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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 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.

1. 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

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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.

2. 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.

2.1. 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 2200 patients at these clinics with HbA1c > 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.

2.2. 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 pre-visit 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 min 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.

2.3. Study arms

2.3.1. 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.

2.3.2. 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. Fig. 1 provides more detail on current care management activities at the sites as well as the specific activities in each arm. Fig. 2 indicates the timing of each of these activities for both arms of the study.

2.4. 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.

2.5. 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:

- H_1 better disease control (HbA1c, blood pressure)
- H_2 greater disease and treatment knowledge
- H_3 higher self-efficacy to manage diabetes
- H_4 greater adherence to self-care behaviors
- H_5 less diabetes-related distress
- H_6 improved diabetes-related quality of life.

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

H_7 Limited health literacy will be associated with the above health outcomes in the enhanced usual care arm, but not in the intervention