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Recruiting Rural Participants for a Telehealth Intervention on Diabetes Self-Management

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Abstract

Purpose—Recruiting rural and underserved participants in behavioral health interventions is challenging. Community-based recruitment approaches are effective, but they are not always feasible in multisite, diverse community interventions. This study evaluates the feasibility of a rapid, multisite approach that uses rural clinic site coordinators to recruit study participants. The approach allows for rural recruitment in areas where researchers may not have developed long-term collaborative relationships.

Methods—Adults with diabetes were recruited from rural Federally Qualified Health Center (FQHC) clinics. Recruitment feasibility was assessed by analyzing field notes by the project manager and health coaches, and 8 in-depth, semi-structured interviews with clinic site coordinators and champions, followed by thematic analysis of field notes and interviews.

Findings—Forty-seven rural sites were contacted to obtain the 6 sites that participated in the study. On average, sites took 14 days to commit to study participation. One hundred and twenty-one participants were acquired from letters mailed to eligible participants and, in some sites, by follow-up phone calls from site coordinators. Facilitators and deterrents affecting study recruitment fell into 4 broad categories—study design, site, site coordinator, and participant factors.

Conclusion—The rapid multi-site approach led to quick and efficient recruitment of clinic sites and participants. Recruitment success was achieved in some, but not all, rural sites. The study highlights the opportunities and challenges of recruiting rural clinics and rural, underserved participants in multisite research. Suggestions are provided for improving recruitment for future interventions.

Keywords

diabetes; health coaching; recruitment; rural; telehealth

Recruiting rural participants for health intervention research is challenging due to a combination of factors, including large geographic areas, health care clinics with limited resources and heavy workloads, and, in some populations, low literacy rates and transportation obstacles.^{1–4} Rural residents, in comparison to urban residents, tend to be less educated, have lower incomes, are more likely to report poorer health status, suffer more from chronic conditions, are more likely to be uninsured, and are less likely to receive

preventative health care services.^{5–8} Involving multiple rural sites amplifies these challenges as researchers must negotiate increased study complexity and logistics as well as the unique cultural and social characteristics of diverse communities.^{2, 9–15}

One approach to research recruitment in rural communities has been community-based participatory research (CBPR) strategies. The CBPR approach focuses on building trust by directly involving community health center personnel and community members in study design, activities and decision-making.^{16, 17} Another approach, also relying on community relationships, is Practice-Based Research Networks (PBRNs). PBRNs consist of networks of local health practitioners with strong ties in the community and an awareness of the health care issues relevant to clinical practice.^{18–20} The presence of a network allows researchers to build long-term relationships with local care providers and establish a foundation for future research endeavors.^{18, 21} While these approaches have proven successful, they require significant time and effort to establish trusted and mutually beneficial relationships.

Other strategies for rural recruitment have focused less on building collaborative relationships with clinic sites and more on the efficiency of recruiting potential study participants. A systematic review of recruitment strategies of vulnerable populations found that targeted marketing approaches, such as mailings, telephone calls, and media to potential participants achieved reasonably successful participant enrollment.²² Targeted approaches, such as insurance company mailings and community outreach at church and community centers, however, have proven less effective.^{23–25}

Given the importance of including rural participants in health research, researchers must identify meaningful ways to collaborate with rural clinics for recruitment, yet accommodate the time and resource constraints of a research study. This article reports on the feasibility of a rapid, multisite recruitment approach that combines elements of the community-based, practice-based network, and targeted marketing approaches. This approach was used to recruit participants for a randomized, controlled study exploring the effectiveness of health behavior coaching for adults living with diabetes in rural communities. In the following sections, we highlight the opportunities and challenges of rapidly recruiting multiple diverse rural clinics and underserved participants, and suggest implications for recruitment in rural health research.

METHODS

Participants were recruited from 6 rural communities to test the feasibility of delivering nurse coaching remotely via telehealth.

Site Recruitment

Rural Federally Qualified Health Center (FQHC) sites in Northern and Central California were identified and invited to participate. To attain FQHC status, a clinic must serve an underserved population, offer a sliding fee scale, provide comprehensive services, have an ongoing quality assurance program, and have a governing board of directors.²⁶ Rural FQHCs have less than 250 persons per square mile and no incorporated area greater than 50,000 persons.²⁷ Sites were eligible if they had a rural FQHC designation and a minimum of 300 diabetic patients, a population large enough to recruit 60 participants.

We initially engaged clinics that had previous involvement with the university to leverage past working relationships. To recruit additional sites, administrators from FQHC clinics were contacted by phone or email. Interested site administrators completed a survey providing clinic demographics and estimated their ability to recruit at least 60 participants in 2 months. Sites meeting requirements were asked to participate. A cooperative contract

between the university research team and each site was established. Prior to initiation of the study, the project manager visited each site and met with clinic providers and staff to discuss the aims of the study, the intervention, and to get feedback regarding best approaches to recruitment within each community. Sites received \$2,500 to offset expected costs of coordinating the project.

Participant Recruitment

The administrator at each site designated a staff member to serve as a coordinator whose primary function was initiating participant recruitment. This design was necessary because federal Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules prohibit outside researchers from directly contacting patients without prior consent. Before contacting potential participants about the study, all remote site coordinators completed the Collaborative Institutional Training Institute (CITI) research ethics training as required by the university's Internal Review Board (IRB).

To recruit participants, remote site coordinators used clinic records to identify patients with diabetes. Patients who were eligible were mailed a letter describing the study. In sites where target recruitment was not attained through mailed requests, or low literacy levels were a concern, site coordinators called potential participants. Once patients indicated interest in the study, coordinators shared contact information with research staff.

The study team contacted all individuals who expressed interest and delivered a brief 5-minute scripted explanation of the project. Participants who confirmed interest were mailed an initial survey and written consent forms with prepaid return envelopes. Upon returning the materials, participants were randomly assigned to a control or intervention group. The intervention group received nurse-led health behavior coaching sessions via telehealth technology in the participant's home; the control group received usual care. For study inclusion, participants had to be 18 or older, have a diagnosis of Type 1 or Type 2 diabetes, speak English or Spanish, have a telephone, and be receiving care at one of the rural FQHC sites. Office visits or other clinical care were not required. Participants were excluded from the study if they reported any hearing impairments that might interfere with the conversational coaching intervention. Participants were not initially offered compensation for their involvement. However, as an incentive to reduce attrition, a \$40 gift card was offered at the end of the study to all participants completing the final survey.

Data Collection and Analysis

The data collected for this feasibility analysis included field notes from the project manager and 3 health coaches as well as open-ended survey responses from study participants. In addition, clinic site administrators and site coordinators (n=8; 3 partnering clinics were part of 1 parent administrative organization, so the clinic site administrator and coordinator were the same for these 3 sites) were interviewed about their experiences with the study using a semi-structured interview guide. Interviews were recorded and transcribed.

Field notes and transcripts from the interviews were entered into Dedoose, a qualitative and mixed methods software program.²⁸ Using thematic analysis,^{29–31} 2 independent coders (the 1st and 2nd authors) identified codes anticipated from the literature (eg, limited resources) and codes that emerged from the data (eg, participant familiarity with research and coordinator's research experience). Emerging themes were reviewed by all the authors and codes were grouped into prominent themes following multiple discussions and memoing techniques.³² Throughout the analysis, the authors verified the reliability and validity of the findings by continuously looking for confirming and contradictory evidence of the themes.³³

RESULTS

Facilitators and Barriers to Recruitment

Thematic analysis led to the identification of 12 key issues that positively or negatively impacted site and participant recruitment efforts. Second level analysis consolidated these 12 key issues into 4 main levels that mapped onto the major components of the study: 1) study design; 2) sites; 3) site coordinators; and 4) participants (see Table 1). Each site encountered facilitators and barriers at each of the 4 levels identified, although each was not necessarily salient in every site. In the 4 sections that follow, the facilitators and barriers found in the level will be discussed in terms of their influence on recruitment efforts.

Study Design-Level Recruitment Factors

Two design issues—HIPAA regulations and the complexity of the research material—created barriers for site and participant recruitment, and 2 design factors—site payment and prior relationships—facilitated site recruitment.

HIPAA Regulations—Because HIPAA precluded researchers from direct recruitment, the study design required an intermediary (site coordinator) at the clinic. Introducing a 3rd party for recruitment required a more intricate research design and made recruitment more cumbersome. For instance, participants who indicated interest could not be immediately enrolled by the site coordinator. Instead, the coordinator communicated participant information to the study team. Added to this was the need to have a sufficient number of participants before an orientation meeting could be scheduled. Consequently, the orientation meeting occurred, on average, almost 3 months after initial contact by letter. As a site coordinator noted, “I think that for our population..., they receive the letter, then they have to respond, and then after that they would get contacted, and then after that we get set up with a meeting, so I think it was such a long process for them.”^a

Complexity of Materials—HIPAA-related requirements increased the study complexity and required extra informed consent materials. For example, participants were mailed a letter with study information, 2 copies of a 6-page study consent form, 2 copies of a 4-page HIPAA consent form, and a 12-page survey. The amount and complexity of the study material intimidated some participants unfamiliar with research. As a site administrator noted, these issues contributed to low response rates and added work for site coordinators:

Literacy is also a big issue for our [patient population] and obviously the letter was written at a particular level, based on human subject review [requirements] and things like that. So there had to be key components within the letter but I think, what [the site coordinator] found herself doing a lot was—number one, a lot of patients didn’t understand the letter—so she had to give a quick summary of what the letter was in regards to. It wasn’t, oh yeah, I got the letter and I understand.

The extra complexity led some sites, especially those with low patient literacy rates, and the research team to increase staff time to assist participants with completing forms and surveys. The rapid multisite approach was designed to offset literacy and language barriers. For instance, study materials were written at a fifth-grade reading level and translated into Spanish. Assistance was available to help participants fill out forms. Despite these efforts, over 50% of interested and randomized participants did not complete study paperwork and ultimately failed to enroll (Figure 1, 7a & 7d).

^aExcerpts were edited by deleting hesitations and false starts to improve readability.

Site Payment—Each participating clinic received \$2,500 to offset costs of staff time to recruit participants. No site administrators suggested they participated because of the payment, but for some clinics it made the participation process less burdensome. Site administrators reported using the funds for salary offset, supplies, and updating computer equipment. For instance, a site administrator commented,

[W]e [used the funds]...to offset any costs of the effort that we had been asked [to do] so that we wouldn't be losing...manpower hours that were necessary for other parts of the clinic. We didn't want anybody to feel that they were experiencing a deficit in manpower or finances by participating. So we were hoping it would at least even some of that out.

Prior Relationship or Reputation of the University—Clinic sites that had a prior relationship with the university were approached first. This was a significant facilitator for participation for 4 clinics. As one site administrator explained, “Well, I think a lot of it has to do with our relationship, our affiliation, partnership, with the university. We want to support your organization as I hope you want to support us so there's that mutual benefit to each other.” For these clinics, the study was seen as mutually beneficial, serving to strengthen their relationship with the university. Four clinic administrators also identified the reputation of the university as contributing to their decision to participate:

I think that because it is a university there's kind of a level of credibility already just being associated with a university and because it's such a well-known university especially focused on healthcare issues or healthcare in general, so I think that was definitely a plus.

Site-Level Recruitment Factors

Initial contact was made by phone or email to 47 rural FQHC sites. Fifteen of these clinics expressed interest in participating. Follow-up discussion between the project manager and site administrators resulted in the final recruitment of 6 sites (4 from previous university partnerships). The average time between initial contact and study commitment was 14 days with a range of 5 to 40 days. Reasons clinics gave for declining participation were having fewer than 250 active diabetic patients and having limited staff resources to assist with recruitment due to recent layoffs. Two clinics had diabetic educators and felt the service would duplicate what was already offered to their clients. An additional 2 clinics withdrew because of an inability to fulfill participant recruitment requirements.

The sites that participated met pre-defined requirements regarding their clinic population and structure. However, they differed significantly in their prior exposure to research, their history of diabetes education, and resources available to recruit participants. Depending on their presence or absence, these factors served as either facilitators or barriers to recruitment.

Prior Experience with Research—Sites with prior research experience (n=2) had an easier time recruiting participants than sites with no prior experience. Understanding the basic logistics of research, such as identifying potential research subjects and managing study material, allowed these clinics to address unexpected occurrences common in studies. One of the most successful sites was a clinic that had been involved in clinical trial research and had extensive experience assisting with recruitment. As their site administrator said, “I would not say we are full of clinical researchers in our organization at all, but we have a strong interest in working with other organizations and supporting evidence-based practice and research.”

History of Diabetes Education—All recruited sites had a history of offering diabetes education. However, most had reduced health education resources and saw the study as partial replacement. For instance, 2 sites had eliminated diabetic educator positions. In these clinics, the site administrators indicated the study provided renewed attention to diabetes, which served as a major incentive to participate. A site administrator commented:

We eliminated our diabetic educator position.... many of the primary care physicians were disappointed with that decision and...[we think] participating in this study may assist us with our diabetic educational needs in the future by collaborating with you.

Providing access to a valuable service was a strong incentive in decisions to participate.

Resources—As part of the rapid multisite approach, potential sites were screened for capacity and resources to recruit participants with minimal time commitment. One site coordinator noted that she spent, “a total of maybe 10 to 12 hours and that was from the beginning of [sending out] letters and then the follow-up at the end.” Only one clinic coordinator noted challenges with finding staff time to complete their part of recruitment. One site coordinator reported that staff turnover negatively impacted recruitment efforts; specifically, the lead site administrator left the organization, and the project was “kind of [in] a standstill.” Although a replacement administrator was found and the recruitment process was completed, this example highlights a potential challenge coordinating with on-site staffing.

A resource that varies widely among rural clinics is their access to and use of technology. The intervention did not have specific clinic technology requirements, since the coaching occurred in participants’ homes. Clinics, however, did have to efficiently identify their patient population with diabetes. All but one clinic had this capacity. One clinic lacked the ability to search for eligible participants through an electronic health record or billing database, a significant barrier to recruitment. The site administrator commented, “The only thing that I remember being kind of difficult on our end was because of our limited computer system—and the difficulty in actually naming the patients who have diabetes in any structured, data driven kind of way.” This clinic had to rely on more time intensive and less comprehensive strategies for locating potential study participants.

Site Coordinator-Level Recruitment Factors

Site coordinators, who played a major role in recruitment, were selected by the clinic administrator rather than the research staff. This approach was chosen because of administrators’ knowledge of their clinic’s flow and resources, and their ability to identify an individual with the skills and time to accomplish the tasks. Participant recruitment was impacted by 2 main factors—site coordinators’ knowledge and experience with research studies and their level of direct patient and provider contact.

Knowledge About Research Studies—The biggest challenge for site coordinators, whose job titles ranged from medical records assistant to clinical trials coordinator, was their lack of experience with research studies. The majority of coordinators were selected for their administrative skills. Only one site coordinator had direct experience with recruiting participants for research. The lack of experience with recruitment created difficulties in articulating the parameters and benefits of the study. As one coordinator explained:

I think there were a couple times when I was talking to patients and they actually thought they were going to get billed. And I tried to explain to them, “no, this is just a survey, it’s just an experiment type thing that we’re trying to help out the community” and I don’t think they really understood.

The research team provided coordinators with a script to read. However, when potential participants wanted additional information or needed clarification about what it meant to be in a research study, this posed a challenge. The most successful coordinators, as one site administrator noted, were those who could “communicate the [study] message in [the patient’s] language and kind of showed them the benefits of their participation.”

Contact with Potential Participants and Providers—Coordinators had varying levels of interaction with patients. For instance, one coordinator, a medical records assistant, had no direct interactions with patients and did not live in the community. The lack of patient contact was not an issue with the administrative aspects of the coordinator position, such as mailing letters or calling potential participants, but it did hinder direct recruitment efforts because coordinators were not able to draw on established relationships to encourage study participation. Most coordinators also had minimal interactions with healthcare providers, which may have impacted recruitment. In the original study design, healthcare providers were expected to refer their patients with diabetes to the study coordinator to obtain study information. Some provider referrals occurred—approximately 12% of participants stated they were encouraged by their provider to enroll—but provider involvement and interaction with coordinators was low. A site coordinator commented on providers’ roles in recruitment:

The providers seem to be overwhelmed with a lot of paperwork and they have certain time to see their patients. So I don’t believe that they really got into it—there was not a lot of support from the doctors and not because they didn’t want to, it’s just the time limit that they were given. So unfortunately, I don’t think the doctors had a role in this research.

Participant-Level Recruitment Factors

One hundred and twenty-one adults participated in the study (Figure 1, 7b & 7c). The average number of participants recruited from each clinic was 20. The time from site involvement to participant recruitment averaged 27 days with a range of 19 to 38 days. The response rate for the 3,226 letters mailed to eligible participants was 12% (Figure 1, 2a & 2c). Of the 121 enrolled participants, 76% were recruited by letters and the remaining 24% were recruited by site coordinator phone calls. Participants reported a variety of reasons for enrolling in the study. The most common facilitator was a desire to improve their understanding of diabetes. Some interested participants were not enrolled because they did not return study materials, attend an orientation session, nor respond to calls from researchers (n=262) (Figure 1, 4a, 7a, 7d). Of those contacted by the research team who chose not to participate (n=109), the primary reasons for not participating were illness of self or family, time commitment concerns or a belief that their diabetes was under control.

Interest in Increasing Knowledge of Diabetes—Participants stated that improving their diabetes care was the primary reason they enrolled in the study. For instance, in post-intervention surveys, participants reported: “I wanted to get my diabetes under better control,” “[I wanted] to better understand diabetes and learn new and better ways to manage it,” and “Whatever I’m doing isn’t working; [I] needed new ideas.” For these participants, the opportunity to receive direct nurse coaching—something they were not able to receive through the clinic—was the key factor. Several participants had a broader view of their enrollment in the study, suggesting that they participated because they were interested in improving the health of others and “help[ing] people with diabetes.” Whether for personal gain or furthering research more generally, the study was able to provide a perceived benefit that facilitated recruitment.

Study Logistics—The study was designed to minimize issues related to transportation, scheduling and time commitment. Utilizing telehealth technology allowed the intervention to occur in participants' homes. The nurse coaches offered flexible coaching appointments during evenings or weekends. There was, however, an initial orientation meeting held at the clinics for the intervention group. At this orientation, participants were given an overview of the study and were introduced to the concept of coaching based on motivational interviewing. Logistical barriers, such as transportation and scheduling, were issues in this initial stage of the study. Approximately 58% of participants who initially indicated interest did not return study material or attend the orientation. The anticipated time commitment also discouraged some participants. Most of the commitment concerns were related to personal and/or family health issues.

Familiarity of and Interest in Clinical Research—In the most disadvantaged clinics, site coordinators reported low levels of participation because of potential participants' lack of familiarity with clinical research. For many, the language and culture surrounding clinical research was unclear and unfamiliar. For instance, respondents were unsure about the costs involved, the relationship of the study to the clinic, why the coordinator was contacting them, and more generally, what participating in research entailed. While the study material and site coordinators explained this information, some participants remained uncomfortable with these issues and declined participation.

DISCUSSION

A rapid, multisite approach was used to recruit rural FQHC clinics and participants for a telehealth behavioral coaching intervention. Despite challenges with HIPAA requirements and some sites' inexperience with research protocols, we found the approach was efficient and yielded samples comparable to other intervention studies based in rural or underserved communities.^{23, 34} The findings highlight several key factors for improving rural recruitment for research interventions.

Communicate Value at Multiple Levels

Our approach required involvement from clinic administrators, providers, staff, and patients. Thus, communicating the study's value at each of these levels was important for recruitment. For administrators, we highlighted the direct and indirect benefits of the intervention, including opportunities to provide a service to patients and to establish or re-establish relationships with a well-respected university healthcare system. These were valuable incentives for rural clinics that often have limited resources and minimal outreach beyond their community.

The potential value of the study was communicated to providers and staff through a site visit where the research team shared the goals and anticipated benefits of the project. Although providers supported the research, their involvement in recruitment was limited because of the time and resource constraints of rural practice. Staff involvement, however, was high because of our research design. Ongoing conversation between the research team and staff helped to reinforce their commitment to the study.

The findings also highlight the importance and challenges of communicating the value of research to rural participants, who may lack interest in and knowledge of research.^{1, 35, 36} Study participants noted they valued the opportunity to increase their knowledge and understanding of diabetes and self-care, but recruitment was hindered because the study team could not directly communicate the study's value. As Cudney et al² found in their 4 rural recruitment experiences, "most people do not understand health care or research language." Although clinic coordinators were recruited to serve as a liaison between the

study team and the community, several did not have enough knowledge about the specific research project, or research more generally, to communicate benefits or assuage fears of rural participants. In future studies, it will be important to increase interaction with providers and to provide clinic coordinators additional training and support to communicate project goals and benefits to participants. In addition, researchers need to increase the explicit value of research studies for participants. They must take into account the multiple challenges and priorities rural participants must balance, such as co-morbid health conditions of themselves or others, and demonstrate how the study can impact these areas of their lives.

Build Sustainable Relationships and Research Infrastructure

The challenges we encountered with inexperienced coordinators and HIPAA regulations underscore the importance of developing sustained, collaborative research partnerships with rural clinics similar to the Practice-Based Research Networks model. PBRNs, such as the Oregon Rural Practice-based Research Network (ORPRN), have fostered strong, long-term relationships with clinics and their communities.^{19, 37–41} Long-term relationships allow researchers to build rapport with providers, understand the needs within communities, and develop a community-centered research agenda that is feasible given clinics' staffing and technology resources. Solutions to technologic barriers may be addressed by granting access to resources at the disposal of the university, which will ultimately benefit clinic functioning, improve care, and develop "local research infrastructure."²

A well-documented barrier to conducting clinical research is the impact of HIPAA regulations.^{42–44} The HIPAA issues we encountered parallel challenges in other research studies.^{3, 45, 46} HIPAA regulations impact the ability to contact participants directly, the complexity of materials and forms, and the recruitment time and financial resources required.^{43, 44, 47} An established research infrastructure, with on-site coordinators and staff experienced with research and approved to handle HIPAA requirements, would have ameliorated some of these obstacles. PBRNs have addressed this issue by developing practices and toolkits aimed at reducing the barriers of complex consent in areas where literacy is a challenge. Toolkits provide staff training materials, communication strategies, and examples of successful streamlined HIPAA documents.⁴⁸ These resources may have helped eliminate some of the barriers we experienced in this area.

Developing long-term relationships with multiple sites is not always practical and can be challenging, especially when sites are remote. In our approach, we built upon established partnerships by reaching out to existing university relationship and also developed new partnerships. We found that a single recruitment strategy was not adequate because local culture and expectations varied. Taking account of cross-site differences, we developed a flexible research design that allowed site administrators and coordinators to provide input about improving recruitment while building rapport for future relationships.

Lower the Threshold for Participant Involvement

We eliminated as many barriers to participation as possible by offering the telehealth intervention in the participant's home and providing coaching sessions during evenings or weekends. However, participants were still required to attend an introductory session at the clinic. This was a critical barrier, especially for participants in migrant farming communities where transportation was difficult and in economically depressed communities where disability, unemployment and competing priorities made attendance burdensome. This was a distinct area where some of the previously identified challenges of rural residents such as lower income, lower education, and poorer overall health status, had an impact on recruitment success. Instead of on-site orientation, rural intervention studies could minimize barriers to participation by disseminating introductory information through other avenues,

such as group conference calls, orientation DVDs, or local cable broadcast, which would eliminate the need to travel outside the home. This is especially important in rural clinics that serve a wide geographic population. Small stipends, such as the \$40 gift card offered at the end of the study, may also lessen the burden of participation.

The rapid multisite approach is one strategy for time-efficient and successful rural recruitment. Identifying multiple strategies for recruiting and conducting research with rural communities can encourage researchers that have not established community relationships to engage in rural health research. This work is critical to understanding the factors that contribute to health and social disparities. Highlighting the value of intervention research, building partnerships and research infrastructure, and minimizing the inconvenience to participants will improve rural recruitment efforts and the quality of research.

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Figure 1.
Course of Participant Recruitment

Table 1**Categories of Recruitment Facilitators & Barriers**

<i>Study Design</i>	<ul style="list-style-type: none"> • HIPPA regulations • Complexity of study materials • Site payment • Prior relationship or reputation of the university
<i>Sites</i>	<ul style="list-style-type: none"> • Prior experience with research • History of diabetes education • Resources
<i>Site Coordinators</i>	<ul style="list-style-type: none"> • Knowledge about research studies • Contact with potential participants
<i>Participants</i>	<ul style="list-style-type: none"> • Interest in increasing knowledge of diabetes • Study logistics • Familiarity of and interest in clinical research