

ISSUES IN CLINICAL NURSING RESEARCH

**Methodological and Ethical
Issues Emerging From Pilot
Testing an Intervention With
Women in a Transitional Shelter**

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This article focuses on the methodological and ethical issues that emerged during the pilot test of a social support intervention with women who had experienced homelessness and were living in a transitional shelter. The overall goal of this project was to improve their health outcomes, more specifically their health maintenance behaviors and general health. This article briefly describes the nursing intervention to set the context for analyzing six methodological and ethical issues: (a) maintaining investigator relationships with shelter staff, (b) reducing bias, (c) dealing with sensitive issues, (d) adjusting the intervention to meet the women's needs, (e) managing attrition, and (f) sustaining informed relationships with participants. Flaskerud and Winslow (1998) called for research designs with vulnerable populations that move beyond description and epidemiology, to intervention and outcomes. They also argued that it is critical for nurse scientists to explain the methodological challenges they encounter in research with vulnerable populations. This article offers such an explanation for future interventions with women who have histories of homelessness.

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OVERVIEW OF INTERVENTION

Evidence suggests that even when residing in service-intensive shelters, women with histories of homelessness frequently continue to experience health problems, including substance abuse, other mental health problems, and the sequelae from the trauma of domestic violence (Rog, McCombs-Thornton, Gilbert-Mongelli, Brito, & Holupka, 1995; Rog & Ponirakis, 2002). They also tend to have limited health maintenance (Hatton, 1997; Hatton, Kleffel, Bennett, & Gaffrey, 2001). Therefore, the skill-building intervention tested in this study was designed to assist sheltered women to (a) prioritize health maintenance behaviors, (b) access support from peers, (c) identify barriers to seeking health care, and (d) utilize health care resources in the community. To accomplish these goals, the intervention nurse met with women in groups for four to eight sessions at a transitional shelter. After these initial group sessions, the nurse continued meeting with each woman individually on a monthly basis for 12 months. The intervention was adapted from the work of Norbeck and her colleagues (DeJoseph, Norbeck, Smith, & Miller, 1996; DiMartile Bolla, DeJoseph, Norbeck, & Smith, 1996; Norbeck, DeJoseph, & Smith, 1996) and followed a set of modules with specific objectives and activities for each session.

Fifty-eight women (27 experimental and 31 control) participated. All received remuneration for their participation. Their mean age was 30 years (range 19 to 45). Thirty-five (60%) women reported they were White, 11 (19%) African American, 7 (12%) Latina, and 5 (9%) Other. Of the participants, 21% had less than a high school education (mean = 11.62 years). All had custody of at least one child, received California's Medicaid Program (MediCal), or had health insurance from an employer.

METHODOLOGICAL AND ETHICAL ISSUES

Maintaining Investigator Relationships With Shelter Staff

As is common with underfunded community agencies that deliver services to vulnerable populations, there was a high staff turnover. During the 2-year study, there were three different clinical directors, and only two of the four case managers who worked directly with clients remained the same. Because of the longitudinal design of the study, staff attrition made it difficult to maintain relationships with persons who played an essential role in providing access to participants. Staff had heavy workloads and considerable

responsibilities for client safety and progress in the program; as such, the study reported here was only peripherally important in their day-to-day routine. During the course of the project, the principal investigator and research assistants made considerable effort to maintain visibility and entrée in the setting by attending staff conferences, visiting the shelter regularly, and participating in graduations as clients progressed in the transitional program. Early in the project, investigators provided a lunch for staff and told them in detail about the research and their importance in its success. When visiting the shelter to locate clients, the research team generally provided food and beverages not only for study participants but for staff as well. Thus, successful research projects with community agencies require not only sophisticated research methods but also pragmatic efforts on the part of all members of the research team.

In future research, investigators recommend acknowledging the effort necessary to maintain relationships with staff and budgeting for this. An additional strategy is to use women who have successfully completed the shelter program and are in drug recovery as on-site coordinators with compensation. These women can facilitate ongoing relationships with staff and act as liaisons between staff and other research team members. Flaskerud and Winslow (1998) argued for such use of targeted group members in community research programs with vulnerable populations.

Reducing Bias

To reduce bias in the project, the three team members who served as the intervention nurses did not collect the research data from participants. Data collectors consisted of three different team members, all nurses. The data collection interviews, nevertheless, may have acted as a minimum intervention. Noteworthy were the situations data collectors encountered during interviews when participants asked about health-related matters. Ethically, the data collector nurses considered it their responsibility to respond appropriately, and participants were referred to appropriate community resources. In addition, participants reported to the data collectors that questions such as *When was the last time you had a pap smear?* triggered a sense of the importance of having such a test, and several noted later that they then had the test done. As one participant in the control group noted, *"It (the data collection interview) made me aware of a lot of stuff that I wouldn't take care of. . . . I mean stuff that I would just let go. Eye exam, dentist . . . it has made me more aware of it."*

Investigators recommend that research team members carefully discuss the possibilities of questions and health concerns during data collection and plan for appropriate and consistent responses. In addition, because findings from previous research have indicated that treatment as usual often does not increase health maintenance among women in transitional shelters, future research that compares two or more nursing interventions rather than a treatment as usual control group is warranted.

Dealing With Sensitive Issues

A number of sensitive issues emerged during the conduct of this study. First, because women in the project often had histories of illegal substance use, as well as other illegal activities, the principal investigator sought and obtained a certificate of confidentiality from the National Institutes of Health to protect data (Lutz, Shelton, Robrecht, Hatton, & Beckett, 2000). Nevertheless, California state statutes still required reporting harm to self and others as well as abuse. All researchers carefully addressed these issues during the informed consent process and particularly emphasized the obligation to report abuse and harm. In one instance, a participant reported an attempted suicide to a team member. This situation was addressed by working with the participant's case manager, who then assisted her in contacting a mental health professional.

Team members were called on to address other situations in which women were in crisis. One participant reported repeated sexual assaults in her workplace to the data collector, who then encouraged the woman to report the situation to the local police. This latter instance increased the team's awareness of the environments encountered by these particularly vulnerable women as they sought to re-enter the workforce. Research assistants on projects in which these issues might emerge require training to effectively address such problems.

Evaluating the Intervention to Meet the Needs of Participants

Flaskerud and Winslow (1998) argued that a critical methodological issue in research with vulnerable populations is establishing the strength and dose of interventions. Originally, only one of the four initial support group sessions emphasized identifying an appropriate health care professional in the community and making an appointment to accomplish a health maintenance goal. Although all participants in this study had either subsidized or

private health insurance, they were generally unfamiliar with their eligibility for various services. It thus became clear that the intervention required additional time to increase their knowledge about service eligibility, the nature of general health maintenance, and procedures for obtaining health care. In addition, women frequently had a variety of competing obligations in the shelter that conflicted with their attendance at the support group meetings, such as meetings with parole officers, appointments with other service agencies, and child care responsibilities. Participants in the experimental group indicated that an increased number of group sessions would benefit them. To meet the women's health needs and offer greater opportunity for learning, the team increased the support group sessions from four to eight. Building flexibility into the pilot project allowed investigators to learn more about the intervention and make appropriate adjustments.

A second consideration, with regard to the intervention itself, had to do with the number of health problems the women in the study had that influenced the consistent delivery of the intervention. Although most experimental group participants reported they benefited from the group sessions, some found it difficult to participate. One participant's disruptive behaviors interfered with the group process, as her psychiatric medications were adjusted. Several others had only limited participation. Therefore, to successfully evaluate these field interventions, researchers require not only a clearly developed protocol for training the interventionists but also a systematic means to carefully monitor the dosage of the intervention as to its amount, frequency, and duration with each participant. Sidani (1998) described a statistical technique that accounts for such variation among participants in complex field settings and provides a means to quantify a participant's exposure to the intervention. For example, if a woman is assigned to the experimental group but she attends no sessions, she receives a dosage score of zero. This strategy quantifies the dosage of the intervention as a continuous variable for use in statistical analysis, and Sidani argued, it enhances the validity of the inferences about the intervention's effectiveness.

Managing Participant Attrition

One of the most challenging tasks of the project was the management of attrition. Shelter staff members routinely tested residents for substance use, and if they tested positive, they were asked to leave the shelter, or as the staff said, they were "exited." Other reasons women left the shelter included physical assault of another resident, noncompliance with shelter rules, severe exacerbation of mental illness, and transfer to another community

agency or state for protection against threats from a violent partner. To manage attrition from the project, all participants completed a locator form when initially recruited into the study. On this form, they indicated a relative or friend the investigators could contact should they leave the shelter. As the study progressed, investigators found it helpful to update these locator forms monthly. Ultimately, 66% of the sample completed the study. In future research, investigators recommend expanding the locator updates to every 2 weeks and including incentives that increase at each time point for participants updating the forms. In addition, investigators need to consider immutable factors beyond the scope of most nursing interventions, which contribute to participant's leaving a research project, and plan accordingly to increase sample size. Future research that focuses on a profile of risk for dropping out of a shelter program would also provide useful information for targeting highly susceptible women. Further research that explores what is the critical time (Susser et al., 1997) for attrition from the shelter is also warranted.

Sustaining Informed Relationships With Participants

As noted earlier, the intervention tested here was designed to promote a nurse-client relationship. Indeed, such relationships were important for the long-term follow-up of many of the women in the project, who had highly chaotic lives. Yet, over time, certain behaviors came to the attention of the research team as, perhaps, an indication that some participants may not have wanted to continue in the study; however, they could not say "no." Some women repeatedly failed to return phone calls and missed appointments for 1:1 follow-up sessions. When this became evident, a lively discussion occurred among the research team members. Viable questions arose such as Did these women miss appointments due to other life demands? Did these women want to withdraw from the study but lacked the assertiveness and communication skills to voice their wishes? Did they fear that stopping their participation would jeopardize their relationship with the shelter despite having been assured that would not be the case during the consent process? Or did they fear that stopping would jeopardize their relationship with a nurse in whom they had developed considerable trust?

"Not showing up" is also a factor that frequently leads researchers to feel ineffective and frustrated and sets up a negative interactional condition for delivery of the intervention. Health professionals in the community often label "no-show" patients as "noncompliant," and thus these negative inter-

actional conditions extend to the broader delivery of health services. Because the intent of the intervention tested was skill building, in future research, investigators recommend addressing these behaviors directly and exploring with participants in the early sessions why they miss appointments, how to cancel an appointment, and how to withdraw not only from the care of a health professional with whom they are dissatisfied but also from the very study itself. Training for the likelihood that participants may not show up for all intervention and data collection sessions, as well as strategies for handling no-shows, is critical for members of the research team.

For future research, investigators also recommend a 2-step approach to consenting participants. Step 1 would use a group meeting for women to discuss the research project and the meaning of informed consent. Step 2 would involve obtaining the actual consent after women have had ample time to think about the implications of their participation in the project (Anderson & Hatton, 2000). Women in the transitional shelter had multiple concerns that ranged from custody of their children; recovery from alcohol and other drugs; severed relationships with family, friends, and partners; and probation mandates. The decision to enter a research project requires time to make an informed decision. Ideally, investigators recommend having one consentor (i.e., the designated research team member who obtains consent from participants) to keep the role distinct from the interventionist and data collector. A participant could thus contact the consentor at a later date should she wish to withdraw from the study.

CONCLUSIONS

As nurse scientists progress in their efforts to test interventions with vulnerable populations, they will encounter unique methodological and ethical challenges that can be daunting in light of the expectations for rigor in research. By addressing these issues and presenting them to the larger research community, nurse scientists can generate a dialogue about strategies for conducting research with marginalized groups, including women with histories of homelessness. Susser et al. (1997) commented on the broad social and historical factors that lead to homelessness. They argued that although it may be unrealistic to assume that homelessness can be alleviated by health interventions alone, with sensitive research methods it should be possible to learn how to reduce its associated health risks.

NOTE

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