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EMPIRICALLY GROUNDED CLINICAL INTERVENTIONS

Cognitive behavioural group therapy for insomnia (CBGT-I) in patients undergoing haemodialysis: a randomized clinical trial

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Abstract

Background: Given the many complications of drug therapy, it seems reasonable to use non-pharmacological therapies that can improve mental and physical disorders in haemodialysis patients.
Aims: This study aims to determine the effectiveness of cognitive behavioural group therapy for insomnia (CBGT-I) in sleep quality, depression, anxiety and general psychological health of haemodialysis patients.
Method: This randomized clinical trial was conducted on 116 haemodialysis patients who were randomly assigned to experimental (n=58) and control (n=58) groups. In the experimental group, CBGT-I was provided during nine weekly sessions. Data collection tools included Pittsburgh Sleep Quality Index (PSQI), Beck Depression Inventory-II (BDIII), Beck Anxiety Inventory (BAI), General Health Questionnaire (GHQ-28), Clinical Global Improvement Scale (CGI), Client Satisfaction Questionnaire (CSQ) and Working Alliance Inventory-Short Form (WAI-S). Data were analysed by SPSS-25 and $p<.05$ was considered significant.
Results: The findings demonstrated that CBGT-I compared with control group was effective in improving sleep quality ($p<.001$, $\eta^2=.790$), depression ($p<.001$, $\eta^2=.616$), anxiety ($p<.001$, $\eta^2=.682$) and general psychological health ($p<.001$, $\eta^2=.871$). Participants of CBGT-I showed notable improvements as a result of the treatment, were satisfied with treatment, and had a good therapeutic relationship.
Conclusions: CBGT-I is effective in reducing depression and anxiety in addition to improving sleep quality and general psychological health in haemodialysis patients. Therefore, it is recommended to be used as a complementary treatment for these patients.

Keywords: cognitive behavioural group therapy for insomnia; depression; kidney failure; mental health

Introduction

Chronic renal disease (CRD) can be considered as one of the major health problems with an estimated prevalence of 13.4% worldwide. Many people with this disease have progressed to end-stage renal disease (ESRD) and will undergo haemodialysis (Hill *et al.*, 2016). In Iran, statistics show an increasing trend of the disease, with an estimated growth of 22.6% per year (Kiani *et al.*, 2018). Haemodialysis is a stressful process which can lead to depression, anxiety, sleep disorder, fatigue, weakness, reduced daily activities, etc. (Ibrahim *et al.*, 2018).

Sleep disturbance, including insomnia, is one of the most common dialysis-related problems. Some studies have reported its prevalence to be over 75% (Mirghaed *et al.*, 2019). Insomnia increases the risk of depression and anxiety, and reduces the ability to cope with stress (Anwar and Mahmud, 2018). Conversely, sleep problems are much more prevalent among

individuals with depression and anxiety disorders (Geoffroy *et al.*, 2018; Ramsawh *et al.*, 2009). Thus, in a vicious cycle, anxiety and depression lead to sleep problems, on one hand, and, on the other hand, sleep problems lead to anxiety and depression.

Gerogianni *et al.* (2019) have reported the prevalence of anxiety and depression in hemodialysis patients to be 45% and 26.6%, respectively. Longitudinal studies have demonstrated that for patients on haemodialysis, those who had a clinician diagnosis of depression have higher rates of hospitalization days with higher rates of dialysis withdrawal and mortality (Hedayati *et al.*, 2008; McDade-Montez *et al.*, 2006). Lower quality of life (Cukor *et al.*, 2013), dialysis initiation or death (Loosman *et al.*, 2015) are evidently associated with anxiety disorder in haemodialysis patients with chronic kidney disease. Early identification and remission or improvements of distress symptoms, including depression, anxiety and general emotional well-being, have been a long-standing treatment goal by the nephrology community when taking into account the high prevalence and dire consequences of depression and anxiety (K/DOQI Workgroup, 2005).

Cognitive behavioural group therapy for insomnia (CBGT-I)

One of the most important factors affecting the psychological status of patients with chronic renal failure is how to cope with the disease and the stresses arising therefrom. Medication discrepancies are common in CRD, affecting the majority of patients. Also, as medication count is high among patients with CRD/ESRD, adherence to pharmacological treatments may be more problematic in this population. Moreover, there are concerns as to whether anti-depressant, benzodiazepines, hypnotic drugs and their side-effects can be well tolerated (Ibrahim *et al.*, 2018; Pagel and Parnes, 2001; Palmer *et al.*, 2016). So, non-pharmacological behavioural methods are used which may also have therapeutic benefit (Ibrahim *et al.*, 2018; Pagel and Parnes, 2001). Furthermore, concerns against use of medication for insomnia are so important that international guidelines universally recommend CBT as the first-line treatment, not only because of the safety concerns about medication, but also because it leads to longer-term benefits to sleep compared with the use of medication (Qaseem *et al.*, 2016; Wilson *et al.*, 2019).

Cognitive behavioural therapy for insomnia (CBT-I) is a tailored, structured, short-term, and evidence-based approach that consists of various strategies, including sleep restriction and compression, stimulus control, sleep hygiene, cognitive restructuring, and relaxation training. The connection between the way we think, the things we do, and how we sleep is the focus of exploration for CBT-I. The treatment tests thoughts and feelings about sleep in order to gauge their accuracy in addition to evaluating behaviours based on their ability to promote sleep. After CBT-I, up to 70 to 80% of the patients with primary insomnia spent less time to fall asleep, more time spent asleep, and reduced waking after sleep onset (Qaseem *et al.*, 2016; Trauer *et al.*, 2015). In a randomized controlled trial, CBT-I compared with pharmacotherapy led to the greatest changes in sleep-onset latency and sleep efficiency while maintaining therapeutic gains at long-term follow-up (Jacobs *et al.*, 2004). In a blinded, randomized, split-plot experimental study on 107 patients with insomnia and depression, participants were randomized to one of three groups: anti-depressant + CBT-I (4 sessions), CBT-I + placebo pill, and anti-depressant + 4-session sleep hygiene control, and while all groups improved on measures of depression and self-reported sleeping after treatment, only the CBT-I groups improved on objective sleep, whereas sleep worsened for those in the anti-depressant + 4-session sleep hygiene group (Carney *et al.*, 2017). Chen *et al.* (2011) in a study on 72 sleep-disturbed haemodialysis patients showed that tri-weekly CBT-I compared with sleep hygiene education significantly improves sleep quality, depression, anxiety and fatigue. The high-sensitive C-reactive protein, IL-18, and oxidized low-density lipoprotein levels also significantly declined with CBT-I in comparison with the control group. In another study on 103 maintenance haemodialysis, the scores of somatization in the following categories were

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significantly lower in the CBT (sleep-related behaviour modification and progressive muscle relaxation) group compared with the control group: depression, anxiety, hostility, total sleep quality, subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, hypnotics, and daytime dysfunction (Hou *et al*., 2014).

One way to increase the availability of treatment is to offer group therapy, which can be more cost-effective as it allows a larger number of patients to be treated at the same time (Tucker and Oei, 2007). A relatively less studied approach to CBT-I which is called CBGTI gives precedence to group formats due to their perceived advantages in many types of psychotherapy, including cognitive behavioural therapies (Bieling *et al*., 2006; Yalom and Leszcz, 2005). In a randomized controlled trial study by Jansson and Linton (2005) on patients seeking care for insomnia, more participants in the CBGT-I than self-help information package made meaningful improvements in sleep onset latency, time awake after sleep onset, and sleep efficiency at the 1-year follow-up.

Research questions

CBT-I and CBGT-I are effective for sleep disturbance, depression and anxiety in many different samples. This can be particularly important in cases (such as haemodialysis patients) where sleeping and anti-depressant medications are not ideal (e.g. due to contraindications, cost, or treatment resistance) (Cunningham and Shapiro, 2018); however, it seems that these approaches have not been well studied in haemodialysis patients. This study was performed to determine the effectiveness of CBGT-I on patients undergoing haemodialysis looking to propose a better therapeutic approach to healthcare for these individuals. As such, the question is whether CBGT-I compared with a control group can improve the sleep quality, depression, anxiety and general psychological health in patients with ESRD and poor sleep quality, clinical depression and clinical anxiety.

Method

Background of the study

The current study was a parallel randomized controlled trial. It was approved by the National Ethics Committee of Neyshabur Islamic Azad University (approval reference no. IR.IAU.NEYSHABUR.REC.1397.020) and, prior to the start of the study, it was registered as prospective research with Iranian Randomized Clinical Trials (reference no. IRCT20171219037967N1). Clinician-rated outcome assessments were administered by an individual who was not involved in the treatment of participants.

Inclusion and exclusion criteria

The research inclusion criteria were the experience of ESRD, having undergone haemodialysis for at least 3 months, a minimum of diploma education, voluntary participation in the study, age $\geq$20 years, PSQI score $\geq$5, BDI-II score $\geq$15, BAI score $\geq$8, GHQ-28 score $\geq$7, and failure to receive a simultaneous psychological treatment at the time of research. The exclusion criteria were having acute psychotic symptoms or suicide attempts in the beginning or through the treatment, mental disability, and failure to complete research.

Participants and sample

All participants were recruited from the haemodialysis ward in Mashhad from April 2019 to March 2020; the researcher selected only patients who met the inclusion criteria. A CONSORT diagram which illustrates the participant flow throughout the study is presented

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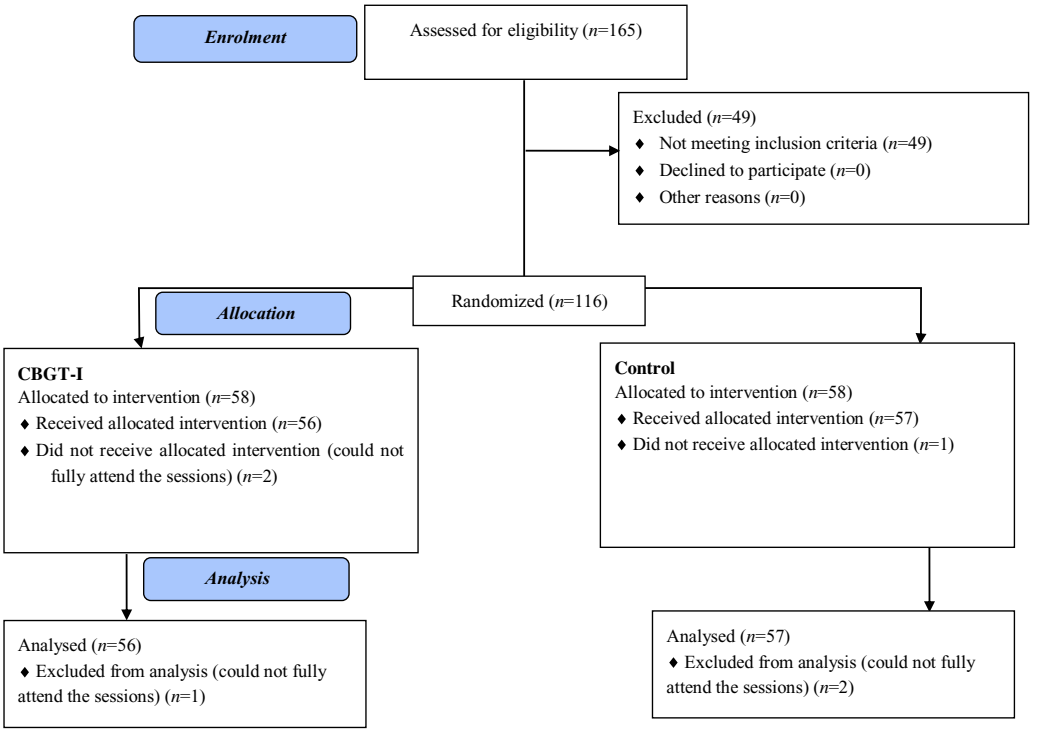

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) diagram illustrating the flow of participants through the study.

in Fig. 1. Of the patients introduced to the researchers for participating in the study (n=165), 27 patients due to PSQI score <5, BDI-II score <15, BAI score <8 or GHQ-28 score <7, 10 patients due to acute renal failure, six patients due to haemodialysis less than 3 months, two patients due to receiving other psychotherapies, one patient because of mental disability, two patients due to acute psychotic symptoms and one patient because of suicide attempt were excluded from the research. Ultimately, 116 patients who met the inclusion criteria were randomly assigned to two groups. Randomization was based on permutation block. Accordingly, 58 blocks were allocated to the individuals, each containing one person from the intervention group and one person from the control group. A general practitioner who was blind to the study objectives prepared the randomization.

During CBGT-I sessions, two subjects were not able to complete the sessions, each for a different reason, one due to inability to follow the timetable of treatment sessions (30-year-old single man with 5-year history of haemodialysis) and one patient refused to participate after two sessions for unknown reasons (27-year-old women with 1-year history of haemodialysis). Also, one subject in the control group was excluded from the research due to his child's illness and his declining to continue the research project (41-year-old married man with 3-year history of haemodialysis).

Procedure

All participants responded to the PSQI, BDI-II, BAI and GHQ-28 in the pre-test and post-test. Furthermore, CGI, CSQ and WAI-S were completed at post-treatment by the experimental group.

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Reviews were made to all the participant questionnaires to make sure they have been completed accurately.

Experimental group participants received group intervention during nine sessions of 90 minutes on a weekly basis, but the control group did not receive this intervention until the end of the treatment phase. The control group members were told that they should wait for approximately 3 months to receive CBGT-I. After that, they could use this treatment service provided by the therapist if they were willing.

Instruments

Except for self-rating questionnaires, all assessments were performed by a clinical psychologist who did not attend CBGT-I. PSQI was the primary outcome and other measures were the secondary outcomes.

Pittsburgh Sleep Quality Index (PSQI; Buysse et al., 1989)

The PSQI is a 19-question, self-rated questionnaire which assesses sleep quality and disturbances and has seven domains which include: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction. Scores less than 5 represent desired sleep quality, and scores of 5 and higher indicate sleep disorder (Buysse *et al.*, 1989). The validity of the PSQI has been investigated in different studies (Shochat *et al.*, 2007). Backhaus *et al.* (2002) reported the reliability level of PSQI in individuals with first insomnia to be 0.85 through Cronbach's alpha method and 0.87 through the test–retest method. Its reliability in a sample of 40 Iranian patients with chronic insomnia was estimated to be 0.87 (Khaledipaveh *et al.*, 2018). In the present study, the reliability of this questionnaire was calculated to be 0.83, using Cronbach's alpha method.

Beck Depression Inventory-II (BDI-II; Beck et al., 1996)

The BDI-II is a 21-item self-report instrument for measuring the severity of depression based on a 4-point scale with a possible total score between 0 and 63. The reliability and validity of the BDI-II have been well established, with a test–retest reliability coefficient of 0.93 and internal reliability of 0.86 (Beck *et al.*, 1996). A test–retest reliability of .91 was found in a sample of 109 Iranian nurses working in critical care units (Mogharab *et al.*, 2016). In the present study, Cronbach's alpha was calculated to be 0.92.

Beck Anxiety Inventory (BAI; Beck et al., 1988)

The BAI is a 21-item scale that measures the severity of anxiety. Ratings are obtained on a 4-point scale with a possible total score between 0 and 63 (Beck *et al.*, 1988). The BAI has shown the coefficient of 0.75 for the test–retest reliability after 1 week and 0.87 for internal consistency (Beck and Steer, 1991). In an Iranian study, its reliability in a sample of 250 out-patients with various medical complaints was estimated to be 0.85 through the test–retest method (Afkham-Ebrahimi et al., 2010). In the present study, Cronbach's alpha was calculated to be 0.83.

General Health Questionnaire (GHQ-28; Goldberg et al., 1976)

The GHQ-28 is one of the most validated questionnaires to screen for emotional distress and possible psychiatric morbidity. Two main concerns are identified by measuring psychological wellbeing/general psychological health through the GHQ-28: (1) the inability to carry out normal functions; and (2) the appearance of new and distressing phenomena. Here, a lower score indicates better psychological wellbeing and mental health status. Through factor

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analysis, the GHQ-28 has been divided into four subscales: somatic symptoms, anxiety and insomnia, social dysfunction, and severe depression (Goldberg *et al.*, 1976). Cronbach's α coefficient was 0.92 for the total scale (Ignatyev *et al.*, 2012). In an Iranian study, its reliability was estimated to be 0.81 through the test–retest method (Gohari *et al.*, 2020). Quek *et al.* (2001) showed that a short form of GHQ is suitable, reliable, valid and sensitive to clinical change in urological disorders. In the present study, Cronbach's alpha for GHQ-28 was calculated to be 0.86.

Clinical Global Impression Scale (CGI; Guy, 1976)

The CGI rating scale is a clinician-administered measure of symptom severity, treatment response and the efficacy of treatments in clinical trials for many psychological disorders (Diefenbach *et al.*, 2006). The CGI has three subscales: severity of illness, global improvement, and efficacy index. We used the global improvement subscale of the CGI at the end of CBGT-I. A score of 1 in the improvement subscale of CGI indicates an improvement in subjects as a result of the treatment; clients report more improvement as the score approaches 1 and they report less improvement in the treatment as the score approaches 7. High internal consistency was demonstrated by a kappa statistic of 0.971 and Cronbach's alpha of 0.998 (Targum *et al.*, 2012). Its reliability in a sample of 36 Iranian patients was estimated to be 0.94 through the Cronbach's α method (Shareh *et al.*, 2022). In the present study, Cronbach's alpha was calculated to be 0.98.

Client Satisfaction Questionnaire (CSQ, Larsen et al., 1979)

The CSQ has eight questions and is one of a limited number of standardized satisfaction measures used widely across mental health services (Kelly *et al.*, 2018). The internal consistency coefficient of this scale based on Cronbach's alpha ranged from 0.83 to 0.94 (Attkisson and Zwick, 1982). Reliability of CSQ in a sample of 23 patients with obsessive-compulsive disorder calculated to be 0.93 through the Cronbach's alpha method and 0.89 through the test–retest method (Shareh, 2014). In the present study, Cronbach's α was calculated to be 0.91.

Working Alliance Inventory-Short Form (WAI-S; Tracey and Kokotovic, 1989)

The WAI-S is a reliable, valid and widely used tool for measuring therapeutic alliance. It is a 12-item instrument scored on a 7-point Likert scale (Smits *et al.*, 2015). A meta-analytic review estimated that the test–retest reliability was approximately 0.73 (Martin *et al.*, 2000). Its reliability in a sample of 36 Iranian patients was estimated to be 0.88 through the Cronbach's α method (Shareh *et al.*, 2022). In the present study, Cronbach's α of the whole inventory was calculated to be 0.89.

Treatment and therapists

The present study consisted of two groups of 58 patients who met the inclusion criteria. Both groups received dialysis treatments in parallel. In the experimental group, patients attended the CBGT-I sessions when they were out of haemodialysis. There were eight concurrent intervention groups. The range number of participants in each group was n=7–9. Nine 90-minute group sessions of CBGT-I were conducted weekly by a licensed clinical psychologist with extensive specialized training in group, CBT, CBGT, CBT-I and CBGT-I therapy models (with more than 3700 hours of academic training, including courses, theory, clinical practice for 10 years, and weekly supervisions). Therapeutic sessions were held in a separate room from the haemodialysis ward, which was coordinated by the head of the department who was involved in the research directly but was informed to the aims of the

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Table 1. The summary of treatment sessions

Session	Content of the treatment sessions
Session 1	Introduction of CBGT-I program, talking about stress regarding chronic renal disease and haemodialysis, understanding of sleep quality, anxiety and depression
Session 2	Psychoeducation: educating patients about the importance of good sleep hygiene, talking about the effects of diet, exercise, and sleeping environment on falling and staying asleep. The self-monitoring of mood status
Session 3	Breathing exercises, guided imagery and self-soothing techniques for experiencing positive feelings, better sleep and decreasing pain
Session 4	Progressive muscular relaxation, body scan practice, autogenic training
Session 5	Programming pleasant activities, stimulus control and reclaiming the bedroom as a place for restful sleep
Session 6	Recognizing unhelpful automatic thinking and explaining the relationship between thinking and emotion
Session 7	Cognitive restructuring: identifying, challenging, and altering the thoughts and beliefs that contribute to insomnia and pain and then challenging and altering unhelpful thoughts by evaluating them more objectively
Session 8	Cognitive restructuring: identifying, challenging, and altering the thoughts and beliefs that contribute to insomnia, pain, sadness and anxiety and then challenging and altering unhelpful thoughts by evaluating them more objectively
Session 9	Sleep restriction: calculating the total time spent asleep on a typical night and adjusting the time in bed to reflect this amount, plus 30 minutes, then beginning to gradually increase the time in bed once a person spends the majority of his/her time in bed sleeping, planning for sleep quality, anxiety and depression management

study. To monitor the accuracy of treatment implementation and fidelity of the intervention and to reduce therapeutic drift, the psychotherapist received regular individual supervision from another psychologist specialized in CBGT-I (an Associate Professor of Clinical Psychology). Not being involved in the research directly and not communicating with the patients, he just checked the records of each session and related activities with the patients and provided feedback to the therapists after each session throughout the study period.

While participants in the control group suffered from sleep problems, depression and anxiety, there were no group sessions for them to undergo psychotherapy with regard to these problems. The control group received psychoeducation consultation in a group format which consisted of providing general guidelines about the haemodialysis treatment and emotional support for the patients' psychological suffering, related to the disease and medical treatment complications. In other words, they enjoyed the benefits of sharing their suffering in a group and talking to a psychologist. Another psychologist, different from the one who conducted the CBGT-I and unaware of the patients' allocation in addition to the study objectives, was in charge of this process. During the following 3 months, this psychological care was provided whenever necessary to guarantee the patients' rights of assistance. No other type of psychological care was administered to the patients throughout the research period.

Organization of the CBGT-I program

The content of CBGT-I sessions was taken from the book *Cognitive Behavioral Therapy for Chronic Illness and Disability* (Taylor, 2009) and also from the latest research work done in this field (Chen *et al.*, 2011; Ng *et al.*, 2019; Paardekooper *et al.*, 2020; Pigeon, 2010). The summary of the content of the treatment sessions is given in Table 1.

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Data analyses

One-way analysis of covariance (ANCOVA) was employed to compare the differences between CBGT-I and control groups. ANCOVA with the pre-treatment value as a covariate and the post-treatment values as dependent variables was used to account for the difference in the effectiveness of the treatment depending on pre-treatment severity. As four significance comparison tests were conducted, a Bonferroni correction was applied leading to an adjusted alpha of 0.012. The desired alpha-level must be divided by the number of comparisons in order to obtain a *p*-value for determining significance level in Bonferroni correction. To calculate the effect size, partial eta squared (η^2=SSeffect/SSeffect+SSerror) was provided. A general guideline for interpreting η^2 based on Stevens (2002) is as follows: small (0.01), medium (0.06) and large (0.14). No power analysis was conducted prior to data collection.

Results

Almost all participants were present until the end of the study. None of the patients in the intervention group discontinued because of a CBGT-I adverse effect. Participant characteristics are given in Table 2. The mean age was 43.7±6.4 years in the experimental group and 46.4±7.9 years in the control group. Forty-four participants were female (39%) and 69 participants were male (61%). Eighty-eight participants had diabetes mellitus as the main underlying disease. Other underlying conditions were hypertension, heart disease or other causes. Although most of the participants had combined medical diseases including hypertension, diabetes, cerebrovascular disease, and coronary artery disease, their overall physical states were stable during CBGT-I. In terms of demographic characteristics, the results of *t*-test (for age) and χ^2 showed that homogeneity between groups has been achieved ($p>.05$) (Table 2).

The rate of CGI scores in the experimental group varied between 1 and 5 (mean=1.92, *SD*=1.18), indicating that participants showed notable improvements post-treatment. Also, satisfaction with the protocol, as indicated by the CSQ, was high (mean=29.66, *SD*=2.08, range=26–33). The mean WAI-S score was 5.93 (*SD*=0.90, range=5–7), which indicates a good therapeutic relationship (Table 3).

Descriptive statistics show that the mean scores of experimental groups in depression, anxiety, general psychological health and sleep quality are lower than those of the control group in the post-test (Table 4). To perform ANCOVA test, in addition to the interval scale of the variable's measurement, normal distribution of variables (Kolmogorov–Smirnov Z=.859–1.79, all $p>.05$) and homogeneity of variances (Levine's test F=1.36–3.02, all $p>.05$) was also confirmed.

Table 4 shows that CBGT-I compared with control group leads to improvement in sleep quality ($F_{1,110}$=414.98, $p<.001$, effect size of 0.79), decrease in depression ($F_{1,110}$=176.63, $p<.001$, effect size of 0.61), decrease in anxiety ($F_{1,110}$=235.70, $p<.001$, effect size of 0.68), and improvement in general psychological health ($F_{1,110}$=744.16, $p<.001$, effect size of 0.87). The observed power for all tests was 1. The corrected *p*-values for determining significance level in Bonferroni correction were less than 0.012, which gave rise to the conclusion that the differences in all outcome measures were significant. According to the results of Table 4, the mean of the experimental group after the implementation of CBGT-I has changed in the components considered in sleep quality (from 11.35 to 8.21), depression (from 28.92 to 22.07), anxiety (from 23.85 to 18.92) and general psychological health (from 44.57 to 36.42).

Regarding the subscales of PSQI, the CBGT-I group, compared with the control group, had better performance in the post-test in dimensions including subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, and sleep disturbances (all $p<.001$). For components of daytime dysfunction and the use of sleep medication, the results showed that

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Table 2. Participant characteristics

		n=57	*n*=56	
		Control group	Experimental group	*p*
Age				
	Mean±*SD*	46.4±7.9	43.7±6.4	0.71
Gender				
	Female	20 (35%)	24 (43%)	0.51
	Male	36 (65%)	32 (57%)	
Marital status				
	Married	47 (82%)	43 (77%)	0.45
	Single	10 (18%)	13 (23%)	
Education				
	Diploma	15 (26%)	18 (32%)	0.49
	Higher diploma	42 (74%)	38 (68%)	
Occupational status				
	Employed	30 (52%)	32 (57%)	0.81
	Unemployed	11 (19%)	9 (16%)	
	Retired	12 (22%)	13 (23%)	
	Student	4 (7%)	2 (4%)	
Insurance				
	With insurance	52 (91%)	48 (86%)	0.36
	Without insurance	5 (9%)	8 (14%)	
History of hospitalization				
	Yes	16 (29%)	20 (35%)	0.38
	No	41 (71%)	36 (65%)	
Underlying disease				
	Diabetes	30 (53%)	32 (57%)	0.81
	Hypertension	11 (19%)	10 (18%)	
	Heart disease	7 (12%)	4 (7%)	
	Other	9 (16%)	10 (18%)	
History of mood disorders				
	Yes	21 (37%)	20 (35%)	0.90
	No	36 (63%)	36 (65%)	
History of anxiety disorders				
	Yes	19 (33%)	21 (38%)	0.64
	No	38 (67%)	35 (62%)	
History of suicide attempt				
	Yes	5 (9%)	3 (5%)	0.48
	No	52 (91%)	53 (95%)	
History of psychotic disorders				
	Yes	4 (7%)	5 (9%)	0.71
	No	53 (93%)	52 (91%)	
History of taking psychotropic medication				
	Yes	14 (25%)	11 (20%)	0.53
	No	43 (75%)	45 (80%)	
History of receiving counselling and psychotherapy	Yes	14 (25%)	10 (18%)	0.38
	No	43 (75%)	46 (82%)	

Table 3. Patient's satisfaction, improvement and therapeutic relationship after CBGT-I

	Lowest score	Highest score	Mean	Standard deviation
Clients' satisfaction (CSQ)	26	33	29.66	2.08
Overall improvement of clients (CGI)	1	5	1.92	1.18
Therapeutic relationship (WAI-S)	5	7	5.98	.90

CSQ, Client Satisfaction Questionnaire; CGI, Clinical Global Improvement Scale; WAI-S, Working Alliance Inventory-Short Form.

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Table 4. Descriptive statistics and univariate analysis of covariance results to examine intergroup differences in cognitive behavioural group therapy and control groups

Variables	Subscales	Time	Mean (*SD*)		ANCOVA		
			CBGT	Control	*F*	*p*	η^2
PSQI	Subjective sleep quality	Pre-test	1.64 (.72)	1.57 (.73)	27.58	.000	.200
		Post-test	1.35 (.81)	1.78 (.67)			
	Sleep latency	Pre-test	2.57 (.73)	2.71 (.59)	31.94	.000	.225
		Post-test	1.57 (.73)	2.29 (.70)			
	Sleep duration	Pre-test	2.14 (.99)	2.08 (.96)	22.96	.000	.173
		Post-test	1.57 (.91)	1.94 (.89)			
	Habitual sleep efficiency	Pre-test	1.14 (.51)	1.08 (.71)	18.86	.000	.146
		Post-test	.92 (.59)	1.15 (.75)			
	Sleep disturbances	Pre-test	1.28 (.45)	1.30 (.49)	18.50	.000	.144
		Post-test	1.07 (.46)	1.35 (.48)			
	Use of sleep medication	Pre-test	1.07 (.80)	.93 (.68)	3.51	.064	.031
		Post-test	1.00 (.76)	.92 (.70)			
	Daytime dysfunction	Pre-test	1.50 (1.19)	.85 (1.05)	.850	.358	.008
		Post-test	1.21 (1.02)	.80 (.95)			
	PSQI (total)	Pre-test	11.35 (3.72)	10.61 (3.51)	414.98	.000	.790
		Post-test	8.21 (3.19)	10.42 (3.34)			
BAI		Pre-test	23.85 (6.13)	22.73 (6.52)	235.70	.000	.682
		Post-test	18.92 (5.37)	22.12 (6.22)			
BDI-II		Pre-test	28.92 (7.81)	27.00 (6.71)	176.63	.000	.616
		Post-test	22.07 (7.54)	26.38 (7.31)			
GHQ	Somatic symptoms	Pre-test	7.64 (1.81)	8.13 (1.66)	111.27	.000	.503
		Post-test	6.71 (1.49)	8.73 (1.71)			
	Anxiety and insomnia	Pre-test	14.00 (3.05)	13.47 (3.18)	501.16	.000	.820
		Post-test	11.50 (2.57)	13.57 (3.16)			
	Social dysfunction	Pre-test	8.28 (1.80)	8.84 (2.80)	218.95	.000	.666
		Post-test	6.92 (1.59)	8.76 (2.63)			
	Severe depression	Pre-test	14.64 (3.50)	14.58 (3.45)	735.99	.000	.870
		Post-test	11.28 (2.70)	14.75 (3.59)			
	GHQ (total)	Pre-test	44.57 (8.22)	45.91 (10.02)	744.16	.000	.871
		Post-test	36.42 (6.75)	45.77 (10.21)			

PSQI, Pittsburgh's Sleep Quality Index; BAI, Beck Anxiety Inventory; BDI-II, Beck Depression Inventory-II; GHQ, General Health Questionnaire; CBGT, cognitive behavioural group therapy; *SD*, standard deviation; η^2, effect size.

there is no significant differences between CBGT-I and control groups. Also, the CBGT-I group had better performance than the control group in the post-test in all subscales of GHQ including somatic symptoms, anxiety and insomnia, social dysfunction and severe depression (all $p<.001$).

Discussion

Based on the results of CSQ and CGI, it seems that this treatment has been well accepted by patients undergoing haemodialysis and has had good effects on them. In addition, the WAI-S score indicates a good therapeutic alliance. The therapeutic alliance is a strong predictor of psychotherapy or counselling client outcome (Ardito and Rabellino, 2011).

According to the main findings of the present study, compared with the control group, CBGT-I positively improved sleep quality, depression, anxiety and general psychological health of haemodialysis patients. Among the patients who received CBGT-I, 54% improvement in sleep quality, 36% improvement in depressive symptoms, 41% improvement in anxiety symptoms, and 39% improvement in general psychological health were reported.

It is noteworthy to say, while there are differences between the treatment and control group post-intervention, the mean score of both groups remained higher than the cut-off point across both groups even after treatment for: sleep disorder (based on PSQI scores), general psychological

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health problems (based on GHQ-28 scores), in the 'moderate' range for depression (based on BDI-II scores) and anxiety (based on BAI scores).

CBGT-I for sleep quality

The findings of this study showed that CBGT-I improved the total score of sleep quality and its dimensions including subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency and sleep disturbances in haemodialysis patients and it has not affected other dimensions. Based on these findings, we can conclude that CBGT-I reduces the effects of insomnia. Multiple studies show that by conducting CBT-I, 70 to 80% of patients with primary insomnia experience less time to fall asleep, more time spent asleep, and reduced waking after sleep onset (Trauer *et al.*, 2015). Our findings are in line with the study of Chen *et al.* (2011) on 72 sleep-disturbed haemodialysis patients showing that tri-weekly CBT-I compared with sleep hygiene education is more effective for correcting disorganized sleep patterns, and for reducing inflammation and oxidative stress in haemodialysis patients. The results of our study are consistent with the results of the study of Hou *et al.* (2014) on 103 maintenance haemodialysis patients, concluding a type of CBT (sleep-related behaviour modification and progressive muscle relaxation) improves mental state and sleep quality of haemodialysis patients with insomnia. However, the type and frequency of treatment used in our study (9-session CBGT-I) is somewhat different from the research of Chen et al. (2011) and Hou *et al.* (2014). In a randomized controlled trial study by Jansson and Linton (2005) comparing the effects of CBGT-I and a self-help information package in patients with insomnia, significantly more participants in the CBGT-I met criteria at the 1-year follow-up for clinically meaningful improvements in sleep onset latency, time awake after sleep onset, and sleep efficiency. Although diverging from Jansson and Linton study, we conducted CBGT-I on a special sample (haemodialysis patients) with no follow-up, and the results of our study in line with Jansson and Linton study indicated that the CBGT-I is more effective than the control group in improving sleep. However, Jansson and Linton compared CBGT-I with a self-help information package while we compared CBGT-I with a psychoeducation consultation group.

The results of our study are consistent with the study by Jacobs *et al.* (2004) who suggested that in most measures, CBT-I was the most effective sleep intervention; it produced the greatest changes in sleep-onset latency and sleep efficiency, yielded the largest number of normal sleepers after treatment, and maintained therapeutic gains at long-term follow-up. In that study, pharmacotherapy produced only moderate improvements during drug administration and returned measures toward baseline after drug use discontinuation. A study by Morin *et al.* (2002) suggested that both cognitive behavioural and pharmacological treatments increased the total sleep duration by 15% after 4 weeks, but only the cognitive behavioural interventions maintained their effect after 9 weeks. Also, a systematic review showed that CBT-I is more effective than benzodiazepine and non-benzodiazepine drugs in the treatment of insomnia in the long term (Mitchell *et al.*, 2012).

For components of daytime dysfunction and the use of sleep medication (from the PSQI), the results showed that CBGT-I did not affect these components. In explaining the result, it can be said that the consumption of various types of analgesics and sedative regulators, blood glucose control drugs, blood pressure medication and so on that the patient uses daily for improvement of multiple physical symptoms associated with haemodialysis, drug tolerance and overlapping their effects cause insomnia and, therefore, the patient's inability to reduce daily problems and reduce the use of sleep medication (Ibrahim *et al.*, 2018). Also due to the wide range of side-effects induced by haemodialysis on other body organs, deep pain caused by connecting the haemodialysis device to the patient's arteries, the strain of the continuation of haemodialysis on the patient, the physical weakness due to the complications of the disease

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and the disintegration of the electrolyte order blood biochemistry, therapeutic intervention probably did not have a significant effect on these components (Hawamdeh *et al.*, 2017).

Additionally, the results showed that the patients' sleep quality in the control group has not decreased over time, which indicates that sleep problems are serious in haemodialysis patients, and emphasizes the importance of interventions such as CBGT-I to improve sleep quality.

CBGT-I for depression and anxiety

Results of the present study demonstrate that CBGT-I was effective in depression and anxiety of haemodialysis patients. This is somewhat consistent with the findings obtained by Duarte *et al.* (2009) which showed that CBGT is an effective treatment for major depression in haemodialysis patients. In their study, after 3 months of intervention (12 CBGT sessions) and after 9 months of follow-up, the intervention group had significant improvements compared with the control group (received the usual treatment offered in the dialysis unit) in the average scores of the BDI and in quality-of-life dimensions. It seems that the methods, processes and results of our study are relatively similar to this study, but in Duarte *et al.* study, the rate of improvement in depression (based on BDI score) was about 3 points higher in the intervention group (probably due to more treatment sessions and more focused treatment on depression in the Duarte *et al.* study) and our study results were not followed up. The findings of our study are similar to those of Carney *et al.* (2017), Cunningham and Shapiro (2018) and Behenck *et al.* (2021). Carney *et al.* (2017) showed that CBT-I + anti-depressant medication improved depression and objective and subjective sleep. Cunningham and Shapiro (2018) in a systematic review concluded that CBT-I and CBGT-I are effective in treating sleep disturbances associated with depression.

In explaining the results, it can be mentioned that CBGT and CBGT-I improve a person's hope by improving beliefs and teaching mental imagery, rational thinking, and relaxation techniques through increasing efficiency and self-efficacy. Use of the cognitive behavioural model and its positive effect on reducing stress, anxiety, depression and hopelessness have shown this method to be an appropriate technique to improve the mental health of haemodialysis patients (Chen *et al.*, 2011).

CBGT-I for general psychological health

The data analysis of our study demonstrated that the intervention has been effective in improving the general psychological health of the participants. Although few studies have evaluated the effectiveness of CBT-I and CBGT-I in general psychological health, there are many studies that show CBT and CBGT are effective in improving general psychological health (Henriksson *et al.*, 2016; Sohn *et al.*, 2018). It seems that improving negative psychological symptoms such as depression and reducing individual stress can lead to increased hope and improves one's attitude towards illness, future and self; as a result, the person will feel more satisfied and relaxed. Individual and group-based CBT and CBT-I treatments prepare the ground for people to recognize their own irrational thoughts and causes reduction in depression and anxiety by providing solutions (Picariello *et al.*, 2018; Qaseem *et al.*, 2016; Trauer *et al.*, 2015). In CBT/CBGT, patients change the content of negative thoughts about the disease through recognizing and challenging cognitive errors and doing behavioural experiments. In addition, it is said that changing thoughts could help in emotional development, adoption, and flexibility through the experience of positive feelings and attention to bright aspects of life. Having a balanced attitude and view towards life, which is achieved through CBT/CBT-I and CBGT/CBGT-I, may be a contributing factor in these positive outcomes (Espie *et al.*, 2019; Paardekooper *et al.*, 2020; Valsaraj *et al.*, 2016).

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Limitation

Although our CBGT-I program was feasible and effective, some limitations existed. First, the sample was limited to those who have ESRD, sleep disturbance, clinical depression, and clinical anxiety. This limits the generalizability of the findings. Second, we did not include drop-outs in our analysis. So, there may be some limitations because the analyses conducted do not adhere to the 'intention to treat' principle. However, it is very unlikely that the results of this study substantially differ from the results of the analysis that adheres to the principle of 'intention to treat' as only three participants (two in the CBGT-I group and one in the control group) were excluded from analyses. Third, we did not carry out a longitudinal follow-up and therefore could not confirm the long-term effect. In the future, a randomized controlled study with a larger and more representative ESRD sample and long-term observation will be needed to support the results of the present study. Also, the effectiveness of CBGT-I can be evaluated on outcomes such as cognitive flexibility, metacognitions, etc., which are factors that may play a role in depression, anxiety and sleep problems. This evaluation can identify factors that CBGT-I may improve sleep problems, depression, anxiety and general psychological health by affecting these factors.

Conclusion

The results of this study show the favourable effects of CBGT-I on improving sleep quality, depression, anxiety and general psychological health in haemodialysis patients. Given the increasing prevalence of ESRD and the high prevalence of sleep disturbances as well as depression and anxiety in haemodialysis patients, it is recommended that health organizations highlight the efficacy of this method and increase access to it. By doing so, it is hoped that more patients will receive effective and appropriate treatment of insomnia, depression and anxiety in order to improve their mental health and quality of life.

Data availability statement. Data are not publicly available due to privacy and ethical restrictions.

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Author contributions. **Hossein Shareh:** Conceptualization (lead), Data curation (supporting), Formal analysis (lead), Investigation (supporting), Methodology (lead), Project administration (lead), Resources (supporting), Software (supporting), Supervision (lead), Validation (lead), Visualization (lead), Writing – original draft (lead), Writing – review & editing (lead); **Morteza Hasheminik:** Data curation (equal), Investigation (equal), Project administration (equal), Resources (equal), Writing – original draft (equal); **Mehdi Jamalinik:** Conceptualization (equal), Data curation (equal), Investigation (equal), Project administration (equal), Resources (equal), Writing – original draft (equal).

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Conflict of interest. The author declare none.

Ethical standards. All the research meets ethical guidelines, including adherence to the legal requirements of the study country. Also, in this study the provisions of the Declaration of Helsinki were respected. Some of the ethical issues considered in this study were: explanation of the study objectives and obtaining the written informed consent of the study participants, the right to withdraw from the study, absence of any physical or psychological harm to participants, answering the participants questions and making results available if desired.

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