

A Meditation Based Cognitive Therapy (HMBCT) for Primary Insomnia: A Treatment Feasibility Pilot Study

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Abstract

Previous research has indicated a critical need for cost-effective alternative therapies. The present pilot study aimed to evaluate a novel, cost-effective therapy for treating insomnia. The study employed a randomized controlled trial with two groups: therapy and control. Participants were screened using research diagnostic criteria for insomnia recommended by the American Academy of Sleep Medicine (AASM) before undergoing simple randomization. The study included participants from Hindu, Muslim, and Christian faiths who were assigned to either the therapy group (Hare Krishna Mantra Based Cognitive Therapy: HMBCT) or the non-therapy group (control with relaxing music). Both groups underwent six weeks of treatment with traditional cognitive-behavioral therapy techniques, including stimulus control, sleep restriction, and sleep hygiene. Each week, participants in the therapy group received six 45-minute sessions of HMBCT in the evening and were asked to practice the therapy in the evening of the day of sleep recording. Sleep quality was assessed using behavioral measures, sleep logs, and polysomnography recordings before and after the six-week treatment period. There was a one-week period before and after the six weeks when no treatment was provided. Results showed that HMBCT significantly improved sleep quality measures, including a 61% reduction in Epworth Sleepiness Scale (ESS) scores and an 80% reduction in Insomnia Severity Index (ISI) scores. Participants did not take any sleep-inducing medication during the study. These findings suggest that adding mantra chanting to traditional cognitive-behavioral therapy may improve sleep quality.

Keywords Polysomnography \cdot Behavioural sleep measures \cdot Meditation \cdot Insomnia \cdot Mantra \cdot Cognitive Behavioural Therapy (CBT) \cdot Hare Krishna

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Introduction

Insomnia affects one in three individuals at some point in their lives (US National Sleep Foundation), with 18 million people in the US experiencing sleep apnea and 20 million suffering from restless leg syndrome (Institute of Medicine: US Committee on Sleep Medicine and Research, 2006). However, current medications used to treat insomnia can have side effects and lead to addiction (Huang et al., 2014). Thus, alternative therapeutic techniques are needed. Clinical guidelines by the American Association for Sleep Medicine (AASM) propose that Cognitive Behavioural Therapy (CBT) accompany pharmacologic treatments for chronic insomnia (Schutte-Rodin et al., 2008). CBT schemes and variants have been developed and generalized for various disorders, including Cognitive Behavioural Therapy for Insomnia (CBT-I), which demonstrated efficacy with large effect sizes on sleep logs and polysomnography parameters (Epstein et al., 2012). However, research suggests a relatively low probability of eliminating insomnia after CBT (Buysse et al., 2011; Morin et al., 2009). Furthermore, there is an imbalance between the number of CBT professionals and the growing number of insomnia patients (Prakash, 2007). There is a dire need for cost-effective alternative therapies that can add to the list of well-established therapies for insomnia. National Health Interview Survey (NHIS) reports a 3.5% increase in alternative therapies from 2002 to 2007, with meditation being among the top five complementary health approaches (Clarke et al., 2015). Meditation-based therapies find a unique place in the literature among alternative therapies. Since 2006, meditation has been a part of the initiative for the National Policy of Integrative and Complementary Practices of the National Health Service in Brazil (Field, 2009; Sampaio et al., 2017). Mantra meditation, which involves repeating a mantra, such as a word, sound, or symbol, has been proposed to synchronize the left and right hemispheres of the brain (Dudeja, 2017; Bhaskar et al., 2020). OM-based mantra meditation, which involves loud chanting, has been shown to offer relaxation, as indicated by enhanced theta power and amplitude in naive meditators (Harne et al., 2018). These changes in theta power were linked to reduced cortical arousal across all cortical regions (Jacobs & Friedman, 2004; Behera & Reddy, 2014).

Various spiritual traditions advocate using mantra-based chanting, including Niyyah, Salah (the prescribed prayers of Islam), and Monodic Christian chant, particularly Gregorian. The Vedas, a vast corpus of literature originating in the ancient Indian sub-continent, refer to the Hare Krishna mantra as a spiritual tool designed to purify the mind and achieve spiritual consciousness. Recent studies have reported stress reduction (Niva et al., 2021) and improved psychosocial functioning (Wolf et al., 2003) following Hare Krishna mantra chanting. In this study, we developed Hare Krishna mantra-based Cognitive Therapy (HMBCT), an adaptive therapy that combines mantra meditation with behavioral techniques for the treatment of primary insomnia. The HMBCT method employs audible chanting of the Hare Krishna mantra as an alternative therapy for insomnia.

CBT-I is an effective psychological and behavioral treatment for insomnia, as established by its well-documented standards of efficacy (Morin et al., 1994). Originally designed to address chronic or severe cases of insomnia (Chesson et al., 1999), CBT-I has been shown to have enduring clinical implications despite being a short-term intervention (Morin et al., 1999). In contrast, pharmacological treatments have demonstrated lower efficacy rates (Friedman, 2002; Krystal et al., 2003). Recent research has focused on the implementation of mindfulness-based CBT or acceptance-based CBT for insomnia, with significant improvements observed in various sleep parameters such as total waking time, sleeponset latency (SOL), sleep quality, sleep efficiency (SE), and the Pittsburgh Sleep Quality Index (PSQI) global score (Charoensukmongkol, 2014; Gong et al., 2016).

In a study by DeViva et al. (2005), CBT-I significantly improved subjective sleep measures, including waking time after sleep onset, total sleep time, and sleep quality. Similarly, a recent study by Ulmer et al. (2011) using CBT-I and Imagery Rehearsal (IR) treatment on 22 veterans showed significant improvements in the subjective severity of insomnia and sleep quality compared to a monitor-only control group. Schoenfeld et al. (2012) reported that post-IR therapy deviations from sound sleep remained clinically notable, while CBT-I effectively improves sleep-related disturbances and can be provided by novice trainers (Manber et al., 2012). These novel therapies fall under the umbrella of behavioral therapy, which includes other therapies such as dialectical behavioral therapy (Linehan, 1993), acceptance and commitment therapy (Pankey & Hayes, 2003), and mindfulness-based cognitive therapy (Segal et al., 2002). Recently, anecdotal reports suggested that mantra meditation could improve sleep quality in primary insomnia subjects. Thus, we were motivated to explore the combination of CBT-I and mantra chanting.

This pilot study was intended to evaluate the impact of a combination of CBT-I principles, including sleep restriction therapy, stimulus control therapy, and sleep hygiene, along with mantra chanting-based training. This preliminary investigation aimed to assess the effects of a six-week, six-session therapy on sleep disruptions in individuals with primary insomnia. The study aimed to generate precise hypotheses for a more extensive, controlled trial.

Method

Study Design

This study employed a simple randomized parallel group design using HMBCT and was conducted at the Indian Institute of Technology Kanpur (IITK) in India. Prior to group assignment, baseline measurements were taken from participants, and polysomnography recordings were obtained from all subjects at pre- and post-treatment time points. The treatment group underwent HMBCT chanting on the day of their recording in addition to standard guidelines of CBT (stimulus control, sleep restriction therapy & sleep hygiene), while the control group was instructed to listen to relaxing music before sleep without any mantra treatment, but along with standard CBT guidelines. After data collection, participants were asked to maintain a regular Electronic Sleep Diary (ESD) to record sleep parameters and were randomly assigned to either the treatment or control group. The study aimed to test the usefulness of HMBCT in improving sleep quality in subjects with primary insomnia. Participants were unaware of their group assignment, and the staff conducting behavioural and polysomnography recordings were also blinded to the treatment given. Therapy sessions were conducted weekly away from the sleep lab, and the entire experimental program, including subject recruitment, therapy efficacy evaluation, and follow-up, is depicted in Fig. 1. The inclusion of a control group allowed for an examination of the efficacy of HMBCT treatment over the effects of just listening to relaxing music while controlling for other factors. This study falls within the Stage I scope and norms of the Stage-wise Model of Behavioural Therapies (Rounsaville et al., 2001).

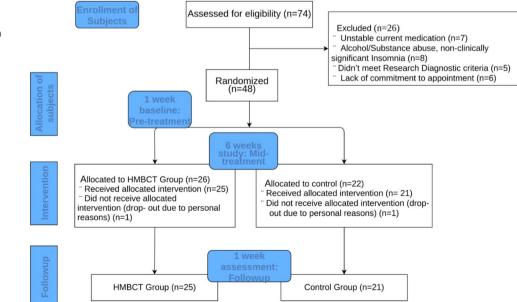
Participants

A total of 48 male participants, with an age range of 19–45 years and a mean age of 25.23 (SD=4.68) for the HMBCT group (n=26) and 23.82 (SD=3.01) for the control group (n=22), were recruited for this study. Participants were recruited through advertisements or recommended by doctors and had an average education duration of 15.82 years. All participants were required to maintain an ESD throughout the one-week baseline, six-week treatment, and one-week post-treatment follow-up period. Table 1 presents the demographic characteristics of the two groups.

The specific inclusion criteria followed recommended guidelines for insomnia research (Edinger et al., 2004). The participants (1) met diagnostic criteria for primary insomnia screened through structured psychiatric and sleep interviews (Williams et al., 1992; First et al., 1996); (2) had no notable medical illnesses affecting sleep; (3) had a mean Wake After Sleep Onset (WASO) and/or SOL>30 min in a week of sleep log monitoring; (4) had complaints of daytime fatigue and sleepiness; (5) had Insomnia Severity Index (ISI)>15; and (6) had sleep disturbance of at least three nights per week for a minimum of 6 months.

Candidates were excluded who (1) reported alcohol or drug abuse or unstable current medication in the past year or had non-clinical noteworthy insomnia (Edinger et al., 2004); (2) could not commit enough time to participate in the study (n=6); and (3) had Total Sleep Time (TST) 6 h, SE>85%, WASO>60 min in a week of sleep log monitoring, ISI>22 and a stable sleep period between 22:00 and 08:00 h.

The study recruited participants who were students or employees of the university based on their informed consent and willingness to participate in an 8-week study. The study



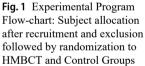


Table 1Demographic character-
istics of participating subjects

Attributes	HMBCT Group (Mean, Standard Deviation)	Control group (Mean, Stan- dard Deviation)	Test Statistic	Aggregate	P value
	(N=26)	(N=22)		(N=48)	
Age (years)	(25.23, 4.68)	(23.82, 3.01)	t=1.477	(24.06, 4.51)	0.147
Education (years)	(16.22, 2.00)	(15.42, 1.21)	t=1.599	(15.87, 1.50)	0.117
Marital Status (Indicated in the rows below)			$\chi^{2(1)} = 0.002$		0.958
Married	(4, 14.80)	(3, 14.28)		(7, 14.58)	
Unmarried	(23, 85.20)	(18, 85.72)		(41, 85.42)	
Insomnia Duration, years	(0.9, 0.64)	(0.57, 0.24)	t=2.186	(0.75, 0.35)	0.034
Comorbidity (%)	16.67%		$\chi^{2(1)} = 0.008$		0.928
Medical	(5, 18.50)	(3, 14.28)		(8, 16.67)	
Psychiatric	(3, 11.10)	(2, 9.50)		(5, 10.42)	

 Table 2 Sample Means of self-reported measures (ESS, ISI, PSQI, Cognitive PSAS, and Somatic PSAS) for both treatment and control groups in the format of Mean (Standard Deviation)

	Pre-treatment	Mid-treatment	Post-treatment
	Mean (Stan-	Mean (Stan-	Mean
	dard Deviation)	dard Deviation)	(Standard
			Deviation)
ESS	12.59 (1.91)	8.48 (0.51)	5.59 (0.50)
HMBCT	13.8 (3.2)	14.5 (2.9)	10.6 (2.7)
Control			
ISI	16.33 (3.71)	12.70 (3.06)	6.56 (2.95)
HMBCT	19.0 (3.6)	16.9 (3.2)	14.5 (2.9)
Control			
PSQI	13.81 (2.79)	10.30 (2.35)	4.78 (2.06)
HMBCT	13.3 (2.7)	13.4 (2.7)	12.7 (2.6)
Control			
Cognitive PSAS	22.22 (3.71)	17.96 (2.56)	15.41 (1.39)
HMBCT	23.0 (3.1)	20.1 (2.6)	19.1 (1.8)
Control			
Somatic PSAS	14.30 (3.07)	12.00 (2.27)	11.00 (1.64)
HMBCT	13.5 (3.0)	13.1 (2.0)	13.0 (1.8)
Control			

was conducted in accordance with the latest version of the Declaration of Helsinki and was approved by the Institute Ethics Committee of the university (IITK/IEC/2015-16/2/1). Both groups were provided with similar instructions, which explained that the study aimed to measure improvements in sleep quality resulting from nonpharmacological treatment.

Screening

During the pre-treatment period, screening interviews were conducted to assess participants' eligibility for the study measurements. Only primary-stage insomniacs were included in the study based on the screening interviews. A total of 74 male participants were enrolled in the study, as it was challenging to find a female polysomnographic technician for this preliminary study. The screening criterion was the Structured Clinical Interview for DSM-IV (SCID), which was a segment of the Duke Structured Interview for
 Table 3 Sample Means and standard deviations for sleep parameters

 from Polysomnography Behavioural recordings data in the format

 given by Mean (Standard Deviation)

Polysomnography data	Baseline	Post-treatment	
Time in Bed (TIB), (in minutes)			
HMBCT	479.0(6.1)	470.47(2.89)	
Control	474.2(11.5)	466.0(4.0)	
Total Sleep Time, (in hours)			
HMBCT	5.70(0.39)	7.02(1.5)	
Control	5.73(0.47)	6.37(1.0)	
Sleep Efficiency, (in percent)			
HMBCT	71.50(4.91)	89.51(4.41)	
Control	72.41(5.33)	81.92(4.16)	
Sleep Onset Latency, (in minutes)			
HMBCT	32.34(6.01)	14.95(5.31)	
Control	29.75(5.63)	21.85(5.50)	
Wake After Sleep Onset (WASO),			
(in minutes) HMBCT	44.9(5.04)	24(2(4.55))	
	44.8(5.04)	24.62(4.55)	
Control	42.93(4.57)	33.48(3.80)	
Total Arousals, (in minutes)			
HMBCT	54.77(5.42)	38.85(4.43)	
Control	48.9(5.13)	42.02(9.35)	
Percent Rapid Eye Movement			
Sleep, (in %)			
HMBCT	11.85(4.00)	21.40(3.52)	
Control	11.97(3.47)	17.43(5.13)	

Sleep Disorders (DSISD). After the screening, some subjects were excluded based on (1) unstable current medication (n = 7); (2) alcohol or substance abuse or dependence in the past year or non-clinically significant insomnia (n=8); (3) failure to meet Research Diagnostic Criteria for Insomnia (n=5); and (4) lack of commitment to appointments (n=6). Screened participants were randomly assigned in a blinded manner to either the HMBCT treatment group or the control group. The final screened subjects included 26 patients who received HMBCT and 22 who were assigned to the control group, with one participant dropping out from both groups during the intervention period.

Demographic Distribution

The demographic distribution of the two groups is presented in Table 1. The participants' groups consisted of 48 men in the age group 19–45 years (mean=24.06, SD=4.5). All participants were Indians and either staff/employees (n=5) or students (n=43) of IITK. The mean education duration of the CBT group (mean=16.22, SD=2) is slightly higher than that of the monitor-only control group (mean=15.42, SD=1.21). Most were unmarried (n=41), with a mean insomnia duration of 0.75 years. 16.67% of the participants had medical comorbidity, and 10.42% had some psychiatric comorbidity.

Measures

The study utilized various measures, including the Duke Structured Interview for Sleep Disorders (DSISD), Folstein Mini-Mental Status Exam (MMSE), sleep diary, sleep ritual diaries, ISI, Pre-Sleep Arousal Scale (PSAS), PSQI, Epworth Sleepiness Scale (ESS), and polysomnographybased measures. The primary measures consisted of polysomnography-based measures, ISI, PSAS, PSQI, and ESS, while DSISD, Folstein MMSE, sleep diary, and sleep ritual diaries were considered secondary measures. A detailed description of the measures can be found in the supplementary material at the provided link (https://bit.ly/3fsj4r0). Baseline characteristics of the primary and secondary measures are provided in the supplementary material.

Procedure

Following the screening protocol, 48 participants were eligible for the final study and were randomized into the HMBCT group (n=26) and the control group (n=22). Due to the potential for unequal sample sizes resulting from simple randomization with a small sample size (Schulz & Grimes, 2002), the sample sizes were uneven, with 26 subjects in the HMBCT group and 22 in the control group. A trainer led the HMBCT group with formal training in mantra meditation, and a professional sleep practitioner who is a fellow of AASM. The participants received six weeks of HMBCT treatment, and one week of baseline ESD measurements were collected. A total of 94 polysomnography recordings were collected, with 48 taken before treatment and 46 after treatment. Participants meeting eligibility criteria were asked to maintain a sleep diary, which was assessed one week before treatment, three weeks into treatment, three weeks later, and one week after six weeks of treatment. Based on questionnaire answers and the oneweek sleep diary outcomes, participants were randomized into either the control group (n=22) or the HMBCT group (n = 26). Participants in the HMBCT group received six sessions of HMBCT over six weeks, while the control group did not receive any HMBCT training but instead listened to relaxing music and received standard practices of CBT for insomnia (stimulus control, sleep restriction therapy and sleep hygiene). Participants in the control group were asked to listen to their favorite music before sleeping. One participant dropped out of each group. After the sixth session, the participants completed a post-intervention sleep diary for the last week.

During the HMBCT intervention, each training session was divided into three steps. The first step involved a simple mindful meditation practice where participants mentally evaluated their day while sitting with their backs straight. The second step required participants to listen to and chant along with a senior practitioner's audio recording of a mantra tune while sitting cross-legged. In the third step, participants listened to and chanted along with the same mantra tune while lying down in a Shavasana position. In addition to the three-step training, participants in the HMBCT group were taught other CBT-I strategies, such as stimulus control, sleep restriction, and sleep hygiene, during training sessions. Supplementary material containing sleep diary outcome measures can be accessed through this link (https://bit.ly/3fsj4r0). Analysis of the sleep diary data indicated that the inclusion of the three-step HMBCT training method resulted in improved sleep parameters compared to relying solely on stimulus control, sleep hygiene, and sleep restriction. The HMBCT group underwent six training sessions over six weeks and were encouraged to practice the three-step mantra chanting method daily before sleep. Both groups received training in stimulus control, sleep hygiene, and sleep restriction, but only the HMBCT group practiced the three-step mantra chanting method during training sessions. The average duration of each training session was 45 min.

Data Analysis

The present study utilized repeated-measures analysis of variance (RM-ANOVA) to assess measures collected at three time points (baseline, mid-treatment, and post-treatment) in both the control and intervention groups. Additionally, post-hoc paired t-tests were conducted within both groups to compare sleep and polysomnography indicators at baseline and after a four-month monitor-only period. Effect sizes were calculated using Cohen's d for mixed model comparisons and partial eta squared for ANOVA as a measure of variance. Various indices of clinical importance were calculated to verify the performance of treatment. Supplementary material with more details on data analysis can be found at the link (https://bit.ly/3fsj4r0). Table 2 of the supplementary

material also presents specific results from this section, including effect size analysis for secondary measures.

Results

Epworth Sleepiness Scale (ESS)

A repeated measures analysis of variance (RM-ANOVA) was conducted for the Epworth Sleepiness Scale (ESS) using the group (HMBCT, Control) as the between-subjects variable and time (pre-treatment, mid-treatment, and post-treatment) as the within-subjects variable. The results showed a significant main effect of time (F = 64.495, p < 0.001, $\eta 2 = 0.584$) and group (F = 71.782, p < 0.001, $\eta 2 = 0.609$), as well as a significant interaction effect between time and group (F = 12.288, p < 0.001, $\eta 2 = 0.211$). Further analysis using Bonferroni multiple comparisons revealed no significant difference between the groups at baseline (t = -0.588, p=0.559). The control group did not show a significant change over time from baseline to mid-treatment (p=1) but showed a significant change over the next half of the study (p < 0.001). On the other hand, the HMBCT group showed a significant change across the baseline towards the end of the therapy period (t = 10.1, p < 0.001, d = 1.4), with corresponding p values less than 0.001.

Insomnia Severity Index (ISI)

The current study employed RM-ANOVA to examine the effects of the HMBCT intervention compared to a control group, with the group (HMBCT, Control) as the betweensubjects variable and time (pre-treatment, mid-treatment, and post-treatment) as the within-subjects variable. The analysis revealed a significant main effect of time (F = 49.930, p < 0.001, $\eta 2 = 0.520$) and group (F = 161.186, p < 0.001, $\eta 2 = 0.778$) in addition to a significant time \times group interaction (F = 27.076, p < 0.001, η 2 = 0.371). Bonferroni multiple comparisons indicated no significant difference between groups at baseline (t= -1.54, p=0.128), but the difference became significant over time. The HMBCT group (t=18.1,p < 0.001, d = 2.49) demonstrated significant improvement in insomnia symptoms towards the end of the therapy period (corresponding p values are less than 0.001), while the control group did not change significantly. Post-treatment mean ISI values were close to 7, indicating a decrease in insomnia symptoms due to the therapy. Almost 60% of participants in the therapy group demonstrated no clinically relevant insomnia with ISI values less than 7, while 90% of the control group continued to experience insomnia.

Pittsburgh Sleep Quality Index (PSQI)

The study conducted RM-ANOVA with the group (HMBCT, Control) as the between-subjects variable and time (pre-treatment, mid-treatment, and post-treatment) as the within-subjects variable to examine the effect of the intervention on PSQI scores. Results revealed a significant main effect of time (F = 77.794, p < 0.001, $\eta 2 = 0.628$) and group (F = 61.040, p < 0.001, $\eta 2 = 0.570$), along with a significant time \times group interaction (F = 20.054, p < 0.001, $\eta 2 = 0.304$). Bonferroni multiple comparisons revealed no significant difference between groups at baseline (t = -0.975, p=0.334), but the difference became significant with time. The HMBCT group showed a significant improvement in PSQI scores from baseline to mid-treatment (t = 14.75, p < 0.001, d = 2.75) with corresponding p values less than 0.001. Moreover, the change of PSQI for the treatment group from mid-treatment to end-treatment was also statistically significant (t = 5.387, p < 0.001, d = 1.03). On the other hand, only a significant difference was observed for the control group from the mid-treatment to post-treatment period, with mean PSOI values post-treatment close to 5, indicating minimal difficulty in maintaining sleep.

Cognitive PSAS (Pre-Sleep Arousal Scale)

The results of RM-ANOVA with the group (HMBCT, Control) as the between-subjects variable and time (pretreatment, mid-treatment, and post-treatment) as the withinsubjects variable showed significant main effects of time (F = 109.051, p < 0.001, $\eta 2 = 0.703$) and group (F = 11.784, p < 0.001, $\eta 2 = 0.204$), as well as a significant time × group interaction (F = 8.422, p < 0.001, $\eta 2 = 0.155$). Bonferroni multiple comparisons revealed no significant difference between groups at baseline (t= -0.730, p=0.472), but the difference became significant over time. Both the HMBCT (t= 14.45, p < 0.001, d=2.8) and the control group's scores changed significantly from the baseline to the treatment end period (t= 11.126, p < 0.001, d=2.5).

Somatic PSAS

The present study employed a repeated measures analysis of variance (RM-ANOVA) with the group (HMBCT, Control) as the between-subjects variable and time (pre-treatment, mid-treatment, and post-treatment) as the within-subjects variable to examine the effects of a mindfulness-based cognitive therapy intervention on sleep quality. Results revealed a significant main effect of time (F=10.716, p<0.001, η 2=0.189) and group (F=36.228, p<0.001, η 2=0.441), as well as a significant time × group interaction (F=3.627, p<0.001, η 2=0.073). Bonferroni post-hoc comparisons

indicated that there were no significant differences between groups at baseline (t= -1.315, p=0.195), but significant differences were observed during the post-treatment period (t= -5.3818, p<0.001). The HMBCT group demonstrated significant improvement in sleep quality from baseline to end of treatment (t=6.638, p<0.001, d=1.296), whereas no significant differences were observed in the control group's sleep quality scores from baseline to end of treatment.

The statistical analysis for sleep diary-based measures can be found in the supplementary material at the link (https://bit.ly/3fsj4r0); additionally, a summary of the same is included in the discussion section.

Polysomnography (PSG) Based Measures

To address the design that involves conducting PSG measurements before and after administering therapy in both groups, a univariate analysis of covariance and paired t-test were utilized.

Time in Bed (TIB)

Univariate analysis of covariance (ANCOVA) was conducted to examine the effects of group (HMBCT, Control) on PSG measurements before and after administering therapy, with pre-treatment PSG measure value selected as the covariate. Results showed a significant effect of group (F(1,45)=15.642, p<0.001, $\eta\rho^2$ =0.258), indicating that the HMBCT group had a smaller TIB value post-treatment. Further analysis using paired samples t-test revealed a significant change in the mean TIB score in the HMBCT group (t(26)=7.266, p<0.001, d=1.39).

Total Sleep Time (TST)

In this study, a Univariate ANCOVA was performed to analyze the effect of group (HMBCT, Control) as the betweensubjects variable and the pre-treatment PSG measure value as the covariate on the post-treatment PSG measurements. The results indicate a statistically significant effect of group (F(1,45)=37.77,P<0.001, $\eta\rho^2$ =0.456), where the HMBCT group had a larger TST value post-treatment. Furthermore, paired samples t-test reveals a statistically significant change in the mean TST score in the HMBCT group (t(26)=-12.437, P<0.001, d=2.39).

Sleep Efficiency (SE)

The study employed a univariate ANCOVA with the group (HMBCT, Control) as the between-subjects variable and the pre-treatment PSG measure value as the covariate. The results indicate a significant effect of group

(F(1,45)=34.94,P<0.001, $\eta\rho^2$ =0.437) on the post-treatment SE value, with the HMBCT group showing a larger SE value. Furthermore, the paired samples t-test showed a significant change in the mean SE score in the HMBCT group (t(26)=-12.218, P<0.001,d=2.34).

Sleep Onset Latency (SOL)

After conducting univariate ANCOVA with the group (HMBCT, Control) as the between-subjects variable and the pre-treatment PSG measure value as the covariate, a statistically significant effect of group was found (F(1,45)=32.33, P<0.001, $\eta\rho^2$ =0.418). Paired samples t-test also revealed a significant change in the mean SOL score in the HMBCT group (t(26)=-12.273, P<0.001,d=2.36).

Wake After Sleep Onset (WASO)

Univariate ANCOVA was performed with the betweensubjects variable of the group (HMBCT, Control) and the pre-treatment PSG measure value as the covariate. The results show a significant effect of group (F(1,45)=47.008,P<0.001, $\eta\rho^2$ =0.511), indicating that the HMBCT group had a lower mean value of WASO score post-treatment compared to the control group. The paired samples t-test also revealed a statistically significant change in the mean WASO score in the HMBCT group (t(26)=-13.135, P<0.001,d=2.53).

Total Arousals

Univariate ANCOVA was performed with the group (HMBCT, Control) as the between-subjects variable, and the pre-treatment PSG measure value was used as the covariate. Results indicate a significant effect of group (F(1,45) = 7.955, P<0.001, $\eta\rho^2$ =0.150), with the HMBCT group having a smaller mean total arousal in their sleep at post-treatment. Additionally, a paired samples t-test revealed a statistically significant change in the mean total arousal scores in the HMBCT group (t(26)=11.413, P<0.001, d=2.2).

Percentage REM (Rapid Eye Movement) sleep

Univariate ANCOVA was performed with the group (HMBCT, Control) as the between-subjects variable, and the pre-treatment measure value was utilized as the covariate. The results showed a statistically significant effect of group (F(1,45)=13.525,P<0.001, $\eta\rho^2$ =0.231), where the HMBCT group had a larger mean percent REM sleep value post-treatment. Furthermore, paired samples t-test confirmed a significant change in the mean percent REM sleep score in the HMBCT group (t(26)=-8.576, P<0.001,d=1.65).

Discussion

The statistical analysis revealed evidence of intervention improving sleep outcome measures (TST, TIB, WASO, SOL, SE, Total arousals, REM%, ISI, PSQI, ESS, and PSAS). The magnitude of Cohen's effect size in the withinsubjects framework was found to be significant for total arousals (d=2.2), TIB (d=1.39), %SE (d=2.34), ESS (d=1.4), ISI (d=2.49), PSQI (d=2.75), WASO (d=2.53)and moderate for TST (d=2.39). In particular, the CBT-I portion of our therapy focused on relaxation training (the three-step mantra-based chanting followed in HMBCT belongs to the class of relaxation training technique in CBT-I (Perlis et al., 2006)) and behavioural attributes of stimulus control and sleep hygiene. 80% of the subjects experienced a 32% decrease in total arousal. A detailed examination of weekly differences in total arousals showed a quasi-linear trend with a mean per week reduction of (2-3)arousals across the six weeks of intervention. At the end of the intervention, 7.4% of participants in the HMBCT group met the diagnostic criteria for insomnia, and two individuals scored below the threshold for clinically noticeable insomnia on the ISI scale. The changes in TST indicated a gradual decline from baseline until week 2 of the intervention, possibly due to the introduction of sleep restriction followed by moderate growth over the next four weeks of intervention. This pattern is typical in behavioral therapy studies that incorporate sleep restriction and stimulus control (Perlis et al., 2006), and extrapolation suggests that further improvements beyond the six-week period are likely. In summary, the combination of CBT-I and mantra chanting resulted in significant improvements in sleep quality for individuals with primary insomnia, and these improvements were more robust compared to several previous studies on CBT-I alone.

The sleep ritual, which was administered along with the chanting of the mantra, can be incorporated within the CBT-I framework. CBT-I is non-specific and requires trained practitioners to teach the participants. In this study, we have incorporated a few aspects of it and introduced a novel cognitive technique to the intervention. Such an intervention was easy to follow and showed an overall improvement in nocturnal sleep insomnia in the HMBCT group. The intervention also demonstrated a reduction in sleep arousal, daytime sleepiness symptoms, and sleep-related disbelief compared to the control group. It is possible that the slight improvement in sleep quality observed in the control group may be attributed to the psychological placebo attention effect and/or the effect of listening to preferred music. Most notably, the sleep ritual practices significantly improved sleep quality by reducing sleep arousal and decreasing daytime sleepiness in the HMBCT group.

The high attendance and recruitment rates and the low dropout rate suggest that adults with insomnia are willing to participate and comply with a combined treatment approach that includes HMBCT. The degree of consistency regarding the recommended sleep education guidelines is moderate. There was an average deviation of $10 \min(SD=6)$ observed between the prescribed TIB and the actual TIB and an average deviation of 12 min (SD = 7) observed between the prescribed Time Out of Bed (TOB) and the actual TOB. These variations are comparable to the compliance with sleep schedules reported for older adults (Chand & Grossberg, 2013). It is important to note that moderate compliance with the sleep ritual sessions may still have contributed to the significant improvements observed in the therapy group. However, further research with larger sample sizes is needed to confirm these findings and to determine the optimal frequency and duration of sleep ritual sessions for improving sleep quality in individuals with insomnia. Additionally, future studies could explore ways to enhance adherence to the sleep ritual intervention to maximize its effectiveness.

Limitations & Future Directions

The pilot study conducted in this work provides initial evidence for the feasibility and potential effectiveness of HMBCT in treating insomnia. However, further research is needed to validate these findings and to determine the effectiveness of HMBCT compared to other established treatments for insomnia, such as CBT-I. Additionally, larger sample sizes, longer follow-up periods, and more diverse participant populations could provide more generalizable and robust results.

Our study population consisted exclusively of individuals who had completed their secondary education up to diploma, BTech, MTech, and doctoral studies, specifically students and employees of the Institute. Future work may also separately examine the effects of Hare Krishna mantra chants compared to CBT-I on subjects diagnosed with primary sleep insomnia. Readers can access a concise treatment manual as supplementary material at the following link: https://cutt.ly/tRXxGjz. Future works should also incorporate power spectral analysis on sleep EEG recordings to evaluate the neural correlates of sleep insomnia (Kalak et al., 2012; Zhao et al., 2021). It was claimed that high frequency in REM correlates with higher sleep efficiency (Zhao et al., 2021). It was also reported that the Heart Rate Variability parameters (HRV) increase with psychological well-being (Damerla et al., 2018). All of the studies referenced, including the current pilot study, will be utilized to formulate a hypothesis for a future large-scale study.

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Declarations

Competing interests The authors have no competing interests to declare relevant to this article's content.

Ethical approval All procedures performed in studies involving human Participants were in accordance with the ethical standards of the institutional and/or Indian Council for Medical Research or comparable ethical standards (IITK/IEC/2015-16/2/1).

Informed consent Informed written consent was obtained from all individual participants included in the study.

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