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The Role of Treatment Perceptions in Intervention Evaluation: A Review

Le rôle des perceptions du traitement dans l'évaluation des interventions : une revue

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Article abstract

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The Role of Treatment Perceptions in Intervention Evaluation: A Review

Le rôle des perceptions du traitement dans l'évaluation des interventions : une revue

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Keywords

acceptability;
preferences;
credibility;
expectancy;
intervention

Abstract

Introduction: With the emphasis on patient-centeredness, the interest in examining people's perceptions of health interventions has resurged. Mounting evidence suggests that people's perceptions play an important role in their pursuit and use of interventions in the practice and research contexts. In research, participants' perceptions of the treatments under evaluation affect their behaviors reflected in enrollment, attrition, and treatment implementation (i.e., engagement and enactment by participants), all of which contribute to outcomes. **Objectives:** The objectives of this review are to generate a common understanding of treatment perceptions and to increase awareness of their role in intervention evaluation trials. **Method:** A literature review was conducted of conceptual and empirical articles that examined the contribution of participants' perceptions of treatment to enrollment, attrition, as well as treatment implementation and outcome achievement in intervention evaluation studies. **Results:** In this paper, we clarify the conceptualization and operationalization of four types of perceptions: acceptability, preferences, credibility and expectancy. We also describe the way in which these perceptions influence participants' behaviors (i.e., mechanism of action), and we summarize relevant empirical evidence. **Implications and conclusion:** Researchers are encouraged to account for participants' perceptions in making inferences about interventions' effectiveness or lack thereof.

Résumé

Introduction : Dans un contexte où l'accent est mis sur les soins centrés sur le patient, l'intérêt d'examiner les perceptions des personnes à l'égard des interventions de santé a refait surface. De plus en plus de preuves suggèrent que les perceptions des personnes jouent un rôle important pour s'engager dans l'intervention à la fois dans les contextes cliniques et de la recherche. En recherche, les perceptions qu'ont les participants des interventions évaluées affectent leurs comportements. Cela se reflète dans le recrutement, l'attrition, l'implantation et l'engagement dans l'intervention, lesquels contribuent aux résultats de la recherche. **Objectifs :** Les objectifs de cette revue sont de générer une compréhension commune des perceptions des interventions et d'accroître la sensibilisation quant à leur rôle dans les recherches évaluant des interventions. **Méthode :** Une revue de la littérature a été réalisée. Des articles conceptuels et empiriques examinant l'influence des perceptions des participants sur le recrutement, l'attrition, l'implantation et l'engagement dans l'intervention, ainsi que sur l'atteinte des résultats dans les études d'évaluation des interventions ont été synthétisés. **Résultats :** Dans cet article, nous clarifions la conceptualisation et l'opérationnalisation des quatre types de perceptions : l'acceptabilité, les préférences, la crédibilité et la perception de l'efficacité du traitement. Nous décrivons aussi la manière dont ces perceptions influencent les comportements des participants (c.-à-d. le mécanisme d'action) et résumons les preuves empiriques pertinentes. **Implications et conclusion :** Les chercheurs sont encouragés à prendre en considération les perceptions des participants en tirant des conclusions sur l'efficacité ou le manque d'efficacité des interventions.

Mots-clés

acceptabilité;
préférences;
crédibilité;
perception de
l'efficacité;
intervention

INTRODUCTION

With the emphasis on patient-centeredness, interest in examining people's perceptions of health interventions has resurged (Greenhalgh et al., 2016; Staniszewska et al., 2010). Mounting evidence suggests that people's perceptions play an important role in pursuing and using interventions in practice and research. In practice, patients are inclined not to seek and initiate interventions they view unfavorably, even if the interventions have demonstrated effectiveness; further, they may show low levels of implementation (i.e., engagement and enactment) of such interventions, which yield less-than-optimal improvement in outcomes (De Las Cuevas et al., 2018; Diller et al., 2013; Elliott & Hunsley, 2015). Similarly, in research, participants' perceptions of treatments under evaluation affect their behaviors, represented in the rates of enrollment, attrition, and implementation of treatment, all of which contribute to outcomes (Kendra et al., 2015). Accordingly, participants' perceptions of interventions or treatments have the potential to introduce bias. This bias should be addressed in order to strengthen the validity of conclusions or inferences regarding interventions' effectiveness in evaluation trials, and to generate practice-relevant evidence.

In the extant research literature, several terms have been used to reflect perceptions of health interventions: acceptability, credibility, perceived helpfulness, expectancy, outcome expectations, and preferences (Sandell et al., 2011). Some researchers have used these terms interchangeably (e.g. Sekhon et al., 2017; 2018). Others have distinguished four perceptions that represent different domains of the overall construct of acceptance: acceptability, preferences, credibility, and expectancy. The distinction is made at the theoretical and operational levels, and is supported by evidence showing moderate associations among the four perceptions (e.g. Haanstra et al., 2015) and between each perception and participant's behaviors in trials.

To clarify the distinction among the four perceptions and to understand how they contribute to participants' behaviors and outcomes in intervention evaluation studies, we conducted a review of conceptual and empirical articles that examined participants' perceptions of treatments and their associations with enrollment, attrition, treatment implementation and outcomes.

In this paper, we clarify the conceptualization of acceptability, preferences, credibility and expectancy. We describe the ways in which they are formed and how they influence participants' behaviors (i.e., mechanisms of action), which has not been explicitly delineated in the methodological literature. We summarize relevant empirical evidence supporting the contribution of treatment perceptions to participants' behaviors and outcomes in intervention studies. The aims are to generate, across disciplines, a common understanding of treatment perceptions and to increase awareness of their role in intervention evaluation trials. The ultimate goal is to encourage researchers to account for participants' perceptions in making inferences about interventions' effectiveness or lack thereof.

1) CONCEPTUALIZATION OF TREATMENT PERCEPTIONS

Treatment perceptions (i.e., acceptability, preferences, credibility, and expectancy) are viewed as distinct domains of the construct of acceptance. In this section, we provide conceptual and operational definitions that distinguish the four types of perceptions. We also indicate the point in time surrounding the delivery of an intervention in a trial at which the perceptions are usually assessed. The time of assessment is consistent with the definitions, as reported in the literature. The four perceptions are assessed independently from or with limited exposure to the intervention. They differ from satisfaction, which reflects people's appraisal of the intervention made on the basis of their actual experience with the intervention (Sidani & Epstein, 2016). Although satisfaction may reflect another domain of the construct of acceptance, it is not addressed in this paper.

1.1 Acceptability

Acceptability refers to judgments of whether an intervention's methods and techniques are appropriate in addressing the health problem that an intervention targets (Kazdin, 2006; Sekhon et al., 2017; 2018). It denotes the appraisal of an intervention relative to four attributes: appropriateness in addressing the health problem, anticipated effectiveness in improving the health problem, potential risks or discomforts, and convenience or ease with which participants can implement an intervention and its respective treatment recommendations in daily life (Diller et al., 2013; Lengel & Mullins-Sweat, 2017; Miner et al., 2016). Acceptability reflects the desirability of an intervention to potential participants; it is commonly assessed independently of exposure to the intervention (Elliott, 1988) as illustrated in a large number of descriptive studies (e.g., Bluestein et al., 2011; Elliott & Hunsley, 2015; Fox et al., 2018; Sidani et al., 2018a).

In clinical trials, acceptability is measured at pretest, using a systematic process consisting of two steps. In step 1, participants review the description of an intervention, which is derived from the theory underpinning the intervention and evidence of its effectiveness. The description: states the intervention's name; clarifies its goals; delineates its main components and activities, and the treatment recommendations that participants are to carry out; specifies the mode and dose at which the intervention is delivered; and identifies the benefits and risks associated with the intervention. In step 2, participants rate the intervention relative to four attributes: perceived appropriateness, effectiveness, risks and convenience (Fox et al., 2018; Sidani et al., 2018a). This rating helps participants recognize what they value most about the intervention that makes it more or less desirable (Harrison et al., 2014).

1.2 Preferences

Preferences refer to the choice of treatment (Goates-Jones & Mills, 2008). They represent the specific treatment, among different options, that participants want to have to address their health problem (Stalmeier et al., 2007). Preferences are usually assessed prior to exposure to an

intervention; they form the basis for allocating participants to treatment in preference trials. In preference trials, participants who decline randomization are requested to indicate the treatment of choice to which they are allocated (Sidani, 2015).

To accurately reflect participants' choice, preferences are elicited after participants gain an understanding and rate the acceptability of the treatment options. Assessment of preferences follows the systematic process described previously for measuring acceptability. Participants review the description of each treatment under consideration and rate its acceptability. Once they have rated all treatments, they indicate the one they prefer (Fox et al., 2018; Sidani et al., 2018a). Having participants rate all interventions prior to indicating their preference helps them to clarify the attributes they value most, and compare and contrast the different interventions relative to the most valued attributes. Such comparisons contribute meaningfully to their choice.

1.3 Credibility

Credibility represents participants' endorsement of an intervention's rationale (Mooney et al., 2014; Smith et al., 2013). It is the extent to which participants view that an intervention makes sense in terms of how it works in addressing the health problem. Credibility is about participants' perceptions that the principles underlying an intervention are logical and the intervention components (including methods, techniques and treatment recommendations) are coherent, contributing meaningfully to the management or resolution of the health problem (Sandell et al., 2011).

Credibility is assessed after learning about an intervention's rationale. Often, an intervention's rationale is introduced early in its delivery (Mooney et al., 2014), usually in the first treatment session. In this session, it is common to inform participants about an intervention's goals, components and activities, and to discuss its rationale, that is, how the intervention works in addressing the health problem. Credibility is measured towards the end of the first session, with items inquiring about participants' beliefs about

how logical, believable and convincing the intervention is in its potential to address the health problem (Haanstra et al., 2015; Mooney et al., 2014).

1.4 Expectancy

Expectancy refers to participants' prognostic beliefs about the helpfulness or usefulness of an intervention (Constantino et al., 2007). It is operationalized as the anticipated effectiveness of an intervention, that is, the extent to which participants believe that an intervention is likely to be effective in addressing the health problem and improving other health-related outcomes (Colagiuri, 2010; Haanstra et al., 2015; Smith et al., 2013; Younger et al., 2012).

Similar to credibility, expectancy is measured after an intervention has been described in the first session, as explained previously. Expectancy is assessed towards the end of this session, using items to rate the perceived potential effectiveness of an intervention.

2) FORMULATION OF PARTICIPANTS' PERCEPTIONS OF INTERVENTIONS

Participants' perceptions of treatments under evaluation, including the experimental intervention and the comparison treatment (e.g., treatment-as-usual or usual care), are formulated early in a trial. Participants present with a health problem that can be addressed, prevented, managed or resolved by the treatments included in the trial.

Participants differ in their demographic, socio-cultural and general health profiles. Participants of diverse profiles hold specific beliefs about the causes of the problem and about appropriate strategies or remedies to treat it and to improve health (Cohen et al., 2015). For instance, some participants may believe in the biological causes (e.g. chemical imbalance) of depression (Kemp et al., 2014; Steidtmann et al., 2012). Others attribute mental illness to genetic causes (Wright et al., 2012). Participants with these beliefs view pharmacotherapy as an acceptable, credible and potentially effective treatment for mental health problems. Other participants may believe that life

stress is the main determinant of mental health problems and consider psychological interventions as acceptable, credible and effective (Givens et al., 2007). Thus, participants entering a trial may have different perceptions of the treatments under evaluation. They perceive favorably the one that is consistent with their beliefs about the health problem and its treatment.

Participants are also aware of different pharmacological, behavioral, psychological, and complementary treatments that address the health problem. They gain knowledge about these treatments from a range of sources. For example, there is ample information about treatments on the Internet. Information on health promotion strategies is available in short articles in many newspapers, newsletters, and audio-visual documentaries, and discussed in television or radio talk shows. Participants acquire intervention-related knowledge from family, friends or health professionals (Mills et al., 2011). Participants may have prior experience with the treatments under evaluation; they may have either actually used or witnessed others use the treatments. Participants' prior knowledge or experiences inform their perceptions of the treatments upon entry into a trial. Participants' initial perceptions of the treatments may be reinforced or may change during the treatment period, influencing their behaviors in a trial. These behaviors contribute, positively or negatively, to outcome achievement. The mechanisms through which participants' perceptions influence enrollment, attrition, and implementation of an intervention, as well as experience of beneficial outcomes, are described next.

Evidence supporting the influence of treatment perceptions is presented in the respective sections. Where findings of studies converge, the evidence is synthesized. Where discrepancies in findings were found, the following possible contributing factors are identified:

- a) conceptual factors, such as differences in the types of treatment, and
- b) methodological factors, such as differences in instruments administered to measure acceptability, preferences, credibility and expectancy.

3) INFLUENCE OF PERCEPTIONS ON ENROLLMENT

3.1 Overview

During recruitment and the consent process, participants become aware of the experimental and comparison treatments included in the trial. As required by research ethics, participants are provided information on the treatments prior to obtaining their consent. Participants are briefly informed of the treatments' names (e.g., cognitive behavioral therapy), components (i.e., content, activities), mode and dose of delivery, benefits and risks, without revealing which is the experimental treatment and which is the comparison treatment. At this initial stage, participants get a general sense of the treatments. This knowledge, in combination with participants' beliefs about the health problem and its treatment or their previous experience with the interventions, contribute to the development of favorable or unfavorable treatment perceptions. In particular, perceived acceptability and preferences may influence participants' enrollment in a trial.

3.2 Mechanism

Participants' beliefs, prior experiences, and exposure to information on the treatments during the consent process, contribute to their perceived acceptability and preferences for the treatments under evaluation. These treatments may include different active interventions such as pharmacotherapy and cognitive behavioral therapy for insomnia; an active intervention and a placebo treatment; an active intervention and treatment-as-usual; or an active intervention and a no-treatment control condition (e.g. watchful waiting).

Some participants consider all treatments included in a trial as unacceptable; they may refuse enrollment and seek treatment outside the trial. Low enrollment rates have two consequences. First, they reduce the trial sample size, which weakens the statistical power to detect significant effects of the experimental intervention (Kowalski & Mrdjenovich, 2013); the intervention is claimed ineffective. Second, low enrollment rates demand additional resources (e.g. hiring a large number of recruiters) and time to expand recruitment efforts and acquire the required sample size. Other

participants have favorable perceptions of all or one of the treatments. They enroll in the trial and are enthusiastic about the prospect of receiving the treatment they consider acceptable and hence, prefer.

It is possible that participants who view the treatments as unacceptable differ from those with favorable perceptions on personal and health characteristics. Thus, the accrued sample is likely comprised of participants with preferences for the treatments under evaluation, which influences improvement in outcomes as explained in later sections.

3.3 Supporting evidence

Evidence indicates that participants with and without preferences differ on some socio-demographic (e.g., gender) and health (e.g., severity of health problem) characteristics (Sidani, 2015). Accordingly, participants differ from non-participants, whereby the accrued sample is likely comprised of participants with particular personal and health profiles, and favorable perceptions of the treatments. Participants' profiles and perceptions may confound the effects of the experimental intervention yielding biased estimates of its effects; these effects may not be replicated in research and practice (Leykin et al., 2007), which is an issue of external validity.

4) INFLUENCE OF PERCEPTIONS ON ATTRITION

4.1 Overview

Participants with varying levels of perceived acceptability and preferences for the treatments under evaluation enroll in a trial. During and after the consent process, participants become aware of the treatment assignment method and their allocated treatment. The method of assignment is based on either chance in randomized trials or on participants' preferences in preference trials. Participants are then exposed to the allocated treatment. Health interventions are usually given in individual or group sessions that are facilitated by therapists, or modules that are self-completed by participants. The first session or module covers detailed information about the treatment.

Participants may react differently to the method of assignment, to the treatment to which

they are allocated, and to the treatment to which they are actually exposed. Participants with negative reactions may withdraw from the trial prior to (i.e., pre-inclusion or early attrition) or after (i.e., post-inclusion attrition) exposure to treatment (Fernandez et al., 2015). Participants' perceptions of treatment are likely to influence their reactions, which contribute to attrition. Attrition is a major threat to validity. Perceived acceptability and preferences for treatment contribute to pre-inclusion attrition. Perceived credibility of treatment to which participants are assigned and treatment expectancy contribute to post-inclusion attrition.

Pre-inclusion attrition

Mechanism. Participants with varying levels of acceptability and preferences may react differently to the method of assignment. The influence of participants' preferences for a treatment on their reactions to the method of assignment has been more extensively investigated than the contribution of participants' acceptability of a treatment to their reactions to the method of assignment.

Participants with preferences for one of the treatments can react negatively to randomization. They may consider randomization unacceptable and unfair because it disregards their right to be actively involved in treatment decision-making and their desire to get their preferred treatment. Participants expressing non-acceptance of randomization may refuse further enrollment in the trial because of discomfort with being randomized to the non- or least- preferred treatment (Mills et al., 2011; Sidani et al., 2017). Alternatively, participants with preferences for all treatments or a particular one may indicate willingness to be randomized and continue their involvement in the trial. Participants with preferences for all treatments may be indifferent to randomization because they are aware that they will be allocated to any of the treatments they view favorably. Participants preferring a particular treatment realize that after all, randomization is useful: with randomization, they have a 50% chance of being allocated to their preferred treatment (Bradley-Gilbride & Bradley, 2010). In contrast, participants may react positively to

preference-based allocation to treatment and continue their involvement in the trial.

Once known, participants are informed of the assigned treatment, regardless of the method used. They may react and behave differently depending on the match between the allocated and the preferred treatment. Participants with matched treatment are likely to be enthusiastic, and to continue their involvement in the trial to receive the treatment they want. Participants with mismatched treatment are likely to be disappointed and to withdraw from the trial to seek treatment elsewhere, thereby increasing pre-inclusion attrition. High pre-inclusion attrition rates increase the need to expand recruitment efforts, lead to reduced sample size and statistical power to detect significant intervention effects (a threat to statistical conclusion validity), and yield biased (i.e., confounded with characteristics and perceptions of participants who complete the study) intervention effects (a threat to internal validity) that are not replicated (a threat to external validity).

Supporting evidence. Three systematic reviews found participants' reactions to randomization to influence pre-inclusion attrition. Two reviews consistently reported lower attrition rates in trials or arms of trials that accounted for preferences in assigning participants to treatment than in those that randomly assigned participants to treatments (King et al., 2005; Wasmann et al., 2019). Further, evidence synthesized in two reviews indicates that large proportions of participants refused randomization or further involvement in the randomized trial because randomization did not account for their preferences (Beasant et al., 2019; Wasmann et al., 2019).

Post-inclusion attrition

Mechanism. Consenting participants are exposed to the assigned treatment. Those assigned to no-treatment control or treatment-as-usual do not receive any information or contact from the trial's therapists during the treatment delivery period; they may be disappointed and withdraw from the trial. This leads to higher post-inclusion attrition rates in the comparison, than the experimental intervention, group. Thus, the number of

participants who complete the trial is unbalanced in the two groups, which may be associated with unequal between-group variance. If not accounted for, unequal variance reduces the probability of detecting significant intervention effects (Sidani, 2015).

Participants assigned to active interventions attend the first session or self-complete the first module during which they receive detailed information on the allocated treatment. Participants gain a comprehensive understanding of the allocated intervention in terms of 1) why and how it works which shapes their perceived credibility, and 2) its likely effectiveness which informs their perceived expectancy. This understanding can reinforce participants' prior favorable perceptions or alter their views of the intervention, and may influence their continued involvement in the trial.

Participants who continue to hold favorable perceptions, indicated by high credibility and expectancy, of the allocated treatment are motivated to complete treatment (Kendra et al., 2015; Mooney et al., 2014). They are likely to complete the trial, resulting in low attrition rates in this participant subgroup. Participants who change their perceptions and express less favorable views of the treatment, indicated by low credibility and expectancy, may experience discontentment with the allocated treatment. This participant subgroup has the tendency to withdraw from treatment, resulting in high attrition rates. This pattern of withdrawal among the two subgroups has adverse consequences, depending on their distribution within the treatment groups. Specifically, if a comparable number of participants withdraw from the treatment to which they were assigned, then the size of the treatment groups is reduced, resulting in an underpowered trial and potential type I error, suggesting that the intervention is ineffective. If the number of participants who drop out of the treatment groups is non-equivalent, then differential attrition is likely. Differential attrition occurs when the number; the socio-

demographic and health characteristics; and the treatment perceptions of participants who withdraw from one treatment (e.g., experimental) are not comparable to those of participants who drop out of the other treatment (e.g., comparison). With differential attrition, participants assigned to the treatments under evaluation are not comparable on characteristics measured at pretest. Differences in these characteristics and treatment perceptions may be associated with differences in participants' implementation and response to treatment, thereby confounding the intervention's effects on the outcomes (Sidani, 2015).

Supporting evidence. There is increasing evidence supporting the contribution of treatment perceptions on post-inclusion attrition. The influence of preferences has been investigated by comparing attrition rates for participants who were allocated (randomly or by preference) and received the treatment that matched or mismatched their preference. The results of individual studies (e.g. Kwan et al., 2010; Sidani et al., 2015) and systematic reviews (Preference Collaborative Review Group, 2009; Swift & Greenberg, 2012; Swift et al., 2011; 2013; Wasmann et al., 2019; Winter & Barber, 2013) were consistent in showing lower post-inclusion attrition rates for participants who received matched treatment. In a few studies, the simultaneous influence of credibility and expectancy was examined. The findings indicated that credibility, but not expectancy, was associated with attrition; participants with low credibility ratings were likely to withdraw from the treatment to which they were exposed (Boettcher et al., 2013; Merincavage et al., 2017; Narimatsu et al., 2016). Further, in a naturalistic study of psychotherapy implemented by 66 therapists in several outpatient clinics, patients (n = 707) rated their expectancy of the therapy they received; those reporting high expectancy had lower probability of withdrawal from treatment (Zimmermann et al., 2017).

5) INFLUENCE OF PERCEPTIONS ON IMPLEMENTATION OF INTERVENTIONS

5.1 Overview

Participants who continue to view the allocated treatment favorably, attend the remaining treatment sessions or self-complete the remaining modules. Experience with the intervention may reinforce or alter their perceptions, and consequently influence treatment implementation which entails engagement and enactment of treatment. Engagement is reflected in participants' attendance at the treatment sessions or self-completion of the modules, and involvement in the activities planned for each session/module (Hasson, 2010). Enactment refers to the actual performance and adherence to the treatment recommendations in daily life (Prowse & Nagel, 2015). The influence of perceived credibility and expectancy on attendance and adherence has been frequently examined (Wasmann et al., 2019).

5.2 Mechanism

Initial exposure to treatment generates perceptions of credibility and expectancy. Participants who view the allocated treatment as credible and potentially effective are usually content. They are motivated to engage and enact the treatment, which they believe will be effective in addressing the health problem. The sense of contentment and motivation is heightened among participants assigned to their preferred treatment. Motivated participants are likely to attend all planned treatment sessions or complete all modules. During the sessions, they are attentive to the content covered and actively involved in the treatment activities such as discussion of treatment recommendations, possible challenges in enacting the recommendations, and strategies to overcome these challenges. They are equipped with the knowledge and skills required to correctly implement and adhere to treatment recommendations in daily life (Beatty & Binnion, 2016; Haanstra et al., 2015; Nock et al., 2007).

Participants who develop unfavorable perceptions of the allocated treatment are likely discontent, disappointed and unmotivated to implement the intervention. Some participants

may not attend the remaining sessions. Others may be selective in the treatment sessions they attend and the modules they complete, and in the treatment recommendations they enact. For instance, they attend sessions covering content they view as important or useful, and carry out the recommendations they consider relevant or consistent with their beliefs and lifestyle. These behaviors have the potential to threaten validity. Participants with unfavorable perceptions of and disappointment with the allocated treatment may withdraw, especially in situations of mismatched treatment. Attrition reduces statistical power and differential attrition introduces confounds. Other participants may not enact all treatment recommendations and experience no or limited improvement in outcomes, which contributes to their dissatisfaction with treatment (Sidani et al., 2018b). Dissatisfied participants may cross-over to another treatment under evaluation or seek additional treatment outside the trial. Cross-over has the potential of disrupting the balance, in number and profile, between treatment groups and hence, of introducing confounds. Receiving additional concurrent treatment weakens the confidence in attributing improvement in outcomes, solely, to the experimental intervention. Cross-over and concurrent treatment are major threats to internal validity.

5.3 Supporting evidence

Evidence supporting the influence of treatment perceptions on implementation was generated from two lines of inquiry. The first focused on examining the impact of treatment preferences on treatment implementation, with the assumption that participants who receive treatment matching their preference have favorable perceptions, carry out and adhere to its recommendations and do not cross-over. Consistency was noted in the results of six studies in supporting higher levels of engagement and enactment (operationalized in attendance at treatment sessions and application of treatment recommendations) for participants who received their preferred treatment (Sidani, 2015). Wasmann et al. (2019) conducted a systematic review of trials that included two arms representing random and preference-based assignment to treatments; they

reported a higher mean percentage of participants who crossed over in the random (14.5%) than the preference (6.3%) arms.

The second line of inquiry was concerned with directly measuring participants' perceptions of the allocated treatment's credibility and expectancy, and examining the association of these perceptions with enactment of treatment recommendations. The type and mode of delivery of the interventions varied across studies. The interventions included: medication for physical or mental health problems (De Las Cuevas et al., 2018; Eaton et al., 2019; Krueger et al., 2005); psychological treatments (Beatty & Binnion, 2016); cognitive-behavioral therapy for social anxiety (El-Alaoui et al., 2015), insomnia (Dong et al., 2018), relaxation (Narimatsu et al., 2016) or body dysmorphic disorder (Gentile, 2019); self-help interventions for body dissatisfaction (Geraghty et al., 2010) or social anxiety (Boettcher et al., 2013); and physiotherapy (Tijou et al., 2010), delivered in face-to-face, or internet self-directed modules. The findings were consistent in showing high levels of enactment for participants who perceived the allocated treatment as credible and/or had high expectancy of its effectiveness.

6) INFLUENCE OF PERCEPTIONS ON OUTCOMES

6.1 Overview

Participants' perceptions are developed during initial exposure to and receipt of treatment, and are affected, to some extent, by the method of assignment to treatment. Participants' perceptions influence their experience of improvement in outcomes and are major threats to internal validity.

6.2 Mechanism

Treatment perceptions influence outcomes directly or indirectly (Nock et al., 2007; Reicherts et al., 2016). The direct influence is reflected in the placebo response. Participants who appraise a treatment, whether experimental or comparison, as acceptable, credible, and potentially useful, develop high expectancies of its effectiveness in managing the health problem and in improving other health-related outcomes. Regardless of the level of treatment exposure, participants report

improvement in outcomes. This improvement, however, may be associated with participants' placebo response initiated by the anticipated benefits of the treatment more so than with the active ingredients of the treatment to which they were actually exposed and they enacted (Frisaldi et al., 2017; Gaudiano et al., 2013; Younger et al., 2012). In this situation, it is difficult to dissociate the true causal effects of the treatment (i.e., effects that are theoretically associated with its active ingredients) from the placebo response attributable to treatment perceptions. The difficulty is encountered when treatment perceptions are not measured. When participants in the experimental treatment group have very favorable perceptions and exhibit the placebo response, then there is great potential of confounding; that is, the observed high improvement in outcomes can be generated by the treatment, the placebo response, or the interaction between them. The effects of treatment may be overestimated and non-replicable.

When participants in the comparison treatment group have favorable perceptions and demonstrate a high placebo response, then the ability to detect significant between-group differences is low, potentially yielding underestimated effects. When participants in any group perceive the allocated treatment favorably and exhibit a placebo response, then the probability of type II error is high because participants in the two groups have comparable levels of improvement in the outcomes, making it difficult to detect significant between-group differences (Colagiuri, 2010).

The indirect influence of treatment perceptions is hypothesized to be mediated by participants' implementation of the allocated treatment. Participants who rate the treatment as acceptable, preferred and credible tend to have high expectancy of its effectiveness. If participants are assigned to their desired treatment, they are likely motivated to attend all planned sessions or complete all modules; are actively involved in the sessions' or modules' activities; and carry out treatment recommendations correctly and at the prescribed level. High adherence may lead to improvement in the outcomes.

6.3 Supporting evidence

The direct influence of treatment perceptions is well supported empirically. The contribution of the placebo response is illustrated by results of systematic reviews that failed to demonstrate the benefits of pharmacological treatments including analgesics, antidepressants, and surgical interventions compared to respective placebo treatments (Frisalda et al., 2017; Wartolowska et al., 2016).

There is ample evidence supporting the direct association between credibility and outcomes. The evidence is generated from several studies that evaluated psychological (Beard et al., 2011; Goates-Jones et al., 2008; Mooney et al., 2014; Nock et al., 2007; Nordgreen et al., 2012), cognitive-behavioral (El-Alaoui et al., 2015; Hedman et al., 2012; Narimatsu et al., 2016), and surgical (Haanstra et al., 2015) treatments. These studies' findings were consistent with those of a recent meta-analysis (Constantino et al., 2018) in demonstrating a positive but weak (i.e., small effect sizes) association between credibility and outcomes. Participants who rated the allocated treatment as credible were likely to experience larger improvements in outcomes, compared to those viewing it as not credible.

The relationship between expectancy and outcomes was examined in studies of psychological (Beard et al., 2011; Boettcher et al., 2013; Nock et al., 2007), cognitive, behavioral, cognitive-behavioral (Beasley et al., 2017; El-Alaoui et al., 2015; Goossens et al., 2005; Smeets et al., 2008), surgical (Haanstra et al., 2015), and acupuncture (Linde et al., 2007; Sherman et al., 2010) treatments. The results supported a positive association between treatment expectancy and outcomes. Participants with high expectancy of the allocated treatment experienced high levels of improvement in the outcomes.

Several studies and systematic reviews investigating the influence of preferences for psychological, behavioral and complementary treatments on outcomes had mixed results. In three studies (Beasley et al., 2007; Foster et al., 2010; Sherman et al., 2010; Stewart et al., 2008) and one systematic review (Wasmann et al., 2019), a match between the assigned and preferred treatment was not beneficial in improving

outcomes. In contrast, two studies (Kocsis et al., 2009; Kwan et al. 2010) and three systematic reviews (King et al., 2005; Preference Collaborative Review Group, 2009; Swift et al., 2011) found that participants who received the preferred treatment reported improvement in the outcomes (average effect size < 0.31).

One study examined the indirect effects of treatment perceptions on outcomes and found that participants who received the preferred treatment exhibited high adherence to that treatment. In turn, adherence was associated with the achievement of beneficial outcomes (Kwan et al., 2010).

IMPLICATIONS AND CONCLUSION

This paper describes the way in which participants' perceived acceptability, preferences, credibility, and expectancy of treatments can influence enrollment, attrition and treatment implementation in evaluation trials. Evidence indicates that treatment perceptions are potential threats to the validity of conclusions regarding the effectiveness of interventions. Therefore, it is critical to measure and account for treatment perceptions in outcome analysis to determine the true causal effects of interventions (Beasley et al., 2017). Assessment is done at different points in the trial using validated self-report measures, such as the Acceptability of Intervention Measure (Weiner et al., 2017) and the Stanford Expectations of Treatment Scale (Younger et al., 2010).

Accounting for treatment preferences is proposed as a general approach to improve enrollment, reduce attrition, and promote implementation of health interventions (Sidani et al., 2017; 2018b; Wasmann et al., 2019). Two strategies have been proposed to account for treatment preferences in trials. The first consists of introducing a preference arm to the trial design, or using preference trials (Beasant et al., 2019; Sidani, 2015). The second strategy involves examining treatment perceptions' contribution to outcomes. Appropriate statistical analyses are applied to determine the direct and indirect (mediated through treatment implementation) effects of treatment perceptions on outcomes. The results

provide valid estimates of the intervention's causal effects on the outcomes.

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