Study Title: Health literacy intervention to improve diabetes outcomes among rural primary care patients

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Version No.: *10*

Date: *02-04-2019*

Background and Rationale

Diabetes Mellitus (DM) is an immense and complex public health challenge. Currently DM effects 8.3% of the U.S. population with rates expected to increase by over a third in the next 10 years.[1-3] The disease lowers life expectancy by as much as 15 years, doubles the risk of heart disease and is the leading cause of kidney failure, lower limb amputation and adult onset blindness. Complications from DM cost an estimated $116 billion annually in direct medical cost in the U.S. Reducing the disease and economic burdens of DM and improving the quality of life for these patients is a public health priority.

According to the National Rural Health Survey, DM is one of the top health concerns in rural areas, ranking number 2 among southern states.[4,5] Rural areas have a 17% higher DM rate compared to urban areas and patients tend to be diagnosed later, receive substandard care and have minimal exposure to DM education compared to urban counter parts.[5] Rural communities grapple with health system barriers such as a lack of specialist care and the capacity of primary care clinics to train their staff to adequately implement DM programs.[6] Environmental barriers including high rates of poverty, poor access to local clinical care, and a lack of public transportation compound the problem of limited access to DM interventions and health promotion. Community barriers in these areas often include unsafe walking spaces, few exercise facilities and grocery stores lacking affordable, healthy produce. Social and cultural barriers also impact diabetes management and intervention access. Although the importance of addressing DM is well recognized, translating clinical, evidence-based self-management interventions for practical implementation has proven difficult, particularly for rural communities.[6,7]

Given these issues, there is a critical need for replicable, sustainable DM interventions tailored for rural clinics that aim to improve health outcomes.[7] Strategies to improve DM outcomes in rural areas include telemedicine programs, web based efforts, telephone help lines and use of lay community health advisors.[6-8] A recent review of these practices found most had strengths such as improving knowledge, self-efficacy and self-care practices and some improved HbA1c and LDL levels but all had significant limitations, particularly cost, staffing, fidelity and sustainability.[7] Web-based intervention studies identified barriers to efficacy including lack of technological skills of participants and access to home computers and high speed internet in rural areas. Rural community health advisor limitations included isolation, lack of support, burn out and high turnover.[7] None of the reported programs were clinic-based, which could mitigate the barriers described, and none specifically addressed the prevalent problem of patient limited literacy, which can be a significant barrier to understanding DM self-management and behavior change that disproportionately affects rural areas.

<u>The Need for Clinic-Based Self-Management Interventions</u>

Although evidence for DM management strategies is well established, implementing and sustaining practical strategies in resource-poor primary care settings that disproportionately care for DM patients is challenging.[9] Quality DM care and patient self-management require a structured approach to care and follow-up that includes attention to process indicators such as foot and eye exams, regular measurement of HbA1c, and patient self-management education and support. With the adoption of the Patient Centered Medical Home (PCMH) model, primary care clinics are increasingly offering more appropriate DM medical services as part of population health management, however, education, counseling and behavioral monitoring is often limited, variable and sometimes nonexistent. Even though patient self-management is the cornerstone of DM care and outcomes, only about half of patients report ever receiving DM education to promote it, with even lower rates in rural areas.[3,10] Proper DM self-care requires patients to be engaged, have

considerable knowledge, a range of skills, and sustain multiple health behaviors.[11] While some approaches to promoting patient self-management have been evaluated with promising results, questions remain on how best to implement them in the most effective, efficient, and sustainable manner. Interventions are needed that have been designed for patients in rural community clinics that have limited resources and disproportionately care for patients with low literacy.

Health Literacy, Self-Management Behaviors, and Diabetes Outcomes

Health literacy is the capacity to understand basic health information and make appropriate health decisions, and limited health literacy is associated with a higher prevalence of disease in the US, including diabetes.[12-14] Numerous studies have demonstrated that DM patients with lower health literacy are likely to have less knowledge about disease and treatment and poorer self-management behaviors that are necessary to control their glucose and manage their diet and exercise; they are less likely to engage in regular care with their providers and to understand and appropriately use their medications.[15-19] This poor self- management translates into worse clinical outcomes resulting from medication errors, missed appointments, and diet, exercise and monitoring non-adherence. New cost effective approaches to DM are needed for primary care clinics based around a chronic disease model, which addresses all of these issues. Evidence suggests approaches to DM care and self-management need to embed programs in physician practices and modify clinical practice to include education and counseling that involves patients in the process of their own care, along with ongoing monitoring and continued follow-up.[20-22] Our proposed model includes the components of the Health Literate Care Model for primary care clinics, which is based on a chronic disease model and incorporates health literacy best practices. This model, and our approach, relies on patients' full engagement and clinics' continued outreach, and encourages both patients and the health care system to be activated and engaged in improving health outcomes.

The American College of Physicians (ACP) Diabetes Health Literacy Intervention

Members of this team (Drs. Davis, Arnold, Wolf, and consultants Drs. Seligman and Schillinger) conducted studies based on the American College of Physicians (ACP) low literacy diabetes guide and brief counseling framework they developed. Results from the first study revealed that patients wanted information focused on how to manage DM rather than being educated about the disease and why they should manage it better. Patients also expressed that they wanted ongoing support. Physicians in the study expressed that they wanted to inform patients about the severity of the disease and importance of the HbA1C test and checking blood sugar. The ACP Diabetes Guide addresses understanding diabetes, eating right, being active, checking blood sugar, taking medicines, keeping feet healthy, and insulin. This guide is written on a 5th grade reading level, formatted for reading ease, and focused on health behavior change. A total of 96 colorful pictures of actual people with diabetes help connect patients to the content.[23] Since development, the ACP Diabetes Guide has been distributed nationally to over 5 million individuals. The team then conducted three intervention studies using the ACP DM guide and brief counseling framework with vulnerable populations in safety net clinic settings. Findings revealed that the protocol was feasible and equally effective with both low and high literacy patients. With funding from the Office of Minority Health,[24] Drs. Davis and Arnold conducted a study in 3 federally qualified health centers in Louisiana with 247 predominately African American patients. Findings indicated that engagement through longer term follow-up was most feasible with a familiar health coach in these resource-poor clinics. Most recently, the Missouri Foundation for Health funded another evaluation under the leadership of Dr. Wolf, expanding the research to 9 community clinics in Missouri to evaluate two different implementation approaches and to assess health outcomes (N=671 patients). Results from this study revealed that strategies are

needed to increase follow-up and embed the protocol in clinics. Clinics that are designated as patient-centered medical homes and are using electronic health records (EHRs) are particularly well-suited for implementing the tested approaches. Successful DM intervention in rural clinics should likely include the following elements: face-to-face sessions with a clinic-based health coach, multiple phone call follow-up touch points with a familiar coach, embedding the protocol in clinic processes and using tools such as EHRs, and low literacy materials that are easy to read and actionable. All of these elements are integrated into the approach for the proposed research.

Conceptual Framework

Longstanding research on health behaviors has identified several important determinants of whether or not an individual performs a specific health behavior, including but not limited to: proper awareness (knowledge), attitudes towards the behavior, perception of social norms and one's own sense of self-efficacy in performing the behavior.[25-29] The design of the ACP intervention as led by Dr. Davis was carefully informed not only by health literacy principles, but by 1) principles of multimedia learning that highlight the benefits of learning actionable content through pictures and graphics versus text alone (Diabetes Guide includes >90 images to provide explicit examples of healthy food portions, exercise, medication use, etc.), and 2) self-efficacy theory, which supports the need for modeling behavior and setting achievable goals to build confidence for continual self-management improvement. The action plan sections of the Diabetes Guide, coupled with health coach brief counseling protocols that are highly structured and frequent, encourage patients to choose meaningful and attainable goals to build confidence over time. Examples of possible action plans, per topic, are offered to help model possible goals or to guide a patient in choosing their own.

Dr. Howard Koh, former Assistant Secretary of DHHS, has proposed a Health Literate Care Model based on the chronic care model.[30,31] The model encourages both patients and providers to be activated and engaged and suggests that improving health outcomes relies on patients' full engagement. Our strategy, in combination with PCMH standards achieved by each clinic, and previous clinic training by Dr. Hadden in implementing health literacy strategies recommended in the Agency for Health Care Quality and Research's (AHRQ) Health Literacy Universal Precautions Toolkit[32] address many of the attributes included in this model: 1) assuming all patients are at risk of not sufficiently understanding their disease or self- management; 2) providing clear communication following plain language principles and easy to read, culturally appropriate materials, 3) confirming and ensuring patients understand via the '*teach back'* technique, 4) providing close follow-up with patients using a health coach, 5) incorporating provider health literacy training and point-of-care clinical reminders for medication reviews, 6) use of an electronic health record (EHR) to track progress. *We will use health coaches to ensure constant patient engagement and provide the tools necessary to frequently monitor action plans and performance.*

Hypothesis and/or Specific Aims or Objectives

The primary aims and hypotheses are to:

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

2. Compared to 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 arm.

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

4. Determine the fidelity of all intervention components, and explore any identified patient, provider (physician, nurse, health coach), and/or health system barriers to implementation.

5. Assess the costs associated with implementing the ACP intervention from a health system perspective.

Study Design and Procedures

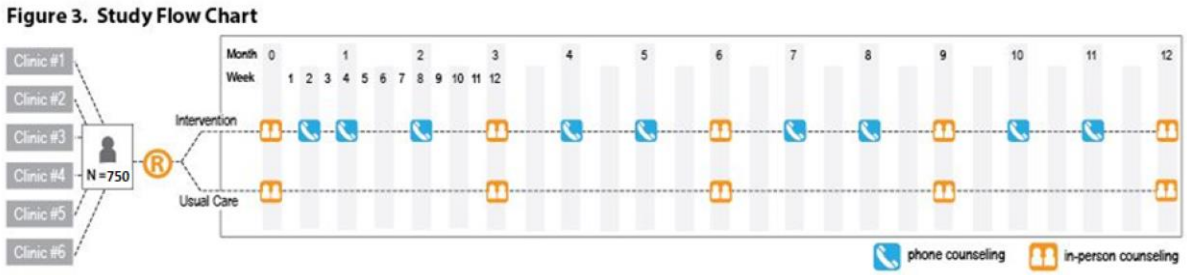
We will conduct a 2-arm, patient-randomized, pragmatic trial among 750 patients in Arkansas with type 2 diabetes to test the effectiveness and fidelity of a multifaceted, health coach-led, low literacy, self-management intervention to improve behavioral and clinical outcomes compared to enhanced usual care in level 3 patient centered medical homes. Enhanced usual care differs from standard diabetes care because enhanced usual care includes patient resources associated with PCMH (team-based care, electronic health records, and care coordination). Eligible, consented patients will be followed for 1 year post baseline interview. Those receiving the ACP intervention will be administered the ACP health literacy strategy at baseline, with 'front-loaded' telephone or in-person follow-up education approximately every 3 months, counseling and action-planning occurring at approximately 2 weeks, 4 weeks, and 8 weeks and then monthly between quarterly clinical visits. In-person, 'point-of-care' counseling sessions will occur quarterly, coinciding with diabetes routine clinical visits. We intentionally aimed to optimize the number of 'touch points' over 1 year, taking into account a reasonable workload for health coaches. Addressing Aim 3, which seeks to ascertain the minimum number of action plans necessary to achieve clinical diabetes goals, or an increasing benefit is seen with more touch points (no threshold). Primary outcomes include intermediary biomarkers indicative of proper disease self-management (HbA1c, blood pressure, LDL cholesterol). In addition, secondary outcomes to be measured include diabetes and treatment-related knowledge, self-efficacy, disease-related distress and quality of life, activation, health behaviors and health services utilization. To determine the reliability and costs associated with delivering the intervention, we will also closely monitor the implementation process and evaluate the fidelity of the components and strategies.

Diabetes Education: Enhanced Usual Care and Intervention

STANDARD DIABETES MEDICAL CARE In Both Arms	
Care Management	▪ 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	▪ ADA 'Living Well with Diabetes' Workbook: - 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 arranges in sequence of review	▪ ACP 'Living with Diabetes' Guide: An everyday guide for you and your family - 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	▪ 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 ▪ This and other diabetes education varies by provider, practice, and time	▪ 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: - *How sure are you that you can carry out this action plan during the next week?* - *How important is carrying out this action plan to you?* - Identify new action plan if either patient rating is 7 or below
Follow-Up	▪ Follow-up at scheduled clinic visits approximately every 3 months ▪ No standard, practices vary over time	▪ 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 - 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	▪ Documentation in EHR with nursing note whether post visit DM counseling occurred (yes or no) and when	▪ 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. Study flow chart



Study Sites

The project will engage six UAMS Regional family medicine clinics in regions of Arkansas that are underserved and rural. All clinics have implemented the Patient-Centered Medical Home (PCMH) model of care and achieved the highest level of accreditation, level 3. All regional medical centers have participated in implementation of health literacy best practices using the Agency for Healthcare Quality and Research (AHRQ)'s Health Literacy Universal Precautions Toolkit for the last two years. The majority of patients served by these clinics is low-income and there is a high rate of chronic disease in each clinic's patient population. There are approximately 2,205 total patients at these clinics with HbA1c greater than 7.5%, which denotes that an individual has perhaps not yet achieved tight glycemic control and therefore may be at elevated risk for diabetes-related complications. All clinics have agreed to participate. Letters of support from the clinic directors are included.

Preliminary Studies

In Arkansas, Dr. Hadden conducted a survey and queried the EHR at each of the performance sites to determine 1) the need for a standard diabetes education and self-management training curriculum such as the proposed ACP intervention, 2) modalities best suited for rural patients, including patients having land or cell phones the use of text messaging and/or patient portals to set action plans and to report back on progress. All site staff reported back current variable practices in terms of diabetes education – and all reported a high level of enthusiasm for participating in the present study. The EHR indicated 97% of patients have a cell or land line phone. Yet half of patients either did not have an unlimited texting plan, lacked familiarity with texting, or reported not wanting to receive text communications for their health. This was equally reported with regard to web-based communications. Thus, our team chose a health coach-led, telephone based approach**.**

Preparation phase

Research Assistants (RAs) at each site will be provided an ID and password to login directly to Northwestern University's (NU's) REDCap software. This allows for secure, straightforward electronic entry of participant responses by the RA and generation of output data files compatible with statistical programs. A staff analyst at NU will oversee the database structure and quality assurance activities under the supervision of Drs. Wolf and Kwasny. We will register the trial protocol at ClinicalTrials.gov.

Study in-services and trainings will build on our previous experience gained in our research conducted in community clinics and will use adapted, updated, and standardized

curricula and materials. Investigators will coordinate with the Regional Family Medical Center Director and Medical Director at each clinic to identify, orient and train a part-time research assistant (RA), nurses and the health coach at each clinic. In all clinics the investigators will provide an on-site orientation for primary care providers and staff including the RA, nurses and health coaches. The orientation will be held at a convenient time for the clinic and will provide an overview of the study, review of study protocol, an introduction of the RAs, as well as identification of participating nurses (for enhanced usual care) and health coaches (for ACP intervention). In the orientation, providers will be encouraged to talk about the importance of diabetes self-management with their type 2 diabetes patients and inform them that a nurse or health coach will talk to their patients about things they can do to be healthy in the study arms. Work flows will be introduced in the orientation that will address and reduce risk of contamination between study arms.

The 1.5 day long clinic training session developed by Drs. Arnold and Davis is based on previous experience training RAs in community clinics. The training will include tailored discussion of 1) roles and responsibilities; 2) HIPAA and IRB mandates (completion of Human Subjects Training Program - CITI; 3) effective recruitment communication and interviewing with attention paid to health literacy and culture; and 4) gathering and recording data including administering the structured survey electronically using REDCap software. Role playing will be used to fine tune training for obtaining informed consent and interviewing patients.

The two-day training developed by Drs. Arnold, Davis and Wolf will be informed by previous staff training in community clinics using the ACP guide and brief counseling framework. The session will take place in a central location and will include discussion of roles and responsibilities of the health coach for this project, and a review of the counseling framework. Skill-building will focus on brief education and coaching to facilitate patients' setting health goals and creating highly specific and easily achievable action plans. Training will also include skill building in motivational interviewing, clear communication and use of health literacy best practices (slowing down, using plain language, reducing numeracy demands, pointing out key messages in the guide book and using teach-back to confirm understanding). The theory-based training is designed to improve health coaches' capacity to enhance patients' understanding of their disease and problem-solving ability to change their health behavior and adhere to their action plans. The training will also focus on effective telephone counseling and follow up, employing strategies developed in previous research to reach patients by phone. Instruction will also be provided on use of a tracking system to recorded number of contacts (phone and in person), length of time spent in each contact, number of attempts to reach patients, and the content of each session.

Nurse training will cover an overview of the usual care diabetes materials in the enhanced usual care arm only (the "Living Well with Diabetes: a self-care workbook"). A review of the standards for usual care delivery will be provided to avoid contamination, as well as training on the tracking system. This will be provided by the Director of Research for the family medical centers in collaboration with the study team.

Randomization. After the initial phone call to recruit participants, the RA will assign patients interested in participating to either the intervention or to the enhanced usual care arm based on an allocation table created prior to study recruitment using a simple 1:1 randomization scheme, stratified by site. Patients will receive a $30 Walmart gift card at baseline, a $30 Walmart gift card at 3 months and a $30 Walmart gift card at 6 months for their participation. If the patient has a phone call for the 3 month follow-up, they can get their gift card the next time they come into clinic

or they can get it at the 6 month visit, whatever is convenient for them. We considered alternative randomization schemes, including physician and clinic-level randomization, but our team carefully determined randomization at the patient level to be the most rigorous and appropriate approach. Physician level-randomization was viewed as not feasible since patients at these practices frequently see multiple providers (attendings and residents) over the course of a year, and are not 'bonded' to just one physician. Clinic-level randomization was also viewed as not an option given too few sites to assign, and the considerable diversity still seen across these practices, by size, staffing and patient population that would make it unlikely to have equivalent study arms.

Blinding. As with most behavioral interventions, it will not be possible to fully blind researchers, healthcare providers, and study subjects to intervention vs. enhanced usual care assignments. However, we have purposefully designed our trial to prevent certain threats to contamination between study arms. Patients will be told they will receive one of two models of diabetes education and self-management support. While they will not be deliberately made aware of the approach not received, we do recognize that there is an unavoidable risk of patients learning from other patients involved in the study. Similarly, physicians and other prescribers will not be intentionally made aware of their patients' study assignments. However, it is very likely that as health coaches will be trained to include monthly progress notes on patients' action plans in the EHR for providers to read, enrollment status to arm will be recognized. But neither patient nor healthcare provider will have access to any of the intervention components, as that solely resides with the health coach who will only be serving intervention patients, having no role with enhanced usual care subjects for the term of the trial. This commitment has been strongly made by UAMS and clinic leadership (see Letters of Support).

Qualitative provider/clinic barriers and facilitators to implementation

To address aim 4: Determine the fidelity of all intervention components, and explore any identified patient, provider (physician, nurse, health coach), and/or health system barriers to implementation, a focus group of health coaches will be coordinated in Little Rock. All health coaches will be invited and provided lunch. The health coach moderator guide (Appendix C) will be used to elicit qualitative data. To elicit qualitative data from clinic staff and physicians, structured telephone interviews (Appendix D) will be conducted with 2 nurses, 2 physicians, and 1 clinic administrator from each of the following study sites: Jonesboro, Texarkana, and Pine Bluff. Focus group and phone interviews will be audio recorded.

Evaluation Phase

Covariates:

We will collect socio-demographic information (age, sex, race/ethnicity, education, income, financial stress), social support (Tangible Social Support Scale) and health status (self-reported overall health status, BRFSS 2013 Diabetes Module, comorbid conditions, and total number of medications). The Newest Vital Sign (NVS)will be used to assess health literacy in this study.

Effectiveness outcomes:

A diabetes knowledge assessment devised by this team 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.) will be used. (See study battery)

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 (CHAI), which assesses participants' 'activation' or motivation to participate in healthcare decisions and actions.

Self-Management Behaviors

Diet. The following BRFSS 2013 modules will be used to assess diet: Fruits & Vegetables, Sugar Drinks, Sodium or Salt-Related Behavior

Physical Activity. Self-report items of moderate and vigorous physical activity in the last 30 days from the Behavioral Risk Factors Surveillance System (BRFSS) will be asked.[37]

Medication Adherence. Adherence will be measured using the Adherence to Refills and Medications Scale – Diabetes (ARMS-D).

Diabetes-related Quality of Life

Diabetes Distress. The Diabetes Distress Scale (DDS) is a 17-item measure of diabetes-related emotional distress. 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) physical health (function) short form along with the PHQ-9 Depression Scale will be collected. Nurses will be notified if patients' scores indicate the need for follow-up either by the PCP or PCBHF, based on existing clinic protocol.

Clinical Outcomes

Hemoglobin A1c (HbA1c) and LDL cholesterol lab values, along with systolic and diastolic blood pressure values are collected as part of routine clinical care approximately every 3 months, and will be recorded from the medical record following each visit. *Body Mass Index.* Height and weight will also be taken from the medical record and the standard calculation for BMI applied (kg/m^2). In addition, weight (in lbs.) will be recorded separately for weight gain/loss as an additional outcome.

Health Services Use

We will ask patients to self-report emergency department/urgency care visits, and hospitalizations. Dates of clinic appointments during the study period may be recorded from the medical record.

Fidelity outcomes:

Receipt of Diabetes Materials

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).

Receipt of nurse/health coach counseling

We will ask patients to self-report whether their health coach/nurse reviewed the diabetes materials and/or provided counseling. 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.

Provider-Patient Communication

We will ask questions adapted from the Consumer Assessment of Health Providers Survey (CAHPS)[41] to evaluate the extent and quality of nurse/health coach counseling.

Perceived Helpfulness

Items previously validated from our team's earlier Missouri 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?' If patients do not want to continue, we will ask if they mind reporting why.

Table 1. Study Timeline

TASKS	Y1				Y2				Y3				Y4			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
PREPARATION PHASE:																
Organize research team, convene DSMB	■															
Protocol development	■															
Purchase ACP Diabetes Guides	■															
Prepare and refine EHR tools	■	■														
Site orientation, logistics planning		■														
Train health coaches		■														
Create databases		■														
Integrate, pilot, debug ACP intervention		■														
IMPLEMENTATION PHASE:																
Implement intervention			■	■	■	■	■	■	■	■	■	■	■			
Recruit, consent participants			■	■	■	■	■	■	■	■						
Conduct baseline interviews			■	■	■	■	■	■	■	■						
Conduct 3 and 12 month interviews				■	■	■	■	■	■	■	■	■	■	■		
Seek process feedback from clinical staff				■				■				■			■	
EHR data extraction									■	■	■	■	■	■	■	
EVALUATION PHASE:																
Clean & analyze data				■	■	■	■	■	■	■	■	■	■	■	■	■
Summarize and interpret findings										■	■	■	■	■	■	■
Provide feedback to sites, review scalability								■				■				■
Submit manuscripts for publication							■	■	■	■	■	■	■	■	■	■
Present findings at national venues							■	■	■	■	■	■	■	■	■	■

Qualitative provider/clinic barriers and facilitators to implementation

To address aim 4: Determine the fidelity of all intervention components, and explore any identified patient, provider (physician, nurse, health coach), and/or health system barriers to implementation, qualitative descriptions of health systems barriers to implementation will be collected from health coaches, nurses, physicians, and clinic leadership/administration. (see Appendices C & D, moderator's guide).

Study Population

Recruitment

The population of interest in this study is primary care patients with uncontrolled diabetes. To ensure human subjects' protection and autonomy in consent, the following are included in our

eligibility criteria: 1) 21 years of age or older, and 2) English speaking. The exclusion criteria are: 1) uncorrectable vision, hearing, or cognitive impairments that limit the ability to access intervention materials; and 2) those who are too ill to participate due to recent hospitalization or other recently documented illnesses. The English speaking criterion is included because not all measures and materials involved in the clinical trial are available in languages other than English.

We will recruit 750 patients (n=375 per arm). Eligible participants will be identified through EHR queries. The Central RA/care coordinator will make all pre-visit calls to eligible patients. The Central RA/care coordinator will provide information about the study in the pre-visit call, and ask if the patient is interested in participating in the study. If the patient is interested, the Central RA/care coordinator will ask the patient to meet with the Site RA for about 1 hour, review and sign the informed consent document, and begin baseline data collection. At each clinic, the Site RA will receive lists of interested patients and their scheduled appointment times, greet patients upon check in and escort them to a private space, explain the study, answer any questions the patient might have, and obtain written consent. The Site RA will then collect baseline data through a structured interview. Participants who are randomized to the intervention arm will also meet with the health coach for about 30 minutes. Participants will also meet with their provider if scheduled.

Informed Consent

Participants will provide written consent using procedures approved by the Institutional Review Board (IRB) of UAMS. Recruitment will be done over the phone by the Central RA/care coordinator. Patients who are interested in participating will be asked to meet in person with a Site RA for about 1 hour. When the patient arrives for their appointment, the Site RA will review the consent form, answer any questions, obtain written consent, then administer the brief baseline in-person interview. Informed consent documents will be composed at a fifth grade or lower reading level, be summarized, followed by a brief “teach back” to confirm understanding of key points of consent. The formal consent of each subject, using the IRB-approved consent form, will be obtained before that subject is submitted to any study procedure.

All subjects for this study will be provided a consent form describing this study and sufficient information in language suitable for subjects to make an informed decision about their participation in this study. The person obtaining consent will thoroughly explain each element of the document and outline the risks and benefits, alternate treatment(s), and requirements of the study. The consent process will take place in a private room at the clinic, and subjects may take as much time as needed to make a decision about their participation. Participant privacy will be maintained and questions regarding participation will be answered. No coercion or undue influence will be used in the consent process. This consent form will then be signed by the subject or legally acceptable surrogate, and the individual obtaining the consent at the clinic before the scheduled physician appointment. A copy of the signed consent will be given to the participant, and the informed consent process will be documented in each subject’s medical record. The original signed informed consent document will be filed in the participant’s research record.

Inclusion/Exclusion Criteria

Eligible participants will be 21 years of age or older, speak English, are active patients that have had one or more visits to a regional family medical center study site, have a confirmed diagnosis of type 2 diabetes as documented in the EHR, have a recent Hemoglobin A1c reading of ≥7.5% and ≤10%. Participants who have uncorrectable visual or hearing impairments or cognitive impairments that limit their ability to access intervention materials will be excluded, as well as those who are too ill to participate based on extreme cases. Extreme cases will be

identified using the following ICD10 codes: Dementia (F01, F02, F03), Alzheimer's disease (G30), and blindness (H54.0, H54.1, H54.8). Clinic notes and information provided by the patients will also be used and reviewed by the study team.

Qualitative provider/clinic barriers and facilitators to implementation

To address aim 4: Determine the fidelity of all intervention components, and explore any identified patient, provider (physician, nurse, health coach), and/or health system barriers to implementation, past and present health coaches will be recruited for a focus group. Clinic nurses, physicians, and leadership/administrators who participated in the implementation of the project will be recruited for structured telephone interviews. All clinic focus group participants will be recruited by the project manager. No participant identifying information will be collected and waiver of written informed consent will be requested. The focus group will be conducted in March of 2019. The structured phone interviews will be conducted in May-June of 2019.

Risks and Benefits

Protection against Risk

Before the proposed research is initiated with human subjects, UAMS IRB approval will be obtained. The UAMS IRB guidelines are in accordance with the U.S. Department of Health and Human Services assurances. In the event that a breach in confidentiality occurs, the UAMS IRB detailed process for reporting will be followed under the direction of the PI. Any unusual occurrences or deviations from the protocol will be documented in the participants file and immediately reported to the PI to determine appropriate recourse. This research study is deemed to be of minimal risk to patients due to the educational nature of the intervention.

Research data will be managed in REDCap, (Research Electronic Data Capture), a secure, web-based, HIPAA-compliant data collection platform, which is password protected and accessible only to the research team. Information linking subjects with their unique identifier will be kept in the REDCap database, with access restricted to study personnel. Study data, by necessity, will include personal identifiers, in order to schedule and track study visits and collect medical record data for study outcomes. However, study team members will only be given access to data necessary for their project roles, described in more detail below. Patients will be assigned a unique identification number and all study data housed outside of REDCap will be de-identified using this number. We believe that in using these methods we will be compliant with the "Standards for Privacy of Individual Identifiable Health Information" under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. Participants consented to the intervention will be informed in all cases about their rights as research subjects. They may withdraw at any time during the study without penalty or loss of any healthcare benefit or service to which they are entitled. We will also attempt to reduce shame and performance anxiety as a result of interviews through extensive training of the research assistants.

Potential Benefits

Individuals who participate may gain greater knowledge and understanding about their diabetes and self-care by participating in this research. Additionally, clinics and medical homes can potentially benefit from this intervention research through the dissemination of successful strategies. The potential benefits to the field of health literacy and public health are significant; understanding health literacy in the context of diabetes self-management may lead to future interventions to improve it, which could have a significant impact on public health.

Data Handling and Recordkeeping

The Principal Investigator will carefully monitor study procedures to protect the safety of research subjects, the quality of the data and the integrity of the study. Northwestern University (NU) will be used as a central location for data processing and management. Study data will be collected and managed using NU's REDCap, which is installed on secure NU servers located in HIPAA compliant data centers. UAMS personnel needing access to the data will be provided affiliate Northwestern IDs to access REDCap directly through NU's VPN. REDCap includes a user management system allowing project owners to grant and control varying levels of access to data (e.g. de-identified-only data views) for other users. Study team members will only be given access to data necessary for their project roles. For example, only those involved in scheduling and/or meeting with patients directly will have access to patient identifiers. In addition, Research Assistants (RAs) at each site (six sites total) will be assigned to their own Data Access Group which restricts access to their site's records. Each group is blinded to all other data/records. Those managing and analyzing the data will only have access to de-identified data.

Data Analysis

Baseline characteristics and demographics will be summarized overall and by clinic using descriptive statistics (mean ± 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 H_1-H_6) 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, diabetes-related distress, diabetes-related quality of life and other clinical outcomes (blood pressure, LDL, cholesterol, BMI). Survey data will be collected at baseline, 3 and 6 months; clinical data will be collected at baseline, 3, 6, 9, and 12 months. The primary time point of interest for H_1-H_5 is three-month follow up and 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 assume missing data are missing at random, and analyses will consist of parametric statistical tests. Relevant statistical assumptions will be assessed as appropriate, and 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) in which overall mean (μ) follow-up outcome (e.g., HbA1c at 6 months) across groups will be modeled as follows:

$$\mu_i = \beta_0 + \beta_1 I(ACP\ intervention_i) + \beta_2(Baseline_i) + \epsilon_i,$$

where *i* corresponds to the individual subject (*i=1,…,total N)*, β_0 serves as an intercept, $\beta_1$serves as the intervention effect [*I(ACP intervention$_i$)* is an indicator variable for active ACP intervention arm], β_2 represents the effect of baseline value of the corresponding outcome variable, and ϵ_i represents random error. Primary analyses will test the null hypothesis H_0: $\beta_1 = 0$ against the two-sided alternative at the 5% level of significance. Similar analyses will be employed 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 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 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), the subjects will be classified by literacy level (lower literacy or higher literacy), and above analyses will be repeated within each arm but include an indicator for literacy group. Further, the primary model (above) will be modified to include a literacy level effect and corresponding arm-by-literacy level interaction term.

To address 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.

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 involve the "as treated" dataset. Additional sensitivity analyses will examine multiple imputation methods such as: "best-case", "worst-case", null scenario, and propensity score methods. These multiple imputations will result in no less than five imputed datasets from which we may obtain at least five overall parameter estimates with corresponding standard errors. From these, we will estimate an overall average for all primary and secondary outcomes with appropriate standard errors to determine whether overall conclusions are sensitive to these missing data.[42] In cases where data may not be assumed MAR (i.e., we suspect non-ignorable missingness), we will explore pattern mixture models and/or selection modeling to conduct further sensitivity analyses.

Power and Sample Size Considerations

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 (1.9, according to previous data). 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: 90% retention at six months (n= 675, 337 per arm) and 84% retention at 12 months (n=630, 315 per arm). For our primary outcome at 6 months, we will be able to detect a clinically meaningful difference in HbA1c across arms of ≥ 0.43 with 80% power. With sample size set by the primary outcome of HbA1c at 6 months, we also present differences we will be able to detect with at least 80% power for the secondary clinical outcome of systolic blood pressure and for the subgroup analyses.

Qualitative provider/clinic barriers and facilitators to implementation

To address aim 4: Determine the fidelity of all intervention components, and explore any identified patient, provider (physician, nurse, health coach), and/or health system barriers to implementation, qualitative descriptions of health systems barriers to implementation will be collected from health coaches, nurses, physicians, and clinic leadership/administration. (see

Appendices C & D, moderator's guide). Interviews and focus groups will be transcribed verbatim and verified for accuracy. Transcripts will be coded using NVIVo software. In addition, Dr. Arnold's notes taken during focus groups will be saved in Microsoft Word. These will also be entered using statistical software. The constant comparative method of grounded theory will be used to identify developing themes. Commonalities and differences in perspective understanding beliefs acceptance knowledge between patients and providers and oncologist and PCP will be analyzed across sub populations.

Ethical Considerations

This study will be conducted in accordance with all applicable government regulations and University of Arkansas for Medical Sciences research policies and procedures. This protocol and any amendments will be submitted and approved by the UAMS Institutional Review Board (IRB) to conduct the study.

Dissemination of Data

Results of this study may be used for presentations, posters, and/or publications. The publications will not contain any identifiable information that could be linked to a participant.

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Appendices

A. Diabetes Questionnaire (Study Battery)
B. Letters from Family Medical Centers
C. Moderator's Guide for Health Coaches
D. Structured Interview Guide