CJNR 2015, Vol. 47 Nº 1, 17–34

Attrition in Randomized and Preference Trials of Behavioural Treatments for Insomnia

Souraya Sidani, Richard R. Bootzin, Dana R. Epstein, Joyal Miranda, Jennifer Cousins

Preferences for treatment contribute to attrition. Providing participants with their preferred treatment, as done in a partially randomized clinical or preference trial (PRCT), is a means to mitigate the influence of treatment preferences on attrition. This study examined attrition in an RCT and a PRCT. Persons with insomnia were randomly assigned (n = 150) or allocated (n = 198) to the preferred treatment. The number of dropouts at different time points in the study arms was documented and the influence of participant characteristics and treatment-related factors on attrition was examined. The overall attrition rate was higher in the RCT arm (46%) than in the PRCT arm (33%). In both arms, differences in sociodemographic and clinical characteristics were found between dropouts and completers. The type of treatment significantly predicted attrition (all $p \leq .05$). The results provide some evidence of a lower attrition rate in the PRCT arm, supporting the benefit of accounting for preferences as a method of treatment allocation.

Keywords: treatment preferences, preference trial, attrition, methodology, intervention research

Résumé

Taux d'abandon dans le cadre d'essais de thérapies comportementales contre l'insomnie avec répartition aléatoire et selon les préférences des participants

Souraya Sidani, Richard R. Bootzin, Dana R. Epstein, Joyal Miranda, Jennifer Cousins

Les préférences en matière de traitement influent sur le taux d'abandon. Offrir aux participants le traitement qui correspond à leurs préférences, comme dans le cadre d'un essai clinique avec répartition partiellement aléatoire ou selon les préférences, constitue un moyen d'atténuer l'incidence de la préférence en matière de traitement sur le taux d'abandon. La présente étude examine les taux d'abandon observés lors d'un essai clinique avec répartition aléatoire et d'un essai clinique avec répartition partiellement aléatoire ou selon les préférences. Un groupe de personnes souffrant d'insomnie se sont vu attribuer une thérapie comportementale de façon aléatoire (n = 150) et les membres d'un autre groupe selon leurs préférences (n = 198). Le nombre d'abandons au sein de chacun des groupes a été consigné à différents moments de l'étude, puis une analyse des caractéristiques des participants et des facteurs liés à chaque thérapie a été effectuée afin de déterminer leur influence sur le taux d'abandon. Le taux d'abandon global s'est avéré plus élevé au sein du groupe avec attribution aléatoire de la thérapie (44 %) qu'au sein de l'autre groupe (33 %). Dans les deux groupes, des différences d'ordre sociodémographique et liées à des caractéristiques cliniques ont été observées entre les participants ayant abandonné et ceux qui ont terminé la thérapie. Le type de thérapie suivi permettait de prédire de façon notable s'il y aurait abandon (tout $p \leq 0{,}05$). Les résultats montrent un taux d'abandon moins élevé parmi les participants qui se sont vu attribuer une thérapie selon leurs préférences, ce qui appuie l'hypothèse selon laquelle il y a un avantage à tenir compte des préférences dans la méthode d'attribution des traitements.

Mots-clés : préférences en matière de traitement, essai avec répartition selon la préférence, taux d'abandon, méthode, recherche

Introduction

Attrition or withdrawal of eligible participants before, during, or after exposure to treatment presents a major threat to internal and external validity in randomized clinical trials (RCTs) (Valentine & McHugh, 2007). Attrition is often attributed to personal and clinical characteristics of participants (e.g., education, health status), features of the study (e.g., burdensome procedures), and attributes of the treatment (e.g., complex and inflexible protocols) (Ahern & LeBroque, 2005; Kemmler, Hummer, Widschwendter, & Fleishhacker, 2005). Preferences for treatment have been recently recognized as factors contributing to attrition in an RCT (Preference Collaborative Review Group [PCRG], 2009). Participants may have a preference for the experimental or the comparison treatment. With random assignment, participants are allocated to the preferred or non-preferred treatment. Those assigned to the non-preferred treatment may be disappointed at not receiving the treatment of choice and hence withdraw from the trial (Sidani, Miranda, Epstein, & Fox, 2009). Providing participants with the treatment of choice is a means to mitigate the influence of treatment preferences on attrition, as evidenced in the results of two meta-analyses (PCRG, 2009; Swift, Callahan, & Vollmer, 2011) showing a lower attrition rate for participants assigned to a treatment that is congruent with their preferences (i.e., matched), as compared to participants with mismatched treatment.

Behavioural therapies for managing insomnia have demonstrated efficacy, evidenced by large effect sizes in reducing sleep onset latency and in improving sleep quality and moderate effects sizes in decreasing the length of time awake after sleep onset and in increasing total sleep time (Irwin, Cole, & Nicassio, 2006; Morin et al., 2006). However, trials of behavioural therapies for insomnia are plagued with high attrition rates, estimated at 40% (Ong, Kuo, & Manber, 2008). Recent evidence (Epstein, Sidani, Bootzin, & Belyea, 2012; Hebert, Vincent, Lewycky, & Walsh, 2010) relates withdrawal to participants' characteristics (e.g., health status) and perceptions of the behavioural therapies (e.g., dislike of the treatment). The extent to which attrition is reduced by providing persons with insomnia the behavioural treatment of their choice is not known and was investigated in this two-arm trial.

The arms represented two designs commonly used to determine the influence of treatment preferences: the RCT and the PRCT (partially randomized clinical or preference trial). In the RCT, participants indicate their preference at baseline but are randomized to treatment. The influence of preference is usually examined by categorizing participants into the match subgroup (i.e., received treatment that is consistent with their choice) and the mismatch subgroup (i.e., received non-preferred treat-

ment) and comparing the subgroups on attrition (PCRG, 2009). In the PRCT arm, participants indicate their preference, which then guides their allocation to treatment. Those with no preference are randomly assigned to treatment, whereas those expressing a preference for a particular treatment are allocated to that treatment (for details, see Sidani, Miranda, et al., 2009).

The overall purpose of the trial was to examine attrition and predictors of attrition in the RCT and PRCT arms. The predictors were as follows: participants' demographic, sleep, and psychological characteristics; perceived acceptability of the treatments measured at pre-test; type of treatment to which the participants were assigned; and method of allocation to treatment. These predictors have been found to be associated with attrition in previous studies (e.g., Epstein et al., 2012; Hebert et al., 2010). The study's specific objectives were to (1) describe the attrition rate at different points in time (before, during, and after completion of treatment) and the overall attrition rate in the RCT and PRCT arms; (2) describe the overall attrition rate for the subgroups of participants assigned to each treatment randomly or on the basis of preference; (3) explore reasons for withdrawal reported by participants in the RCT and PRCT arms; (4) compare participants who withdraw and those who complete the study on demographic and clinical characteristics, measured at pre-test, within the RCT and PRCT arms; and (5) examine predictors of attrition in the RCT and PRCT arms of the study.

Materials and Methods

Design

The two-arm trial was conducted at two sites that participated in a large methodological study to evaluate the utility of different research designs in enhancing the validity and clinical relevance of findings in intervention evaluation research (Sidani, Epstein, Bootzin, Mortiz, & Sechrest, 2007). The sites were located at research-intensive universities in large US cities. The application of the same participant eligibility criteria and recruitment strategies was intended to maintain the comparability on pre-test demographic and clinical characteristics of the samples accrued at the two sites. At both sites, the same behavioural treatments for insomnia were implemented by master's-prepared therapists who were given standardized training in the conceptualization and delivery of the treatments and who adhered to the protocol manual in delivering the treatments. Further, the same methods were applied to measure the outcomes at pre-test, post-test, and follow-up.

At both sites, eligible participants completed measures of demographic, psychological, and sleep characteristics at pre-test. After providing

these data, participants completed the Treatment Acceptability and Preference (TAP) scale (Sidani, Epstein, Bootzin, Moritz, & Sechrest, 2009). This scale provides a written description of the behavioural treatments under evaluation and contains items to rate the acceptability of each treatment and questions about treatment preferences. In the RCT arm, participants responded to the items assessing treatment acceptability but were not asked to indicate which treatment they preferred, in order to minimize the ethical consequences of ignoring participants' preferences (PCRG, 2009). Participants were then randomly assigned to treatment, using sequential opaque, sealed envelopes. In the PRCT arm, participants rated the treatments' acceptability and indicated their preferred treatment; those who had no preference were randomly assigned to treatment, whereas those who expressed a preference were allocated to the treatment of choice. A $40 incentive was given to offset transportation costs associated with attending the data collection and treatment sessions at the study office.

The study protocol was approved by the Institutional Research Board at the participating academic institutions. All participants provided informed, written consent prior to enrolment.

Setting and Sample

Persons with chronic insomnia formed the target population. Inclusion criteria were as follows: (1) community-dwelling, non-institutionalized adult 21 years or older; (2) proficiency in English; (3) complaint of difficulty falling asleep and/or maintaining sleep as indicated by sleep onset latency and/or time awake after sleep onset of at least 30 minutes per night, for 3 or more nights per week, ascertained using a sleep diary kept for 14 days at pre-test, and at least 3 months' duration as reported by participants. Exclusion criteria were as follows: self-reported diagnosis of sleep apnea, cognitive impairment reflected in a score of less than 27 on the Mini-Mental State Exam (Folstein, Folstein, & McHugh, 1975), or psychological impairment evidenced by a Global Severity Index T score of over 50 on the Brief Symptom Inventory (Derogatis & Melisaratos, 1983).

Persons with insomnia were recruited through advertisements in local newspapers and newsletters and distribution of flyers and brochures to community health centres and clinics. Persons interested in the study were asked to contact the research office for more information.

Treatment Options

The behavioural treatments for insomnia included sleep education and hygiene (SEH) and multi-component intervention (MCI). SEH provided

information about sleep processes and functions and about general strategies to promote sleep, such as avoiding caffeine at night and nicotine around bedtime. The information was given in a booklet that participants could read at their convenience. SEH was found minimally effective in reducing the severity of insomnia and in improving sleep outcomes, such as sleep efficiency (Morin, Culbert, & Schwartz, 1994). The MCI consisted of stimulus control therapy (SCT) and sleep restriction therapy (SRT), in addition to SEH. The specific instructions making up the SCT focus on developing new sleep habits and rising at the same time every morning, with the goals of re-associating the bed and bedroom with sleep and forming a consistent sleep pattern (Bootzin & Epstein, 2011). SRT restricts the amount of time spent in bed to the person's sleep time identified through the sleep diary maintained at pre-test and developing a consistent sleep–wake schedule (Wohlgemuth & Edinger, 2000). The MCI was administered in four 90-minute group sessions followed by two telephone contacts over a 6-week period. It was found to be effective in reducing the severity of insomnia and improving sleep outcomes (Morin et al., 2006).

Sample Size

The sample size was estimated to detect differences in the sleep outcomes, of a moderate magnitude, between behavioural therapies and method of allocation to treatment (i.e., random and preference). Medium-sized effects (.4–.6) were anticipated on the basis of (1) results of systematic reviews indicating that SEH is a minimally effective treatment and the MCI had moderate-to-large effects on sleep outcomes (Morin et al., 1994), and (2) findings of a meta-analysis showing a low–moderate effect for treatment preferences on outcomes (Swift et al., 2011). Applying Cohen's (1992) criteria for a medium effect size for the treatment and method of treatment allocation comparisons, and setting alpha at .05 and beta at .80, the number of participants needed was 50 per group. The total sample size was 300, distributed as follows: 100 (50 x 2 treatment groups) for the RCT arm and 200 (50 x 2 treatment groups x 2 methods of treatment allocation) for the PRCT arm.

Variables and Measures

Demographic variables. Age, sex, education level, ethnicity, and employment status were assessed using standard questions. Education level was represented by number of years of formal schooling. To balance the distribution across meaningful categories, ethnicity was dichotomized into white and non-white and employment status into employed and non-employed.

Sleep variables. The sleep outcomes included sleep parameters, perceived sleep severity, beliefs about sleep, and self-efficacy about sleep. The sleep parameters were assessed using the sleep diary, completed daily upon awakening and returned to a voice-mail service to minimize recall bias. 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 sleep parameters, computed from relevant diary data, were (1) sleep onset latency (SOL): length of time, in minutes, to fall asleep; (2) wake after sleep onset (WASO): length of time, in minutes, spent awake, over all awakenings; and (3) sleep efficiency (SE): the percentage of the total time in bed actually asleep. Perceived insomnia severity was measured using the Insomnia Severity Index (ISI) (Morin, 1993). The ISI contains seven items that have demonstrated internal consistency reliability and concurrent and construct validity (Morin, Belleville, Bélanger, & Ivers, 2011). Self-efficacy about sleep was measured using the nine-item Self-Efficacy Scale (Lacks, 1987). It inquires about confidence in carrying out sleep-related behaviours, such as feeling relaxed when lying in bed, and demonstrated acceptable reliability (Cronbach's α = .82) in this study.

Psychological variables. The psychological variables included depression and sleep-related anxiety. The Center for Epidemiologic Studies–Depression (CES–D) scale (Radloff, 1977) was used to assess depressive mood. It has established psychometric properties in different populations (Naughton, Shumaker, Anderson, & Czajkowski, 1996). Sleep-related anxiety was measured using the Sleep Anticipatory Anxiety Questionnaire (SAAQ) developed by Bootzin, Shoham, and Kuo (1994). The SAAQ captures pre-sleep cognitive and somatic arousal. It has been found to be reliable and valid (Kuo, Raccioppo, Bootzin, & Shoham, 1994).

Treatment acceptability and preferences. Acceptability and preferences for the SEH and MCI were assessed using the TAP measure, which has been shown to have acceptable psychometric properties (Sidani, Epstein, et al., 2009). The measure presents information on each treatment's goals, activities, mode of delivery, dose, effectiveness, and side effects, followed by items requesting participants to rate the acceptability of each treatment separately, using a five-point scale ranging from *not at all* acceptable (0) to *very* acceptable (4). Participants in the PRCT arm are then asked if they have preferences among the treatments they rate and which treatment they prefer to receive to manage their insomnia.

Attrition. A log was used to track participants' withdrawal from the study at different time points and to document the reasons they gave for dropping out. Attrition rate was computed as the percentage of participants who withdrew after being found eligible and providing written consent and baseline data. Attrition rates were calculated for (1) early withdrawal — that is, after completion of pre-test measures but before exposure to treatment; (2) withdrawal during the 6 weeks of treatment; (3) late withdrawal — that is, after completion of post-test measures but prior to the 3-month follow-up; and (4) overall withdrawal — that is, at any time during the study.

Data Analysis

The sleep parameters were computed from pertinent items of the sleep diary and averaged over the 14-day period at baseline. Total scores were computed for each sleep and psychological characteristic as well as for treatment acceptability. A factorial analysis of variance for continuous variables and a chi-square test for categorical variables were used to determine the comparability of participants' characteristics assigned to SEH and MCI, randomly or by preference, in the RCT and PRCT arms.

To address objective 1, the attrition rates were computed for the RCT and PRCT arms for each time point and across all time points (overall attrition). To address objective 2, the overall attrition rates were estimated for those assigned to the SEH and the MCI randomly or by preference. Chi-square test was used to examine differences in the number of participants who withdrew from the study by arm (RCT vs. PRCT), method of treatment allocation (random vs. preference), and type of treatment (SEH vs. MCI). To address objective 3, the reasons given by participants for dropping out were content analyzed and the number reporting the same reason was calculated. To address objective 4, independent sample *t* test was used to compare participants, within each arm of the study, who did and did not withdraw on pre-test variables. To address objective 5, logistic regression was applied to identify predictors of attrition in both arms of the study (i.e., data from all participants were pooled for this analysis). The predictors were entered into the regression model, using the forced entry method, in three blocks. The first block included treatment-related variables — that is, perceived acceptability, type of treatment, and method of treatment allocation. The second block consisted of sociodemographic characteristics. The third block contained the clinical (i.e., sleep and psychological) characteristics. The Wald test and its associated *p* value and the odds ratio (OR) indicated variables that significantly contributed to attrition in the RCT and PRCT arms.

Results

Attrition Rates

In the RCT arm, 183 persons showing interest in the study agreed to be screened; 33 did not meet all eligibility criteria and 150 were found eligible and provided written consent. The numbers of consenting individuals who withdrew from the trial before, during, and after exposure to treatment are reported in Table 1. The early withdrawal rate was 35.3%, the dropout rate during the treatment period was 2.0%, and the late withdrawal rate was 8.6%. The overall attrition rate was 46%. A total of 97 participants completed the pre-test measures. Of these, 45 (46.3%) were randomized to SEH and 52 (53.7%) to MCI. The percentage who withdrew from the study was 16% for those randomized to SEH and 12.8% for those randomized to MCI.

Table 1 *Number of Withdrawals*

Study Time Point	RCT Arm	PRCT Arm
Number of participants	150	198
Number of withdrawals before treatment (early)	53	35
Number of withdrawals during treatment period	3	16
Number of withdrawals after treatment (late)	13	15
Total number of withdrawals from study	69	66

In the PRCT arm, 224 persons underwent screening; 26 were not eligible and 198 were eligible and consented to participate. The numbers of consenting individuals who withdrew at different time points are presented in Table 1. The early attrition rate was 17.6%, the dropout rate during the treatment period was 8.0%, and the late withdrawal rate was 7.5%. The overall attrition rate was 33.3%. A total of 163 participants completed the pre-test measures. Of these, 31 indicated no preference for the insomnia treatments and were randomly assigned to SEH (n = 15) and MCI (n = 16); the percentages of these participants who withdrew from the study were 20% and 0%, respectively. The remaining participants (n = 132) expressed a preference and were allocated to the chosen treatment: 21 selected SEH and 111 MCI; the percentages of these participants who dropped out were 19.1% and 8.3%, respectively.

Results of the chi-square test comparing the total number of participants who withdrew from the study between the trial arms (RCT vs. PRCT), method of treatment assignment (random vs. preference), and

type of treatment (SEH vs. MCI) indicated no statistically significant differences (all $p > .05$). However, the overall attrition rate was slightly higher in the RCT (46%) than the PRCT (33.3%); this difference is related to the higher early withdrawal rate observed in the RCT (35.3%) compared to the PRCT (17.6%).

Reasons for Withdrawal

In both study arms, most of the participants who dropped out of the study did not return the research assistant's phone call inquiring about their reasons for doing so (30% in the RCT, 43% in the PRCT). The reasons stated by the remaining participants were categorized into characteristics of participants, study, and treatment (Table 2). Some participants gave more than one reason; therefore, the percentages were computed for the total number of reasons provided within each arm. The most frequently stated reasons for withdrawal related to characteristics of participants, representing 37.6% and 46.4% of the reasons given in the RCT and PRCT arm, respectively. Characteristics of the study accounted for 18.1% of the reasons given in the RCT and 12.5% of those given in the PRCT arm. Characteristics of treatment were reported more commonly in the RCT arm (19.4%) than in the PRCT arm (7.1%).

Table 2 ***Reasons for Withdrawal***

Reason	RCT Arm	PRCT Arm
Characteristics of participants		
Too busy	13	10
No longer interested	10	
Relocation	2	7
Health condition	2	7
Improved sleep		2
Transportation	2	
Characteristics of study		
Scheduling conflict	10	5
Inadequate compensation		1
Dislike filling in sleep diary	3	1
Characteristics of treatment		
Demanding	4	
Dislike treatment	5	3
Getting treatment elsewhere	2	
Treatment did not work	4	1

Table 3 *Pre-test Characteristics by Type and Method of Allocation to Treatment Within RCT and PRCT Arms*

	RCT		PRCT			
	Random		Random		Preference	
Characteristic	**SEH**	**MCI**	**SEH**	**MCI**	**SEH**	**MCI**
Number of participants	45	52	15	16	21	111
Age (mean)**	52.4	55.2	45.3	39.8	42.0	49.6
Sex (*n* women)	3	2	3	0	4	7
Marital status (*n* married)	30	25	6	12	11	59
Education (mean years)	15.9	16.7	16.4	16.1	17.6	15.7
Ethnicity (*n* white)	42	45	14	14	16	97
Employment (*n* employed)	83	28	12	15	17	81
SOL (mean)	35.2	45.3	32.2	45.3	37.3	41.3
WASO (mean)*	48.9	56.9	48.1	52.9	36.5	49.7
SE (mean)**	72.4	69.1	74.9	69.6	74.9	71.2
ISI (mean)**	18.2	17.1	13.9	17.7	15.5	17.0
SES (mean)	2.4	2.3	2.6	2.2	2.5	2.4
CES–D (mean)	13.5	11.9	14.6	15.6	10.8	13.1
SAAQ (mean)	2.3	2.2	2.2	2.5	2.2	2.2
Acceptability of MCI (mean)**	2.4	2.6	2.1	2.6	1.9	2.6
Acceptability of SEH (mean)**	2.3	2.1	2.4	2.4	2.7	1.6

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

Legend: SOL = sleep onset latency; WASO = wake after sleep onset; SE = sleep efficiency; ISI = Insomnia Severity Index; CES–D = Center for Epidemiologic Studies–Depression scale; SAAQ = Sleep Anticipatory Anxiety Questionnaire; MCI = multi-component intervention; SEH = sleep education and hygiene

Predictors of Overall Attrition

The predictors of overall attrition included the participants' socio-demographic, sleep, and psychological characteristics and perceived acceptability of the behavioural treatments, measured at pre-test, as well as the treatment assigned and the method of treatment allocation. The average values on these characteristics are presented in Table 3 for the subgroups, in the RCT and PRCT arms, allocated to the SEH and MCI randomly or by preference. Factorial analysis of variance and chi-square test comparing these characteristics by study arm, method of allocation, and type of treatment showed statistically significant differences on five characteristics.

Age. On average, participants in the RCT arm were older than those in the PRCT arm, $F(1, 254) = 13.8$, $p < .01$, $\eta^2 = .05$. Those assigned to the SEH randomly or by preference were younger than those allocated to the MCI using either method, while those in the PRCT randomized to the MCI were the youngest subgroup (i.e., method of treatment allocation x type of treatment interaction effect), $F(1, 254) = 4.2$, $p = .03$, $\eta^2 = .01$.

WASO. The average number of minutes awake after sleep onset differed by type of treatment, $F(1, 253) = 4.8$, $p = .02$, $\eta^2 = .01$; participants assigned to SEH randomly or by preference had a lower mean than those in the MCI.

Sleep efficiency. There was a statistically significant main effect for type of treatment, $F(1, 253) = 6.6$, $p = .01$, $\eta^2 = .02$. Participants allocated to the MCI randomly or by preference reported lower levels of sleep efficiency than those assigned to the SEH using either method.

Perceived severity of insomnia. A statistically significant study arm x type of treatment interaction effect was found, $F(1, 247) = 8.5$, $p = .004$, $\eta^2 = .03$. In the PRCT arm, those allocated to the SEH randomly or by preference perceived lower levels of insomnia severity than those assigned to the MCI by either method.

Treatment acceptability. The perceived acceptability of SEH and MCI differed for participants allocated to these treatments, regardless of the method of treatment allocation and study arm, $F(1, 256) = 20.5$, $p < .01$, $\eta^2 = .07$ for MCI; $F(1, 256) = 18.6$, $p < .01$, $\eta^2 = .06$ for SEH. There was a tendency for participants to rate the assigned treatment as slightly more acceptable than the alternative one; the differences in rating were prominent among participants expressing preferences for the treatments under evaluation.

The extent to which these variables contributed to the overall attrition was examined using logistic regression analysis. The selected predictors were entered in three blocks. In the first block, consisting of treatment-

related variables, only the type of treatment had a statistically significant association with attrition (OR = .74, 95% confidence interval: .35 - .90, Wald test = 3.85, p = .049), indicating that participants assigned to the SEH (regardless of method of allocation) were more likely to withdraw from the study. The second and third blocks, including sociodemographic and clinical characteristics, showed no statistically significant relationship with attrition (all $p > .05$).

Discussion

The findings of this study indicate (1) a slightly higher overall attrition rate in the RCT arm as compared to the PRCT arm, with the largest percentage of participants dropping out prior to exposure to the allocated treatment; (2) a slightly higher percentage of participants withdrawing from the RCT as compared to the PRCT and reporting treatment-related factors as reasons for doing so; (3) participants who withdrew differed from those who completed the study on two characteristics assessed at pre-test in the RCT and one characteristic in the PRCT; and (4) the type of allocated treatment was the only significant predictor of attrition. The method of assignment to treatment did not contribute significantly to attrition.

The results pertaining to the attrition rate and reasons for withdrawal are consistent with and extend the trends reported in the literature on attrition in general and on behavioural treatments for insomnia. The overall attrition rates observed in the RCT and PRCT arms are within the range (10–40%) reported for studies evaluating behavioural therapies for insomnia in clinical settings (Ong et al., 2008). However, the overall attrition rate in the RCT was higher by 12.7 percentage points than the rate in the PRCT arm. This difference is attributed to the higher rate of early attrition (i.e., before exposure to treatment) in the RCT as compared to the PRCT; the difference was 17.7 percentage points. The exact reason for early withdrawal from the RCT may be difficult to identify. A review of reasons for withdrawal provides some explanation. A larger number of participants in the RCT than in the PRCT mentioned treatment-related factors (treatment is demanding, dislike of treatment), loss of interest in the study, and scheduling conflict as reasons for withdrawal (Table 2). These reasons reflect unfavourable reactions to the trial, which may be related to disappointment with the randomized treatment. Disappointment and subsequent dissatisfaction with treatment represent the mechanism underlying attrition in an RCT (PCRG, 2009). Participants in the RCT arm viewed the MCI as slightly more acceptable than the SEH and may have been dismayed if they were randomized to the SEH. Dismayed participants may have dropped out early. This

point is supported in the larger percentage of participants in the RCT arm dropping out of the SEH (16%) than out of the MCI (12.8%). This finding also suggests that participants with preferences enrol in an RCT because they are aware that they have a 50% chance of being randomized to the preferred treatment; however, they withdraw from the trial early on to avoid exposure to the allocated treatment if it is incongruent with their choice (Bradley, 1993).

In contrast, participants in the PRCT arm were asked to indicate their preferences and were allocated to their chosen treatment. The "act of choosing" a treatment and the subsequent sense of control may explain participants' decision to pursue treatment (Leykin et al., 2007), as implied in the lower early withdrawal rate relative to the RCT arm. However, a slightly larger percentage of participants in the PRCT than the RCT dropped out during treatment. The reasons for withdrawal given by these participants cannot account for this finding. Since many participants in the PRCT arm dropped out without stating a reason, it is not possible to rule out the following factors as contributing to attrition during the treatment period: (a) dissatisfaction with some aspects of treatment delivery, such as therapeutic alliance with the therapist, experienced benefits, or discomfort (i.e., side effects) associated with the allocated therapy (Ong et al., 2008); and (b) changing health condition or sleep pattern of participants. The role that these factors, particularly satisfaction with treatment, play in influencing attrition should be further investigated under the random and preference methods of treatment allocation.

Participants who withdrew and those who completed the study differed on a small number (1–2) of characteristics: age, ethnicity, and WASO. The results of these comparisons should be viewed with caution, particularly in the PRCT arm. The comparisons were done on a large number of variables in both arms, potentially leading to type I error. In the PRCT arm, the numbers of dropouts and completers were not balanced, which may have led to violation of the equality of variance assumption and potential incorrect conclusions. Nonetheless, the differences in sociodemographic and clinical characteristics of dropouts and completers observed in the RCT and PRCT arms have been reported in previous studies (Ahern & LeBroque, 2005). In general, this consistent finding suggests that differences in the profile of dropouts and completers are prevalent in intervention evaluation trials that use random or preference-based methods of assigning participants to treatments. The differences result in self-selection bias; the sample of participants who complete a study may not represent all subgroups of the target population, which limits the generalizability of results pertaining to the effects of the treatment and the contribution of preferences.

Of the sociodemographic, clinical, and treatment-related variables included in the regression analysis, only the type of treatment significantly predicted attrition. Method of treatment assignment was not associated with withdrawal. Participants allocated to the SEH, randomly or by preference, were more likely to withdraw from the trial. There are two explanations for this finding. First, significant differences were observed in the sociodemographic (age) and clinical (WASO, sleep efficiency, insomnia severity) characteristics and treatment acceptability for participants allocated to the SEH and the MCI randomly or by preference. These differences could have confounded the influence of treatment on attrition. Second, the SEH is considered minimally effective in managing insomnia (Morin & Benca, 2012). It is possible that participants who received this treatment, regardless of allocation method, did not experience improvement in their sleep. A few participants in the RCT and PRCT arms indicated that the treatment "did not work" (Table 1). Therefore, they may have lost interest in the study and thus withdrew. Perceived ineffectiveness of treatment has been reported as a reason for withdrawal (Ahern & LeBroque, 2005; Kemmler et al., 2005). This raises questions about the suitability or appropriateness of including minimally effective treatments in trials aimed at evaluating the influence of treatment preferences on attrition, adherence, and outcomes. Treatments with differential acceptability and effectiveness may contribute to differential attrition, as was found in this study, which represents a major threat to the validity of conclusions regarding the effects of treatment and/or preferences. Therefore, treatments of comparable acceptability and effectiveness should be selected in preference trials.

The implementation of the RCT and PRCT arms in this study points to some limitations of these designs in examining the contribution of treatment preferences in intervention evaluation research. In the RCT arm, the high rate of early withdrawal raises the possibility that participants with strong preferences declined to enrol in the study to avoid randomization to the non-preferred treatment. Thus, enrolees may hold weak or no preferences that do not affect their responses to the randomly assignment treatment; this, in turn, could lead to incorrect conclusions about the impact of preferences (Swift et al., 2011). Alternatively, with randomization participants may be incidentally allocated to their treatment of choice; when a large proportion of participants (e.g., > 75%) receive the preferred treatment, the distribution of those allocated to the treatments randomly or by preference is unbalanced, limiting the comparisons among the groups defined by type of treatment and method of allocation and the resulting conclusion regarding the influence of treatment preferences. A similar unbalanced distribution is highly likely in the

PRCT arm if most participants choose one treatment over the alternative treatments under evaluation, as was the case in this study.

Conclusion

The results of this study provide evidence of lower early and overall attrition rates in the PRCT arm, which is consistent with the findings of two meta-analyses (PCRG, 2009; Swift et al., 2011). However, additional research is needed to determine the reproducibility of the findings when alternative treatments are active, equally effective behavioural therapies for insomnia and to elucidate the mechanism responsible for the low attrition among participants allocated to the preferred treatment.

References

Ahern, K., & LeBroque, R. (2005). Methodological issues in the effects of attrition: Simple solutions for social scientists. *Field Methods, 17*(1), 53–69.

Bootzin, R. R., & Epstein, D. R. (2011). Understanding and treating insomnia. *Annual Review of Clinical Psychology, 7,* 435–458.

Bootzin, R. R., Shoham, V., & Kuo, T. F. (1994). Sleep anticipatory anxiety questionnaire: A measure of anxiety about sleep. *Sleep Research, 23,* 188.

Bradley, C. (1993). Designing medical and educational intervention studies. *Diabetes Care, 16*(2), 509–518.

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.

Cohen, J. (1992). A power primer. *Psychological Bulletin, 112*(1), 155–159.

Derogatis, L. R., & Melisaratos, N. (1983). The Brief Symptom Inventory: An introductory report. *Psychological Medicine, 13*(3), 595–605.

Epstein, D. R., Sidani, S., Bootzin, R. R., & Belyea, M. J. (2012). Dismantling multicomponent behavioral treatment for insomnia in older adults: A randomized controlled trial. *Sleep, 35*(6), 797–805.

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.

Hebert, E., Vincent, N., Lewycky, S., & Walsh, K. (2010). Attrition and adherence in the online treatment of chronic insomnia. *Behavioral Sleep Medicine, 8*(3), 141–150.

Irwin, M. R., Cole, J., & Nicassio, P. M. (2006). Comparative analysis of behavioural interventions for insomnia and their efficacy in middle-aged adults and in older adults 55+ years of age. *Health Psychology, 25*(1), 3–14.

Kemmler, G., Hummer, M., Widschwendter, R., & Fleishhacker, W. W. (2005). Dropout rates in placebo-controlled and active control clinical trials of antipsychotic drugs — a meta-analysis. *Archives of General Psychiatry, 62*(12), 1305–1312.

Kuo, T. F., Raccioppo, M., Bootzin, R. R., & Shoham, V. (1994). Construct validity of the Sleep Anticipatory Anxiety Questionnaire (SAAQ). *Sleep Research, 23,* 202.

Lacks, P. (1987). *Behavioral treatment for persistent insomnia*. New York: Pergamon.

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,* 209–217.

Morin, C. M. (1993). *Insomnia: Psychological assessment and management*. New York: Guilford.

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.

Morin, C. M., & Benca, R. (2012). Chronic insomnia. *Lancet, 379*(9821), 1129–1141. doi:10.1016/s0140-6736(11)60750-2

Morin, C. M., Bootzin, R. R., Buysse, D. J., Edinger, J. D., Espie, C. A., & Lichstein, K. L. (2006). Psychological and behavioral treatment of insomnia: Update of the recent evidence (1998–2004). *Sleep, 29*(11), 1398–1414.

Morin, C. M., Culbert, J. P., & Schwartz, M. S. (1994). Nonpharmacological interventions for insomnia: A meta-analysis of treatment efficacy. *American Journal of Psychiatry, 151*(8), 1172–1180.

Naughton, M. J., Shumaker, S. A., Anderson, R. T., & Czajkowski, S. M. (1996). Psychological aspects of health-related quality of life measurement: Tests and scales. In B. Spilker (Ed.), *Quality of life and pharmacoeconomics in clinical trials* (2nd ed.) (pp. 117–131). Philadelphia and New York: Lippincott-Raven.

Ong, J. C., Kuo. T. F., & Manber, R. (2008). Who is at risk for dropout from group cognitive-behavior therapy for insomnia? *Journal of Psychosomatic Research, 64*(4), 419–425.

Preference Collaborative Review Group. (2009). Patients' preferences within randomized trials: Systematic review and patient level meta-analysis. *British Medical Journal, 338*(7686), a1864.

Radloff, L. S. (1977). The CES-D scale: A self-report depression scale for research in the general population. *Applied Psychological Measurement, 1*(3), 385–401.

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.

Sidani, S., Epstein, D. R., Bootzin, R. R., Moritz, P., & Sechrest, L. (2009). Assessment of preferences for treatment: Validation of a measure. *Research in Nursing and Health, 32*(4), 419–431.

Sidani, S., Miranda, J., Epstein, D., & Fox, M. (2009). Influence of treatment preferences on validity: A review. *Canadian Journal of Nursing Research, 41*(4), 52–67.

Swift, J. K., Callahan, J. L., & Vollmer, B. M. (2011). Preferences. *Journal of Clinical Psychology: In Session, 67*(2), 155–165.

Valentine, J. C., & McHugh, C. M. (2007). The effects of attrition on baseline comparability in randomized experiments in education: A meta-analysis. *Psychological Methods, 12*(3), 268–282.

Wohlgemuth, W. K., & Edinger, J. D. (2000). Sleep restriction therapy. In K. L. Lichstein & C. M. Morin (Eds.), *Treatment of late-life insomnia* (pp. 147–166). Thousand Oaks, CA: Sage.

Acknowledgements

This study was funded by the National Institutes of Health/National Institute of Nursing Research (NR05075) and 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.

Souraya Sidani, PhD, is Professor and Canada Research Chair, Daphne Cockwell School of Nursing, Ryerson University, Toronto, Ontario, Canada. Richard R. Bootzin, PhD, is Professor, Department of Psychology, University of Arizona, Tucson, United States. Dana R. Epstein, PhD, is Chief, Nursing Research and Evidence-Based Practice, Phoenix Veterans Affairs Health Care System, Phoenix, Arizona. Joyal Miranda, RN, PhD, is Assistant Professor, Daphne Cockwell School of Nursing, Ryerson University. Jennifer Cousins, PhD, is Lecturer, Department of Psychology, University of Pittsburgh, Pennsylvania, United States.