ORIGINAL ARTICLE

Long-Term Maintenance of Therapeutic Gains Associated With Cognitive-Behavioral Therapy for Insomnia Delivered Alone or Combined With Zolpidem

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Study objectives: To document the long-term sleep outcomes at 12 and 24 months after patients with chronic insomnia were treated with cognitive-behavioral therapy (CBT), either singly or combined with zolpidem medication.

Methods: Participants were 160 adults with chronic insomnia. They were first randomized for a six-week acute treatment phase involving CBT alone or CBT combined with nightly zolpidem, and randomized for a six-month extended treatment phase involving CBT, no additional treatment, CBT combined with zolpidem as needed, or CBT with zolpidem tapered. This paper reports results of the 12- and 24-month follow-ups on the main outcome measures derived from the Insomnia Severity Index and sleep diaries.

Results: Clinical improvements achieved 6 months following the end of treatment were well-maintained in all four conditions, with insomnia remission rates ranging from 48% to 74% at the 12-month follow-up, and from 44% to 63% at the 24-month follow-up. Participants receiving CBT with zolpidem taper in the extended treatment phase had significantly better results than those receiving CBT with continued zolpidem as needed. The magnitude of improvements on sleep diary parameters was similar between conditions, with a slight advantage for the CBT with zolpidem taper condition. The addition of extended CBT did not alter the long-term outcome over improvements obtained during the initial 6-week CBT.

Conclusions: The results suggest that CBT for insomnia, when delivered alone or in combination with medication, produce durable sleep improvements up to two years after completion of treatment. These long-term results indicate that even if a combined CBT plus medication approach provide an added benefit immediately after treatment, extending CBT while tapering medication produce better sustained improvements compared to continued use of medication as needed.

Keywords: Insomnia, sleep, treatment, CBT, nonpharmacological, behavioral, medication.

Statement of Significance

Cognitive-behavioral therapy (CBT) and benzodiazepine receptor agonists are the most effective treatments for chronic insomnia. The main findings of this study suggest that CBT, either delivered alone or combined with medication, produces improvements in the quality and quantity of sleep that are well sustained up to two years after the end of treatment. The main implication of these findings is that CBT should be provided as first-line therapy to all patients with persistent insomnia, whether or not they also receive medication.

INTRODUCTION

Cognitive-behavioral therapy (CBT) and benzodiazepine receptor agonists are the first-line therapeutic options for chronic insomnia. Each of these two treatment modalities has its own advantages and limitations, with medication producing rapid sleep improvement whereas CBT yields more durable benefits. Few studies have evaluated combined CBT and medication therapies despite their potential synergistic effects. Findings from such studies generally suggest that combined approaches are slightly more effective than medication alone, but they produce similar benefits when compared to CBT alone.[1–6] The literature on long-term outcomes of combined therapies is even more limited, with only two studies having reported follow-up data extending to intervals of 12 months or longer after treatment. One study included 63 adults who were randomized to a six-week treatment involving CBT, zolpidem, combined CBT and zolpidem, or placebo.[3] Twelve months after treatment, improvements on sleep diary measures were maintained for the CBT and combined conditions but not for medication alone. In another study in which 78 older adults were randomly assigned to one of four conditions (CBT, temazepam, combined CBT and temazepam, placebo), it was found that treatment gains were better maintained at the 12- and 24-month follow-ups for CBT compared to temazepam, whereas the long-term outcome was more variable for the combined condition.[1] Additional examination of long-term outcomes is important because insomnia is often a recurrent or persistent problem,[7] and even if treatment is effective in the short-term, its clinical value for insomnia disorder should also take into account its long-term impact. The objectives of the present study were to compare the long-term (12- and 24-month) follow-ups of different treatment sequences involving CBT and hypnotic medication (zolpidem) in 160 patients with chronic insomnia.

METHODS

Detailed information about the study design and methodology, and the main findings regarding the efficacy of CBT, singly and combined with medication, after post-acute treatment, post-extended treatment, and 6-month follow-up, have been reported previously.[8,9] This paper focuses on 12- and 24-month follow-up data.

Participants

Participants were included in the study if they were 30 years of age or older and met criteria for chronic insomnia disorder, i.e., difficulty initiating or maintaining sleep lasting more than six months, with associated distress or functional impairment.[10,11] Exclusion criteria were the presence of a serious medical condition related to insomnia; use of medication altering sleep; history of psychotic or bipolar disorder, or suicide attempt; more than two past episodes of major depression; substance use

disorder in the past year; evidence of sleep-disordered breathing or sleep-related movement disorder; and night-shift work or irregular sleep schedule.

Procedure

After the initial telephone screening, all eligible individuals underwent a second-stage screening to assess inclusion and exclusion criteria. This assessment included a sleep interview,[12] the Structured Clinical Interview for DSM-IV (SCID-IV),[13] a medical history and physical examination, and polysomnography (to rule out other sleep disorders). Participants were randomized to receive an initial six-week acute treatment involving CBT, delivered alone (CBT; $N = 80$) or combined with nightly 10-mg zolpidem (COMB; $N = 80$). This was followed by a six-month extended treatment during which those receiving CBT initially were further randomized to extended monthly CBT sessions (CBT–CBT) or no additional treatment (CBT-no tx), and those receiving combined treatment initially were randomized to extended monthly CBT while zolpidem medication was tapered (COMB-taper) or extended CBT combined with medication as needed (COMB-prn; 10 pills per month). Participants completed assessments at baseline, post-acute treatment (6 weeks), post-extended treatment (6 months), and at 6-, 12-, and 24-month follow-ups.

Treatments

In the six-week acute treatment phase, participants in both CBT and COMB conditions received six weekly CBT sessions, in a group format, led by clinical psychologists. The CBT interventions, delineated in a treatment manual, included restriction of time in bed, stimulus control, cognitive therapy, and sleep hygiene education. Participants in the COMB condition also received 10 mg of an oral formulation of zolpidem, to be taken 30 minutes before bedtime on a nightly basis. They received the medication during weekly consultations with a primary care physician, who used a structured manual and also monitored insomnia symptoms, adverse effects, and compliance (pill count).

In the six-month extended treatment phase, participants in the CBT–CBT arm received six monthly CBT sessions, in an individual format. The content of these sessions was more flexible and included interventions to maintain therapeutic gains and cope with residual insomnia (e.g., stress management, relaxation). Participants in the CBT-no tx arm did not receive any further treatment during the extended phase. Participants in both COMB-taper and COMB-prn conditions received six monthly individual CBT sessions as described above. Those assigned to COMB-taper received a written withdrawal schedule with their last medication supply of the acute treatment phase. Those assigned to COMB-prn continued to meet with the physician on a monthly basis during the extended phase and received 10 zolpidem pills per month, with the instruction to use the medication only when needed. They received a written withdrawal schedule at the end of the extended treatment phase.

Further details about CBT and zolpidem content, format, and delivery are available elsewhere.[8]

Measures

Insomnia Severity Index

The Insomnia Severity Index (ISI)[12,14] is a 7-item questionnaire assessing the severity of sleep difficulties. It was used as the main outcome measure. Total score ranges from 0 to 28. Insomnia remission was defined as an ISI total score below 8, corresponding to the absence of insomnia.

Sleep Diary

Participants filled out a sleep diary prospectively for two consecutive weeks at each assessment. The main outcome measures derived from the sleep diary were sleep onset latency (SOL), wake time after sleep onset (WASO; including early morning awakening, i.e., time elapsed between last awakening and rising time), total sleep time (TST), and sleep efficiency (SE; ratio of TST on time spent in bed).

Statistical Analyses

Analyses were based on a 4 (treatment groups/sequences: CBT–CBT, CBT-no tx, COMB-taper, COMB-prn) × 3 (assessments: 6-, 12-, 24-month follow-up) split-plot randomized design, using baseline scores as covariate. As the main objective of this study was to document long-term outcomes, and because post-acute treatment, post-extended treatment, and 6-month follow-up results have been reported previously, only the a priori contrasts (simple effect) comparing treatment groups/sequences at 6- (for comparison purposes), 12- and 24-month follow-ups are reported here. These contrasts include the simple main effect across the four treatment arms and pairwise comparisons between conditions when simple main effect was significant. All analyses were based on an intent-to-treat model. Linear mixed models were used for continuous dependent variables and generalized linear mixed models were used for binary dependent variables. To control for multiple comparisons, a per family error rate was adopted in which all comparisons for each dependent variable were performed within the nominal error rate.

RESULTS

Sample Description

Participants were 160 adults with chronic insomnia (97 women, 63 men; mean age = 50.3 ± 10.1 years; mean education = 14.7 ± 3.5 years). Mean insomnia duration was 16.4 ± 3.5 years, and 73.8% of participants presented with mixed insomnia including both difficulty initiating and maintaining sleep. Of the 160 participants randomized to CBT or COMB for the initial 6-week acute treatment phase, 11 dropped out during treatment. Of the 149 participants randomized to one of the four 6-month extended treatment sequences, 8 dropped out during treatment. Of the 141 participants who completed both treatment phases, 124 completed the 12-month follow-up (29 CBT–CBT, 34 CBT-no tx, 33 COMB-taper, 28 COMB-prn) and 110 completed the 24-month follow-up (29 CBT–CBT, 32 CBT-no tx, 27 COMB-taper, 22 COMB-prn). Participants who completed follow-ups were compared to those who were lost to follow-up, and there was no significant group difference on sociodemographic variables, sleep diary parameters at baseline, or insomnia remission rate at post-extended treatment. The only

significant difference was that participants lost to follow-up had a higher ISI score at baseline compared to those who completed follow-ups (mean ISI = 18.6 for participants who did not complete the 12-month follow-up vs 17.1 for completers, $p = .03$; 18.4 vs 16.9 for the 24-month follow-up, $p = .02$). For further details on characteristics of study participants, see Morin et al.[8] Compliance with medication (pill count) and CBT (number of sessions attended, weekly therapist ratings) was assessed in the acute treatment phase only, and data on these measures were reported previously.[9,15]

Comparisons of Treatment Sequences at the 12- and 24-Month Follow-Ups

Adjusted means and standard errors for SOL, WASO, TST, and SE are presented in Table 1 for each of the four treatment groups at the 6-, 12-, and 24-month follow-ups. At the 6-month follow-up, the treatment group effect was significant for WASO ($p = .001$) and SE ($p = .002$) but not significant for SOL or TST ($p > .19$). Post hoc tests comparing different treatment sequences showed that patients treated with combined CBT plus medication initially, followed by CBT alone and no additional medication (COMB-taper condition) exhibited greater sleep improvements than patients treated with other combinations (i.e., shorter WASO: 42.8 vs 54.1 to 67.8 min; higher SE, 87.9 vs 82.1 to 83.5%). These differences were no longer present at the 12-month follow up, with no significant group effect for any of the four sleep diary variables ($p > .18$). At the 24-month follow-up, a significant treatment effect was also found for WASO and SE, with post hoc tests revealing a similar pattern as the one observed at the 6-month follow-up, i.e., a significantly shorter WASO and a higher SE (i.e., better outcomes) in the COMB-taper condition compared to the other three conditions (WASO: 46.2 vs. 59.7 to 71.7 min, SE: 86.9 vs. 81.2 to 83.7%). The

Table 1—Adjusted Means and Standard Errors of Sleep Diary Variables at 6-, 12-, and 24-month Follow-ups, Controlling for Baseline.

	Baseline (raw means)	6-month FU (*df* = 208)	12-month FU (*df* = 208)	24-month FU (*df* = 208)
Sleep onset latency (min)				
(a) CBT–CBT	37.2	14.6 ± 2.6	16.2 ± 1.8	16.4 ± 2.4
(b) CBT-no tx		17.5 ± 1.4	18.0 ± 2.4	20.8 ± 2.3
(c) COMB-taper	29.7	13.5 ± 1.4	18.2 ± 3.4	15.1 ± 1.9
(d) COMB-prn		17.4 ± 2.1	16.6 ± 1.7	17.0 ± 2.3
Group effect at each time	—	$F = 1.59$, $p = .19$	$F = 0.18$, $p = .91$	$F = 1.22$, $p = .31$
Wake time after sleep onset—including early morning awakening (min)				
(a) CBT–CBT	116.5	54.1 ± 3.7	59.1 ± 6.1	59.7 ± 5.1
(b) CBT-no tx		67.8 ± 4.5	71.2 ± 7.5	71.7 ± 4.9
(c) COMB-taper	128.6	42.8 ± 4.2	48.9 ± 7.1	46.2 ± 4.7
(d) COMB-prn		54.9 ± 5.9	64.8 ± 8.2	65.2 ± 7.9
Group effect at each time	—	$F = 5.58$, $p = .001$; b > a = c = d	$F = 1.67$, $p = .18$	$F = 4.78$, $p = .003$; c < a = b = d
Total sleep time (hours)				
(a) CBT–CBT	5.73	6.54 ± 0.14	6.46 ± 0.09	6.66 ± 0.13
(b) CBT-no tx		6.50 ± 0.13	6.62 ± 0.14	6.65 ± 0.14
(c) COMB-taper	5.81	6.76 ± 0.13	6.81 ± 0.17	6.87 ± 0.14
(d) COMB-prn		6.53 ± 0.15	6.55 ± 0.17	6.65 ± 0.19
Group effect at each time	—	$F = 0.78$, $p = .50$	$F = 1.30$, $p = .28$	$F = 0.55$, $p = .65$
Sleep efficiency (%)				
(a) CBT–CBT	69.0	85.1 ± 1.3	83.5 ± 1.5	83.7 ± 1.2
(b) CBT-no tx		82.1 ± 1.2	81.5 ± 1.7	81.2 ± 1.1
(c) COMB-taper	68.6	87.9 ± 1.0	85.5 ± 2.2	86.9 ± 1.3
(d) COMB-prn		83.5 ± 1.4	82.4 ± 1.9	82.3 ± 2.0
Group effect at each time	—	$F = 4.96$, $p = .002$; c > b = d	$F = 0.79$, $p = .50$	$F = 3.88$, $p = .01$; c > a = b = d

Note: When the condition effect was significant at a given time, pairwise comparisons were performed and means with different letter subscripts are significantly different. Raw baseline means are presented for comparison purposes, while adjusted means and standard errors are presented for the three follow-up assessments. df = degrees of freedom; FU = follow-up.

treatment group effect was not significant for SOL or TST at the 24-month follow-up.

Figure 1 presents the total score on the ISI at baseline, and at the 6-, 12-, and 24-month follow-ups, and the percentage of participants achieving insomnia remission (ISI score < 8) at each follow-up assessment. For ISI total scores, there was a significant treatment condition effect at the 6-month follow-up, $F(3,217) = 7.71$, $p < .001$, with post hoc tests revealing significantly lower ISI scores (i.e., better outcome) in the COMB-taper condition ($M = 5.5$) than in the other conditions (from 8.7 to 9.0). There were no significant between-group differences at the 12-month follow-up, $F(3,217) = 1.71$, $p = .17$, and the simple main effect failed to reach significance at 24-month follow-up, $F(3,217) = 2.20$, $p = .09$. For remission, the COMB-taper condition presented a higher remission rate compared to the other conditions at the 6-month (69.9% vs 40.0 to 44.3%) and 12-month follow-up (73.8% vs 47.8 to 52.7%), but the simple main effects failed to reach significance ($p = .07$ at 6-month and $p = .15$ at 12-month). No difference was found at 24 months, $F(3,217) = 0.88$, $p = .45$, even if the COMB-taper condition showed a larger remission rate (62.7% vs 43.7 to 54.5%).

Moderation analyses were completed to test the effect of sex on the condition × time interaction. Results revealed a significant third-order sex × condition × time interaction for three out of five outcomes: ISI total score, $F(6,209) = 2.79$, $p = .01$, TST, $F(6,200) = 2.27$, $p = .04$, and SE, $F(6,200) = 2.25$, $p = .04$. In the COMB-prn treatment arm, women exhibited improvement from the 6- to the 24-month follow-up, while men displayed worsening of symptoms (i.e., for ISI total score: from 9.1. to 7.2, $p = .001$ for women, vs from 8.8 to 9.8, n.s. for men; for TST: from 6.4 to 6.8 hours, $p = .002$ for women, vs. from 6.7 to 6.5, $p = .03$ for men; for SE: from 81.7 to 83.3%, $p = .02$ for women, vs from 86.0 to 81.2%, $p = .03$ for men). The only other significant contrast was observed in the CBT–CBT condition for the ISI total score from 6- to 24-month follow-up, with a non-significant worsening for women (from 6.7 to 6.5, $p = .03$) and a significant improvement for men (from 9.7 to 7.0, $p = .008$) from the 6- to the 24-month follow-up.

Magnitude of Changes From Baseline to Long-Term Follow-Up

From baseline to the 24-month follow-up (approximately 31 months later), SOL decreased by an average of 11.0 to 19.2 minutes (all $p < .01$) across treatment sequences, with the absolute values remaining below 30 minutes in all four conditions. WASO decreased by 60.1 minutes for CBT–CBT, 41.0 minutes for CBT-no tx, 76.0 minutes for CBT-taper, and 62.3 minutes for CBT-prn (all $p < .001$). Decreases in SOL and WASO correspond to sleep improvements (i.e., shorter time spent awake). TST increased from baseline to the 24-month follow-up by 0.79 hour for CBT–CBT, 0.78 hour for CBT-no tx, 1.07 hour for COMB-taper, and 0.81 hour for COMB-prn (all $p < .001$). Finally, SE increased by an average of 14.0% in the CBT–CBT group, 10.5% in the CBT-no tx group, 17.9% in the COMB-taper group, and 13.3% in the COMB-prn group (all $p < .001$), with absolute values remaining above 81% (86.9% for CBT-taper). Increases in TST and SE correspond to improvements in sleep (i.e., longer sleep duration, higher SE). Overall, all four conditions produced similar improvements over a 31-month period, with an advantage for the COMB-taper treatment arm on most end points.

The extent of changes from baseline to the 24-month follow-up was very similar to those observed from baseline to post-extended treatment, with one notable exception for TST. Indeed, TST had improved by 0.30 to 0.70 hour, depending on

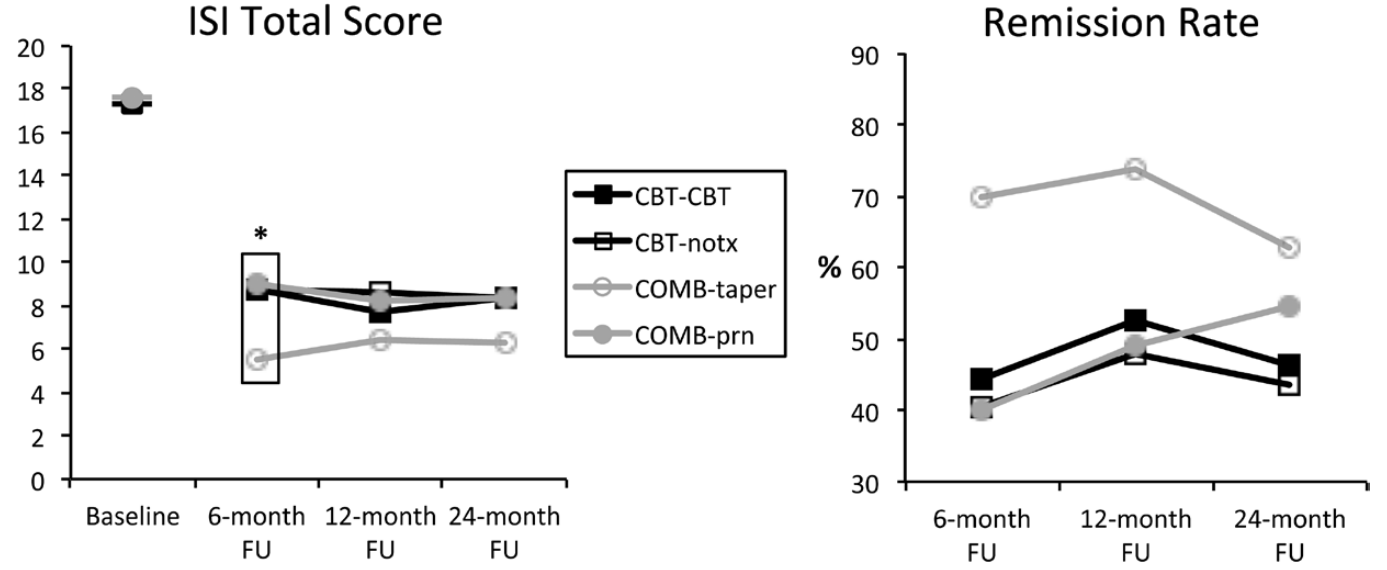

Figure 1—ISI total score and remission rate for each of the four treatment conditions at the 6-, 12-, and 24-month follow-ups. Raw baseline data are presented for the ISI total score for comparison purposes. Adjusted means (ISI) and percentages (remission) are presented for the three follow-up assessments. *ISI total score was significantly lower in COMB-taper than in the other conditions at the 6-month follow-up. FU = follow-up; ISI = Insomnia Severity Index; Remission = ISI total score below 8.

the condition, from baseline to post-extended treatment, while TST increases reached 0.78 to 1.07 hour from baseline to the 24-month follow-up. Thus, sleep changes achieved following sequential therapies were well-maintained for SOL, WASO, and SE, and further gains were made for TST. Changes from baseline to the 12-month follow-up were very similar to those from baseline to the 24-month follow-up for all sleep diary parameters and all four conditions.

Medication Use at the 12- and 24-Month Follow-Ups

After the two treatment phases, participants were free to seek prescription medication or use over-the-counter products for sleep if they chose to do so. They were asked to record their use of sleep aids on the two-week sleep diary they completed for each follow-up assessment. Based on these sleep diary data, at the 12-month follow-up, 12.1% of the total sample reported using prescribed sleep aids, for an average of 2.7 nights per week (users only), and there was no significant group difference (CBT–CBT, 14.1%, CBT-no tx, 17.8%, COMB-taper, 18.0%, COMB-prn, 4.4%, $F(3,208) = 0.95$, $p = .42$). At the 24-month follow-up, 15.6% of participants used medication, for an average of 2.7 nights per week (users only). Although the absolute number of users were relatively small, there was a significant difference between conditions, $F(3,208) = 3.19$, $p = .02$, suggesting that significantly more participants were using medication in the subgroup who did not receive extended CBT (CBT-no tx, 29.3%) and among those who received medication on an as needed basis during extended treatment (COMB-prn, 31.0%) compared to the other conditions (CBT–CBT, 8.0%; COMB-taper, 6.7%).

DISCUSSION

Consistent with the results obtained at the end of treatment and at the early (6-month) follow-up,[8] these long-term results indicate that CBT for insomnia, when delivered alone or in combination with medication, produces durable improvements up to two years after completion of treatment. Indeed, sleep improvements and reductions of insomnia symptoms observed at the end of treatment and at 6-month follow-up were well sustained at the 12- and 24-month follow-ups, with few differences among treatment sequences, which favored the treatment sequence starting with the combined CBT plus medication approach followed by medication tapering.

These results have important implications for clinical practice. First, insomnia is often a recurrent or persistent problem and it is important to document long-term as well as short-term outcomes with any therapies for chronic insomnia disorder. Second, clinicians are often faced with the decision of if and when to discontinue sleep medications. The present results suggest that while medication may provide an added value to CBT in short-term insomnia management, it is best to discontinue such medication after a few weeks of therapy, while continuing with CBT follow-ups so that patients can presumably integrate newly learned self-management skills for dealing with residual or recurrent insomnia symptoms. Also, despite the intuitive appeal of using an "as needed drug therapy", this sequential method tested in the present study actually yielded inferior results to that of combined therapies followed by drug taper (both CBT-taper and CBT-prn involved six monthly CBT sessions during the extended treatment phase). Although one might argue that using medication nightly may be a more effective strategy than intermittent use to optimize long-term outcome, the efficacy of such approach has yet to be demonstrated. Furthermore, the long-term data on sleep medication usage argues for a more conservative approach with regard to the duration of medication treatment. Indeed, participants who received sleep medication over the 6-month extended treatment period, even on an as needed basis, were more likely to resume or continue using such medications at long-term follow-ups relative to those who were tapered after the initial 6-week therapy. This finding would suggest limiting duration of hypnotic use.

The addition of extended CBT did not augment the long-term sleep outcome over that obtained with a six-week course of CBT without treatment extension. These results are surprising because extended CBT was more flexible in allowing the use of additional therapeutic strategies (e.g., stress management, relaxation) targeting specific residual insomnia symptoms. One would have expected added benefits from this more individualized, symptom-focused therapeutic approach. Nonetheless, even if extended CBT did not seem to provide an added benefit for sleep per se, it was associated with lower use of medication in the long term as suggested by the significantly lower proportion of patients using sleep medication in that subgroup relative to those who only received CBT during the initial six-week period without any extension.

Despite the very favorable short- and long-term outcomes obtained with different sequential therapies for insomnia, there are still a substantial proportion of individuals with chronic insomnia who do not respond to current therapeutic approaches, whether behavioral or pharmacological, and used in combination or sequentially. The design of additional treatment tailoring strategies is clearly warranted in order to optimize insomnia management.

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