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Effectiveness of the unified protocol in insomnia comorbid with anxiety disorders: case series report

Efectividad del protocolo unificado en insomnio comórbido a trastornos de ansiedad: reporte de serie de casos

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Abstract:

Insomnia is the sleep disorder with the greatest comorbidity with emotional disorders and its diagnosis and treatment is considered of relevance to public health. Specific psychological treatments do not address both disorders, which translates into greater time and cost for the patient. As an alternative, transdiagnostic treatments have been recently developed and tested. These treatments are focused on identifying common mechanisms associated with the etiology and maintenance of different disorders (e.g., neuroticism, rumination or avoidance). The unified protocol for the transdiagnostic treatment of emotional disorders (UP) is a cognitive-behavioral intervention that has shown broad adaptability to various comorbid conditions such as insomnia and anxiety disorders. Objective: to evaluate the effect of the UP on insomnia and comorbid anxiety symptoms in a sample of Mexican adult patients (N=6). **Method**: A non-controlled quantitative pilot study was carried out with a within-subject design with pre- and post-treatment measurements as well as visual inspection of the results. The variables assessed were quality (ICSP) and severity (ISI) of the sleep, sleep diary, insomnia (ESE), and anxiety symptoms (GAD-7). For the analysis of results, the Reliable Change Index (RCI) was calculated. **Results:** a decrease was observed in the scores of the 6 participants in the ICSP, ISI, ESE and GAD-7 consistent with the changes reported in the sleep diary. The RCI calculations achieve reliability in 5 of the 6 participants. **Conclusion:** based on these results we can say that the intervention was clinically significant for the participants, however, research needs to be done with a controlled research design, larger number of participants, measuring the transdiagnostic mechanisms, and using polysomnography measures that allow these findings to be generalized.

Keywords:

Insomnia, Emotional disorders. Transdiagnostic Treatments.

Resumen:

El insomnio es el trastorno del sueño con mayor comorbilidad con los trastornos emocionales y su diagnóstico y tratamiento se considera de relevancia para la salud pública. Los tratamientos psicológicos específicos no abordan ambos trastornos, lo que se traduce en mayor tiempo y coste para el paciente. Como alternativa, recientemente se han desarrollado y probado tratamientos transdiagnóstico. Estos tratamientos se centran en identificar mecanismos comunes asociados con la etiología y el mantenimiento de diferentes trastornos (p. ej., neuroticismo, rumiación o evitación). El protocolo unificado para el tratamiento transdiagnóstico de los trastornos emocionales (UP) es una intervención cognitivo-conductual que ha mostrado amplia adaptabilidad a diversas condiciones comórbidas como el insomnio y los trastornos de ansiedad. Objetivo: evaluar el efecto de la UP sobre el insomnio y los síntomas comórbidos de ansiedad en una muestra de pacientes adultos mexicanos (N=6). Método: Se llevó a cabo un estudio piloto cuantitativo no controlado con un diseño intrasujeto con mediciones previas y posteriores al tratamiento, así como inspección visual de los resultados. Las variables evaluadas fueron calidad (ICSP) y severidad (ISI) del sueño, diario de sueño, insomnio (ESE) y síntomas de ansiedad (GAD-7). Para el análisis de resultados se calculó el Índice de Cambio Confiable (RCI). Resultados: se observó una disminución en las puntuaciones de los 6 participantes en el ICSP, ISI, ESE y GAD-7 consistente con los cambios informados en el diario de sueño. Los cálculos del RCI alcanzan fiabilidad en 5 de los 6 participantes. Conclusión: con base en estos resultados podemos decir que la intervención fue clínicamente significativa para los participantes, sin embargo, es necesario realizar investigaciones con diseños de investigación controlados, mayor número de participantes, midiendo los mecanismos transdiagnóstico y utilizando medidas polisomnografías que permitan estos hallazgos. ser generalizado.

Palabras Clave:

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INTRODUCCIÓN

Emotional disorders (ED), which encompass anxiety, depressive and related disorders (Bullis et al., 2019), represent a public health problem due to the negative impact on the quality of life of people who suffer from them (Estancial Fernández et al., 2019). The prevalence is estimated to be 4.4% worldwide (Chodavadia et al., 2023) with a high comorbidity rate (between 30 and 60%; Choi et al., 2020).

Addressing EDs generates an expenditure on public health services users of $6,475 dollars per year for anxiety and $2,735 for depression (Alwhaibi & Alhawassi, 2020), which translates into an annual expenditure of $326 billion dollars in the health budget worldwide (Jain et al., 2022). Due to this, health systems have begun to look for treatments that are more cost-effective, short-term, and that maintain achievements over time (Le et al., 2021).

Among the characteristics that define EDs we find: (a) a tendency to experience emotions in a more intense and unpleasant way, (b) the rejection of the emotional response (e.g., "I will go crazy" or "I am a weak person") and (c) attempts to avoid being in contact with emotions (Barlow et al., 2014). The biological vulnerability variable related to the etiology and maintenance of EDs is the neuroticism personality dimension, which is defined as the tendency to experience frequent and intense negative emotions in response to various sources of stress (Barlow et al., 2014). This biological predisposition increases the hyper-excitation of limbic structures while producing limited inhibitory control of cortical structures (Dong et al., 2020; Joseph et al., 2021). This reactivity directly impacts sleep quality by causing longer wakefulness, a greater number of awakenings, and a longer sleep onset latency (Calkins et al., 2013).

Due to these characteristics, people with ED have a high comorbidity with insomnia, it is estimated that anxiety is the main one (27%), followed by depression (19%) (Pappa et al., 2022). This is relevant, since sleep deprivation derived from insomnia impacts the severity of ED symptoms, making them chronic and with a high relapse rate (Ypsilanti et al., 2018).

Despite the high comorbidity between ED and insomnia, clinical practice guidelines suggest giving a separate treatment for each of these conditions (Lam et al., 2016). However, it has been observed that adherence to the two treatments tends to be low, in addition to increasing the cost and time, which makes short-term recovery difficult (Torres-Granados et al., 2023). In addition, it has been observed that combined implementation does not always manage to reduce the symptoms of the comorbid disorder; for example, sleep may not improve, even if anxiety symptoms have decreased (Wallsten et al., 2021). Due to this, the use of transdiagnostic treatment perspectives that clinically improve both presentations has begun to be considered (McGowan et al., 2016).

Due to this, a trend has emerged to increase the evidence of transdiagnostic treatments in insomnia (Dolsen et al., 2014; Ishii et al., 2021; Milanak, et al., 2023), some based on neuroticism (Bullis & Sauer-Zavala, 2017), others on emotional regulation (Cerolini & Lombardo, 2022), experiential avoidance (Johann & Hertenstein, 2022), or symptoms of affective disorders (Blom & Jernelöv, 2022).

Among the interventions, the Unified Protocol for the transdiagnostic treatment of EDs (UP; Barlow et al., 2018) stands out. The UP is a cognitive behavioral treatment focused on treating the mechanisms associated with the etiology and maintenance of EDs (Barlow et al., 2011). To achieve this general objective, the treatment is aimed at: 1) Teaching the adaptive value of emotions, 2) Defining and modifying avoidance strategies that decrease emotional distress, and 3) Increasing tolerance to emotional distress (Barlow et al., 2016). The UP is divided into 8 modules, 5 of which train in 5 specific emotional regulation skills. It has a duration range of 12 to 20 sessions and can be administered in an individual (face-to-face or online) or group format (Osma, 2019).

Regarding the use of PU in insomnia, there are currently only two single-case studies, the first is by Bullis and Sauer-Zavala (2017) who adapted and modified the PU for its application to a young man who had not obtained favorable results with the standard treatment, however, measurement parameters in insomnia are not mentioned and it focuses more on showing the therapeutic modifications made. The second study is of a 32-year-old man diagnosed with insomnia. After the treatment, improvements were observed in sleep onset latency, sleep quality and a decrease in the number of insomnia nights and its severity (Doos Ali Vand et al., 2018).

Considering the above, the present investigation aims to evaluate the preliminary clinical utility of UP in insomnia symptoms comorbid with anxiety disorders in a sample of Mexican adult patients. The work was carried out under the hypothesis that both insomnia symptoms, sleep quality and anxiety symptoms will improve after the intervention.

METHOD

Research design

A single-case quantitative study was conducted with an intra-subject design with pre- and post-treatment measures (Ato-García & Vallejo-Seco, 2015).

Participants

Non-probability convenience sampling was used. The sample consisted of 6 participants, of which 5 were women and 1 was a man. Age ranged from 27 to 42 years. All participants had been diagnosed with anxiety disorder by their primary health center and presented symptoms of insomnia, diagnoses confirmed through a general evaluation by a sleep medicine specialist (See Table 1). The participants were candidates for a

larger randomized clinical trial (NCT05951803), however, as they did not meet the inclusion criterion of having the document proving the PCR test to confirm the diagnosis of COVID-19, they could not continue and were offered the treatment as a reward for their time in the initial evaluation.

Table 1.

Sociodemographic characteristics of the participants.

Sex	Age	Marital status	Occupation	*Residence*	*Time with insomnia*	Dx
F	27	Single	student	CDMX	6 months	GAD
F	35	Married	cashier	CDMX	12 months	GAD
F	40	Married	merchant	CDMX	12 months	PD
F	37	Soltera	cashier	Edomex	24 months	PD
F	32	Married	housewife	Edomex	6 months	IAD
M	42	Single	electrician	Edomex	24 months	TAS

Nota: F=Female, M=Male. Dx: Diagnosis. GAD= Generalized anxiety disorder. PD= Panic disorder. IAD= Illness anxiety disorder. TAS= Social anxiety disorder. CDMX= Mexico City. Edomex= State of Mexico

Instrumentos

Datos sociodemográficos. They were given a registration form for the variables: sex, age, marital status, occupation, residence, time with insomnia and diagnosis.

Ad hoc Diagnostic Clinical Interview for Anxiety Disorder. A 60-minute interview session was conducted where signs and symptoms of anxiety disorders were asked based on the International Classification of Diseases, tenth edition (World Health Organization, 2000; Mexican Social Security Institute, 2019).

Ad hoc Diagnostic Clinical Interview for Insomnia. A 30-minute interview session was conducted where symptoms of chronic insomnia were asked based on the International Classification of Diseases, tenth edition (WHO, 2000; Mexican Social Security Institute, 2011).

Sleep diary (Carney, et al., 2012). Self-reporting form that subjectively assesses the number of sleepless nights, subjective sleep quality, number of awakenings per night, and sleep efficiency.

Pittsburgh Sleep Quality Index (PSQI; Buysse et al., 1989). Self-administered questionnaire that assesses sleep quality. It is made up of 24 items and the total score ranges from 0 to 21 points; where a total score of less than 5 points indicates good sleep quality and a score greater than 5 points is interpreted as poor sleep quality. In the Mexican population, it obtained a Cronbach's alpha of 0.78 (Jiménez-Genchi et al., 2008).

Insomnia Severity Index (ISI; Morin et al., 2011). Self-administered questionnaire with 8 items on a Likert-type response scale from 0 (not at all) to 4 (very severe), which assesses nocturnal symptoms, sleep quality, and daytime symptoms of insomnia. It has a reliability of 0.82 in its original version and has similar psychometric indicators in a version validated in Spanish (Fernández-Mendoza et al., 2012). In its version for the Mexican population, it obtained a reliability coefficient of 0.84 (Álvarez-García et al., 2023).

Epworth Sleepiness Scale (ESS; Johns, 1991). Self-administered questionnaire that assesses the propensity to fall asleep in eight everyday situations. It is composed of eight items that are scored on a four-point Likert scale ranging from no probability (0) to high probability (3). Total scores range from 0 to 24. The authors propose the following cohort points for interpretation: 0-10 normal sleepiness, 10-12 marginal sleepiness, and greater than 12 as excessive sleepiness. In the Mexican population, it has a Cronbach's alpha of 0.89 (Sandoval-Rincón et al., 2013).

Generalized Anxiety Disorder-7 (GAD-7; Spitzer et al., 2006). Self-administered questionnaire that assesses the presence and severity of generalized anxiety symptoms. It consists of 7 items on a Likert scale ranging from 0 (not at all) to 3 (almost every day). The assessment consists of the sum of the scores of each item, with a range of 0 to 21 points. A score greater than 10 is considered to be generalized anxiety. Among its psychometric properties, the version translated into Spanish has a high internal consistency with a Cronbach's alpha of 0.84 (García-Campayo et al., 2010).

Procedure

A call was made within the General Hospital of Mexico where people were invited to a sleep treatment study. Interested users were referred to the hospital's sleep disorders clinic for initial evaluation. Once the evaluation was completed, it was observed that 6 participants did not meet all the criteria of the randomized clinical trial, so it was decided to provide them with an alternative treatment, in order to avoid incurring ethical violations by leaving them without any intervention. A transdiagnostic treatment was considered to improve insomnia symptoms and, in turn, impact anxiety symptoms, with UP being a favorable option due to its high efficacy (e.g., Sakiris, & Berle, 2019; Schaeuffele et al., 2024). In the present study, the UP version adapted for insomnia by Bullis and Sauer-Zavala (2017) was used, implemented in an individual format through teleconsultation. The registration forms and patient manual were used (Barlow et al., 2011a; See Table 2).

Table 2

Unified Protocol for insomnia comorbid with anxiety disorders.

Module	Description	Sessions
Understanding your emotions	*The patient is taught to identify the 3 elements (thought, physical sensation and behavior) of the emotional response at bedtime and how these interfere with the onset of sleep.*	2
Emotional awareness	The patient is trained in mindfulness exercises. Using breathing as an anchor point, the goal is to not judge the thoughts and physical sensations that prevent sleep.	2
Cognitive flexibility	The patient is taught to understand the relationship between negative automatic thoughts and poor sleep habits and how this prolongs wakefulness.	2
Opposing emotional behaviors	Se enseña al paciente a identificar comportamientos que influyan en el inicio de sueño (acostarse más temprano, tomar medicamentos para dormir) o disminuyan el impacto negativo de la privación de sueño (cancelar actividades en la mañana, tomar café para mantenerse despierto).	2
Afrontando las sensaciones físicas	The patient is taught to identify the physical sensations experienced at bedtime (hyperventilation, increased heart rate) that prevent them from falling asleep, leading to avoiding the bedroom or bed.	3
Emotional exposure	The patient is taught to identify all the situations that he or she avoids due to insomnia (getting up early, changing appointment times). The goal is for the person to get used to doing them again. Through a hierarchy, the person is exposed to them until he or she becomes accustomed to them.	3
Relapse prevention	Skills acquired during treatment are reviewed and put into practice in hypothetical scenarios that may generate difficulties.	1

Note: According to the modification made, module 1 of the original UP is omitted.

Ethical considerations

The participants received the informed consent which contained the description of the protocol that was approved by the ethics and research committee of the General Hospital of Mexico OF. No. HGM-DG-254-DI2023. Once the protocol was read, they were asked to sign it and were reminded that they could leave the study whenever they wanted.

Statistical analysis

A descriptive analysis of the sociodemographic variables was performed. In addition, the Reliable Change Index (RCI) was calculated to determine whether, once the intervention was completed, the instrument scores had reached a "normal" criterion according to the cut-off points of each of them: ISI (11.7), ESS (10.2), PSQI (5.1) and GAD-7 (10.0) (Jacobson & Truax, 1991). Finally, a visual inspection of the scores of the sleep diary parameters was performed.

RESULTS

Per-person changes in psychometric measures.

Under the previously mentioned parameters, the RCI were carried out, according to which it was observed that in the severity of insomnia and drowsiness, 90% of the sample managed to normalize the scores, while 100% of the participants normalized the quality of sleep and anxiety symptoms according to the PSQI and GAD-7 respectively. In the individual analysis, it was observed that 5 of the 6 participants have normalized the scores in the 4 questionnaires. However, participant 4 did not achieve these changes in 2 of the 4 questionnaires (See Table 3).

Changes per person based on sleep diary.

According to the sleep diary indicators, all participants showed a decrease in the number of sleepless nights and the number of awakenings per night. This is proportional to the subjective sleep quality and subjective sleep efficiency. It is important to mention that in these measurements participant 4 showed improvement in the subjective assessment of sleep, something that was only accompanied by the ICSP sleep quality scores (See Table 4).

Table 3.

Evaluation results.

	Instruments											
	PSQI			ISI			ESS			GAD-7		
Participantes	Pre	Post	RCI	Pre	Post	RCI	Pre	Post	RCI	Pre	Post	RCI
1	12	6	-2.3	15	5	-4.5	14	8	-2.0	15	5	-4.2
2	15	5	-3.9	18	9	-4.0	13	5	-2.7	17	7	-4.2
3	13	3	-3.9	18	6	-5.4	16	6	-3.4	17	8	-3.8
4	17	3	-5.5	14	10	**-1.8***	13	8	**-1.7 ***	13	5	-3.3
5	20	4	-6.3	15	7	-3.6	18	9	-3.0	18	9	-3,8
6	23	6	-6.7	22	12	-4-5	18	10	-2.7	20	8	-5.0

Nota: PSQI= Pittsburgh Sleep Quality Index. ISI=Insomnia Severity Index. ESS= Epworth Sleepiness Scale. GAD-7= General Anxiety Disorder-7, RCI= Reliable Change Index. *= unreliable change.

DISCUSSION AND CONCLUSIONS

This pilot study aims to evaluate the clinical utility of UP in the treatment of insomnia and comorbid anxiety symptoms. The results have confirmed the initial hypothesis, as insomnia and anxiety scores decreased significantly while psychometric and self-report indicators improved significantly. This is consistent with current hypotheses that insomnia is a maintenance factor of EDs (Mirchandaney, et al., 2022), so having a treatment that addresses both conditions will reduce the negative impact on the physical and mental health of the person suffering from it (Kristjánsdóttir et al., 2016).

However, the present study sought to increase the evidence of the UP in insomnia symptoms comorbid to ED, specifically, anxiety disorders. The results obtained in this pilot study report on the clinical utility of emotional regulation strategies trained in the UP to improve both anxious and insomnia-related symptoms. For example, regarding mindfulness strategies and opposing emotional behaviors, we can mention that, according to the metacognitive model, mindfulness would decrease the arousal that maintains wakefulness and that has been identified in people with high neuroticism (Ong & Smith, 2017; Zamani et al., 2022). On the other hand, teaching the patient strategies opposite to emotional behaviors will result in a short-term weakening of the sleep/wake association and in a long-term improvement in sleep quality (Agar et al., 2023; Vriend, & Corkum, 2011), however, in order to corroborate this, it would be important for future studies to carry out polysomnographic measurements to corroborate these changes (Zhao et al., 2021).

Table 4.

Sleep diary indicators.

	Indicators							
N	NSN		NAPN		SSQ		SSE	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
1	4	1	3	0	2	8	30	80
2	5	0	3	0	3	10	35	75
3	6	0	2	1	3	8	20	60
4	5	1	4	0	3	7	40	75
5	6	0	3	1	2	8	35	80
6	6	0	5	0	2	8	30	70

Nota: NSN= Number of sleepless nights. NAPN= Number of awakenings per night. SSQ= Subjective sleep quality. SSE= Subjective Sleep Efficiency.

Thus, the results obtained in the present investigation agree with those obtained by Doos Ali Vand et al. (2018) by decreasing the severity of insomnia symptoms, sleep efficiency and improving sleep quality. Although the results obtained are encouraging, they are preliminary and future studies in this field should improve the weaknesses found in the studies carried out so far (case reports), for example, they should use randomized controlled designs, together with instruments that allow the evaluation of transdiagnostic mechanisms, such as neuroticism, or emotional regulation and polysomnographic measures.

Finally, the present study follows the trend of increasing evidence on the versatility and clinical utility of the UP in various psychological, psychiatric (Carlucci et al., 2021) and

comorbid conditions to medical conditions (Osma et al, 2021), which represents an improvement in public health systems.

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