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Rationale and development of a randomized pragmatic trial to improve diabetes outcomes in patient-centered medical homes serving rural patients

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Abstract

Proper diabetes self-care requires patients to have considerable knowledge, a range of skills, and to sustain multiple health behaviors. Self-management interventions are needed that can be readily implemented and sustained in rural clinics with limited resources that disproportionately care for patients with limited literacy. Researchers on our team developed an evidence-based, patient-centered, low literacy intervention promoting diabetes self-care that includes: 1) the American College of Physicians (ACP) Diabetes Guide that uses plain language and descriptive photographs to teach core diabetes concepts and empower patients to initiate behavior change; 2) a brief counseling strategy to assist patients in developing short-term, explicit and attainable goals for behavior change ('action plans'); and 3) a training module for health coaches that prepares them to assume educator/counselor roles with the Diabetes Guide as a teaching tool. While the intervention has previously been field tested and found to significantly improve patient knowledge, self-efficacy, and engagement in related health behaviors, its optimal implementation is not known. This project took advantage of a unique opportunity to modify and disseminate the ACP health literacy intervention among patients with type 2 diabetes cared for at rural clinics in Arkansas that are Patient-Centered Medical Homes (PCMH). These practices all had health coaches that could be leveraged to provide chronic disease self-management mostly via phone, but

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also at the point-of-care. Hence we conducted a patient-randomized, pragmatic clinical trial in 6 rural PCMHs in Arkansas, targeting individuals with uncontrolled type 2 diabetes.

Keywords

Health literacy; diabetes; patient-centered medical home; rural; pragmatic trial

Introduction

Diabetes Mellitus (DM) is a primary health concern particularly in rural areas, which have a 17% higher DM rate compared to urban areas [1]. Rural patients tend to be diagnosed later, have more limited access to medical and specialist care, have minimal exposure to diabetes education and experience greater transportation challenges compared to urban counter parts [2]. Rural patients are also more likely to live in poverty and have limited literacy [3]. Public health strategies to improve DM outcomes in rural areas have used distance methods such as telemedicine programs, web-based educational efforts, telephone help lines, and lay community health advisors [4–8]. Most of these strategies improved knowledge, self-efficacy and self-care practices and some improved Hemoglobin A1c (HbA1c), but all had significant limitations; particularly cost, staffing, fidelity and sustainability [9]. Web-based studies identified barriers such as patients' lack of technological skills, access to home computers and high speed internet connections. Rural community health advisor limitations included isolation, lack of support, burn out and high turnover [9]. None of these rural programs were clinic-based, and none addressed the prevalent problem of limited patient health literacy, which can be a significant barrier to understanding DM self-management and behavior change.

To respond to the many challenges of caring for vulnerable patients with diabetes and other chronic conditions, new standards have been set to organize care. The 'Patient-Centered Medical Home' (PCMH) concept, is a philosophy for improving access, quality and efficiency of primary care and providing services that promote on-going management of chronic disease [10]. PCMH clinics are encouraged and incentivized to use health coaches to promote chronic disease education and self-management [11,12] and to track test results over time [13].

Clinic interventions promoting DM self-management need to address health literacy, defined as an individual's capacity to understand basic health information and make appropriate health decisions [14]. Limited health literacy, which is common in rural areas, is associated with a higher prevalence of disease, including diabetes [15–17]. DM patients with lower health literacy have less knowledge about disease and treatment, poorer self-management behaviors, are less likely to engage in regular care with providers, and to understand and appropriately use their medications [18–22]. Poor self-management translates into medication errors, missed appointments, and challenges with diet, exercise and monitoring, resulting in worse clinical outcomes. New cost effective approaches to DM are needed for rural community clinics based around a chronic disease model, which addresses all of these issues. The Department of Health and Human Services (DHHS) has called for health

information that is accurate, accessible, understandable and actionable and for more patient-centered health services [17]. Evidence suggests that approaches to DM care and self-management need to embed programs in clinics and involve patients in the process of their own care, along with ongoing monitoring and continued follow-up [23–25].

In response to the need for rural PCMHs to provide effective diabetes self-management education and resources to their patients, a randomized pragmatic trial was designed to test a health literacy intervention compared to enhanced usual care.

Materials and Methods

This pragmatic trial tests the effectiveness and fidelity of embedding the American College of Physicians (ACP) diabetes health literacy intervention among patient-centered medical homes throughout rural Arkansas. The institutional review board of the University of Arkansas for Medical Sciences (UAMS) approved all study procedures.

Study sites

The project engages six UAMS regional family medicine clinics in Arkansas that are underserved and rural. All clinics have implemented the PCMH model of care and achieved the highest level of accreditation, level 3. The majority of patients served by these clinics are low-income and there is a high rate of chronic disease in each clinic's patient population. There are over 2,200 patients at these clinics with HbA1c greater than 7.5%, an indication that an individual has likely not achieved tight glycemic control and therefore may be at elevated risk for diabetes-related complications.

Participants

Eligible participants: 1) are 21 years of age or older, 2) speak English, 3) have a cell phone or land line 4) are active patients at a regional family medical center study site, 5) have a confirmed diagnosis of type 2 diabetes as documented in the EHR, and 6) have an HbA1c of >7.5% but <10% recorded in their chart; we include those patients who demonstrate a need for improvement (>7.5%) but exclude those who would not readily benefit from diabetes education and self-management training (<10%).

We will recruit 750 patients (n=325 per arm). Eligible participants will be identified through monthly EHR queries. A list of patients from this query is reviewed by the central Research Assistant (RA) who makes previsit calls to patients. The central RA provides information about the study in the pre-visit call and asks if the patient is interested in talking with the site RA about the study. If the patient is interested, the care coordinator schedules the appointment and asks the patient to arrive 60 minutes early for their next clinic visit to meet with the RA. The central RA will also let all patients know if he/she will be meeting with someone at the clinic after their doctor visit who will provide diabetic counseling. At each clinic, the RA greets patients upon check in and escorts them to a private space, explains the study, conducts the informed consent process, and then collects baseline data through a structured interview with those patients who consent.

Study Arms

Intervention.—The American College of Physicians (ACP) Health Literacy Strategy is an evidence-based, patient-centered, low literacy intervention promoting diabetes self-care that includes: 1) the ACP Diabetes Guide that uses plain language and descriptive photographs to teach core diabetes concepts and empower patients to initiate behavior change; 2) a brief counseling strategy to assist patients in developing short-term, explicit and attainable goals for behavior change ('action plans') [26,27]; and 3) a training module for health coaches that prepares them to assume educator/counselor roles with the ACP Guide as a teaching tool [26,28–31]. The health coach will review the ACP Diabetes Guide at baseline and give to patients to take home. The counseling strategy will consist of 'front-loaded' telephone follow-up education, counseling and action-planning occurring at 2, 4, and 8 weeks and then monthly between quarterly diabetes routine clinical visits where in-person, 'point-of-care' counseling sessions will occur. We intentionally aimed to optimize the number of 'touch points' over 1 year, taking into account a reasonable workload for health coaches.

Enhanced Usual Care.—Participants assigned to the Enhanced Usual Care (EUC) arm will be given the American Diabetes Association (ADA) Living Well with Diabetes workbook [32] at their baseline visit by a nurse. While all patients in the EUC receive a commonly used education resource (ADA guide), initial and follow up diabetes education is not standardized and varies in that arm. Figure 1 provides more detail on current care management activities at the sites as well as the specific activities in each arm. Figure 2 indicates the timing of each of these activities for both arms of the study.

Randomization

Prior to the initial phone call to recruit participants, the central RA will assign patients interested in participating to either the intervention or to the enhanced usual care arm based on a simple 1:1 randomization scheme, stratified by site. Patients must be randomized prior to consenting at the in person baseline interview in order to schedule the health coach to administer the intervention at the baseline visit.

Study Aims and Hypotheses

Aim 1.—Test the effectiveness of the ACP diabetes health literacy intervention to improve a range of diabetes-related outcomes among rural patients.

Compared to enhanced usual care, patients receiving ACP intervention will demonstrate:

- H₁ better disease control (HbA_{1c}, blood pressure)
- H₂ greater disease and treatment knowledge
- H₃ higher self-efficacy to manage diabetes
- H₄ greater adherence to self-care behaviors
- H₅ less diabetes-related distress
- H₆ improved diabetes-related quality of life.

Aim 2.—Compared to enhanced usual care, evaluate whether the intervention reduces disparities by patient literacy level.

H₇ Limited health literacy will be associated with the above health outcomes in the enhanced usual care arm, but not in the intervention arm.

Aim 3.—Investigate whether a threshold or gradient effect exists between the amount of follow-up counseling (number of action plans) and intervention effectiveness.

Data Collection

Interviews are conducted by RAs in person at baseline, 3 and 6 months post baseline to capture study outcomes. Study data will be collected and managed using REDCap electronic data capture tools hosted by the Northwestern University Clinical and Translational Sciences (NUCATS) Institute [33]. Patients receive a \$30 gift card at baseline, 3 months, and 6 months for their participation.

Clinical Outcomes

Hemoglobin A1c (HbA1c) lab values, along with systolic and diastolic blood pressure values are collected as part of routine clinical care at every 3 months, and will be recorded from the medical record at each visit. *Body Mass Index (BMI)*. Height (in centimeters/meters) and weight (in kilograms) will also be taken from the medical record and the standard calculation for BMI applied (kg/m²). In addition, weight (in lbs) will be recorded separately for weight gain/loss as an additional outcome. We also will ask patients to self-report emergency department/urgency care visits and hospitalizations. Dates of clinic appointments during the study period will be recorded from the medical record.

Patient Outcomes

Treatment knowledge.—A diabetes knowledge assessment including 14 multiple choice items was devised by this team and other expert consultants (Drs. Hilary Seligman and Dean Shillinger) that is appropriate for lower literate adults and emphasizes actionable diabetes treatment-related concepts (normal blood sugar range, foods and activities that increase/decrease blood sugar, blood pressure, proper medication use, signs of hypoglycemia, etc.) [26,30].

Diabetes self-efficacy.—Self-efficacy will be assessed using an 8-item measure developed by Sarkar [34] asking respondents to rate their confidence in their ability to perform individual diabetes self-care activities, such as monitoring their blood glucose, getting medical attention, and taking care of their health. We will also collect the Consumer Health Activation Index, which assesses participants' 'activation' or motivation to participate in healthcare decisions and actions [35].

Self-management behaviors.—The Behavioral Risk Factors Surveillance System (BRFSS 2013) Fruits & Vegetables, Sugar Drinks, and Sodium or Salt-Related Behavior modules will be used to assess diet. Selfreport items of moderate and vigorous physical activity in the last 30 days from the BRFSS will be asked [36]. Adherence will be measured

using the Adherence to Refills and Medications Scale - Diabetes (ARMS-D) [37], an 11-item self-reported scale of diabetes medication adherence with 2 subscales: a 7-item medication taking subscale and a 4-item refill subscale.

Diabetes-Related Quality of Life

Diabetes distress.—The Diabetes Distress Scale (DDS) is a 17-item measure of diabetes-related emotional distress [38–40]. It has four subscales corresponding to emotional burden, physician-related distress, regimen distress, and diabetes interpersonal distress.

Quality of life.—Patient-Reported Outcomes Measurement Information System (PROMIS) is a national resource providing state-of-the-art tools for assessing patient symptoms and health outcomes. The physical health (function) short form will be collected [41] along with the PHQ-9 Depression Scale [42].

Covariates

We will collect socio-demographic information, social support (Tangible Social Support Scale), [43,44] and health status (self-reported overall health status, BRFSS 2013 Diabetes Module [45], comorbid conditions, and total number of medications). Additionally, the Newest Vital Sign (NVS), a reliable screening tool used to determine risk for limited health literacy by asking questions about a nutrition label will be administered [46].

Fidelity Measures

We will ask patients whether they received all of the diabetes materials (yes/no), and if they still have them at each follow-up encounter (3 and 6 months). Using health coach logs, we will document for each follow-up time interval, whether the patient was reached (yes/no), and if yes, the time spent with the patient. For those in enhanced usual care, we will review nursing notes to document the number of nurse encounters for diabetes education per patient, and ask patients to also self-report prevalence of nurse counseling. We will ask questions adapted from the Consumer Assessment of Health Providers Survey (CAHPS) [47] to evaluate the extent and quality of nurse/health coach counseling. Items previously validated from our team's earlier study will be used in this trial, where patients will be asked upon study completion 2 questions: 'On a scale of 1 to 10, one being not helpful at all and 10 being extremely helpful, how helpful was this process of setting action plans to improving your health?' and 'If given the opportunity, would you like to continue to set action plans with the health coach/nurse?'

Data Analysis Plan

Baseline characteristics and demographics will be summarized overall and by clinic using descriptive statistics (mean $\pm$ standard deviation for continuous variables, frequencies and percentages for categorical variables, and medians/quartiles as appropriate for ordinal variables). Analyses across all relevant outcomes (i.e., those corresponding to H₀–H₆) will mirror one another in general, with primary outcome being defined as HbA1c levels at six months. Secondary outcome measures include disease and treatment knowledge scores, self-efficacy scores, adherence to self-care behaviors, and diabetes-related quality of life at 3 and

6 months and other clinical outcomes (blood pressure, Low-density Lipoprotein (LDL) cholesterol, BMI) at 6 and 12 months. The primary time point of interest for clinical outcomes (H_6) is six-month follow-up, but subjects will be followed through 12 months in order to examine sustainability. We will examine missing data patterns to assure they are missing at random [48], and analyses will consist of parametric statistical tests when we do not have evidence that statistical assumptions are violated; nonparametric analyses and/or transformations of variables will be explored in the event of violations.

Aim 1 analysis for each outcome will consist of an analysis of covariance (ANCOVA), modeling the overall mean follow-up outcome (e.g., HbA1c at 6 months) across groups, controlling for the baseline value of the corresponding outcome variable. Comparisons will be made for all relevant outcomes at three and/or six-month follow-up (to examine efficacy/effectiveness) and 12-month follow-up (to examine sustainability). Baseline variables (demographics, comorbidities, health literacy, etc.) will be explored one at a time, in turn, for association with outcome(s), and where appropriate, models will be adjusted for significant baseline prognostic variables. Exploratory analyses will employ linear mixed effects models that include a fixed treatment arm, baseline value, relevant prognostic variables, and time effects along with a random subject effect in order to account for within-subject association among outcome observations. Exploratory analyses will involve inclusion of a fixed change-point or spline term(s) to examine changes in slope over different time periods and/or higher order/interaction terms. In order to examine whether there may be a difference across clinic, a random clinic effect will be examined as well, and where appropriate, subgroup analyses by clinic will be employed.

To address Aim 2 (H_7), subjects will be classified by literacy level (limited, adequate), and previous analyses will be run testing for moderation by literacy. For Aim 3, we will analyze only those subjects randomized to the ACP intervention arm. We will examine association of (a) number of contacts with each subject and (b) length of contact time, with each relevant outcome variable (H_1 - H_6) at follow-up via a linear model as above. Each model will include an intercept, baseline value for the relevant variable, and variable (a) and/or (b), along with any additional demographics/prognostic variables found relevant in Aims 1 and 2.

All analyses will follow an intent-to-treat (ITT) principle in which all subjects enrolled in the study, regardless of adherence to the study protocol, will be analyzed according to the arm to which they were randomized. Sensitivity analyses will be used to examine the “as treated” dataset. As this is a pragmatic trial, all analyses will be run at a two-sided type 1 error rate of 5%.

Sample Size and Power

Power and sample size calculations were based on primary outcome of HbA1c at six months, assuming an independent two-sample t-test, type I error rate of 5%, and equal variances across arms. Note that primary outcome analyses will employ ANCOVA, and as a result, the power calculations presented here are considered conservative since we anticipate the inclusion of baseline values in ANCOVA to result in better precision in estimating an intervention effect. We plan to enroll 750 subjects, with minimal anticipated dropout: 84% retention at six months ($n=630$, 315 per arm) and 80% retention at 12 months ($n=600$, 300

per arm). For our primary outcome at 6 months, assuming a mean (SD) of 8.4 (1.9) for the usual care arm based on a previous study [28,40], we will be able to detect a clinically meaningful difference in HbA1c across arms of > 0.43% with >80% power. With 0.5% being an accepted clinically meaningful difference in A1c [49], this sample enables us to detect such a difference. With sample size set by the primary outcome of HbA1c at 6 months, we will also be able to detect a minimum difference of 4.25 in systolic blood pressure (SBP) with 80% power, assuming a mean (SD) SBP of 138.4 (19.0) for usual care [28,40]. Assuming 35% will have limited literacy in each arm [3] (n= 110 limited, 205 adequate) we will also be powered to detect minimum differences of 0.64 and 6.28 in HbA1c and SBP systolic blood pressure, respectively, by literacy level for Aim 2.

Conclusions

PCMHs are increasingly commonplace in community health centers [50] with over 60% having earned a PCMH designation [51]. The PCMH model for primary care practices quickly advanced the quality of the medical management of diabetes through the dissemination and use of evidence-based medicine standards and tracking. This includes greater attention to process indicators such as foot and eye exams, and regular measurement of Hemoglobin A1c (HbA1c). Promotion of electronic health records (EHR) adoption also has been a requirement of level 3 PCMH status, and specifically more meaningful use of EHRs to promote quality and safety. While actual PCMH definitions and designations may still vary, the widespread adoption of PCMH components (e.g. coordinated care, evidence-based principles, process indicators, EHRs) have been shown to improve the quality of medical care for diabetes and other chronic conditions, improve outcomes, reduce disparities and lower costs [52]. Many PCMH clinics employ health coaches to manage the patient education needs of their high risk patients to improve outcomes using a population health approach.

What is arguably more variable within community health centers, regardless of PCMH status, is access and appropriateness of patient education and self-management services, despite health education being the cornerstone of diabetes care [10]. Only half of patients with DM report having ever received diabetes education and self-management support, with rates lowest in rural areas [53,54]. Implementing and sustaining diabetes education and self-management strategies in safety-net, primary care settings is difficult due to limited resources and vulnerable patient populations (lower socioeconomic status, limited health literacy, greater disease burden) [55]. Proper self-management requires patients 'engagement, considerable knowledge, a range of skills, and sustaining multiple health behaviors [56]. While some approaches to promoting self-management have been evaluated with promising results, questions remain on how best to implement and sustain them in the most effective, efficient, and sustainable manner. Interventions are critically needed for patients in less-resourced rural clinics.

The patient-randomized pragmatic trial described addresses current needs of patients, providers and practices, and tackles an important disparity for those patients with lower health literacy who often suffer worse outcomes and benefit less from education.

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STANDARD DIABETES MEDICAL CARE In Both Arms		
Care Management	<ul style="list-style-type: none">▪ Quarterly visits with PCP: hemoglobin A1c and blood pressure measurement at each visit. exams and tests per ADA standards of medical care▪ Pre-visit phone calls from care coordinators to schedule appointment and labs, remind patients of next clinic visit▪ Enrollment in and access to online patient portal▪ Integrated EHR for clinical tracking and reporting▪ Medical care action plans established by PCP in patient EHR	
DIABETES EDUCATION AND SELF-MANAGEMENT SUPPORT		
	'Enhanced' Usual Care Arm	Intervention Arm
materials	<ul style="list-style-type: none">▪ ADA 'Living Well with Diabetes' Workbook:<ul style="list-style-type: none">- 69 page booklet, workbook format- Written at 7th grade level- 12,250 words- 7 chapters: understanding diabetes, blood glucose meal planning, physical activity, medication, overall health, & tools- Chapters arranged in sequence of review	<ul style="list-style-type: none">▪ ACP 'Living with Diabetes' Guide: An everyday guide for you and your family<ul style="list-style-type: none">- Colorful 56 page booklet- Written at a 5th grade level- 5,751 words- Developed with providers and patients nationally. Addresses topics they identified as most important: understanding DM, eating right, being active, checking blood sugar, taking medicine, keeping feet healthy and learning about insulin- Designed to be easily understandable across literacy levels using plain language, conversational tone, limited information and 96 descriptive photographs- Focused on behavior and small actionable steps for behavior change
counseling	<ul style="list-style-type: none">▪ 15 minute, in-person session with clinic nurse to review content in ADA diabetes booklet and answer any patient questions▪ Basic orientation of nurses to the ADA workbook and process for reviewing information with patients completed in preparation phase	<ul style="list-style-type: none">▪ 15 min evidenced-based in-person education and counseling sessions with health coach▪ Introduce and review each chapter of the guide. Use guide as teaching tool▪ Use motivational interviewing skills to engage pt. Elicit info on what they know and do.▪ Counseling based on behavior change model focused on facilitating goal setting. The patient (not provider) creates specific behavioral action plan. Coach elicits domain patient is willing to work on and coaches the patient to create a small, easily achievable behavior they are willing to initiate this week.▪ The coach then asks: On a scale from 1 to 10:<ul style="list-style-type: none">- <i>How sure are you that you can carry out this action plan during the next week?</i>- <i>How important is carrying out this action plan to you?</i>- Identify new action plan if either patient rating is 7 or below
Follow-Up	<ul style="list-style-type: none">▪ Follow-up at scheduled clinic visits approximately every 3 months▪ No standard, practices vary over time	<ul style="list-style-type: none">▪ In-person 15 min education & counseling sessions at approximately 3,6, 9, and 12 months with health coach▪ Phone calls with health coach to inquire about progress on action plans, use motivational interviewing to problem-solve or establish new action plans<ul style="list-style-type: none">- Bi-weekly post-visit phone calls for first 3 months (2,4,and 8 weeks after baseline encounter)- Monthly post-visit phone calls between clinic visits after 3 months (4,5,7, 8, 10,and 11 month calls)▪ Survey data will be collected at baseline, 3 and 6 months; clinical data will be collected following baseline, 3, 6, 9, and 12 months
Clinical Integration	<ul style="list-style-type: none">▪ Documentation in EHR with nursing note whether post visit DM counseling occurred (yes or no) and when	<ul style="list-style-type: none">▪ EHR tools and prompts for health coach follow-up phone calls or face-to-face meetings, documentation of call attempts▪ Health coach received information on patients' glycemic control (HbA1c lab value at visit) prior to patient counseling session▪ Health coach documents in EHR every month using care note function: describes and provides update for PCP detailing patient's diabetes action plans and progress towards goals▪ Email to PCP via EHR if patient does not complete 2 consecutive action plans, identifying barriers is known, or if any concerns arise

Figure 1.
Diabetes Education: Enhanced Usual Care and Intervention

Figure 2.
Study flow chart