burden; sleep-related cognitions and behaviours; and the credibility, satisfaction, adherence and adverse events of CBTI. Assessments were conducted at baseline, 3, 6, and 12-month.

Results: Only a significant time-effect but no group-by-time interaction was found in the primary outcome. Several secondary outcomes had significantly greater improvements in CBTI group, including higher depression remission at 12-month (59.7% vs. 37.9%, $\chi^2 = 6.57$, $p = .01$), lower anxiolytic use at 3-month (18.1% vs. 33.3%, $\chi^2 = 4.72$, $p = .03$) and 12-month (12.5% vs. 25.8%, $\chi^2 = 3.26$, $p = .047$), and lesser sleep-related dysfunctional cognitions at 3 and 6-month (mixed-effects model, $F = 5.12$, $p = .001$ and .03, respectively). Depression remission rate was 28.6%, 40.3%, and 59.7% at 3, 6, and 12-month, respectively in CBTI group and 28.4%, 31.1%, and 37.9%, respectively in no CBTI group.

Conclusion: CBTI may be a useful early intervention to enhance depression remission and reduce medication burden in patients with first-episode depressive disorder and comorbid insomnia.

KEYWORDS
Chinese, cognitive behavioural therapy, comorbid insomnia, first-episode, mood disorders

1 | INTRODUCTION

Insomnia is a widespread problem among people with mood disorders. About 80% of people with major depressive episode and 40% with bipolar disorder experience insomnia (Geoffroy et al., 2018; Steinan et al., 2016). Insomnia can occur before and represents a risk factor for new onset of mood disorders (Hertenstein et al., 2019), sometimes persists despite remission of mood symptoms (Carney et al., 2007), and is an independent factor influencing the course of mood disorders (Boland et al., 2020).

Although pharmacological therapies for insomnia are effective, their use is limited by concerns regarding long-term efficacy and potential for abuse, dependence, and adverse effects. The American College of Physicians, American Academy of Sleep Medicine, and European Sleep Research Society recommend cognitive behavioural therapy for insomnia (CBTI) as an initial treatment for chronic insomnia disorder (Edinger et al., 2021; Qaseem et al., 2016; Riemann et al., 2017). CBTI can be used as a transdiagnostic intervention for psychiatric disorders with comorbid insomnia. Similar CBTI components are applicable across diagnoses (Hertenstein et al., 2022). Both sleep and non-sleep symptoms, quality of life, and dysfunctional beliefs about sleep can be helped with CBTI (Manber et al., 2016; Thakral et al., 2020). Studies have shown that CBTI is efficacious for alleviating depressive symptoms in major depressive disorder with comorbid insomnia (Manber et al., 2008, 2016; Sadler et al., 2018; Watanabe et al., 2011) and for improving mood symptoms in bipolar disorder (Harvey et al., 2015); while changes in dysfunctional beliefs about sleep may mediate mood improvement (Carney et al., 2022). In addition, CBTI may prevent depression onset in individuals with insomnia. Studies of digital CBTI in community samples showed that the severities of both insomnia and depression were reduced (Cheng et al., 2019; Christensen et al., 2016) and the incidence of moderate-to-severe depression at 1 year was also reduced (Cheng et al., 2019).

To further examine the application of CBTI, we performed a randomized controlled trial of CBTI as an early intervention in clinical population. Although self-help CBTI is cost-saving, its implementation in Chinese patients can be challenging (Ho et al., 2014; Wong, Chung, & Au, 2021). Face-to-face small-group nurse-administered CBTI has been used in general practice and is found to be effective in improving sleep and mental health (Espie et al., 2007; Sandlund et al., 2017). We hypothesized that add-on small-group nurse-administered CBTI in routine psychiatric service could improve sleep, depression, and quality of life, enhance remission, prevent relapses, and reduce medication burden in first-episode mood disorders with comorbid insomnia.

2 | METHODS

2.1 | Study design

The study was an assessor-blind randomized controlled trial conducted at two regional psychiatric outpatient clinics, which received referrals from government general outpatient clinics and private GPs and psychiatrists with no restriction in patient's age Assessments were conducted at baseline, 3, 6, and 12-month. We followed the CONSORT recommendations (Boutron et al., 2008).

2.2 | Participants

Patients aged ≥18 years having a current and first-episode depressive or bipolar disorder and a current insomnia disorder were our target population. To examine the effectiveness of CBTI for improving early outcome, participants had to have received psychiatric treatment for less than 12 months prior to baseline. Mood disorder and insomnia disorder diagnoses were based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria (American Psychiatric Association, 2013).

Exclusion criteria were (1) significant cognitive impairment and psychotic symptoms, based on a Mini-mental State Examination (Folstein et al., 1975) score of 23 or below and the Positive and Negative Syndrome Scale (Kay et al., 1987) items on delusions, conceptual disorganization, and hallucinatory behaviour at moderate severity or above; (2) a diagnosis of schizophrenia, delusional disorder, neurocognitive disorders, or learning disability; (3) having a highly unstable medical or psychiatric condition or a strong suicidal risk; (4) having a diagnosed but untreated sleep disorders, including narcolepsy, obstructive sleep apnea, and periodic leg movement disorder; and (5) past or current treatment with CBTI or therapist-guided deep breathing exercise, progressive muscle relaxation, biofeedback, or guided imagery. To allow prompt recruitment and randomization, polysomnography was not included. We did not charge any fee or provide any monetary incentive for attendance of the CBTI sessions, but a HK$100 travel allowance was paid for each study visit.

2.3 | Study procedure

The study was reviewed and approved by the local Institutional Review Boards (HKU/HA HKW UW-16-057 and KC/KE-16-0164/FR-3) and was registered at clinicaltrials.gov (identifier: NCT03000894). Eligible subjects provided written informed consent and participated in a comprehensive face-to-face interview. Research team psychiatrists (KFC and CTL) confirmed that subjects satisfied the inclusion and exclusion criteria, specifically being the first episode of mood disorder and receiving psychiatric treatment for less than 12 months. After completion of baseline assessment, subjects were randomly assigned to CBTI group and no CBTI group in 1:1 by an independent administrator according to a random block list of 6, 8, or 10. The block size of 6, 8, or 10 was chosen for the convenience of forming CBTI groups. The random block size list was generated using computer software prior to study commencement and was stored in a computer. Patients' psychiatrists and researchers responsible for assessment, data input, and data analysis were blind to group allocation.

2.4 | Intervention

2.4.1 | Cognitive behavioural therapy for insomnia

Subjects received four sessions 90 min group CBTI administered by a trained nurse therapist every 2 weeks. Each group had 6–8 participants. Participants who dropped out were not replaced. The treatment content was adopted from a well-established CBTI manual (Morin & Espie, 2003) and the translated Chinese version (Yang et al., 2008). The most salient information of the treatment manual was summarized. The language for Hong Kong Chinese was edited. Details of the treatment content are presented in Table S1. Session 1 consists of a programme overview, the roles of cognition and behaviour as perpetuating factors, sleep hygiene advice, the use of sleep diary as self-monitoring, and goal setting. Session 2 includes activity scheduling, relaxation training, and stimulus control. Session 3 covers sleep restriction and cognitive restructuring. The last session reviews the major points of CBTI and the treatment goal, and explains the barriers interfering with the implementation of CBTI, the pharmacological treatment of insomnia, including gradual hypnotic withdrawal, and relapse prevention. At the end of each session, patients were provided with paper CBTI materials. We tried to contact the patients who missed treatment sessions and send them CBTI materials. All patients received routine psychiatric care, which consisted of consultation and treatment by psychiatrist (roughly 10-min follow-up sessions every 2–16 weeks). There was no restriction on pharmacological treatment and referrals to other professional services, such as community psychiatric nurse for home visits (roughly once a month) and medical social worker. Referral to clinical psychologist could be made but waiting time for the first consultation could take months.

Nurse training on administration of CBTI was provided by the first author and a clinical psychologist and consisted of a review of the CBTI manual and skill sharing using videotape on CBTI. All treatment sessions were audiotaped and reviewed by the first author to monitor therapist adherence to the manual. Any deviation from the manual was dealt with by discussion between the nurse therapist and the first author.

2.4.2 | No CBTI

Patients received routine psychiatric care the same way as in the CBTI group.

2.5 | Measures

Insomnia Severity Index (ISI; Bastien et al., 2001) was used as the primary outcome. Secondary outcomes included Clinical Global Impressions of Severity (CGI-S; Guy, 1976), 17-item Hamilton Depression Rating Scale ($HDRS_{17}$; Hamilton, 1960), Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983), Somatic Symptom Inventory (SSI; Kroenke et al., 1994), Epworth Sleepiness Scale (ESS; Johns, 1991), Multidimensional Fatigue Inventory (MFI; Smets et al., 1995), Sheehan Disability Scale (SDS; Leon et al., 1997), 36-item Short Form Health Survey (SF-36; Ware et al., 1993), 16-item Dysfunctional Beliefs and Attitudes About Sleep Scale (DBAS; Morin et al., 2007), Pre-sleep Arousal Scale (PSAS; Nicassio et al., 1985), Self-Efficacy for Sleep Scale (SESS; Lacks, 1987), and Sleep Hygiene Practice Scale (SHPS; Lin et al., 2009). Outcome measures were selected to assess insomnia, depression and other relevant symptoms, daytime functioning, quality of life, and sleep-related cognitions and behaviours. The scales' content, number of items, scoring, score interpretation, and psychometric properties are listed in Table S2. ISI, HADS, ESS, MFI, SF-36, DBAS, and SHPS have previously been validated in Chinese populations (Chung, 2000; Chung et al., 2011, 2014, 2016; Lam et al., 2005; Leung et al., 1999; Lin et al., 2009). Insomnia response and remission were defined as a 6-point or greater reduction and a score of 7 or below in ISI, respectively (Bastien et al., 2001; Yang et al., 2009); while depression response and remission were defined as a 50% or greater reduction and a score of 7 or below in $HDRS_{17}$, respectively.

Medication burden and symptom exacerbation were assessed during each study visit. Patients were asked the actual usage of medications in the past week. Benzodiazepines and non-benzodiazepine hypnotics were presented in mg diazepam; while antidepressants were presented in mg fluoxetine, using published conversion equivalents (Ashton, 2007; Sackeim et al., 2019). Symptom exacerbation was defined as any worsening that required hospital admission, visit to the Accident and Emergency department, or additional clinic visit.

Subjects were asked to evaluate CBTI's credibility, satisfaction, and adherence at immediate post-treatment using a validated measure (Vincent, 1990) and scales we developed and used in a previous study (Ho et al., 2014; Table S2). Adverse events were asked using an open-ended question: "Have you had any discomforts when practicing cognitive behavioral therapy for insomnia?"

2.6 | Data analysis

2.6.1 | Sample size estimation

A meta-analysis of group CBTI showed that the effect size for sleep efficiency between group CBTI and nonactive controls was 0.48 (Koffel et al., 2015). We assumed a between-group effect size of 0.50. The minimum number of subjects needed in each group was 64, based on a type I error of 0.05 and a power of 80%. We estimated a 15% attrition rate at immediate post-treatment, and a further 10% at each follow-up; hence a sample size of 99 in each group (or roughly 200 in total) was planned.

2.6.2 | Data management and analysis

We used SPSS version 26 for statistical analysis. The intention-to-treat principle was adopted for the analysis of continuous variables by

linear mixed-effects modelling, which allowed for serial correlation of repeated measures and missing data. Within-group and between-group effect and group-by-time interaction were obtained. Standardized within-group and between-group effect size were computed by dividing the difference in means by the pooled standard deviation. Dichotomous outcomes, like remission and response rates, were compared based on observed value by the χ^2 test. A per-protocol analysis was performed to examine whether completion of the intervention programme impacted on outcomes. For treatment credibility, satisfaction and adherence, as there was no valid cutoff score, the absolute approach was used. A mean score of 0–40th, 40–60th, and 60–100th percentile represent negative, ambivalent, and positive response, respectively (Spector, 2007).

3 | RESULTS

3.1 | Subjects' characteristics

The participant flowchart is shown in Figure 1. The mean age of the sample was 46.8 years; 72.0% were female, 53.5% had paid employment, and 99.5% were having major depressive disorder (Table 1). A majority of the sample (80.0%) were taking antidepressants, of which 55.5% received selective serotonin reuptake inhibitors. More than half of the sample (56.0%) required hypnotics, mostly non-benzodiazepine hypnotics (38.0%). The mean ISI and $HDRS_{17}$ scores at baseline were 17.6 and 12.6, respectively.

A total of 102 patients were randomized to receive CBTI; however, 21 patients (20.6%) did not attend any session while only 41 patients (40.2%) attended all four sessions. The number of patients who completed outcome assessment at 3, 6, and 12 months were 158, 151, and 138, respectively, corresponding to a follow-up rate of 79.0%, 75.5%, and 69.0% (Figure 1). There was no significant difference between patients who continued versus those lost-to-follow-up, except for a lower baseline treatment credibility in patients who were lost-to-follow-up (unpaired t test, $p = .002$). There was no significant difference in the follow-up rate between CBTI group and no CBTI group (χ^2 test, $p > .05$).

3.2 | Efficacy

3.2.1 | Primary outcome

Mixed-effects analysis showed that there was a significant time effect but no significant group-by-time interaction in ISI (Table 2). The within-group effect size from baseline to 12 months for CBTI group and no CBTI group were 1.44 and 1.30, respectively. Insomnia response rate at 3 months was 36.4% in CBTI group and 22.2% in no CBTI group, but the difference was marginally nonsignificant ($\chi^2 = 3.83$, $df = 1$, $p = .05$; Table 3). No significant difference was found in insomnia response rates at 6 and 12 months and insomnia remission rates at all-time points. At 12 months, insomnia remission rate was only 22.2% in CBTI group and 18.2% in no CBTI group.

3.2.2 | Secondary outcomes

Daytime symptomatology, functioning, and quality of life

Depression remission rate at 12 months was significantly higher in CBTI group (59.7%), compared to no CBTI group (37.9%; $\chi^2 = 6.57$, $df = 1$, $p = .01$; Table 3). The difference remained significant based on the intention-to-treat sample (43/102, 42.2% vs. 27/98, 27.6%, $\chi^2 = 4.69$, $df = 1$, $p = .03$). However, there was no significant difference in depression response rates at all time points and depression remission rates at 3 and 6 months. There was no significant group-by-time interaction in CGI-S, $HDRS_{17}$, HADS, SSI, ESS, MFI, SDS, and SF-36 at 3, 6, and 12 months (Table 2).

Sleep-related cognitions and behaviours

There was a significant group-by-time interaction in DBAS at 3 and 6 months ($p = .001$ and .03, respectively), with a greater reduction in CBTI group (Table 4). However, no significant difference was found in other sleep-related cognitive and behavioural factors.

Medication burden

Anxiolytics was less often used in CBTI group than in no CBTI group. The difference was significant at 3 months (18.1% vs. 33.3%, $p = .03$) and 12 months (12.5% vs. 25.8%, $p = .047$). However, the difference in the rate of hypnotics use and average dosages of benzodiazepines and antidepressants were non-significant (Table 5).

Symptom exacerbation

There was no significant difference in the rate of symptom exacerbation at all time points (Table 4).

Treatment credibility, satisfaction, adherence, and adverse events

The mean credibility score was 15.1 ($SD = 3.3$), corresponding to 56th percentile and an ambivalent response. The mean satisfaction score was 22.6 ($SD = 4.8$), corresponding to 73th percentile and a positive response. For treatment adherence, the mean score was 14.0 ($SD = 3.2$), representing 67th percentile, which could be interpreted as a positive response. None of the 66 respondents who had attended CBTI reported any adverse event.

Per-protocol analysis

Only 41 of the 102 subjects in the CBTI group completed all treatment sessions. Mixed-effects analysis showed that there was no significant group-by-time interaction in ISI, the primary outcome ($p = .099$). Of the secondary outcomes, DBAS, SHPS, and MFI had significant group-by-time interactions, with greater improvements in CBTI group ($p = .0001$, 0.009, and 0.047, respectively).

4 | DISCUSSION

The hypothesis that add-on small-group nurse-administered CBTI could improve early outcome in first-episode mood disorders with comorbid insomnia was partially supported. Although CBTI did not have any significant effect on ISI, the primary outcome, depression

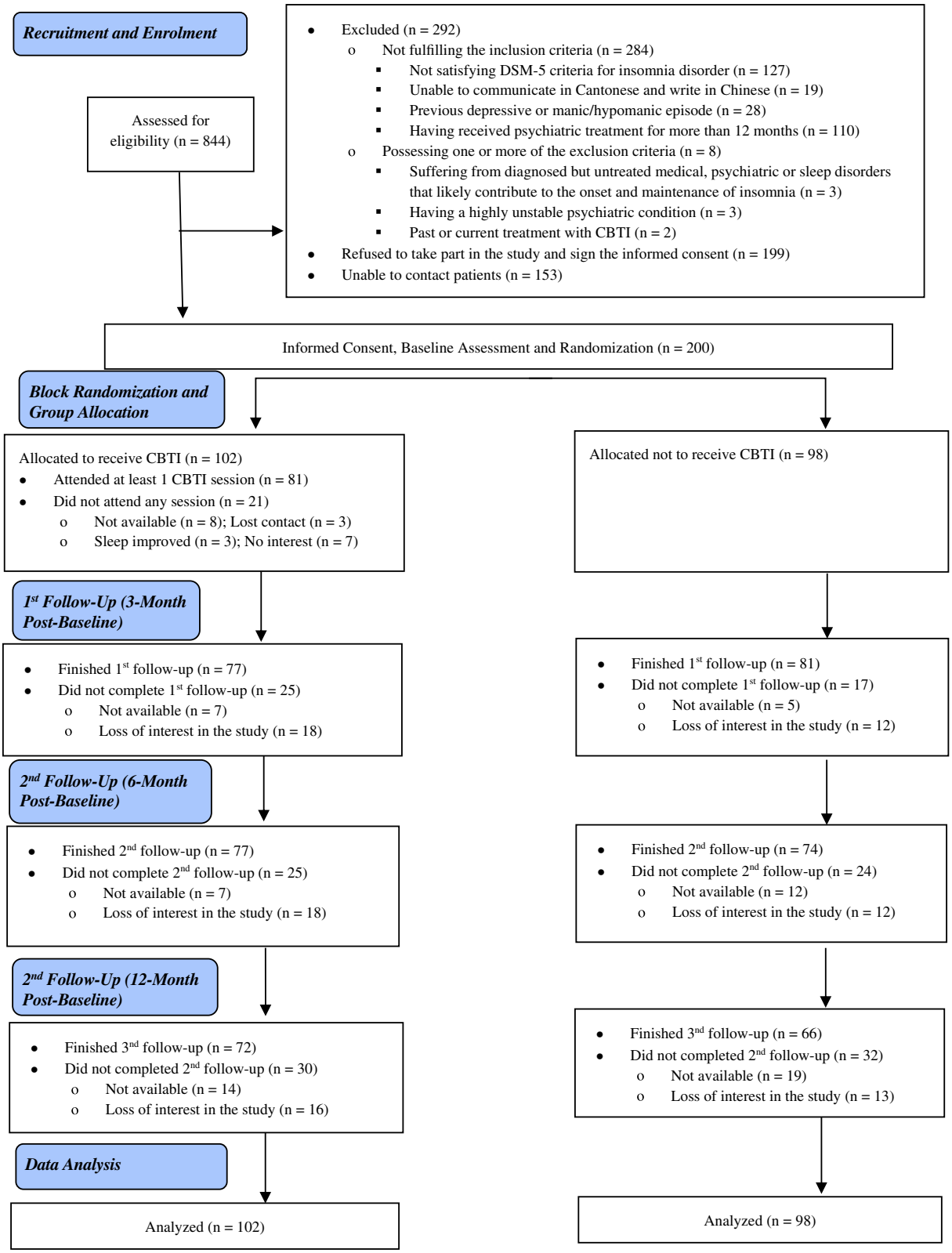

FIGURE 1 Participant flowchart.

remission rate was significantly higher and the use of anxiolytics was significantly lower in the CBTI group. Dysfunctional attitudes about sleep were also lower in the CBTI group. Satisfaction and adherence of CBTI were positive and no adverse event was reported. Our findings suggested that small-group CBTI might be a useful early intervention for first-episode mood disorders with comorbid insomnia.

TABLE 1 Demographic and clinical characteristics of the participants at baseline.

Variables[a]	CBTI ($n = 102$)	No CBTI ($n = 98$)	Total ($n = 200$)	χ^2/t value	p-Value
Age, y	47.95 ± 11.63	45.63 ± 11.75	46.82 ± 11.71	1.403	0.162
Sex, male/female	24/78	32/66	56/144	2.064	0.151
Education, y	11.54 ± 3.64	10.99 ± 3.43	11.27 ± 3.54	1.098	0.273
Marital status				1.442	0.696
Never married	22 (21.6%)	28 (28.6%)	50 (25.0%)		
Married	53 (52.0%)	46 (46.9%)	99 (49.5%)		
Divorced	23 (22.5%)	20 (20.4%)	43 (21.5%)		
Widow	4 (3.9%)	3 (3.1%)	7 (3.5%)		
Occupation				4.780	0.687
Professional and associate professional	13 (12.7%)	6 (6.1%)	19 (9.5%)		
Clerical worker	14 (13.7%)	14 (14.3%)	28 (14.0%)		
Skilled and semi-skilled worker	14 (13.7%)	20 (20.4%)	34 (17.0%)		
Unskilled worker	14 (13.7%)	12 (12.2%)	26 (13.0%)		
Student	2 (2.0%)	3 (3.1%)	5 (2.5%)		
Housemaker	9 (8.8%)	11 (11.2%)	20 (10.0%)		
Unemployed	22 (21.6%)	22 (21.6%)	44 (22.0%)		
Retired	14 (13.7%)	10 (22.4%)	24 (12.0%)		
Type of mood disorder				2.967	0.227
Major depression	102 (100%)	97 (99.0%)	199 (99.5%)		
Bipolar disorder	0 (0%)	1 (1.0%)	1 (0.5%)		
Insomnia duration, m	49.87 ± 71.21	46.54 ± 78.15	48.24 ± 74.52	0.315	0.753
Chronic medical illnesses	33 (32.4%)	25 (25.5%)	58 (29.0%)	1.137	0.286
ISI	17.33 ± 5.15	17.94 ± 4.88	17.63 ± 5.01	−0.853	0.395
$HDRS_{17}$	12.20 ± 5.06	13.05 ± 4.80	12.62 ± 4.94	−1.225	0.222
Use of hypnotics				0.101	0.999
Non-benzodiazepine hypnotics	38 (37.3%)	38 (38.8%)	76 (38.0%)		
Benzodiazepines	6 (5.9%)	6 (6.1%)	12 (6.0%)		
Antihistamine	3 (2.9%)	3 (3.1%)	6 (3.0%)		
Combination	8 (7.8%)	8 (8.2%)	16 (8.0%)		
Nil	46 (45.1%)	42 (42.9%)	88 (44.0%)		
Use of antidepressants				4.909	0.427
SSRI	53 (52.0%)	58 (59.2%)	111 (55.5%)		
SNRI	6 (5.9%)	5 (5.1%)	11 (5.5%)		
Tricyclics	4 (3.9%)	1 (2.5%)	5 (2.5%)		
Others	11 (10.8%)	6 (8.5%)	17 (8.5%)		
Combination	6 (5.9%)	10 (10.2%)	16 (8.0%)		
Nil	22 (21.6%)	18 (18.4%)	40 (20.0%)		
Antipsychotics, lithium or anticonvulsants	13 (12.7%)	7 (7.1%)	20 (10.0%)	1.743	0.187

Abbreviations: CBTI, cognitive behavioural therapy for insomnia; $HDRS_{17}$, 17-item Hamilton Depression Rating Scale; ISI, Insomnia Severity Index; SNRI, serotonin-norepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor.

[a]Data are presented as mean ± *SD* or *n* (%).

Previous studies have examined the efficacy of CBTI in patients with depression and comorbid insomnia (Manber et al., 2008, 2016; Sadler et al., 2018; Watanabe et al., 2011). The findings supported that both insomnia and depression improved following CBTI, except for one study (Manber et al., 2016). There are a number of potential explanations for the lack of significant effect on insomnia by CBTI in our study. First, all subjects received routine psychiatric care; hence the beneficial effects of CBTI could be masked by concomitant hypnotics and antidepressants. Second, previous studies found that CBT had weaker effects on Chinese clients than their Western

TABLE 2 Insomnia, daytime symptomatology, functioning, and quality of life.

Variables	CBTI ($n = 102$) Mean ± SE[a]	Within-group effect size	No CBTI ($n = 98$) Mean ± SE[a]	Within-group effect size	Between-group effect size	*p*-Value for time effect	*p*-Value for group by time interaction
ISI							
Baseline	17.3 ± 0.53		17.9 ± 0.54				
3-month	14.0 ± 0.58	0.59	15.5 ± 0.57	0.43	0.26	0.0001	0.28
6-month	14.0 ± 0.59	0.59	14.0 ± 0.60	0.68	0.00	0.0001	0.60
12-month	9.0 ± 0.61	1.44	10.1 ± 0.64	1.30	0.17	0.0001	0.61
CGI-S							
Baseline	4.2 ± 0.11		4.4 ± 0.12				
3-month	3.5 ± 0.12	0.60	3.8 ± 0.12	0.50	0.25	0.0001	0.45
6-month	3.4 ± 0.13	0.65	3.6 ± 0.13	0.63	0.15	0.0001	0.94
12-month	3.0 ± 0.13	0.99	3.4 ± 0.14	0.76	0.29	0.0001	0.27
$HDRS_{17}$							
Baseline	12.20 ± 0.53		13.05 ± 0.54				
3-month	11.24 ± 0.57	0.17	11.23 ± 0.57	0.32	0.00	0.0001	0.16
6-month	9.70 ± 0.58	0.45	10.85 ± 0.59	0.39	0.19	0.0001	0.71
12-month	7.66 ± 0.60	0.79	9.59 ± 0.62	0.59	0.31	0.0001	0.26
HADS							
Baseline	22.86 ± 0.78		22.58 ± 0.79				
3-month	20.59 ± 0.84	0.28	20.64 ± 0.83	0.24	0.01	0.004	0.74
6-month	19.96 ± 0.86	0.35	20.81 ± 0.87	0.21	0.10	0.047	0.36
12-month	18.00 ± 0.89	0.58	18.78 ± 0.92	0.44	0.09	0.0002	0.47
SSI							
Baseline	68.24 ± 2.91		68.21 ± 2.97				
3-month	61.84 ± 3.17	0.21	66.62 ± 3.14	0.05	0.15	0.60	0.27
6-month	51.32 ± 2.91	0.58	51.44 ± 2.97	0.56	0.00	0.0001	0.98
12-month	45.41 ± 2.91	0.78	43.79 ± 2.97	0.81	0.05	0.0001	0.77
ESS							
Baseline	10.78 ± 0.54		9.31 ± 0.55				
3-month	11.45 ± 0.58	0.11	10.32 ± 0.58	0.18	0.19	0.03	0.57
6-month	11.35 ± 0.60	0.09	10.03 ± 0.60	0.12	0.22	0.23	0.85
12-month	11.16 ± 0.62	0.06	10.24 ± 0.64	0.15	0.14	0.19	0.60
MFI							
Baseline	47.86 ± 2.15		48.78 ± 2.19				
3-month	46.00 ± 2.35	0.08	47.38 ± 2.33	0.06	0.06	0.55	0.89
6-month	45.72 ± 2.15	0.10	44.82 ± 2.19	0.18	0.04	0.14	0.63
12-month	42.76 ± 2.15	0.23	39.96 ± 2.19	0.40	0.13	0.002	0.36
SDS							
Baseline	18.68 ± 0.73		18.12 ± 0.75				
3-month	16.13 ± 0.80	0.33	16.54 ± 0.79	0.20	0.05	0.03	0.34
6-month	16.14 ± 0.82	0.32	16.82 ± 0.83	0.16	0.08	0.15	0.33
12-month	13.80 ± 0.85	0.61	15.27 ± 0.87	0.35	0.17	0.006	0.16
SF-36							
Baseline	38.33 ± 1.88		38.77 ± 1.91				
3-month	44.07 ± 2.01	0.29	42.21 ± 2.01	0.17	0.09	0.04	0.32
6-month	46.11 ± 2.07	0.39	41.81 ± 2.10	0.15	0.20	0.16	0.12
12-month	50.56 ± 2.15	0.60	44.18 ± 2.22	0.26	0.29	0.03	0.05

Abbreviations: CGI-S, Clinical Global Impressions of Severity; ESS, Epworth Sleepiness Scale; $HDRS_{17}$, 17-item Hamilton Depression Raing Scale; HADS, Hospital Anxiety and Depression Scale; ISI, Insomnia Severity Index; MFI, Multidimensional Fatigue Inventory; SDS, Sheehan Disability Scale; SF-36, 36-item Short Form Health Survey; SSI, Somatic Symptom Inventory.

[a]Estimated mean and standard error from linear mixed-effects model adjusted for last assessment time.

TABLE 3 Insomnia and depression response and remission status and rate of symptom exacerbation at study time points.

	CBTI[a]	No CBTI[a]	Risk ratio	χ^2 value	*p*-Value
Insomnia					
Response (≥6-point reduction in ISI total score compared to baseline)					
3-month	28/77 (36.4%)	18/81 (22.2%)	1.56	3.83	**0.05**
6-month	31/78 (39.7%)	28/74 (37.8%)	1.11	0.06	0.81
12-month	37/72 (51.4%)	30/66 (45.5%)	1.23	0.49	0.49
Remission (<7 points in ISI total score)					
3-month	9/77 (11.7%)	9/81 (11.1%)	1.00	0.01	0.91
6-month	11/78 (14.1%)	12/74 (16.2%)	0.92	0.13	0.72
12-month	16/72 (22.2%)	12/66 (18.2%)	1.33	0.35	0.56
Depression					
Response (≥50% reduction in $HDRS_{17}$ total score compared to baseline)					
3-month	10/77 (13.0%)	10/81 (12.3%)	1.00	0.02	0.90
6-month	16/77 (20.8%)	17/74 (23.0%)	0.94	0.11	0.74
12-month	32/72 (44.4%)	20/66 (30.3%)	1.60	3.26	0.09
Remission (≤7 points in $HDRS_{17}$ total score)					
3-month	22/77 (28.6%)	23/81 (28.4%)	0.96	0.001	0.98
6-month	31/77 (40.3%)	23/74 (31.1%)	1.35	1.38	0.24
12-month	43/72 (59.7%)	25/66 (37.9%)	1.72	6.57	0.01
Symptom exacerbation that requires admission, visit to A&E or additional clinic visits					
Baseline to 3-month	5/77 (6.5%)	10/81 (12.3%)	0.50	1.57	0.21
3-month to 6-month	5/77 (6.5%)	8/74 (10.8%)	0.63	0.89	0.34
6-month to 12-month	5/72 (6.9%)	5/66 (7.6%)	1.00	0.02	0.89

[a]Data are presented as proportion (%).

TABLE 4 CBTI cognitive and behavioural processes.

Variables	CBTI ($n = 102$) Mean ± SE[a]	Within-group effect size	No CBTI ($n = 98$) Mean ± SE[a]	Within-group effect size	Between-group effect size	*p*-Value for time effect	*p*-Value for group by time interaction
DBAS							
Baseline	6.93 ± 0.17		6.66 ± 0.18				
3-month	5.93 ± 0.19	0.55	6.57 ± 0.19	0.05	0.33	0.58	0.00
6-month	6.11 ± 0.19	0.45	6.51 ± 0.19	0.08	0.21	0.46	0.03
12-month	5.77 ± 0.20	0.62	6.12 ± 0.21	0.27	0.17	0.03	0.06
SHPS							
Baseline	80.8 ± 1.7		80.9 ± 1.7				
3-month	76.2 ± 1.9	0.25	80.4 ± 1.8	0.03	0.22	0.77	0.05
6-month	76.2 ± 1.9	0.25	81.0 ± 1.9	0.01	0.25	0.93	0.08
12-month	77.1 ± 1.9	0.20	78.1 ± 2.0	0.15	0.05	0.21	0.80
SESS							
Baseline	20.73 ± 0.60		20.04 ± 0.61				
3-month	23.32 ± 0.66	0.41	21.88 ± 0.65	0.28	0.22	0.004	0.40
6-month	22.94 ± 0.67	0.34	22.71 ± 0.68	0.41	0.03	0.001	0.68
12-month	25.41 ± 0.70	0.71	23.21 ± 0.73	0.47	0.30	0.0001	0.22
PSAS							
Baseline	45.41 ± 1.22		45.44 ± 1.24				
3-month	41.94 ± 1.33	0.27	43.14 ± 1.32	0.18	0.09	0.06	0.50
6-month	42.88 ± 1.36	0.19	41.16 ± 1.38	0.32	0.12	0.006	0.43
12-month	38.20 ± 1.42	0.54	39.97 ± 1.47	0.40	0.12	0.002	0.48

Abbreviations: DBAS, Dysfunctional Beliefs and Attitudes about Sleep; PSAS, Pre-sleep Arousal Scale; SESS, Sleep Self-efficacy Scale; SHPS, Sleep Hygiene Practice Scale.
[a]Estimated mean and standard error from linear mixed-effects model adjusted for last assessment time.

TABLE 5 Medication burden.

	CBTI[a]	No CBTI[a]	Risk ratio	χ^2 Value	*p*-Value
Hypnotic use[b]					
Baseline	55/102 (53.9%)	59/98 (60.2%)	0.93	0.81	0.37
3-month	29/77 (37.7%)	35/81 (43.2%)	0.83	0.50	0.48
6-month	30/77 (39.0%)	32/74 (43.2%)	0.94	0.29	0.59
12-month	21/72 (29.2%)	29/66 (43.9%)	0.72	3.25	0.07
Anxiolytic use[c]					
Baseline	29/102 (53.9%)	33/98 (60.2%)	0.88	0.64	0.42
3-month	14/77 (18.1%)	27/81 (33.3%)	0.52	4.72	0.03
6-month	15/77 (20.8%)	24/74 (23.0%)	0.63	3.30	0.07
12-month	9/72 (12.5%)	17/66 (25.8%)	0.53	3.26	0.047
Antipsychotic and mood stabilizer use[d]					
Baseline	10/102 (53.9%)	5/98 (60.2%)	2.00	1.59	0.21
3-month	7/77 (9.1%)	7/81 (8.6%)	1.00	0.01	0.92
6-month	11/77 (14.3%)	8/74 (10.8%)	1.38	0.46	0.50
12-month	9/72 (12.5%)	6/66 (9.1%)	1.50	0.41	0.52
Benzodiazepines and non-benzodiazepine hypnotics in mg diazepam equivalent/week					
Baseline	21.44 (3.57)	26.03 (3.64)			
3-month	18.06 (3.78)	26.72 (3.78)			
6-month	17.41 (3.86)	25.18 (3.92)			
12-month	15.47 (3.99)	22.16 (4.11)			
Antidepressants in mg fluoxetine equivalent/week					
Baseline	101.5 (11.0)	109.7 (11.3)			
3-month	124.5 (11.8)	127.6 (11.8)			
6-month	123.8 (12.0)	144.8 (12.3)			
12-month	119.8 (21.3)	139.0 (12.8)			

[a]Data are presented as proportion (%) or mean (*SD*).
[b]Benzodiazepines, non-benzodiazepine hypnotics and anti-histamines.
[c]Benzodiazepines, pregabalin, and beta-blockers.
[d]Conventional and atypical antipsychotics, lithium, valproate, lamotrigine and carbamazepine.

counterparts (Ng & Wong, 2018). Third, only 40% of the subjects in CBTI group attended all treatment sessions. The unsatisfactory attendance might be due to that Chinese people were less psychologically minded and less interested in psychological treatment (Hua et al., 2007). In view of the limited efficacy and low attendance, future implementation of CBTI in Chinese population should include cultural elements tailormade to the subjective experience of insomnia in Chinese (Yung et al., 2016) and measures to enhance treatment attendance (Ho et al., 2014). Our findings that the CBTI group had higher depression remission rate and lower anxiolytics use are in line with previous studies of the positive effect of CBTI on mood (Manber et al., 2008; Sadler et al., 2018; Watanabe et al., 2011); possibly mediated via a reduction in dysfunctional cognitions about sleep (Carney et al., 2022).

Although there was a significant reduction in insomnia severity from baseline to 12 months, insomnia remission rate remained very low, at less than 25% at 12 months. Previous studies on the treatment of chronic insomnia in Chinese patients obtained mixed results, with remission rate ranging from 15.4% to 96.6% (Birling et al., 2018; Wong et al., 2017). Further research is definitely needed to find out the effectiveness of CBTI in Chinese populations.

There are strengths and limitations in this study. We recruited a large sample to examine the effects of CBTI in real-world patients and obtained follow-up data for up to 12 months. However, we did not include a non-active control group and the beneficial effects of CBTI may be due to non-specific factors of group support and extra attention from a nurse therapist. In addition, multiple secondary outcomes and time points were analysed; hence, the significant findings should be treated with caution. Also, the efficacy of CBTI may be underestimated because only 40% completed all treatment sessions. Per-protocol analysis could not detect any significant effect on the primary outcome, but a greater number of secondary outcomes were improved, compared to the intention-to-treat analysis. Another limitation was that the sample was over-represented by middle-aged and

older subjects. In view that CBTI is designed as an early intervention, future studies in adolescents and young adults are necessary. Lastly, credibility, acceptance, adherence, and adverse events were based on self-report among those who attended the treatment sessions.

In conclusion, we found that small-group nurse-administered CBTI might be a useful early intervention for patients with first-episode depressive disorder and comorbid insomnia. Further studies with measures to enhance the attendance of CBTI and the use of a non-active control group are needed to find out the actual benefit of CBTI as an early intervention of depressive disorder.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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