Published in final edited form as:

J Nerv Ment Dis. 2001 May ; 189(5): 299–306.

Psychiatric Outpatients Report Their Experiences as Participants in a Randomized Clinical Trial

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Abstract

We conducted exit interviews with 45 outpatients with severe and persistent mental illness (SPMI) who had participated in a randomized clinical trial. The interviews followed a semi-structured format, and were audiotaped for later transcription and rating by two independent raters. Content analyses of the interviews revealed that most participants evaluated their experiences quite favorably. For example, most noted that the assessment process was thought-provoking and motivational, and that the intervention groups led to increased self-confidence and new friendships. Although a few participants noted that the assessment contained sensitive material, all appreciated the frequent reminders that information disclosed was strictly confidential. These results indicate that persons living with a SPMI often enjoy participating in behavioral research, which can yield immediate benefits to patient-participants. Exit interview research such as this can help investigators to understand reasons for consent and participation, to identify needs for protocol modifications, and to facilitate the integration of evidence-based interventions into the mental health care systems.

Introduction

Questions regarding the value of research participation by individuals diagnosed with a severe and persistent mental illness (SPMI) have been raised by concerned family members and mental health providers (Hall, 1999; Mason et al., 1998; Vogel-Scibilia, 1999). Some believe that patients with a SPMI may be incapable of determining the relative risks and benefits of research participation and, in some cases, may be unable to provide informed consent (Roberts and Roberts, 1999). Because persons with a SPMI are more likely to be poor, socially isolated, and lonely, they may be more easily coerced into research participation compared to more affluent and socially networked persons. Thus, there is concern that patients with a SPMI might be taken advantage of by researchers eager to enroll participants (Stanley et al., 1981). Others have raised concerns regarding the quality of care that psychiatric patients might receive in a research setting (Kocsis et al., 1981).

Recognition of such concerns, coupled with growing activism from consumers of mental health services and their families has led to an enhanced commitment to consumer empowerment and participatory action research (Corrigan and Garman, 1997; Nelson et al., 1998). These movements seek to promote a more collaborative approach toward research by incorporating consumers' experiences, opinions and needs into the design, implementation, and improvement

of research. Such participant involvement affords consumers an important role in research development as well as participation (Heller et al., 1996).

Consistent with this trend, some researchers have solicited opinions from patients about their perceptions of research participation (Vogel-Scibilia, 1999). Seeking patients' views regarding their experience in research projects allows investigators to identify areas of research that are important to patients, to question how patients' experiences may affect research outcomes (Mason et al., 1998), to develop more effective recruitment and retention strategies (Mezey, 1999), and to identify unintended costs and benefits of research participation (Kocsis et al., 1981). However, nearly all of the published research conducted with individuals diagnosed with a SPMI have focused on drug trials. Relatively little attention has been devoted to the experiences of SPMI who participate in behavioral research and, to our knowledge, no research has investigated the experience of psychiatric patients in trials evaluating health promotion interventions. The absence of such research is puzzling given that persons living with a SPMI disproportionately engage in health-damaging behaviors, such as risky sexual practices (Carey et al., 1997, 1999), alcohol and other drug use (Regier et al., 1990), cigarette smoking (Tanskanen et al., 1997), and inactive lifestyles (Hutchinson et al., 1999).

The purpose of this report is to provide information regarding the experiences of 45 outpatients who recently completed their participation in a randomized clinical trial (RCT) that was designed to promote healthier behaviors among adults with a SPMI. In this report, we focus on information obtained during semi-structured "exit interviews" and use content analysis to identify common patients' perspectives on having participated in a longitudinal study (Mezey, 1999). Conducting exit interviews with patient-participants provides patients with a greater voice in the research endeavor, and helps to supplement quantitative data that will be presented in subsequent outcome papers when the trial is completed. These data will allow us to better understand the experience of patients as well as to identify aspects of the protocol that may benefit from modification (Everett and Boydell, 1994).

Methods

Participants

Participants ($n = 45$) included 23 women and 22 men ($M = 38$ years of age, $SD = 9.0$) who were being treated for a severe and persistent mental illness at one of three outpatient psychiatric clinics affiliated with a state psychiatric hospital. Primary diagnoses based on SCID interviews included schizophrenia (31%) or schizoaffective disorder (13%), major depression (35%), bipolar disorder (15%), and other (e.g., delusional disorder; 4%). The majority (83%) had at least one previous inpatient hospitalization. Racial/ethnic background included European-American (67%), African-American (27%), Native-American (5%), and Other (2%).

Procedures

All participants had consented to join the "Health Improvement Project" (HIP). The HIP is an ongoing randomized clinical trial funded by the National Institute of Mental Health that seeks to evaluate the efficacy of two risk reduction programs: (a) an HIV-risk reduction program to promote safer sexual behavior in order to avoid infection with HIV or other STDs, and (b) a substance use reduction program to promote reductions in the use of alcohol, tobacco, caffeine, and other non-prescribed drugs. These two interventions are compared to a standard care (i.e., control) group.

As part of their experience in the HIP, participants were asked to attend four assessments that occurred at (a) baseline, (b) six weeks later (i.e., post-intervention), (c) three months later, and

(d) six months later. These individualized assessments were conducted by a research team member at locations separate from the clinics where patients received their standard care. Participants had been randomized to one of three intervention conditions: (a) HIV risk reduction, (b) substance use reduction, or (c) a standard care control. The HIV risk and substance use reduction interventions met in small, same-gender groups that were facilitated by two psychologists. Participants assigned to the standard care control condition were also asked to attend the four assessments but did not receive a supplemental intervention as part of the trial.

After the six-month follow-up assessment, 45 participants were invited to take part in an “exit interview.” The participants represented approximately 10% of the entire sample, and were invited regardless of whether they had attended all sessions. It was explained that this exit interview would involve a discussion about their experiences in the research project with a MA- or PhD-level psychologist. Patients were told that the discussion would last about one hour and that we sought their honest views regarding their experiences so that we might improve our procedures for future projects. A \$10 monetary incentive was offered to offset their travel expenses and time.

At the meeting, interviewers followed a semi-structured interview to assure that comparable information would be obtained from all participants. However, the open-ended interview questions also provided participants with several opportunities to offer their unique perspectives. Aspects of the study that were discussed included reasons for joining and continuing; impressions of the assessment and intervention sessions; and perceived impact, if any, of the research experience on their health-related behaviors. The interviews were audiotaped and later transcribed verbatim. To assure the transcriptions were accurate, a random selection of 20% of the transcripts and audiotapes were compared. The transcripts reflected the audiotapes exactly.

Content analysis of the transcripts was used to code responses to interview questions and to cluster similar responses (Weber, 1990). Two trained research team members, who did not conduct the interviews, independently coded statements in each transcript. The two raters categorized participant responses into separate descriptive categories. Reliability between coders approximated 100%. This measure of reliability was calculated before any disagreements in coding were resolved (Krippendorff, 1980). Jointly, the two coders extracted quotes to validate the descriptive categories and illuminate the experiences of the interviewed participants. Validity in this study was enhanced in two ways. First, written data sheets that were transcribed verbatim from the taped interviews were used as the primary data source. Second, as a form of semantic validity, patients' words were not altered (even if grammatically incorrect or phrased unclearly) as they were entered into the content category tables.

Results

Raters' codings revealed five descriptive content areas regarding participants' experiences in the HIP: study recruitment and retention, individual assessments, group interventions, confidentiality, and behavior change. Each of these content areas is described briefly, and illustrative quotes are presented to highlight the thematic material.

Recruitment and Retention

When asked why they decided to participate in the HIP, a number of participants noted that the monetary incentive was initially important, but other benefits motivated them to complete the project. As an illustration, one woman explained that although she joined “for the money” she continued because the project “gave me a chance to get out and relax and talk to someone.” Many others identified additional reasons for joining the study. For example, one woman

reported that she decided to participate because “I needed something in my life, something positive. I needed to do something positive because six months ago (before joining the HIP) I had never completed a rehab or a program.” A male participant reported “I guess I wanted to be part of something, to help out society ... I just thought it might help somewhere down the line.” One other woman in the substance use reduction group recalled “I decided to participate in your project because of the money. Now that I look at it I've got more than the money, I've got a little wisdom.”

Participation in the twice-weekly intervention sessions provided patients with a sense of accomplishment as they learned valuable skills both regarding the topic presented as well as other life skills. For example, one man said “I decided it would be helpful if I could improve my health ... I could ultimately discuss matters to help me feel my way through life and know I'm accomplishing something.” Another reported that he agreed to participate because “I thought it was a good way to make money at first and then I kind of liked the way you talked about the use of alcohol and drugs. I thought I had a hard time coming to that point (of getting) some sort of concrete thoughts (on that).” A female participant said “I wanted to participate. I wanted to quit drinking (and now) I got my (study completion) certificate right on the wall!”

Participants also noted that they were treated with respect and appreciation. Apparently being treated this way was a refreshing experience and was one that several participants identified as an incentive to participate in the study. When one client described why he liked being in the study, he said “the way they (research team members) talked to you and made you feel like a person, instead of just an object or something.” Another commented that both the research personnel as well as other participants were a major reason for continuing with the study. He related his experience in this way: “I got to know some people and some charitable people. A lot of times you don't get that, you get a lot of prejudices and negativity and the stigma of mental illness. ‘You stay in your place and we'll stay in ours.’ (There was) none of that here.”

Individual Assessments

Part of the HIP included four individualized assessments that lasted about two hours each. These assessments involved responding to questions about health-related behaviors, including sexual behavior, drug and alcohol use, and participating in a videotaped role-play assessment. As one woman divulged, “You know part of me was so tempted to lie, so I wouldn't sound like an idiot. (I'd) say yeah I'm using condoms, but I just couldn't do it.... That's not right, they [the research team] are trying to learn about people's behaviors. They (would) have just wasted a whole survey on me because that's misrepresentation of the person they are interviewing.”

Positive statements regarding the individualized assessment sessions were noted. One woman said “I like being able to be on a one basis (sic) with someone about my habits. It was sort of therapeutic in that it helped benefit me in a way. That's something I never sat down and talked to my therapist about was my personal habits. It (the project) helped me to understand my habits so if that issue came up I would be able to discuss it better.”

A male described his reaction to some of the assessment experiences. “We did role playing... which brought into our consciousness the fact that other people are dealing with the same question (like) meeting a pretty girl...making a fine impression. This kind of tells you what to do, so you don't have to wonder, ...well I've never been in this situation before, what should I do? They told us right away how to deal with it.”

One woman described her experience this way: “You know, I learned to stand up and be persistent. I used to have a problem saying no ... and this taught me how to be persistent, you know. To say no because, you know, (the audiotaped actor on the role-play) started saying come on, come on. And I liked the part where I was kind of feeling (as if) that person was

really there, cause I have been in that spot before.” Similarly, another female participant reported “Everyday you deal with people asking you if they can borrow money and stuff like that. It's easier now (after completing the role-play assessments) for me to say no than it was before. I learned how to be self-assertive.”

Not all patients found the assessments to be uniformly positive. For example, use of videotapes for role plays bothered one woman who said: “I didn't like being videotaped ... I just felt very intimidated, it was very intrusive. I don't like that it was going back to somebody who I don't even know who's watching me.” Another aspect of the assessments that was unsettling to some was the assessment of socially sensitive material, including sexual behavior and substance use. One female remarked: “They (the questions) were embarrassing, but I didn't mind “cause it kind of opened it up and showed me exactly what I have been doing.” It is particularly important in research studies that deal with sensitive topics such as sexuality, to realize that the experiences of participants can vary and lead to different reactions and interpretations. For example, one man said “The sexual questions, they made me feel uncomfortable... I would think to myself (that you should) kind of slack off on the sex questions. It does bother me because I was sexually abused when I was a kid and it's hard to think about it.” Another woman reported “I wanted to say that the only thing that bothered me was the questions. Each time, I had to answer the same questions over and over again and it made me nervous because I didn't know if I was answering the right way.”

Although almost all patients were taking medication for their SPMI and none was acutely psychotic at the time of the assessments, the assessments were difficult for some participants who were experiencing some symptoms of mental illness. For example, a woman with a history of depression said: “When I was depressed, (the assessment was hard) ... and when I get depressed, everything seems hard on me.” A man who was diagnosed with paranoid schizophrenia said: “Being researched kind of bothers you and it doesn't bother you. I was research. They know everything. They have everything on file; somewhere there is a computer, a case file made out of 50-60-100 years. They have the goods on me.” Interestingly, both of these participants continued in the study despite their discomfort.

Many participants commented on positive outcomes they experienced from completing the assessments. As one man reported “All these questions opened me up (about things) that I wouldn't normally talk about. It gave me a sense of awareness. It's definitely a positive program. And now (I) could be more of a role-model.” Similarly another participant commented “It does give you a sense of awareness and being aware is the key to a lot of things. It's a reality check. It really opens the mind.” Female participants commented on these sessions in a similar manner “I just think it was beneficial for me because there were some questions that (the research team member) asked that no one else has ever asked ... I just thought that it would benefit me. It would help me by talking more and more about what's going on.” Another woman said that being asked multiple questions about her substance use behaviors made her more aware of her intake. Similarly, questions about her use of nicotine raised her awareness. She commented “Well, she would ask me questions then I would think to myself, geez, that's a lot of smoking. I'll try and cut down. It honestly helped me to get more (perspective) in respect to my nicotine. Made me more aware of it.”

Group Intervention Sessions

Many participants who attended group intervention sessions relayed positive experiences to us. A woman in the substance use reduction group alluded to the social support obtained by participating in the sessions. As she described what she liked about the sessions: “sometimes you are stuck in your own problems, you start to think you are the only one in these problems... sometimes you forget that everybody else is out there, so there is somebody out there worse off than you and that's struggling just like you are. It makes you feel like you aren't alone.” A

male participant in an HIV risk reduction group recalled “Getting to know I wasn't the only one in certain circumstances and how other people were handling them (was important).” The group “helped me to become strong enough to end a relationship because of the trust that I didn't have coming from her. And it helped me in my mind about diseases ... and why I should end it and carry on with my own life.” Another male commented about the positive atmosphere in the group sessions and remarked “We got involved, all of us. There was a group of like seven of us and we all got to know each other and got in our comfort zones and started speaking out.” A male enrolled in a substance use reduction group reported “I never missed any sessions. They (other participants in the group) were really great guys. I have their phone numbers. Just seeing those guys make changes, like seeing (a person) go from three pots of coffee to no caffeine at all. It's like – wow – that was good. We all got along. We were all in the same boat pretty much, just trying to make, not major changes, but slow, slow changes.”

Several participants reflected on their experiences in the groups and the interaction between group members. As one woman recalled “I think it was just the atmosphere and talking and seeing everyone else's point of view and hearing what happened to them and what they've lost and everything. The longer I sat and listened, I thought, Hmmm ... ”

Because of the informed consent procedure, all participants (including control participants) were aware that there were intervention groups. Even those participants who were not randomized to a group intervention commented on their desire to be part of one. A man said “I wasn't in a group. I wanted to be just (for) experience, like to know what other people go through and maybe I could learn something from them. How not to make the mistakes they made or go in that direction.”

Confidentiality

Research team members continually reassured participants of the confidentiality of their responses during each assessment, which clearly had a positive effect for several participants. For example, one male in the control group said, “You could take a break at any time. Each time they let you know that anything you say is not going to be spread across town.” A similar attitude was reported by many others who participated in group interventions. “(The group) made me feel like they weren't going to make fun of me or they weren't going to act funny at the answers I gave them ... I felt it was all confidential ... so I didn't have anything to worry about.”

Behavioral Change

Participants were asked during the interviews whether they had considered or had already made any behavioral change after the intervention. Many participants considered changing either substance use or risky sexual behaviors. A few participants described the difficult and complex process involved in making such changes. One woman recounted “I mostly made changes in my friends. I stopped hanging out with them. I knew if I continued to hang out with them that I would continue to drink and I was going to end up in the same situation that I wanted to get out of. So, I had to stop (drinking alcohol). It was hard.” Similarly, a male enrolled in a substance use reduction group reported “I learned that after time (drugs) eventually take their toll ... I had to make some decisions to burn some bridges with some friends. (It) was difficult to hang around with people who were doing things that you just know you can't do anymore because they are not healthy. And to say I can't be around these people anymore. It's difficult. That was a real hard part.” After participating in a HIV risk reduction group, many participants reported contemplating changing their risky sexual behaviors and had even decided to discuss its influence with friends. For example, one woman said proudly “I have been discussing (this program) with people ... and I have told them why I decided to have safe sex.”

Overall Perceptions

The majority of participants reacted positively to study participation, and described positive outcomes that resulted from their participation. Interestingly, this was true for participants in each of the three experimental conditions, including the control group. One woman was particularly eloquent in her summary of her experience of the project: “There’s a lot of fun in this project. You got the chance to really know yourself. This program taught me how to be on time. My self-esteem got built. I dress(ed) sharp just to come here. I felt good about myself, I felt really good about myself, like I was part of something. I was helping ... me (with emphasis) ... and you (the research team) do a project. That meant a lot to me.”

Discussion

The current study yielded several important findings worthy of review and discussion. First and most important, participants in the current study did not find the research experience to be aversive, coercive, or otherwise detrimental to their well-being. Clearly, the lack of such a finding does not guarantee that participation in this or any other RCT will be benign. However, the abundant patient reports identifying positive aspects of their participation would suggest that, on average, involvement in RCTs of behaviorally-based interventions such as the Health Improvement Project can add appreciable value to the standard care treatment provided in most outpatient facilities. Furthermore, the additional attention associated with individualized assessments, and the increased opportunity for new friendships through group sessions, were consistently identified as positive aspects that improved the quality of patients’ lives. This information suggests that engaging in behavioral research projects provides a positive experience for adults with a severe and persistent mental illness.

In addition to the reassurance afforded by the primary finding, several other important findings emerged from this research effort. One interesting and not completely unexpected finding emerged regarding the motivational qualities of the individual assessments. Consistent with prior clinical experience and empirical evidence (Weinhardt et al., 2000), some patients reported that the assessment experience prompted them to rethink their risk behavior and contemplate behavior change (even if they were not in an intervention condition). Several leading theorists identify motivation as an important component of behavior change (Prochaska et al., 1992; Fishbein and Middlestadt, 1989; Fisher et al., 1995). For many behaviors, such as risky sexual behavior, enhanced motivation is not adequate to provoke behavior change (Fisher and Fisher, 1992); that is, motivation is seen as a necessary but not sufficient for the adoption of safer sexual practices. For other behaviors, such as reducing alcohol consumption, motivational enhancement can sometimes be sufficient (Miller, 2000). Because outcome data from the HIP are not yet available (the trial is ongoing), we cannot address this issue with the current data set, but simply identify the occurrence of motivational enhancement during the assessment process.

Additional positive reports regarding the research experience that were identified by participants included increased self-confidence as a result of the behavioral skills training that they received, and the formation of new friendships as a result of the group interventions. Bandura (1997) has argued that self-efficacy is an important determinant of subsequent behavior change. According to this view, believing that you are capable of changing a maladaptive behavior often precedes attempts to actually change the behavior (Forsyth and Carey, 1998). In addition to enhanced self-efficacy, several leading theories that seek to explain modification of risky sexual behavior or substance use acknowledge the importance of social skills (Bellack et al., 1997; Fisher and Fisher, 1992; Monti and O’Leary, 1999). Thus, patients’ identification of the self-confidence and sense of enhanced social skills is noteworthy.

The role of social norms that promote healthy behavior, and the importance of social support when attempting to modify health-damaging behaviors are also consistent with psychosocial theory, clinical experience, and empirical research (Sheeran et al., 1999). For example, Roffman et al. (1997) found that satisfaction with social support was associated with a more positive response to a HIV risk reduction program in gay and bisexual men. Such social support may even be more important among adults who are severely and persistently mentally ill, and often lack a strong support network.

Several patients also noted that participating in the research allowed them to make a contribution to the care of other patients, and to contribute to science through their participation. This altruistic motive and the relatively novel sense of contributing to society is one that has been recognized by research on biomedical research on schizophrenia (Roberts et al., 2000), and seems to be equally applicable to behavioral research.

One of the concerns that did emerge regarding the research experience was a concern about privacy. Several participants raised this issue, but also stated that the reassurances provided by assessors and group facilitators helped to allay their concerns. Future researchers will do well to recognize this concern, and develop procedures to address this important issue. In the age of information technology, and increased access to medical and other records, we have found it helpful to store all confidential clinical and personal data separately from names or other identifiers. We have also routinely requested Certificates of Confidentiality from the National Institutes of Health when we collect sensitive information, especially if we assess illegal behavior or other information that might be subject to subpoena.

Our results indicated that monetary incentives can be important to recruiting participants to RCTs. Even though our incentives were modest (typically \$10 per occasion), they were helpful to patients living on a very low income and helped them to justify the time and expense associated with participation. Investigators in future research who can afford to provide such incentives would be wise to consider them. It is noteworthy that not a single participant mentioned joining for the money and subsequently disliking the program, nor did any participant report feeling used, bored, or exploited.

One troubling aspect of the use of financial incentives in RCTs is that community-based programs do not have resources for such incentives or, even if they did, might find it difficult to justify the use of monetary incentives to oversight boards or funding sources. In this study, however, many participants became aware of the non-monetary benefits of participation once they were enrolled. These included the direct clinical benefits (e.g., enhanced motivation for behavior change, increased skills or confidence) as well as the indirect benefits (e.g., contact with compassionate research staff, new friendships). Some patients also stated how important low-cost but meaningful markers of their participation (e.g., completion certificates) meant to them.

Three strengths of our methodology warrant mention. First, our sample included both intervention and control participants, as well as patients who completed all sessions and those who did not. This sampling strategy allowed us to avoid biased feedback from only those participants who received an intervention or who attended all sessions. A second strength was that we employed a semi-structured interview, which afforded us the opportunity to gather similar data from all participants, but also allowed for unique information to emerge. Third, our content analyses included two independent raters, who provided reliable ratings and a consistent set of themes.

As with any study, there are also limitations of our work that deserve mention and should be considered when interpreting the findings of our work. First, the sample reflects the views of those patients who consented to participate in a RCT, and may not be representative of all

patients, Second, the sample size we studied included only 45 participants. Although large for a qualitative study, such a sample does not assure the representativeness of the findings. It is possible that our sample may not reflect the views of the population of adults living with a SPMI who participate in research. Third, interviewers who met with participants were part of the research team. Although this was not obvious to participants (due to the size of our team), it is still possible that participants may have been reluctant to express criticism of the research team. We would not modify this methodology, as it affords more advantages than disadvantages, but we acknowledge it here to alert readers to this possibility.

Conclusions

The results of this investigation of the experience of psychiatric patients in a RCT revealed that most patients found the experience to be beneficial. The concerns raised by patients involved issues such as sensitive questioning and confidentiality, which are issues that can be allayed with careful, clinically sensitive procedures. From a methodological perspective, the primary concern that was identified involved the importance of monetary incentives for the recruitment of research participants, which might constrain the transfer of effective interventions to community-based treatment facilities. Given the importance of “technology transfer” (Glasgow et al., 1999; Kalichman et al., 1997), this issue warrants further research. Positive aspects identified by patients included both the direct benefits of the interventions (e.g., enhanced skills and confidence), as well as several indirect benefits (e.g., new sources of social support) associated with being part of such a larger, prosocial endeavor.

Acknowledgements

This study was supported by a grant from the National Institute of Mental Health to the first author (R01-MH54929). The authors thank the participants for their valuable contributions to this research. We also thank the many colleagues who assisted with the Health Improvement Project, especially Christopher Correia and Kristen Brewer.

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