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Treatment Agreement, Adherence, and Outcome in Cognitive Behavioral Treatments for Insomnia

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Abstract

Background—Patient adherence has been identified as an important barrier to the implementation of evidence-based psychological treatments.

Objective—In cognitive behavioral treatments (CBT) for insomnia, the current study examined 1) the validity of therapist ratings of patient agreement and adherence against an established behavioral measure of adherence, and 2) the relationship between treatment agreement, adherence, and outcome.

Methods—Participants were 188 adults meeting DSM-IV-TR criteria for chronic insomnia who were randomized to receive behavior therapy, cognitive therapy, or CBT for insomnia. Treatment agreement/adherence was measured by 1) weekly therapist ratings of patient agreement and homework completion, and 2) adherence to behavioral strategies (ABS) derived from patient-reported sleep diary. Outcome measures were Insomnia Severity Index and insomnia remission (Insomnia Severity Index < 8).

Results—Therapist ratings of patient agreement as well as homework completion were significantly associated with sleep diary derived global ABS. Therapist-rated patient agreement and homework completion as well as global ABS predicted greater insomnia symptoms reduction from pre-treatment to post-treatment. Patient agreement also predicted insomnia symptoms reduction from pre-treatment to 6-month follow-up. Patient agreement, adherence, and ABS measures during treatment significantly predicted insomnia remission at post-treatment and all but therapist rating of homework completion predicted remission at 6-month follow-up.

Conclusion—Greater patient agreement and adherence (therapist ratings and ABS) during treatment predicted better treatment outcome. Therapist-rated treatment agreement and adherence correspond well with patient-reported sleep diary derived adherence measure. These simple,

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deployable therapist-rated patient agreement and adherence can potentially be useful for treatments for other disorders.

Keywords

Insomnia; Cognitive Behavior Therapy; Treatment Adherence; Agreement; Homework

Although evidence-based psychological treatments are effective single or adjunctive treatments for mental disorders, there is room for improvement. Poor patient adherence has been highlighted as an important barrier to the implementation of psychological treatments (Callan et al., 2012; Harvey & Gumpert, 2015). The WHO (2003) defines adherence as “the extent to which a person's behavior - taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider.” The term “adherence” is preferred over compliance to emphasize the notion of concordance, cooperation, and partnership between patients and providers (Bissonnette, 2008). Patient adherence is typically measured via therapist rating of homework completion, which is a strong predictor of treatment outcome (e.g., Mausbach, Moore, Roesch, Cardenas, & Patterson, 2010). In line with the WHO definition of adherence, patient agreement with session content has also been conceptualized as core to the process of change (Street, Makoul, Arora, & Epstein, 2009) and predicts a broad range of outcomes (Lasalvia, Bonetto, Tansella, Stefani, & Ruggeri, 2008). While it appears that these therapist ratings of agreement and adherence have predictive validity, other indices of reliability and validity are not yet available.

Insomnia is a highly prevalent and disabling condition (Hajak et al., 2011). Behavioral strategies, including sleep restriction treatment and stimulus control, are effective insomnia interventions (Morgenthaler et al., 2006). Adherence to behavioral strategies during cognitive-behavioral therapy (CBT) for insomnia has been associated with greater sleep improvements in most studies (e.g., Matthews, Arnedt, McCarthy, Cuddihy, & Aloia, 2013). Methods for assessing adherence to behavioral strategies for insomnia has widely varied across investigations. The *Adherence to Behavioral Strategies* (ABS) coding grid is one method for quantifying behavioral adherence measures (e.g., adhering to prescribed bedtime and risetime) derived using from patient-reported sleep diary. ABS has been applied with increasing frequency, and is predictive of CBT for insomnia outcome (e.g., Matthews, Schmiede, Cook, Berger, & Aloia, 2012; Tremblay, Savard, & Ivers, 2009). However, calculating adherence from sleep diary can be time consuming and unlikely to be feasible in certain clinical settings. Also, while sleep diary is completed for insomnia treatment, simple therapist ratings of adherence can be useful across a wide range of treatments.

The present study employed data from a randomized controlled trial comparing the efficacy of behavior therapy (BT) and cognitive therapy (CT) relative to the full CBT for chronic insomnia. The first aim was to validate simple therapist ratings of patient adherence against sleep diary-derived Adherence to Behavioral Strategies (ABS). We hypothesized that therapist ratings of patient agreement and adherence would be positively associated with global ABS. The second aim was to examine whether patient agreement and adherence predicted insomnia outcomes at post-treatment and 6-month follow-up. The hypothesis

tested was that better overall agreement and adherence (therapist ratings and global ABS) would be associated with greater insomnia symptoms reduction and higher remission rates. Exploratory aims were to test: 1) which specific ABS components predicted better insomnia outcomes; 2) which pre-treatment clinical and insomnia-related variables predicted greater agreement and adherence.

Methods

Study Overview

Participants were 188 adults with chronic insomnia recruited from March 2008 to November 2011 from two sites: XX and XX. They were randomized to receive 8 sessions of behavior therapy (BT; $n = 63$), cognitive therapy (CT; $n = 65$), and cognitive behavioral therapy (CBT; $n = 60$). BT includes stimulus control and sleep restriction. CT includes strategies targeting cognitive maintaining processes of insomnia. CBT for insomnia includes both the BT and CT components delivered in an integrated fashion. There were 63.5% female participants in BT, 69.2% in CT, and 53.3% in CBT. Mean age (in years) was 48.5 ($SD = 13.6$) for BT, 46.7 ($SD = 12.8$) for CT, and 46.9 ($SD = 11.3$) for CBT. All study procedures were approved by the XX and XX institutional review boards. All participants provided informed consent. Detailed study design, eligibility criteria, and treatment descriptions can be found elsewhere (Harvey, Bélanger, et al., 2014).

Measures

For the insomnia outcomes, Insomnia Severity Index (ISI; Bastien, Vallières, & Morin, 2001) was completed at baseline, post-treatment, and 6-month follow-up. Remission from insomnia (i.e., $ISI < 8$) and was calculated at post-treatment and 6-month follow-up.

Adherence to Behavioral Strategies (ABS; Tremblay et al., 2009) was derived from self-reported daily sleep diaries during BT and CBT for insomnia. ABS scoring was completed by therapists in-session, and independently verified by trained research assistants. Five behaviors were evaluated: (1) *Bedtime*, if goes to bed > 15 min before prescribed bedtime; (2) *Risetime*, if stays in bed or wakes up > 30 min past prescribed rising time; (3) *Getting out of bed*, if fails to get out of bed when sleep-onset latency or time awake after sleep onset exceeds 20 min on a given night; (4) *Time and duration of naps*, if nap started after 3:00 p.m. and duration exceeded 60 min; (5) *Sleep window*, if stays in bed > 30 min over the prescribed time in bed. Average ABS across sessions was calculated for global and specific ABS (see Supplemental Material).

Therapists rated patient's treatment agreement with the session content (0% 'Did not accept/agree' to 100% 'Full acceptance/agreement') and homework assignment completion (0% 'Did not complete' to 100% 'Fully completed') after each session.

Based on prior research (e.g., Matthews et al., 2013; Tremblay et al., 2009), the following baseline variables were tested as predictors of treatment agreement and adherence: psychiatric comorbidities (SCID; First, Spitzer, Gibbon, & Williams, 1995), daytime fatigue (MFI; Smets, Garssen, Bonke, & De Haes, 1995), daytime impairment (WSAS; Mundt, Marks, Shear, & Greist, 2002), patient's treatment expectation at session 1 (CEQ; Devilly &

Borkovec, 2000), duration of insomnia (self-report), dysfunctional beliefs about sleep (DBAS; Morin, 1994), and sleep-related safety behaviors (SRBQ; Ree & Harvey, 2004).

Data Analysis

Multiple linear regression was used to examine the association between each of the average weekly therapist ratings and the average weekly global ABS. Multilevel modeling was used to analyze the effect of each agreement/adherence variable measured during treatment on the changes of insomnia symptoms scores from pre-treatment to post-treatment and 6-month follow-up. Logistic regression was used to analyze the effect of each agreement/adherence variable measured during treatment on the binary outcome of insomnia remission. Tobit regression was used to examine pre-treatment predictors of therapist ratings, as the ratings are censored at 100%. For analyses related to therapist ratings of patient agreement and adherence, data from all three conditions were utilized; for analyses related to ABS, only data from BT and CBT for insomnia were included because behavioral strategies were not part of CT. Standardized coefficients for all variables (except for insomnia remission) were reported. The standardized coefficient indicates the mean change in standard deviation units of y for a one standard deviation change in x . Significance level of $\alpha = 0.05$ was used throughout. All analyses were adjusted for the two study sites, stratification factors (age group and comorbidity), and treatment conditions.

Results

Construct Validity of Therapist Ratings of Patient Agreement and Adherence versus Adherence to Behavioral Strategies (ABS)

Table 1 presents the descriptive statistics for all study variables. Table 2 presents correlation coefficients between average weekly therapist ratings of agreement and adherence and ABS global and specific components. As shown in Table 3, greater average weekly therapist ratings of patient agreement ($b = 0.46, p < 0.001$) and homework completion ($b = 0.54, p < 0.001$) were significantly associated with greater global ABS during acute treatment, after accounting for study site, treatment condition, stratification factors (comorbidity, age group).

Predictive Validity of Agreement and Adherence Measures for Treatment Outcome

Insomnia Symptoms—As shown in Table 4, therapist ratings of patient agreement significantly predicted insomnia symptoms reductions from pre-treatment to post-treatment ($b = -0.27, p = 0.001$) and to 6-month follow-up ($b = -0.14, p = 0.037$). Therapist ratings of homework completion significantly predicted insomnia symptoms reductions from pre-treatment to post-treatment ($b = -0.14, p = 0.045$), but not to 6-month follow-up ($b = 0.001, p = 0.984$). Global ABS significantly predicted insomnia symptoms reduction from pre-treatment to post-treatment ($b = -0.18, p = 0.018$), but not to 6-month follow-up ($b = -0.11, p = 0.152$).

Remission—As shown in Table 5, greater average therapist ratings of agreement ($OR = 2.59, p < 0.001$) and global ABS during acute treatment ($OR = 1.99, p = 0.006$) significantly predicted insomnia remission at post-treatment. Greater therapist ratings of patient agreement ($OR = 1.63, p = 0.015$) and global ABS ($OR = 1.54, p = 0.035$) also significantly

predicted insomnia remission at 6-month follow-up. Greater therapist rating of homework completion predicted insomnia remission at post-treatment ($OR = 1.84, p = 0.008$), and 6-month follow-up at trend level ($OR = 1.37, p = 0.088$).

Exploratory Analysis

As shown in Tables 4 and 5, among the specific ABS components, only adherence to getting out of bed when awake at night significantly predicted insomnia symptoms reduction from pre-treatment to post-treatment ($b = -0.22, p = 0.002$) and to 6-month follow-up ($b = -0.20, p = 0.008$) as well as insomnia remission at both post-treatment ($OR = 2.63, p < 0.001$) and 6-month follow-up ($OR = 2.23, p = 0.001$). None of the other specific ABS components significantly predicted treatment outcome. For predictors of agreement and adherence, greater daytime fatigue at pre-treatment predicted worse therapist ratings of patient agreement ($b = -0.58, p = 0.008$) as well as worse global ABS ($b = -0.05, p = 0.050$) and therapist ratings of homework completion ($b = -0.62, p = 0.084$) at trend level. Greater treatment expectancy at session 1 predicted better patient agreement ($b = 0.36, p < 0.001$). There was also a non-significant trend between greater dysfunctional beliefs about sleep ($b = -0.20, p = 0.091$) and worse global ABS. No other variables at pre-treatment predicted agreement or adherence.

Discussion

The first aim was to validate therapist ratings of patient agreement and adherence against Adherence to Behavioral Strategies (ABS) derived from patient-reported sleep diary. As expected, therapist ratings of patient agreement and homework completion were significantly and positively associated with global ABS. To our knowledge, only one prior study has examined therapist ratings of patient adherence in CBT for insomnia using a therapist-rated global impression of patient adherence (“How adherent was patient”) and showed good convergent validity with other adherence measures (Vincent & Hameed, 2003).

The second aim was to examine whether better patient agreement and adherence predicted insomnia outcome. As expected, therapist ratings of patient agreement significantly predicted greater reduction of insomnia symptoms from pre- to post-treatment and to 6-month follow-up. Similarly, therapist rating of homework completion and global ABS significantly predicted greater reduction of insomnia symptoms from pre-treatment to post-treatment. Additionally, therapist rating of agreement and adherence and global ABS were significant predictors of insomnia remission at post-treatment and 6-month follow-up, except that therapist rating of homework completion was associated with remission at 6-month follow-up at trend level.

There are several interpretations of these results. First, they are consistent with previous research drawing a positive link between homework adherence and treatment outcome both concurrently and longitudinally (Decker et al., 2016; Kazantzis, Whittington, & Dattilio, 2010). Second, they suggest the importance of less studied construct of patient agreement with session contents and recommendations, which is in line with the WHO’s broader definition of adherence emphasizing on patient agreement (World Health Organization, 2003). Third, our results also add to the predictive validity of the measure of adherence to

behavioral strategies based on sleep diary (i.e., ABS), which was previously validated only in CBT for insomnia comorbid with breast cancer (e.g., Matthews et al., 2012; Tremblay et al., 2009).

Exploratory analysis suggests that adherence to getting out of bed during nocturnal awakening alone appears to explain the significant findings of global ABS in relation to insomnia outcomes, which is consistent with previous research (Tremblay et al., 2009). This item appears to be a difficult behavioral strategy for adherence (i.e., lowest adherence and highest variability in Table 1), hence therapists should pay greater attention to troubleshooting barriers to adherence. Exploratory analysis also suggests that baseline daytime fatigue contributes to poor adherence, which is consistent with prior research (Matthews et al., 2012). Given that we previously found no significant time or group \times time interaction on daytime fatigue (Harvey et al., 2014), suggesting that neither time nor any of the sleep interventions alleviated daytime fatigue, it may be interesting to investigate effective strategies to manage daytime fatigue, which may improve treatment agreement, adherence, and outcome.

Several limitations should be noted. First, therapist ratings of patient agreement and adherence are still in the process of being formally validated. Second, homework contents vary across treatment conditions (e.g., CBT for insomnia includes both BT and CT homework) in the current study, although treatment condition was adjusted for in all models. Future research may investigate the potential differences across treatments in patient adherence and whether treatment condition moderates the link between adherence and treatment outcome. Third, because the calculation of ABS was approximated during session, it is possible that seeing sleep diaries during sessions may have influenced therapist ratings of agreement and adherence.

To summarize, the current study provides evidence for the convergent validity of therapist ratings of patient agreement and adherence against patient-reported sleep diary derived adherence measures during acute treatment as well as evidence for the predictive validity of these measures of patient agreement and adherence during treatment for treatment outcomes at post-treatment and 6-month follow-up. Adherence to certain treatment recommendations may be more predictive of treatment outcome than others and daytime fatigue may be an important factor contributing to worse adherence during treatment. Important priorities for future research are to further examine the relationship between patient agreement and adherence to treatment recommendations, identify the specific treatment components for which adherence is critical for favorable outcomes, and to further explore barriers to, and strategies to improve, treatment adherence.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Public Health Significance

Simple and easily deployable therapist ratings of patient agreement and adherence during treatment correspond well with behavioral measure of adherence and are predictive of treatment outcome. Results highlight the importance of monitoring patient agreement and adherence during treatment as a potential pathway to improve treatment outcome.

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Table 1

Descriptive statistics of study variables.

Variable	N	Mean	SD	Min	Max
<i>Therapist rated agreement and adherence during treatment</i>					
Patient agreement	165	86.19	12.06	32.00	100.00
Homework completion	165	80.99	17.85	0.00	100.00
Global ABS during treatment	122	5.34	0.92	2.33	7.00
<i>Specific ABS components during treatment</i>					
Bedtime	122	6.17	0.92	2.90	7.00
Risetime	122	5.08	1.39	0.48	7.00
Time and duration of napping	122	5.91	1.56	0.00	7.00
Sleep Window	122	5.05	1.41	0.00	7.00
Getting out of bed during nocturnal awakening	120	4.51	2.11	0.00	7.00
<i>Insomnia Severity Index</i>					
Pre-treatment	188	17.92	3.43	9.00	26.00
Post-treatment	169	8.62	4.59	0.00	22.00
6-month follow-up	160	8.58	4.96	0.00	24.00
<i>Insomnia Remission (Insomnia Severity Index < 8)</i>					
Post-treatment	169	46.75			% Remitted
6-month follow-up	160	52.50			

Note. ABS = Adherence to Behavioral Strategies. Sleep window is only available during treatment (S2-7). SD = standard deviation.

Correlation Coefficients Between Therapist Ratings of Patient Agreement and Adherence and Adherence to Behavioral Strategies (ABS)

Table 2

	1	2	3	4	5	6	7	8
1. Therapist rating of patient agreement	1.00							
2. Therapist rating of homework completion	0.40**	1.00						
3. Global Adherence to Behavioral Strategies (ABS)	0.42**	0.38**	1.00					
Specific ABS components:								
4. Bedtime	0.36**	0.37**	0.66**					
5. Risetime	0.18*	0.27**	0.67**	0.39**	1.00			
6. Napping	0.22**	0.13	0.44**	0.07	0.02	1.00		
7. Sleep window	0.33**	0.38**	0.44**	0.74**	0.81**	0.09	1.00	
8. Getting out of bed during nocturnal awakening	0.28**	0.14	0.61**	0.21**	0.06	0.14	0.13	1.00

Note. ABS= Adherence to Behavioral Strategies. All variables were averaged across weekly ratings.

*** < .05.

* < .10.

The correlation coefficients were unadjusted for study site, treatment conditions, and stratification factors (age, group, comorbidity).

Associations between Therapist Ratings of Patient Agreement and Adherence During Treatment and Adherence to Behavioral Strategies (ABS)

Table 3

Global ABS during treatment (outcome)	Beta	SE	t	p	95% CI
Therapist rating of patient agreement	0.46	0.10	4.76	<0.001	[0.27, 0.65]
Therapist rating of homework completion	0.54	0.12	4.35	<0.001	[0.29, 0.78]

Note. Beta = standardized regression coefficient. ABS = Adherence to Behavioral Strategies. Results are based on multiple linear regression, including one therapist rating (or average global ABS during treatment) and controlling for treatment condition, study site, and stratification factors (age, group, comorbidity).

Table 4
 Therapist Ratings of Patient Agreement and Adherence and Adherence to Behavioral Strategies (ABS) During Treatment Predicting Insomnia Symptoms Reduction from Pre-treatment Through 6-Month Follow-up

Insomnia Severity Index (ISI) scores (outcome)	Effect of adherence on ISI from pre to post			Effect of adherence on ISI from pre to 6-month follow-up			Effect of adherence on ISI from post to 6-month follow-up		
	Beta	SE	p	Beta	SE	p	Beta	SE	p
Therapist rating of patient agreement	-0.27	0.07	0.001	-0.14	0.07	0.037	0.13	0.07	0.073
Therapist Rating of homework completion	-0.14	0.07	0.045	0.001	0.07	0.984	0.14	0.08	0.064
Global Adherence to Behavioral Strategies (ABS)	-0.18	0.08	0.018	-0.11	0.08	0.152	0.07	0.08	0.407
Specific ABS components									
Bedtime	-0.10	0.08	0.212	-0.03	0.08	0.754	0.07	0.08	0.376
Risetime	-0.05	0.07	0.532	-0.07	0.07	0.381	-0.02	0.08	0.808
Napping	-0.02	0.08	0.794	0.09	0.09	0.320	0.11	0.09	0.234
Sleep window	-0.07	0.08	0.349	-0.01	0.08	0.912	0.06	0.08	0.422
Getting out of bed during nocturnal awakening	-0.22	0.07	0.002	-0.20	0.07	0.008	0.02	0.08	0.748

Note. ISI = Insomnia Severity Index. Beta = standardized regression coefficient. Results are based on multilevel modeling. Only Time × Adherence variable results are presented in this table. All models were adjusted for treatment condition, study site, and stratification factors (age group, comorbidity). pre = pre-treatment, post = post-treatment.

Table 5
 Therapist Ratings of Patient Agreement and Adherence and Adherence to Behavioral Strategies (ABS) During Treatment Predicting Insomnia Remission

	<i>OR</i>	<i>SE</i>	<i>p</i>
<u>Remission at post-treatment (outcome)</u>			
Therapist rating of patient agreement	2.59	0.69	<0.001
Therapist rating of homework completion	1.84	0.42	0.008
Global Adherence to Behavioral Strategies (ABS)	1.99	0.50	0.006
Specific ABS components			
Bedtime	1.56	0.38	0.068
Risetime	1.17	0.25	0.449
Nap	0.90	0.21	0.644
Sleep window	1.45	0.33	0.102
Getting out of bed during nocturnal awakening	2.63	0.68	<0.001
<u>Remission at 6-month follow-up (outcome)</u>			
Therapist rating of patient agreement	1.63	0.33	0.015
Therapist rating of homework completion	1.37	0.25	0.088
Global Adherence to Behavioral Strategies (ABS)	1.54	0.31	0.035
Specific ABS components			
Bedtime	1.23	0.23	0.271
Risetime	1.18	0.23	0.407
Nap	0.83	0.17	0.358
Sleep window	1.31	0.26	0.174
Getting out of bed during nocturnal awakening	2.23	0.52	0.001

Note. *OR* = Odds Ratio. Results were based on logistic regression for remission at post-treatment and 6-month follow-up respectively. All adherence variables included were assessed during acute treatment phase and were averaged across weekly sessions. All models were adjusted for treatment condition, study site, and stratification factors (age group, comorbidity).