

Method of Treatment Allocation: Does It Affect Adherence to Behavioural Therapy for Insomnia?

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Adherence to treatment is critical in determining the effects of behavioural therapy and may be affected by participants' preference for treatment. The purpose of this study was to determine the extent to which method of allocation to treatment (random vs. preference-based) influences adherence (exposure and enactment) to behavioural therapy. Participants received behavioural therapy for the management of insomnia randomly or by preference. Exposure was assessed as attendance at the treatment sessions, enactment as self-reported application of treatment recommendations. Participants ($N = 262$) attended a mean of 5.6 treatment sessions, applied the treatment recommendations frequently, and reported high levels of overall compliance. There was no difference between the random and preference groups in terms of exposure to and enactment of treatment. Randomization to the preferred treatment, dissatisfaction with the allocated treatment, and self-report bias could play a role in the findings and should be explored in future research.

Keywords: treatment preferences, adherence, enactment, exposure, methodology, intervention research

Résumé

Méthode d'attribution des traitements : a-t-elle une influence sur l'adhésion à une thérapie comportementale contre l'insomnie ?

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L'adhésion au traitement a un effet déterminant sur l'efficacité d'une thérapie comportementale et est susceptible d'être influencée par les préférences des participants en matière de traitement. L'objectif de la présente étude est de déterminer la mesure dans laquelle la méthode d'attribution des traitements (aléatoire ou fondée sur les préférences) exerce une influence sur l'adhésion (exposition ou mise en action) à une thérapie comportementale. Les participants à l'étude se sont vu attribuer une thérapie pour la gestion de l'insomnie selon une méthode aléatoire ou fondée sur leurs préférences. L'exposition a été définie et évaluée comme une présence aux séances de thérapie et la mise en action comme l'application des recommandations associées à la thérapie, selon les déclarations des participants eux-mêmes. Les participants ($N = 262$) ont assisté en moyenne à 5,6 séances de thérapie, ont appliqué les recommandations associées à la thérapie de façon fréquente et ont indiqué avoir fait preuve d'un degré élevé de respect de la thérapie en général. Aucune différence n'a été observée entre les groupes avec attribution aléatoire et ceux avec attribution selon les préférences en ce qui concerne l'exposition à la thérapie et la mise en action de celle-ci. La répartition aléatoire des participants à la thérapie préférée, l'insatisfaction de participants quant à la thérapie attribuée et le caractère subjectif des déclarations des participants ont possiblement joué un rôle dans l'établissement des résultats et devraient être analysés plus en profondeur dans le cadre d'une prochaine étude.

Mots-clés : préférences en matière de traitement, adhésion, mise en action, exposition, méthode, recherche

Introduction

Adherence to treatment is important in determining the effectiveness of behavioural therapy in producing the hypothesized improvement in outcomes. Less than optimal adherence to treatment has been reported in a meta-analysis; specifically, 40% of patients took the medications as prescribed but twice as many did not adhere to the recommended health behaviours related to diet, exercise, and smoking. Furthermore, the odds of a good outcome are three times higher in adherent compared to non-adherent patients (DiMatteo, Giordani, Lepper, & Croghan, 2002). Similarly, a meta-analysis of psychological interventions for pathological gambling (Pallesen et al., 2003) found that attendance at a large number of planned sessions was associated with improved outcomes.

Several factors have been identified as predictors of adherence to treatment. The factors are categorized into (1) characteristics of participants, such as age, beliefs, and lifestyle; (2) characteristics of the clinical problem experienced by participants, including its chronicity and perceived severity; and (3) characteristics of the treatment, such as invasiveness and complexity (Brawley & Culos-Reid, 2000; Martin, Bowen, Dunbar-Jacob, & Perri, 2000). Treatment preferences have been recognized as factors influencing adherence (TenHave, Coyne, Salzer, & Katz, 2003). Allocation of participants to their preferred treatment has been proposed as a way to mitigate this influence (Corrigan & Salzer, 2003; Rowe et al., 2005).

This methodological study investigated the extent to which assigning participants to their treatment of choice, as compared to randomizing them to treatment, enhances adherence to behavioural therapy in the context of an intervention evaluation trial.

Treatment Adherence

Generally, adherence refers to patients' involvement in treatment activities (Wilbur, Chandler, & Miller, 2001). Involvement in behavioural therapy encompasses exposure to and enactment of treatment (Borrelli et al., 2005; Burgio et al., 2001). *Exposure* relates to attendance at the planned treatment sessions during which the treatment recommendations or strategies to change the target behaviour are discussed and practised. *Enactment* is application of the treatment recommendations in the context of daily life between treatment sessions. Appropriate and consistent application of treatment recommendations contributes to behavioural change and subsequent outcome achievement. Deviations in participants' implementation of the treatment reduce the potency of the intervention and increase variability in post-treatment outcomes. This increased variability

translates into increased error variance and lowers the statistical power to detect significant treatment effects (Gibson, 2003).

Treatment Preferences

The phrase “treatment preferences” refers to participants’ choice of therapy — that is, the treatment they desire for the management of the presenting clinical problem (Sidani, Epstein, Bootzin, Moritz, & Miranda, 2009). Individuals enrolled in a trial may have preferences for the treatments under evaluation. The preferences are generated from previous knowledge and experience and from information about the treatments disclosed during the process of obtaining consent (Sidani & Braden, 2011).

In randomized trials, participants’ preferences are ignored when participants are randomly assigned to treatment. Randomization creates two subgroups. The first comprises those who, by chance, are assigned to their preferred treatment. These participants may develop enthusiasm for, engage in, and adhere to treatment. In contrast, the second subgroup consists of participants who receive the non-preferred treatment. They may be disappointed because they are deprived of their treatment of choice. They may lose their motivation for the treatment and may not initiate, engage in, and adhere to the allocated treatment. Ultimately, they achieve poor outcomes, which contributes to misleading conclusions about treatment effectiveness (Howard & Thornicroft, 2006; Huibers et al., 2004; Preference Collaborative Review Group, 2009).

Preference trials are intended to address treatment preferences that threaten the validity of conclusions in intervention research. In this design, participants are given information about the treatments, requested to indicate their treatment of choice, and allocated to their chosen treatment. Participants with no preference are randomized to treatment (Bradley, 1993). Provision of the preferred treatment is believed to enhance engagement in and adherence to treatment (Leykin et al., 2007).

Influence of Treatment Preferences on Adherence

A total of 10 studies evaluated the influence of allocating participants to the preferred treatment on adherence to treatment. The studies involved different treatments for the management of various clinical problems. Their results were inconsistent in supporting the utility of preference-based allocation in improving adherence to treatment. The same conclusion was reached in two systematic reviews of studies that examined the influence of preferences on adherence to treatment for depression (Gelhorn, Sexton, & Classi, 2011; Winter & Barber, 2013).

Of the 10 studies, the results of three showed no statistically significant difference in attendance at treatment sessions between participants

allocated to the preferred and non-preferred therapy for the management of diabetes (Hitchcock Noël et al., 1998) and depression (Dobscha, Corson, & Gerrity, 2007; Mergl et al., 2011). The remaining seven studies reported higher levels of adherence among participants receiving treatments that were congruent with their preferences. The treatments included pharmacological, educational, and behavioural therapies for depression (Bedi et al., 2000; Chilvers et al., 2001; Hunot, Horne, Leese, & Churchill, 2007; Kwan, Dimidjian, & Rizvi, 2010; Raue, Schulberg, Heo, Klimstra, & Bruce, 2009) and for the management of heart disease (Janevic et al., 2003) and mental health problems (Macias et al., 2005).

In the above studies, adherence was operationalized as exposure to treatment — that is, attendance at the planned sessions for non-pharmacological therapy. The studies reviewed did not examine the extent to which accounting for treatment preferences influences the enactment of therapy. Also, the evidence regarding the contribution of preference-based allocation to treatment enactment is limited.

Since enactment is another critical aspect of adherence, the overall purpose of this study was to determine the extent to which the method of allocation (random vs. preference) in a treatment evaluation trial influences adherence as operationalized by both exposure to and enactment of the behavioural intervention.

Methods

Design

The data for the study were obtained from a large methodological trial examining the utility of different research designs in enhancing the validity and clinical relevance of findings related to the effectiveness of behavioural interventions (Sidani, Epstein, Bootzin, Moritz, & Sechrest, 2007). The data set pertained to those who were assigned to the same behavioural therapy for the management of chronic insomnia on the basis of chance or preference, the purpose being to control for possible variability in adherence to different treatments and hence to examine the unique influence of allocation method (random vs. preference) on adherence. Assignment to treatment took place after eligible consenting individuals provided pre-test data. One group of participants were randomly assigned to the behavioural therapy using opaque, sealed envelopes that were opened in their presence to reveal the allocated treatment. The other group were assigned to the preferred treatment, which was determined in a systematic process: the participants were provided information about the treatments under investigation, asked to rate the acceptability of these treatments, and asked to indicate their treatment of choice (for details, see Sidani et al., 2009). Differences between the two groups in terms of per-

sonal and clinical characteristics were examined and controlled for statistically, to minimize their potentially confounding influence on treatment adherence.

Sample

Participants were eligible for the methodological trial if they were 21 years of age or older, were non-institutionalized, were English-speaking, and complained of chronic insomnia described as difficulty falling or staying asleep of at least 30 minutes per night for 3 or more nights per week ascertained by means of a 14-day sleep diary and at least 3 months' duration as reported by participants. Individuals were excluded if they had sleep apnea (self-reported) and were under treatment for sleep apnea, cognitive impairment (score < 27 on the Mini-Mental State Exam; Folstein, Folstein, & McHugh, 1975), or psychological impairment (Global Severity Index T score > 50 on the Brief Symptom Inventory; Derogatis & Melisaratos, 1983).

The study comprised 262 participants assigned to the same behavioural therapy. This sample size was adequate to detect small-moderate differences in adherence (exposure and enactment) between participants allocated by chance or preference, setting beta at .80 and p at $\leq .05$ (Cohen, 1992).

Intervention

The intervention was behavioural therapy for the management of chronic insomnia. It consisted of two components. The first provided information about sleep, factors contributing to insomnia, and recommendations for promoting sleep. The second offered support to participants in applying the recommendations by discussing barriers to their implementation in daily life and assistance with generating ways to overcome the barriers. Two categories of recommendation, general and specific, were presented. The general recommendations consisted of strategies to use during the day or evening to promote good sleep, such as engaging in physical activity during the day and avoiding caffeine and nicotine in the evening. The specific recommendations included instructions to go to bed only when sleepy, avoid any non-sleep-related activities in bed, get out of bed if unable to fall asleep or get back to sleep within 15 to 20 minutes, wake up at the same time every day, and avoid naps, or, if needed, take a nap, in bed, for no more than 30 minutes (Bootzin & Epstein, 2011). The intervention was given in four face-to-face group sessions of 60 to 90 minutes' duration and two individual telephone sessions that lasted 15 to 20 minutes. The six sessions were offered once a week over a 6-week period.

Variables and Measures

Personal characteristics. Standard items were used to assess participants' age, gender, education level, race, marital status, and employment status. Education level was quantified with the number of years of formal schooling. Race and marital and employment status were represented in the following categories: white versus non-white, married versus non-married, and employed versus non-employed.

Clinical characteristics. Participants indicated the types of insomnia they experienced: difficulty falling asleep and/or difficulty staying asleep and the length of time they had had insomnia. The severity of insomnia was assessed using the sleep diary and the Insomnia Severity Index (ISI). Participants completed the sleep diary for 14 days prior to receiving the therapy. They reported the daily values upon waking to a voice-mail service, to minimize recall bias. The sleep parameters, computed from relevant diary data, included (1) sleep onset latency, or the length of time, in minutes, to fall asleep; (2) wake after sleep onset, or length of time, in minutes, awake across all awakenings; and (3) sleep efficiency, or the percentage of the time in bed actually asleep. The sleep diary demonstrated test-retest reliability ($r = .69-.93$) and validity, evidenced by significant correlation between the values of the respective sleep parameters estimated with data reported in the sleep diary and recorded using actigraphy (Buysse, Ancoli-Israeli, Edinger, Lichstein, & Morin, 2006). The ISI was administered at pre-test to assess participants' perceived severity of their sleep problem. The ISI contains seven items measuring the nature, severity, and impact of insomnia. It has excellent internal consistency reliability (Cronbach's $\alpha \geq .90$) and construct validity (Morin, Belleville, Bélanger, & Ivers, 2011).

Adherence. The two aspects of adherence, exposure to and enactment of treatment, were examined in this study. *Exposure* was assessed via attendance at group and telephone sessions. The therapists leading the sessions recorded the presence or absence of each participant at each scheduled treatment session and the total number of sessions attended was counted. *Enactment* of treatment recommendations was reflected in three ways. *First*, participants reported on their application of the following behavioural therapy recommendations: (1) using the bed for sleep only and not for any other activity, (2) getting out of bed when unable to fall asleep or fall back to sleep within 15 to 20 minutes, and (3) taking a nap in bed only if necessary. Three items related to the application of these recommendations were integrated into the sleep diary form, and therefore were completed by the participants daily throughout the 6 weeks of treatment. Enactment of these recommendations was quantified in two ways: the number of days, within each treatment week, that each recommendation

was applied; and the number of days that its application was not needed (e.g., the participant did not take a nap). *Second*, participants were requested to indicate whether or not, within 1 week following completion of treatment, they implemented the strategies to promote sleep that represented the sleep hygiene recommendations. The 13 recommendations were as follows: engaging in physical activity during the day, avoiding vigorous exercise around bedtime, reducing noise in the bedroom, reducing light in the bedroom, maintaining a comfortable temperature in the bedroom, avoiding a heavy evening meal, having a light bedtime snack as needed, avoiding alcohol before bed, avoiding caffeine before bed, avoiding nicotine before bed, putting the clock out of sight in the bedroom, avoiding long naps, and avoiding stressful thoughts when in bed. The total number of strategies applied was computed. *Third*, an additional item was used to measure overall compliance with the treatment within 1 week after treatment completion. Overall compliance was rated on a five-point scale ranging from *not at all* (0) to *very much* (4).

Data Analysis

Descriptive statistics (frequency, mean, standard deviation) were used to characterize the sample relative to personal and clinical characteristics. Independent samples *t* test for continuous variables and chi-square test for dichotomous variables were used to examine differences in these characteristics between the two groups of participants: those randomized (random group) and those allocated on the basis of preference (preference group) to the behavioural therapy. Baseline variables that showed differences between the random and preference groups were considered as covariates in subsequent analyses and were controlled for statistically. One-way analysis of covariance was used to compare the two groups on the number of sessions attended (exposure), number of sleep hygiene recommendations applied (enactment), and self-reported overall compliance with treatment (enactment), while controlling for the covariates. Repeated measures analysis of covariance was done to determine differences in the application (enactment) of the behavioural therapy recommendations between the groups across the 6 weeks of treatment, while controlling for baseline differences. Statistically significant main group effect and interaction (group x time) effects supported the influence of treatment allocation method on adherence.

Results

Personal Characteristics of Participants

Participants ranged in age from 21 to 90 years with a mean of 56 (\pm 16.1) years. The sample comprised slightly more women (59.5%) than

men (40.5%). Education level varied from 3 to 30 years of formal schooling with a mean of 15.7 years (± 3.5). Approximately half of the participants were married (53.3%) and approximately half were employed (55.6%). The majority (90%) were white.

Clinical Characteristics of Participants

The majority of participants indicated that they experienced difficulty falling asleep (72.5%) and difficulty staying asleep (91.5%). On average, they had had insomnia for 11 (± 11) years. The mean values of the sleep parameters obtained with the sleep diary were as follows: 42.9 minutes for sleep onset latency (± 30.7 , range: 1.9 to 235.5); 54.4 minutes for wake after sleep onset (± 33.9 , range: 0 to 201.5); and 69.9% for sleep efficiency (± 10.4 , range: 27 to 90). The mean score for perceived insomnia severity was 17.6 (± 3.9 , range: 8 to 28), indicating that, on average, participants experienced clinical insomnia of moderate severity.

Method of Treatment Allocation

Of the 262 participants, 164 (63.1) were randomized to the behavioural therapy and 96 (36.9%) were allocated to this treatment based on their preference.

Group Comparison on Personal and Clinical Characteristics

The average values on the personal and clinical characteristics for the random and preference groups are presented in Table 1. Statistically significant differences were observed for three characteristics: age, $t(257) = 4.6, p = .001$; gender, $\chi^2(1) = 9.2, p = .004$; and employment status, $\chi^2(1) = 18.9, p = .001$. Those in the preference group were young, employed women. Since age and employment status were related (older participants were not employed), only age and gender were considered covariates in subsequent group comparisons to determine the influence of method of allocation to treatment on adherence.

Group Comparison on Adherence to Treatment

After controlling for baseline differences in age and gender, there were no statistically significant differences in exposure and enactment between the random and the preference groups. In terms of exposure, the mean number of sessions attended was 5.7 ($\pm .54$) in the random group and 5.6 ($\pm .63$) in the preference group, $F(1, 234) = 2.69, p = .10$. The adjusted mean values for the enactment of the behavioural therapy recommendations over the 6 weeks of treatment are shown in Table 2. The number of days on which the first recommendation, using the bed for sleep only, was applied was comparable in the two groups, $F(1, 232) = 1.05, p > .05$, and over time, $F(5, 229) = .61, p > .05$. The number of

	Random Group (n = 164)	Preference Group (n = 96)
<i>Personal characteristics</i>		
Age (mean)	59.5 (15.4)	50.2 (15.7)
Gender (% female)	52.5	71.6
Education (mean)	15.7 (3.4)	15.6 (3.7)
Marital status (% married)	56.1	48.4
Employment status (% employed)	45.1	72.6
Race (% white)	90.2	89.4
<i>Clinical characteristics</i>		
Type of insomnia		
Difficulty falling asleep (%)	73.2	71.9
Difficulty staying asleep (%)	92.0	91.6
Duration of insomnia (mean)	10.3 (10.7)	12.3 (11.6)
Sleep onset latency (mean)	44.7 (29.8)	40.3 (22.3)
Wake after sleep onset (mean)	57.0 (36.8)	49.8 (27.1)
Sleep efficiency (mean)	69.1 (11.1)	71.2 (9.2)
Insomnia severity (mean)	17.8 (4.0)	17.2 (3.8)

days on which this recommendation was not needed was slightly higher in the preference group, $F(1, 234) = 3.34, p = .069$, throughout the treatment period, $F(5, 230) = 1.35, p > .05$. Participants in both groups applied the second recommendation, getting out of bed if cannot fall asleep or fall back to sleep within 15 to 20 minutes, with similar frequency, $F(1, 234) = .65, p > .05$, which decreased significantly over time, $F(5, 230) = 5.32, p = .001$. The number of days on which application of the second recommendation was not needed did not differ between groups, $F(1, 234) = .85, p > .05$, or over time, $F(5, 230) = 1.67, p > .05$; however, the preference group reported a slightly higher number of days on which this recommendation was not needed than the random group in the last 4 weeks of treatment. For the third recommendation, taking a nap in bed, there was no statistically significant effect for group, $F(1, 234) = 2.39, p > .05$, or time, $F(5, 230) = .64, p > .05$, even though the mean values were consistently lower for the preference group as compared to the random group across the 6 weeks of treatment. The number of days on which the third recommendation was not needed did not differ between groups, $F(1, 234) = .38, p > .05$, or over time, $F(5, 232) = .72, p > .05$.

Table 2 Between-Group Mean Scores on Enactment of Therapy Recommendations Across Treatment Period												
Recommendation	Week 1		Week 2		Week 3		Week 4		Week 5		Week 6	
	R	P										
Use bed to sleep only: number of days applied	6.4	6.1	6.4	6.2	6.4	6.1	6.5	6.2	6.4	6.2	6.3	6.4
Use of bed to sleep only: number of days not applicable	.05	.23	.06	.14	.06	.20	.05	.23	.05	.19	.06	.15
Get out of bed: number of days applied	2.0	1.9	1.7	1.7	1.9	1.6	1.7	1.3	1.7	1.5	1.6	1.5
Get out of bed: number of days not applicable	2.3	2.3	2.7	2.8	2.6	3.0	2.9	3.2	2.8	3.3	2.8	3.1
Take nap in bed: number of days applied	1.0	0.7	0.9	0.6	0.9	0.6	0.8	0.6	0.8	0.5	0.7	0.4
Take nap in bed: number of days not applicable	4.9	5.0	4.7	5.0	4.7	4.8	5.0	5.3	5.0	5.1	5.2	5.2

Legend: R = Random group; P = Preference group

On average, participants reported applying approximately seven of the 13 sleep hygiene recommendations after treatment completion. The mean number of recommendations applied was 6.8 for the random group and 6.7 for the preference group, $F(1,234) = .04, p > .05$. In addition, there was no significant between-group difference in post-treatment self-reported compliance, $F(1,205) = 1.85, p > .05$. The mean score was 3.1 for the random group and 2.9 for the preference group, reflecting an above-average level of self-reported compliance with treatment.

Discussion

This study extends previous research investigating the influence of participants' preferences for treatment on adherence to treatment by examining two aspects of adherence: exposure to and enactment of treatment. Exposure was assessed using the number of planned intervention sessions attended by participants, consistent with previous studies. Enactment was indicated by participants' reported application of specific treatment recommendations and overall compliance with treatment, which were not systematically evaluated in previous studies. Overall, exposure to and enactment of behavioural therapy for insomnia were comparable for those who were randomized and those who were allocated to the preferred treatment, even though the latter group showed a slightly higher degree of enactment of the therapy recommendations over the 6 weeks of treatment. The results are consistent with the findings of three studies (Dobscha et al., 2007; Hitchcock Noël et al., 1998; Mergl et al., 2011), indicating that accounting for treatment preferences is not associated with enhanced adherence to treatment. Taken together, these results contradict those found in seven studies (Bedi et al., 2000; Chilvers et al., 2001; Hunot et al., 2007; Janevic et al., 2003; Kwan et al., 2010; Macias et al., 2005; Raue et al., 2009) and imply that participants receiving their preferred treatment exhibit higher levels of adherence than those not allocated to their treatment of choice. There are four possible explanations for the inconsistency of findings related to the contribution of treatment preferences to adherence.

First, differences in the target population and the treatments under evaluation could account for the inconsistent findings. Persons who experience a pervasive and burdensome clinical problem that affects usual functioning and many domains of health, such as insomnia, for a long time may encounter challenges in initiating, engaging in, and adhering to treatment, particularly if the treatment is demanding. For instance, the participants in the present study reported clinical insomnia of moderate severity for an average of 11 years. Chronic insomnia is associated with negative consequences, including daytime fatigue, which impairs physical,

psychological, and social functioning (Bootzin & Epstein, 2011). Thus participants may have felt that they lacked the energy and motivation needed to attend all treatment sessions and apply all treatment recommendations. The implementation of behavioural therapy for insomnia demands much effort to modify the way one approaches sleep, the bedroom environment (e.g., light, noise), general daily habits (e.g., activity, caffeine intake), and sleep habits (e.g., getting out of bed if not asleep, consistent wake-up time) (Epstein & Bootzin, 2002). Participants who were not willing to initiate and maintain these changes, or who desired a “quick fix” for their sleep problem (Epstein, Babcock-Parziale, Haynes, & Herb, 2012), may have withdrawn from the study. Consequently, those who remained in the study and completed post-test measures may represent a biased sample comprising individuals in desperate need of treatment and willing to expend much effort to apply treatment recommendations in order to manage their insomnia. This is suggested in the observed mean values on the indicators of exposure to and enactment of treatment, implying moderate to high levels of attendance at the sessions and application of specific therapy recommendations for both groups (random and preference).

Second, it is possible that participants randomized to the behavioural therapy preferred this treatment. If so, this subgroup of participants received treatment congruent with their preference, which contributed to their initiation of and adherence to treatment. The size of this subgroup may have affected the magnitude of the difference in adherence levels between the random and preference groups (Sidani & Braden, 2011). If a large number of those in the random group received congruent treatment, then they were satisfied with the allocated treatment and were eager to apply and follow its recommendations. Their performance would not differ from that of participants allocated to their preferred treatment, thereby reducing the power to detect significant between-group (random and preference) differences in adherence. This explanation is highly plausible, because 82% of the sample were randomized to the behavioural therapy for which they expressed a preference. Conversely, it is possible that those allocated to behavioural therapy on the basis of their choice were dissatisfied with it. In other words, although members of this subgroup were given the treatment they desired, they may not have evaluated it favourably once exposed to it. For instance, they may have disliked its constituent activities (e.g., group discussion) or may have viewed its specific recommendations (e.g., maintaining a consistent wake-up time) as incongruent with their lifestyle. Accordingly, they would not have attended all treatment sessions or applied all treatment recommendations, as proposed by Huibers et al. (2004) and Kiesler and Auerbach (2006). The association of satisfaction with adherence to

treatment should be investigated in future research on the influence of treatment preferences.

Third, the data on enactment were obtained through self-report. This method of data collection is prone to bias. Specifically, participants may have indicated that they were following the treatment recommendations during the 6 weeks of treatment because they were aware that the researchers and therapists were reviewing their sleep diary, which was necessary to determine the total sleep time to prescribe. Therefore, they may have wanted to draw a positive image of themselves or to please the therapists, which may have resulted in social desirability bias and an overestimate of their adherence level. The participants' post-treatment self-report regarding application of the recommendations and overall compliance with treatment could be tainted by recall bias, in addition to social desirability bias. Other means of assessing enactment of treatment, such as report by objective measures and participants' significant other or bed partner, should be explored to improve the validity of adherence measurement. Further, measurement of enactment could be expanded to capture the extent to which the treatment recommendations are applied correctly, as suggested by Borrelli et al. (2005), and there is still a need to apply these throughout the treatment period, as was done in this study. The correct and consistent application of insomnia treatment recommendations, such as getting out of bed if one cannot fall asleep or fall back to sleep, yields improvement in the early weeks of treatment; this improvement, manifested in consolidated sleep, reduces the need to apply the treatment recommendation. This may explain the study findings indicating that participants who received the behavioural therapy on the basis of preference, as compared to those who were randomized, reported a slightly higher number of days on which the recommendations were not needed.

Last, the persons with insomnia who participated in the study could represent a selective subgroup of the target population. It is possible that non-adherent participants withdrew from the study for various reasons, including dislike of using the diary (capturing sleep and treatment enactment data). Therefore, participants in the study could be characterized as adherent.

The findings suggest that allocation of participants to the treatment of choice may not significantly enhance exposure to behavioural therapy for the management of chronic insomnia, but may contribute to slightly higher enactment of treatment recommendations early in the treatment period. Also, the results highlight areas for further investigation to elucidate the contribution of preferences to adherence. It is important to assess participants' evaluation of and satisfaction with the allocated treatment, in the random and preference groups, and to determine the extent to

which satisfaction influences adherence to treatment directly or mediates the relationship between treatment preferences and adherence, as suggested by Bradley (1993). The validity of the findings on adherence would be greatly enhanced if the concept's key aspects, exposure and enactment, were to be measured using a mix of self-report, reports of others, and objective measures. In addition, a comprehensive assessment of enactment should cover not only the application of the recommendations pertaining to each treatment component, but also the extent to which the recommendations were applied correctly.

Conclusions

The results of this study show that accounting for preferences in allocating participants to treatment, in the context of a trial, does not significantly improve adherence to treatment. Conceptual and methodological factors may have contributed to the findings and should be further investigated to elucidate the mechanism through which preferences affect exposure to and enactment of treatment.

References

- Bedi, N., Chilvers, C., Churchill, R., Dewey, M., Duggan, C., Fielding, K., . . . Williams, I. (2000). Assessing effectiveness of treatment of depression in primary care: Partially randomized preference trial. *British Journal of Psychiatry, 177*, 312–318.
- Bootzin, R. R., & Epstein, D. R. (2011). Understanding and treating insomnia. *Annual Review of Clinical Psychology, 7*, 435–458.
- Borrelli, B., Sepinwall, D., Ernst, D., Bellg, A. J., Czajkowski, S., Breger, R., . . . Ogedegbe, G. (2005). A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health behaviour research. *Journal of Consulting and Clinical Psychology, 73*(5), 852–860.
- Bradley, C. (1993). Designing medical and educational intervention studies. *Diabetes Care, 16*(2), 509–518.
- Brawley, L. R., & Culos-Reed, N. (2000). Studying adherence to therapeutic regimens: Overview, theories, recommendations. *Controlled Clinical Trials, 21*(5 Suppl), 156S–163S.
- Burgio, L., Corcoran, M., Lichstein, K. L., Nichols, L., Czaja, S., Gallagher-Thompson, D., . . . Schulz, R. (2001). Judging outcomes in psychosocial interventions for dementia caregivers: The problem of treatment implementation. *Gerontologist, 41*(4), 481–489.
- Buysse, D. J., Ancoli-Israeli, S., Edinger, J. D., Lichstein, K. L., & Morin, C. M. (2006). Recommendations for a standard research assessment of insomnia. *Sleep, 29*(9), 1155–1173.
- Chilvers, C., Dewey, M., Fielding, K., Gretton, V., Miller, P., Balmer, B., . . . Harrison, G. (2001). Antidepressant drugs and generic counselling for treat-

- ment of major depression in primary care: Randomized trial with patient preference arms. *British Medical Journal*, 322(7289), 772–775.
- Cohen, J. (1992). A power primer. *Psychological Bulletin*, 112(1), 155–159.
- Corrigan, P. W., & Salzer, M. S. (2003). The conflict between random assignment and treatment preference: Implications for internal validity. *Evaluation and Program Planning*, 26(2), 109–121.
- Derogatis, L. R., & Melisaratos, N. (1983). The Brief Symptom Inventory: An introductory report. *Psychological Medicine*, 13(3), 595–605.
- DiMatteo, R., Giordani, P. J., Lepper, H. S., & Croghan, T. W. (2002). Patient adherence and medical treatment outcomes: A meta-analysis. *Medical Care*, 40(9), 794–811.
- Dobscha, S. K., Corson, K., & Gerrity, M. S. (2007). Depression treatment preferences of VA primary care patients. *Psychosomatics*, 48(6), 482–488.
- Epstein, D. R., Babcock-Parziale, J. L., Haynes, P. L., & Herb, C. A. (2012). Insomnia treatment acceptability and preferences of male Iraq and Afghanistan combat veterans and their healthcare providers. *Journal of Rehabilitation Research and Development*, 49(6), 867–878.
- Epstein, D. R., & Bootzin, R. R. (2002). Insomnia. *Nursing Clinics of North America*, 37(4), 611–631.
- Folstein, M., Folstein, S., & McHugh, P. (1975). Mini-Mental State: A practical method for grading the cognitive state of patients for the clinician. *Journal of Psychiatric Research*, 12(3), 189–198.
- Gelhorn, H. L., Sexton, C. C., & Classi, P. M. (2011). Patient preferences for treatment of major depressive disorder and the impact on health outcomes: A systematic review. *Primary Care Companion for CNS Disorders*, 13(5), ii. doi: 10.4088/PCC.11r01161
- Gibson, C. M. (2003). Privileging the participant: The importance of sub-group analysis in social welfare evaluations. *American Journal of Evaluation*, 24(4), 443–469.
- Hitchcock Noël, P., Marsh, G., Larme, A. C., Correa, A., Meyer, J., & Pugh, J. A. (1998). Patient choice in diabetes education curriculum. *Diabetes Care*, 21(6), 896–901.
- Howard, L., & Thornicroft, G. (2006). Patient preference and randomized controlled trials in mental health research. *British Journal of Psychiatry*, 188, 303–304.
- Huibers, M. J. H., Bleijenberg, G., Beurskens, A. J. H. M., Kant, I., Knottnerus, J. A., van der Windt, D. A., . . . van Schayck, C. P. (2004). An alternative trial design to overcome validity and recruitment problems in primary care research. *Family Practice*, 21(2), 213–218.
- Hunot, V. M., Horne, R., Leese, M. N., & Churchill, R. C. (2007). A cohort study of adherence to antidepressants in primary care: The influence of antidepressant concerns and treatment preferences. *Primary Care Companion Journal Clinical Psychiatry*, 9(2), 91–99.
- Janevic, M. R., Janz, M. K., Dodge, J. A., Lin, X., Pan, W., Sinco, B. R., & Clark, N. M. (2003). The role of choice in health education intervention trials: A review and case study. *Social Science and Medicine*, 56(7), 1581–1594.

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- Kiesler, D. J., & Auerbach, S. M. (2006). Optimal matches of patient preferences for information, decision-making and interpersonal behavior: Evidence, models, and interventions. *Patient Education and Counseling*, 61(3), 319–341.
- Kwan, B. M., Dimidjian, S., & Rizvi, S. L. (2010). Treatment preferences, engagement, and clinical improvement in pharmacotherapy versus psychotherapy for depression. *Behavior Research and Therapy*, 48(8), 799–804.
- Leykin, Y., DeRubeis, R. J., Gallop, R., Amsterdam, J. D., Shelton, R. C., & Hollon, S. D. (2007). The relation of patients' treatment preferences to outcome in a randomized clinical trial. *Behavior Therapy*, 38(3), 209–217.
- Macias, C., Barreira, P., Hargreaves, W., Bickman, L., Fisher, W., & Aronson, E. (2005). Impact of referral source and study applicants' preference for randomly assigned service on research enrollment, service engagement, and evaluative outcomes. *American Journal of Psychiatry*, 162(4), 781–787.
- Martin, K. A., Bowen, D. J., Dunbar-Jacob, J., & Perri, M. G. (2000). Who will adhere? Key issues in the study and prediction of adherence in randomized controlled trials. *Controlled Clinical Trials*, 21(5 Suppl), 195S–199S.
- Mergl, R., Henkel, V., Allgaier, A. K., Kramer, D., Hautzinger, M., Kohen, R., . . . Hegerl, U. (2011). Are treatment preferences relevant in response to serotonergic antidepressants and cognitive-behavioral therapy in depressed primary care patients? Results from a randomized controlled trial including a patients' choice arm. *Psychotherapy and Psychosomatics*, 80(1), 39–47.
- Morin, C. M., Belleville, G., Bélanger, L., & Ivers, H. (2011). The Insomnia Severity Index: Psychometric indicators to detect insomnia cases and evaluate treatment response. *Sleep*, 34(5), 601–608.
- Pallesen, S., Nordhus, I. H., Kvale, G., Nielsen, G. H., Havik, O. E., Johnsen, B. H., & Skjotskift, S. (2003). Behavioral treatment of insomnia in older adults: An open clinical trial comparing two interventions. *Behavior Research and Therapy*, 41(1), 31–48.
- Preference Collaborative Review Group. (2009). Patients' preferences within randomized trials: Systematic review and patient level meta-analysis. *British Medical Journal*, 338(7686), a1864.
- Raue, P. J., Schulberg, H. C., Heo, M., Klimstra, S., & Bruce, M. L. (2009). Patients' depression treatment preferences and initiation, adherence, and outcome: A randomized primary care study. *Psychiatric Services*, 60(3), 337–343.
- Rowe, G., Lambert, N., Bowling, A., Ebrahim, S., Wakeling, I., & Thomson, R. (2005). Assessing patients' preferences for treatment for angina using a modified repertory grid method. *Social Science and Medicine*, 60(11), 2585–2595.
- Sidani, S., & Braden, C. J. (2011). *Design, evaluation, and translation of nursing interventions*. Ames, IA: Wiley-Blackwell.
- Sidani, S., Epstein, D. R., Bootzin, R. R., Moritz, P., & Miranda, J. (2009). Assessment of preferences for treatment: Validation of a measure. *Research in Nursing and Health*, 32(4), 419–431.
- Sidani, S., Epstein, D., Bootzin, R., Moritz, P., & Sechrest, L. (2007). *Alternative methods for clinical research: Final report*. Bethesda, MD: National Institutes of Health/National Institute of Nursing Research.

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- TenHave, T. R., Coyne, J., Salzer, M., & Katz, I. (2003). Research to improve the simple randomized clinical trial. *General Hospital Psychiatry, 25*(2), 115–123.
- Wilbur, J., Chandler, P., & Miller, A. M. (2001). Measuring adherence to a women's walking program. *Western Journal of Nursing Research, 23*(1), 8–32.
- Winter, S. E., & Barber, J. P. (2013). Should treatment for depression be based more on patient preference? *Patient Preference and Adherence, 7*, 1047–1057.

Acknowledgements

This study was funded by the National Institutes of Health/National Institute of Nursing Research (NR05075) and was partially supported by resources provided by the Phoenix Veterans Affairs Health Care System.

Statement: The contents do not represent the views of the Department of Veterans Affairs or the United States Government.

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