

LESSONS LEARNED FROM A VERY SMALL PILOT STUDY

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ABSTRACT

This report describes the lessons learned from a very small (three-family, nine-person) pilot study of the feasibility of in-home educational intervention for persons with diabetes in rural African American families. Lessons learned included the need to liberalize sample criteria, appreciation of the difficulties of scheduling visits with working rural families and maintaining standard intervals between visits, documentation of the learning needs of people with prior diabetes education, realizing that Caucasian nurses were accepted into African American homes and gaining insights into communication styles, finding that children were enthusiastic participants, and that even small studies produced some diffusion beyond the participants. The families all exhibited the self-reliance considered characteristic of rural families. Investigators without experience in rural nursing or research are urged to seek consultation and to pilot their study for feasibility and logistics.

INTRODUCTION

Researchers agree that few research endeavors are more useful than pilot studies—small scale studies that enable researchers to test ideas; evaluate and refine methods of recruitment, intervention, measurement, and analysis; assess participant and investigator burden and benefit; refine project timelines; and identify unanticipated problems or benefits, all with minimal expenditure compared to the final full-scale project (Fox & Ventura, 1983; Prescott & Soeken, 1989; Dallas, Norr, Dancy, Kavanaugh, & Cassata, 2005; van Teijlingen, Rennie, Hundley, & Graham, 2001; Perry, 2001; Jairath, Hogerney, & Parsons, 2000; Carfoot, Williamson, & Dickson, 2004; Hundley & van Teijlingen, 2002; Hinds & Gattuso, 1991; Richardson, Selby-Harrington, & Sorenson, 1993). What is less apparent from research reports of a single study is the progression of pilot studies from very small ones directed at the most basic question of “Is this idea at all feasible?” to test runs of a complete intervention based on several preliminary studies (Melnyk, 2003). The purpose of this report is to describe the lessons learned from a very small (three-family, nine-person) pilot study directed at the basic feasibility of an in-home educational intervention for persons with diabetes in rural African American families. Assessing feasibility for this idea involved not only the details of the intervention but working within the characteristics of rural environments and in a culturally competent way with African Americans.

Background

Type 2 diabetes is a major health problem for African Americans in whom the disease is approximately 1.6 times as common as in Caucasians. The prevalence and rate of complications are increasing and the age of onset is decreasing (Anderson-Loftin & Moneyham, 2000; Hughes, Love, Peabody, & Kardong-Edgren, 2001). The difficulties of self-management may be even greater for rural than for urban residents. Besides the usual demands of living with diabetes, rural dwellers disproportionately experience such barriers to care as a lack of providers; lack of education; poverty that limits the purchase of care, medication, and diabetes supplies; lack of transportation to providers of care and diabetes education; lack of insurance; and low literacy and health literacy. African Americans may hold cultural beliefs such as “sugar” is not serious, large bodies are attractive, disease is the will of God, and reliance on folk medicine that may hinder adherence to medical advice and diabetes control (Anderson-Loftin & Moneyham, 2000); Hughes et al. 2001; Schorling & Saunders, 2000; Keyserling et al. 2000). Distrust of research and healthcare professionals resulting from the well-publicized Tuskegee syphilis study may also negatively affect care seeking and use of self-management information (Jones, 1993).

The literature on diabetes education supports incorporation of the family and multiple generations to increase support for the person with diabetes and address primary prevention; human- and relationship-oriented rather than knowledge-focused education; assessment of social support, environment, socioeconomic status, gender roles, and values of the patient and family; and a focus on participation, demonstration, and empowerment rather than on mere “telling” (Norris, Engelgau, & Narayan, 2001; Agency for Healthcare Research and Quality, 2002; Fisher, et al., 1998; Hanson, et al., 1995; Bailey & Lherisson-Cedeno, 1997; & Celano & Kaslow, 2000). Research on diabetes education with African Americans is highly consistent with those recommendations. They desire professional assistance in linking their behavior with diabetic consequences, managing symptoms and practicing self-management skills, making healthy choices, discussion of the value of folk remedies, increasing family and community social support, and culturally sensitive education (Anderson-Loftin & Moneyham, 2000; Hughes et al. 2001; Schorling & Saunders, 2000; and Keyserling et al. 2000).

In a previous study the authors were the first to document that children aged 3 to 18 were active caregivers to adults with diabetes (Jacobson & Wood, 2004). We found no studies that actively included each member of an inter-generational family in the intervention or that included young children as potential caregivers of adults with diabetes or as participants in diabetes education for their own future welfare.

Home visits have been used successfully in many studies to educate parents about child development (Brooten et al.1986; Brooten, Youngblut, Deatrck, Naylor, & York, 2003; Kearney, M.H., York, R., & Deatrck, J., 2000; Kitzman et al. 1997) and to improve patients’ self-management of chronic disease, including asthma and diabetes (Butz et al. 2005; Catov, Marsh, Youk, & Huffman, 2005; Huang, Wu, Jeng, & Lin, 2004). Home visits offer the advantages of privacy, convenience, and participant comfort free from the distractions and pace of a more public environment.

Study Background

The study, approved by the university IRB as low-risk, high-benefit, tested the feasibility of an in-home educational intervention for persons with type 2 diabetes in rural African American families. The study was conceptually based in the idea that a chronic disease like diabetes is truly a family affair with both the persons with diabetes and the family benefiting from increased knowledge of diabetes self-management, the literature on the extended family common among many African Americans (Celano & Kaslow, 2000) and the strong African American cultural tradition of caregiving for relatives (Hughes, Love, Peabody, & Kardong-Edgren, 2001). A family was defined as an adult with type 2 diabetes age 21-55 (we wished to focus on the age group with young children in the home), an adult support person (spouse, partner, or significant other), and a child between the ages of 9 and 18. Previous diabetes education was not a study restriction, as we reasoned that the education received by most rural African Americans may very well have been brief, not understood, or a long time ago and that the realities of living with the disease would have evoked more specific questions about disease management. Children were included in the belief that their possible roles as caregivers and their proximity to an adult with diabetes comprised not only a benefit for the adult but a teachable moment for the child as well.

Building on 20 years of experience in diabetes education and research in clinical agencies, minority communities, and worksites, the investigators carefully planned the intervention to ensure that the volume of content was manageable for each visit and permitted time for interaction among the participants. The intervention consisted of seven home visits: one for screening, consent, and baseline assessment; four for teaching (daily self-care, nutrition and activity, medications, and prevention of complications); and two for immediate and delayed follow-up. The visits were planned to occur over seven to nine months. The teaching plans, based on social cognitive theory (Baranowski, Perry, & Parcel, 1997) included content for each member of the family triad, brief didactic information about the visit's focus, much use of pictorial materials and materials needing only low levels of literacy, assessments of the family's experiences with the topic, and demonstration and return demonstration of one or more skills such as reading food labels or performing foot inspections.

All diabetes content was based on the American Diabetes Association (ADA) Standards of Care (ADA, 2002). The chief outcome measure for the adult with diabetes was the hemoglobin A_{1c}. Measures for all study participants included diabetes knowledge, general health, body mass index, activity levels, family functioning, dietary intake, and program satisfaction. Standardized data collection tools were used whenever possible. Specifically, the Diabetes Knowledge Test (Villagomez, 1989), the Godin Physical Activity Questionnaire (Godin & Shephard, 1985), revisions of the Godin scale to measure occupational and household activity, 24-hour diet recall, 3-day food history, SF-12 (Ware, Kosinski, & Keller, 1996), and objective activity measures using pedometers were used in all data collection. Program satisfaction and family functioning in regard to disease management were measured using investigator-developed tools.

Questions and answers were exchanged throughout the sessions. Children were included in all aspects of the teaching sessions; however, age-appropriate handouts and

time-limited active participation by the children helped ensure that the children focused on the teaching content and were stimulated but not fatigued.

Visits were not tape-recorded as both investigators attended all visits and made detailed field notes jointly immediately after each visit. We noted recruitment and retention success, preparation and travel time, scheduling changes and missed appointments, questions asked, effective explanations, participant activity and affect, and questions to discuss as possible refinement. Participants were recruited through area diabetes educators.

Quantitative data analysis for this very small sample was minimal and done by hand. Pre- and post-knowledge of diabetes scores increased and performance of self-management skills improved for all. The intervention was highly rated, and all participants indicated they would recommend the intervention to friends.

The lessons learned were generated by three methods. We discussed each visit immediately afterward, reviewed our field notes, and examined the comments made on the study evaluations completed by the participants.

LESSONS LEARNED

Recruitment

Despite careful explanation to diabetes educator recruiters, all of whom we knew well, recruitment did not go smoothly or rapidly. The requirements for younger people with type 2 diabetes with children in the home and a willing, available adult support person ruled out the large share of many diabetes educators' case loads, who were older people. People were referred to us who did not meet the criteria. Eleven families were contacted for eligibility and interest in participation to obtain three eligible families. Five were qualified, five families consented, and three families completed the study.

The reasons for attrition of the two eligible families were varied. One young mother smilingly consented, completed the baseline data, and could never, despite many calls from us, identify a good time for a subsequent visit. According to the referring diabetes educator, she was highly resistant to acknowledging her diabetes. We believe that she consented only to please her mother and grandmother who were highly concerned about her. This provided a cultural insight into the power of African American mothers and grandmothers over their daughters and the ability of an unenthusiastic participant to avoid not only participation but angering her elders by using a socially plausible excuse. Another woman with diabetes was very interested in participating but her adult support person (her daughter) stayed for only a few minutes of the first two sessions and announced that she was moving and could not continue. We also realized, after several months of trying to recruit families with a non-diabetic adult support person, that this exclusion criterion was inappropriate given the high incidence of diabetes among spouses and family members in the African American culture. We relaxed this criterion and recruited one more family. The total time to acquire three eligible families who completed the study was nine months.

The Families

The three families recruited were very different. The first consisted of a middle-aged man with diabetes who worked as a schoolteacher and minister, a neighbor and parishioner

as the adult support person, and the man's 17-year-old daughter. The wife, also diabetic, attended but was not a subject. Both were college educated. They were extremely close and affectionate and regarded the adult support person as a member of the family. They accepted us into their home as though we were old friends, and we never sensed any barriers to communication or rapport.

The second family consisted of an adult female (grandmother) with diabetes, her adult daughter, and a ten-year-old grandson. This family had no telephone, intermittent electricity and gas, and no transportation. Income (and sometimes, food) came solely from the grandmother's part-time employment at a local fast food restaurant. The grandmother had never learned to read or write, and the grandson helped her with all written communication. The home was extremely dilapidated and in a dangerous neighborhood. This family posed the challenge of delivering education to an illiterate person, a person who would not "accept charity" from a local clinic where some help with medications was available, the concern of personal danger for us, and the "heartstring tug" of wanting to do more but realizing that our discomfort was not shared by the family as this was the way life was and, likely, always would be for them.

The third family consisted of an adult male with diabetes, his wife with diabetes as the adult support person, and their 13 year old daughter. The man was employed in a physically demanding job and rotated shifts—another challenge to diabetes self-management. The wife was employed full-time as a teacher's aide in a local school. They lived in a very rural area, and traveled 75 miles for health care. Although always very pleasant, they eventually admitted to us that they had started out "trying to put on a good front for you white professors" but had decided we really were good people.

The families who completed the study were not what we had expected to find in that two of them were solidly middle-class and had access to the Internet. Although we had intentionally not defined "family" as a husband, wife, and child because of the prevalence of single parents and fictive (honorary) kin in African American families, two of the three families fit a nuclear pattern. In two of the families, the person with diabetes was the adult male, and both female spouses, one who served as the adult support person and one who did not, also had diabetes. We included the spouse who was not the adult support person in all the teaching but did not collect outcome data from her.

Travel

The one-way distance to the homes of participants ranged from 5-150 miles. Like community health and home health nurses, we quickly learned the importance of obtaining good directions and that neither compass points (north, west, etc.) nor miles were used. Typical directions were "turn right by the big magnolia tree and go about 10 minutes." We learned to leave early for initial visits to allow time for getting lost and to call prior to embarking on the trips to ensure that the families were available as planned. Cellular phone communication was not always possible in many of the remote areas. The timing of visits for late afternoon or evening meant that we often drove back in the dark on unlit winding rural roads.

The Home Visits

All visits were held in the late afternoon and evening to accommodate the school and work schedules of participants. To facilitate the intervention and for safety reasons, both investigators traveled to all visits. Coordinating travel times was especially challenging considering the teaching schedules of both investigators and the work, recreational, and church schedules of the families. The family that was closest geographically was the most difficult to contact because of the need to make arrangements through the adult support person and accounted for the only missed appointments we experienced.

Seven visits lasting 2-2 ½ hours were planned. We encountered no initial objection to the length of the visits, as participants were grateful for the help and their questions accounted for one hour of each visit. In keeping with Southern views about politeness and African American views about caring and respect, each visit began with social pleasantries and inquiries about the family reunion or the daughter's basketball game. We then reviewed the "homework" or application of learning from the previous visit, presented about 15 minutes worth of information about the visit's main topic, practiced skills such as glucose testing and foot care, and contracted with participants about activities before the next meeting. All three families indicated they enjoyed the learning meetings, but by the conclusion of the study, the investigators recognized that the families were tiring of the visits and the difficulties in scheduling.

Maintaining an environment conducive to learning was sometimes difficult. Ringing telephones, visitors who walked in and stayed for parts of the sessions, other children and pets running around, dinner time conflicts, and televisions were distractions.

Diabetes Knowledge

Although all three adults with diabetes had participated in diabetes education from one to ten hours within the past year, none of them truly understood the mechanisms of diabetes development, medications, the daily tasks required for self-management such as foot care, and implications for development of related chronic health problems such as heart disease. As we had anticipated, they were either unable to remember what they had been told, had not understood it when they were taught, or had many more questions to ask as a result of the passage of time. Reading food labels proved to be a revelation for all participants (except for the woman who could not read). One teenage girl revealed that she had been eating a can of Lite Spam® every noon, believing it to be low fat and one serving. The link between diabetes and heart disease was also new and of concern to the participants.

Activity is a critical component of diabetes self-management as well as a strategy to delay or prevent the development of diabetes. Each participant wore a pedometer for several days during the study. The teenage girls found the pedometers to be "cool" and liked wearing them at school. All participants were surprised at the limited steps they walked per day and eagerly discussed strategies for incorporating more activity into a typical day. Given the rural environments and family economic circumstances, gyms and exercise facilities were unavailable or unaffordable.

Blood sugar testing was problematic for all of the adults with diabetes. They didn't like to "stick" themselves, were unsure of the desired frequency of testing, and wanted to

know the minimum number and timing of testing to allow adequate control. The woman with limited resources certainly could not afford test strips. Although we provided a meter and 50 strips, we realized that all she had learned about testing would not be practiced once the strips ran out. Buying food and paying the rent and electric bill took priority over self-care.

The Children

Although the inclusion of children in the family intervention was the chief innovation of this study idea, it also provided us with the most initial concerns for feasibility. Would children participate? Would their attention wander? Would they be willing to practice the skills of glucose testing and footchecks? Would their adult relatives with diabetes welcome their assistance? To our delight, the children (aged 9, 13, and 17) were enthusiastic active participants. They stayed for each session, asked good questions, shared learning about health from school, did their between-sessions homework, and learned the skills, with only a minimum of tickling their relatives' feet for fun during footchecks. The youngest child, the grandchild of the illiterate participant, told us, "I am so happy that I have learned all this. Now I could save my gran's life because I know about too much and too little sugar and I can test her." The parents told us that it was comforting to know their children understood their problems and had learned how to help them and that they would encourage the children to eat healthier and be more active.

The Investigators

Organization and flexibility when working with families were of paramount importance. A day planned around a scheduled visit that was cancelled just prior to leaving town was one of the frustrations encountered several times. Because the visits were in the late afternoon or evening, the investigators frequently worked all day, then left near the end of the work day to begin the trip for a family visit and returned near midnight. Although the visits were always inspiring to the researchers, the demanding logistics of visiting rural families became apparent very early and raised the issue of whether we could hire interveners willing to work such erratic schedules and travel the rural areas at odd hours for a future trial.

We were genuinely amazed to see the volumes of data collected from only the three families and how challenging managing the data was. In retrospect project management software or at least a spreadsheet should have been used from the beginning, even for this 9-participant study.

Monitoring Unexpected Outcomes

A very positive outcome of the feasibility study was the evidence of diffusion of the intervention beyond the participants. The adult support person for the minister with diabetes was also the church "kitchen lady." She wanted to alter the menus for church meals to improve the health of the minister and the congregation and started preparing a heart- or diabetes-friendly main dish and dessert each Sunday. The minister's spouse was alarmed at

how few steps she walked in a day and formed a group at work who walked around the parking lot for 15 minutes at lunchtime each day. When we learned that she had never tested her own blood sugar because of fear about piercing her skin, we contracted with her to do it herself. After several weeks of not accomplishing the goal, she finally tested herself and was delighted with her improved self-sufficiency. The teenage daughter of the heavy equipment operator with diabetes reported that her friends at school were intrigued with her pedometer, bought their own, and resolved to walk more. Her diabetic mother, a teacher's aide with responsibility for visiting classrooms with the snack cart every morning, decided to support the principal's proposal for replacing chips and soda with fruit, baked chips, juice, and water. We also learned that the people who quietly drifted in and out during home visits were friends or relatives with diabetes who had been invited to hear "the talk" on food or medications.

DISCUSSION

Despite the small sample size this very small pilot study was helpful to us in planning future work. On the positive side we learned that a family is an appropriate unit for diabetes education, that people with prior diabetes education still had major learning needs, that children were enthusiastic participants, and that Caucasian nurses were welcomed into African American homes. The sample criteria need to allow a spouse with diabetes to be the adult support person to obtain adequate numbers of families with young children. We realized that having two investigators make each visit facilitated simultaneous activities for the participants and that the different personalities and communication styles of the investigators were complementary. Very importantly, even this small study produced some diffusion of results beyond the participants. Negative—or at least thought-provoking—insights included the logistics of visiting scattered rural families, maintaining suitable control over the spacing and duration of visits for a larger study, determining an optimal number of visits, and resisting the urge to try to teach everything instead of what is most necessary.

An important process in our study was observation of family dynamics. Although our families appeared to have excellent relationships, investigators in a family intervention must exercise caution not to become a part of negative family communications and actions. We were also struck by the family pride and spirit of self-reliance that all families exhibited and that is considered characteristic of rural families (Dunkin, 2000).

We approached families with the idea and the statement that "we do not know as much about cultural differences in ideas about disease and disease management as we would like to know". We were encouraged to find that participants would spontaneously make remarks like, "I'd understand that better if you said thus and so" or assured us when we asked if our communication was clear and respectful.

Implications

This very small pilot functioned as intended to "guide the development of the research plan rather than being a test of the already-developed plan" (Prescott & Soeken, 1989, p. 60). We encourage other investigators to conduct feasibility studies. Those without

experience in rural areas should definitely obtain consultation about the characteristics of rural people and locales in general and the target population in particular.

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