Digital cognitive behavioral therapy for insomnia – The first Georgian version. Can we use it in practice?

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Abstract

Insomnia is a common sleep disorder which has a 5–6% prevalence rate and shows high social impact. At least 10% of patients with insomnia will see a medical specialist. Hence, 20,000–40,000 people in Georgia require medical help for insomnia. Treatment of insomnia is very effective. Pharmacotherapy is common, but it is recognized that cognitive behavioral therapy (CBT) is a better choice, since it is safe for patients and shows sustainable improvement. CBT of insomnia is not currently available in Georgia.

The aim of our study was to evaluate a Georgian version of an innovative, internet-delivered digital CBT (dCBT) for insomnia in terms of therapeutic efficacy, adherence, and ease of handling.

The Georgian digital cognitive behavioral therapy for insomnia was developed as an analogue of Dutch dCBT “i-Sleep.” All online materials were made applicable for the Georgian population through translation, validation by translation back to the original language, and adaptation to the Georgian reality, in order to avoid linguistic, cultural, and social pitfalls.

Fifty-two adult patients with insomnia were recruited for the study: 34 women and 18 men, aged 18–64 years (mean: 33.5 years). Inclusion criteria included: age over 18, access to internet, and sufficient skills to use electronic devices. The patients who were treated pharmacologically continued their usual medication and received dCBT in addition to this treatment. DCBT was guided by a therapist. Clinical efficacy was evaluated on the basis of Insomnia Severity Index (ISI), measured before the dCBT and one month after its completion.

25 out of 52 patients (48%) completed a full dCBT course. Mean ISI in this group dropped from 22.88 to 8.24 (P < 0.01), showing significant therapeutic effect one month after CBT completion. 27 patients (52%) stopped treatment for various reasons at different stages of dCBT. Sixteen patients dropped out from the first module (31%). 7 patients older than 50 years encountered problems with handling electronic devices and the platform itself. 9 patients stopped therapy, showing bad adherence for different reasons, mostly related to finding the sessions time-consuming and being disappointed by the absence of immediate therapeutic effect. Eleven more patients (21%) stopped at sleep restriction, finding it difficult to accomplish sleep restriction-related tasks. In general, patients found dCBT quite comprehensive and easy to handle.

This data suggests that the Georgian version of dCBT for insomnia is a promising therapeutic tool, comparable with international analogues in terms of efficacy and adherence. Further studies, involving a greater number of patients and long-term follow-up are required for the final assessment of therapeutic efficacy and sustainability of results.

1. Introduction

Sleep loss and sleep disorders affect an individual’s performance, safety, and quality of life. Compared to healthy individuals, those suffering from sleep disorders are less productive, have an increased health safety, and quality of life. Compared to healthy individuals, those suffering from sleep disorders are less productive, have an increased health

Association of Sleep Medicine (AASM) and is characterized by “a persistent difficulty with sleep initiation, duration, consolidation or quality that occurs despite adequate opportunity and circumstances for sleep and results in some form of daytime impairment, 3 or more nights per week, for 3 or more months” (ICSD-2) (Ellis, 2014). Besides disturbed sleep and impaired daytime functioning, insomnia is associated with mental health disorders (Pigeon et al., 2017). It can contribute to cardiovascular disease (Khan and Aouad, 2017) and type 2 diabetes (Vgontzas et al., 2009). In a recent randomized trial, Espie and co-authors established that insomnia severely affects 3 key areas of the
quality of life: functional health status, psychological well-being, and patient-generated, sleep-related quality of life (Espie et al., 2018). Treatment of insomnia can be very effective. Therapy is based on pharmacological means, but it is recognized that Cognitive Behavioral Therapy for insomnia (CBT-I), is a better choice, as it is safe for the patient and shows stable, long-lasting improvement (Baglioni and Riemann, 2014; Riemann et al., 2017; Van Sraten et al., 2018).

Up to now, the common way to deliver CBT-I was face to face contact (at least 6 times) with a trained therapist. Such therapy is not available in Georgia, due to the shortage of trained therapists for CBT-I, patients’ mobility problems and therapy-related expenses that are not covered by insurance companies and/or the state. This leads to increased medical costs associated with doctor visits, hospital services, prescriptions, and over-the-counter drugs with no- or temporary clinical efficacy, common serious adverse effects and further social and psychological impairment of patients. In some countries, there is convincing evidence that CBT can be successfully delivered through an e-health system, “digital therapy.” Digital therapy is even available through hand-held devices like tablets and smartphones, making this method highly accessible and affordable, as well as the fastest-evolving therapy medium (Espie et al., 2014).

Use of e-health therapy for insomnia is innovative in most countries of the world, and particularly, in Georgia. In countries where the method has been introduced (USA, Canada, UK, the Netherlands), the results are impressive in terms of adherence, medical efficacy and cost effectiveness (Espie et al., 2014, 2018; Kaldo et al., 2015), a recent randomized clinical trial, carried out among 1771 participants, provided strong support for the hypothesis that dCBT is effective in improving functional health, psychological well-being, and sleep-related quality of life in people reporting insomnia (Espie et al., 2018). Cognitive Behavioral Therapy of insomnia is currently not implemented in Georgia.

The aim of our study was to assess a Georgian version of a novel internet-delivered dCBT for insomnia in terms of sleep related clinical efficacy, adherence and ease of handling.

2. Methods

This study was carried out as a longitudinal, case-control study, comparing insomnia severity index (ISI) at baseline and one month after dCBT intervention in a group of patients diagnosed with insomnia. The study was conducted at the SEIN-SKUH Epilepsy and Sleep Centre, S. Rchechinashvili University Hospital (SKUH) in Tbilisi, Georgia. The study protocol was approved by the SKUH Ethics Review Board. This study was conducted as a pilot study for the assessment of first Georgian digital CBT for insomnia.

2.1. Participants and recruitment

Participants were recruited from patients with sleep disorders, who had addressed the SEIN-SKUH Epilepsy and Sleep Centre from June 1, 2017 to June 1, 2018. Persons diagnosed with insomnia and interested in participation signed an informed consent form. Each patient had a face-to-face meeting with the investigator, who explained and demonstrated how to use dCBT and gave detailed instructions on the frequency and regularity of sessions. Digital CBT was guided by a therapist. During the dCBT, feedback was available via an Internet module, e-mail, or telephone.
Table 1
Descriptive characteristics (dCBT (n = 52)).

| Demographic                                      |   |
|--------------------------------------------------|---|
| Age, mean                                        | 19–64 (33.5) |
| Sex                                              |   |
| Women                                            | 34 (65%) |
| Men                                              | 18 (35%) |
| Employment                                       | No. (%) |
| Employed                                         | 23 (44%) |
| Unemployed                                       | 12 (23%) |
| Retired                                          | 5 (10%) |
| Full-time homemaker                              | 12 (23%) |
| Partner                                          | No. (%) |
| Yes                                              | 38 (73%) |
| No                                               | 14 (33%) |
| Lifestyle                                         |   |
| Caffeine consumption                             | No. (%) |
| Never                                            | 2 (4%) |
| 1–2 per day                                      | 20 (39%) |
| More than twice per day                          | 30 (58%) |
| Alcohol consumption                              | No. (%) |
| Never                                            | 6 (12%) |
| Once a week                                      | 35 (67%) |
| 2–3 times per week                               | 10 (19%) |
| > 4 times per week                               | 1 (2%) |
| Smoking                                          | No. (%) |
| Never                                            | 10 (19%) |
| Often                                            | 35 (67%) |
| Rarely                                           | 7 (14%) |
| Exercising                                       | No. (%) |
| Never                                            | 10 (19%) |
| 1–2 Times per week                               | 27 (52%) |
| > 4 per week                                     | 4 (8%) |
| Health                                           |   |
| BMI, mean                                        | 25.2 |
| Medical diagnosis                                | No. (%) |
| Heart disease or high blood pressure             | 19 (37%) |
| Diabetes                                         | 5 (10%) |
| Hormonal problems                                | 6 (12%) |
| Stroke or other neurological problems             | 1 (2%) |
| Any other diagnosis                              | 5 (10%) |
| Prescribed sleep medication                       | No. (%) |
| Nonprescribed sleeping medication                 | 15 (29%) |
| Depression or anxiety                            | 23 (44%) |

Inclusion Criteria were:

a) Diagnosis of insomnia (AASM-3);
b) Age: 18 years of age or older;
c) Access to internet and electronic devices;
d) Sufficient experience in using such devices;
e) No comorbid sleep disorders requiring other treatment;
a) No neurological, somatic or psychiatric disorders, requiring acute care and being contraindicated for insomnia CBT;
b) Other comorbidities and medicine (including sleep medicine) were not restricted;
c) No night shift work.

204 patients, admitted to our Centre with compliance on sleep disturbance were screened for the diagnosis of insomnia. Insomnia was diagnosed according to the AASM guidelines (Rieman and Spiegelhalder, 2014). Clinical assessment, insomnia severity index (ISI), and sleep diaries were applied as standard diagnostic procedures. Polysomography (PSG) and actigraphy were carried out in complicated cases to differentiate insomnia from other sleep disorders. Fig. 1 presents the flow of patients during primary screening, recruitment, and intervention.

3. Intervention

Research is based on an absolutely innovative e-health approach to the therapy of insomnia in Georgia. The Georgian digital cognitive behavioral therapy for insomnia was developed as an analogue of a Dutch dCBT “i-Sleep” (https://www.i-sleep.nl). All online materials were made applicable for the Georgian population through translation, validation by translation back to the original language, and adaptation to the Georgian reality, in order to avoid linguistic, cultural and social pitfalls.

Online module is divided into an introduction and 5 different sessions. All sessions are accompanied by a sleep diary. Depression and anxiety were assessed by Beck Depression Inventory and Spielberger Anxiety Self-Assessment Questionnaire. The program includes behavioral, cognitive, and educational parts (Espie et al., 2018). Each session covers a different topic: 1. Sleep and your habits; 2. Improving your sleep patterns; 3. Less worrying, more relaxation! 4. Changing your thoughts; 5. And now? It takes about 30 min to read the text in each session. Patients receive information, corresponding to their own condition, and carry out some exercises (relaxation exercises, sleep hygiene, sleep restriction techniques, and cognitive strategies to change wrong thoughts and misperceptions) about 1–2 times per week, for 30–60 min. The last session is devoted to the evaluation of progress and formation of a future plan.

The aim of the module is to give more insight into patients’ insomnia and to enable them to practice other habits and eventually experience fewer problems. The major advantage of an online module is that patients can do the exercises at home on their own electronic devices, whenever it suits them. They can read the results of the completed exercises and physician’s feedback at a later stage. They can also send the physician a message through the “message” function. This online module is always supported by a therapist. The therapist reviews what the patient fills in during the different sessions and gives feedback. The exercises that patients complete online are confidential and only intended for them and their therapist.

3.1. Assessment points

Assessment took place at baseline, before the intervention, and post-treatment – 1 month after dCBT completion.

3.2. Outcome measures

Clinical efficacy was evaluated by means of the Insomnia Severity Index (ISI) at baseline and after intervention. Adherence was checked by login frequency and regularity, as well as the number of completed sessions. The ease of handling of the CBT program was rated by patients in a special review field.

Patient dropout was calculated to assess overall efficacy and ease of handling of the Georgian dCBT program. Possible influence of the ISI at baseline on patient dropout rate was calculated. As this is a descriptive study, we used simple statistical measures to evaluate the results – two sample t-test and a confidence interval.

3.3. Results

Fifty-two adult patients with insomnia were involved into the study: 34 women and 18 men, aged 18–64 years (mean: 33.5 years). The patients did not stop their usual medication and received dCBT in addition to their treatment. Descriptive characteristics of the study group can be found in Table 1. Twenty-five out of 52 patients (48%) completed a full dCBT course. Mean ISI in this group dropped from 22.88 to 8.24 (P < 0.01), showing significant therapeutic effect within one month after the CBT (Fig. 2). In total, 27 patients (52%) stopped treatment at different stages of the dCBT, for various reasons. Sixteen patients dropped out from the first session (31%). Interestingly, 7 patients older...
than 50 years reported difficulties of handling electronic devices and the platform itself as a cause for stopping the CBT. 9 other patients stopped therapy, showing bad adherence for different reasons, mostly related to finding the sessions time-consuming and being disappointed by the absence of immediate therapeutic effect. Eleven more patients (21%) stopped at sleep restriction, finding it difficult to accomplish sleep restriction-related tasks. The results of the adherence to dCBT can be found in Table 2. Insomnia severity at the baseline did not appear to influence the adherence to dCBT.

| Patients (n = 52) | No. (%) | Age | Sex, no. (%) | Sex, no. (%) |
|------------------|---------|-----|-------------|-------------|
| Completed treatment |         |     |             |             |
| Total            | 25 (48%) | 19-52 | 17 (33%) | 8 (15%) |
| Difficult to handle devices | 27 (52%) | 24-64 | 17 (33%) | 10 (19%) |
| Too time consuming | 7 (14%)  | 50-64 | 3 (6%)  | 4 (14%) |
| Absence of immediate beneficial effects | 9 (17%)  | 19-52 | 6 (12%)  | 3 (6%) |
| Dropped form the “sleep restriction” module | 11 (21%) | 24-54 | 3 (6%)  | 8 (15%) |

Fig. 3. Effect of initial ISI on treatment accuracy, P value < 0.86, Confidence Interval (CI) > 95%.

4. Discussion

Cognitive behavioral therapy is recognized as a first line treatment for chronic insomnia (Baglioni and Riemann, 2014; Riemann et al., 2017; Van Sraten et al., 2018). It is already well established that digital CBT, delivered through electronic devices, is as effective as face to face therapy, and not only shows sustained improvement of sleep related outcomes (Espie et al., 2014; Kaldo et al., 2015), but also demonstrates positive effects on functional health, psychological well-being, and sleep-related quality of life of people with insomnia (Espie et al., 2018). Our primary findings provide support to the conclusion that the Georgian version of dCBT for insomnia may be considered as an effective treatment tool. The positive effect is mirrored in significant decline of the ISI after 1 month of treatment completion.

This data is in concordance with previous studies (Espie et al., 2018; Kaldo et al., 2015). More than half of our patients (52%) did not complete the entire course of the CBT, for different reasons. The rate of patient dropout is comparable with similar studies. In a recent randomized trial carried out by Espie and co-authors on dCBT “Sleepio,” 853 participants were logged on for at least 1 session, 491 participants (57.6%) completed at least 4 sessions and 413 participants (48.4%) completed all 6 sessions (Espie et al., 2018). The percentage of participants who fully completed “Sleepio” and the Georgian dCBT module are in line - about 48%. The major reasons for the discontinuation of therapy in our study were: difficulties of handling of electronic devices in elderly patients, bad adherence due to size and complexity of dCBT content and/or interface, and application of the sleep restriction task. These reasons for stopping the dCBT, identified via patient feedback, should be taken into consideration for future improvement and tailoring of the Georgian dCBT version, in order to achieve an effective and easy-to-handle tool for insomnia dCBT. Baseline ISI did not appear to influence the adherence to dCBT.

5. Conclusion

Our primary findings provide support to the conclusion that the Georgian version of insomnia dCBT is a promising therapeutic tool, comparable with international analogues in terms of efficacy and adherence. Significant reduction of the ISI in response to dCBT intervention is a major strength of this study. High accessibility, ease of handling, and cost effectiveness are the undoubted advantages for the practical application and dissemination of the Georgian version of insomnia dCBT all over the country. Still, the validity of our data is limited, due to the study design and the small number of patients. Further research with randomized trial, based on a greater number of patients, is required in order to receive strong support for the efficacy and accessibility of the Georgian dCBT for insomnia.

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