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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 three months after completion of intervention protocols (duration approximately three months), all participants were administered a posttest and, for intervention participants, process evaluations. This sequence allowed sufficient time to pass for participants to obtain a medical appointment, to correspond with Medicare's coverage of HbA1c, and for possible changes to occur in physical outcomes (Centers for Medicare and Medicaid Services, 2016). Fig. 1 highlights the timing of the data collection and intervention protocols. Participants were paid $25 for each assessment, a standard honorarium rate in this region.

2.4. Theoretical basis

The Chronic Care Model provides theoretical grounding, proposing that improved health outcomes are mediated through informed, prepared patients who interact with a proactive health care provider team (Bodenheimer et al., 2002; Hung et al., 2007). Trained Community Health Workers (CHWs) conducted the group self-management education program (Diabetes Self-management Program) which addresses the model's community domain *plus* served as the Patient Navigators to facilitate access to the clinical environment, addressing the model's health system domain. Clinical Navigator CHWs assisted with appointment setting, reminders, transportation, dependent care, etc. (Albright et al., 2009; Stellefson et al., 2013).

2.5. Intervention

Half of the 41 adults with T2DM were randomized to the control group and maintained their standard of care (no CHW), while the half in the CCN intervention group received the DSMP plus Clinical Navigation. The six in-person, group-based self-management educational sessions took place every other or every third week; participants met in the field office. Table 2 highlights the units for the 6 session program.

Materials were modified to ensure that they were culturally appropriate and accessible to those with a fifth grade reading level. Participants in the CCN intervention group also received coordinated clinical navigation for clinical care, if needed. Need was determined by a review of medical records; if the participant did not follow up on his or her scheduled medical appointments (every three months) more than twice in two years, then clinical navigation was provided (Studts et al., 2012). If determined to be in need of navigation (8/23 intervention participants), the CHW called the participant to determine whether he or she was planning on attending the medical appointment. If the participant was not planning to attend the medical visit, the CHW assisted in rescheduling, arranging transportation, finding dependent care options and motivating on follow through. The day before the appointment, the CHW called to check on the patient to make sure that she or he planned to make the clinic visit and offered assistance.

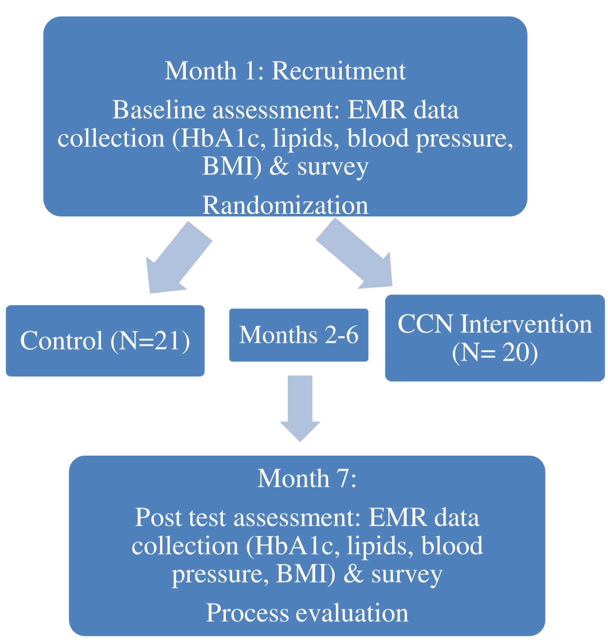

Fig. 1. Study flow diagram, Appalachian Kentucky, USA, 2014–2015.

2.6. Analysis

Summaries of sample characteristics and the main study variables at baseline are provided in Tables 2 and 3, and stratified by the intervention arm. Results of descriptive analyses are also discussed in text. Intent-to-treat (ITT) analyses were conducted using analysis of covariance (ANCOVA) with adjustment for baseline scores in order to compare changes in the mean scores of the main study variables within each intervention-arm between baseline and posttest. We chose this approach, in consultation with the project biostatistician, to increase statistical power and to account for baseline differences in the scores of the intervention and control groups. Only adjusted means are presented in the table with 95% CIs. An alpha of 0.05 was used for this study. All the analyses were carried out using Stata 13.

3. Results

3.1. Socio-demographic characteristics

As highlighted in Table 3, the mean age of the sample was 58.2 years, two thirds were women, and the majority (55%) was married. Reflecting the demographics of Appalachian Kentucky, the sample was racially homogeneous (100% non-Hispanic White) and most (63%) had completed high school or had a General Educational Development credential (GED). About a fifth either had less than a high school education or had graduated from college/earned an advanced degree. More than half (59%) indicated an annual household income between $10,000 and $19,000, and a quarter had an annual household income between $20,000 and $29,000. Most (87%) participants reported being unemployed and almost two thirds indicated that they struggle to make ends meet. Most (92%) participants had health insurance, including private or company sponsored insurance, Medicaid, or Medicare. With the sample means of about 40 (SD = 7.33) and 34 (5.98) for the aggregate physical and mental health score (SF-12), respectively, the self-reported health status in this sample was much lower than the national average of 50.

3.2. Diabetes management, psychosocial and primary outcomes variables at baseline

At baseline, participants showed a suboptimal diabetes self-management profile (Table 4). On average, participants received adequate exercise or consumed a healthy diet for 3.48 (SD = 2.26) and 3.68 (SD = 1.32) days, respectively, of the past seven days. Participants engaged in blood glucose monitoring for 4.66 (SD = 2.55) days out of seven, on average. Foot care was the best managed domain of diabetes self-management, with participants checking their feet an average of 5.32 (SD = 2.10) days per week.

Participants also had suboptimal psychosocial scores; the mean raw Patient Activation Measure (PAM) score was 38.17 (SD = 5.01) out of a possible range from 13 to 52. This score places research participants in the second stage of patient activation, suggesting a lack of knowledge about the condition and minimal success with behavior change (Hibbard et al., 2005). Overall, participants lacked strong diabetes empowerment; most tentatively endorsed their ability to take care of their diabetes, turn their diabetes goals into a plan,

Table 3
Sample characteristics at baseline, Appalachian Kentucky, 2014–2015 ($N = 41$).

Variables	Full sample ($N = 41$)	Intervention group ($N = 20$)	Control group ($N = 21$)
Mean age, standard deviation (SD)	58.24 (10.77)	58.55 (10.39)	57.95 (11.36)
Sex			
Male	34.15%	20.00%	47.62%
Female	65.85%	80.00%	52.38%
Race/Ethnicity			
Non-Hispanic white	100%	100%	100%
Marital status			
Married/partnered	55.00%	42.11%	66.67%
Divorced/separated/widowed	40.00%	47.37%	33.33%
Never married	5.00%	10.53%	0.00%
Mean number of people in household	2.08 (1.23)	1.84 (0.90)	2.28 (2.29)
Highest grade of school completed			
Less than high school	19.51%	10.00%	28.57%
High school/General Educational Development (GED) credential	63.41%	60.00%	66.67%
College or higher	17.07%	30.00%	4.76%
Annual household income			
$10,000 or less	7.69%	10.53%	5.00%
$10,000–$19,999	58.97%	63.16%	55.00%
$20,000–$29,999	25.64%	26.32%	25.00%
$30,000–$39,999	5.13%	0.00%	10.00%
$40,000 or higher	2.56%	0.00%	5.00%
Subjective financial status			
Struggle to make ends meet	68.29%	70.00%	66.67%
Just about enough to get by	31.71%	30.00%	33.33%
More than I need	0.00%	0.00%	0.00%
Insurance status			
Uninsured	7.32%	10.00%	4.76%
Insured			
Private insurance	7.32%	10.00%	4.76%
Company sponsored insurance	4.88%	5.00%	0.00%
Medicare	36.41%	35.00%	38.10%
Medicaid	24.39%	30.00%	19.05%
Other	48.78%	45.00%	52.38%
Respondents currently work			
No	87.18%	78.95%	95.00%
Yes	12.82%	21.05%	5.00%
Attendance of church or other religious services			
More than once a week	26.83%	40.00%*	14.29%
Once a week	29.27%	35.00%	23.81%
A few times a month	9.76%	0.00%	19.05%
A few times a year	4.88%	10.00%	0.00%
Once a year or less	4.88%	5.00%	4.76%
Never	24.39%	10.00%	38.10%
Time spent in private religious activities, such as prayer, meditation or bible study			
More than once a day	28.21%	45.00%*	10.53%
Daily	43.59%	50.00%	36.84%
Two or more times a week	7.69%	5.00%	10.53%
Once a week	0.00%	0.00%	0.00%
A few times a month	7.69%	0.00%	15.79%
Rarely or never	12.82%	0.00%	26.32%
Aggregate physical health component score (SF-12)	39.56 (7.33)	39.45 (7.23)	39.67 (7.61)
Aggregate mental health component score (SF-12)	33.70 (5.98)	33.17 (5.65)	34.21 (6.37)

* $p < 0.05$.

know how to cope with diabetes, ask for support, etc. The overall diabetes empowerment score was 3.96 (SD = 0.39) on a scale ranging between 0 and 5, indicating an average extent of empowerment.

The mean BMI of 35.73 (SD = 6.66) was well within the range for obesity, and approximately 30% of the participants had a BMI over 35. Mean systolic and diastolic blood pressure was 138.32 (SD = 19.92) and 75.49 (SD = 8.93), respectively, with 31% having high blood pressure (>140/90 mmHg). The mean lipid profile (HDL cholesterol, LDL cholesterol, and triglycerides) also fell above the optimal range. Nearly half (43%) of the participants had LDL cholesterol >130 mg/dL. The mean HbA1c was 8.96%, with 54% of participants having HbA1c levels >8.0%, considerably higher than the 7.0% recommended by the ADA (American Diabetes Association, 2016; American Diabetes Association, 2015).

3.3. Diabetes management, psychosocial and primary outcome study variables at posttest interview

Table 5 displays the results of the analyses examining the effects of the intervention within each intervention arm, adjusting for the baseline levels of the parameters of interest. While some positive trends in diabetes self-management activities, such as diet, foot checking, and blood glucose monitoring, were observed in the anticipated and positive direction, they approached but did not reach statistical significance. Both groups showed a positive increase in patient empowerment, but a negative change in self-efficacy (although neither group experienced a statistically significant change).

Regarding the main diabetes health outcomes, both the intervention and control groups showed an increase in mean BMI between baseline and post-test but the change was not statistically significant for either

Table 4
Primary study variables at baseline, Appalachian Kentucky, 2014–2015 ($N = 41$).

	Full sample ($N = 41$)	Intervention group ($N = 20$)	Control group ($N = 21$)
Mean diabetes self-management score by domain			
Diet	3.68 (1.32)	4.00 (1.50)	3.36 (1.07)
Exercise	3.48 (2.26)	3.48 (2.26)	3.02 (2.30)
Blood glucose monitoring	4.66 (2.55)	5.18 (2.05)	4.17 (2.92)
Foot care	5.32 (2.10)	5.70 (1.76)	4.95 (2.36)
Raw patient activation measure (PAM) score	38.17 (5.01)	39.35 (2.35)	37.05 (6.51)
Diabetes empowerment scale mean score	3.96 (0.39)	4.10 (0.30)	3.81 (0.43)*
Body mass index (BMI) (kg/m^2)	35.73 (6.66)	37.39 (8.55)	34.15 (3.73)
Hemoglobin A1c (HbA1c) (%)	8.96 (2.01)	8.98 (2.40)	8.94 (1.62)
Triglycerides (mg/dL)	318.87 (339.83)	330.47 (371.69)	309.48 (320.80)
Blood pressure (BP):			
Systolic BP (mmHg)	138.32 (19.92)	142.05 (24.47)	134.76 (14.06)
Diastolic BP (mmHg)	75.49 (8.93)	75.55 (10.73)	75.43 (7.06)
HDL cholesterol (mg/dL)	54.21 (34.37)	54.28 (35.28)	54.13 (33.64)
LDL cholesterol (mg/dL)	133.68 (50.77)	121.17 (52.87)	147.76 (45.86)
Total cholesterol (mg/dL)	227 (117.59)	265 (111.72)	211.8 (128.88)

* $p < 0.05$.

group. The decrease in the HbA1c levels, systolic and diastolic blood pressure as well as mean HDL and LDL cholesterol and triglycerides, did not differ statistically significantly between the two groups. Combined, while none of these findings was significant at the 0.05 level, the study results suggest that the community to clinic navigation intervention produced some positive trends in some diabetes health and self-management outcomes.

3.4. Feasibility

Feasibility (including cost, retention, and satisfaction) was high (Bowen et al., 2009). Project costs, including staff, transportation, facilities, and materials but excluding research components, were approximately $29,950 ($730 per person). Nearly all (94%) intervention arm participants completed every session. In-depth interviews documented a high level of satisfaction, with all but three participants indicating that they were extremely satisfied with the program and those three noted that they were "very satisfied;" all but one of the participants responded that they would recommend participating in the CCN project to a friend; and every participant indicated that the program had been either very helpful or helpful to their diabetes self-management.

Participants ranked the following three programmatic features as the most beneficial: (1) having a local and knowledgeable community health worker lead the sessions; (2) conducting the sessions in a group format; and (3) keeping a log of self-management goals and outcomes. Participants suggested enhancing the intensity as well as the duration (four additional sessions); checking back in with the group every three months; including "booster shot" activities—for example, forming friendly competitions with walking groups; and including faith messaging.

4. Discussion and conclusion

Diabetes self-management has long been considered a cornerstone of T2DM prevention, control and treatment; nowhere is improved self-management more essential than highly burdened health disparities communities with health care professional shortages and reliant on their own care (Peek et al., 2007; Spencer et al., 2011). The CCN project is among the first to test a hybrid model whereby community health workers help participants learn diabetes self-management by leading a group education program and by providing clinical navigation to obtain health clinic visits. The CCN project's feasibility, including modest cost and successful enrollment, retention, and satisfaction, suggests potential for future programmatic success: CHW programs, particularly programs operating in high need environments and implementing evidence-based programming in an acceptable and culturally consonant matter, have demonstrated strong return on investment, integration into existing systems, and expansion into new venues and populations (Bowen et al., 2009; Rosenthal et al., 2010).

Despite this promise, we faced notable challenges in implementing this CCN intervention that likely undermined outcomes. First, participants demonstrated a very limited awareness of even the most basic

Table 5
Mean change in diabetes outcome measures within intervention arms between baseline and post-test, Appalachian Kentucky, 2014–2015, $N = 41$.

Variables	Intervention mean (CI) $N = 20$	Control mean (CI) $N = 21$	*P*-value
Diabetes self-management			
Diet	0.75 (0.28, 1.22)	0.24 (−0.19, 0.67)	0.12
Physical activity	−0.18 (−0.99, 0.62)	−0.02 (−0.77, 0.73)	0.77
Blood glucose monitoring	0.12 (−0.92, 1.16)	0.01 (−0.96, 0.97)	0.87
Foot care	0.84 (0.20, 1.48)	1.23 (0.63, 1.82)	0.38
Diabetes empowerment score	0.04 (−0.08, 0.15)	0.03 (−0.07, 0.14)	0.96
Patient activation measure	−0.97 (−1.96, 0.02)	−1.04 (−1.98, −0.10)	0.92
Aggregate physical health	1.56 (−1.79, 4.91)	−0.06 (−3.09, 2.98)	0.47
Aggregate mental health	−1.80 (−4.51, 0.92)	−0.37 (−2.82, 2.08)	0.44
BMI (kg/m^2)	0.11 (−2.15, 2.37)	0.54 (−1.55, 2.64)	0.78
HbA1c (%)	−0.88 (−1.55, −0.20)	−0.32 (−0.94, 0.31)	0.22
Triglycerides (mg/dL)	−118.3 (−175.9, −60.78)	−53.95 (−103.0, −4.89)	0.09
Systolic BP (mmHg)	−3.26 (−8.87, 2.36)	−5.82 (−11.04, −0.61)	0.50
Diastolic BP (mmHg)	−1.59 (−5.46, 2.28)	−4.99 (−8.58, −1.39)	0.20
HDL cholesterol (mg/dL)	−5.97 (−12.81, 0.88)	−9.39 (−16.23, −2.54)	0.48
LDL cholesterol (mg/dL)	−10.99 (−32.18, 10.19)	−30.13 (−51.32, −8.95)	0.21

Note: All analyses were adjusted for baseline value of each outcome of interest.

T2DM management, requiring CHWs to present rudimentary information about self-management, including simplifying language, limiting written handouts, and employing time consuming "teach back" approaches (Koh et al., 2013). Most participants indicated they had never had a diabetes self-management education class; we suspect that our intervention could not completely overcome the substantial attention needed to improve outcomes. CHWs also had to balance program rigor and fidelity with practical complexities, including inadequate transportation, poor weather, and increasing stress and dependence on these middle aged adults because of an addiction epidemic (Appalachian Regional Commission, 2014; Schoenberg et al., 2012).

Data analyses revealed some surprising findings. Specifically, some positive changes were observed for diabetes self-management in the control group, even though they did not receive any guidance or education training associated with the intervention. Additionally, changes in some measures – patient activation and aggregate mental health score – occurred in the opposite direction from what we had expected. Some of the positive changes in the control group may be attributed to social desirability or a Hawthorne effect. It is possible that mere participation in the surveys – lasting 60–90 min – might have prompted some participants to better manage their condition. To address this possible contamination, we propose increasing sample size, expanding the time between baseline and posttest interview, and, consistent with intervention participant recommendation, increasing the dosage of the intervention itself.

In the opposite direction, the minor decreases in the aggregate mental health component score and patient activation measure could result from intervention participants' realization that they are actually not practicing such optimal self-management. That is, prior to the intervention, some participants may have considered their diabetes self-management as optimal, but over the six weeks of workshops, they may have come to realize the necessity of significant lifestyle changes, which is both daunting and depressing. Nevertheless, such increased awareness may constitute a positive step to improve T2DM management.

4.1. Limitations and future directions

This study has several limitations, including a modest sample size, limited geographical reach, multiple statistical comparisons, increasing the probability of Type 1 error, a limited dosage, and a relatively short posttest follow up period. As recommended by our project biostatistician, our future randomized clinical trial will involve 1200 participants. Although the CCN project has very low cost, we are unable to offer comparison with the standard of care since we cannot estimate standard costs. Another limitation involves the recruitment venues (FQHCs), which likely reduced the need for clinical navigation, since participants already had a regular source of care that they visited on an ongoing basis—at least regularly enough to be recruited for our pilot study. In the future, we will expand to non-clinical locations, including community centers and faith institutions to expand sample size and to enroll participants who may be in heightened need of clinical navigation. Additionally, although the project used an evidence-based intervention, participants indicated that it was too brief. Existing studies on challenging to change behaviors suggest that longer programs may have more positive effects (Nigg and Long, 2012). Finally, to decrease the possibility of contamination and to assess the long term potential for the CCN intervention, we plan to add an additional follow up assessment. Despite these limitations, this research provides extensive guidance on next steps, including increasing sample size, expanding recruitment venues, increasing intervention dosage, and, ultimately, disseminating to other underserved populations.

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