The Qualitative Report

Volume 26 | Number 3 How To Article 17

3-12-2021

Research Recruitment: A Case Study on Women with Substance Use Disorder

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Recommended APA Citation

Cook, K. J., & Larson, K. L. (2021). Research Recruitment: A Case Study on Women with Substance Use Disorder. *The Qualitative Report*, *26*(3), 1012-1020. https://doi.org/10.46743/2160-3715/2021.4746

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Abstract

Women with substance use disorder may evade research participation because of individual and societal factors. Limited information exists on recruitment of women with substance use disorder. The purpose of this study was to delineate recruitment challenges among women with substance use disorder and identify successful recruitment strategies. An exploratory case study was used to examine recruitment of women with substance use disorder. This case study was informed by a pilot study in 2017-2018, where data were generated from 25 direct observations and three key informants from a drug rehabilitation treatment agency. Analysis took an explanation-building approach, which incorporated chronological field notes from direct observations, memos from key informant conversations, and the extant literature to revise our initial proposition. Macro-level contextual factors influencing recruitment were: (a) establishment of a triage system, (b) reactivation of agency ethics committee, (c) scheduled accreditation site visits, (d) varied guidelines, and (e) required treatment regimen. Recruitment may benefit from multiple sites, staff training in protocol, increased researcher presence, and the opportunity for women's voices to be heard. This study advances knowledge of macro-level challenges faced during recruitment of women with substance use disorder in southeast USA. Indirect and direct recruitment, when combined, could maximize participation.

Keywords

research recruitment, women, substance use disorder, case study

Acknowledgements

Appreciation is given to Dr. Chandra Speight for reviewing this article. KC and KL analyzed data, were major contributors to writing, and read and approved the final manuscript. The authors declare that they have no competing interests.

The Qualitative Report 2021 Volume 26, Number 3, 1012-1020
https://doi.org/10.46743/2160-3715/2021.4746

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Women with substance use disorder may evade research participation because of individual and societal factors. Limited information exists on recruitment of women with substance use disorder. The purpose of this study was to delineate recruitment challenges among women with substance use disorder and identify successful recruitment strategies. An exploratory case study was used to examine recruitment of women with substance use disorder. This case study was informed by a pilot study in 2017-2018, where data were generated from 25 direct observations and three key informants from a drug rehabilitation treatment agency. Analysis took an explanation-building approach, which incorporated chronological field notes from direct observations, memos from key informant conversations, and the extant literature to revise our initial proposition. Macro-level contextual factors influencing recruitment were: (a) establishment of a triage system, (b) reactivation of agency ethics committee, (c) scheduled accreditation site visits, (d) varied guidelines, and (e) required treatment regimen. Recruitment may benefit from multiple sites, staff training in protocol, increased researcher presence, and the opportunity for women's voices to be heard. This study advances knowledge of macro-level challenges faced during recruitment of women with substance use disorder in southeast USA. Indirect and direct recruitment, when combined, could maximize participation.

Keywords: research recruitment, women, substance use disorder, case study

Introduction

Research recruitment of vulnerable populations, such as women with substance use disorder (SUD), is difficult because of many personal factors. Women with SUD are among the United States' most vulnerable populations. Almost 16% of women in the child-bearing stage used illicit drugs in 2016 (Center for Behavioral Health Statistics and Quality, 2017). Substance misuse during pregnancy increases the incidence of adverse maternal and infant outcomes, underscoring the importance of developing strategies to increase prevention and treatment efforts. Research participation among women with SUD could contribute to generating new knowledge necessary for improving maternal and infant outcomes. The authors of this paper experienced challenges in recruiting women with SUD while conducting a pilot study about the influence of SUD on breastfeeding decisions. The purpose of this paper is to delineate challenges identified while recruiting women with SUD for a pilot study and suggest strategies for successful research recruitment.

Pilot Study

The current study was informed by challenges identified during a qualitative descriptive pilot study conducted from 2017 to 2018. The pilot study aimed to determine factors affecting breastfeeding decision-making among women with SUD (Cook & Larson, 2019). The research protocol included recruitment and interviews at a drug rehabilitation treatment (DRT) agency. Women in the pilot study were residents of a rural, economically distressed region in eastern North Carolina where 26.3% of individuals met the federal poverty level, compared to 14.5% of individuals in the nation (US Census Bureau, 2016). Poverty influences participation in research through childcare and transportation barriers, such as lack of vehicle ownership, high gas prices, and unreliable public bus systems. Institutional Review Board (IRB) approval to use the pilot data for an exploratory case study was obtained. Ethical issues were addressed throughout the pilot study via IRB amendments (Table 1).

Table 1
Study Timeline Memo of Recruitment Efforts

Month	Recruitment Efforts
January 2017	Rapport developed with DRT[a] agency nurse manager Agency letter of support obtained IRB[b] application submitted
February 2017	IRB approval obtained One participant recruited by indirect approach
April 2017	Amendment 1: To interview at multiple locations IRB approved amendment Two participants recruited by indirect approach
June 2017	Notification of activation of agency ethics committee Research protocol submitted to ethics committee for approval
September 2017	Ethics committee business on hold due to agency accreditation visit
November 2017	Agency ethics committee approved research protocol
December 2017	Amendment 2: Direct recruitment approach and additional study sites IRB approved amendment Ethics committee approved amendment
January 2018	Amendment 3: Incentives for participants Researcher presence increased at DRT agency (1-2 times/week) Presentations to group sessions; Recruitment resumed
February 2018	IRB approved amendment Agency ethics committee approved amendment
March 2018	Recruitment resumed Researcher presence increased at DRT agency (2-3 times/week) Two participants recruited by direct approach
June 2018	One more participant recruited by direct approach

[a]DRT- Drug Rehabilitation Treatment, [b]*IRB- Institutional Review Board*

Literature Review

An iterative literature review on research recruitment of women with SUD, excluding alcohol, emphasized power differentials and experiential differences as major challenges to research recruitment. Since studies on research recruitment of women with SUD were limited, the search was broadened to include research recruitment of people who use drugs (PWUD). Ten studies were relevant; seven in international settings (Boucher et al., 2017; Brown et al., 2019; Grové, 2019; MacVicar, Humphrey, & Forbes-McKay, 2018; Sirdifield, Owens, & Brooker, 2016; Thong, Ulph, Barrowclough, & Gregg, 2019; Thornton, Harris, Baker, Johnson, & Kay-Lambkin, 2016) and three in the United States (Ballard, Cooper, & Young, 2019; Batista et al., 2016; Ryan, Smeltzer, & Sharts-Hopko, 2019). The literature emphasized individual factors as prominent challenges regarding research recruitment of women with SUD and PWUD.

Power differentials between researcher and gatekeepers, and gatekeepers and participants, frequently influence research recruitment. Sirdifield et al. (2016) described the issue of power differentials between offenders on probation and healthcare providers, as well as between gatekeepers and researchers. In this study of offenders on probation, the ethics committee recommended that probation officers introduce the study to eligible participants; however, researchers believed this approach was coercive (Sirdifield et al., 2016). Research recruitment carries a risk of coercion in the informed consent process, as vulnerable individuals may feel judged for declining or agreeing to participate in a study (Ballard et al., 2019; Ryan et al., 2019). Ballard et al. (2019) determined feasibility of using web-based recruitment strategies in opioid use research to minimize coercion. Investigators explained that the use of web-based recruitment would be helpful in decreasing stigmatization for PWUD, thus increasing their comfort with research participation (Ballard et al., 2019; Grové et al., 2019). Other investigators explained that web-based recruitment captures hard-to-reach populations and those with a higher severity of drug use (Thornton et al., 2016). However, Grové et al. (2019) argued that those of lower socioeconomic status may be missed, resulting in a study sample that is not representative of the population.

Several studies considered the pros and cons of indirect and direct recruitment in the context of power differentials. While indirect recruitment may minimize power differentials between researchers and participants, it requires multi-level research buy-in with professional and paraprofessional agency staff, which introduces power differentials with gatekeepers and both participants and researchers (Mirick, 2014). One author used indirect recruitment of offenders on probation to minimize researcher bias but preferred direct recruitment to protect individual rights of research participation (Sirdifield et al., 2016). Other investigators recommended direct recruitment to promote researcher familiarity with the community (Batista et al., 2016; Boucher et al., 2017; MacVicar et al., 2017).

Experiential differences between researcher and participant, such as lack of familiarity with participants and cultural dissonance, has contributed to low participation rates in research for women with SUD (Batista et al., 2016). Investigator lack of familiarity with the target population has led to inappropriate solutions, decreased trust and credibility, and hindered the rigor of the study (Brown et al., 2019; Thong et al., 2019). One team of investigators further indicated that visibility of the research team with participants and the community engendered research participation. Participants desired personal contact to build rapport with researchers (Thong et al., 2019). Investigators explained that their ability to relate to participants based on similarities in culture, race, or medical diagnosis was foundational for successful recruitment (Boucher et al., 2017; MacVicar et al., 2018). Other researchers suggested including community members in research projects as they share the cultural and social needs of the study population (Batista et al., 2016; Brown et al., 2019).

Methods

This exploratory case study was informed by the research recruitment process of women with SUD for a pilot study about breastfeeding decision making in eastern North Carolina. Case studies presented with multiple data sources are helpful in the development of future research to support validity and minimize bias (Hyett, Kenny, & Dickson-Swift, 2014; Yin, 2018). This case was chosen because of the challenges experienced while recruiting women with SUD for a pilot study. The pilot study served as the point of reference for analysis of factors that influenced research recruitment with this population.

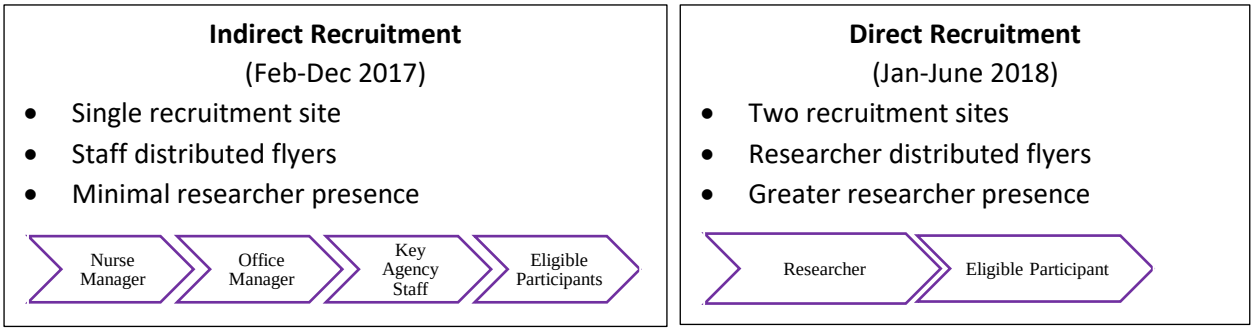
The first author (KC) is a Registered Nurse and an International Board-Certified Lactation Consultant who works with women with SUD and their infants in an academic medical center. A collaborative relationship was developed with the nurse manager at the DRT agency that serves women with SUD, rapport was built, and agency support for the pilot study was gained. The nurse manager of the DRT agency served as research liaison and gatekeeper for the pilot study.

Data Collection

Data were generated from 25 direct observations and three key informants in a DRT agency. During recruitment, direct observations of the DRT were conducted to identify structural factors related to research participation. These structural factors included location of group meetings, childcare arrangements, and location of bathrooms for drug screens. Seven conversations were conducted with three key informants: the head nurse and two office managers. Observations and conversations were between 15 minutes and three hours and were documented as chronological memos and field notes. The study timeline of recruitment efforts is shown in Table 1.

Indirect recruitment. Three women were recruited within the first three months of the study. Initially, we used an indirect recruitment approach to maximize relationships between gatekeeper and participant. Indirect recruitment involved managers and agency staff in the distribution of research announcements to eligible participants (Figure 1). Research announcements requested that interested participants contact the principal investigator (PI) to schedule an interview. Research recruitment coincided with establishment of a new agency triage system, supervised by the head nurse. In the initial IRB protocol, interviews were conducted at the DRT agency to minimize barriers. However, eligible participants identified transportation to the DRT agency as a barrier to participation, thus an amendment was submitted for in-home interviews. Five months into the pilot study, the DRT agency ethics committee was reactivated, which halted recruitment until the study could be locally approved. In addition, accreditation visits were scheduled during this time which further delayed recruitment.

Figure 1
Indirect versus direct recruitment



Direct recruitment. Direct recruitment and a second site of the DRT agency were used to enroll three additional women (Figure 1). Direct recruitment involved greater researcher presence by allowing the PI to conduct presentations about the study at group sessions in the agency. After one month of unsuccessful recruitment, an IRB amendment was submitted to offer $20 gift cards as participant incentives. During each presentation two to three women requested more information, and several men took information for their partners.

Data Analysis

Two investigators, the PI and a qualitative researcher, met biweekly to discuss recruitment progress and review field notes and memos from the observations and conversations. Field notes and memos were then organized to derive a coherent account of the case (Miles, Huberman, & Saldaña, 2020). Biweekly research meetings on study protocol led to further review of the literature and revisions to the initial IRB through amendments. Macro-level contextual factors within the agency led to further conversations with the nurse manger and agency staff. Reflexivity was addressed through iterative comparison of an initial explanatory proposition to chronological memos and field notes of the data and extant literature, thus resulting in a revised explanatory proposition (Table 1; Yin, 2018). Rigor was achieved through prolonged contact, self-reflexivity and data triangulation (Creswell & Poth, 2018).

Results

Our initial explanatory proposition was that personal or micro-level factors, such as lack of transportation and childcare, resulted in low research participation. The revised proposition of this case study is that primarily macro-level contextual factors affected research recruitment of women with SUD, requiring frequent modifications. Macro-level agency factors that delayed or limited recruitment were: (a) the establishment of a triage system, (b) reactivation of the agency ethics committee, (c) a scheduled accreditation site visit, (d) varied agency guidelines, and (e) required treatment regimen. While the target enrollment was 10 participants, a total of six women with SUD were recruited over an 11-month timeframe. Indirect and direct recruitment yielded three participants each. Interestingly, all six women were recruited from the same site that allowed greater researcher presence.

First, the nurse manager role as study liaison was compromised by the concurrent establishment of the triage system at the time of the study. This meant the nurse manager's time was occupied with frequent calls with other health care entities for client placement. Second, the agency ethics committee had been inactive, but this pilot study prompted the decision for reactivation to ensure client protection. The research proposal was sent to this committee for approval, which meant that the study was on hold until the committee could convene. Third, lengthy accreditation site visits were scheduled during the pilot study time frame. This meant that the ethics committee was further delayed in meeting to approve the pilot study. Fourth, agency guidelines varied by site. For example, one site offered the PI a waiting area, whereas the other did not. Participants were successfully recruited from the site that offered a waiting area. Lastly, the agency required new clients to attend three 4-hour therapy sessions per week and to present to the agency for daily medication dosing. These requirements were burdensome for women with SUD who often have transportation and childcare challenges. Key informants were helpful in navigating the time commitments of the triage system, ethics committee, and accreditation site-visits during the study time frame. Field notes and memos of these contextual factors were critical in helping to understand macro-level factors.

Findings from this study uncovered macro-level factors impeding research recruitment: a single research site, minimal initial researcher presence, low staff engagement with study protocol, and marginal opportunity for women's voices to be heard. During the process of analysis these findings led to frequent amendments allowing researchers to address these factors as they unfolded in the pilot study. The use of multiple research sites allowed for ongoing recruitment efforts where guidelines varied by site. Initially, the study liaison trained staff on the study protocol. When the study liaison time became compromised, it became evident that direct recruitment by the researcher was essential to successful recruitment. Increased researcher presence fostered rapport with agency staff and participants. The researcher worked diligently with the agency staff to recruit women with SUD, listen to the women's experiences, and present their voices accurately.

Discussion

This exploratory case study advances nursing science through the unique examination of a case on research recruitment of women with SUD and constitutes a foundational step toward improving maternal and infant outcomes. Notably, indirect and direct recruitment approaches yielded the same number of study participants. Gaining trust of women with SUD to participate in research is "complex, personal, and intense" (Dempsey, Dowling, Larkin, & Murphy, 2016, p. 485). Thus, we suggest using a combination of indirect and direct recruitment approaches in vulnerable population research protocols to circumvent the complex nature of recruiting this population. This case study of women with SUD is congruent with other studies of vulnerable populations that require more researcher time and compassion to build trust and rapport (Batista et al., 2016; Brown et al., 2019). The daily battle with treatment and recovery experienced by women with SUD in the context of multiple macro-level barriers, when considered in the design of research protocols, could promote efficient research and foster rapport and trust between researcher and participants (Batista et al., 2016; Boucher et al., 2017).

Initially, we believed that fear of legal repercussions would prevent women with SUD from participating in research, as it hindered them from seeking treatment (Stone, 2015). Conversely, the women recruited were very open about their past experiences, sharing information that would not be expected from those who fear legal consequences. This may be due to several factors. These women had already faced their fear of legal involvement and built their trust in the DRT agency; therefore, agreeing to participate in research supported by the agency was perceived to pose minimal risk. Any residual fears were mitigated when the researcher discussed how participant privacy would be protected during the study. Many participants expressed a desire to help other women with SUD be more successful than themselves. Some participants even expressed how sharing their personal stories and experiences was therapeutic for them. In agreement with the authors' suppositions, a few participants voiced concern about their ability to participate due to childcare arrangements. The researcher allowed children to be present during interviews for those who expressed this concern openly as a barrier to their ability to participate.

Consistent with findings of this case study, some investigators have addressed recruitment challenges through frameworks such as "risk environments" (Boucher et al., 2017, p. 4), while other researchers discussed participant-, institutional-, and recruiter-level challenges (Batista et al., 2016). Though the researchers did not label them as micro- and macro-level challenges, the institutional-level challenges could be viewed as macro-level. Despite similarities in research challenges in the literature, macro-level contextual factors were the prominent findings for this case study. Though this sample was largely young and White it is consistent with the population served by the DRT agency. Furthermore, this study provides

insight into potential challenges that may be faced with research recruitment of women with SUD in southeastern USA.

Implications for Research and Practice

Implications for research include the use of multiple research sites, staff training in research protocol, increased researcher presence, and greater opportunity for women's voices to be heard. One implication to increase women's voices in this research is to expand eligibility criteria to all women with SUD who have ever breastfed. We feel that expansion of eligibility criteria would increase research participation. Though other unexpected challenges to research recruitment may arise, implementing the suggested strategies will help minimize macro-level challenges experienced, and thus optimize successful recruitment of women with SUD. One implication for practice is for researchers to volunteer their time to serve on DRT agency advisory councils to learn about agency policies and share university research guidance with agency leaders. Policies on research recruitment of women with SUD were not found in the literature. Hence, we believe that a lack of research policies at some agencies may pose additional challenges to research recruitment. Conversely, improved research participation of women with SUD could influence expansion of services offered, improve health care delivery, and inspire state and federal policy changes.

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Acknowledgements: Appreciation is given to Dr. Chandra Speight for reviewing this article. KC and KL analyzed data, were major contributors to writing, and read and approved the final manuscript. The authors declare that they have no competing interests.

Article Citation

Cook, K. J. & Larson, K. L. (2021). Research recruitment: A case study on women with substance use disorder. *The Qualitative Report, 26*(3), 1012-1020. https://doi.org/10.46743/2160-3715/2021.4746