

L'influence des préférences de traitements sur la validité : une étude

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L'affectation au hasard de participants à des traitements expérimentaux et comparatifs est censé améliorer la comparabilité des groupes d'étude quant aux caractéristiques de base. Malgré ses avantages, l'affectation au hasard entraîne des problèmes de validité. Cette approche ne tient pas compte des préférences de traitements exprimées par les participants. Si l'affectation est faite sans prendre en compte ces préférences, celles-ci influenceront sur l'adhésion à l'étude, la représentativité de l'échantillonnage accumulé, l'occurrence d'attrition, l'adhésion au traitement et les résultats. Cet article méthodologique décrit les mécanismes qui sous-tendent l'influence des préférences de traitements sur la validité externe et interne d'une étude d'évaluation d'interventions. Les auteures présentent des preuves empiriques en soutien à leur argumentation et proposent des modèles de recherche alternatifs qui tiennent compte des préférences de traitements à des fins de futures recherches en sciences infirmières.

Mots clés : préférences de traitements, modèles de recherche alternatifs, problèmes de validité.

Influence of Treatment Preferences on Validity: A Review¹

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Random assignment of participants to experimental and comparison treatments is believed to enhance the comparability of the study groups on baseline characteristics. Despite its benefits, random assignment presents threats to validity. It ignores participants' treatment preferences. If not accounted for when participants are allocated to treatments, preferences influence enrolment in the study, representativeness of the accrued sample, attrition, adherence to treatment, and outcomes. This methodological article describes the mechanisms underlying the influence of treatment preferences on the external and internal validity of an intervention evaluation study. The authors present empirical evidence to support the points of discussion. They describe alternative research designs that account for treatment preferences, for use in future nursing intervention research.

Keywords: treatment preferences, research designs, randomized clinical trial, partially randomized clinical trials, threats to validity

Introduction

The randomized controlled trial (RCT) is considered the gold standard design for evaluating the effects of interventions on intended outcomes (Richardson, 2000; Shadish, Cook, & Campbell, 2002). Random assignment, a key feature of the RCT, is believed to minimize selection bias and ensure internal validity. Allocating participants on the basis of chance enhances the comparability of participants in the experimental and comparison groups on measured and unmeasured variables, before implementation of the treatment under evaluation. This initial group comparability reduces the potential confounding influence of baseline characteristics on the post-treatment outcomes. This in turn strengthens confidence in attributing the changes in the outcomes, observed following treatment delivery, to the intervention (Abel & Koch, 1999; Cook, 1993). Despite its benefits, random assignment presents threats to validity in intervention evaluation research. Participants, especially those with preferences for treatment options (experimental or comparison), may resent randomization. They may feel it is unfair, decreases their sense of control, and reduces

¹ The contents of this article do not represent the views of the US Department of Veterans Affairs or the United States government.

their chances of receiving the preferred treatment option (Bradley, 1993; Ellis, 2000; Stevens & Ahmedzai, 2004). Preferences for treatment are increasingly being implicated as threats to internal and external validity (Howard & Thornicroft, 2006; McPherson & Britton; 2001; TenHave, Coyne, Salzer, & Katz, 2003).

In this article we focus on the mechanisms that underlie the influence of treatment preferences on external and internal validity. We present empirical evidence, synthesized from the relevant literature, to support the points of discussion. We describe alternative research designs that account for treatment preferences, to guide their use in studies evaluating nursing interventions. We first introduce a conceptualization of treatment preferences in order to define this concept.

Conceptualization of Treatment Preferences

Treatment preferences represent persons' choices of treatment; that is, they reflect the specific intervention or treatment option they want to receive (Stalmeier et al., 2007) to address a clinical problem or promote their health. Preferences are derived from the persons' understanding of, experience with, and attitudes towards the treatment option (Corrigan & Salzer, 2003; Sidani, Epstein, Bootzin, Moritz, & Miranda, 2009; Wensig & Elwyn, 2003).

Individuals gain an understanding of the treatment options through exposure to relevant information. This information is obtained prior to or upon enrolment in the study. Prior to enrolment, it is obtained directly from different sources, including health-care professionals, family members, or friends; from written materials available in print or online; and from media presentations. Upon enrolment in a trial, persons are informed of the treatment options offered within the study context, as part of the process for obtaining informed consent. Regardless of its accuracy, the knowledge gained contributes to the formulation of preferences. Experience with the treatment, whether personal or vicarious, refers to the exposure to and application of the treatment option. Experience has been found to shape preferences: Persons who previously used an option are likely to select it, particularly if they found it effective; otherwise, they tend to choose alternative treatments (Awad, Shapiro, Lund, & Feine, 2000; Gum et al., 2006; Jansen et al., 2001; Miranda, 2004).

Attitude towards treatment represents the person's appraisal of the treatment options as acceptable or unacceptable (Van der Berg et al., 2008). Attitudes are based on careful consideration of the following treatment attributes: appropriateness for addressing the clinical problem or promoting health, suitability to individual lifestyle, effectiveness, severity

of side effects, and convenience (Sidani et al., 2009). Acceptable treatments are those perceived as appropriate, suitable, effective, convenient, and having minimal side effects of low severity. Persons develop preferences for treatment options they view as acceptable.

Treatment preferences influence engagement in and adherence to treatment as well as the outcomes (Kiesler & Auerbach, 2006; Lang, 2005; Mills et al., 2006; Tacher, Morey, & Craighead, 2005). They therefore represent factors that confound treatment effectiveness and weaken the validity of study conclusions.

Influence of Preferences on Validity

Preferences for treatment influence individuals' decision to enrol in a trial, which affects external validity. Preferences also influence attrition, adherence to treatment, and outcomes, which weaken internal validity.

Influence on External Validity

Two interrelated mechanisms explain the influence of treatment preferences on external validity: low enrolment rate, and non-representativeness of the sample. Preferences are emerging as a reason for non-enrolment in an RCT (Thomas, Croft, Paterson, Dziedzic, & Hay, 2004). Eligible individuals have a preference for the experimental or comparison treatment under evaluation. Results of a large number of descriptive and experimental studies show that 60% to 100% of participants have clear preferences for one of the treatment options offered within the context of the study. Persons with a preference may decline enrolment in an RCT because they are unwilling to risk being randomly assigned to their non-preferred treatment (Ellis, 2000; McPherson & Britton, 2001; TenHave et al., 2003). Individuals with a preference resent allocation to treatment on the basis of chance and wish to be actively involved in treatment decision-making (Jenkins & Fallowfield, 2000). The results obtained by Arega et al. (2006) indicate a strong association between preferences and willingness to be randomized. The results of four other studies support this association. Patients who perceived the intervention under evaluation as improper treatment for their condition declined enrolment in an RCT of adjuvant therapy for breast cancer (Stevens & Ahmedzai, 2004). About 10% of schools taking part in an RCT of peer-led sex education withdrew from the trial because of random assignment to the non-preferred treatment (Oakley et al., 2003). In an RCT evaluating the effectiveness of a brief physiotherapy intervention, 45% of eligible persons refused to be randomized to treatment because of preferences and decided not to enrol in the trial (Klaber Moffett et al., 1999). In another study (Macias et al., 2005), 30% of eligible individuals

declined participation because they wanted to avoid the risk of receiving the non-preferred treatment for managing mental health problems. With such a high refusal rate (up to 45%), the rate of enrolment decreases; this in turn may increase the length of the enrolment period or, with limited funds and resources to accommodate a prolonged enrolment period, may yield a sample size smaller than required to attain adequate statistical power.

Persons with preferences form a subgroup of the target population. If these individuals decline enrolment in an RCT, then the accrued sample may not be representative of all subgroups making up the target population (Howard & Thornicroft, 2006; Millat, Borie, & Fingerhut, 2005). Thus participants differ from non-participants on at least two characteristics: preference for treatment, and willingness to be randomized. As indicated by the results of previous studies, non-participants have clear treatment preferences and are unwilling to be randomly assigned to treatment. Accumulating empirical evidence indicates differences in sociodemographic characteristics and severity of the presenting problem between individuals who have preferences and are unwilling to be randomized and those who have no preferences and are willing to be randomized. King et al. (2005) conducted a systematic review of studies that investigated preferences for medical treatments. They found that participants with preferences were more likely than those with no preferences to be women, well-educated, White, and employed. The results of five additional studies (Bedi et al., 2000; Cooper et al., 2003; Gum et al., 2006; Heit et al., 2003; Vuorma et al., 2003) consistently support the relationship between perceived severity of the presenting problem and treatment preferences. Participants reporting high levels of problem severity tend to select intensive, invasive treatment. The observed differences in sociodemographic characteristics and perceived severity of the presenting problem between persons with preferences who decline enrolment and persons with no preferences who participate in an RCT may compromise sample representativeness. The sample consists of a subgroup of the target population, which limits the generalizability of the RCT findings to all subgroups making up the target population (Lambert & Wood, 2000; Millat et al., 2005).

Influence on Internal Validity

Persons with preferences for the experimental or comparison treatment under evaluation may decide to enrol in an RCT. They may consider participation in the RCT their only opportunity to obtain their preferred treatment since they have a 50% chance of being assigned to it (Bradley, 1993). The enrolment of participants in the RCT threatens

internal validity because these participants react differently depending on the treatment option to which they are allocated.

In an RCT, participants are randomly allocated to the experimental or comparison treatment group, regardless of their preference. Thus randomization creates two subgroups within each experimental and comparison group. One subgroup represents participants who are randomly assigned to the treatment of their preference. The other subgroup comprises participants who are allocated to the non-preferred treatment. Participants assigned to the preferred intervention are satisfied with the treatment they receive. Accordingly, they develop enthusiasm for treatment, actively engage in the treatment activities, and comply with the treatment as prescribed. Consequently, they may demonstrate the expected improvement in the outcomes. In contrast, participants assigned to the non-preferred treatment experience disappointment because they are deprived of their treatment of choice. They respond in two possible ways.

First, they may decide to withdraw from the study. Attrition weakens the validity of the RCT findings. It reduces the sample size included in the “as treated” analysis, thereby decreasing the statistical power to detect significant treatment effects. Attrition can lead to non-comparability on baseline characteristics of the experimental and comparison treatment groups; this can result in uncontrolled confounding variables that influence the outcomes. Thus the changes in outcomes, observed after treatment implementation, cannot be attributed with confidence to the treatment (Shadish et al., 2002).

Second, participants assigned to the non-preferred treatment may experience a sense of demoralization that shapes their subsequent reaction. This subgroup of individuals has low motivation to engage in and adhere to treatment. Non-adherence to treatment is associated with poor outcomes (Halpern, 2003; Huibers et al., 2004; McPherson & Britton, 2001).

The location of these two subgroups within the experimental and comparison groups will bias the estimates of the treatment effects, thereby threatening the validity of the RCT conclusions. For instance, when the participants randomly assigned to their preferred treatment are equally distributed across the experimental and comparison groups, the within-group variance in the outcomes observed at post-test is high and the power to detect significant treatment effects is reduced. When the number of participants with a preference for the experimental treatment who are randomly allocated to their treatment of choice is larger than the number of participants with no preference who are assigned to the comparison group, the between-group variance in the post-test outcomes is

high, potentially leading to overestimation of the treatment effects (Sidani, 2006).

The influence of treatment preferences on attrition, adherence to treatment, and outcome has been investigated in several studies (e.g., Adamson, Sellman, & Dore, 2005; Bedi et al., 2000; Gum et al., 2006; Klaber Moffett et al., 1999; Mills et al., 2006) and is synthesized in three recent systematic reviews (King et al., 2005; Preference Collaborative Review Group, 2009; Swift & Callahan, 2009). The results pertaining to the influence of treatment preferences on attrition differ across the three reviews. King et al. (2005) found no significant differences in attrition rates for participants assigned to treatment groups based on chance (i.e., random) or on preference. The Preference Collaborative Review Group (2009) reports lower attrition rates for participants who were randomly assigned to treatment groups compared to those who were allocated to the treatment of preference; this finding is contrary to expectations. In contrast, Swift and Callahan (2009) estimated an overall effect size of 0.58, whereby lower attrition rates were observed for participants allocated to treatment of choice, as hypothesized. The exact reason for the inconsistent findings is unclear, but it could be related to differences in the target populations and treatments investigated.

Four studies examined the influence of treatment preferences on adherence to the intervention. The results are consistent. They show higher rates of attendance at the planned treatment sessions (Bedi et al., 2000; Hitchcock Noël et al., 1998; Janevic et al., 2003) and of engagement in treatment activities (Macias et al., 2005) for participants allocated to the preferred treatment than participants randomly assigned to treatment.

The results of the three systematic reviews examining the influence of treatment preferences on outcomes varied slightly. In their review, King et al. (2005) focused on studies that evaluated medical treatments. Seven of the 19 studies included in the review reported significant outcome differences between participants allocated to treatment based on preference and those allocated based on chance. Better outcomes were observed for participants allocated to the treatment of preference in five of the seven studies and for those randomized to treatment in the other two studies. In their meta-analysis, the Preference Collaborative Review Group (2009) analyzed participants' data pooled from eight trials of treatment for musculoskeletal conditions (e.g., back and neck pain). Participants who received the treatment of their choice showed greater improvement than those randomized to the non-preferred treatment. The effect size was 0.15. Swift and Callahan (2009) reviewed 26 studies that investigated pharmacological, psycho-educational, and behavioural treatments for the management of psychological conditions (e.g., depression). The overall

effect size was 0.15 (CI₉₅: .09 to .21). Participants who received the preferred treatment exhibited more improvement than those who were randomized. The findings of the systematic reviews provide evidence supporting the influence of treatment preferences on outcome; however, the influence appears to be of small magnitude. The exact reason for the small effect of preferences on outcomes is unclear and requires further exploration. However, the method for assessing treatment preferences is a methodological factor that could account for the observed small effect. The reports of studies that were included in the systematic reviews and that investigated preferences provided minimal detail on the procedure used to elicit preferences for the treatments under evaluation. Specifically, the study report did not describe the treatment information that was provided to participants or the form in which this information was presented. Yet the nature and presentation of treatment-related information affect participants' perception of an intervention and their expressed preferences (Becker, Davis, & Schaumberg, 2007; Say & Thompson, 2003; Tarrier, Liversidge, & Gregg, 2006; Wragg, Robinson, & Lilford, 2000). Bowling and Rowe (2005) state that the results of these studies should be viewed with caution due to the non-standardized and non-rigorous method used to elicit treatment preferences. The expressed preferences are not well informed and do not accurately represent participants' choice. Error of measurement is known to attenuate the magnitude of a relationship between variables (Streiner & Norman, 2008). Future research should use a systematic procedure and validated measure for assessing preferences, as described by Sidani (2006) and Sidani et al. (2009).

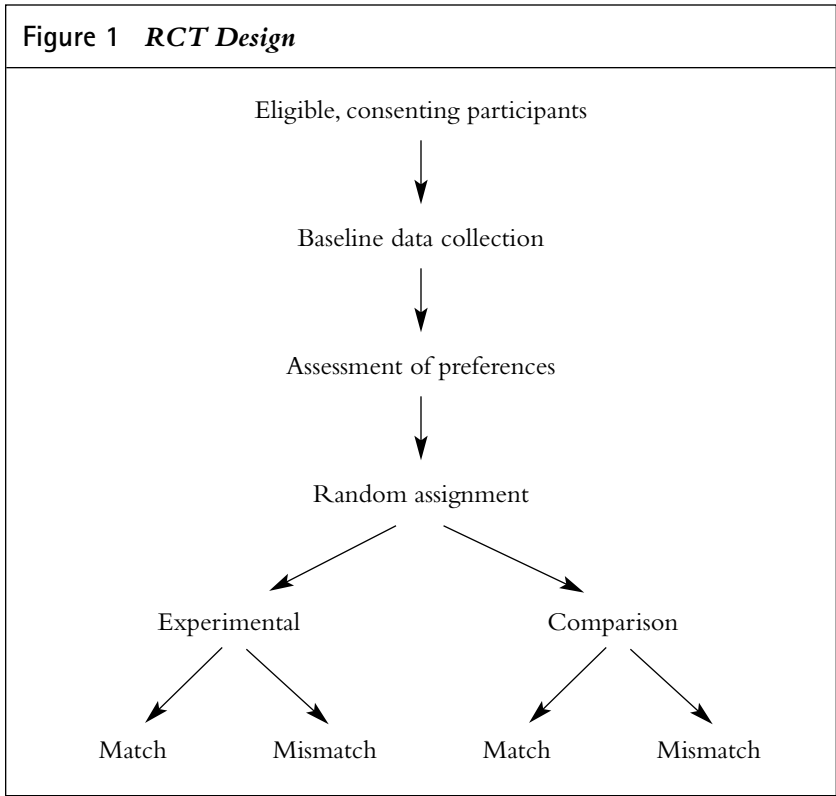
In summary, the empirical evidence available to date suggests that treatment preferences contribute to the decision whether to enrol in an RCT, adherence to treatment, and achievement of outcomes. The evidence is not clear regarding the influence of treatment preferences on attrition. Accounting for preferences when allocating participants to the experimental and comparison treatments in an RCT may mitigate the influence of preferences and strengthen the validity of conclusions related to the effectiveness of the intervention under evaluation.

Designs for Investigating Treatment Preferences

Three types of design are used to investigate treatment preferences: RCT, partially randomized clinical trial (PRCT), and two-stage PRCT. Each of these designs has its strengths and limitations, which guide their selection for future studies of preferences.

In the standard RCT, participants' preferences are assessed after consent is obtained but before randomization. A record is kept of each participant's expressed preferences. Participants are randomly assigned to

the treatment options offered within the context of the RCT, as is usually the case in this design. They are categorized into two groups (matched and mismatched), based on the treatment of preference and the treatment actually received. In the matched group, participants are randomly allocated to the preferred intervention; in the mismatched group, participants are randomly allocated to the non-preferred intervention (Figure 1). This design is illustrated in Klaber Moffett et al.'s (1999) study. The matched-mismatched group is included as a between-subject factor in the analysis aimed at determining the effectiveness of treatment. A significant treatment (i.e., experimental and comparison) by match (i.e., matched and mismatched) group interaction effect indicates differences in the outcomes among participants in the experimental group with matched and mismatched treatment and participants in the comparison group with matched and mismatched treatment. The strength of this design is the randomization of participants to treatment, which maintains the comparability of participants at baseline. Its limitations are (a) the fact



that random assignment ignores participants' preferences elicited at baseline, which may not be well received by participants and may be viewed as unethical; and (b) the sample size is often estimated to detect significant treatment effects and hence may not be adequate to detect significant interaction (i.e., treatment by match) effects reflecting the influence of preferences on outcome achievement (Preference Collaboration Review Group, 2009).

The partially randomized clinical trial (PRCT) was first described by Bradley (1993) and is well illustrated in the design implemented by Coward (2002). At baseline, participants' preferences for the treatment under study are elicited. Participants are requested to indicate whether they have a preference for a particular treatment. Those who express a preference are asked to identify their preferred treatment. Those who indicate that they have no preference are randomly assigned to the treatment options; those with a preference are allocated to the treatment of their choice (Figure 2). Comparison of the four resulting groups deter-

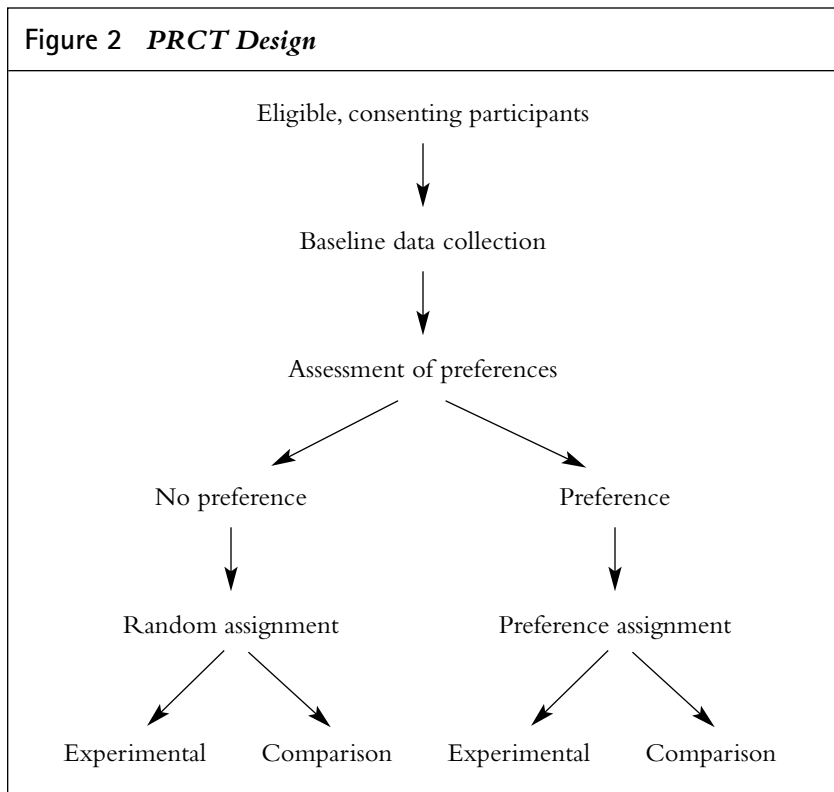
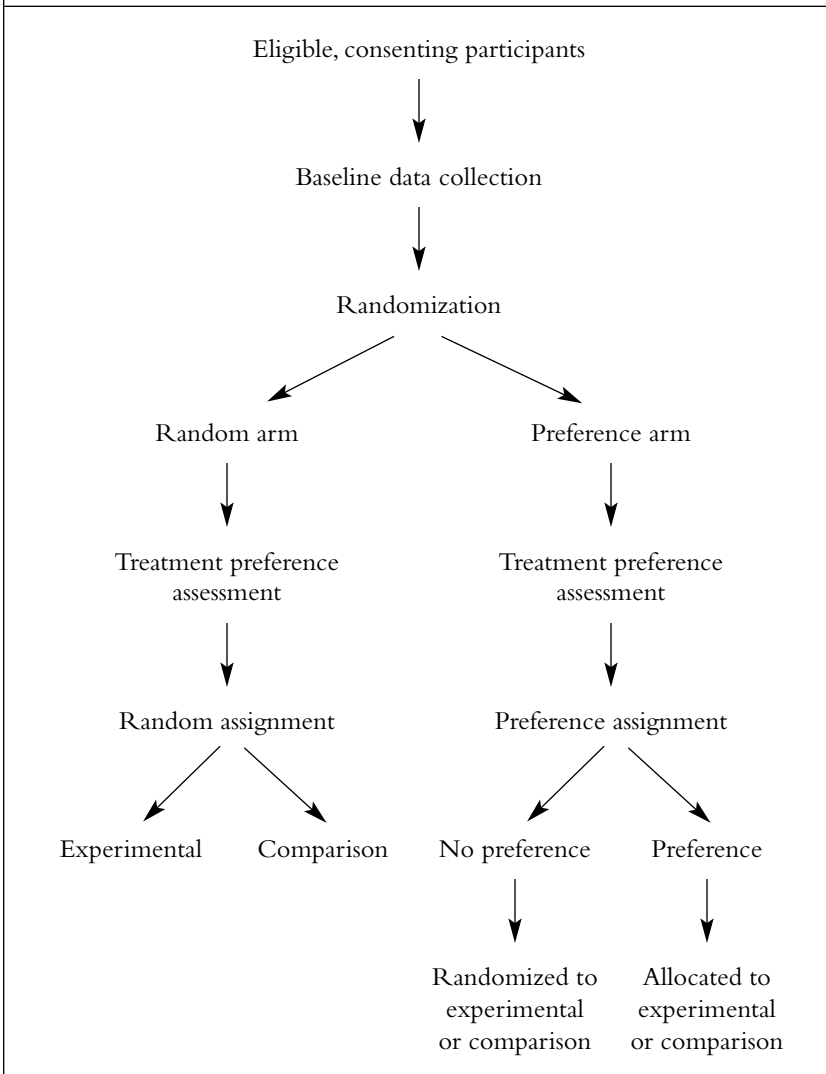


Figure 3 *Two-Stage PRCT Design*



mines the extent to which preferences affect treatment outcomes. Specifically, significant differences in outcomes between participants who received the experimental treatment based on chance and those who received it based on preference indicate if and to what extent preferences contribute to treatment outcomes. Although accounting for preferences is advantageous, this design has two limitations. First, as observed in

several studies, in particular Coward (2002), most participants ($\geq 60\%$) have preferences. Consequently, more participants are allocated to the treatment of their choice than are randomly assigned to treatment. The resulting unbalanced group size limits meaningful between-group comparison aimed at examining the influence of preferences. Second, participants with preferences may differ from those without preferences on baseline characteristics. Initial non-comparability of the groups may confound the effects of the treatment and preferences on the outcomes, thereby threatening the validity of the conclusions regarding treatment effectiveness.

The two-stage PRCT is meant to overcome the limitations of the PRCT. In this design, participants are randomized to the random or preference arm of the trial, thereby preserving initial comparability and balanced size of the groups. In the random arm, participants are randomly assigned to the treatment under investigation, as is usually done in an RCT. In the preference arm, participants indicate their preference; those with no preference are randomly allocated to treatment and those with a preference are allocated to their treatment of choice (Figure 3). Comparison of participants who received the same intervention in the random and preference arms determines the influence of preferences on outcomes. Therefore the two-stage PRCT is the most appropriate design for dismantling the contribution of treatment preference. Implementation of the two-stage PRCT may necessitate an increased sample size. This type of design has been used in some studies evaluating medical treatments that were included in the systematic review carried out by King et al. (2005).

Conclusions

Although the contribution of treatment preferences has been investigated in the medical and behavioural sciences, it has not been extensively addressed in nursing. Accounting for treatment preferences has methodological advantages. It promotes enrolment in an intervention evaluation study, adherence to treatment, satisfaction with treatment, and improvement in outcomes (Lang, 2005; Mills et al., 2006). The methodological advantages of accounting for treatment preferences demand careful consideration of preferences when designing, implementing, and evaluating nursing interventions. Nurse researchers are encouraged to further investigate treatment preferences with the goals of developing interventions that are acceptable to the various groups making up the target population and promoting adherence to and satisfaction with treatment as well as outcome achievement in the context of research.

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