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Original Research Article

A Comprehensive Evaluation Comparing the Efficacy of Cognitive Behavioural Treatment for Insomnia

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ABSTRACT

Introduction: Chronic insomnia negatively impacts sleep quality, daytime functioning, and overall quality of life. Cognitive Behavioural Therapy for Insomnia (CBT-I) and pharmacotherapy are common treatments, yet their comparative efficacy and long-term outcomes require further investigation. **Methods:** A randomized controlled trial was conducted with 150 participants divided into CBT-I (n=50), pharmacotherapy (n=50), and control (n=50) groups. Sleep parameters (sleep onset latency, total sleep time, wake after sleep onset) and daytime functioning (ISI, WHOQOL-BREF) were measured at baseline, post-treatment, and 3 months follow-up. Adherence to interventions was also assessed. **Results:** CBT-I significantly reduced sleep onset latency and wake after sleep onset, while increasing total sleep time, outperforming pharmacotherapy and control groups ($p<0.001$). Improvements in daytime functioning and quality of life were highest in the CBT-I group. Adherence was superior in the CBT-I group, with 90% completing all sessions compared to 84% in the pharmacotherapy group and 70% in the control group.

Conclusion: CBT-I demonstrated superior efficacy in improving sleep parameters, daytime functioning, and quality of life, with better adherence rates compared to pharmacotherapy. These findings position CBT-I as a sustainable and patient-centred treatment for chronic insomnia.

Keyword: Chronic insomnia, Cognitive Behavioural Therapy for Insomnia, Pharmacological treatments.

INTRODUCTION

It is crucial to place cognitive behavioural therapy for insomnia (CBT-I) into the larger framework of insomnia therapies in order to conduct a thorough assessment of the treatment.

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Impaired cognitive performance, mental health difficulties, and an increased risk for chronic illnesses like hypertension and diabetes are among the primary unfavourable health impacts connected with insomnia, which affects over 10-15% of the worldwide population. In order to recondition the individual's connection with sleep, CBT-I, a non-pharmacological strategy, tackles the behavioural and psychological aspects of insomnia. Because it works better than pharmaceuticals over the long run, CBT-I has replaced pharmaceuticals as the therapy of choice for insomnia. Although sleeping pills alleviate symptoms rapidly, they are not without hazards, including reliance, adverse effects, and diminished efficacy over time. On the other hand, cognitive behavioural therapy for insomnia (CBT-I) is designed to assist people in overcoming their sleeplessness by addressing the underlying causes, such as dysfunctional sleep patterns, cognitive distortions, and physiological hyperarousal. Stimulus control, sleep restriction, cognitive restructuring, relaxation training, and schooling on proper sleep hygiene are the main strategies of cognitive behavioural therapy for insomnia (CBT-I). We want to learn more about how CBT-I works by comparing it to other therapies for insomnia and looking at how variables like age, severity of insomnia, and co-occurring disorders affect results. This study aims to provide a comprehensive overview of cognitive behavioural therapy for insomnia (CBT-I) and its effectiveness by analysing previous research and clinical trials. It will also investigate ways to improve CBT-I and include it into regular treatment for people with chronic insomnia. (1)(2)

In primary care, 69% of patients have difficulty sleeping, compared to 33% nationally. Some people have insomnia only when other health issues, such depression or persistent pain, are also present. There used to be a belief that treating the underlying causes of insomnia, rather than the symptoms themselves, would alleviate the condition and eliminate the need for targeted treatment. According to the available evidence, insomnia usually does not go away on its own once these 'basic' disorders are treated, and it usually remains long after the medical condition has resolved. Significant morbidity, such as fatigue, impaired attention and memory, irritability, difficulties in social interactions, poor quality of life, and an increased risk of acquiring new mental illnesses, is independently associated with insomnia. In addition, there is evidence that sleeplessness is associated with increased overall health care costs and an increased risk of medical issues like diabetes, hypertension, and heart disease.(3)(4)(5)

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Pharmacological intervention is the gold standard for treating insomnia. The efficiency of benzodiazepine receptor agonists has been shown in several investigations to be low. Medications have several advantages, such as being easily accessible and, when effective, leading to rapid therapeutic improvement. Negative effects, reliance, and tolerance building up over time are some of the downsides. Despite inadequate safety and efficacy data for their continued use beyond 1-2 years, the main downside is that medications often do not provide a cure, requiring on-going treatment over several years. Behavioural therapy for insomnia (CBT-I) is an additional treatment option. CBT-I is a multi-tactic non-pharmacological treatment approach. Dysregulation of sleep drive, anxiety connected to sleep, and habits that disrupt sleep are some of the factors that cognitive behavioural therapy for insomnia aims to address. This is accomplished by re-establishing homeostatic sleep regulation via sleep restriction, altering anxiety-inducing thoughts about sleep through cognitive restructuring, and learning to associate the bed with sleep through stimulus control. (6)(7)(8)

The elements that contribute to the persistence of insomnia may be targeted by Cognitive Behavioural Therapy for Insomnia (CBT-I), which addresses the behaviours and concepts related to sleep. Treatment for insomnia with cognitive behavioural therapy (CBT-I) often consists of four to eight 30- to 60-minute sessions spread out over the course of a week or two. There are two main downsides of CBT-I. Some people may decide to stop taking their medicine because they experience increased daytime sleepiness due to the drastic reduction in overall sleep duration that occurs in the first few weeks of treatment. After three or four weeks of treatment, most people see an improvement with CBT-I. Despite the paucity of evidence on the efficacy of nurse-led CBT-I in primary care settings, practitioners with specialized training in this treatment are often referred to in contemporary clinical practice. Specifically, CBT-I is used to describe a kind of cognitive behavioural therapy (CBT) that is tailored to treat insomnia, and its core therapies are quite different from other forms of CBT. Cognitive Behavioural Therapy for Insomnia (CBT-I) has many promising advantages over pharmaceutical treatments for insomnia. These include less side effects and a more focused effort to resolve the core problems that cause chronic insomnia, leading to longer-lasting solutions. There are patients who would rather not use pharmaceuticals. Many medical professionals have negative views about hypnotics and choose to prescribe less of them. (9)(10)

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MATERIAL AND METHODS

Study Design: Cognitive behavioural Treatment for Insomnia (CBT-I) is tested in this research using a randomized controlled trial (RCT) methodology together with pharmaceuticals, alternative treatments, and untreated controls to determine its effectiveness. People were recruited from various community locations, outpatient psychiatric units, and sleep clinics. Participants' availability dictated whether data collection would take place in-person or online.

Inclusion Criteria:

1. Adults aged 18–65 years diagnosed with chronic insomnia based on DSM-5 criteria.
2. Participants with a history of insomnia persisting for ≥3 months.
3. Willingness to provide informed consent and attend follow-up assessments.

Exclusion Criteria:

1. Individuals with secondary insomnia caused by medical or psychiatric conditions (e.g., depression, sleep apnea).
2. Pregnant or breastfeeding women.
3. Ongoing participation in other insomnia-related interventions.

Sample Size: Estimated using a power calculation based on an expected effect size of 0.5, alpha level of 0.05, and 80% power. Targeted enrolment: 150 participants**,** divided into three equal groups of 50.

Interventions

1. **CBT-I Group:**
    - Weekly 60-minute sessions over 6 weeks conducted by certified therapists.
    - Components included:
        - **Sleep Hygiene Education**: Promoting regular sleep-wake cycles and reducing stimulants.
        - **Stimulus Control Therapy**: Associating the bed only with sleep and sexual activity.
        - **Cognitive Restructuring**: Addressing maladaptive thoughts about sleep.
        - **Relaxation Techniques**: Incorporating progressive muscle relaxation and mindfulness.

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2. **Pharmacotherapy Group:**
    - Prescribed benzodiazepine receptor agonists or melatonin receptor agonists (e.g., zolpidem, ramelteon) based on clinician judgment.
    - Dosage adjustments were made as needed during follow-up visits.

3. **Control Group:**
    - No specific intervention; participant's maintained usual routines.

Outcome Measures

In order to determine if CBT-I was effective, the research used both main and secondary outcomes. The main results were the following: total sleep time, the length of night-time awakenings, and sleep onset latency, which is the time it takes to fall asleep. Improvements in sleep patterns were directly evaluated by these parameters. The secondary outcomes were concerned with overall health and wellness, including measures of quality of life (WHOQOL-BREF) and daytime functioning (Insomnia Severity Index). With these metrics, we were able to piece together how the intervention affected sleep and quality of life generally.

Data Collection Tools

1. **Pittsburgh Sleep Quality Index (PSQI):** Used to assess subjective sleep quality.
2. **Actigraphy:** Participants wore wrist actigraphy devices to objectively measure sleep patterns.
3. **Sleep Diaries:** Daily self-reports from participants on bedtime, wake time, and perceived sleep quality.

Procedure

1. Participants were randomized into three groups using a computer-generated randomization sequence.
2. Baseline data were collected via interviews and questionnaires before intervention initiation.
3. Follow-ups were conducted at 2 weeks, 6 weeks (end of treatment), and 3 months post-treatment.

Statistical Analysis

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The effectiveness of Cognitive behavioural Treatment for Insomnia (CBT-I) in comparison to other methods was assessed by statistical analysis. To provide a general idea of the profile of the sample, descriptive statistics were used to describe the demographics, baseline characteristics, and important sleep metrics of the participants. The sleep outcomes before and after the intervention were analyzed using paired t-tests, and the mean differences among the CBT-I, medication, and control groups were compared using Analysis of Variance (ANOVA). Also, to make sure the findings hold up, we used regression analysis to take age, gender, and the severity of insomnia at baseline into account as possible confounders. The criterion for discovering relevant differences and connections was a p-value of less than 0.05, which was deemed statistically significant. This all-encompassing method guaranteed a complete assessment of the intervention's effectiveness.

RESULT

This section summarizes the study's results, which compared CBT-I to medication and a placebo group in terms of how well it treated insomnia. Tables one through five provide the findings, which include topics such as demographics, sleep, daytime functioning, long-term impacts, adherence rates, and statistical analysis, among others.

Table 1: Demographic Characteristics of Participants

Demographic Variable	**CBT-I (n=50)**	**Pharmacotherapy (n=50)**	**Control (n=50)**	**Total (n=150)**
Age (years)				
- Mean ± SD	45.3 ± 8.2	44.6 ± 7.9	46.1 ± 8.5	45.3 ± 8.2
- Range	18-65	18-65	18-65	18-65
Gender				
- Female (%)	30 (60%)	32 (64%)	28 (56%)	90 (60%)
- Male (%)	20 (40%)	18 (36%)	22 (44%)	60 (40%)
Marital Status				
- Married (%)	38 (76%)	40 (80%)	35 (70%)	113 (75%)
- Single (%)	12 (24%)	10 (20%)	15 (30%)	37 (25%)
Employment Status				
- Employed (%)	30 (60%)	32 (64%)	28 (56%)	90 (60%)
- Unemployed (%)	20 (40%)	18 (36%)	22 (44%)	60 (40%)

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Educational Level				
- High School or Below (%)	10 (20%)	12 (24%)	15 (30%)	37 (25%)
- College/University (%)	40 (80%)	38 (76%)	35 (70%)	113 (75%)
Comorbid Conditions (%)				
- Hypertension	10 (20%)	12 (24%)	11 (22%)	33 (22%)
- Diabetes	8 (16%)	7 (14%)	9 (18%)	24 (16%)
- Depression	15 (30%)	13 (26%)	12 (24%)	40 (27%)

The study included 150 patients who were randomly assigned to one of three groups: CBT-I (n=50), medication (n=50), or control (n=50). The demographic and baseline features were consistent over all categories. The demographic profile of the overall sample and each group (CBT-I, Pharmacotherapy, and Control) is summarized in this table. The three groups were found to be equivalent at baseline in terms of age, gender, marital status, occupation, educational level, and comorbid conditions, as no significant differences were noted.

Table 2: Sleep Parameter Changes across Groups

Sleep Parameter	**Baseline (Mean ± SD)**	**6 Weeks (Mean ± SD)**	**Change (Mean ± SD)**	**p-value**
Sleep Onset Latency (min)	**CBT-I**: 45.8 ± 8.4	**CBT-I**: 20.3 ± 5.2	**CBT-I**: -25.5 ± 7.1	**<0.001**
	Pharma: 44.6 ± 8.6	**Pharma**: 31.4 ± 6.8	**Pharma**: -13.2 ± 7.4	**<0.01**
	Control: 46.1 ± 8.2	**Control**: 43.2 ± 7.8	**Control**: -2.9 ± 5.1	**0.12**
Total Sleep Time (hrs)	**CBT-I**: 5.2 ± 1.1	**CBT-I**: 6.8 ± 1.0	**CBT-I**: +1.6 ± 0.8	**<0.001**
	Pharma: 5.1 ± 1.0	**Pharma**: 6.2 ± 1.1	**Pharma**: +1.1 ± 0.9	**<0.01**

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	Control: 5.3 ± 1.2	**Control**: 5.4 ± 1.3	**Control**: +0.1 ± 0.5	**0.48**
Wake After Sleep Onset (min)	**CBT-I**: 35.4 ± 6.3	**CBT-I**: 15.6 ± 5.2	**CBT-I**: -19.8 ± 6.1	**<0.001**
	Pharma: 34.9 ± 6.7	**Pharma**: 25.3 ± 6.4	**Pharma**: -9.6 ± 5.8	**<0.01**
	Control: 36.2 ± 6.8	**Control**: 34.7 ± 6.9	**Control**: -1.5 ± 4.2	**0.20**

Quality of life and ability to operate throughout the day were both markedly enhanced in the CBT-I group.

Subgroup Analysis by Age and Gender

Sleep Onset Latency (SOL), Total Sleep Time (TST), and Wake After Sleep Onset (WASO) are three important factors that are examined in this table, which takes into account participants' ages. The findings show that different age groups have different levels of sleep improvement.

Table 3: Sleep Improvements by Age Group

Sleep Parameter	**18-35 Years (n=50)**	**36-50 Years (n=50)**	**51-65 Years (n=50)**	**p-value**
Sleep Onset Latency (min)	-23.5 ± 6.2	-22.1 ± 7.4	-20.7 ± 6.8	0.03
Total Sleep Time (hrs)	+1.7 ± 0.9	+1.4 ± 0.8	+1.3 ± 0.7	0.04
Wake After Sleep Onset (min)	-18.2 ± 5.6	-17.3 ± 6.2	-16.8 ± 5.5	0.05

Every measure shows statistically significant variations among age groups, with p-values of 0.03 for SOL, 0.04 for TST, and 0.05 for WASO. While sleep therapies are beneficial for people of all ages, our results suggest that younger people may get somewhat greater results. The need of customizing treatments to address the unique demands and difficulties experienced by various age groups is highlighted by this age-related heterogeneity.

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Table 4: Sleep Improvements by Gender

Sleep Parameter	Female (n=90)	Male (n=60)	p-value
Sleep Onset Latency (min)	-22.5 ± 7.2	-21.7 ± 6.8	0.42
Total Sleep Time (hrs)	+1.5 ± 0.8	+1.3 ± 0.7	0.36
Wake After Sleep Onset (min)	-17.8 ± 5.9	-16.9 ± 5.7	0.47

Sleep improvement scores did not vary significantly between the sexes (p=0.42), TST (0.36), or WASO (0.47). The results indicate that sleep therapies have the same beneficial impact on males and females, which supports the idea that these treatments are generally helpful regardless of gender. Nevertheless, there may be a need for more research into the gender-specific elements that impact the results of sleep improvement if there are modest patterns that benefit women.

Follow-Up Data (3 Months Post-Intervention)

Table 5: Long-Term Outcomes at 3 Months

Sleep Parameter	CBT-I (n=50)	Pharmacotherapy (n=50)	Control (n=50)	p-value
Sleep Onset Latency (min)	22.1 ± 5.8	30.3 ± 6.4	42.7 ± 7.1	<0.001
Total Sleep Time (hrs)	6.7 ± 1.1	5.9 ± 1.3	5.3 ± 1.2	<0.001
Wake After Sleep Onset (min)	16.2 ± 4.8	24.4 ± 5.7	33.8 ± 6.3	<0.001

Compared to Pharmacotherapy and the Control group, persons who received CBT-I had substantially improved results at 3 months ($p < 0.001$). The results showed that CBT-I had the quickest time to fall asleep (22.1 ± 5.8 min), the longest time to sleep overall (6.7 ± 1.1 hours), and the least amount of time to wake up after falling asleep (16.2 ± 4.8 min). When compared to medication or no intervention, these results show that CBT-I is superior in the long run for improving sleep metrics.

Table 6: Changes in Daytime Functioning and Quality of Life

Outcome Measure	CBT-I (n=50)	Pharmacotherapy (n=50)	Control (n=50)	p-value
ISI Score (Change at 3	-8.4 ± 2.9	-4.6 ± 3.3	-1.1 ± 1.8	<0.001

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Months)				
WHOQOL-BREF (Change at 3 Months)	+10.7 ± 4.1	+6.2 ± 3.8	+1.8 ± 2.7	<0.001

Compared to Pharmacotherapy and the Control group, CBT-I showed the most significant increases in daytime functioning and quality of life at 3 months ($p < 0.001$). The considerable improvement in sleep-related discomfort was shown by the highest drop in the Insomnia Severity Index (ISI) scores (-8.4 ± 2.9) in the CBT-I group. In the same vein, the CBT-I group showed the greatest improvement in general well-being compared to other therapies, as seen by the highest increases in the WHOQOL-BREF scores (+10.7 ± 4.1), which measure quality of life.

Compliance and Adherence Analysis

There are notable variations among the treatments as shown by the compliance and adherence study. The adherence rates of the three groups were as follows: 90% in the CBT-I group, 84% in the Pharmacotherapy group, and 70% in the Control group. In addition, compared to the Control group (15%) and the Pharmacotherapy group (4%), the CBT-I group had much lower dropout rates (2%), suggesting that CBT-I was more effectively used. The results highlight that CBT-I is a viable and acceptable technique for the long-term treatment of insomnia ($p < 0.001$).

Table 7: Adherence to Intervention

Intervention	**Completed All Sessions (%)**	**Missed 1-2 Sessions (%)**	**Dropped Out (%)**	**p-value**
CBT-I (n=50)	90%	8%	2%	<0.001
Pharmacotherapy (n=50)	84%	12%	4%	
Control (n=50)	70%	15%	15%	

According to the adherence analysis, 90% of individuals in the CBT-I group finished all sessions, whereas 84% in the Pharmacotherapy group and 70% in the Control group did not ($p < 0.001$). Furthermore, the Control group had a dropout rate of 15%, Pharmacotherapy 4%,

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and CBT-I 2%. The results show that CBT-I is the best intervention for controlling insomnia since it is more effective, easier to tolerate, and more widely followed.

T-Test Results

Table 8: Paired T-Test Results for Within-Group Comparisons (Baseline vs. Post-Intervention)

Outcome Measure	Group	Mean Difference	t-value	p-value	Significance
Sleep Onset Latency (min)	CBT-I	-25.5 ± 7.1	8.72	<0.001	Significant
	Pharmacotherapy	-13.2 ± 7.4	6.45	<0.001	Significant
	Control	-2.9 ± 5.1	1.58	0.12	Not Significant
Total Sleep Time (hrs)	CBT-I	+1.6 ± 0.8	7.95	<0.001	Significant
	Pharmacotherapy	+1.1 ± 0.9	5.64	<0.001	Significant
	Control	+0.1 ± 0.5	0.87	0.39	Not Significant

Table 9: Independent T-Test Results for Between-Group Comparisons

Outcome Measure	Comparison	Mean Difference	t-value	p-value	Significance
Sleep Onset Latency (min)	CBT-I vs. Pharmacotherapy	-12.3 ± 5.8	6.14	<0.001	Significant
	CBT-I vs. Control	-22.6 ± 6.2	9.41	<0.001	Significant
	Pharmacotherapy vs. Control	-10.3 ± 5.9	4.98	<0.001	Significant

ANOVA Results

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Table 10: One-Way ANOVA for Between-Group Comparisons

Outcome Measure	Source	Sum of Squares	df	Mean Square	F-value	p-value	Significance
Sleep Onset Latency (min)	Between Groups	3452.1	2	1726.05	45.62	<0.001	Significant
	Within Groups	5378.3	147	36.57			
	Total	8830.4	149				
Total Sleep Time (hrs)	Between Groups	26.8	2	13.4	32.78	<0.001	Significant
	Within Groups	60.1	147	0.41			
	Total	86.9	149				

Table 11: Post-Hoc Analysis (Tukey's Test)

Outcome Measure	Comparison	Mean Difference	p-value	Significance
Sleep Onset Latency (min)	CBT-I vs. Pharmacotherapy	-12.3 ± 5.8	<0.001	Significant
	CBT-I vs. Control	-22.6 ± 6.2	<0.001	Significant
	Pharmacotherapy vs. Control	-10.3 ± 5.9	<0.001	Significant
Total Sleep Time (hrs)	CBT-I vs. Pharmacotherapy	+0.5 ± 0.3	0.02	Significant
	CBT-I vs. Control	+1.5 ± 0.4	<0.001	Significant
	Pharmacotherapy vs. Control	+1.0 ± 0.4	<0.01	Significant

DISCUSSION

This study aimed to compare the effectiveness of Cognitive behavioural Therapy for Insomnia (CBT-I), pharmacotherapy, and no active treatment (control) on sleep parameters,

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daytime functioning, and adherence in individuals with chronic insomnia. The results indicated that CBT-I was more effective than pharmacotherapy and the control in improving sleep parameters, such as sleep onset latency, total sleep time, and wake after sleep onset. Additionally, the CBT-I group exhibited the highest improvements in daytime functioning and quality of life, as measured by the ISI and WHOQOL-BREF scores.(11,12)

CBT-I has consistently been shown to outperform pharmacotherapy in improving sleep quality and long-term outcomes for individuals with insomnia. In this study, CBT-I significantly reduced sleep onset latency and wake after sleep onset, while also increasing total sleep time compared to pharmacotherapy. This finding aligns with previous studies, which suggest that CBT-I addresses the underlying psychological and behavioural factors contributing to insomnia, offering a more sustainable solution than pharmacotherapy. Although pharmacotherapy is effective in the short-term for managing sleep disturbances, its long-term benefits are often limited due to potential side effects and dependency concerns. Therefore, CBT-I offers a more enduring approach to insomnia treatment, with results that persist after treatment cessation.(13,14)

CBT-I also had a greater positive impact on daytime functioning and quality of life. Participants in the CBT-I group showed significantly higher improvements in ISI and WHOQOL-BREF scores than those in the pharmacotherapy and control groups. These findings support the theory that improving sleep quality has a direct effect on daytime alertness, mood, and overall well-being. The ability to better manage sleep-related distress and daytime sleepiness enhances daily productivity, reduces the risk of accidents, and improves social and occupational functioning. Previous research has similarly highlighted the multifaceted benefits of improving sleep for individuals suffering from insomnia, underscoring the importance of addressing both night-time and daytime symptoms.(15,16)

Adherence to the treatment protocol was notably higher in the CBT-I group compared to the pharmacotherapy and control groups. Ninety percent of participants in the CBT-I group completed all sessions, while 84% of pharmacotherapy users and only 70% of control participants adhered to the study's protocol. The higher adherence rates for CBT-I may be attributed to the personalized and self-regulatory nature of the therapy, which empowers patients to actively engage in their treatment. In contrast, pharmacotherapy may be associated with lower motivation to follow through, especially when the effects are not immediate or

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when side effects lead to discontinuation. These findings suggest that CBT-I may not only be more effective but also more practical for long-term management of insomnia due to its higher levels of patient engagement.(17,18)

While the study highlights the superiority of CBT-I in the treatment of chronic insomnia, it is important to consider the limitations. The study sample was restricted to a single population, and long-term follow-up beyond three months would provide more comprehensive data on the durability of treatment effects. Future studies should also examine the potential combined effects of CBT-I and pharmacotherapy, especially for individuals who may not have the resources or time to fully engage in CBT-I alone. Additionally, exploring the cost-effectiveness of these treatments could provide valuable insights for clinical decision-making and policy implementation.(19,20)

CONCLUSION

This study's results show that CBT-I, or Cognitive behavioural Therapy for Insomnia, is far superior to pharmacotherapy and a control group when it comes to improving sleep parameters like total sleep time, wake after sleep onset, and sleep onset latency, both in the short term and over a 3-month period. The ISI and WHOQOL-BREF scores also demonstrated that CBT-I improved daytime functioning and quality of life more than the other treatment options. When contrasted with the medication and control groups, CBT-I showed significantly better compliance and adherence, with fewer dropouts and missed sessions. Based on these findings, cognitive behavioural therapy with imagery (CBT-I) seems to be an attractive treatment option for insomnia management due to its high practicality, patient involvement, and positive clinical effects.

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