





BRIEF COMMUNICATION

Acceptance and commitment therapy-based behavioral intervention for insomnia: a pilot randomized controlled trial

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Objective: To evaluate a protocol for acceptance and commitment therapy-based behavioral intervention for insomnia (ACT-BBI-I) in adults compared to cognitive behavioral therapy for insomnia (CBT-I).

Methods: Forty-five adults with chronic insomnia were randomized to ACT-BBI-I or CBT-I. Both interventions were performed in six weekly group sessions. The common treatment elements in both protocols included stimulus control and sleep restriction. CBT-I is focused on the cognitive restructuring of maladaptive beliefs about sleep and the daytime effects of insomnia. ACT-BBI-I focuses on therapeutic processes of acceptance, availability, values, defusion, and commitment. The results were evaluated through the following instruments: a sleep diary, the Insomnia Severity Index, the Epworth Sleepiness Scale, the Hospital Anxiety and Depression Scale, the Acceptance and Action Questionnaire-II, and the Dysfunctional Beliefs and Attitudes about Sleep scale.

Results: Both interventions had a significant positive impact on sleep patterns, insomnia, anxiety, beliefs about sleep, and psychological flexibility. All improvement was maintained at the 6-month follow-up.

Conclusion: The results suggest that integrating principles of ACT with behavioral techniques may be useful for treating insomnia. Further research should identify whether the principles of ACT result in added effectiveness compared to behavioral components alone.

Clinical trial registration: RBR-7nc5wq

Keywords: insomnia; acceptance and commitment therapy; cognitive behavioral therapy

Introduction

There is a large body of evidence on the efficacy of cognitive behavioral therapy for insomnia (CBT-I).¹⁻³ Although many patients have beneficial experiences with CBT-I, some do not respond to this modality of intervention. One study found that 19-26% of participants failed to show any response to treatment, and the overall reduction of insomnia symptoms average only 50-60%.⁴ Moreover, adherence to stimulus control and sleep restriction techniques is difficult for many participants,⁴ whereas modified treatment can improve the effects of existing treatments for insomnia and outcomes for a greater number of participants. Acceptance and commitment therapy-based behavioral intervention for insomnia (ACT-BBI-I) is a different approach that uses behavioral components of

stimulus control and sleep restriction, but with components of ACT that modulate psychological intervention. Rather than controlling the symptoms, this potentially useful intervention focuses on accepting the feelings and thoughts associated with insomnia through value-based actions.⁵⁻⁷ In contrast to other insomnia treatments based on mindfulness,⁸ ACT includes clarification of personal values and value-based action planning.⁶

ACT-BBI-I has shown favorable results in preliminary studies^{5,7} with participants refractory to CBT-I. In a case study by Dalrymple et al.,⁷ ACT-BBI-I was applied in nine sessions to a 40-year-old male participant refractory to CBT-I. This participant was having difficulty adhering to the stimulus control and sleep restriction techniques and had already tried a cognitive approach in a previous trial of CBT-I. ACT-BBI-I led to improved sleep efficiency (SE)

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and greater adherence to stimulus control and sleep restriction techniques. The authors point out that participant adherence to some of the behavioral components of CBT-I may be difficult and that ACT contributed to the treatment by helping the participant accept the feeling of discomfort (fatigue) that occurs during sleep restriction and stimulus control strategies.

ACT represents a paradigm shift in the management of insomnia since it focuses on the participant from a macro perspective, aiming to increase his/her behavioral and psychological flexibility, not concentrating exclusively on symptom control.^{5,7} The positive results of ACT-BBI-I in studies with small samples^{5,7} indicate the need for additional studies, including randomized controlled trials with more participants to assess the effectiveness of ACT-BBI-I in insomnia treatment.

This pilot study had two primary aims: 1) to assess the efficacy of an ACT-BBI protocol for chronic insomnia in adults; and 2) to investigate the treatment's effect on daytime sleepiness, depression, anxiety, beliefs about sleep, and psychological flexibility. The use of ACT to treat insomnia does not exclude techniques that have already proven effective, such as stimulus control and sleep restriction, but rather adds elements that can be easily integrated into these techniques. The first hypothesis was that ACT-BBI-I would work as effectively as CBT-I. The second hypothesis was that ACT-BBI-I would also result in improved daytime sleepiness, depression, anxiety, beliefs about sleep, and psychological flexibility.

Methods

The study employed a two-arm randomized design. The participants were randomly assigned to one of two groups: CBT-I or ACT-BBI-I. Outcomes were assessed at post-treatment and at the 6-month follow-up. This study was approved by the research ethics committee where the services were performed and was registered in the Brazilian Clinical Trials Registry (RBR-7nc5wq).

Participants were recruited from March 2018 to November 2018 through advertisements. The study assessments and interventions were conducted at the Sleep Outpatient Unit (Ambulatório de Sono), Instituto de Psiquiatria, Hospital das Clínicas, Faculdade de Medicina, Universidade de São Paulo, Brazil. Interested persons accessed the REDCap database platform and responded to an initial screening questionnaire to verify eligibility. The following inclusion criteria were used during the participant selection process: 1) 18 to 59 years old, and 2) meeting criteria for chronic insomnia – i) difficulty initiating and/or maintaining sleep, defined as a sleep onset latency and/or wake after sleep onset ≥ 30 min, with a corresponding sleep time of ≤ 6.5 h per night; ii) insomnia more than three nights per week for more than 3 months; iii) the sleep disturbance (or associated daytime fatigue) causes significant distress or impairment in social, occupational, or other areas of functioning. This definition represents a combination of criteria from the American Academy of Sleep Medicine,⁹ the International Classification of Sleep Disorders,¹⁰ and the Diagnostic and Statistical Manual of

Mental Disorders,¹¹ along with quantitative cutoffs typically used in insomnia research. Exclusion criteria were: 1) unstable clinical or psychiatric comorbidities according to the Mini International Neuropsychiatric Interview¹²; 2) use of illicit drugs or alcohol; 3) illiteracy or cognitive disorders; 4) unavailability to attend the face-to-face sessions.

A total of 45 participants met the eligibility criteria and were randomized into the comparative treatment (CBT-I) or treatment (ACT-BBI-I) groups, as shown in Figure 1. The allocation list was generated using online randomization software. Seventeen participants received ACT-BBI-I treatment and completed the post-treatment and 6-month follow up assessments; five participants from this group dropped out. Sixteen participants from the CBT-I completed the treatment and post-treatment assessments; seven participants from this group dropped out and two declined to participate in the 6-month follow-up assessment.

The participants were organized into a total of eight therapeutic groups, four ACT-BBI-I and four CBT-I. For both treatments, the intervention occurred over six weekly sections in groups of four to six participants, conducted by a therapist and a co-therapist, both of whom were trained psychiatrists and/or psychologists.

The common treatment elements in both protocols refer to behavioral components, which include psycho-education about sleep, sleep hygiene, stimulus control, and sleep restriction. The CBT-I protocol was based on Harvey et al.¹³ Beyond the behavioral components, the focus of cognitive intervention for insomnia is on cognitive restructuring of maladaptive beliefs regarding sleep and the daytime effects of insomnia. For the ACT-BBI-I groups, the cognitive intervention focused on the therapeutic processes of acceptance, availability, values, defusion, and commitment used in ACT. The present protocol was based on the ACT Manual developed by Hayes et al.⁶ Chart 1 presents the content of each session for both groups.

A sleep diary was used throughout the treatment process to modulate sleep restriction therapy and as a comparative follow up. Each week, the participants submitted their diaries at the beginning of the group sessions to the co-therapist, who calculated SE and prescribed time in bed individually at the end of each session.

The assessment occurred at three time-points: pre-treatment, post-treatment, and at 6-month follow-up, in which the following instruments were used: the Insomnia Severity Index (ISI),¹⁴ Epworth Sleepiness Scale,¹⁵ Hospital Anxiety and Depression Scale,¹⁶ Acceptance and Action Questionnaire-II (AAQ-II),¹⁷ and Dysfunctional Beliefs and Attitudes about Sleep 10-Item Scale.¹⁸ These parameters were assessed online using REDCap. Outcomes (sleep onset latency [SOL], number of awakenings [NA], wake after sleep onset [WASO], total sleep time, SE, insomnia, daytime sleepiness, depression, anxiety, beliefs about sleep and psychological flexibility) were compared using two-way analysis of variance (ANOVA) for repeated measures, and the interaction test was used to test the null hypothesis. Findings with a p-value or type I error probability of less than 5% were considered statistically significant.

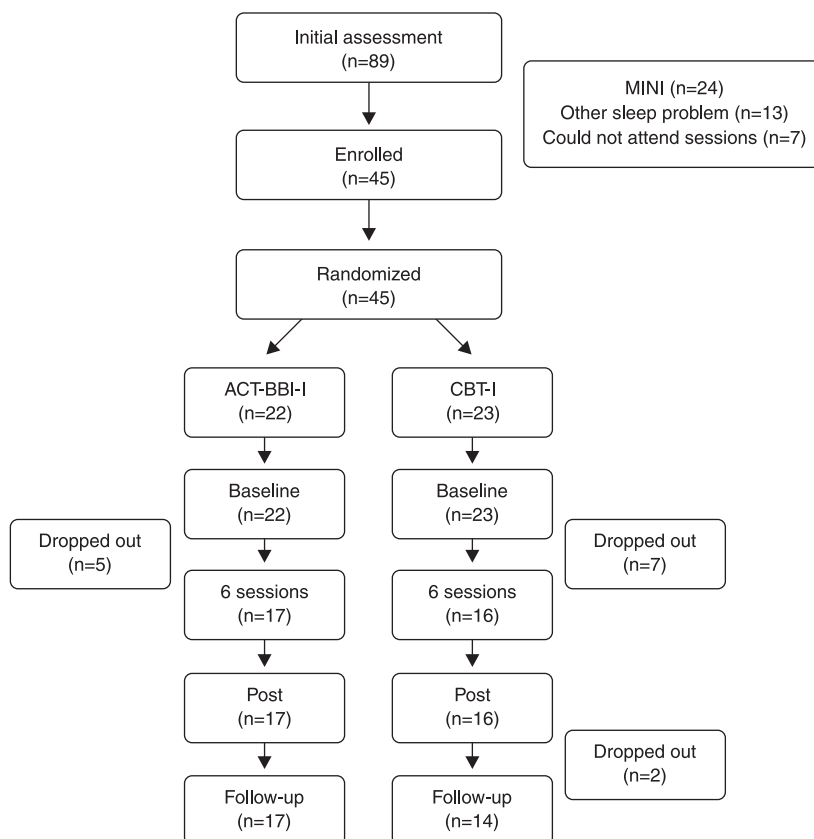


Figure 1 Flow diagram showing the flow of participants through the trial. ACT-BBI-I = acceptance and commitment therapy-based behavioral intervention for insomnia; CBT-I = cognitive behavioral therapy for insomnia; MINI = Mini International Neuropsychiatric Interview.

Ethics statement

All procedures involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all participants included in the study.

Results

The sample consisted predominantly of women (60%), 43% were married, the mean age was 40.2 years (standard deviation [SD] = 10.5, range 18 to 59 years), and most participants were college graduates (71%). The chronicity of insomnia among participants was 9.7 years (SD = 7.9, range 1 to 32 years). The psychiatric comorbidities identified with the Mini International Neuropsychiatric Interview were stable. The most frequent comorbidities were depression (36%), anxiety (27%), bipolar disorder (3%), and attention deficit hyperactivity disorder (3%). In the initial phase of the study, 30% of the participants used sleep medication occasionally: zolpidem (21%), melatonin (6%), and benzodiazepine (3%).

In the Dysfunctional Beliefs and Attitudes about Sleep Scale, the belief “After a poor night’s sleep, I know that it will interfere with my daily activities on the next day,” was

the most frequently endorsed by the participants (75%). Of the AAQ-II’s items on psychological flexibility, the statement “It seems like most people are handling their lives better than I am” was the most frequently endorsed by participants (60%). No differences were observed among the sociodemographic variables of the two groups, nor in the baseline characteristics ($p > 0.05$), except in SOL, which was significantly higher in the ACT-BBI-I group.

The ANOVA results for each outcome are presented in Table 1. After both treatments (ACT-BBI-I and CBT-I), significant reductions were observed in SOL, NA, WASO, SE, insomnia, anxiety, beliefs about sleep, and psychological flexibility. After the intervention, approximately half of the participants from both groups were in remission from insomnia, based on a cutoff of < 8 on the Insomnia Severity Index. The clinical improvements were maintained at the 6-month follow-up in both groups. The only significant difference between the groups was NA, for which the ACT-BBI-I group presented significantly greater improvement.

Discussion

In this first randomized controlled trial of a group ACT-BBI-I in adults, positive effects were found for SOL, NA, WASO, SE, insomnia, anxiety, beliefs about sleep, and psychological flexibility. The results of this pilot study

Chart 1 Week-by-week schedule for acceptance and commitment therapy-based behavioral intervention for insomnia (ACT-BBI-I) and cognitive behavioral therapy for insomnia (CBT-I)

Sessions	ACT-BBI-I	CBT-I
1	Brief explanation of ACT Review sleep diary and reinforce self-monitoring Psychoeducation about sleep Sleep hygiene	Brief explanation of CBT Review sleep diary and reinforce self-monitoring; Psychoeducation about sleep Sleep hygiene
2	Review sleep diary Review of home practice and problems with procedures (sleep hygiene) Stimulus control therapy Creative hopelessness Mindfulness exercises	Review sleep diary Review of home practice and problems with the procedures (sleep hygiene) Stimulus control therapy Cognitive restructuring of maladaptive beliefs regarding sleep and the daytime effects of insomnia
3	Review sleep diary Review of home practice and problems with procedures (sleep hygiene, stimulus control) Review of home practice and problems with ACT procedures Sleep restriction therapy Creative hopelessness and acceptance Acceptance and defusion Mindfulness exercises	Review sleep diary Review of home practice and problems with procedures (sleep hygiene, stimulus control) Review of home practice and problems with cognitive procedures Sleep restriction therapy Cognitive restructuring of maladaptive beliefs regarding sleep and the daytime effects of insomnia
4	Review sleep diary Review of home practice and problems with procedures (sleep hygiene, stimulus control, sleep restriction) Review of home practice and problems with ACT procedures; Self as context and defusion Acceptance and mindfulness exercises	Review sleep diary Review of home practice and problems with procedures (sleep hygiene, stimulus control, sleep restriction) Review of home practice and problems with cognitive procedures Cognitive restructuring of maladaptive beliefs regarding sleep and the daytime effects of insomnia
5	Review sleep diary Review of home practice and problems with procedures (sleep hygiene, stimulus control, sleep restriction) Review of home practice and problems with ACT procedures Values and committed action Mindfulness exercises	Review sleep diary Review of home practice and problems with procedures (sleep hygiene, stimulus control, sleep restriction) Review of home practice and problems with cognitive procedures Cognitive restructuring of maladaptive beliefs regarding sleep and the daytime effects of insomnia
6	Review sleep diary Adjust sleep window for upcoming weeks Continue focus on maintaining treatment gains and relapse prevention Values and committed action Review of homework assignments Final progress of interventions Mindfulness exercises Closure	Review sleep diary Adjust sleep window for upcoming weeks Continue focus on maintaining treatment gains and relapse prevention Cognitive restructuring of maladaptive beliefs regarding sleep and the daytime effects of insomnia Review of homework assignments Final progress of interventions Closure

support our initial hypothesis that both groups would result in reduced insomnia symptoms and improvements in other variables, such as anxiety, beliefs about sleep, and psychological flexibility immediately after treatment and at 6 months post-treatment. To our knowledge, this is the first study to compare ACT-BBI and CBT for chronic insomnia, as well as the first such trial conducted in Brazil.

It is important to mention that behavioral components, such as stimulus control and sleep restriction, were used in both groups, which may have contributed to similar results in both groups, considering that the efficacy of behavioral therapy components is well established.¹⁻³ By using established behavioral components that are known to be effective for chronic insomnia in both groups, it was possible to investigate the added value of acceptance therapy and cognitive restructuring therapy. The focus of

the cognitive therapy was to modify cognition and beliefs about sleep, while the focus of the ACT was to increase psychological flexibility and establish a non-judgmental attitude towards sleep. Although the impact of stimulus control and sleep restriction is well known, using methods that invest in improving psychological flexibility is somewhat paradoxical to the aim of the traditional CBT-I approach, which seeks to reframe the patient's beliefs and habits.¹³ The aim of this study was to explore potentially effective therapeutic modalities rather than determine which was more effective for treating chronic insomnia, whether from the behavioral or cognitive perspective. This approach is similar to non-inferiority trials, which seek to demonstrate that a new treatment is equivalent to an already validated intervention.

With a new paradigm unlike traditional CBT-I cognitive restructuring, ACT-BBI-I provides alternative strategies

Table 1 Outcomes by treatment groups and protocol phases

	ACT-BBI-I			CBT-I			p-value
	Pre-treatment (n=17)	Post-treatment (n=17)	Follow-up (n=17)	Pre-treatment (n=14)	Post-treatment (n=14)	Follow-up (n=14)	
SOL	92.4 (68.5)	43.8 (43.8)		39.4 (33.6)	18.1 (11.3)		0.062
NA	2.2 (1.2)	1.1 (1.0)		1.4 (1.8)	1.3 (1.6)		0.037
WASO	33.5 (24.9)	8.7 (5.9)		26.9 (24.6)	15.0 (11.5)		0.220
TST	338.2 (73.3)	369.5 (64.9)		328.5 (92.5)	339.4 (52.7)		0.385
SE	66.6 (13.7)	82.4 (11.7)		76.2 (15.0)	87.7 (5.2)		0.390
ISI	19.1 (4.3)	10.6 (5.1)	9.5 (3.6)	16.4 (3.5)	7.2 (3.2)	9.0 (6.1)	0.368
ESS	6.4 (5.7)	5.7 (4.8)	5.7 (3.7)	6.9 (4.0)	4.9 (3.1)	6.3 (5.8)	0.531
HADS-A	10.4 (4.6)	8.5 (4.3)	9.3 (4.1)	9.6 (4.0)	7.2 (3.3)	7.6 (4.2)	0.801
HADS-D	7.2 (5.1)	5.7 (2.8)	6.7 (3.9)	7.6 (4.6)	5.7 (3.2)	6.3 (3.3)	0.847
DBAS	80.9 (12.8)	53.9 (17.3)	54.4 (17.7)	75.6 (18.2)	32.7 (16.7)	35.8 (23.3)	0.139
AAQ-II	29.4 (11.1)	26.1 (8.5)	28.0 (8.2)	26.6 (9.1)	21.1 (8.3)	22.5 (7.1)	0.614

Data presented as mean (standard deviation).

AAQ-II = Acceptance and Action Questionnaire-II; DBAS = Dysfunctional Beliefs and Attitudes about Sleep; ESS = Epworth Sleepiness Scale; HADS = Hospital Anxiety and Depression Scale; HADS-A = Hospital Anxiety Scale; HADS-D = Hospital Depression Scale; ISI = Insomnia Severity Index; NA = number awakenings; SE = sleep efficiency; SOL = sleep onset latency; TST = total sleep time; WASO = wake after sleep onset.

for accepting unpleasant experiences while not directly addressing or attempting to change a single predominant symptom. These acceptance strategies may have positively influenced the results, particularly by encouraging patients to let go of sleep control and increase their willingness to experience the short-term discomfort associated with sleep restriction techniques. Therefore, this type of approach could improve adherence to behavioral strategies in insomnia treatment for some participants. One possible explanation is that the acceptance component reduced counterproductive sleep effort by increasing acceptance of physiological and mental arousal, which helped promote sleep. The commitment involved in ACT included planning value-based actions, in addition to the willingness to make the behavioral changes necessary to promote a better relationship with sleep. Similar results were found by Dalrymple et al.⁷ and Hertenstein et al.⁵

Interestingly, both groups showed improvement in AAQ-II and Dysfunctional Beliefs and Attitudes about Sleep scores, which refer to psychological flexibility and maladaptive beliefs about sleep, respectively. Those findings are in agreement with our hypothesis that sleep improvement would have a positive influence on the respective psychological aspects. Our hypothesis for these changes is that improvement in beliefs and psychological flexibility were positive by-products of the sleep improvement observed in both treatment conditions and not necessarily the direct result of an exclusive treatment per se. One important contribution of this study is that both interventions affect not only on sleep, but anxiety, beliefs about sleep, and psychological flexibility as well.

Our study had a number of strengths, including the use of validated outcome measures, a good uptake rate and inclusion of adults with and without psychiatric comorbidities, and participants treated with or without hypnotic medication, reflecting the real life experience of adults with insomnia.

The limitations include the small sample size, the lack of a control group, and that sleep was only assessed with subjective measures. A sleep diary was not used at the 6-month follow-up. Moreover, it cannot be inferred which

specific therapeutic elements were responsible for the clinical improvements, ACT or behavioral elements of stimulus control and sleep restriction.

Our finding that integrating ACT principles with traditional behavioral techniques of CBT-I is also effective for insomnia and is consistent with certain other studies in this field.⁵⁻⁷ Future randomized controlled trials should be conducted to compare ACT-BBI-I with a CBT-I intervention and a pure behavioral intervention for insomnia. Besides that, future research should involve a randomized controlled trial with an ACT protocol without sleep restriction and stimulus control to measure whether ACT is effective for treating insomnia, while evaluating which type of participants might benefit from an acceptance-based versus traditional CBT-I approach.

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Disclosure

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