Randomized controlled clinical trials are often considered to be the "gold standard" for health research. Consequently, understanding the reasons people participate in these trials, especially minority groups who are often under-represented in clinical trials, or populations who have chronic illnesses or abuse drugs, is salient for successful recruitment, retention, and project design. This paper describes the results of a study that was designed to examine some of the ways in which participants in a randomized double blind clinical trial perceived their participation in the clinical trial, and the reasons they gave for continuing in the study. All of the participants were individuals who were using drugs and were infected with the HIV-1 virus, and had participated in a chemoprevention trial. The data from an exit interview were analyzed thematically in order to reveal units of meaning concerning participation and continuation in the clinical trial. The analysis revealed 3 higher-level concepts, or themes, that guided participation: increased health awareness, personal enhancement, and sociability. The data clearly indicated that involvement and retention in the trial were directly related to the ways in which the participants interpreted the study, perceived the benefits they derived from participating, and imbued their participation with value so that it was important and relevant to their own perceptions of health, as well as personal and social well being. (Ethn Dis. 2004; 14:469-475)

Key Words: Barriers to Participation, Participant Interpretation, Randomized Control Clinical Trials, Retention

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INTRODUCTION

Randomized controlled trials (RCT) are often considered the "gold standard" method for evaluating or testing medical treatments. Relatively little is known, however, about why participants decide to become involved in studies, or what their involvement means to them. Almost all the literature examining RCTs has focused on methodological issues related to design, recruitment, and implementation. Clinical trial investigators face a number of obstacles/dilemmas in understanding retention and participation in a clinical trial or protocol. Although there are no theories of retention, per se, a variety of factors have been correlated with retention, such as: age,1 ethnicity and gender,2 education level,3 psychological distress,4 illness severity,5 patterns of healthcare utilization6 and study characteristics.7-11 The stereotypical participant who is likely to drop out is portrayed as an older, non-White male, with limited education, multiple health problems, increased life stress, and a pattern of erratic healthcare utilization.12

A number of the published reports focusing on how participant factors contribute to retention have not included individuals actually enrolled in a study, but instead have relied on hypothetical scenarios in order to evaluate the willingness of individuals who represent potential trial populations, especially minority groups who are often under-represented in clinical trials.13-16 The focus of this research involves the investigation of participants’ motivation for participation, and their attitudes about randomization.17-20

A small number of studies have focused on participants’ perspectives concerning their experiences and motives.21-23 Some researchers23 found that participants often feel confused about the randomization process used in many RCTs and often give distorted accounts of the process. Consequently, participants reportedly adopt several approaches to make sense of randomization. For example, Featherstone and Donovan22 found that some participants became distrustful, while others put their trust in the clinician and beliefs about fate and destiny; still others continued to struggle with perceived inconsistencies.

The aim of the present study was to explore some of the ways in which participants in a randomized double blind clinical trial perceived their participation, and the reasons they gave for continuing in a study when they did not know whether they were receiving a placebo or a supplement, or whether the supplement was a viable treatment. Specifically, we wanted to understand retention from the perspective of the participants. The study involved an examination of the reasons individuals gave for continued participation, and, therefore, a search for the underlying meaning of the experience. The participants in the study were infected with the HIV virus, and reported current (80%) or past use of drugs. This difficult to reach population is of special interest, as substance abuse has been associated with non-adherence to highly active antiretroviral therapy (HAART), which may have a great impact on disease progression.24-25 We believe information related to participation is invaluable, both for developing research protocols that enhance participant satisfaction, and increase retention through planning and...
Relatively little is known, however, about why participants decide to become involved in studies, or what their involvement means to them.

monitoring participant satisfaction, and for enabling researchers to identify participants who intend to withdraw. The small number of published reports that address retention factors specifically from the participants’ perspective substantiate the importance of this study.

The data reported here examined how HIV drug users viewed their participation in a clinical trial, and should provide information that is particularly salient for RCT research involving: 1) heterogeneous study groups; 2) populations who have chronic illnesses or abuse drugs; 3) the homeless; 4) complex protocols (eg, involving multiple behavioral or pharmacological interventions, such as highly active antiretroviral therapy [HAART]); or 5) long recruitment and follow-up periods.

METHODS

Recruitment and Enrollment

The selenium therapy clinical trial, conducted from 1998 to 2000, was designed to determine whether supplemental selenium, as a chemopreventive agent, could enhance the immune system and reduce viral-load to slow HIV-1 disease progression in men and women who were substance abusers. The project was developed from research indicating that low plasma levels of the essential trace element, selenium, were significantly associated with faster disease progression, as well as a greatly increased risk for HIV-1 related mortality.26 Treatment with selenium, conversely, has been demonstrated to have immunostimulatory and chemopreventive effects,27–28 and may have an important role in preventing HIV-1 replication.29

Two hundred fifty-nine individuals were recruited to participate in the RCT selenium study. Potential participants were identified from the AIDS clinics at the University of Miami School of Medicine/Jackson Memorial Hospital, and the affiliated Homestead Outreach Center. Most of the participants were African Americans (73%), but also comprised Hispanics (21%), Caucasians (6%), and Asians (1%), ranging in age from 24 years to 54 years. An outreach worker was employed as a recruiter and staff person. She participated throughout the study and provided a “case-managed” approach to the study by contacting and assisting participants in keeping their appointments. She supported participants, kept channels of communication open, and enhanced the ability of the researchers to be sensitive to adherence and retention issues. Informed consent was obtained from all individuals, and the Human Studies Committee of the University of Miami School of Medicine Institutional Review Board approved the investigation.

Procedures

Following consent, HIV-1+ participants were enrolled in the randomized, double blind placebo-controlled selenium therapy clinical trial. Enrollment criteria included past or present use of illegal drugs, being 18 years of age or older, having a confirmed HIV-positive status, and having adequate selenium status (>85 g/L). The statistician randomly assigned eligible participants to receive either a placebo or selenium. Since this was a randomized double-blind control study, neither the researchers nor the participants knew what treatment type had been assigned to each individual. A nutritional dose of selenium (200 μg/day) was selected, based on its low risk of secondary effects and toxicity, and ability to modulate specific immune parameters in our pilot studies.

Run-in Period

Following the informed consent interview, a one-month run-in period, in which a 30-day supply of placebo was dispensed, was conducted with all participants. This enabled the participants to experience a clinical trial and was implemented to decrease the risk of non-adherence. Additionally, the recruiter was employed as an outreach worker throughout the study, thus providing a “case-managed” approach to the study. The recruiter contacted and assisted participants in keeping their appointments.

Evaluations

Supplements of either a nutritional dose of selenium (200 μg/day), or a placebo of the same appearance (Nutrition 21), were dispensed each month at a community-based University of Miami research clinic, and safety/toxicity was assessed. The supplement and placebo were indistinguishable in color and taste. Study participants were evaluated at baseline, and every 6 months over the course of the trial. The baseline visit and 6-month evaluations included a complete medical examination and assessment. Demographic information, drug use, and medical history, including antiretroviral treatment, were recorded for all participants, and confirmed by comparison with data from clinical charts. Following the interview, a physical examination was conducted, and blood was drawn to evaluate nutritional and immune parameters. HIV disease staging was established using standard Centers of Disease Control and Prevention criteria, and was based on patient’s report of opportunistic infections and/or medical records. HIV disease progression was established by clinical symptoms and CD4 cell counts obtained during the study visits.
Exit Interview

As the study came to a close, an exit interview was conducted with participants who were active in the study, and had completed the 6-month evaluation. The session consisted of a short interview with the individuals, involving a questionnaire, which was primarily self-administered, although in some cases an interviewer wrote the answers for the participant. The questionnaire included general questions concerning the type of social services and health care participants were receiving, as well as inquiries directed toward determining retention patterns, such as whether they thought they had been taking the selenium or the placebo. Other questions focused more on uncovering how respondents felt about their participation, such as how they felt during the period they were taking the supplement/placebo. Additionally, they were asked to respond to 3 open ended questions: “What were the main reasons you participated in the study”; “Do you think the study helped you in any way? (please explain your answer)”; and “What were the main reasons you came to your monthly visits?” They were also asked to comment on the main barriers to their keeping the monthly appointments.

Analysis

The information from the exit interview was evaluated using a qualitative approach focusing on content analysis. We approached the study from a perspective that builds on the theory of Explanatory Models (EM).30–31 Originally, the explanatory model was developed to examine the process by which illness is patterned and interpreted. In our analysis we built on this theory to look at participation in a clinical trial, rather than illness, per se. Instead of asking directly, we attempted to elucidate the meaning of participation, without directly leading or forcing the question. Therefore, we looked for themes that emerged from participants’ explanations of why they participated in the study.

The qualitative analysis was conducted following the recommendations for qualitative analysis.32–33 The answers provided by the participants were read several times, then initial code categories were developed from the elements of the respondents’ statements. The process involved examining, comparing, labeling, and categorizing the information. Elements from the statements about the experience of participating in the study were extracted, then grouped into themes or conceptual categories. Once the emergent themes were developed, the interviews were re-read to ensure that the themes were appropriate to the data. The themes were then grouped into higher-level concepts based on the relatedness or connections between, the conceptual categories.

Analysis of the demographic data (age, ethnicity, gender, education level, living situation) and health-related variables was performed using SPSS software version 10 (SPSS, Inc., Chicago, Ill), following examination of distribution, skewness, and presence of outliers. Chi-square analysis, odds ratio analyses, and t tests were used to assess significant differences across the sample. Previous findings from the selenium trial highlighted the impact of nutritional chemoprevention on the pathogenesis of mycobacterial disease,34 as well as on hospital admissions,35 and the patient’s psychological burden.36

RESULTS

Characteristics of the Study Group

The present study focused on patterns of participation and adherence in the 157 subjects who completed the 6-month evaluation and were active in the study. After the exit interview had been conducted and the project was concluded, unblinding revealed that 81 (52%) of the participants had received the placebo, and 76 (48%) had received the selenium.

As shown in Table 1, most of the participants were African Americans (73%). Men and women were almost equally represented (49% and 51%, respectively). The mean age of the participants was 40.7 years (SD=6.7; range 24–54). The majority of the participants indicated that they lived at home, although a number of individuals utilized shelters (10%), and some considered themselves homeless (8%). The education level of the participants was high. Forty-one percent of the sample had attended some middle or high school, 36% had graduated high school, and 16% had some college education. The sample was approximately evenly divided in terms of those who received food stamps (48%), and those who did not (52%). A significant number of these individuals (75%) were receiving SSI assistance. Sixteen percent of the participants accessed a variety of other assistance programs, such as Medicare, Medicaid, South Florida Network, and private charitable organizations, such as Food for Life, Camilus House, and Christ Crusades.

<table>
<thead>
<tr>
<th>Table 1. Demographics of the sample</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>77</td>
<td>49</td>
</tr>
<tr>
<td>Male</td>
<td>81</td>
<td>51</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>African-American</td>
<td>114</td>
<td>73</td>
</tr>
<tr>
<td>Hispanic</td>
<td>29</td>
<td>19</td>
</tr>
<tr>
<td>Caucasian</td>
<td>12</td>
<td>8</td>
</tr>
<tr>
<td>Housing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Live at home</td>
<td>125</td>
<td>81</td>
</tr>
<tr>
<td>Homeless or live in shelter</td>
<td>29</td>
<td>19</td>
</tr>
<tr>
<td>Education level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Some grade school</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>Some middle/high school</td>
<td>65</td>
<td>41</td>
</tr>
<tr>
<td>Graduated high school</td>
<td>57</td>
<td>36</td>
</tr>
<tr>
<td>Some college</td>
<td>23</td>
<td>15</td>
</tr>
<tr>
<td>Graduated college/Post Baccalaurete</td>
<td>6</td>
<td>4</td>
</tr>
</tbody>
</table>

Ethnicity & Disease, Volume 14, Autumn 2004
Barriers to Participation

Attendance at the monthly appointments was high, and the average number of visits was 14.6 (x̄=14.6; range 6–27). The number of individuals who provided reasons for missing their monthly visits was small (N=16). The most common reason for missing appointments was being in jail, or needing to attend a probation visit. Other barriers affecting attendance fell into 3 main categories: 1) other priorities; 2) being sick or under the influence of drugs; or 3) family conflicts. One individual who attended 10 of the 27 visits gave the following explanation: “I couldn’t come because of schedule changes, taking children to school, and being sick.” Another respondent who attended 9 appointments said: “I came because I promised to come. If I couldn’t, it was due to family conflicts.” Similarly, one individual who was able to attend 16 visits indicated: “I could not come because of other medical appointments that took priority.”

Reasons for Participating, and Beliefs about the Study

Ninety-eight percent of the participants indicated that coming to the clinical trial visits helped them, and provided a variety of reasons for coming to the appointments. Only a few participants (N=18) indicated that the monetary reimbursement was an incentive. The most common reason given (N=52) for continued participation was to obtain the medication (selenium/placebo). When the other responses were reviewed, 2 important themes emerged: emotional support and health support. The emotional support category was characterized by statements such as: “The reason I come for my monthly visits it was to better myself”; “...to talk to the staff and meet other people”; “...for moral support”; and “...to learn about myself.” Fifty-eight percent of the respondents indicated they participated in the program for some aspect of what they perceived as health support. Inter-
viewees explained their attendance and retention as follows: “The reason I came to my monthly visits was to get my vitamins and other tests”; “The reason I came for my visits was because you are a good and nice Dr. and I want to get better by continuing in the study”; “The reason I came was better treatment and vitamins”; and “If I am not working I always come. I want to be healthy.”

Chi-square tests demonstrated that gender, ethnic group, living condition, and education level did not influence the reasons for participation. Additionally, gender, treatment (placebo/sele-
nium), and living condition did not influence the number of appointments the participants attended.

The main protocol feature of the study was that it was a randomized, double-blind control study. Consequently, neither the researchers nor the participants knew what treatment type had been assigned to each individual. As indicated above, the randomization list was made available to the researchers after the exit interview had been conducted and the project was concluded (January, 2002). During the exit inter-
view, the participants were asked whether they thought they were receiving the placebo or the selenium. Seventy-seven of the participants (52%) thought they had been receiving the selenium. Only 3 individuals (2%) thought they were receiving the placebo, and 67 (46%) indicated they didn’t know what they had received. Of the 86 individuals who answered the question asking why they thought they were taking the selenium/placebo, 69 (80%) thought they were taking the selenium. The most common (37%) perceptions were that the treatment affected them positively by increasing or enhancing their energy level. These individuals said such things as: “I thought it made me have energy”; “...gave me energy and appetite”; “I have been feeling much better, not as lazy as I used to be”; “...because of energy increase and less mood swings”; and “the selenium gave me a lot more energy and get up and go.” Other individuals indicated it increased their appetite; resulted in better health, or affected their sense of taste by statements such as: “taste and the way it made me eat”; “I think I was taking the selenium because my CD4 was up and I gained more pounds”; “What made me think I was taking selenium is because I feel better”; “It was making me eat a lot”; and “They give me a good appetite.”

The analysis of the respondent’s answers concerning whether they thought the study helped them led to a description of the participants’ attitudes and thoughts about participation, based on their experience and perceptions. Nine-
ty-seven units related to the reasons for participation in the study were drawn from the respondents’ answers to the question of how they thought their participation in the study helped them. The units were grouped into 21 different elements. These are considered to be components of an explanation of participation outcome, which can be interpreted to relate to a definition of the meaning of participation. These components, presented in Table 2, were re-
grouped into 8 main ideas, or conceptual categories: weight/appetite/nu-
trition issues; aspects of personal health directly related to HIV; general health issues; medication; health education; counseling and help; increased self-es-
teeem; and social needs and support.

The first 5 components point to the respondents’ concerns about basic health awareness, and reflect their feelings that participation in the study provided them with direct health benefits, such as understanding their health, ob-
taining specific information about their viral level or CD4 count, or becoming more aware about diet and nutrition issues. For example, responses included statements such as: “The study helped me because my CD4 counts increased”; “The study helped me because it gave me a chance to check up on my health”; “It maintained my CD4 count in the
Table 2. Description of “how participation in the project helped” as expressed by respondents

<table>
<thead>
<tr>
<th>Elements From Respondent’s Statements</th>
<th>Conceptual Categories</th>
<th>Higher Level Concepts</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. More aware of weight, diet or nutrition (5)*</td>
<td>Weight/appetite/nutrition issues (5)</td>
<td>Increased health awareness</td>
</tr>
<tr>
<td>2. More aware of HIV (2)</td>
<td>Aspect of personal health directly related to HIV (11)</td>
<td></td>
</tr>
<tr>
<td>3. Blood test, CD4 count, viral load status (9)</td>
<td>General health issues (19)</td>
<td></td>
</tr>
<tr>
<td>4. Feel stronger and have more energy (5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Feel better; have been healthier; prolong life (10)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Helped with memory or alertness (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. The medicine (pills) helped (4)</td>
<td>Medication (11)</td>
<td></td>
</tr>
<tr>
<td>8. Participation enhanced consistency with medication (5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Increased awareness about health, addiction, or resources (8)</td>
<td>Health education (16)</td>
<td></td>
</tr>
<tr>
<td>10. Helped keep up health (5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Helped with being more careful about safe sex (3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Provided encouragement and counsel (4)</td>
<td>Counseling and help (12)</td>
<td>Personal enhancement</td>
</tr>
<tr>
<td>13. Provided motivation (2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Something to live for; awareness that there is hope for a better life (5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Helped become more consistent (1)</td>
<td>Increased self esteem (7)</td>
<td></td>
</tr>
<tr>
<td>16. Do things never did before; provide opportunity for change (2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. Feel better about myself; happy now (5)</td>
<td>Social needs and support (12)</td>
<td>Sociability</td>
</tr>
<tr>
<td>18. It is a good place; feels like home (2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>19. Fellowship; meet people with same condition (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20. Staff provided social needs (3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21. A reason to get out of the house (1)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Number of respondents mentioning the element.

right category”; “The study increased my awareness of HIV”; and “It taught me a lot. I learned a lot of things about HIV, about safe sex and all of that.” Additionally, some individuals indicated they benefited from the study because they felt better while they were enrolled and participating (eg, “Because I feel better than just slow or lazy. Now I am going places and exercising”), they were more consistent about taking all of their medications, they practiced safer sex, and were able to learn more about their substance addiction and HIV.

A number of respondents viewed their participation in the clinical trial as enhancing their personal growth and self-esteem, or felt it provided them with meaning for living. These interviewees said such things as: “Participating made me aware there was hope for a better life”; “Just coming in helped”; “I like myself better”; “It helped me because I had the opportunity to change due to the encouragement of the staff” and “I came because I need help.” These types of responses reflect the emotional support and personal enhancement that regular participation can provide for participants.

Finally, it was clear that a number of the participants viewed their involvement in the trial as a way to attain social contact with other individuals. These respondents said such things as: “They made me feel at home, Dr. Q and S were very nice, I will miss them”; “I made good friends like Dr. Q and S”; “It gave me a place to come and meet other people with the same condition.” For some, the staff represented a group of individuals they could talk to, and who could provide them with support and sympathy; for others, participation provided a way to meet other people, especially individuals who were in a similar life situation of coping with HIV and substance abuse.

Overall, the respondents’ statements clearly suggest that they imbued their participation with meaning that encompassed medical and health support, emotional support, and sociability. Therefore, the 8 conceptual categories that were developed from the elements of meaning can be seen as falling into 3 higher level concepts, or themes: increased health awareness, personal enhancement, and sociability.

**DISCUSSION**

The present study is one of the first to examine how HIV-1 infected male and female drug users view and interpret their participation in a randomized, controlled clinical trial. A high proportion of the sample had more than a high school education, and the majority of the participants were African-American. The stereotype of the typical dropout, as described in the current literature, is an older non-White male with limited education, multiple health problems, and a high degree of life stress. Although this fits the profile of most of the males in the study, and also applies to many of the females, the clinical trial had a very high rate of retention (72%).

The high rate of retention appears
The high rate of retention appears to have been influenced by several factors that were structured into the research project.

The treatment, their beliefs did not appear to affect their willingness to participate, nor the number of appointments they kept. There was considerable uniformity in the perceived benefits of the pills (regardless of whether they were selenium or placebo). In this way, it appears the participants were able to make sense out of the randomization process, and afforded it with positive outcomes in terms of how they perceived their physical and emotional health.

The findings from this study also suggest that a number of factors can affect an individual’s ability to keep appointments, even when compliance is high. The very fact that the study participants were both HIV+ and substance abusers presents a number of potential barriers to attendance. The most common reason for missed appointments was being in jail or needing to attend probation appointments. Additionally, illness, personal conflicts, and other priorities, such as work schedules or being out of town, were cited as reasons for missing visits.

Finally, in this study we explored the reasons for participation, and the significance participation had for participants. We documented their perceptions of how involvement in the clinical trial helped them. Consequently, we were able to uncover the reasons for participation. It is evident that the process of achieving personal benefit enabled participants to value their experience.

We were able to ascertain many “units of reasons” for participation from the participants’ responses. Using qualitative analysis, we regrouped the responses in 21 elements of value/significance that formed a smaller number of conceptual categories. Overall, the emergent themes emphasize the fact that participants imbue their participation with positive benefits. Participation provided the individuals in this study with a means for learning about their illness and receiving health care, and gave them a way to actively engage in health enhancing, or maintaining, behaviors. In addition, many of the men and women obtained emotional support through their participation, and appeared to find ways to give new meaning to their lives, especially when they were coping with the physical and emotional ramifications of both HIV infection and substance abuse. The impact and value of participation is highlighted by the quote from one participant: “I will miss the study, God bless you all.”

To our knowledge, this is one of the first times that participants’ perceptions have been described. They provide us with a window for understanding why individuals participate in clinical trials, and we hope this understanding will enable us to develop more sensitive and appropriate protocols, of particular importance for maintaining adherence to complex antiretroviral regimens. We are keenly aware that the HIV-1 infected men and women in this study are those who were willing to participate in a research trial, and are not a random sample. Therefore, these conclusions may not be extrapolated to the HIV-1 infected drug-using population in general. Nevertheless, these data caution us to avoid an oversimplified and medicalized perspective of retention and participation. Retention and participation need to be perceived as multidimensional, and as including such factors as participant characteristics, structure of the research, and the context of the study. Our results highlight the need for integrating information about the subjective experience of participation into studies, thus enabling a more collaborative environment for the researcher and the participant, as well as facilitating the development of a theoretical framework that can benefit both clinical research and healthcare programs.

REFERENCES

**AUTHOR CONTRIBUTIONS**

Design and concept of study: Shor-Posner, Moreno-Black

Acquisition of data: Shor-Posner, Burbano, O’Mellan

Data analysis and interpretation: Moreno-Black, Shor-Posner, Miguez-Burbano, Burbano, O’Mellan, Yovanoff

Manuscript draft: Moreno-Black, Shor-Posner, Miguez-Burbano, Burbano

Statistical expertise: Moreno-Black, Yovanoff

Administrative, technical, or material assistance: Shor-Posner, Miguez-Burbano, Burbano

Supervision: Shor-Posner, Moreno-Black