

Une exploration des préférences des patients en matière de traitements dans le cadre d'une étude sur échantillon partiellement aléatoire et contrôlé

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L'étude sur échantillon partiellement aléatoire et contrôlé (ÉÉPAC) est une conception modifiée dont le but est de tenir compte des préférences des participants en matière de traitement. Les connaissances concernant les facteurs qui influencent ces préférences sont très limitées. Cette étude évalue le degré de consentement des participants à collaborer à un processus aléatoire ainsi que les facteurs qui influent sur leurs préférences en matière de traitement. Les données quantitatives et qualitatives cueillies dans le cadre d'une ÉÉPAC de deux interventions comportementales dans des cas d'insomnie ont été analysées. Parmi les participants, 75 % ont refusé d'être aléatoirement assignés à un groupe thérapeutique. Ce chiffre a grimpé à 90 % après l'introduction de renseignements concernant les deux interventions. L'information que détenaient les participants concernant le traitement, la pertinence de celui-ci et leur capacité d'y adhérer selon leur perception ont influencé leur préférence en matière de traitement. Quelques participants qui n'avaient pas de préférence marquée et qui nécessitaient un traitement étaient disposés à être assignés de façon aléatoire. Les résultats soulèvent des questions concernant l'impact de la préférence en matière de traitement et de la procédure d'assignation sur la validité des conclusions de l'étude.

Mots clés : préférence en matière de traitement, ÉÉPAC

An Exploration of Participants' Treatment Preferences in a Partial RCT

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The partial RCT is a modified design meant to account for participants' treatment preferences. Little is known about the factors that influence such preferences. This study investigated the extent to which participants are willing to be randomized and the factors that affect their treatment preferences. The quantitative and qualitative data collected as part of a partial RCT evaluating 2 behavioural interventions for insomnia were analyzed. Of the participants, 75% were unwilling to be randomly allocated to a treatment group. This figure increased to 90% after information on the 2 interventions was provided. Participants' knowledge of the treatment, its suitability, and their perceived ability to adhere to it influenced their treatment preference. A few participants who had no strong preference and who required treatment were willing to be randomized. The findings raise questions about the impact of treatment preference and allocation procedures on the validity of study conclusions.

Keywords: treatment preference, random assignment, partial RCT

Introduction

Demonstrating the effectiveness of interventions is a prerequisite for their use in practice. Effectiveness is concerned with the robustness of the intervention outcome under actual conditions and with different clinical populations (Sidani, & Braden, 1998; Whittemore & Grey, 2002). Studies to evaluate the effectiveness of interventions focus on the clinical applicability of the treatment under investigation and seek to duplicate the situations that clinicians will encounter in their practices (Streiner, 2002; TenHave, Coyne, Salzer, & Katz, 2003). Of the situations that clinicians encounter, selection of the most appropriate treatment for individual patients reflects an important aspect of patient-centred care. Patient-centred care (PCC) is viewed as an approach that results in high-quality care (Attree, 2001; Larrabee & Bolden, 2001). Its essence is to view each patient as a unique person, respect patients' values and beliefs, and respond flexibly to patients' individual needs and preferences (Lauver et al., 2002; McCormack, 2003). Application of PCC implies that nurses assess patients' needs, values, and preferences; inform patients of available treatment options and the risks and benefits of each; ask patients which

treatment they prefer; and provide patients with the treatment of their choice (O'Connor, Mulley, & Wennberg, 2003; Tunis, Stryer, & Clancy, 2003). Interventions that are consistent with patients' preferences are posited as beneficial, as they increase patients' sense of personal control, patients' satisfaction with care, and the achievement of desired outcomes (Cahill, 1996).

Patient preference is the expression of the value of various courses of action following informed deliberation on their risks and benefits (Bowling & Ebrahim, 2001). Inquiring about patients' treatment preferences is necessary to guide practice. Knowledge about which interventions have been perceived by patients as acceptable, suitable, and desirable assists the practitioner in selecting which ones to discuss with and recommend to patients. Interventions that have been found to be effective but viewed by patients as unacceptable, unsuitable, or undesirable will not be adhered to in everyday life (Morin, Gaulier, Barry, & Kowatch, 1992; Vincent & Lionberg, 2001), thereby hindering the achievement of desired outcomes (Bradley, 1993). It is therefore important that patient preferences be assessed and accounted for in the evaluation of an intervention's effectiveness.

The randomized control trial (RCT), often considered the gold standard for evaluating the effectiveness of interventions, does not take patient preferences into account. Random assignment of participants to the experimental or control group is the key feature of RCT design. This is the most critical safeguard of internal validity; however, it ignores the participants' desires and preferences regarding the treatment options included in the study. Several authors propose alternative research designs in which the participants' treatment preferences are examined (e.g., Lambert & Wood, 2000; McPherson, & Chalmers, 1998) and taken into account in the allocation of participants to a treatment group (e.g., Brewin & Bradley, 1989; Coward, 2002). The partial RCT is proposed as a modified RCT design in which patients' treatment preferences are taken into consideration while the rigour of the RCT design is maintained (Torgenson & Sibbald, 1998). The partial RCT allows participants to say whether they would rather be randomly allocated to a treatment option or allocated to their preferred treatment.

Little is known about the process underlying participants' preferences regarding method of allocation and treatment options offered in effectiveness studies (Horne, 1999). The purposes of the present study were to (1) determine the extent to which participants are willing to be randomly assigned to a treatment before and after being informed about the options, and (2) explore the factors that influence participants' treatment preferences. The data for the study were obtained from a large partial RCT evaluating the effectiveness of two behavioural interventions, stim-

ulus control instructions (SCI) and sleep restriction therapy (SRT), in managing insomnia.

Literature Review

Accounting for participants' treatment preferences, as is done in a partial RCT, has advantages and disadvantages. These are discussed at the methodological and clinical levels.

Several studies have investigated patients' treatment preferences. Overall, the results indicate that most participants (60–79%) express a preference for a particular intervention (e.g., Awad, Shapiro, Lund, & Feine, 2000; Morin et al., 1992; North-West Uro-Oncology Group, 2002; Torgerson, Klaber-Moffet, & Russell, 1996; Vincent & Lionberg, 2001; Walter, Vincent, Furer, Cox, & Kjernisted, 1999). Accounting for such preferences has several methodological advantages. It makes recruitment of participants and achievement of the required sample size easier, as compared to the traditional RCT. The results of some studies indicate that many people who are unwilling to be allocated to a treatment based on chance refuse to take part in an RCT (King, 2000). People may decline to participate in an RCT if they highly favour one treatment option, are aware that they have only a 50% chance of receiving it, and wish to avoid receiving the less desired treatment (Bradley, 1993). For instance, O'Reilly, Martin, and Collins (1999) found that only one of 20 patients agreed to be randomized to either of two treatments for prostate cancer. They report that patients who were well informed about the two treatments refused random assignment, preferring to make their own treatment choice. Thus, the rather small number of persons who agree to participate reflect a subgroup of the target population who are willing to take the risk of receiving any treatment. Informing potential participants that their treatment preferences will be taken into consideration is an effective strategy for increasing the rate of participation in a study and facilitates achievement of the required sample size. Furthermore, the resultant sample is representative of the target population and the results are generalizable to various subgroups of the population (TenHave et al., 2003).

In contrast to random assignment, accounting for participant preferences can minimize attrition and promote adherence to the treatment protocol. Random assignment may result in a mismatch between the treatment option that participants prefer and that to which they are randomly allocated. Participants who do not receive their preferred treatment may become demoralized, disappointed, uncooperative, noncompliant, and prone to drop out of the study. Attrition reduces the sample size, which decreases the statistical power to detect significant interven-

tion effects. Offering participants the treatment of their choice improves their satisfaction with and adherence to the treatment they receive and reduces attrition (Corrigan & Salzer, 2003; TenHave et al., 2003). Retention of a large number of participants and adherence to the intervention increase the statistical power to detect significant intervention effects (Lipsey, 1990; Shadish, Cook, & Campbell, 2001).

Accounting for patient preferences in a research study may lead to results that are clinically useful and that provide a profile of participants who have strong preferences for a particular treatment and who benefited most from the intervention under evaluation. Equipped with this type of knowledge, nurses can provide care that is based on the best available evidence while responding to their patients' values and wishes (O'Connor et al., 2003). The benefit of providing care in accordance with patient preferences is illustrated in a study conducted by Ruland (1998). This study found that when nurses were given information on their patients' preferences regarding self-care goals, 74% tailored their care to those preferences, which, in turn, resulted in the achievement of self-care goals.

In contrast, accounting for participants' treatment preferences in a partial RCT has methodological disadvantages. First, it requires a large sample. A large sample is necessary to ensure adequate statistical power to compare the four groups of participants: those assigned to the experimental group and are either satisfied or disappointed with the treatment received, and those assigned to the control group and are either satisfied or disappointed with the treatment received. The four groups may vary in their response to the intervention and the achievement of the expected outcomes (Bradley, 1993; Corrigan & Salzer, 2003; McPherson & Britton, 2001; TenHave et al., 2003). Second, if participants are allowed to choose the method of assignment to a group (random or preference) and the treatment option, then there is an increased possibility of an unbalanced design resulting — that is, an unequal number of participants in the four groups (Corrigan & Salzer). Several strategies can be used to address this limitation, such as randomly selecting a subsample from the larger group size to equal the smaller group size, conducting the analysis with the unequal and the equal group sizes, and comparing the results to determine whether the between-group differences are due to unequal group size. Third, the assignment of participants to their preferred treatment option may increase their expectation that the treatment will be effective and cause them to respond accordingly, resulting in improved outcomes (Corrigan & Salzer). The evidence supporting this limitation is inconclusive. In some studies treatment preference was associated with the achievement of outcomes (e.g., Thomas, Craft, Paterson, Dziedzic, & Hay, 2004), but in other studies it had no impact on outcomes (e.g., Klaber-Moffett et al., 1999).

There are a few published studies investigating participants' treatment preferences using a partial RCT (e.g., Coward, 2002; Thomas et al., 2004). However, the reports of these studies provide limited information on the process underlying such preferences. Specifically, the factors that shape the preferences are not clear or explicit. Yet these factors would assist in the identification of the specific information that patients need during the process of forming their treatment preferences, which is a requirement of PCC. This study represents an attempt to describe this process in terms of the factors that influence participants' preferences with regard to the allocation procedure and the treatment options.

Study Design

Data for this study were obtained from a large partial RCT evaluating the effectiveness of two behavioural interventions for managing insomnia. The partial RCT design consisted of asking participants about their preferences for either of the two interventions and assigning them accordingly. A questionnaire was used to elicit their preference with regard to the allocation procedure and the intervention under investigation. The quantitative and qualitative data collected in this questionnaire were used to address the objectives of the study.

The questionnaire was administered by the researcher, in an individual interview format, after the participants consented to take part in the study and completed the pretest measures. The interview proceeded as follows. First, the participants were asked whether they were willing to be randomly allocated to a treatment group. Second, they were informed, using a script, of the nature, effectiveness, and disadvantages of each intervention. Third, they were requested to evaluate each intervention on its acceptability, suitability, and effectiveness in managing their insomnia. Finally, they were asked which intervention they preferred and how they wished to be assigned to one of the two interventions — that is, either randomly or based on their preference. Participants with a preference were allocated to their preferred/selected intervention, while those with no preference were randomly allocated to a treatment group by means of an opaque, sealed envelope. The researcher documented, verbatim, each participant's verbal responses throughout the interview. The participants' quantitative answers to the questions eliciting their qualitative verbal responses comprised the data for understanding the process underlying their preferences.

Sample

The convenience sample consisted of 67 participants. Persons were eligible for the study if they (1) lived in a non-institutional dwelling in the

community, (2) were 21 years of age or older, (3) were able to read and write English, and (4) had a complaint of insomnia that met the criteria for disorder regarding initiation or maintenance of sleep — that is, sleep onset latency and/or time awake after sleep onset of 30 minutes or more per night for a minimum of 3 nights per week, of 3-month duration or longer, as corroborated by sleep diaries and self-report. Exclusion criteria included cognitive impairment as ascertained by a Mini-Mental State Exam score of over 27 and the presence of severe psychological impairment evidenced by the Brief Symptom Inventory Global Severity Index T-score of under 50. The behavioural intervention for managing insomnia requires the active participation of the client in making the behavioural changes, which may be hindered by cognitive or severe psychological impairment.

Variables and Measures

A treatment-preference questionnaire was developed by the investigators to elicit information about the participants' preferences regarding treatment allocation method (i.e., random or based on preference) and the two behavioural interventions for managing insomnia (i.e., SCI or SRT). The questionnaire consisted of four parts. The first part inquired whether the participant was, in general, willing to be randomly assigned to a treatment option in a research study. The second part described one intervention for managing insomnia in terms of its name, nature, effectiveness (based on available empirical evidence), and disadvantages. Following the description, the participants were asked to rate the intervention for suitability, acceptability, effectiveness, and their willingness to adhere to it. The third part included a description of the other intervention and the rating scales to evaluate it. In the fourth part, participants were asked how they would like to be assigned to one of the two treatment options described in the second and third parts — that is, based on chance or on preference. The responses to the questions in the first and fourth parts of the questionnaire formed the quantitative data analyzed in this study to determine the extent to which participants were willing to be randomly assigned to treatment. In the last part of the questionnaire, the participants commented verbally on their choice. The researcher recorded these comments in writing. These responses formed the qualitative data that were content analyzed to identify the factors that influenced preferences with regard to the intervention.

Procedure

The study protocol was approved by the Research Ethics Board at the University of Toronto. When obtaining participants' consent, the research assistant (RA) described the purpose of the study, the data-collection

procedure, participants' rights as human subjects, the two behavioural interventions offered in the study, and the procedure for treatment allocation (i.e., the participants were told that the two interventions demonstrated efficacy and that they could choose the one they wished). After obtaining consent and pretest data, the RA administered the treatment preference questionnaire. The RA read the questions and the response options, and recorded the option selected by the participant. The RA did not provide any information not available on the questionnaire and did not discuss the participant's choice. After rating each intervention, the participants indicated how they wished to be allocated. Those who chose to be randomly assigned learned about their assignment by opening a sealed envelope. Those who were not willing to be randomly assigned were asked which of the two treatment options they preferred and were then assigned to an experimental group based on their preference. The participants' verbal responses upon learning of their group assignment were recorded at the end of this data-collection session.

Data Analysis

Descriptive statistics were used to characterize each participant's profile and responses to the treatment preference questionnaire. In reviewing participants' responses to the initial question (i.e., first part of the questionnaire) and the final question (i.e., fourth part of the questionnaire) concerning treatment allocation, the participants were classified into four groups: (1) those who consistently chose not to be randomly assigned, (2) those who consistently chose to be randomly assigned, (3) those who changed their decision from random to preference allocation, and (4) those who changed their decision from preference to random allocation. Within each group, verbal responses were content analyzed. The emerging themes reflected factors that influenced the participants' preferences regarding the method of allocation and the interventions.

Results

The results are presented in relation to the participants' profiles, the participants' responses to the treatment preference questionnaire, and the factors that influenced their preferences. The majority (69%) of the 67 participants were women, with a mean age of 45 years ($SD = 16$). Most (42%) were married, well-educated (mean years of education = 17, $SD = 4$), and employed either part-time or full-time. They rated their insomnia as severe, bothersome, and interfering with daily functioning. Their perceived severity of insomnia was supported by mean scores on sleep onset latency ($mean = 50$ minutes, $SD = 36$) and wake after sleep onset ($mean = 54$ minutes, $SD = 39$).

When initially asked about their willingness to be randomly assigned to a treatment group, 50 participants (75%) responded that they were not willing to be randomly assigned. However, after learning about the two particular treatment options offered in the study and rating each, 60 participants (90%) chose not to be randomly assigned. Thus, 12 participants (18%) changed their mind about how they wanted to be assigned once the information on the interventions was provided, and 55 (82%) did not change their mind. Of those who changed their mind, some selected random allocation first and allocation based on preference second, while others selected preference first and random allocation second. Of those who did not change their mind, some consistently selected random allocation and others consistently selected allocation based on preference. The distribution of the participants across the four groups is presented in Table 1.

Table 1 *Distribution of Participants in Method of Treatment Allocation*

Group	N (%)	Themes
1. Consistently chose treatment allocation based on preference	49 (73)	Suitability (<i>n</i> = 27) Acquired knowledge (<i>n</i> = 20) Familiarity (<i>n</i> = 18) Compliance (<i>n</i> = 17) Control (<i>n</i> = 16)
2. Consistently chose randomization	6 (9)	No preference (<i>n</i> = 6) Just wanted treatment (<i>n</i> = 3)
3. Changed from randomization to preference	11 (16)	Acquired knowledge (<i>n</i> = 11) Control (<i>n</i> = 6)
4. Changed from preference to randomization	1 (1)	Indiscretion (<i>n</i> = 1) No preference (<i>n</i> = 1)

The themes that emerged during content analysis of the verbal responses identified factors that influenced the choice of allocation procedure. For the first group, five themes explained the consistent choice of treatment allocation based on preference. First, these participants tended to base their choice of treatment on its perceived suitability to their particular sleep problem. One person stated: “The [first] treatment sounds better for me since it deals with a number of...strategies. The [second] treatment looks at time scheduling. I’m very consistent with my bedtimes. I don’t think that’s my problem.” Second, they rejected random

assignment because they preferred to rely on their acquired knowledge of the treatment options rather than on chance. One participant stated: "With the information I got, and knowing myself and the sleep problem I have, I would rather choose myself than leave it to a 50/50 chance; that makes no sense to me." Third, some participants based their decision against random assignment on their familiarity with one of the treatment options — that is, they did not want to risk being allocated to the treatment they were familiar with and had previously received; they wanted to receive the other, new, treatment. Fourth, these participants rejected random assignment based on their perceived ability to comply with one treatment better than the other — that is, participants who believed they were unable to adhere to a treatment protocol wanted to make sure they were not allocated to that treatment. This theme is captured in the following comment: "My life is a busy one. I'm constantly on the go. My sleep schedule often changes based on my plans for the day, so I know the [second] treatment is not for me. I wouldn't be able to follow it." Finally, some participants seized the opportunity to have control over the decision-making process and selected allocation based on preference.

For the second group — those who consistently chose to be randomly assigned — two themes emerged. One theme reflected lack of a strong preference for a treatment option. Within this group, the majority ($n = 6$) did not have a preference for either of the treatment options. After receiving information on the two interventions, they felt they had "not tried" or were "not familiar" with either and therefore did not care which one they received. The second theme related to the need for treatment. Some participants ($n = 3$) did not care about the method of allocation. They just wanted some type of treatment for their sleep problem. One participant explained: "I need a good night's sleep. I'm desperate. I'll do either one. I just want some help."

For the third group — those who changed from random to preference allocation — two themes emerged. These were similar to those identified for the first group, the participants who consistently chose not to be randomly assigned. First, the members of this group changed their mind once they received information on the two treatment options. Soon after learning about the nature, effectiveness, and disadvantages of each intervention, they developed a preference for one over the other. This preference was related to the person's familiarity with one treatment. They felt they had already learned everything there was to know about it. Also, these participants developed a preference for one treatment option based on its suitability to their particular sleep problem. One participant said: "I know what I should and should not be doing to help my sleep, but it's not working. So I'll have to go with [this intervention] and see if [it] helps." Second, the issue of control arose in this group. The par-

ticipants explained that reliance on chance to place them in a treatment option did not consider what was best for them. They preferred to choose a treatment, based on their knowledge of their sleep problem and the information obtained about the treatments. One participant said: "I'd rather rely on myself to make the decision with the information I have...than [take] a 50% chance."

The last group consisted of one participant who changed the response to the method for treatment allocation from preference to random assignment. This person showed indecisiveness and lacked a strong treatment preference. After obtaining the information about the two interventions, the participant was still indecisive as to which one would be more beneficial and therefore chose to be randomly assigned. This participant felt no real connection to either of the two treatments.

Discussion

The results indicate that the majority of participants (75%) would not like to be randomly assigned to a treatment option in any research study. This finding is consistent with that reported by O'Reilly and colleagues (1999) and supports the observation that participants are not willing to be randomly assigned to treatment groups (King, 2000). The proportion of participants who refused random allocation increased to 90% after they were informed of the nature, effectiveness, and disadvantages of the two options. Knowledge of the treatment option was one factor influencing the participants' preference with regard to the options and non-random allocation to treatment. This finding replicates the observation by O'Reilly and colleagues that well-informed patients increasingly refuse randomization and choose to make their own treatment decision. The factors that influenced the participants' choice of treatment included suitability, compliance, and familiarity with the intervention. This finding is supported by the conclusion of Morin et al. (1992) and Vincent and Lionberg (2001), who suggest that patients will not choose or adhere to interventions that are unacceptable, unsuitable, or undesirable. The issue of control in selecting a treatment has been cited as a factor in a person's decision to participate in an RCT and in treatment. Those who have a clear idea about the treatment options under investigation are less willing to leave group assignment to chance (Bradley, 1993; Ellis, 2000; Jenkins & Fallowfield, 2000).

In summary, the results of this study provide preliminary evidence indicating that participants in intervention evaluation studies do not wish to be randomly allocated to a treatment group. These findings elucidate the factors that influence a participant's decision regarding the allocation

procedure. Knowledge of the treatment options apparently informs participants of not only the nature of the treatment but, more importantly, its suitability to their problem and the extent to which they will be able to adhere to it. These factors appear to play a key role in determining their selection of allocation procedure.

These results are based on a rather small sample of persons seeking non-pharmacological treatment for their insomnia. In order to enhance generalizability, they should be replicated with a larger number of participants with different clinical conditions and seeking various types of interventions. Nonetheless, they provide some empirical support for the clinical observations that patients do have treatment preferences and that these preferences are shaped by the perceived suitability of each treatment to their condition and the extent to which their lifestyle permits adherence to it. Nurses can discuss the suitability of interventions and the patients' ability to adhere to treatment when eliciting their preferences, which is an important aspect of PCC. Further, the results show that participants who have no strong preference for a treatment option and participants who perceive a need for treatment are willing to be randomly assigned. It can therefore be concluded that the factors that influence the decision to be allocated based on preference differ from those that influence the decision to be allocated based on chance. The extent to which these factors directly or indirectly affect adherence to treatment, and whether any placebo effect associated with the expectation of improved outcome resulting from the chosen treatment, is not known and should be investigated in future studies.

Conclusion

When given the option of not being randomly allocated to a treatment group and presented with information on the treatments being offered, few participants in intervention studies are willing to be randomly allocated; most tend to choose a treatment based on preference. Information on the treatment and perceptions about its suitability and one's ability to adhere to it, as well as the desire to have a role in decision-making, are factors that affect participants' treatment preferences and their decision with regard to allocation. Therefore, it may be important for researchers conducting intervention studies to account for participants' treatment preferences and to determine the extent to which these preferences influence the outcome of the treatment and the patient's satisfaction with it. Examination of the extent to which patient preferences affect outcomes enhances the validity and clinical relevance of findings in effectiveness research.

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