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Community to clinic navigation to improve diabetes outcomes

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ABSTRACT

Rural residents experience rates of Type 2 Diabetes Mellitus (T2DM) that are considerably higher than their urban or suburban counterparts. Two primary modifiable factors, self-management and formal clinical management, have potential to greatly improve diabetes outcomes. "Community to Clinic Navigation to Improve Diabetes Outcomes," is the first known randomized clinical trial pilot study to test a hybrid model of diabetes self-management education plus clinical navigation among rural residents with T2DM. Forty-one adults with T2DM were recruited from two federally qualified health centers in rural Appalachia from November 2014–January 2015. Community health workers provided navigation, including helping participants understand and implement a diabetes self-management program through six group sessions and, if needed, providing assistance in obtaining clinic visits (contacting providers' offices for appointments, making reminder calls, and facilitating transportation and dependent care). Pre and post-test data were collected on T2DM self-management, physical measures, demographics, psychosocial factors, and feasibility (cost, retention, and satisfaction). Although lacking statistical significance, some outcomes indicate trends in positive directions, including diet, foot care, glucose monitoring, and physical health, including decreased HbA1c and triglyceride levels. Process evaluations revealed high levels of satisfaction and feasibility. Due to the limited intervention dose, modest program expenditures (~$29,950), and a severely affected population most of whom had never received diabetes education, outcomes were not as robust as anticipated. Given high rates of satisfaction and retention, this culturally appropriate small group intervention holds promise for hard to reach rural populations. Modifications should include expanded recruitment venues, sample size, intervention dosage and longer term assessment.

1. Introduction

1.1. Diabetes risk in Appalachia

The prevalence of Type 2 Diabetes Mellitus (T2DM) in Kentucky overall has tripled since 2005 (Cabinet for Health and Family Services, 2013), likely a significant underestimation since approximately 27% of those with T2DM are undiagnosed (Hacker, 2008). Appalachian Kentuckians' diabetes prevalence is 11.8%, compared with 9.8% and 8.9% for the state and nation, respectively (Cabinet for Health and Family Services, 2013; Hacker, 2008). Compared to their suburban and urban counterparts, rural residents also are at elevated risk for poor glycemic control and diabetic complications (Arcury et al., 2003).

As shown in Table 1, health and demographic factors, including poor health literacy (Tessaro et al., 2006), low socioeconomic status, and high rates of obesity, contribute to elevated T2DM prevalence in Appalachia. Health care provider (HCP) shortages are pervasive in Appalachian Kentucky, with over 80% of the 54 counties in Appalachian Kentucky considered HCP shortage areas (US Department of Health and Human Services, 2014).

1.2. Diabetes self-management and clinical management: the two essential components of glycemic control

Diabetes self-management, or self-care activities undertaken in informal settings, constitutes one key determinant of T2DM control (Powers et al., 2015; Schwaderer and Itano, 2007). Clinical management, which the American Diabetes Association (ADA) operationalizes as attending medical appointments every three months, is the second essential component of T2DM control (American Diabetes Association, 2016). Suboptimal clinic attendance is associated with elevated blood sugar, blood pressure and lipids (Parker et al., 2012). For every 10% increase in missed appointments, optimal diabetes control decreases 1.12 times ($p < 0.001$) while poor control increases 1.24 times ($p < 0.001$) (Schectman et al., 2008). National rates of suboptimal clinic attendance vary from 10 to 25% (Torres et al., 2015); our research suggests >30% of Appalachian residents with diabetes regularly miss appointments. Numerous factors account for substandard adherence to

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Table 1
Characteristics of study, county, state and US ref..

	Appalachian County, Kentucky	Kentucky	US
Poverty rate	25%	19%	15%
Per capita income	$17,886	$23,462	$28,155
Premature death	12,028	8769	5317
Fair or poor health	32%	21%	10%
Adult obesity	43%	31%	22%
Physical inactivity	37%	31%	21%
Primary care physician: population	1:1638	1:1588	1:1067
Diagnosed Type 2 Diabetes Mellitus (T2DM)	13.5%	9.8%	8.9%

self-management and clinic appointments, including lack of self-management knowledge, forgotten appointments, inadequate transportation, and competing time demands (Bardach et al., 2011; Schoenberg et al., 2009, 2013; Schoenberg and Drungle, 2001).

Coordinating and enhancing T2DM self-management and clinical management through community to clinic navigation, has great potential to improve health outcomes. HCP and others have widely implemented the Diabetes Self-Management Program (DSMP) to improve self-management education (Lorig et al., 2009). As shown in Table 2, DSMP is a 6-week group program conducted by trained community health workers (CHWs) and consists of diabetes education, self-management, action planning and problem solving, symptom management, and working with family and HCP. The DSMP has been demonstrated to significantly reduce depression, increase communication with physicians, promote healthy eating, and decrease hypoglycemia at 6 and 12 months (Erdem and Korda, 2014; Lorig et al., 2009), but has shown less conclusive evidence on improving clinic attendance (Helduser et al., 2013). Clinical navigation, on the other hand, has been shown to facilitate appointment setting and return visits, improve goal setting, and enhance some self-management (medication taking, blood glucose testing) (Hargraves et al., 2012), but does not improve key psychosocial or other self-management activities (Freund et al., 2008).

The Community to Clinic Navigation (CCN) project addressed limitations in existing research and programs; specifically, few interventions have combined self-management and clinical navigation, most intervention content has not been tailored to cultural and geographic factors, and most interventions have not employed experimental designs (Drozek et al., 2014; de Groot et al., 2012). Additionally, navigation has been implemented almost exclusively in the cancer setting despite showing potential for chronic disease management (Ferrante et al., 2010). We sought to determine the CCN pilot study's promise for improving T2DM outcomes (primary outcomes: diabetes self-management and physical measures) and demonstrating feasibility (primary outcomes: cost, retention and satisfaction) in this rural population.

Table 2
Diabetes self-management program.

Week #	Topic covered
1	Overview on T2DM, including self-management; goal setting; how T2DM affects the body, signs and symptoms, diagnosis, types, incidence, and prevalence
2	Avoiding T2DM complications through medication taking & blood glucose monitoring
3	Improving T2DM outcomes through healthier eating
4	Managing stress and increasing physical activity
5	Avoiding complications: feet, teeth, eyes, sick days, kidneys, blood pressure
6	Wrap up and review

2. Methods and materials

2.1. Recruitment and human subjects protection

Participants were recruited from two federally qualified health clinics (FQHC) in rural Appalachian Kentucky from November 2014–January 2015. Participants met the following eligibility criteria, as indicated through electronic medical records (EMR): age 21 +, Appalachian residence, no major cognitive impairment, and HbA1c levels of 6.5% or higher. Clinic staff, all of whom had received human subject training and certification, reviewed medical records and identified 60 individuals meeting these criteria. Staff then sent potential participants a letter from the clinic physician describing the project, and followed up with a telephone call to determine their interest in participating. Of those 60 patients who were sent a letter, 48 (80%) initially agreed to participate. Upon further screening and contact, four patients were unable to participate and three dropped out of the project prior to baseline assessment. No significant differences were observed between these seven individuals and the 41 individuals who completed the protocols. Participants' demographic and health profiles were similar to the general population of Appalachian adults (Barker et al., 2010). Local interviewers administered human subject's protection protocols, answered questions, and undertook in person assessments. The protocol was approved by the University Institutional Review Board (#14-0314-P6H).

2.2. Measures

The survey, pilot tested by local interviewers to ensure semantic appropriateness, captured data on demographics, spirituality/religiosity, diabetes self-management; health-related quality of life, diabetes empowerment, and patient activation. Primary outcomes included: (1) changes in HbA1c, blood pressure, lipids, and BMI and (2) changes in self-management activities (blood glucose monitoring, diet, physical activity, foot care, medication taking, and medical appointment adherence). Secondary outcomes included changes in relevant psychosocial factors (self-efficacy and patient activation). Spirituality/religiosity data were collected to determine the viability of locating future CCN projects in faith communities and the salience of spiritual messaging, approaches popular in our previous interventions.

EMR data including HbA1c levels, blood pressure, lipids, and BMI were collected by clinic staff on project-provided tablets. Interviewers verbally administered a survey containing the following instruments: (1) the Diabetes Self Care questionnaire to assess self-reported adherence to diabetes self-management, diet, exercise, blood glucose monitoring, and foot care (Toobert et al., 2000); (2) the Medical Outcomes Short-Form Health Survey (SF-12) to evaluate physical and mental health (Ware et al., 1995, 1996); (3) the Short Form Diabetes Empowerment Scale to measure psychosocial adjustment to diabetes (Anderson et al., 2003); and (4) the 13-item Patient Activation Measure to assess patient self-reported knowledge, skills and confidence in managing one's chronic health condition (Hibbard et al., 2005). Finally, during the posttest interview, all intervention participants were asked a series of structured and semi-structured questions to assess the intervention satisfaction and feasibility (Bowen et al., 2009), and obtain recommendations for improvement.

2.3. Study design and protocol

For this randomized clinical trial pilot study, participants met with the interviewer at their home, the project office, or another community location, depending on the participant's preferences. Within a week of this initial meeting, our project biostatistician randomly assigned participants to the intervention or control arm. That same week, all participants engaged in a 60–90-minute-long baseline interview and clinic staff uploaded EMR data on physical measures (HbA1c lipids, blood pressure, and BMI), via secure data capture software. Approximately