REDUCTION OF INSOMNIA THROUGH COGNITIVE TELEPHONE THERAPY

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ABSTRACT

Introduction: Chronic insomnia affects 10-20% of adults and poses a great personal and social burden. Cognitive therapy can reduce it. Objective: To compare the efficacy of cognitive-behavioral therapy for insomnia administered by telephone. Methods: A parallel randomized controlled trial was conducted. Thirty participants with chronic insomnia were randomized. Results: post-treatment sleep efficiency improved by 18.7 ± 8.2 % in the TCCI / T group and by 14.5 ± 10.2 % in the CFI group. Conclusions: The findings support the efficacy of telephone-based CBCT in improving sleep and wakefulness function in people with chronic primary insomnia.

Keywords: Insomnia, cognitive therapy, telephone, sleep.

DOI Number: 10.14704/nq.2022.20.13.NQ88241 Neuro Quantology 2022; 20(13):1947-1954

RESUMEN

Introducción: El insomnio crónico afecta al 10-20% de los adultos y supone una gran carga personal y social. La terapia cognitiva puede disminuirlo. Objetivo: Comparar la eficacia de la terapia cognitivo-conductual para el insomnio administrada por teléfono. Método: Se realizó un ensayo paralelo aleatorizado y controlado. Treinta participantes con insomnio crónico se asignaron al azar. Resultados: la eficiencia del sueño posterior al tratamiento mejoró un 18,7 ± 8,2 % en el grupo TCCI / T y un 14,5 ± 10,2 % para el grupo CFI. Conclusiones: Los hallazgos respaldan la eficacia de la TCCI por teléfono para mejorar la función del sueño y la vigilia en personas con insomnio primario crónico.

Palabras claves: Insomnio, terapia cognitiva, teléfono, sueño.

INTRODUCTION

Chronic insomnia affects 10-20% of adults and poses a great personal and social burden. Chronic insomnia has been linked to reduced quality of life, decreased perceived health, increased risk for psychiatric and substance use disorders, and exacerbation of comorbid health conditions[1]. In the workplace, insomnia is associated with presenteeism (loss of productivity when employees attend work but underperform), equating to 11.3 workdays per year. In addition, the average 6-month direct and indirect costs for adults with untreated insomnia compared with those without insomnia are estimated to be at least $1,200 higher[2].

Despite the magnitude of the problem, the availability of effective treatment for people with insomnia remains suboptimal. First-line prescription and over-the-counter agents provide

rapid symptomatic relief and are widely available, but may be less appropriate for selected groups of patients, may build tolerance with repeated use, and, for many patients, are not as preferable as non-medication approaches[3]. Cognitive behavioral therapy for insomnia (CBTBI) is a multi-component, non-drug treatment targeting behavioral and cognitive factors contributing to chronic sleep disturbances. Multiple controlled trials indicate that 70-80% of patients benefit from CBCT[4], approximately 40% achieve remission of insomnia, and treatment benefits are maintained over time. Although highly effective, CBCT remains underutilized as a primary therapy for chronic insomnia[4].

Insomnia researchers and clinicians have highlighted the need for broader and more rapid dissemination of CCT, proposing models of care such as "stepped care" to help propel CCT to first-line treatment status. Whatever the optimal healthcare solution, various effective treatment delivery modalities will be required to address the scope of the problem. Most clinical trials of CBCT have used group or individual face-to-face modalities, which produce large effect sizes, but are time-consuming, economically inefficient, and available only to selected groups of patients[4]. At the other end of the spectrum, self-help treatments in the form of books or booklets and Internet interventions are accessible to more people with insomnia, but their results have been more modest, and treatment dropout is more significant than in face-to-face trials. In addition, self-help treatments for insomnia may be primarily appropriate for patients with less severe insomnia and those without comorbid disorders[5].

Telephone interventions offer a compromise between traditional face-to-face and self-help interventions. They are more easily accessible and cost-effective than in-person services and incorporate human contact, interaction, and therapeutic alliance lacking in self-help interventions. Interventions delivered by telephone have been successfully used to positively influence other health behaviors such as smoking, physical activity, and diet[5]. In previous insomnia trials, the telephone has generally played a secondary role in supporting non-medication interventions delivered in person or as self-help. Only one controlled trial has directly compared CBCT delivered through three different modalities (telephone, individual, and group) in 45 people with chronic primary insomnia[6]. Sleep/wake diary scores, self-rated insomnia severity, and daytime anxiety and depression symptoms had similar degrees of improvement among the three treatment groups. These improvements maintained at 3- and 6-month follow-ups provide preliminary evidence that telephone-administered CBCT may be as effective as CBCT administered individually or in a group format. However, the design of this study could not support the efficacy of CBCT beyond any simpler intervention or placebo[6].

Therefore, the current study's primary objective was to compare the efficacy of a telephone-delivered CBCT intervention with a simple information control consistent with non-medication insomnia treatments provided in typical primary care settings. It was assumed that persons with chronic insomnia who received telephone-delivered CBCT rather than minimal treatment would show more significant improvement in sleep quality (greater sleep efficiency and greater total sleep time) and more significant reductions in insomnia severity ratings immediately after treatment and at 12 weeks. The hypothesis is that individuals in the telephone-delivered CBCT group would experience improvement in assessments of common sequelae of insomnia, including symptoms of fatigue, depression and anxiety, unhelpful beliefs about sleep, and quality of life.

METHOD

A randomized, controlled, parallel trial was conducted to compare the efficacy of a telephone-administered cognitive-behavioral therapy for insomnia (TCCI/T) with an information leaflet control (CFI). Thirty participants with chronic insomnia were randomized equally to the TCCI or CFI condition using a random number table. TCCI /T participants received four treatment modules with telephone intervention from experienced therapists in four to eight weekly 15- to 60-minute sessions, depending on treatment response. Participants randomized to the CFI condition were instructed to read and follow the recommendations in a TCCI booklet. Self-reported outcomes assessed insomnia severity and daytime functioning before treatment, after treatment, and at the 12-week follow-up. The study was conducted in Ambato.

Potential participants aged 18 to 65 were recruited from local primary care outpatient clinics and the community through advertisements. To be eligible, participants had to meet the Research Diagnostic Criteria criteria for chronic insomnia [7], with documented symptoms on three or more nights per week (> 60 min of total overnight awake time and sleep efficiency < 85 %) according to two weeks of baseline sleep/wake diaries. Exclusion criteria included a diagnosis or high clinical suspicion of a sleep disorder other than insomnia; poorly controlled Axis I psychiatric disorder; uncontrolled medical disorder or pain syndrome that interfered with sleep, causing daytime sleepiness, or was likely to be causally related to insomnia; current nonpharmacologic treatment for insomnia or previously failed trial of CBCT; and routine night shift work. Participants taking sleep medications were not excluded if they met study criteria for insomnia, medications were stable for at least eight weeks, and they agreed to maintain their current medication regimen throughout the study.

Potential participants were assessed for initial eligibility using a mailed screening questionnaire packet followed by a telephone assessment to clarify responses and conduct a further evaluation as needed. Those still eligible provided a 2-week baseline sleep/wake diary to confirm that they met the insomnia study criteria. This study was approved by the Universidad Regional Autónoma de Los Andes (UNIANDES).

Sleep restriction reduces the time spent in bed each night to the patient's estimated average sleep time to increase sleepiness at bedtime. The specific procedures followed for sleep restriction were to (1) determine the average total sleep time reported by the participant using pretreatment sleep diaries; (2) reduce the amount of time spent in bed to match this average or as close as tolerable for the patient; and (3) gradually extend the amount of time in bed once sleep efficiency (time asleep/time in bed) exceeds 85%, until daytime functioning is optimized. Prescribed sleep schedules were never < 5 h per night. Stimulus control consists of instructions designed to associate temporal (bedtime) and environmental (bed, bedroom) cues with rapid sleep onset and establish a regular sleep/wake schedule. The general instructions are: (1) Go to bed only when sleepy or at the prescribed bedtime; (2) Do not use your bed for anything except sleep and sexual activity; (3) If you cannot fall asleep after 15 to 20 minutes, get up and go to another room. Stay awake until you are *very sleepy* and then return to the room to sleep; (4) If you still cannot fall asleep in 15 to 20 minutes, repeat rule 3. Do this as often as necessary during the night; (5) Set your alarm and get up at the same time every morning no matter how much sleep you get during the night; (6) Limit naps or avoid them altogether.

Participants completed validated measures of daytime functioning at pretreatment, post-treatment, and 12-week follow-up, including the Quick Inventory of Depressive Symptomatology: Self-Report (QIDS-SR) to measure the severity of depressive symptoms[8]; State-Trait Anxiety Inventory-Trait subscale (STAI-T) to assess anxiety level[9]; the Multidimensional Fatigue Inventory (MFI-20) to measure daytime fatigue[10]; and the 12-item Short Form Health Survey (SF-12)[11] to measure health-related quality of life.

The database and statistical processing of the data were performed and analyzed in the SPSS 26 statistical program (SPSS Inc., Chicago, IL, USA). Descriptive statistics were used for the results collection, presentation and interpretation. The significance level was set at 0.05 to consider the result significant. In addition, summary measures were used for quantitative data, such as arithmetic mean and standard deviation.

Cohen's d effect sizes were calculated for the within-group difference (pretreatment to post-treatment and post-treatment to 12-week follow-up) separately for the TCCI/T and CFI conditions to assess the magnitude of treatment effects.

RESULTS

Approximately 20% of the study volunteers (33 of 161) who returned completed screening packets and sleep/wake diaries were randomly assigned to one of the treatment conditions. The most common individual reasons for initial exclusion were suspicion of another sleep disorder and poorly controlled medical or psychiatric conditions. Nearly one in five respondents had more than one reason for exclusion. For example, among individuals who returned initial sleep diaries/monitoring, 23% (15 of 63) were

subsequently excluded for not meeting the study criteria for insomnia.

Linear mixed model analyses showed a significant group-by-time interaction (F [2,38.1] = 3.5, P < 0.05) and a main effect of time (F [2,38.1] = 46.7, P < 0.001) for sleep efficiency. *Post hoc analyses* indicated that post-treatment sleep efficiency improved by 18.7 ± 8.2 % in the TCCI / T group and by 14.5 ± 10.2 % for the CFI group (P = not significant). At the 12-week follow-up, sleep efficiency decreased slightly in the TCCI/T group relative to post-treatment and improved slightly in the CFI group (t [25] = 2.6, P < 0.05), although both groups continued to show clinically relevant improvements relative to pretreatment.

A marked response to treatment was defined as a post-treatment ISI score > 8 points lower than the pretreatment score; treatment remission was characterized as a post-treatment ISI score ≤ 7. Using these criteria, 13 of 15 TCCI/T participants had a marked response to treatment at post-treatment compared with 7 of 15 CFI participants (X^2 (1) = 5.40, P < 0.02). In addition, 11 of 15 TCCI/T participants achieved remission of insomnia after treatment compared with 6 of 15 of the IPC participants (X^2 (1) = 3.39, P < 0.06). At follow-up, 9 of 15 TCCI/T participants continued to experience a marked response to treatment compared with 6 of 12 CFI participants (X^2 (1) = 1.20, P = not significant). More participants in the TCCI/T group (12 of 15) than in the IPC group (5 of 12) were classified as being in remission for insomnia at the 12-week follow-up (X^2 (1) = 6.65, P < 0.01).

Post-treatment reductions were found in depressive symptom severity measured by the QIDS-SR (t [26] = 7.0, P < 0.001) and the trait subscale of the STAI (t [27] = 6.1, P < 0.001) for both groups. The SF-12 physical or mental health composite scores found no significant effects or interactions. Within-group improvements in the TCCI /T group were considerable for almost all daytime functioning outcomes; in contrast, within-group effect sizes for CFI participants ranged from minor to moderate for most outcomes. Daytime functioning variables that showed post-treatment improvements continued at post-treatment levels at the 12-week follow-up (Table 1).

Table 1. Daytime functioning outcomes at baseline, post-treatment and 12-week follow-up.

	TCCI by Phone		**Brochure Control**		
Variable	**Mean (SD)**	**Effect Size (Cohen's d)**		**p-value (time effect)**	**Group interaction p-value by time**
Rapid inventory of depressive symptomatology				<0,001	0,97
Pretreatment	9,4(2,8)		11,3(4,8)		
Post-treatment	4,7 (2,3)	1,8	6,9(4,1)	1,0	
Follow-up at 12 weeks	4,5 (2,6)	1,8	6,5 (4,2)	1,1	
General Fatigue				<0,001	0,10
Pretreatment	14,8(2,0)		14,6(3,3)		
Post-treatment	9,6(2,1)	2,5	12,1(4,7)	0,6	
Follow-up at 12 weeks	10,5 (3,0)	1,7	12,3 (4,4)	0,6	
Mental Fatigue				<0,001	0,21
Pretreatment	12,3(2,5)		12,2(2,7)		
Post-treatment	8,9(2,4)	1,4	10,6(2,8)	0,6	
Follow-up at 12 weeks	8,6 (2,4)	1,5	10,5 (3,6)	0,6	

Source: statistical analysis, p≤ 0,05

All participants assigned to CFI received the 15- to the 20-minute telephone review session. TCCI participants completed an average of 5.1 ± 1.7 sessions (range, four to eight sessions). Session duration ranged from 16.7 ± 2.9 min for session 7 to 59.4 ± 12.8 min for session 1. Total session duration was not related to treatment outcome, using the change in ISI score from pretreatment to post-treatment as an index of treatment response (r = 0.19, P = 0.52).

DISCUSSION

The findings of this randomized controlled trial provide preliminary support for telephone-administered CBCT in treating chronic insomnia. Participants who received telephone-delivered CBCT showed significant effects post-treatment for diary-based sleep efficiency, more improvements in insomnia-related cognitions than participants who received an informational booklet, and moderate to significant changes in expected daytime consequences of insomnia. In addition, more TCCI/T participants than CFI participants were classified as"marked treatment responders" post-treatment, and more TCCI/T participants were in remission from insomnia at the 12-week follow-up. Post-treatment effect sizes for CBCT/T on sleep/wake diary and daytime symptom outcomes generally ranged from moderate to large, and hypnotic agents in middle-aged adults with chronic insomnia[12,13]. Finally, the acceptability and feasibility of telephone-based insomnia therapy were supported by excellent retention rates (100%) throughout treatment and at 12-week follow-up.

Current standards for insomnia research advocate the inclusion of measures to assess correlates of insomnia during wakefulness[14,15]. In the current study, we found that both TCCI/T and CFI led to improvements in daytime symptoms of fatigue, depressive symptoms, and trait anxiety. Depressive symptoms of participants in the TCCI/T condition improved from mildly symptomatic to within normal limits with treatment, whereas CFI participants reported moderately high depressive symptoms at baseline and only mild symptoms at the end of treatment.

Although there were no significant group-by-time interactions for any measure of daytime symptoms, the TCCI/T participants consistently showed significant improvements in these outcomes, compared with minor to medium treatment effects for the CFI participants. It is essential to remember that the study excluded potential participants with poorly controlled psychiatric and medical conditions, which likely contributed to restricted ranges in these outcomes at baseline. As a result, our findings cannot be extended to people with chronic insomnia and clinically significant levels of depression, anxiety, and fatigue[16]. However, the findings suggest that the TCCI/T intervention may ameliorate the typical daytime sequelae of chronic insomnia.

The study had components that differed from most insomnia treatment trials. First, participant screening, collection of study assessments, and treatment delivery were conducted by mail and telephone rather than in person. The main benefit of this approach is that study participation was not restricted by place of residence. Screening and study results could also be administered by computer, further improving feasibility and reducing costs[17]. Second, the study intentionally incorporated an a priori criterion of "treatment success" to determine treatment discontinuation rather than administering a predetermined number of treatment sessions (e.g., six or eight sessions). This method was selected because it accurately reflects the approach in most clinical settings.

The TCCI/T participants showed clear benefits in terms of sleep and daytime symptoms after treatment and follow-up, but it is important to note that IPC participants showed improvements of a similar magnitude on most sleep and daytime symptom assessments. This finding was unexpected because other recent insomnia trials using data controls did not find similar improvements in sleep after treatment[18,19]. Differences in methods could explain a more significant response to treatment among our control participants. Similar simple interventions have been used successfully in other areas of sleep medicine[20]. Future studies should seek to clarify which subtypes of insomnia are most likely to respond to these simple insomnia interventions. These assessments should also include daytime symptom measures because our study consistently found greater post-treatment improvement in these variables among TCCI/T participants.

The main strengths of the current study were the randomized controlled trial design, the minimal active intervention comparison condition, and the inclusion of methods to ensure treatment integrity. However, the results should be interpreted in the context of several limitations. The study sample predominantly included women with chronic primary insomnia, a minority of whom had medical/psychiatric comorbidities and used hypnotic medication. The generalizability of our findings to men with insomnia and those with more clinically relevant psychiatric and medical symptoms is unknown. In addition, the observed maintenance of treatment gains during follow-up should be viewed with caution, given that assessments were conducted only 12 weeks after treatment. Primary outcomes were based on subjective reports, the preferred primary outcome for insomnia trials, but are still subject to response bias. Including objective measures of sleep, such as actigraphy or polysomnography, would have strengthened the study design by providing a more detailed assessment of sleep.[21,22]

CONCLUSIONS

In summary, the findings support the efficacy of telephone-delivered CBCT in improving sleep and wakefulness function in persons with chronic primary insomnia. However, future large-scale controlled treatment studies in more diverse samples of persons with chronic insomnia using trained, naïve therapists to deliver the intervention are warranted.

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