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The Contribution of Treatment Allocation Method to Outcomes in Intervention Research

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The purpose of this methodological study was to examine the contribution of treatment allocation method (random vs. preference) on the immediate, intermediate, and ultimate outcomes of a behavioural intervention (MCI) for insomnia. Participants were allocated to the MCI randomly or by preference. Outcomes were assessed before, during, and after completion of the MCI using validated self-report measures. Analysis of covariance was used to compare the post-test outcomes for the 2 groups, controlling for baseline differences. Compared to those randomized, participants in the preference group showed improvement in most immediate outcomes (sleep onset latency, wake after sleep onset, sleep efficiency), both intermediate outcomes (insomnia severity and daytime fatigue), and one ultimate outcome (resolution of insomnia). Using a systematic method for eliciting participants' preferences and involving participants in treatment selection had a beneficial impact on immediate and intermediate outcomes. Additional research should validate the mechanism through which treatment preferences contribute to outcomes.

Keywords: treatment preferences, randomization, preference allocation, behavioural therapy, insomnia, immediate outcomes, intermediate outcomes, ultimate outcomes, methodology, intervention research

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Résumé

L'incidence de la méthode d'attribution des traitements sur les résultats en matière de recherche sur les interventions

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La présente étude méthodologique vise à analyser l'incidence de la méthode d'attribution des traitements (aléatoire ou fondée sur les préférences) sur les résultats immédiats, intermédiaires et ultimes d'une intervention comportementale (MCI) destinée à traiter l'insomnie. Les participants se sont vu attribuer une MCI selon une méthode aléatoire ou fondée sur les préférences. Les résultats ont été analysés avant, pendant et après la fin de la thérapie à l'aide d'un instrument d'autoévaluation validé. Une analyse de la covariance a servi à comparer les résultats au post-test des deux groupes en tenant compte des différences de départ. La comparaison montre une amélioration chez les sujets du groupe avec attribution fondée sur les préférences en ce qui concerne la plupart des résultats immédiats (latence du sommeil, temps d'éveil après l'endormissement, efficacité du sommeil), les deux résultats intermédiaires (gravité de l'insomnie, fatigue diurne) et un résultat ultime (résolution des problèmes d'insomnie). Le fait d'avoir recouru à une méthode systématique pour amener les sujets à exprimer leurs préférences et à les faire participer au choix du traitement a eu un effet bénéfique sur les résultats immédiats et intermédiaires. D'autres recherches devraient permettre de valider le mécanisme par lequel les préférences en matière de traitement contribuent aux résultats.

Mots clés : préférences en matière de traitement, répartition aléatoire, attribution fondée sur les préférences, thérapie comportementale, insomnie, résultats immédiats, résultats intermédiaires, résultats ultimes, méthodologie, recherche sur les interventions

Introduction

There is increasing recognition that preferences for treatment affect the achievement of hypothesized outcomes in intervention evaluation research (Floyd & Moyer, 2010; Howard & Thornicroft, 2006). Allocation of participants to their preferred treatment is an alternative to randomization that provides a means for determining the contribution of preferences to outcomes. It also represents what takes place in the context of practice: patients want to be informed of treatments available to address their presenting health problem, to be actively involved in treatment-related decisions, and to select the treatment that is congruent with their preferences (van der Wejden et al., 2010). This methodological study investigated the influence of the method of treatment allocation (random vs. by preference) on the outcomes of a behavioural therapy for the management of chronic insomnia.

Mechanism Underlying the Influence of Treatment Preferences on Outcomes

Participants in a randomized clinical trial may have preferences for the treatments (experimental or comparison) under evaluation. Results of descriptive studies indicate that 60% to 100% of participants have preferences for the medical, surgical, or behavioural interventions investigated (e.g., Preference Collaborative Review Group, 2009). They enrol in the trial with the hope of receiving the preferred treatment. With randomization, participants are allocated to either the preferred or the non-preferred treatment. These two subgroups of participants react differently and their reactions affect outcome achievement. The first subgroup reacts favourably: participants are enthusiastic because they receive the desired treatment; they are motivated to engage in and adhere to it. Adherence induces the hypothesized improvement in outcomes. In contrast, the second subgroup responds unfavourably: participants are dismayed because they are deprived of the desired treatment; they may withdraw from treatment or become less motivated to engage in and adhere to it, yielding less than optimal outcome achievement (Leykin et al., 2007; Sidani, Miranda, Epstein, & Fox, 2009).

Designs Used to Examine the Influence of Treatment Preferences on Outcomes

Two research designs have been used to examine the influence of treatment preferences on outcomes: the randomized controlled trial (RCT), and the preference or partially randomized clinical trial (PRCT). In the RCT, participants' preferences for the treatments under evaluation are

assessed at baseline, prior to randomization. At the stage of data analysis, participants are categorized as having received a matched (i.e., congruent with their preference) or mismatched (i.e., incongruent with their preference) treatment. The match–mismatch variable is considered a between-subject factor, similar to the treatment group variable, in the outcome analysis. Significant match main effect and match-by-treatment interaction effect determine the contribution of treatment preferences to outcomes.

In the PRCT, participants indicate their preferences at baseline. Those expressing a preference are allocated to the chosen treatment and those without a preference are randomized to treatment. Significant method of treatment allocation main effect and method of allocation-by-treatment interaction effect provide evidence of the extent to which preferences affect the outcomes (Preference Collaborative Review Group, 2009).

A limited number of studies applied the PRCT to investigate the influence of treatment preferences (Winter & Barber, 2013), raising the question: To what extent is the act of choosing treatment (as is done in the PRCT and in the context of practice), compared to random allocation to treatment (as is done in the RCT), advantageous in producing the hypothesized improvement in the outcomes? This question was addressed in this methodological study by comparing the outcomes for participants who received the same behavioural therapy on the basis of chance (i.e., random) or preference (i.e., act of choosing).

Evidence Supporting the Influence of Treatment Preferences on Outcomes

The influence of treatment preferences on outcomes has been investigated in several individual studies involving medical, surgical, psychoeducational, behavioural, and physical therapies for the management of various presenting health problems, such as obesity, chronic pain, diabetes, and depression. The findings were synthesized in one systematic review and three meta-analyses. The results of the systematic review (King et al., 2005) and two meta-analyses (Preference Collaborative Review Group, 2009; Swift, Callahan, & Vollmer, 2011) supported the benefits of providing treatments that are congruent with participants' preferences; these participants demonstrated improvement in the outcomes, which was of a small-moderate magnitude, evidenced by a mean effect size (Cohen's d coefficient) of .15 (95% confidence interval: .01–.31) (Preference Collaborative Review Group, 2009) and .31 (95% confidence interval: .20–.43) (Swift et al., 2011). In contrast, Gelhorn, Sexton, and Classi (2011) found that preferences for depression treatments had minimal impact on outcomes.

The inconsistent findings could be related to across-studies differences in the type of health problem, population, and treatment under investigation as well as the method used to assess treatment preferences. The method for assessing preferences was often not clearly described and could have resulted in the expression of ill-informed preferences that do not accurately reflect participants' choice of treatment (Bowling & Rowe, 2005). In the present methodological study, a systematic method was used to elicit preferences (Sidani, Epstein, Bootzin, Moritz, & Miranda, 2009), and therefore to enhance the congruence between the desired and allocated treatment.

Study Aims

The aim of this study was to determine the contribution of treatment allocation method (random vs. preference) to outcome achievement. Three categories of outcomes were investigated: immediate, intermediate, and ultimate. Immediate outcomes are the changes in participants' condition that are directly impacted by the intervention. Intermediate outcomes represent changes that follow from the achievement of the immediate outcomes and that contribute to the ultimate outcomes — that is, they mediate the intervention's effects. Ultimate outcomes operationalize the goals that the treatment is set to achieve (Rosen & Proctor, 1978).

Methods

Design

The study was part of a large trial that evaluated the utility of different designs in maintaining the validity and enhancing the clinical relevance of conclusions reached in intervention research (Sidani, Epstein, Bootzin, Moritz, & Sechrest, 2007). The large trial included two treatments: the multi-component behavioural therapy, and sleep education and hygiene for the management of chronic insomnia. Assignment to treatment took place after eligible, consenting persons completed baseline measures. Randomization was done with sealed envelopes that were opened in the presence of participants to identify the treatment they were to receive. Allocation on the basis of preference was guided by participants' responses to the Treatment Acceptability and Preference (TAP) scale (Sidani, Epstein, et al., 2009), which revealed their desired treatment.

The data set selected for this methodological study pertained to participants who were allocated to the treatment — that is, the multicomponent behavioural intervention (MCI), either randomly or by preference, and provided post-test outcome data. This decision was made to investigate the main effect of method of treatment allocation on out-

comes, controlling for the potentially confounding influence of treatment type and attrition. Furthermore, differences in baseline variables were anticipated due to self-selection into treatment for participants assigned to the preferred treatment. Therefore, personal characteristics showing differences between the two groups of participants (i.e., assigned randomly or by preference), as well as the pre-test outcomes, were considered covariates in the outcome analysis, in order to control their influence on the post-treatment outcomes.

Sample

Persons with chronic insomnia were eligible if they (1) were community-dwelling, non-institutionalized adults (age 21 or older); (2) were able to read and write English; (3) complained of difficulty falling asleep and/or difficulty staying asleep of ≥ 30 minutes per night, experienced for ≥ 3 nights per week as reported in the 14-day sleep diary kept by participants at pre-test; and (4) experienced insomnia for 3 or more months. The exclusion criteria were sleep apnea (as reported by participants), cognitive impairment (indicated by a score < 27 on the Mini-Mental State Exam; Folstein, Folstein, & McHugh, 1975), and psychological impairment (as ascertained with a Global Severity Index T score > 50 on the Brief Symptom Inventory; Derogatis & Melisaratos, 1983).

A total of 257 participants were selected for this methodological study; 161 were in the random group and 96 in the preference group. This sample size allowed for the detection of between-group differences in the post-treatment outcomes of a moderate magnitude, setting beta at .80 and p at .05 (Cohen, 1992). The statistical control of respective covariates increased the power to detect differences between the random and preference groups.

Intervention

The MCI consisted of three components: sleep education and hygiene, stimulus control therapy, and sleep restriction therapy. Sleep education and hygiene provides information about factors that affect sleep and contribute to insomnia (which is foundational to understanding the remaining treatment recommendations) and about strategies that are implemented during the day (e.g., engagement in physical activity) and around bedtime (e.g., avoiding caffeine and nicotine) to promote sleep. Stimulus control therapy consists of six instructions, such as getting out of bed if cannot fall asleep or go back to sleep within 15 to 20 minutes and waking up at the same time every day; the aim is to re-associate the bed and bedroom with sleepiness. Sleep restriction therapy consists of limiting the time spent in bed to the individual's sleep time and developing a consistent sleep–wake schedule. The MCI was given in

six sessions, once a week over a 6-week period. It has demonstrated effectiveness in reducing the perceived insomnia severity and improving sleep parameters (Morin et al., 2006). Participants' attendance at the MCI sessions was high, with a mean number of 5.7 sessions attended.

Variables and Measures

Personal characteristics. Participants' age, gender, marital status, level of education, employment, and race were assessed using standard questions. Type and duration of insomnia were assessed with relevant items from the Insomnia Interview Schedule (Morin, 1993).

Immediate outcomes. The immediate outcomes for the MCI were the following sleep parameters: (1) sleep onset latency (SOL), representing the length of time, in minutes, it takes to fall asleep; (2) wake after sleep onset (WASO), quantifying the length of time, in minutes, spent awake across all awakenings; (3) total sleep time (TST), referring to the total time, in minutes, spent asleep; and (4) sleep efficiency, reflecting the percentage of the total time in bed actually asleep. The sleep parameters were self-reported with the daily sleep diary kept for 14 days at pre-test, over the 6 weeks of treatment, and for 14 days at post-test. Participants completed the sleep diary upon awakening and returned their responses to a voicemail service daily, to minimize recall bias. The sleep diary is reliable and valid, evidenced by correlation with results of actigraphy (Morin, 1993). The daily sleep parameters were computed from relevant diary data.

Intermediate outcomes. The intermediate outcomes for the MCI included perceived insomnia severity and daytime fatigue. Insomnia severity was measured using the Insomnia Severity Index (ISI; Morin, 1993). It contains seven items related to the nature, severity, and impact of insomnia. A five-point response format is used, ranging from *not at all* (0) to *very much* (4). The interpretation of the total scale score is as follows: a score in the range of 0 to 7 represents no clinically significant insomnia; 8 to 14, sub-threshold insomnia; 15 to 21, clinical insomnia of moderate severity; and 22 to 28, clinical insomnia of high severity (Bastien, Vallières, & Morin, 2001). The ISI has excellent psychometric properties (Morin, Belleville, Bélanger, & Ivers, 2011).

Daytime fatigue was assessed using the Vitality subscale of the Medical Outcome Study, Short Form (SF36). The subscale consists of four items related to the perceived level of tiredness and energy. The transformed score was computed; it ranged from 0 to 100, with high scores representing high vitality. In this study the subscale's items were internally consistent (Cronbach's alpha = .86).

Ultimate outcomes. The ultimate outcomes expected for the MCI were functional status and resolution of the insomnia problem, as

reported by participants. Physical, psychological, and social functioning were measured using the respective subscales of the Medical Outcome Study, Short Form (SF36). Transformed scores, ranging from 0 to 100, were computed for each subscale. Higher scores indicated better functioning. These subscales have demonstrated good reliability and validity in different populations (Ware, Snow, Kosinski, & Gandek, 1993). In this study the Cronbach's alpha coefficient was .78 for the physical and psychological function subscales and .86 for the social function subscale.

Perceived resolution of the insomnia problem was measured using one item, at post-test only. The item stated: Do you still have a problem with insomnia? The response options were *not at all* (0), *a little* (1), *somewhat* (2), *much* (3), and *very much* (4).

Treatment preference. The TAP scale (Sidani, Epstein, et al., 2009) was administered to elicit participants' preference for the treatments. The TAP scale contains (1) a description of the treatment under evaluation — the description specifies the name of the treatment (i.e., MCI), what it is set to achieve, the activities in which the participants engage, the treatment recommendations to follow, the schedule of its delivery, its effectiveness in managing insomnia, and side effects; (2) a set of items for participants to rate their perception of the extent to which the MCI is appropriate and effective in addressing their sleep problem and the extent to which they are willing to comply with it; and (3) an item inquiring about their preference for the treatments. The TAP scale has demonstrated acceptable psychometric properties (Sidani, Epstein, et al., 2009).

Procedure

The study protocol was approved by the Institutional Review Board at the participating sites. Persons with insomnia were recruited through advertisements in local newspapers and the distribution of flyers at community health and sleep clinics. Interested persons phoned the study research office and the research assistant informed them of the study requirements. After securing oral consent, the research assistant administered the screening questionnaire and mailed them copies of the daily sleep diary to determine their eligibility. Eligible persons attended a data-collection session at the study office, during which they provided written consent and completed the pre-test measures. Participants were then allocated to the MCI randomly or by preference. They attended the treatment sessions and completed the daily sleep diary over the 6 weeks of treatment. Trained therapists, including graduate students, postdoctoral fellows, and advanced practice nurses, facilitated the treatment sessions. Two weeks after treatment completion, participants were mailed a package enclosing the outcome measures and the daily sleep diary and requesting them to

return the completed outcome measures in the return envelope and to phone in their responses daily regarding the sleep diary.

Data Analysis

The sleep parameters were computed from relevant diary data and averaged across the 14 days to quantify the respective values for pre-test and post-test, and across the 7 days to represent the respective weekly values during the treatment period. The total scores for the remaining outcomes were calculated as per available instructions. Frequency and measures of central tendency (mean) and dispersion (standard deviation) were used to describe the personal profile of participants in each group. Independent samples *t* test (for continuous variables) and chi-square test (for categorical variables) examined differences in these characteristics between the random and preference groups. Characteristics showing statistically significant between-group differences, as well as the pre-test outcomes, were considered as covariates in the post-test outcome analyses. Analysis of covariance was used to compare the post-test outcomes between the random and preference groups, controlling for the potential confounding influence of the covariates. Repeated measures analysis of covariance, controlling for the same covariates, was used to compare the sleep parameters assessed over the 6 weeks of treatment for the random and preference groups. In addition, the partial eta^2 (η^2) estimated the magnitude of the time, group, and time x group effects.

Results

Characteristics of Sample

As shown in Table 1, participants were middle-aged, well-educated women. About half of the participants were married and employed. The majority were white. Most participants experienced insomnia manifested as difficulty falling asleep and difficulty staying asleep for an average of 11 years. Participants in the random and preference groups differed in age, sex, and employment status. The preference group comprised more women and younger, employed persons. Since age and employment status were related, age and gender were entered as covariates in the post-test outcome comparisons.

There were no statistically significant differences between the random and preference groups in reported insomnia severity and the sleep parameters assessed at pre-test (all *p*'s > .05). On average, participants' sleep problem was of moderate severity, as indicated by a mean score on the ISI of 17.6 (± 3.9), sleep onset latency of 42.9 minutes (± 30.7), wake after sleep onset of 54.4 minutes (± 33.9), and sleep efficiency of 69.9% (± 10.4).

Table 1 ***Personal Characteristics of Sample***

Characteristic	Total Sample (N = 257)	Random Group (n = 161)	Preference Group (n = 96)
Age (mean years)*	56.0	50.2	59.5
Sex (% women)*	59.5	71.6	52.5
Marital status (% married)	53.3	56.1	48.4
Education (mean years)	15.7	15.7	15.6
Employment status (% employed)*	55.6	72.6	45.1
Race (% white)	90.0	90.2	90.1
Type of insomnia			
Difficulty falling asleep (%)	72.5	73.2	71.9
Difficulty staying asleep (%)	91.5	92.0	91.
Duration of insomnia (mean years)	11.0	10.9	11.3

* $p < .05$

Comparisons on Immediate Outcomes

The adjusted mean scores on the sleep parameters observed for the random and preference groups, over the 6 weeks of treatment and at post-test, are reported in Table 2.

Statistically significant differences between groups over time were found for the sleep parameters. For *sleep onset latency,* only the time x group interaction effect was significant, $F(6,226) = 2.43$, $p = 0.035$, partial $\eta^2 = .01$. Although participants in both groups showed a reduction in this parameter, those in the preference group maintained a lower mean score at post-test than those in the random group. It is interesting to note that, on average, the preference group demonstrated a mean decrease of 6.9 minutes from week 1 of treatment to post-test, whereas the random group exhibited a mean increase of 2.9 minutes over the same period. For *wake after sleep onset,* the time x group interaction effect, $F(6,226) = 3.12$, $p = 0.007$, partial $\eta^2 = .01$, and the group main effect, $F(1,231) = 4.89$, $p = .028$, partial $\eta^2 = .02$, were statistically significant. The same pattern as found for sleep onset latency was observed for wake after sleep onset, in that the preference group reported a decrease in this sleep parameter over the treatment period and at post-test; the mean reduction was 4.0 minutes. The random group showed a decrease in the mean wake-after-sleep-onset score over the 6 weeks of treatment but a

Table 2 ***Adjusted Mean Scores for Sleep Parameters Measured During Treatment Period and at Post-test***

Outcome	Time of Measurement	Random Group	Preference Group
Sleep onset latency	Week 1	24.00	28.34
	Week 2	21.23	22.16
	Week 3	21.34	22.43
	Week 4	20.60	20.62
	Week 5	20.13	19.15
	Week 6	20.88	19.75
	Post-test	26.88	21.44
Wake after sleep onset	Week 1	28.38	26.30
	Week 2	25.79	24.03
	Week 3	27.59	23.51
	Week 4	25.46	21.31
	Week 5	26.09	21.49
	Week 6	24.58	23.10
	Post-test	33.38	22.26
Total sleep time	Week 1	326.45	325.97
	Week 2	345.15	345.84
	Week 3	358.45	354.28
	Week 4	364.79	366.88
	Week 5	373.20	367.76
	Week 6	380.84	369.55
	Post-test	376.72	376.11
Sleep efficiency	Week 1	81.03	80.53
	Week 2	83.11	83.40
	Week 3	83.91	83.89
	Week 4	84.76	85.41
	Week 5	84.68	85.46
	Week 6	85.20	84.43
	Post-test	81.84	85.27

slight increase (5.0 minutes) at post-test. For the *total sleep time,* only the time effect was statistically significant, $F(6, 226) = 7.23$, $p = .001$, partial $\eta^2 = .03$, indicating that the mean score on this sleep parameter increased over time in both groups, by an average of 50 minutes. For *sleep efficiency,* the time x group interaction effect, $F(2,226) = 3.46$, $p = .005$, partial $\eta^2 = .01$, and the time main effect, $F(2,226) = 2.84$, $p = .016$, partial $\eta^2 = .01$, were statistically significant. Participants in the preference group

exhibited an increase in this sleep parameter over the treatment period that was maintained at post-test; the post-test mean score was 4.7 points higher than the mean in week 1 of treatment. Those in the random group reported an increase in sleep efficiency during the treatment period that was not maintained at post-test; at the latter time, the mean score was comparable to that found in week 1 of treatment.

Comparisons on Intermediate Outcomes

The adjusted scores on the intermediate outcomes assessed at post-test are shown in Table 3. There were statistically significant between-group differences in perceived insomnia, $F(1,234) = 15.8$, $p < .001$, partial $\eta^2 = .06$, and daytime fatigue, $F(1,239) = 4.8$, $p = .02$, partial $\eta^2 = .020$. On these outcomes, participants in the preference group improved more than those in the random group.

Comparisons on Ultimate Outcomes

The random and preference groups had comparable levels on two ultimate outcomes measured at post-test: physical function, $F(1,238) = .28$, $p > .05$, and psychological function, $F(1,239) = .35$, $p > .05$, yielding effect sizes (partial η^2) close to zero. The preference group had a slightly higher mean score on social function than the random group, $F(1,239) = 3.1$, $p = .07$, partial $\eta^2 = .013$. In contrast, there was a statistically significant difference in the perceived resolution of insomnia, $F(1,248) = 5.1$, $p = .02$, partial $\eta^2 = .020$; participants in the latter group reported that they experienced the insomnia problem to a lesser extent than those in the random group.

Table 3 ***Adjusted Mean Scores for Outcomes Measured at Post-test***

Category of Outcome	Outcome	Random Group	Preference Group
Immediate	Self-efficacy about sleep	3.1	3.1
Intermediate	Perceived insomnia severity*	12.5	9.8
	Daytime fatigue**	51.6	56.7
Ultimate	Physical function	84.8	85.7
	Psychological function	74.8	75.9
	Social function	79.7	84.3
	Perceived resolution of insomnia**	2.0	1.7
	Health-services utilization	0.8	0.8

* $p \leq .01$, ** $p \leq .05$

Discussion

This study extends previous research related to the contribution of treatment preferences on outcomes, in three ways. First, it provided a group of participants the opportunity to be actively involved in the selection of treatment. Thus, it facilitated the examination of the extent to which the act of choosing treatment influences the achievement of outcomes, whereas previous studies focused primarily on determining the effects of receiving matched treatment (i.e., treatment that is congruent with choice) on outcomes in the context of randomization (Winter & Barber, 2013). Second, a systematic method was used to elicit participants' treatment preference. Therefore, the expressed preferences are well informed, based on evaluation of the treatment attributes, and accurate in reflecting participants' choice. In contrast, reports of previous studies do not detail the method followed for identifying treatment preferences, raising questions about the extent to which the treatment information given to participants was unbiased, easy for lay persons to understand, comprehensive, and useful for participants in making a choice. Also, the expressed preferences accurately represented participants' choice, generated from a careful consideration of the treatment's appropriateness, benefits, and convenience. Third, this study extends previous research by examining the influence of treatment preferences on three outcome categories: immediate, intermediate, and ultimate. This distinction among outcomes accounts, at least partially, for the inconsistent findings related to the influence of treatment preferences on outcomes: it is possible that the intervention and treatment preferences have significant effects, of a moderate magnitude, on the immediate and intermediate outcomes, but non-significant or small effects on the ultimate outcomes. The non-significant effects are anticipated because the intervention has indirect effects on the ultimate outcomes, mediated by improvements in the immediate and intermediate outcomes (MacKinnon & Fairchild, 2009). It is important to note that most outcomes examined in this and other studies were assessed using self-report measures. The extent to which the findings supporting the contribution of treatment preferences to outcome achievement is applicable to objectively measured outcomes (such as sleep parameters assessed with actigraphy) should be explored in future research.

Overall, the findings partially support the advantage of involving participants in treatment selection in enhancing the achievement of the outcomes expected of an intervention. Comparisons on the sleep parameters assessed during the 6 weeks of treatment indicated significant differences in sleep onset latency, wake after sleep onset, and sleep efficiency between the random and preference groups over time and a

significant improvement in total sleep time in both groups. This pattern of results suggests that participants provided with the treatment of their choice are motivated to adhere to its recommendations (Leykin et al., 2007; Sidani, Epstein, et al., 2009). Adherence to the recommendations early on in the treatment period yields improvement in the immediate outcomes, which promotes further adherence and consequently greater improvement in outcomes towards the end of the treatment period. Adherence and experience of positive changes in outcomes, sustained over the treatment period, translated into between-group differences in the three sleep parameters assessed following treatment. At post-test, participants in the preference group demonstrated shorter sleep onset latency and wake after sleep onset, and higher sleep efficiency, than those randomized to the intervention. The effect sizes for these sleep parameters were of a small-to-moderate magnitude. The non-significant group difference in total sleep time during and after the treatment period may be due to the sleep restriction therapy component of the MCI. The active ingredient of sleep restriction therapy consists of limiting the amount of time in bed to the actual sleep time and developing a consistent sleep–wake schedule. It is possible that the total sleep time prescribed to most participants was comparable and adequate to induce the sleep drive that promotes a good night's sleep (Epstein, Sidani, Bootzin, & Belyea, 2012). Such positive experience encourages adherence to treatment and achievement of the outcomes regardless of the participants' initial desire for the intervention.

The preference and random groups differed in perceived insomnia severity and daytime fatigue at post-test. The differences in these intermediate outcomes were of small-to-medium magnitude, favouring participants in the preference group. The observed decrease in insomnia severity and daytime fatigue are to be expected as a result of the improvement in most sleep parameters reported by those in the preference group. In addition, the beneficial changes in insomnia severity and daytime fatigue account for the between-group difference in the ultimate outcome of perceived resolution of the insomnia problem. Participants in the preference group had a lower mean score on this outcome, as compared to those in the random group; however, the difference was of a small magnitude. In contrast, the two groups reported comparable levels of physical, psychological, and social function. This finding is expected, for two interrelated reasons: high levels of improvement in function may not be experienced within a very short span of time (i.e., 2 weeks) following treatment, and may be mediated by a reduction in insomnia severity and daytime fatigue. The interrelationships among the immediate, intermediate, and ultimate outcomes were not examined in this study; they should be investigated in future research to determine the

extent to which providing the preferred treatment promotes initiation of the mechanism underlying its effects. This is done by testing its direct effects on the immediate and intermediate outcomes and its indirect effects on the ultimate outcomes, using path or structural equation modelling analysis (MacKinnon & Fairchild, 2009). The results of such mediational analysis indicate significant direct effects on the immediate and intermediate outcomes, significant association between these and the ultimate outcomes, and non-significant direct effects on the ultimate outcomes.

This study's findings are comparable to those expected in a mediational analysis. There were significant differences between the random and preference groups in three of the five immediate outcomes, in the two intermediate outcomes, and in one of the four ultimate outcomes. This pattern of results may explain the inconsistency in identifying the contribution of treatment preferences to outcomes observed in previous research, whereby studies reporting a significant impact of treatment preferences may have examined immediate and intermediate outcomes and those reporting non-significant effects have investigated their direct effects on ultimate outcomes. Other possible factors accounting for the inconsistency are as follows: (1) the rather small sample size included in individual studies, which may have reduced the power to detect the impact of preferences on outcomes; however, the results of three meta-analyses (Gelhorn et al., 2011; Preference Collaborative Review Group, 2009; Swift et al., 2011) pooling data across studies, and hence large number of participants, demonstrated small-to-moderate effects of treatment preferences on outcomes; (2) the unbalanced distribution of participants who received their preferred treatment across the treatment conditions under evaluation, which prevented any meaningful interpretation of differences in the outcomes assessed at post-test (Leykin et al., 2007); (3) use of instruments with limited psychometric properties for assessing treatment preferences and/or outcomes; and (4) the sample composition, whereby studies that examined the influence of treatment preferences in the context of RCT may have included persons willing to be randomized and/or those expressing no strong preferences for the treatments under investigation, as suggested by Leykin et al. (2007).

Involving participants in the selection of treatment and providing the treatment of their choice in intervention evaluation trials appear to contribute to the achievement of positive outcomes. This conclusion confirms the results of naturalistic studies that examined the influence of patients' participation in treatment-related decisions and that indicated increased satisfaction and comfort with the decision made, as the selected treatment is aligned with their expectations and values (Newman, Charlson, & Temple, 2007); adherence to treatment; and improvement in

outcomes (Bower, Gilbody, Richards, Fletcher, & Sutton, 2006; Dwight-Johnson, Unutzer, Sherbourne, Tang, & Wells, 2010; Konradson, Nielson, Larsen, & Hansen, 2012; Swanson, Bastani, Rubenstein, Meredith, & Ford, 2007).

Although these results demonstrate the benefits of providing the treatment of choice, further research is required to elucidate the exact mechanisms through which treatment preferences affect outcomes. The following interfering factors should be explored before the positive direct influence of treatment preferences on the immediate and intermediate outcomes can be established: (1) the possibility that participation in treatment selection enhances the therapeutic alliance between the therapist and participants, as reported by Kwan, Dimidjian, and Rizvi (2010); this alliance has been found to account for more variance in the post-test outcomes than the treatment itself (Fuertes et al., 2007); (2) the likelihood that participants changed their perception of the chosen treatment after experiencing it, as suggested by Lewis, Napolitano, Whiteley, and Marcus (2006); and (3) participants' expectancies (expectations) that the treatment they desire is effective; Glass, Arnkoff, and Shapiro (2001) found a significant association between expectancies and outcomes in 12 of 24 studies and estimated that expectancies accounted for about half of the effectiveness of psychotherapy. Future research could include a mix of quantitative and qualitative methods to examine the mechanisms underlying the influence of preferences on outcomes, while accounting for possible mediators such as therapeutic alliance and treatment or outcome expectancies.

Conclusion

This study extends previous research on the contribution of treatment preferences to outcome achievement. Use of a systematic method for eliciting participants' preferences and allocating them to the preferred treatment had a beneficial impact on the immediate and intermediate outcomes more than on the ultimate outcomes. Additional investigation is needed to determine the indirect effects of preferences on ultimate outcomes (mediated by improvement in immediate and intermediate outcomes) and to clarify the mechanism through which treatment preferences affect the outcomes, while ruling out possible confounds such as outcome expectancies.

Evidence to date supports the contribution of treatment preferences to outcomes in intervention research. Researchers are encouraged to explore the influence of preferences in studies aimed at evaluating the efficacy of interventions using the RCT design or the effectiveness of interventions applying the PRCT design and valid measures of preferences.

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