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Cognitive-behavior therapy singly and combined with medication for persistent insomnia: Impact on psychological and daytime functioning

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ABSTRACT

While impairment of daytime functioning due to poor sleep is often the main determinant for seeking treatment, few studies have examined the clinical impact of insomnia therapies on daytime outcomes. The main objective of this study was to evaluate the impact of cognitive-behavior therapy (CBT), alone and combined with medication, on various indices of daytime and psychological functioning. Participants were 160 individuals with chronic insomnia who received CBT alone or CBT plus medication (zolpidem) for an initial six-week therapy, followed by an extended six-month therapy. Participants treated with CBT initially received maintenance CBT or no additional treatment and those treated with combined therapy initially continued with CBT plus intermittent medication (prn) or CBT without medication (taper). Measures of anxiety and depressive symptoms, fatigue, quality of life, and perceived impact of sleep difficulties on various indices of daytime functioning were completed at baseline, after each treatment stage, and at six-month follow-up. Following acute treatment, significant improvements of fatigue, quality of life (mental component), anxiety, and depression were obtained in the CBT alone condition but not in the combined CBT plus medication condition. Following extended treatment, further improvements were noted for the subgroup receiving extended CBT relative to that with no additional treatment, and for the subgroup receiving CBT and intermittent medication relative to that with CBT but no medication. Improvements were well maintained at the 6-month follow-up. These findings indicate that insomnia-specific therapy is effective at improving daytime and psychological functioning in the short term, and that maintenance therapy produces an added value to optimize long-term outcomes. Trial registration: www.clinicaltrials.gov (#NCT 00042146).

1. Introduction

Chronic insomnia is characterized by both difficulties sleeping at night and problems with daytime functioning or significant distress; the presence of these two features is essential to make the diagnosis of insomnia (American Academy of Sleep Medicine, 2014; American Psychiatric Association, 2013; Edinger et al., 2004). Common daytime problems reported by individuals with insomnia include fatigue or low energy, cognitive problems such as difficulty concentrating or remembering things, mood disturbances, and decreased motivation, all of which can contribute to significant functional impairments at work, at home, or on the road (Buysse et al., 2007; Edinger et al., 2004; Roth et al., 2006). Subjective reports of daytime impairments are not always corroborated by objective findings from neurobehavioral testing (Fortier-Brochu, Beaulieu-Bonneau, Ivers, & Morin, 2012), not unlike the discrepancies between subjective and objective measures of sleep parameters (Krystal, 2007; Riedel & Lichstein, 2000). Yet, the perception of daytime impairments can be a major source of distress for individuals with insomnia and is often the

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main determinant prompting them to seek treatment (Davidson, Aime, Ivers, & Morin, 2009; Gagnon, Belanger, Ivers, & Morin, 2013).

While there is extensive evidence showing that psychological and pharmacological therapies are effective for improving sleep (Buysse, 2013; Krystal, 2009; Morin et al., 2006; National Institutes of Health, 2005), there is surprisingly little evidence that these treatments or the sleep improvements they produce have a significant impact on daytime functioning. Drug studies often incorporate measures of cognitive functioning but this is usually done to demonstrate that there is no residual daytime impairment associated with the drug under investigation. Likewise, few investigations of psychological therapies (mostly CBT) for insomnia have incorporated measures of daytime functioning and in most cases these have been used as secondary outcomes (Morin et al., 2006). Moreover, these studies have yielded inconsistent findings. For instance, some studies found a significant decrease in depressive symptoms following CBT (Belleville, Guay, Guay, & Morin, 2007; Dirksen & Epstein, 2008; Quesnel, Savard, Simard, Ivers, & Morin, 2003), while others did not find any difference between CBT and control conditions (Edinger, Wohlgemuth, Radtke, Marsh, & Quillian, 2001; Espie, Inglis, Tessier, & Harvey, 2001; Jacobs, Pace-Schott, Stickgold, & Otto, 2004; Rybarczyk et al., 2005; Taylor et al., 2014). These studies also report similarly mixed results regarding improvements in anxiety (state, trait, or worry), fatigue, and health-related quality of life.

This relative lack of attention to daytime variables may result from the fact that health regulatory agencies require new drugs to show efficacy on selected sleep parameters, not daytime functioning, whereas most psychological therapies target sleep-related behavioral and scheduling factors, not daytime functioning per se. There is also a common assumption that daytime and psychological functioning will necessarily improve following sleep improvements. The lack of attention to the daytime component of chronic insomnia may explain why only 40–50% of individuals receiving insomnia treatment achieve remission (Morin et al., 2009); if therapy only targets nighttime sleep difficulties, it may be no surprise that daytime functioning does not improve. In order to optimize current therapies for insomnia, it would be important to investigate the extent to which those therapies have a clinical impact in improving psychological and daytime functioning. The inclusion of measures of waking correlates, more specifically mood, fatigue, and quality of life, in insomnia treatment studies has been part of the essential recommendations of an expert consensus for a standard research assessment for insomnia (Buysse, Ancoli-Israel, Edinger, Lichstein, & Morin, 2006).

The objective of this paper was to examine the impact of insomnia therapies, CBT alone and CBT combined with medication, on several indices of psychological and daytime functioning such as mood, fatigue, health-related quality of life, and cognitive functioning. A secondary objective was to compare if an extended treatment, incorporating maintenance CBT or intermittent medication, would enhance daytime outcomes relative to acute interventions.

2. Methods

The results were derived from a larger study that evaluated the short- and long-term effects of CBT, singly and combined with medication, for persistent insomnia, and compared the efficacy of maintenance strategies to optimize long-term outcomes. Additional information on the study design and methodology, and the main findings for the sleep outcome variables are available elsewhere (Morin et al., 2009, 2014).

2.1. Participants

Inclusion criteria were to be aged 30 years or older and meeting diagnostic criteria for chronic insomnia based on a combination of DSM-IV (American Psychiatric Association, 1994) and ICSD-2 criteria (American Academy of Sleep Medicine, 2005). These criteria were further operationalized as follows: (a) difficulties initiating and/or maintaining sleep, defined as a sleep onset latency and/or wake after sleep onset greater than 30 min, with an average sleep time of less than 6.5 h at least 3 nights per week (according to daily sleep diaries); (b) insomnia duration greater than 6 months; and (c) significant distress or impairment of daytime functioning (rating of at least 2 on item 5 or 7 of the *Insomnia Severity Index*). Exclusion criteria were: (a) presence of a serious medical condition (e.g., cancer) directly related to the onset and course of insomnia; (b) use of medications known to alter sleep (e.g., steroids); (c) lifetime diagnosis of a psychotic or bipolar disorder; (d) current diagnosis of major depression, unless treated and in remission; or more than two past episodes of major depression; (e) history of suicide attempt; (f) alcohol or drug abuse within the past year; (g) sleep apnea (apnea/hypopnea index > 15), restless legs, or periodic limb movements during sleep (movement index with arousal > 15 per hour); and (h) night-shift work or irregular sleep patterns. Patients with stable medical (e.g., hypertension) or selected psychiatric (e.g., generalized anxiety disorder) disorders were included in the study provided that these conditions were not judged to be the primary cause of insomnia. Patients using prescribed or over-the-counter sleep medications no more than twice weekly were enrolled after they withdrew from medications. Individuals using alcohol as a sleep aid were required to discontinue this practice at least two weeks prior to baseline assessment.

Of the 486 individuals who completed telephone screening for eligibility, 242 completed second-stage screening consisting of a clinical sleep/insomnia evaluation (Morin, 1993), the Structured Clinical Interview for DSM-IV (SCID-IV) (First, Spitzer, Gibbon, & Williams, 1997), a medical history and physical examination, and polysomnography (PSG). Eighty-two persons were excluded after this screening for various reasons, leaving 160 who were enrolled in the study (97 women, 63 men), with a mean age of 50.3 years ($SD = 10.1$; range = 30 to 72) and a mean education level of 14.7 years ($SD = 3.5$) (see Morin et al. (2009) for a complete participants flow). All patients were Caucasian, and most were married or living with a partner (68.1%), and were employed (73.3%). The majority (73.8%) reported mixed sleep-onset and maintenance insomnia. The average insomnia duration was 16.4 years ($SD = 13.6$). All patients were sleep-medication free prior to entering the study, but 63 (39.4%) had used sleep medication previously. In terms of comorbidity, 24 patients (15.0%) presented a comorbid psychiatric disorder, and there was no significant difference between conditions (13.8% vs 16.3% for CBT and CBT plus medication conditions, respectively), $X^2(1) = 0.20$, $p = 0.66$. The most prevalent diagnoses were specific phobia ($n = 9$), generalized anxiety disorder ($n = 8$), and social phobia ($n = 3$). Small samples size for each diagnosis within condition precluded statistical testing for group differences. In the total sample, 92 patients (57.5%) presented at least one comorbid medical disorder (most commonly a cardiovascular condition).

2.2. Procedure

Participants were randomized to one of two acute treatments: (a) CBT ($n = 80$) or (b) CBT plus medication ($n = 80$). After completing this six-week treatment, they were randomized a second time to an extended treatment for the next six months. CBT patients were randomized to either extended CBT (CBT) or no

additional treatment (No treatment). Patients treated with CBT plus medication initially were randomized to extended CBT and no additional medication (CBT/Taper) or extended CBT plus medication, used on an "as needed" schedule rather than every night as in the acute treatment phase (CBT/Med^{prn}). Assignment to conditions was determined by a computer-generated random allocation schedule. Assessments were conducted at baseline (pre), at the end of the six-week acute (post I) and six-month extended treatment (post II), and at the six-month follow-up. The protocol was approved by the Ethics Committee of the *Institut universitaire en santé mentale de Québec* and all patients provided written informed consent.

2.3. Measures

The *Beck Anxiety Inventory* (BAI) (Beck, Epstein, Brown, & Steer, 1988) and the *Beck Depression Inventory II* (BDI) (Beck, Steer, & Brown, 1996) were used to assess anxiety and depression symptoms (total scores: 0 to 63). The *Multidimensional Fatigue Inventory* (MFI) (Smets, Garssen, Bonke, & De Haes, 1995) measured the severity and degree of impairment produced by fatigue with a total score (20–100) derived from the summation of all items. The *SF-36 Health Survey* (SF-36) (Ware & Sherbourne, 1992) yielded two measures (T scores) of health-related quality of life: Physical Health Component (aggregating physical functioning, role physical, bodily pain, and general health subscales), and Mental Health Component (aggregating vitality, social functioning, role emotional, and mental health subscales). Contrary to the BAI, BDI, and MFI, higher scores on the SF-36 suggest better functioning. The *Insomnia Severity Index (ISI)* (Bastien, Vallières, & Morin, 2001; Morin, 1993; Morin, Belleville, Belanger, & Ivers, 2011) was used to examine the perceived impact of sleep difficulties on daytime functioning in general (item 5 of the standard ISI) and on six specific domains of daytime functioning (additional items to standard ISI version): mood, fatigue, concentration/memory, quality of life, interpersonal relationships, and social or leisure activities. For each item, a five-point scale was used to rate the perceived impact of insomnia (i.e., 0 = not at all impactful; 4 = extremely impactful).

A validated French version was used for all self-reported measures just described.

2.4. Treatment conditions

2.4.1. Cognitive behavior therapy (CBT)

This intervention includes behavioral, cognitive, and educational components (Morin, 1993; Morin & Espie, 2003). CBT was administered by master's level clinical psychologists using a treatment manual (Morin & Espie, 2003). During acute treatment, patients attended six weekly 90-min group therapy sessions. Those assigned to the extended CBT condition attended six additional monthly individual CBT sessions. The focus of these maintenance sessions was on consolidating treatment strategies learned during initial therapy and developing methods for coping with residual insomnia. Patients assigned to the no additional treatment condition did not have follow-up visits after acute treatment.

2.4.2. Combined CBT plus medication (CBT/Med)

Patients assigned to this condition received group CBT (as described above) and zolpidem (10 mg, oral formulation) in the six-week acute phase. The medication was provided in the context of brief (15–20 min), weekly consultation sessions with a general practitioner. The physician used a structured manual. Pill count was conducted at each consultation visit. During extended treatment, patients from the combined approach attended six additional monthly and individualized CBT sessions as described above. In addition, those assigned to extended CBT plus medication as needed (CBT/Med^{prn}) met with the physician monthly and received 10 zolpidem pills per month with the instruction to use their medication only when it was needed. At the end of the extended six-month therapy, medication was discontinued according to a gradual withdrawal schedule. Patients assigned to extended CBT without medication (CBT/Taper) received their last medication supply with a written withdrawal schedule.

2.5. Data management and analysis

Descriptive and inferential statistics were completed using SAS 9.3 statistical software (SAS Institute, Cary NC, 2011). Since participants were randomized twice, two sets of analyses were performed. The first set was based on a 2 (conditions) × 2 (times; baseline, post I) split-plot randomized design and the second set was based on a 4 (conditions) × 4 (times; baseline, post I and II, follow-up) split-plot randomized design. All analyses were based on an intent-to-treat paradigm. To avoid imputation of missing data, linear mixed models (Brown & Prescott, 1999) were used to test group, time, and interaction effects for all dependent variables. A priori contrasts were used to test specific hypotheses, such as pre-post differences and maintenance of treatment gains at follow-up within each treatment condition. To control for multiple comparisons, a "per family" error rate was adopted, where all comparisons for each dependent variable were performed within the nominal error rate. The simultaneous test procedure for factorial design (Kirk, 1995) was used to compute the appropriate corrected alpha level: 5% for main effects and interactions, 5% for time changes during acute treatment and 2% for time changes after extended treatment and follow-up. Confidence intervals were computed at 95% for all tests and temporal changes that failed to reach significance after correction were identified. Between 532 and 564 observations from 160 patients were included in the analyses, giving between 393 and 404 degrees of freedom for the interaction effect when taking into account attrition. Sensitivity analyses performed with G*Power 3.1 software revealed that this sample size allows to detect small effect sizes (between $F = 0.076$ and 0.079) using standard power conditions (alpha = 5% two-tailed, power = 80%). Thus, it appears that this study was appropriately powered to detect even small effect sizes and, consequently, non-significant results observed may be better explained by a lack of therapeutic effect than by a lack of power.

3. Results

Means, change scores, and Cohen's *d* values (of change scores) are presented in Table 1 (for anxiety, depression, fatigue, and quality of life variables) and Table 2 (for the perceived impact of sleep difficulties on daytime functioning in general and on six specific domains). Table 3 presents a general summary of the changes in all daytime functioning measures from baseline to post I and from post I to post III for each treatment condition.

3.1. Attrition

The overall cumulative attrition rate was 6.9% after acute treatment ($n = 11/160$), 11.9% after extended treatment ($n = 19/160$), and 20.6% at 6-month follow-up ($n = 33/160$). Attrition was not significantly different between groups and, except for more men than women dropping out of acute treatment, there was no difference between treatment completers and dropouts.

Table 1
Means and standard errors (SE) for measures of anxiety and depression symptoms, fatigue, and health-related quality of life.

Condition	Acute treatment				Condition	Extended treatment			Follow-up		
	Pre	Post I				Post II			6-months		
	Mean (SE)	*Mean (SE)*	Change (95% CI)	*d*		*Mean (SE)*	Change (95% CI)	*d*	*Mean (SE)*	Change (95% CI)	*d*
Beck Anxiety Inventory (0–63)											
CBT	6.83	3.96	−2.9*	−0.53	CBT	4.50	0.2	0.03	3.60	−0.9	−0.17
	(0.64)	(0.63)	(-4.2, −1.6)			(0.88)	(-1.6, 1.8)		(0.88)	(-2.6, 0.8)	
					No treatment	4.05	0.6	0.11	5.00	1.0	0.18
						(0.87)	(-1.1, 2.3)		(0.88)	(-0.8, 2.7)	
CBT + Med	7.74	6.85	−0.9	−0.17	CBT/Taper	4.46	−1.1	−0.22	4.38	−0.1	−0.02
	(0.63)	(0.64)	(-2.2, 0.4)			(0.89)	(-2.8, 0.6)		(0.90)	(-1.9, 1.7)	
					CBT/Med^{prn}	5.58	−2.8*	−0.55	6.42	0.8	0.16
						(0.90)	(-4.6, −1.1)		(0.91)	(-1.0, 2.7)	
Beck Depression Inventory (0–63)											
CBT	7.70	3.99	−3.7*	−0.69	CBT	4.88	0.4	0.07	5.60	0.7	0.14
	(0.60)	(0.61)	(-4.9, −2.5)			(0.86)	(-1.3, 2.0)		(0.85)	(-1.0, 2.4)	
					No treatment	3.53	0.0	0.01	4.44	0.9	0.18
						(0.83)	(-1.5, 1.6)		(0.83)	(-0.7, 2.5)	
CBT + Med	8.26	7.16	−1.1	−0.21	CBT/Taper	5.30	−0.8	−0.16	5.25	0.0	−0.01
	(0.61)	(0.63)	(-2.4, 0.2)			(0.86)	(-2.5, 0.9)		(0.88)	(-1.8, 1.7)	
					CBT/Med^{prn}	5.80	−2.3*	−0.46	5.62	−0.2	−0.04
						(0.88)	(-4.0, −0.6)		(0.89)	(-2.0, 1.6)	
Multidimensional Fatigue Inventory (20–100)											
CBT	48.06	43.51	−4.6*	−0.34	CBT	41.88	−5.0*	−0.38	45.51	3.6	0.28
	(1.48)	(1.51)	(-7.4, −1.7)			(2.18)	(-9.0, −1.0)		(2.18)	(-0.5, 7.8)	
					No treatment	40.97	0.9	0.07	42.36	1.4	0.11
						(2.14)	(-3.1, 4.8)		(2.14)	(-2.7, 5.4)	
CBT + Med	51.65	51.28	−0.4	−0.03	CBT/Taper	44.05	−4.2 [a]	−0.32	44.05	0.0	0.00
	(1.48)	(1.53)	(-3.2, 2.5)			(2.23)	(-8.4, 0.0)		(2.25)	(-4.4, 4.4)	
					CBT/Med^{prn}	46.14	−8.2*	−0.63	46.66	0.5	0.04
						(2.23)	(-12.4, −4.1)		(2.27)	(-3.9, 4.9)	
SF-36 – Physical component (T score)											
CBT	53.01	53.99	1.0	0.13	CBT	50.84	−2.1	−0.26	52.98	2.1	0.27
	(0.85)	(0.86)	(-0.3, 2.3)			(1.33)	(-4.5, 0.4)		(1.32)	(-0.4, 4.7)	
					No treatment	52.59	−2.5 [a]	−0.32	53.36	0.8	0.10
						(1.29)	(-4.9, −0.1)		(1.29)	(-1.7, 3.2)	
CBT + Med	51.05	51.52	0.5	0.06	CBT/Taper	52.72	0.5	0.06	52.73	0.0	0.00
	(0.84)	(0.86)	(-0.9, 1.8)			(1.34)	(-2.0, 3.0)		(1.35)	(-2.6, 2.6)	
					CBT/Med^{prn}	52.85	2.0	0.26	51.53	−1.3	−0.17
						(1.34)	(-0.5, 4.5)		(1.37)	(-4.0, 1.3)	
SF-36 – Mental component (T score)											
CBT	46.14	50.76	4.6*	0.49	CBT	52.36	3.7*	0.41	49.69	−2.7	−0.30
	(1.06)	(1.08)	(2.3, 7.0)			(1.55)	(0.4, 6.9)		(1.53)	(-6.0, 0.7)	
					No treatment	51.50	−1.4	−0.15	51.14	−0.4	−0.04
						(1.50)	(-4.6, 1.8)		(1.50)	(-3.6, 2.9)	
Combined CBT + Med	44.65	43.92	−0.7	−0.08	CBT/Taper	51.20	3.6 [a]	0.40	50.11	−1.1	−0.12
	(1.05)	(1.09)	(-3.1, 1.6)			(1.57)	(0.2, 6.9)		(1.59)	(-4.6, 2.4)	
					CBT/Med^{prn}	45.86	5.8*	0.65	49.00	3.1	0.35
						(1.57)	(2.5, 9.1)		(1.61)	(-0.4, 6.7)	

Note. * These change scores were statistically significant ($p < 0.05$).
[a] These change scores were no longer significant after applying a correction (p values between 0.02 and 0.05).

3.2. Acute treatment phase (pre to post I)

For the acute treatment phase (pre to post I), simple effects revealed significant reductions of anxiety (BAI), depression (BDI) and fatigue (MFI) symptoms for the CBT group but no significant changes for the combined CBT plus medication group. Tests for interactions showed that the CBT only condition produced a significantly greater decrease of anxiety (2.0 units difference, CI = 0.1, 3.8), depression (2.6 units difference, CI = 0.8, 4.4), and fatigue (4.2 units difference, CI = 0.2, 8.2) symptoms relative to patients treated with CBT plus medication during acute treatment. With regard to health-related quality of life, simple effects revealed significant improvements on the SF-36 mental component scale for the CBT alone group only, while no significant changes were observed on the SF-36 physical component scale. Tests for interactions revealed greater improvement of the mental health component in the CBT only condition relative to the CBT plus medication during acute treatment (5.3 units difference, CI = 2.0, 8.7). Finally, for the perceived impact of sleep difficulties on daytime functioning, simple effects revealed significant improvements on all seven indices of daytime functioning of the extended version of the ISI in both CBT and CBT plus medication conditions (i.e., impact on general daytime functioning and on six specific domains: mood, fatigue, cognition, quality of life, interpersonal relationships, and social/leisure activities). Tests for interactions revealed no significant differential effects of treatment from baseline to post I for any of these indices of daytime functioning.

3.3. Extended treatment phase (post I to post II)

For the extended treatment phase (from post I to post II), simple effects revealed significant change of anxiety and depression symptoms in the CBT/Med^{prn} group only. Tests for interactions revealed no differential treatment impact between groups during extended treatment (from post I to post II). Significant reductions of fatigue symptoms were observed following the extended treatment

Table 2
Means and standard errors (SE) for the perceived impact of sleep difficulties on various domains of daytime functioning (0–4 ratings on ISI additional items).

Condition	Acute treatment				Condition	Extended treatment			Follow-up		
	Pre	Post I				Post II			6-months		
	Mean (SE)	*Mean (SE)*	Change (95% CI)	*d*		*Mean (SE)*	Change (95% CI)	*d*	*Mean (SE)*	Change (95% CI)	*d*
Impact of sleep difficulties on general daytime functioning											
CBT	2.47	1.33	−1.1*	−1.24	CBT	1.11	−0.4*	−0.42	1.17	0.1	0.08
	(0.10)	(0.11)	(-1.4, −0.9)			(0.14)	(-0.7,-0.1)		(0.15)	(-0.3, 0.4)	
					No treatment	0.88	−0.3*	−0.36	0.95	0.1	0.08
						(0.15)	(-0.6, 0.0)		(0.15)	(-0.3, 0.4)	
CBT + Med	2.53	1.48	−1.0*	−1.14	CBT/Taper	1.01	−0.3*	−0.35	0.57	−0.4*	−0.50
	(0.10)	(0.11)	(-1.3, −0.8)			(0.15)	(-0.6, 0.0)		(0.16)	(-0.8, −0.1)	
					CBT/Med^{prn}	1.31	−0.3*	−0.37	1.20	−0.1	−0.13
						(0.15)	(-0.7, 0.0)		(0.16)	(-0.5, 0.3)	
Impact of sleep difficulties on mood											
CBT	1.88	1.09	−0.8*	−0.92	CBT	0.85	−0.4*	−0.45	1.19	0.3 [a]	0.41
	(0.11)	(0.10)	(-1.0, −0.6)			(0.14)	(-0.7, −0.1)		(0.14)	(0.0, 0.7)	
					No treatment	0.69	−0.3	−0.32	0.88	0.2	0.23
						(0.14)	(-0.6, 0.1)		(0.14)	(-0.1, 0.5)	
CBT + Med	1.96	1.37	−0.6*	−0.68	CBT/Taper	0.82	−0.3 [a]	−0.41	0.60	−0.2	−0.26
	(0.11)	(0.10)	(-0.8, −0.3)			(0.14)	(-0.7, 0.0)		(0.15)	(-0.5, 0.1)	
					CBT/Med^{prn}	1.15	−0.4*	−0.51	1.07	−0.1	−0.10
						(0.14)	(-0.7, −0.1)		(0.15)	(-0.4, 0.3)	
Impact of sleep difficulties on fatigue											
CBT	2.22	1.58	−0.6*	−0.66	CBT	1.32	−0.4*	−0.41	1.32	0.0	0.01
	(0.12)	(0.11)	(-0.9, −0.4)			(0.15)	(-0.7, −0.1)		(0.15)	(-0.3, 0.3)	
					No treatment	1.04	−0.4*	−0.46	1.19	0.2	0.16
						(0.15)	(-0.7, −0.1)		(0.15)	(-0.2, 0.5)	
CBT + Med	2.48	1.79	−0.7*	−0.72	CBT/Taper	1.12	−0.4*	−0.42	0.80	−0.3	−0.35
	(0.12)	(0.11)	(-1.0, −0.4)			(0.15)	(-0.7, −0.1)		(0.16)	(-0.7, 0.0)	
					CBT/Med^{prn}	1.32	−0.8*	−0.84	1.56	0.2	0.26
						(0.16)	(-1.1, −0.4)		(0.16)	(-0.1, 0.6)	
Impact of sleep difficulties on concentration and memory											
CBT	2.11	1.40	−0.7*	−0.72	CBT	1.23	−0.5*	−0.50	1.34	0.1	0.12
	(0.12)	(0.11)	(-0.9, −0.5)			(0.15)	(-0.8, −0.2)		(0.16)	(-0.2, 0.4)	
					No treatment	0.85	−0.3	−0.26	0.97	0.1	0.13
						(0.16)	(-0.6, 0.1)		(0.15)	(-0.2, 0.4)	
CBT + Med	2.31	1.62	−0.7*	−0.70	CBT/Taper	1.06	−0.4*	−0.42	0.79	−0.3	−0.29
	(0.12)	(0.12)	(-0.9, −0.5)			(0.15)	(-0.7, −0.1)		(0.16)	(-0.6, 0.0)	
					CBT/Med^{prn}	1.12	−0.7*	−0.72	1.36	0.2	0.26
						(0.16)	(-1.0, −0.4)		(0.16)	(-0.1, 0.6)	
Impact of sleep difficulties on quality of life											
CBT	2.34	1.28	−1.1*	−1.22	CBT	0.98	−0.5*	−0.50	0.98	0.0	0.00
	(0.11)	(0.10)	(-1.3, −0.9)			(0.14)	(-0.7, −0.2)		(0.14)	(-0.3, 0.3)	
					No treatment	0.77	−0.4*	−0.42	0.85	0.1	0.10
						(0.14)	(-0.7, −0.1)		(0.14)	(-0.2, 0.4)	
CBT + Med	2.48	1.38	−1.1*	−1.27	CBT/Taper	0.84	−0.4*	−0.45	0.78	−0.1	−0.07
	(0.11)	(0.10)	(-1.3, −0.9)			(0.14)	(-0.7, −0.1)		(0.15)	(-0.4, 0.3)	
					CBT/Med^{prn}	0.98	−0.6*	−0.65	1.11	0.1	0.16
						(0.15)	(-0.8, −0.3)		(0.15)	(-0.2, 0.5)	
Impact of sleep difficulties on interpersonal relationships											
CBT	1.55	0.73	−0.8*	−0.95	CBT	0.76	−0.1	−0.12	0.85	0.1	0.11
	(0.11)	(0.10)	(-1.1, −0.6)			(0.13)	(-0.4, 0.2)		(0.14)	(-0.2, 0.4)	
					No treatment	0.50	−0.1	−0.11	0.53	0.0	0.04
						(0.14)	(-0.4, 0.2)		(0.13)	(-0.3, 0.3)	
CBT + Med	1.84	1.18	−0.7*	−0.76	CBT/Taper	0.69	−0.2	−0.28	0.39	−0.3[a]	−0.37
	(0.11)	(0.10)	(-0.9, −0.4)			(0.13)	(-0.5, 0.1)		(0.14)	(-0.6, 0.0)	
					CBT/Med^{prn}	0.83	−0.6*	−0.75	0.89	0.1	0.08
						(0.14)	(-0.9, −0.3)		(0.14)	(-0.3, 0.4)	
Impact of sleep difficulties on social or leisure activities											
CBT	1.83	0.94	−0.9*	−0.87	CBT	0.70	−0.4*	−0.40	0.83	0.1	0.14
	(0.13)	(0.12)	(-1.2, −0.6)			(0.15)	(-0.7, −0.1)		(0.16)	(-0.2, 0.4)	
					No treatment	0.46	−0.3 [a]	−0.37	0.61	0.2	0.16
						(0.15)	(-0.7, 0.0)		(0.15)	(-0.2, 0.5)	
CBT + Med	1.99	1.28	−0.7*	−0.70	CBT/Taper	0.73	−0.2	−0.24	0.49	−0.2	−0.26
	(0.13)	(0.12)	(-1.0, −0.4)			(0.15)	(-0.5, 0.1)		(0.16)	(-0.6, 0.1)	
					CBT/Med^{prn}	0.91	−0.7*	−0.73	1.26	0.4[a]	0.38
						(0.16)	(-1.0, −0.4)		(0.16)	(0.0, 0.7)	

Note. * These change scores were statistically significant ($p < 0.05$).
[a] These change scores were no longer significant after applying a correction (p values between 0.02 and 0.05).

for patients receiving extended CBT, CBT/Med^{prn}, and CBT/Taper (not significant after alpha error correction), but not for the condition with no additional treatment. Tests for interactions revealed that patients receiving extended CBT reported larger improvements of fatigue symptoms than CBT patients who received no additional treatment after acute therapy (5.9 units difference, CI = 0.2, 11.5); there was no difference between CBT/Med^{prn} and CBT/Taper groups. For the mental health component score of the SF-36, results were similar to those observed on the MFI: patients who received extended CBT, CBT/Med^{prn}, and CBT/Taper (not significant after alpha correction) reported significant improvements in mental health-related quality of life after extended treatment. Tests for interactions revealed that this improvement was significantly larger for the extended CBT group compared to the no additional treatment group, but there was no difference between CBT/Med^{prn} and CBT/Taper on this measure. For the SF-36 physical component, a significant improvement was seen only in the no treatment group, but it was no longer significant after alpha correction. Regarding the perceived impact of sleep difficulties on daytime functioning (ISI items), simple effects revealed significant changes from post I to post II for general daytime functioning, fatigue, and quality of life in all four conditions. For mood and cognition, significant changes were observed in all three conditions receiving additional treatment but not in patients receiving no additional treatment (change for the mood item in the CBT/Taper condition was no longer significant after correction for alpha error inflation). For the social/leisure activities item, significant changes were observed for all conditions except CBT/Taper (change in the no additional treatment condition was no longer significant after correction). Finally, for the item assessing interpersonal relationships, simple effects revealed a significant change only in the CBT/Med^{prn} group. Tests for interactions revealed a greater improvement on social/leisure activities in the CBT/Med^{prn} condition compared to the CBT/Taper condition (0.4 unit difference, CI = 0.0, 0.9).

3.4. Follow-up (post II to 6-month follow-up)

Comparisons of the post II data with 6-month follow-up showed no further changes for anxiety (BAI), depression (BDI), fatigue (MFI), health-related quality of life (SF-36), and six of the seven indices of the perceived impact of sleep difficulties on daytime functioning (ISI items). The only significant change (after applying a correction) from post II to 6-month follow-up was additional improvement on general daytime functioning in the CBT/Taper condition (See Table 2). Overall, these results suggest that improvements in daytime functioning achieved during treatment were well maintained over time.

4. Discussion

This study evaluated changes in psychological and daytime functioning following insomnia treatment. The main findings indicate that insomnia-specific therapy is effective at improving several indices of psychological and daytime functioning in the short term, and that maintenance therapy produced an added value to optimize long-term outcomes. The first study objective was to examine if there were differential effects of CBT with and without concurrent sleep medication on daytime outcomes. During acute treatment, improvements of mood, anxiety, fatigue, and quality of life (mental health) were obtained with CBT used singly but not when it was combined with medication. Conversely, both acute therapies were associated with improvements of all daytime functioning indices (e.g., mood, energy, concentration, relationships) measured by additional ISI items. A second objective was to evaluate whether an extended treatment adding maintenance CBT sessions or intermittent hypnotic medications would enhance daytime outcomes relative to acute interventions alone. Among participants who received CBT alone in the acute phase, those receiving individualized CBT during the extended treatment showed greater changes in daytime outcomes relative to those receiving no additional treatment, on measures of fatigue, quality of life (mental health), and on most daytime functioning indices evaluated by the ISI. In the combined treatment arm, the group receiving individualized CBT and intermittent medication (prn) showed improvements on the majority of daytime variables, while the extended CBT with no additional medication (i.e., medication taper) showed improvements only for the impact of sleep difficulties on general daytime functioning, fatigue, concentration and memory, and quality of life. Taken together, these results suggest that CBT alone has a greater impact on improving daytime functioning than when it is combined with medication during the initial 6-week treatment, while maintenance CBT and intermittent medication are more effective than no additional treatment or medication tapering during the extended 6-month treatment.

Our previously published results on sleep outcomes from this same study revealed that CBT alone and CBT combined with medication produced similar improvements in nighttime sleep after the six-week acute treatment, with the exception of a greater

Table 3
Summary of improvements in daytime measures during acute and extended treatments.

Outcome measures	Acute treatment: Pre to post I improvements		Extended treatment: Post I to post II improvements			
			Acute treatment: CBT		Acute treatment: CBT + Med	
	CBT	CBT + Med	CBT	No treatment	CBT/Taper	CBT/Med^{prn}
Beck Anxiety Inventory	*					*
Beck Depression Inventory	*					*
Multidimensional Fatigue Inventory	*		*		(*)	*
SF-36 Physical component				(*)		
SF-36 Mental component	*		*		(*)	*
Insomnia Severity Index						
Impact of sleep difficulties on …						
General daytime functioning	*	*	*	*	*	*
Mood	*	*	*		(*)	*
Fatigue	*	*	*	*	*	*
Concentration and memory	*	*	*		*	*
Quality of life	*	*	*	*	*	*
Interpersonal relationships	*	*				*
Social or leisure activities	*	*	*	(*)		*

Note. * = significant improvement; (*) = improvement no longer significant after applying a correction.

increase in total sleep time in the combined treatment arm (Morin et al., 2009). However, the present results indicate that CBT delivered alone is more effective than the combined approach (during acute treatment) in alleviating daytime symptoms, namely depression, anxiety, fatigue, and impairments in health-related quality of life. Such improvements in psychological symptoms and quality of life following CBT for insomnia have been reported in several recent reviews of the literature on self-help CBT (Ho et al., 2014) and CBT in psychiatric populations (Taylor & Pruiksma, 2014) and in veterans (Karlin, Trockel, Spira, Taylor, & Manber, 2014). Very few studies have compared two or more active treatments (pharmacological, CBT, combined) on daytime symptoms associated with insomnia. In one of the few studies to have done so, Jacobs et al. (2004) did not find any difference between the CBT, zolpidem, combined CBT plus zolpidem, and placebo conditions on changes in daytime symptoms from pre- to post-treatment (as measured by the BDI and the Vigor and Fatigue scales of the Profile of Mood States). However, sample size was much lower than in the present study (15–18 participants per arm compared to 80 participants per arm in the acute phase), and baseline levels of depressive symptoms were minimal (and lower than in the present study), which might explain the discrepancies in the findings. Our larger sample size (and hence greater statistical power) may have contributed to clearer findings in our study compared to what has been reported thus far in the literature. For instance, moderate effect sizes were found in previous studies, although changes from pre to post-treatment were often not statistically significant due to lack of power (e.g., Rybarczyk et al., 2005; Taylor et al., 2014).

While neither CBT nor medication specifically targeted daytime functioning, the present findings indicate that treatment benefits extend beyond sleep and also impact on psychological well-being, energy level, and quality of life. Although the specific mechanisms for these changes are unclear, it is conceivable that they were derived indirectly from CBT, which was common to both treatment arms. For instance, CBT promotes the implementation of a regular sleep-wake schedule, planning of social activities to facilitate rising in the morning on weekends, and developing more adaptive and realistic attitudes toward insomnia and its consequences; all those strategies may contribute to improve daytime functioning and lower psychological distress. Another interesting finding of the current study is that better daytime outcomes were achieved with CBT alone than with CBT combined to zolpidem following the acute treatment. It has previously been shown in the same sample that sleep improves more rapidly in the combined treatment arm than in the CBT alone arm (Morin et al., 2014). It is plausible that, since sleep improvement is delayed when CBT is delivered alone, participants have to invest more efforts throughout treatment in order to reach the same level of sleep improvement by the end of treatment. This potentially greater investment and commitment to therapeutic strategies could lead to better results for daytime symptoms. Further investigation of these potential mechanisms is warranted.

An innovative feature of this study was the comparison of several extended treatment strategies. For participants who received CBT alone initially, the addition of extended, individualized CBT produced an added value on measures of fatigue and quality of life (mental), relative to those who did not receive additional treatment. It is interesting to note that extended CBT produced further benefits on daytime symptoms, while it did not yield additional improvements for nighttime sleep (Morin et al., 2009). Unlike during initial treatment, CBT consultations during extended treatment were delivered in an individual rather than group format and the therapists had more flexibility in using additional clinical procedures (e.g., problem solving, fatigue management, stress management) that were more likely to target psychological symptoms and daytime functioning. This might explain the advantage of extended CBT on daytime (but not nighttime) measures.

For those treated with combined CBT and medication initially, the subgroup receiving extended CBT and medication as needed exhibited further improvements on measures of anxiety, depression, fatigue, and quality of life (mental health), while the subgroup treated with CBT but no additional medication fail to show additional improvements on these daytime outcomes. These results are somewhat unexpected and contrary to outcomes following acute treatment, where CBT alone was superior to the combined approach for daytime functioning measures, and also contrary to sleep outcomes which showed that the CBT without additional medication performed better than CBT plus intermittent medication group (Morin et al., 2009). It is possible that switching from a dual (CBT plus medication) to a single treatment modality (CBT), meant that participants experienced more withdrawal symptoms which, in turn, may have worsened their daytime functioning. It is unclear why such withdrawal symptoms would be more pronounced during the day than at night.

Some methodological issues must be taken into consideration when interpreting the results from this study. First, the absence of a group receiving medication alone limits the conclusions about the unique and additive contributions of CBT and medication to daytime outcomes. Second, using pooled data from all participants presenting various severity levels of psychological and daytime impairments precludes a clear delineation of the association between improvements of sleep and daytime functioning. Future studies should examine whether baseline severity of such impairments influence insomnia treatment outcomes and whether the magnitude of sleep improvements is associated with that of daytime improvements. It could be argued that individuals with milder symptoms are more likely to improve or, conversely, that those with more significant impairments have more room for improvement and are thus more likely to benefit from intervention. The latter is supported by a recent trial showing that participants with high and low baseline depression levels had similar sleep improvements following CBT for insomnia, but the subgroup with higher depressive symptoms improved more in both depression and anxiety symptoms (Lancee, van den Bout, van Straten, & Spoormaker, 2013).

The current findings have important clinical implications. First and foremost, they highlight that insomnia-specific therapy improves not only nighttime sleep but psychological and daytime functioning as well. Second, adding medication to CBT does not produce greater improvements of psychological and daytime symptoms relative to CBT alone. Third, maintenance therapy, albeit with lower intensity (i.e., monthly rather than weekly sessions, intermittent rather than nightly medication), provides an added value to the initial short-term intervention for improving psychological well-being, fatigue, and quality of life. Thus, clinicians should carefully evaluate the presenting symptomatology and associated treatment targets, both in terms of nighttime sleep and daytime functioning, when planning insomnia treatment. Insomnia is characterized by both nocturnal and diurnal symptoms (American Academy of Sleep Medicine, 2014; American Psychiatric Association, 2013), but it is often the latter, i.e., psychological distress and daytime impairments that prompt individuals with insomnia to seek treatment (Davidson et al., 2009; Gagnon et al., 2013). While current psychological and pharmacological therapies for insomnia tend to focus exclusively on the nocturnal sleep symptoms, treatment targeting the daytime impairments as well as the nighttime symptoms would probably enhance outcomes.

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