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Cognitive Behavioral Therapy-Insomnia Protocol and Review of Efficacy Studies

Bilişsel Davranışçı Terapi-Uykusuzluk Protokolü ve Etkililik Çalışmalarının Gözden Geçirilmesi

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Abstract

Nowadays, problems related to sleep increase. Insomnia is one of the most frequently encountered sleep disorders in both our country and other countries. The studies investigating the cognitive behavioral therapy based treatment of insomnia disorder and the effectiveness of this treatment approach were reviewed in present study. For the review, the studies on the Cognitive Behavioral Therapy Insomnia (CBT-I) protocol between years 2005-2019 were examined via Medline, PsycINFO, PsycARTICLES, Web of Science, and JStore databases. According to the related literature, CBT-I has shown positive results in decreasing insomnia symptoms, increasing sleep time, and sustaining gains after intervention. Although it is emphasized that the intervention has some disadvantages in some studies, it is not only the treatment of insomnia disorder, but also it is an effective treatment method in the treatment of comorbid disorders such as depression anxiety with insomnia disorder. It is observed that the effectiveness of the CBT-I protocol, which is frequently used in literature and whose effectiveness has been investigated, has not yet been studied in the Turkey. For this reason, in the current study, the studies conducted in the field related to this subject are reviewed.

Keywords: Insomnia, sleep, cognitive behavioral therapy, CBT-I

Öz

Günümüzde uyku ile ilgili problemlerde artış görülmektedir. Hem ülkemizde hem de diğer ülkelerde uykusuzluk bozukluğunun (insomni) en sık karşılaşılan uyku bozukluklarından biri olduğu belirtilmektedir. Bu araştırma kapsamında, uykusuzluk bozukluğunun bilişsel davranışçı terapi temelli tedavisi ve bu tedavi yaklaşımının etkililiğini inceleyen çalışmalar gözden geçirilmiştir. Derleme için Medline, PsycINFO, PsycARTICLES, Web of Science, JStore veri tabanları incelenerek 2005-2019 yılları arasındaki Bilişsel Davranışçı Terapi Uykusuzluk Protokolünü (BDT-U) konu edinmiş çalışmalar incelenmiştir. İlgili alan yazına göre BDT-U'nun uykusuzluk belirtilerini azaltmada, uyunan uyku süresini artırmada, müdahaleden sonra elde edilen kazanımların korunmasında olumlu sonuçları mevcuttur. Yapılan bazı çalışmalarda müdahalenin bir kısım dezavantajlarının olduğu vurgulansa da sadece uykusuzluk bozukluğunun tedavisinde değil, uykusuzluk bozukluğu ile beraber görülen depresyon, anksiyete gibi rahatsızlıkların tedavisinde de bu müdahalenin etkili bir tedavi yöntemi olduğu anlaşılmaktadır. Uluslararası alan yazında sıkça kullanılan ve etkililiğinin araştırıldığı BDT-U protokolünün, ulusal alan yazında etkililik çalışmalarının henüz yapılmadığı görülmüştür. Bu nedenle yapılan çalışmada bu konu ile ilgili uluslararası alan yazında yapılan çalışmalar gözden geçirilmiştir.

Anahtar sözcükler: İnsomni, uykusuzluk bozukluğu, uyku, bilişsel davranışçı terapi, BDT-U

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INSOMNIA disorders affect many people around the world and the incidence has been increasing day by day. Therefore, diagnosis and treatment methods specific to this disorder has also been increasing. In this context, it is noteworthy that it is frequently used in psychosocial interventions as well as pharmacological treatment. However, there is not enough research in the Turkey.

In order to overcome this deficiency, the aim of this study is to introduce the CBT-I protocol, which is frequently used in the literature, and to provide information about its effectiveness. In this review, Insomnia disorder and CBT-I are firstly introduced. Then, information on effectiveness studies related to the CBT-I protocol between 2005 and 2019 is given.

Sleep wake disorders

Sleep is a process that the brain is working effectively, neurophysiological recovery, repair is performed, the awakening of what was learned and stored in the wake; complex neurophysiological and biochemical order (Öztürk 2002). Electroencephalography (EEG) applications are used to investigate sleep (Berger 1929). Researches showed that sleep consists of 5 periods. N-REM (Non-REM period; it includes 4 stages) and REM periods have been discovered to consist of periodic stages (Kryger et al. 2000). It has been found that when this cycle is disrupted, some sleep related disturbances and some other symptoms occur. It is seen that researches about sleep have increased and sleep disorder has become a frequently researched topic in the fields of psychiatry and psychology in the last 40 years (Öztürk 2002). While the physiological structure of sleep is generally examined in the fields of neurology and psychiatry (Öztürk 2008, Parlakoğlu et al. 2013), it is seen that the structural function of sleep, the effects of daily life, problems caused by sleep disorders and the relationship between sleep and other diseases are examined in studies conducted in the field of psychology (Meltzer et al. 2009, Querstret and Cropley 2012, Aydın et al. 2013, Yıldız and Ünal 2017).

Inadequate sleep quality due to deterioration of the sleep cycle can cause both physiological and psychological problems. Sleep disorders may be a disease or a symptom or result of other psychiatric, psychological or physical illnesses (Braunwald and Kasper 2001). When the US-based statistics are examined, it is seen that one in seven adults has chronic sleep disorder (Braunwald and Kasper 2001, Yılmaz 2008) and this problem is mostly experienced as poor sleep at night and daytime sleepiness. In addition, other specified insomnia disorder and circadian rhythm disturbances are other reported disorders (Braunwald and Kasper 2001). When studies done in Turkey is reviewed, it has been noted that sleep disturbance studies are generally conducted in student samples (Aysan et al. 2014, Sarı et al. 2015, Tümer et al. 2017). In an epidemiological study conducted in Turkey, insomnia was observed in 15.3%, daytime sleepiness 5.4%, sleep apnea 13.7% and snoring 9.6% (Demir et al. 2015). Recent studies indicated that sleep disorders are an increasing health problem. Insomnia is one of the most common psychological problems. In 1991, the statistics of the National Sleep Foundation of America reported the presence of this problem in 33% of the American population. In another study, the prevalence of chronic insomnia disorder was reported to be between 10% and 12% worldwide (Morin et al. 2009). Insomnia disorder, falling asleep, difficulties in maintaining sleep, after waking, such as inability to continue again; it is a disorder that occurs at least 3 nights a week and is expected to occur for at least 3 months (American

Psychiatric Association 2013). In addition to these symptoms, it has seen that insomnia is a psychological problem that causes significant impairments in daily functions including symptoms such as exhaustion, decrease in production power, decrease in quality of life and satisfaction (Perlis et al. 1997, American Academy of Sleep Medicine 2005, Kyle et al. 2010). Insomnia is a risk factor for both physical and psychological development (Cole 2003, Vgontzas et al. 2009). In addition, hypertension, heart disease, diabetes (Cole 2003, Baglioni et al. 2011), pain disorders (Piegon et al. 2012), neurological diseases, gastrointestinal diseases, respiratory diseases, excretory system related to insomnia (Taylor et al. 2007). Insomnia disorder can be seen together with physical diseases and some psychological disorders. For example, major depressive disorder (Walsh 2004, Buysee et al. 2008, Manber et al. 2008), anxiety (Taylor et al. 2005, Johnson et al. 2006, Freeman et al. 2012), post-traumatic stress disorder (Inman et al. 1990, Kraków et al., 2001, Pigeon et al., 2013) and alcohol addiction (Brower et al., 2011, Perney and Lehert, 2018).

CBT-I Protocol

The treatment of insomnia, which is associated with many physical and psychological disorders and can sometimes be the result of diseases, can be done with many methods. The first and most frequently used treatment seems to be pharmacological treatment. Benzodiazepine and antidepressant drugs are widely used in the pharmacological treatment of insomnia (Sateia and Nowell 2004, Hachul and Polesel 2017, Neubauer et al. 2018). Although the most commonly used treatment method is pharmacological treatment, it has been found to have many disadvantages (Morin et al. 1999; Holbrook et al. 2000, Smith et al., 2002). For example, Riedel and collegaues (1998) found that hypnotic drugs increased psychological dependence and tolerance; decreased sleep quality and daily functions. After the use of medication have reached the negative results of the recurrence of insomnia disorder. In other words, it is emphasized that although drugs have short-term positive effects, they may have negative consequences in the long term. It has been observed that pharmacologic therapies whose long-term efficacy has been discussed have recently come to the forefront with non-drug therapy (Riemann and Perlis 2009, Wilson et al., 2010). In particular, the Cognitive Behavioral Therapy Insomnia Protocol (CBT-I) is frequently used (Falloon et al. 2011, Drake 2016, Kamen et al. 2017, Ellis 2019, Morse et al. 2019, Randall et al. 2019).

CBT-I is a non-drug treatment with specific steps. In general, the goals of this treatment are to reduce the symptoms of sleep behavior disorder that persists insomnia and to reduce symptoms such as sleep-related anxiety (Morin et al. 1994, 1999, 2006, Mitchell et al. 2012). The CBT-I protocol prepared by Perlis and colleagues (2005) can be applied in different ways and session times can be changed according to the person to whom it is applied. The duration of the protocol is between 4 and 8 sessions and the duration of the sessions is between 60 and 120 minutes. The number and duration of the sessions may vary depending on the client's education, psychological mindset and discomfort. In case of differences in session duration, some methods may be omitted or extra methods may be added depending on the client's situation (e.g. cognitive interventions may be varied or stimulant control, sleep restraint methods may be applied over longer periods of time). Thus, it is expressed that personalization of therapy according to the client is an important feature (Edinger et al. 2001, Edinger and Sampson 2003). The

protocol is administered once a week and the first two sessions are used for evaluation. In the evaluation sessions, both self-report measurements and some measurement devices (EEG, polysomnography, actigraphy, mobile phone programs, etc.) can be taken. After the evaluation of the measurements, it is decided which type of treatment will be applied. In the following sessions, self-monitoring assignments are given and current information is continuously received from the client and these are graphically concretized in the sessions. Behavioral interventions (stimulant control, sleep restriction, sleep hygiene training, etc.) are aimed to improve behavior in the following sessions. In the continuing sessions, gains are deepened by using cognitive intervention methods. The last two sessions are devoted to evaluating the gains and relapse. In recurrence studies; reevaluation of the factors that prepare, initiate and maintain, and risky situations can be identified and appropriate strategies can be prepared. It is also stated that follow-up interviews can be made (Perlis et al. 2005).

When the content of the sessions included in the CBT-U protocol (Perlis et al. 2005) was examined, the sessions included a thorough understanding of the client's complaint, the medical and psychological evaluation of the origins of the insomnia complaint, explaining the protocol to be implemented, deciding the accuracy of this protocol for the implementation of the protocol, or comparing the implementation of this protocol for the client and explaining the concept of sleep diary, encouraging the implementation, and explaining the usefulness of the graphs.

The second session begins with summarizing and examining the sleep diary. Treatment planning should be discussed by specifying the inconsistent areas in the sleep diary. The explanation of the CBT-I model is another content of this session. Stimulant control and sleep restriction methods can be determined and given as homework for next week's session. Finally, it is at the stage of determining a strategy for sleep. In other words, it is completed as a session in which strategies are determined for how to not sleep or to relate time to sleep immediately after waking.

The third session begins with a summary of the week and a review of the sleep diary. Progress so far has continued with addressing gains and non-progressive points. The concept of sleep hygiene is introduced and included in the treatment process. It is recommended that sleep hygiene personalized and adapted to the client and encouraged to apply. It is stated that it is important to develop a good relationship with the client and to support the client to do the homework.

The fourth session is structured as a review session where the gains and blocked points were reconsidered. It is recommended to examine the records kept up to that point, to evaluate the gains objectively and to evaluate what causes problems.

The fifth session involves the incorporation of cognitive elements into the therapy process. It is the process in which negative cognitive factors that cause insomnia are revealed, awareness is created and the discovery of these with the evaluation of sleep progress. The content of this session can be extended to more than one session. Depending on the progress of the client, the content of the session and the methods to be used can be varied.

Although the sixth session is seen as the last session, according to the situation of the client, the sessions can be progressed rapidly and can be completed in 4 sessions or extended to 8 sessions. In this session, in addition to the evaluation of all the gains, intrusive thoughts and negative beliefs that cause insomnia are reviewed. There are a number of ways to cope with relapse and transient insomnia. In addition, it can be seen that the

control sessions can be extended.

Studies on CBT-I have shown that stimulant control therapy, sleep restraint interventions, relaxation exercises and cognitive therapy interventions are the most commonly used intervention methods (Morgenthaler et al. 2006, Morin et al. 2006).

Effectiveness of CBT-I protocol

When literature related to CIS-U is examined, it is seen that intervention is a frequently used method. The results of the studies are examined that this protocol is an effective method for improving sleep (National Institutes of Health 2005, Wilson et al. 2010). In addition, CBT-I is a method that is thought to have less disadvantages compared to drug treatment and it has frequently compared with other treatment methods. When medical treatments are compared with the effectiveness of the CBT-I protocol, features such as the absence of side effects such as drug use in the CBT-I protocol and emphasis on factors that maintain chronic insomnia reveal that this protocol is advantageous (Vincent and Lionberg 2001, Schutte-Rodin et al. 2008). However, some researchers have emphasized that CBT-I may have disadvantages. For example, it has been stated that decreases in the amount of sleep could be observed in the first weeks of therapy and therefore, daytime sleepiness could increase and not to attend sessions could increase. In addition, it has been suggested that the lack of progression during the first 3-4 weeks may be disadvantageous (Edinger and Sampson 2003, Mitchell et al. 2012).

Studies investigating the effectiveness of CBT-I have often focused on comparing placebo groups and intervention groups. The results of these studies showed that the intervention group had more positive results than the placebo group (Buscemi et al. 2005, Morin et al. 2006, Schutte-Rodin et al. 2008, Okajima et al. 2011). Similarly, in the two studies in which studies comparing control and intervention groups were compared, participants in the control group were either placed on the waiting list or provided with sleep hygiene training. Measurements were obtained by using Pittsburgh Sleep Quality Index, Beck Depression and Anxiety Scale and Insomnia Severity Index. The results showed that the group receiving CBT-I intervention had significant differences compared to the other group and that the people in this group improved their sleep positively, e.g. increased sleep time and decreased psychological symptoms due to insomnia (Schutte-Rodin et al. 2008, Okajima et al. 2011). In the review study conducted by Wang and colleagues (2005), the studies published in the databases of Ovid, Medline, PsycINFO, PsycARTICLES, CINAHL, EMBASE between 1993 and 2004 were examined and 7 studies were selected for systematic review. In these 7 studies, the most commonly used methods with CBT-I were stimulant control, sleep restriction, sleep hygiene and cognitive restructuring. When the results of the studies were examined, it was noted that the common themes of the intervention were reduced sleep medication use, increased sleep time, and decreased night wakes. At the same time, the abovementioned methods were compared with the CBT-I and the CBT-I protocol was found to provide more effective results than other interventions. In parallel with these findings, Mitchell and colleagues (2012) selected five studies from MEDLINE, EMBASE, the Cochrane Central Register & PsycINFO databases according to PRISMA criteria and a systematic review study was conducted. The findings showed that the CBT-I protocol was more effective than the pharmacological method in the long run. However, it is concluded that drugs such as benzodiazepine have a short-term and acute effect. It was

stated that this situation could increase the thoughts such as withdrawal from CBT-I intervention, discontinuation and not finding it useful.

Effectiveness of CBT-I in comorbid disorders with insomnia

It is known that insomnia disorder is the only symptom and it is as high as the likelihood of coexistence with another disease (Edinger et al. 2009, Taylor and Pruiksma 2014). In a study conducted by Edinger and colleagues (2009), a randomized controlled study was conducted with participants with insomnia and other comorbid disorders (chronic pain, hypertension, breathing problems and gastrointestinal disorders). In this study, CBT-I was compared with the insomnia disorder group and comorbid diagnoses in terms of effectiveness. Results were obtained by comparing CBT-I and sleep hygiene education groups. According to this; in terms of CBT-I and sleep hygiene groups, both sleep insomnia group and comorbid group participants were observed to have increased sleep time, more vigorous awakening, and no insomnia during the day; the decrease in symptoms in the CBT-I group was reported to be statistically significant for both disease groups. When insomnia disorder group and comorbid diagnoses group were compared; CBT-I was found to be more effective in the insomnia group without comorbid disease. One of the comorbid conditions of insomnia is cancer (Hecker et al. 2016, Johnson et al. 2016). Johnson and colleagues (2016) reviewed the efficacy of the CBT-I protocol for insomnia symptoms in cancer patients in a study. As a result, it was found that sleep quality was increased by 15% in the intervention group (CBT-I) compared to the control groups and the effect power in statistical analyzes was moderate. In parallel with this, it was observed that the insomnia symptoms reported by the individuals had the greatest effect on the decrease in the symptom level.

Insomnia may be the result or cause of physical disorders; it can also be the cause or result of psychological disorders. In recent research, it is reported that people with depression (Dew et al. 1997, Randall et al. 2019), anxiety disorder (Ohayon et al. 2000, Ohayon and Roth 2003), PTSD (Ohayon and Shapiro 2000, Belleville et al. 2011) and alcohol addiction disorder (Cohn et al. 2003; Trivedi et al. 2005) often complain of insomnia. It has understood that CBT-I was used for the insomnia disorder with psychological disorders and effective results were obtained. In addition, there have been positive changes in both sleep quality and comorbid symptoms (Taylor and Pruiksma 2014, Cunningham and Shapiro 2018). In the study conducted by Taylor and Pruiksma (2014), it was stated that positive developments emerged after CBT-I application in comorbid disorders with insomnia symptoms. In addition, CBT-I is an effective protocol for insomnia symptoms associated with depression and anxiety disorder. In other words, both insomnia symptoms decreased, sleep duration increased and depression and anxiety symptoms decreased. Taylor and Pruiksma (2014) emphasized that CBT-I is an effective method in insomnia disorders comorbid with PTSD, and further studies are needed to prove this.

In the literature reviewed, it is frequently reported that insomnia is associated with depressive symptoms. It is seen that CBT-I is used frequently for the treatment of depressive symptom this condition and effectiveness studies are increasing rapidly. In these studies, CBT-I was found to yield beneficial results both in terms of decreased insomnia symptoms and increased duration of sleep and decreased depressive symptoms (Manber et al. 2008, Rybarczyk et al. 2009, Vitiello et al. 2009, Wagley et al. 2009, Watanabe et

al. 2011, Lancee et al. 2012). Norell-Clarke and colleagues (2015) wanted to determine whether there was an effective treatment for insomnia and depressive symptoms by applying CBT-I in group therapy format. The results of the 6-month follow-up group and the relaxation group (RG) group were tested in a randomized controlled study design. When the results were examined, it was found that CBT-I caused more effective improvements for insomnia symptoms and both interventions (CBT-I and RG) for depressive symptoms produced equal development. Another study examined the effectiveness of CBT-I in insomnia associated with anxiety and depressive symptoms. In the study, before the intervention, scales were given to the participants and the participants were divided into 4 groups (low depressive, low anxiety, moderate depressive and moderate anxiety symptom groups) according to the levels of depressive and anxiety symptoms. CBT-I protocol was applied to each of these groups and final measurements were taken. According to the results, positive improvements were observed in terms of sleep quality, total sleep time, and fall asleep time. In addition, when these developments were examined in terms of groups, it was found that there was no significant difference between the groups. In other words, it has been observed that people have improved symptoms of insomnia without the level of depression / anxiety (Hamoen et al. 2014).

The effectiveness of CBT-I was not only studied with insomnia and associated depression and anxiety, but also with other comorbid psychological diseases. Brooks and Wallen (2014) reviewed the studies that included CBT-I interventions used for the treatment of impaired sleep patterns in alcohol addicts. 6 studies were included in the analysis by analyzing specific databases and according to GRADE criteria. The results of the analysis showed that CBT-I is not an effective intervention. However, it was concluded that not all factors could be controlled and that it would be good to perform according to different review criteria. In another study, the effectiveness of CBT-I was tested in cases where psychological and fatigue symptoms were seen as comorbid with insomnia disorder. In a randomized controlled study, it was found that there were significant reductions in symptom levels and insomnia symptoms of the intervention group (Thorndike et al. 2013). Tang (2010) examined the treatment process of CBT-I in an insomnia disorder comorbid with social phobia in his case study. A 5-session CBT-I protocol was administered and progress was monitored over the 9-month period following the intervention. The results of the study showed that sleep quality and duration increased and sleep anxiety decreased. Moreover, it was stated that the developments gained were still continuing at the end of 9 months. It was stated that CBT-I did not find out any gains in social phobia symptoms but it should be supported with studies.

The CBT-I protocol can be seen as a viable intervention even in schizophrenia and bipolar disorders (Steinan et al. 2014, Harvey et al. 2015, Walter et al. 2015, Waite et al. 2016). However, when the studies were examined, it was understood that this protocol was not applied from the beginning to the end but only certain interventions were used. Therefore, the above-mentioned studies will not be mentioned in detail as they do not conform to the context of the review. As can be seen from all the aforementioned studies, CBT-I intervention can be seen not only as an insomnia disorder but also as a method for decreasing the symptoms of insomnia (depression, anxiety, etc.) and other disorders that can be seen as comorbid with insomnia.

Different application forms and effectiveness of CBT-I

When the recent studies are examined, it is seen that CBT-I is not applied only in a face-to-face format. Researches showed that it can be applied as group therapies (Koffel et al. 2015, Norell-Clarke et al. 2015, Cunningham and Shapiro 2018), online therapies (Espie et al. 2012, Cheng and Dizon 2012, Brooks et al. 2018) telephone therapies (Archer et al. 2009, Brooks and Wallen 2014) and self-help books (van Straten and Cuijpers 2009, Espie et al. 2012). Cunningham and Shapiro (2018) examined the different forms of CBT-I and its use in the treatment of depression in a systematic review. In this study, face-to-face CBT-I application, telephone-applied CBT-I and group-applied CBT-I forms were also compared. According to the results, CBT-I has reduced depressive symptoms and regulates sleep disorders in people with depression. In addition, it was found that statistically significant decreases in symptom relief level were obtained in face-to-face CBT-I compared to the other two methods used. In the literature, it was underlined that effective results were obtained when CBT-I was administered as group therapy. It has also been shown that the application of CBT-I in group format has multiple advantages and its effectiveness has been demonstrated. As the economic level, transportation and internet access can create obstacles in face-to-face method, it is observed that the group therapy format shows beneficial results and decreases both the symptoms of insomnia and the symptoms of comorbid disorders (depression, anxiety) (Koffel et al. 2015, Norell-Clarke et al. 2015).

Evidence-based research has been conducted for CBT-I in the form of face-to-face, group, bibliotherapy and online therapy, and positive results have been obtained for improving sleep quality and maintaining sleep patterns in terms of results (Bastien et al. 2004, Lancee et al. 2012). It can be seen that the single-shot (One-Shot) form of CBT-I, which can be applied in structurally different ways, is also used (Randall et al. 2019). This intervention, which was applied as a single session, was applied to convicts in the study. The study conducted with 30 participants, the data were analyzed one week before the first application, the application of the intervention and the last measurement 4 weeks after the application. It has turned out to be an effective application in reducing the symptoms of insomnia. In addition, it has been reported that there are decreases in symptoms of depression and anxiety. The positive results obtained from different forms of intervention, stretching of the intervention, personalization according to the group or individual to be applied are important and features that will increase usability.

Conclusion

The CBT-I protocol is an intervention program specific to insomnia disorder in the principles of cognitive behavioral therapy. Behavioral and cognitive interventions are used in this protocol. With the CBT-I, it is aimed to increase sleep quality, prolong the sleep time and restructure the sleep order. Research has shown that this method was an effective method for reducing the symptoms of insomnia and improving sleep. In addition, insomnia is associated with many physical and psychological disorders and CBT-I can be used in treatment to comorbid processes. In this sense, it has been found that the protocol could provide positive improvements in both insomnia symptoms and other disorders related symptoms in comorbid conditions. However, in some studies, it is seen

that only in insomnia symptoms causes more effective results compared to other comorbid symptoms.

International literature suggests that this method is an effective method for reducing the symptoms of insomnia, improving sleep quality and maintaining gains. On the other hand, the presence of this protocol in the field of sleep disorders is seen as an important contribution in terms of both strengthening the pharmacological treatment and increasing the variety of treatment. Furthermore, the reduction in severity of other disorders, even in comorbid conditions, underlines the strength and importance of the therapeutic effect. On the other hand, research has also shown that this method did not give positive results for sleep change in the short term, and that the rate of discontinuation of therapy may be high (due to short-term effect). When these results are examined together with long-term gains, it is suggested that CBT-I is a permanent and sustainable intervention. A review of the national literature on the CBT-I protocol has been reached (Aslan 2013). Translation, adaptation, efficacy - efficacy, randomized controlled studies have not been conducted yet. In addition to the introduction of the protocol, the aim of this review is to introduce the effectiveness studies in the recent international literature and to be a means of integrating this protocol into the national literature and the field.

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