Résumé

L'expérience/les perceptions des femmes en tant que participantes à un groupe témoin avec attention et à un groupe d'intervention expérimentale, dans le cadre d'un essai clinique randomisé

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Un groupe témoin avec attention peut être utilisé pour contrôler l'effet placebo lors de l'évaluation d'interventions psychosociales et comportementales. Les auteures ont réalisé une étude descriptive qualitative afin de cerner les perceptions de femmes atteintes du syndrome de fibromyalgie concernant leur participation/ expérience au sein d'un groupe témoin avec attention et d'un groupe d'intervention expérimentale, à la suite d'un essai clinique randomisé. Des entrevues semi structurées ont été réalisées auprès de 18 femmes (12 du groupe d'intervention expérimentale et six du groupe témoin avec attention). Les participantes du groupe témoin ont signalé certains bienfaits mais peu de changements comportementaux découlant de la participation à l'essai clinique. Certaines participantes ont été déçues de ne pas avoir bénéficié de ce type d'intervention. Des perceptions de changements dans les attitudes concernant le syndrome de fibromyalgie et certains comportements rapportés par le groupe d'intervention semblent conformes à la théorie sous-jacente à l'intervention. Des interactions sociales négatives et positives avec les autres participantes figurent parmi les effets placebos possibles relevés chez les deux groupes.

Mots clés : groupe témoin, effets placebos, fibromyalgie

Women's Experiences as Members of Attention Control and Experimental Intervention Groups in a Randomized Controlled Trial

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Attention control groups are often used in research testing the efficacy of psychosocial and behavioural interventions in order to control for placebo effects. The authors conducted a descriptive qualitative study to investigate how participants viewed their experiences in attention control and experimental intervention groups following a randomized controlled trial for women with fibromyalgia syndrome. Moderately structured interviews were conducted with 18 women (12 from the experimental intervention group and 6 from the attention control group). Members of the control group reported some benefits but few behavioural changes as a result of participating in the RCT, and some participants expressed disappointment at not receiving the intervention. Perceptions of changes in attitudes towards fibromyalgia syndrome and behaviours reported by the intervention. Possible placebo effects identified in both groups include negative and positive social interactions with other participants.

Keywords: control groups, placebo effects, intervention research, fibromyalgia

An important area of chronic illness research is testing experimental interventions consisting of patient education and/or cognitive-behavioural strategies aimed at self-management and health promotion (Burckhardt, 2002). The use of control groups in randomized controlled trial (RCTs) of patient education and behavioural interventions enables researchers to distinguish between the effect of the hypothesized mechanism of an intervention and the effect of other components of the intervention (Street & Luoma, 2002). Among the challenges associated with the use of control groups in nursing intervention research is the fact that placebo effects may cause difficulty interpreting the results of an RCT if both control and intervention groups show improvement (Fogg & Gross, 2000).

Between January 2004 and December 2006 we conducted an RCT with attention control groups to test a wellness intervention for women with the chronic condition of fibromyalgia syndrome (FMS). The objective of the RCT was to examine the effect of the intervention on the

level of self-efficacy for health promoting behaviours, health promoting activity, and perceived quality of life. Participants in the RCT were randomized to a group in which they would develop skills to engage in health promoting behaviours (intervention group) (N = 98) or a group that would receive information about other health-related topics (attention control group) (N = 89). Participants were not informed which group they were assigned to. Research activities for the two groups were held concurrently at a women's health centre but on different days, to avoid contact between the two groups. The groups had different facilitators. During the study period 10 intervention and 10 attention control cohorts were formed, each containing 8 to 12 participants.

The Lifestyle Counts intervention was based on a theoretical framework incorporating concepts from the Health Belief Model (Becker, 1974), Pender's (1987) model of health promotion and self-efficacy theory (Bandura, 1982). It was first tested among women with multiple sclerosis (Stuifbergen, Becker, Blozis, Timmermann, & Kullberg, 2003) and later adapted for use among women with FMS (Stuifbergen, Harrison, Becker, & Carter, 2004). Lifestyle Counts consisted of eight 2hour lifestyle change classes followed by a supportive environment component. The facilitators for the Lifestyle Counts intervention were a clinical nurse specialist experienced in working with persons with chronic conditions and a woman with a doctoral degree in social work who had FMS. The lifestyle change classes included patient education about health promoting behaviours in the context of FMS, including physical activity, nutrition and stress management, discussions about resources and about barriers to health behaviours, a self-assessment of health behaviours, and the development of strategies for building self-efficacy with respect to health behaviours. The supportive component consisted of bi-monthly phone calls for 3 months during which the facilitators used motivational techniques to assist and support participants as they strove to achieve individual health behaviour goals and develop solutions to perceived barriers to health behaviours.

The attention control group received eight 2-hour classes consisting of information on health topics not covered in the lifestyle change classes. Topics included medications used to treat FMS, heart health, enhancing memory, and understanding health information. The protocol for the control group followed a lecture format and specified that the facilitator, a nurse with a master's degree and experience working with persons with chronic conditions in a research environment, not engage participants in discussions of ways to improve self-efficacy for health behaviours or discuss topics covered in the lifestyle change classes. During follow-up phone calls, made at the same frequency as for the intervention group, participants were asked if they had questions about class content. The results of the RCT indicated that the attention control and experimental intervention groups demonstrated significant improvement (p < .05) on measures of self-efficacy, health promoting behaviours, and quality of life (Stuifbergen et al., in press). In order to gain a better understanding of how the research groups functioned, we conducted a qualitative descriptive study to answer the following research question: *How did attention control and experimental treatment group participants view their experiences in an RCT to test the effects of a wellness intervention for women with FMS?*

Literature Review

Rationale for Attention Control Groups

Activities for the attention control groups are similar to those for the intervention but without the components of the intervention theorized to have an effect on dependent variables (Bickman & Rog, 1998). An assumption underlying the use of control groups in patient education and behavioural intervention research is that the interventions contain specific factors theorized to affect outcome variables as well as non-specific factors, such as social support, that may be therapeutically active ingredients (Schwartz, Chesney, Irvine, & Keefe, 1997). The total effect of an experimental intervention derives from both specific and non-specific factors (Vickers & de Craen, 2000). Random assignment to the control or intervention group is thought to control for the effect the non-specific factors may have on study outcomes such that the magnitude of the between-group differences reflects the efficacy of the specific factors in the experimental treatment (Hakim, 1987).

Placebo Effects

Placebo effects are defined as a change in the dependent variable not attributable to the specific components of the intervention under investigation (Vickers & de Craen, 2000). They likely occur due to a combination of factors, including the nature of the relationship between the participants and members of the research team and the personal characteristics of these individuals, the condition under study, and the research environment (Shapiro, 1964). Participant factors that may account for placebo effects include expectations about the outcome of a study, conditioned responses to the health-care milieu, and personality characteristics (Crow et al., 2001). Personal attributes of members of the research team, such as warmth and empathy towards participants, may influence participants' perceptions of the intervention; also, researchers may unknowingly communicate their attitudes about the study (Street & Luoma, 2002). Because the factors that contribute to placebo effects are

complex and vary from study to study, the placebo effect is not considered a unitary phenomenon that can be reliably replicated (Shapiro & Morris, 1978).

Design of Attention Control Groups

Lindquist, Wyman, Talley, Findorff, and Gross (2007) specify several principles as important to the design of control groups: equivalence of the interventions, distinctiveness versus comparability of interventions, and attractiveness of the control condition. The control group should be equivalent to the experimental group in terms of the time commitment required of participants, amount of attention paid by the researchers, format of activities, and scheduling of follow-ups. The two groups should be conducted contemporaneously to control for history and maturation effects. The control group should not be comparable to the experimental group, meaning that it should not contain elements that may have an effect on study outcomes through a mechanism that differs from that of the experimental intervention. Also, the control group should offer something of value and interest so that it is attractive to participants. Control groups that are attractive to participants and structurally equivalent but not comparable to the experimental intervention contribute to the internal validity of an RCT (Lindquist et al., 2007).

Health information control groups have been used in several intervention studies testing the efficacy of patient education and/or cognitivebehavioural strategies for FMS (Buckelew et al., 1998; Nicassio et al., 1997). In these groups, participants receive information about healthrelated topics but there are no strategies for changing behaviour. A health information control group differs from a patient education intervention, which consists of "planned, organized learning experiences designed to facilitate voluntary adoption of behaviors or beliefs conducive to health" (Burckhardt, 1994, p. 2). The rationale for using a health information control group is that health information alone does not lead to change in behaviour (Bucklew et al., 1998).

Methodology

Design and Procedures

Qualitative description was chosen as the methodology for the study. This method is appropriate when a researcher aims to obtain a comprehensive summary of an event or experience and convey it "in everyday language" (Sandelowski, 2000, p. 336). Sandelowski (2000) describes this approach as not highly interpretive and as instead yielding "largely unadorned answers" to a research question.

After Internal Review Board approval was received, participants who had completed the RCT in the preceding year (n = 63) were invited by letter to participate in an interview about their experiences in the research group. A total of 20 participants contacted the research office to express an interest in the study, 14 from the intervention group and 6 from the control group. A member of the research staff contacted these individuals by phone to describe the purpose of the study and to schedule interviews. The final sample consisted of 6 participants from the control group and 12 from the intervention group, because 2 women from the intervention group were unable to schedule interviews. Recruitment and interviewing took place over a 7-month period (September 2006 through March 2007).

Verbal and written informed consent was obtained at the time of the interview by the first author, who conducted the interviews. All interviews took place in a private room at a women's health centre, with the exception of one interview, which took place in the participant's home. The interviews lasted approximately 45 to 60 minutes. The interview schedule consisted of six open-ended questions (Figure 1). Consistent with Sandelowski's (2000) approach, interview questions were crafted to uncover the basic nature of participants' experiences in the RCT. The interviews were audiorecorded and transcribed verbatim. Each participant received a \$20 gift card to a national chain store for taking part in the study.

Figure 1 Interview Schedule

- 1. What was it like being in the research group?
- 2. Why did you decide to join the research group?
- 3. What was the most valuable thing about being in the research group for you?
- 4. How has being in the research group affected how you think about having FMS?
- 5. How has being in the research group affected your life?
- 6. What would have made the research study a better experience for you?

Sample

The 18 women who made up the sample ranged in age from 34 to 71. The average time since diagnosis of FMS was 8.94 years. Fifteen participants were White, two were African American, and one was Hispanic. Most of the participants (13) were married, one was widowed, two were

divorced, and two indicated that they had never married. The average number of years of education for the sample was 15. The majority of participants (15) were not employed. The average number of classes attended was 6.88 for the intervention group and 6.66 for the control group.

Data Analysis

The transcripts were sorted by research group and the data set for each group was analyzed separately in order to identify similarities and differences in participants' experiences in the two groups. Qualitative content analysis was used to analyze each data set (Morse & Field, 1995; Sandelowski, 2000). This method consists of carefully reading and rereading the transcripts to identify the main topics in the data. The transcripts were coded by hand, which involved marking phrases, sentences, or larger segments and noting, in the margins, the corresponding topics. This process continued until no new topics were identified. Then a description for each topic was developed, which became the category label. Some categories were combined and in some cases subcategories were created. A table was drawn up in a Microsoft Word document in which the marked segments of the transcripts were sequestered under each category label. The next step in the analysis was to construct paragraphs to describe the categories and the relationships between categories. In the final analytic step, the descriptive summaries of the categories were compared across the two data sets.

Trustworthiness of the Data

The trustworthiness of the results of a qualitative research study is assessed by measuring their persuasiveness in convincing readers that they merit attention (Lincoln & Guba, 1985, p. 290). One way to present evidence for trustworthiness is to clearly describe all research activities so that readers can decide if the researcher's conclusions are congruent with the methods and procedures used (Mischler, 1986). Trustworthiness is also enhanced through procedures designed to reduce researcher bias. In the present study, the research team member who conducted the interviews and data analysis was not a facilitator for either of the research groups. At the time of the interviews, she had not been informed about which group the participant had been assigned to, in order to minimize any possible effect of this knowledge on the interview. She discussed her findings with the research team and solicited their perspectives on her conclusions. Finally, the results of the data analysis were reviewed by a researcher with experience in qualitative methods who had not been involved in the RCT (Kahn, 2000).

Findings

Three main categories were identified in each data set. These had to do with participants' interactions with other research participants, perceptions about the classes, and perceived effects of participating in the RCT.

Interactions With Other Research Participants

During the interviews the participants in both groups made many observations about the other women in their research group. This category contained four subcategories that reflected different dimensions of participants' interactions.

"There's somebody out there who understands." Most participants in both groups characterized the opportunity to spend time with other women with FMS as the most valuable part of their experience in the RCT. The women described feeling alone having FMS, which they attributed to the fact that persons close to them often did not understand the diagnosis or its effect on their lives. This perception extended to experiences with physicians, who were described as frequently sceptical of participants' symptoms. "Knowing that I wasn't the only one ... just being able to relate to others and hear their anxiety and their pain and to realize you're not the only one, that's comforting to know."

"We trade ways of doing things that help us." The exchange of symptom-management strategies and health-care resources was integral to participants' interactions in both groups. The women reported that they had tried or were currently using a variety of pharmacological and non-pharmacological modalities to manage their symptoms, and they were eager to learn about and try strategies that were effective for the other women. One participant likened the process of exchanging symptom-management strategies and resources to "a quilt show where you go and put all your pieces on the table."

"All of us are in different places." Despite commonalities in their experiences as women with FMS, participants in both groups were aware of differences among them. Some of these differences had to do with personal and sociodemographic characteristics. For example, participants remarked that with FMS there is "no distinction between race, colour, religion, age" and that the women in the RCT ranged from "redneck to . . . white-collar worker." They expressed surprise that the group included younger women, because they had assumed that only older individuals had FMS. One woman indicated that the diversity of the participants was reassuring in that "you don't place blame on yourself that you were singled out." Differences in socio-economic status gave rise to reflection on how economic circumstances affect one's ability to manage symptoms and/or obtain health services. One participant said, "It's easier for people who have money to deal with this disease than it is for people who don't." Another commented that women of financial means in her group had access to medical specialists and could afford prescription medications and self-management strategies such as water exercise classes. Despite these differences, a participant who described herself as of modest financial means said she "never felt any tension along those lines" in her group.

A frequent topic in the interviews was different attitudes towards FMS among the participants. One woman divided her group into "selfstarters" who were making an effort to improve their situation and individuals who were waiting "for the doctors to find the magic pill." Another woman commented that some of her fellow participants did not seem to be "doing anything to make their situation better."

Perceived differences in attitude towards FMS sometimes led women to compare themselves to their fellow participants. For example, one woman felt "a little bit of pride" for having discovered and used strategies, unlike the other women in her group, to cope with her symptoms. Although they were frustrated with participants who did not, in their view, do enough to improve their situation, the women expressed compassion for those participants who had adverse life circumstances and more severe symptoms. Several women expressed a sense of gratitude that their FMS was "not as severe as [that of] others."

The "Leavers." Only participants from the control group expressed concern or opinions about women who missed classes or left the group altogether. One participant, who referred to these individuals as "leavers," described the absences as "mysterious" and seemed bothered that "nobody ever said anything and it was like they just didn't exist." She wondered why it was so hard for people to invest a few weeks of their time to try to get help. Another participant wanted to know the reasons for the absences and assumed that confidentiality issues prevented the facilitators from discussing the absences. Concern about absences may have been reflective of the women's feelings about attending weekly classes themselves. For example, one woman mentioned that there were times when she was physically unwell or the scheduled topic was not of interest to her but she went to the class anyway.

Perceptions About the Classes

In both groups the interviewees' opinions about the classes were mainly positive. Comments by members of the intervention group revealed that they thought the topics discussed in the Lifestyle Counts classes were "very educational" and that the classes "pretty well covered everything." One participant said that the classes "made you think about things you might not be doing that you could do, or that you should stop doing."

The control group interviewees indicated that they acquired new information in the weekly classes, such as medical conditions associated with FMS and how to research health topics online. Several participants questioned the inclusion of information about disability and long-termcare insurance because these topics were not relevant to their situation or because the emphasis should have been on "being as healthy and independent and self-sufficient as possible." However, one woman said that this information would have been helpful to her when she was trying to obtain disability benefits.

Several control group interviewees expressed regret that they were not in the intervention group, primarily because they did not gain new symptom-management strategies as a result of participating in the RCT: "I was disappointed that I was in the control group, because I wanted to learn something that would be really useful. . . . I wanted some concrete advice that was going to make things better." This sentiment was echoed by another woman, who said that after she reviewed the materials from the other group at the end of the RCT she concluded that the intervention group "would have been more useful." However, the control group interviewees all expressed positive feelings about their participation in the RCT. For example, one woman said that she was glad she was in the trial because it was "a kind of giving, and it's also kind of growing [because] the things I've learned can be a resource to others."

Another difference between the two groups concerned perceptions about the facilitators and guest speakers. Two members of the control group mentioned that they liked the facilitator and were complimentary about how she performed her role. The women who received the Lifestyle Counts intervention discussed the facilitators/guest speakers to a greater extent, often recalling specific information that a particular individual presented in class. Several women from the intervention group described the facilitators and speakers as "good examples" and commented that the facilitators were "slender" and were achieving their goals despite their chronic health condition. One woman noted that it was a very positive thing that the facilitators and guest speakers were not "poor [me], pity me types."

Perceived Effects of Participation in the RCT

The third category consisted of findings related to the women's perceptions of changes in their lives as a result of their participation in the RCT. Shifts in attitudes about FMS and alterations in health behaviour were noted by participants in both groups, although the reports were more extensive among the intervention group interviewees. One member of the intervention group said that, as a result of her experiences in the RCT, she felt "in control of my illness and my illness isn't controlling me." Another Lifestyle Counts participant had a more hopeful outlook on living with FMS because "doing some of the things they had been saying in class and then seeing a change . . . altered my way of thinking what's going to happen to me down the line." Other intervention group participants said that the classes helped them to set realistic goals, pace themselves, follow a more healthful diet, and employ stress- and time-management techniques.

The changes reported by the control group participants were fewer. One woman said she had "blamed myself for having it [FMS] . . . because I'm fat" but after the trial did not feel "so bad and so useless." Another woman thought she was noticing her symptoms sooner.

Participants in both groups attributed changes in attitude towards FMS or in health behaviours to interactions, whether positive or negative, with other women in their group. One participant said that she had learned to manage FMS better because she "pulled the experiences from some of the other ladies." Another indicated that she started taking better care of herself as a result of the example set by a woman in her group. Some changes were attributed to perceptions about the negative qualities of other participants: "It made me say, 'I'm not going there,' because there are still so many women, I think, that left there, like, 'well, this is what I have and this is what I'm going to have and I can't get any better'." The only person in the control group who reported a change in health behaviour after the trial had started lifting weights because the women in her group were "such a lot of whiners that I don't want to be like that."

Only participants in the intervention group attributed changes in attitudes and health practices to their interactions with the facilitators and guest speakers. These changes had to do with the personal characteristics of the facilitators and speakers as well as their credibility as experts in their fields. One woman said that although she knew about some health practices discussed in her group before she entered the trial, "hearing it from the experts up there and knowing this is something you need to be doing, you know it. Get on the ball and do it. And I did."

Discussion

Our study had several limitations. Some of the characteristics of women who volunteered for the study may have differed from those of women who did not volunteer. In addition, approximately twice as many intervention group participants as control group participants volunteered for the study, resulting in unequal sample sizes. The reason for this disparity is not clear, but it may reflect the feelings of control group participants about their experiences in the RCT. Several control group participants expressed disappointment about not being assigned to the intervention group; it is possible that other control group participants who felt this way were disinclined to volunteer for the study.

The findings provide insight into the mechanisms by which non-specific yet therapeutically active ingredients in patient education and behavioural interventions may give rise to placebo effects. The exchange of social support by participants is considered to be an important ingredient in group interventions (Lepore, Helgeson, Eton, & Schulz, 2003). The enthusiasm shown by participants in both groups for the opportunity to interact with other women with FMS is not surprising given that FMS is a stigmatizing condition in which one feels that the legitimacy of one's symptoms is called into question by the absence of external signs and definitive diagnostic tests (Åsbring & Närvänen, 2002). Our findings suggest that the emotional validation and symptom-management techniques exchanged by participants led to behavioural change. There is also evidence that some participants were motivated to make changes by the actions of other women in their group. This is consistent with Bandura's (1982) self-efficacy theory, whereby an individual's belief that they will succeed in a pursuit is strengthened by the success of another person they perceive as similar.

One intriguing finding is that individuals in both groups attributed changes in attitudes towards FMS and health behaviours to negative perceptions of other participants. Placebo effects associated with negative role models in research groups apparently receive less attention in the literature than social support and positive role models. This finding suggests the need to explore the mechanisms by which negative interpersonal interactions in research groups affect study outcomes.

Another finding of relevance to the RCT outcome concerns interactions between the facilitators and the participants. Whereas members of the intervention group indicated that the facilitators and guest speakers were catalysts for change in health behaviour and attitudes towards FMS, there was no evidence of this phenomenon in the control group. This result is congruent with the design of the Lifestyle Counts intervention: The facilitators were in a collaborative goal-setting relationship with participants, and a facilitator and guest speaker with chronic health conditions may have served as role models. However, it is possible that the control group facilitator exerted an influence on participants that resulted in behavioural change, even though this is not apparent in our findings. An "experimenter" can unintentionally affect the behaviour of research participants (Rosenthal, 2002). For example, experimenters may sense reactions by research participants early in an RCT, which can influence their subsequent interactions with participants (Rosenthal, 2002). It is possible that the control group facilitator sensed participants' disappointment about their group assignment and responded in a manner that influenced outcomes. Additionally, the facilitator was a nurse, and health practitioner-client interactions can be therapeutic without the practitioner intending them to be so (Moerman & Jonas, 2002, p. 473).

The fact that several members of the control group were disappointed with their group assignment highlights the challenges associated with designing attractive control conditions. The health information control group was designed to be of value and interest to the study population (e.g., women of various ages with FMS), and evidence from the qualitative study indicates that this goal was largely met. However, it is clear that some members of the control group hoped to learn symptom-management strategies during the RCT, other than the ones they learned in their group. This is not surprising given that existing medical treatment may provide incomplete relief of FMS symptoms (Goldenberg, Burckhardt, & Crofford, 2004).

In some pharmacological or physiological intervention trials, it is possible for research participants to remain unaware of their group assignment. In patient education and behavioural intervention studies, however, participants may surmise which group they have been assigned to and, further, form opinions about the attractiveness of the groups. With respect to the present study, it is not known when the control group participants who expressed a preference for the other group surmised their group assignment. At the conclusion of the RCT, all participants were offered a copy of the materials from both research groups. It is therefore possible that opinions about group assignment, and the relative attractiveness of each group, were formed at this time. It is also possible that participants surmised their group assignment during the RCT as they compared the information they were receiving in class with the description of the groups that was provided in the consent document.

RCT participants who perceive that they are not receiving the experimental intervention can have feelings of demoralization (Street & Luoma, 2002). Street and Luoma (2002) posit that it is an ethical responsibility of researchers to ensure that participants are not worse off at the conclusion of a trial than at its start, and that if a participant's normal functioning is adversely affected by randomization to a control group this responsibility may not have been met. There is no indication that the control group participants in our study experienced demoralization related to their group assignment. In fact, these women reported that they enjoyed the weekly classes and derived benefits from their participation in the RCT. An ethical issue in intervention research is the responsibility of researchers to provide participants with some form of symptom management or standard of care (O'Brien, 1997). In our RCT, members of the attention control group did receive information about symptom-management strategies. Background information gathered prior to the RCT revealed that there was no single standard of care for FMS in this community. In fact, many participants said they had difficulty obtaining health care that they viewed as responsive to their needs. In addition, data collected during the study indicated that participants were availing themselves of a wide array of prescription medications, nutritional supplements, and lifestyle strategies to manage their symptoms. Our participants were not asked to alter their usual symptom-management strategies or medical treatments during the RCT, as we wished to mimic what would happen in the real world if women with FMS attended wellness classes.

Conclusion

The findings of this qualitative investigation of women's experiences in attention control and intervention groups of an experimental wellness intervention RCT indicate that the two research groups functioned largely as expected. Members of the control group reported gaining something of benefit from the RCT but making few behavioural changes as a result of their participation. Perceptions of change in attitudes towards FMS and behaviours reported by the intervention group appeared to be a result of the focus on skill-building and the positive role modelling of facilitators, consistent with the theory underlying the intervention. Possible placebo effects in both groups, including positive and negative social interaction among participants, may have obscured any effect of the intervention. As recommended by the Treatment Fidelity Workgroup of the National Institutes of Health Behavior Change Consortium (Bellg et al., 2004), future studies should continue to explore participants' perceptions of treatments across intervention and control conditions.

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