Original Research

Effectiveness of Internet-Based Cognitive-Behavioral Therapy for Insomnia during Quarantine of Severe Acute Respiratory Syndrome Coronavirus 2 Pandemic: A Controlled Trial

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Received: 01 Apr. 2020 Accepted: 30 May 2020

Abstract

Background and Objective: In the late 2019, an acute respiratory syndrome [severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)] resulted in a pandemic coronavirus disease (COVID-19). This study was designed to compare the efficacy of internet-based cognitive behavioral therapy for insomnia (ICBT-I) with online relaxation training for management of insomnia during SARS-CoV-2 pandemic.

Materials and Methods: This controlled trial was conducted on adults (18-65 years) with the complaint of insomnia who called psychology call centers in Mashhad, Iran, from March to June 2020. Participants with insomnia symptoms starting after SARS-CoV-2 pandemic who had Insomnia Severity Index (ISI) scores of ≥ 15 were included in the study. Five weekly sessions of ICBT-I as the intervention were compared with 5 weekly online relaxation training sessions in the control group. ISI before and after 5 weeks of follow-up was compared in both groups.

Results: From a total cohort of 144 subjects included in the study, 98 were excluded and the remainder were allocated to 23 cases and 23 control subjects. During follow-up period, 5 individuals (21.7%) dropped out in each group. The mean ISI scores improved after therapy (20.6 to 8.5 and 21.8 to 13.0 for intervention and control groups, respectively).

Conclusion: ICBT-I significantly improved insomnia severity during home quarantine of SARS-CoV-2 pandemic. We suggest that ICBT-I could be an effective and feasible alternative in pandemic of an infectious disease. Clients accepted ICBT-I with a minor drop-out in our study.

Keywords: Insomnia; Cognitive behavioral therapy; Internet-based intervention; Remote consultation; COVID-19; SARS-CoV-2

Citation: Farrokhi H, Shid Anbarani B, Seyyedzadeh SI, Taghavi Bojnordi A, Amini M. **Effectiveness of Internet-Based Cognitive-Behavioral Therapy for Insomnia during Quarantine of Severe Acute Respiratory Syndrome Coronavirus 2 Pandemic: A Controlled Trial.** J Sleep Sci 2020; 5(3): 111-116.

Introduction

At the beginning of 2020, a novel coronavirus called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spread rapidly across all over the world and affected more than 3 million people in 200 countries including Iran (1). Home quarantine had been suggested in many countries due to the increment of infected cases and deaths from SARS-CoV-2. Quarantine protocols have led to closing most jobs as well as schools and universities, fall of business, social isolation, financial and working pressures, which along with contradictory news broadcasted through social networks led to psychological problems in the general population. These problems were mainly composed of stress, psychological distress and

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fear of death, anxiety, rumination, and depression (2, 3). About 50 million people stayed at home for more than 1 month facing a new and unpleasant situation in our country. Being separated from friends and family members, lack of freedom, boredom, and uncertainty about future also affected their sleep quality and insomnia during SARS-CoV-2 pandemic (4).

Insomnia means an inability to fall asleep and/or waking up too early in the morning or midnight (5), and its standard management method is cognitive behavioral therapy (CBT) (6). CBT contains cognitive and behavioral techniques. Cognitive techniques include identifying and challenging subjects' dysfunctional attitudes and beliefs about sleep, cognitive reconstruction, and training related to sleep health, and behavioral techniques include stimulus control, sleep restriction, regular sleep planning, relaxation techniques during sleep and during the day, strengthening the connection between sleep and bed, meditation, stress reduction, and lifestyle modification (7).

CBT for insomnia (CBT-I) has been shown to be effective as well as short-term pharmacotherapy in improving sleep latency and its total duration of insomnia in subjects (8).

We used remote consultation instead of face-to-face interview to manage SARS-CoV-2 infection control measures. Internet-based CBT-I (ICBT-I) can help therapists in managing their clients online while addressing cost and distance problems and increasing time and place flexibility (9, 10). This study was designed to evaluate practicability and effectiveness of ICBT-I in the management of insomnia during SARS-CoV-2 pandemic and compare it with online relaxation training technique.

Materials and Methods

Study design: This was a controlled trial on subjects seeking to consult for insomnia through phone calls to 2 general psychology call centers (Ferdowsi University of Mashhad call center and Governmental Psychology Organization call center) in Mashhad, Iran, from March to June 2020. This research project was approved by the Ethics Committee of Mashhad University of Medical Sciences, with the approval code of R.MUMS.MEDICAL.REC.1399.455. All partici-pants signed the informed consent form of the study.

Those subjects who called with complaint of difficulty falling asleep or waking up early in the morning were included in the study if they had all the following criteria: 18 to 65 years of age, insomnia symptoms starting after SARS-CoV-2 pandemic, longer than 2 weeks insomnia symptoms with Insomnia Severity Index (ISI) score of 15 or more, having access to smart phone or computers, displaying sufficient cognitive capacity to provide informed consent assessed by Montreal Cognitive Assessment (MoCA) > 10, and willingness to participate. The study design and protocol were explained to participants and they were asked to announce verbally if they accepted to participate. Those with a perceived history of active medical or psychological disorder in the past 6 months, history of alcohol or substance abuse, or those who were unable to communicate fluently in Persian excluded from the study.

***Sample size*:** G*Power 3 program determined sample size of 17 per group with significance level (α) of 0.05, effect size (d) of 0.80, and power of 80% (11) which led to a minimum number of subjects for studying the effectiveness of the intervention.

***Data collection and procedures*:** The included subjects were first interviewed by a clinical psychologist expert in CBT, to evaluate the psychological state of the individuals and build rapport. Insomnia symptoms were evaluated by web-based ISI at the start of the study and after 5 weeks of follow-up. The demographic characteristics of subjects were assessed by self-reported data collection. Time schedule of each session was planned by the client and consultant. Therapy sessions were given through scheduled Skype online video calls in both intervention and control groups.

***Allocation of participants*:** Participants were allocated to intervention and control groups according to which center they called for psychology consultation. Those who called the psychology call center of Ferdowsi University of Mashhad were allocated to intervention group and were treated by ICBT-I and those who called the call center of Governmental Psychology Organization were treated by online relaxation and mindfulness training techniques and considered as control group (Figure 1).

***Intervention (ICBT-I) group*:** Participants of the intervention group were instructed about ICBT-I techniques, schedules, and therapy sessions.

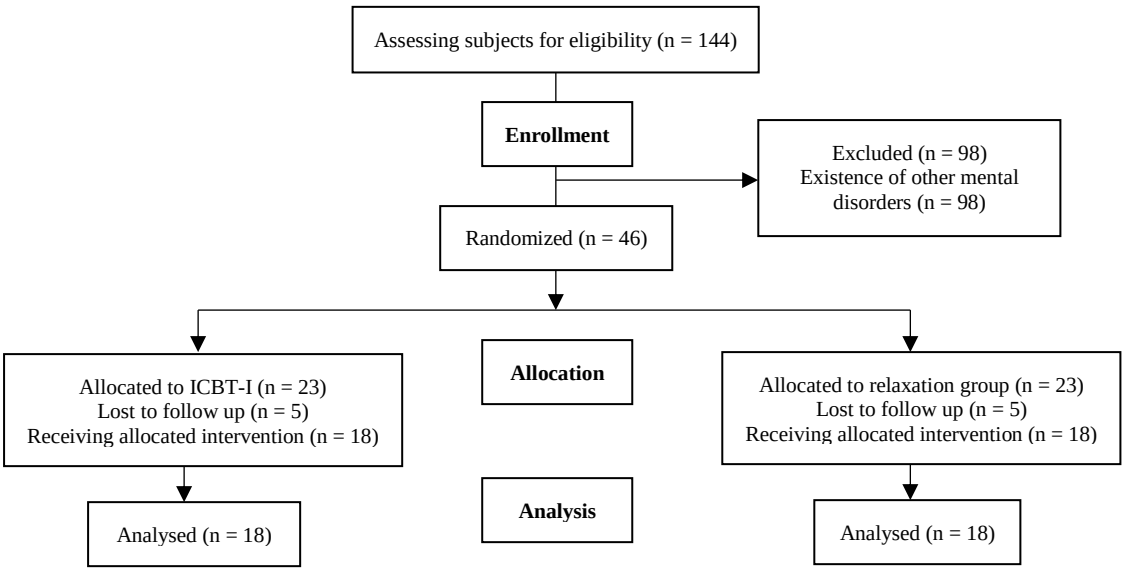

Figure 1. Consort diagram of the trial (ICBT-I: Internet-based cognitive behavioral therapy for insomnia)

ICBT-I consisted of five 2-hour weekly online sessions focusing on facts about sleep, sleep scheduling and stimulus control, cognitive restructuring, and daytime and bedtime relaxation techniques. Cognitive aspects included determining inefficient beliefs about sleep and cognitive reconstruction besides training related to the sleep health, and behavioral techniques included controlling stimulus, restricting sleep, regular sleep schedule, relaxation techniques during sleep and throughout the day, meditation, reducing stress, and lifestyle modification. Participants were instructed to actively practice the learned techniques and they also received regular feedback from their consultant on a weekly basis.

***Control (relaxation) group*:** The control group also received five weekly sessions through Skype online video calls, each session lasting two hours. Clinical psychologists focused on training relaxation and mindfulness techniques to the subjects without using any behavioral or cognitive techniques. The training sessions consisted of training general techniques for relaxation, being in the moment, mindfulness, and anxiety management.

***Instrumentation*:** ISI is a self-report questionnaire with seven items which ask individuals to rate their sleep problems experienced by them during the last 2 weeks based on a Likert scale ranging from zero to four. These seven items evaluate the intensity of problems such as delay in sleep beginning, early morning awakenings, sleep maintenance, satisfaction with the present sleep patterns, daily dysfunction, and distress and anxiety related to the sleep problem. Persian translation of ISI has been shown to be a reliable and valid instrument in evaluating insomnia severity (12). The questionnaire also has cutoff values for insomnia: less than 8 means no insomnia, 8 to 14 means subthreshold insomnia, 15 to 21 means clinical insomnia (moderate severity), and 22 to 28 indicates severe clinical insomnia (13, 14).

***Statistical analysis*:** Analysis of covariance (ANCOVA) was used to compare insomnia scores between ICBT-I and relaxation groups. The data were analyzed by SPSS software (version 20, IBM Corporation, Armonk, NY, USA).

Results

From 144 eligible subjects, 98 individuals were excluded due to a perceived history of concomitant medical or psychological comorbidities. Forty-six participants (28.2% men) with mean ± standard deviation (SD) of age of 31.41 ± 10.85 years were included in the study.

Table 1. Baseline Insomnia Severity Index (ISI) scores and age of 36 subjects having clinical insomnia between relaxation group and internet-based cognitive behavioral therapy for insomnia (ICBT-I) group

Variables	ICBT-I group (Mean ± SD)	Relaxation group (Mean ± SD)	P-value
Age (year)	31.16 ± 9.95	31.66 ± 11.96	0.697
Baseline ISI score	20.61 ± 2.99	21.88 ± 3.67	0.467
N	18	18	-

ICBT-I: Internet-based cognitive behavioral therapy for insomnia; ISI: Insomnia Severity Index; SD: Standard deviation

Table 2. Socio-demographic characteristics of 36 participants with clinical insomnia between internet-based cognitive behavioral therapy for insomnia (ICBT-I) and relaxation groups

Variables		ICBT-I group [n (%)]	Relaxation group [n (%)]	P-value
Gender	Men	7 (38.9)	6 (33.3)	0.732
	Women	11 (61.1)	12 (66.7)	
Marital status	Married	8 (44.4)	7 (38.9)	0.761
	Single	9 (50.0)	10 (55.6)	
	Divorced	1 (5.6)	1 (5.6)	
Education	Illiterate	4 (22.2)	1 (5.5)	0.461
	Diploma	5 (27.7)	7 (38.8)	
	BA	5 (27.7)	5 (27.8)	
	MA	3 (16.6)	4 (22.2)	
	PhD	1 (5.6)	1 (5.6)	

ICBT-I: Internet-based cognitive behavioral therapy for insomnia; BA: Bachelor of Arts; MA: Master of Arts; PhD: Doctor of Philosophy

Twenty-three subjects were allocated to each group with 5 participants (21.7%) losing follow up in each group and 18 cases completing the study in each group.

Tables 1 and 2 indicate that socio-demographic characteristics of 36 subjects (gender, marital status, education level, and age) and baseline ISI scores were similar in intervention and control groups before intervention ($P > 0.05$).

The mean ISI scores before and after five weeks were 20.61 and 8.50 in case group and 21.88 and 13.00 in control group, respectively (Table 3). ISI scores improved in both ICBT-I and relaxation groups.

Table 3. Insomnia Severity Index (ISI) score of subjects in intervention and control groups before and after intervention (n = 18)

	Baseline ISI score: pre-test (Mean ± SD)	Final ISI score: post-test (Mean ± SD)	P-value
ICBT-I group	20.61 ± 2.99	8.50 ± 2.77	< 0.010
Relaxation group	21.88 ± 3.67	13.00 ± 3.21	< 0.010

ICBT-I: Internet-based cognitive behavioral therapy for insomnia; ISI: Insomnia Severity Index; SD: Standard deviation

Before analyzing the research hypotheses, the ANCOVA assumptions were examined. The results indicated that the test was not significant at the level of 0.05 and the distribution of variables was normal. The second assumption was the homogeneity of analysis of variance (ANOVA) (Levene) variable, showing the homogeneity of group variances [$F(1,33) = 0.404$, $P > 0.529$]. The homogeneity test of regression slope was the third assumption, indicating insignificance of the interaction of covariate, pretest, and group at the operating levels (test and control groups). The regression homogeneity assumption was satisfied based on the Pillai's trace of the regression slope [$F(1,33) = 0.018$, $P > 0.895$]. The fourth assumption of multicollinearity testing indicated the avoidance of multicollinearity.

There were significant effects among the participants of both groups [$F(1, 33) = 17.674$, $P < 0.0001$, partial $\eta 2 = 0.34$] (Table 4). However, the examination of the adjusted means of two groups showed that case (ICBT-I) group had a lower average score in ISI after the end of five therapy sessions than control (relaxation) group (Table 3).

The means and SD values of the studied variables corresponding to the ICBT-I group and control group are presented in table 4 after adjusting for covariate variables.

Discussion

Insomnia is the most common sleep disorder worldwide with 25% of the general population reporting symptomatic diagnosis of insomnia and 6% to 10% having full diagnostic criteria for chronic insomnia disorder (15).

Table 4. Tests of between-subjects effects [analysis of covariance (ANCOVA)]

Source	Type III sum of squares	df	Mean square	F	P-value	Partial eta squared	Observed power
Pretest	18.68	1	18.68	2.14	0.031	0.06	0.29
Treatment	154.14	1	154.14	17.67	< 0.001	0.34	0.98
Error	287.81	33	8.72				

Df: Degree of freedom

The prevalence of insomnia symptoms in population exposed to trauma is estimated to range from 41% to 91% (16). Our study showed that both ICBT-I and online relaxation training improved insomnia severity in SARS-CoV-2 pandemic, while ICBT-I was more effective as it ended in significantly lower ISI scores after 5 sessions of therapy.

As this is one of the first studies evaluating the effectiveness of ICBT-I in insomnia during SARS-CoV-2 pandemic, we selected online relaxation training as the standard of care for the control group. Relaxation can improve insomnia but is not as focused on insomnia as ICBT-I.

This study confirms the previous research on the effectiveness of ICBT-I. Both cognitive and behavioral techniques of ICBT-I can improve sleep quality and encourage participants to pursue sleep hygiene habits (17).

Other studies indicated that ICBT-I was broadly as effective and available as face-to-face interventions with specialists in psychology (18, 19). In addition, patients can have access to treatment to learn cognitive and behavioral techniques at their own pace and to telecommunicate with their therapist anywhere in the world (20). Meta-analysis of randomized controlled trials (RCTs) on the effectiveness of ICBT-I in management of insomnia showed that ICBT-I could reduce anxiety and depression in insomnia (19). The rate of dropout was similar in intervention and control groups of our study (21.7%). The lost follow-up of ICBT-I ranges from 7.2% to 29.0% in previous studies (21-23).

This controlled trial was not a randomized one and subject allocation was based on the call center chosen by the individuals, which could adversely affect the study's results. Analysis of sociodemographic characteristics of intervention and control groups showed that groups were similar.

Conclusion

Insomnia is a common complaint during disasters and crises. Quarantine protocols and infection control measures of SARS-CoV-2 pandemic preclude clients and therapists from attending face-to-face office CBT-I. ICBT-I could be an effective and feasible alternative to office CBT-I in pandemic of an infectious disease.

Conflict of Interests

Authors have no conflict of interests.

Acknowledgments

This research has been extracted from an independent research (grant number: 990333) approved by Mashhad University of Medical Sciences. This study received no funds from any organization. The authors enthusiastically thank all staff of Psychology Counseling Services in Ferdowsi University of Mashhad and Governmental Psychology Organization for their kind cooperation.

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