Clinical Trial Protocol

Reducing Emergency Diabetes Care for Older African Americans (COPDE)

NCT03466866
3/14/18

1: SPECIFIC AIMS

African Americans (AAs) with diabetes (DM) go to the emergency department (ED) twice as often as Whites. About 40% of AAs with DM go to the ED each year, and 24% use the ED as their usual place of care (vs. 13% of Whites). These racial disparities reflect differences in socioeconomic (e.g., education, income), individual (e.g., DM self-care practices), and medical (e.g., access to care) factors. The scientific premise of the proposed randomized controlled trial (RCT) is that limited access to primary care and suboptimal DM self-care are two modifiable risk factors that drive high ED use in AAs with DM.

This Phase-III RCT will compare the efficacy of COPDE (COmmunity Care to Prevent Diabetes Emergencies) vs. Enhanced Usual Care (EUC) to reduce the number of DM-related ED visits and/or hospitalizations over 12 months (primary outcome), in 230 AAs with DM, 50 years and older, who are recruited from the ED after an ED visit. COPDE is a culturally relevant intervention that extends from the ED to the community, and aims to improve access to care and DM self-care (secondary outcomes). A mediation analysis will determine whether changes in access to care and/or DM self-care explain COPDE's efficacy. A moderation analysis will determine whether participants who reside in low- vs. high-need communities [defined by Community Need Index scores (i.e., an indicator of the built environment)] respond differently to treatment.

COPDE will begin soon after the participant's index ED visit, when many patients remain uncertain how to manage DM or how to access follow-up care. Community Health Workers (CHWs), who are race-concordant with participants, will: 1) deliver in-home DM education to increase participants' knowledge and skills; 2) use DM-specific Behavioral Activation to improve DM self-care; and 3) facilitate telehealth visits with the participant's primary care physician (PCP) and a DM nurse educator to increase access to care. The control treatment, EUC, is usual medical care that is enhanced with DM self-care education. EUC matches COPDE in treatment intensity (i.e., 6 in-home sessions over 4 months, and 3 booster sessions over the next 8 months) and delivery of culturally relevant DM education, but does not include DM-specific Behavioral Activation or telehealth visits. The treatment comparison will identify COPDE's specific efficacy over and above EUC.

This RCT is significant as the population ages and becomes more racially diverse, and as ED use and costs increase. This RCT is innovative because it: 1) tests the first ED-to-community intervention designed to reduce the need for ED care in AAs with DM; 2) assesses both subjective and objective indicators of access to care; and 3) defines the specific characteristics of COPDE that confer its cultural relevance. If successful, COPDE will meet Healthy People 2020's twin goals of reducing the personal and societal costs of DM and achieving health equity for all Americans. The Specific Aims of this RCT are:

Primary Specific Aim: Test the efficacy of COPDE to reduce the number of incident DM-related ED visits and/or hospitalizations over 12 months (primary outcome) in AAs with DM. Hypothesis: COPDE will halve the number of incident DM-related ED visits and/or hospitalizations relative to EUC over 12 months.

The Secondary Aims are to:

1. Test the efficacy of COPDE to increase perceived access to care over 12 months (secondary outcome). Hypothesis: COPDE will increase Patient Satisfaction Questionnaire-18 scores to a greater extent than EUC over 12 months.

2. Test the efficacy of COPDE to increase realized access to care over 12 months (secondary outcome). Hypothesis: COPDE will increase the number of received Diabetes Quality Metrics (e.g., hemoglobin A1c testing, urine screening) to a greater extent than EUC over 12 months.

3. Test the efficacy of COPDE to improve DM self-care over 12 months (secondary outcome). Hypothesis: COPDE will increase Diabetes Self-Care Inventory scores to a greater extent than EUC over 12 months.

4. Determine if increasing subjective and/or objective indicators of access to care and/or DM self-care mediates COPDE's reduction of DM-related ED visits and/or hospitalizations. Hypothesis: COPDE will reduce DM-related ED visits and/or hospitalizations to the extent that it increases subjective and/or objective indicators of access to care and/or improves DM self-care.

The Exploratory Aims are to: 1) determine whether COPDE reduces "all cause" ED visits/hospitalizations relative to EUC.; 2) determine whether Community Need Index scores, literacy, age, and/or sex moderate treatment effects; 3) determine if COPDE improves glycemic control (i.e., lowers hemoglobin A1c levels), impacts DM-related health beliefs, reduces depression, and/or improves quality-of-life; 4) identify COPDE's treatment features that confer its cultural relevance; and 5) estimate COPDE's costs and net financial benefit to the healthcare system.

2: RESEARCH DESIGN SUMMARY

A. Study Purpose and Rationale: This Phase-III RCT will compare the efficacy of Community Care to Prevent Diabetes Emergencies (COPDE) vs. Enhanced Usual Care (EUC) to reduce incident DM-related ED visits and/or hospitalizations over 12 months in 230 African Americans with diabetes (aged 50 and older), following an ED visit for a DM-related condition.

B. Study Design: This study is a randomized controlled clinical trial in which the unit of randomization is the person. Participants will be randomized 1:1 to COPDE (the experimental treatment) or EUC (the control condition).

C. Sample: The sample will comprise 230 older persons who meet the following criteria:

Inclusion criteria:

1) African American race (self-identified)

2) Age ≥ 50 years

3) Type 1 or 2 DM

4) A DM-related cause for the ED visit in the opinion of the ED physician

5) Has a Jefferson PCP (participants receiving COPDE will have a telehealth visit with their Jefferson PCP).

Exclusion criteria:

1) Medical or psychiatric morbidity (e.g., acute stroke, schizophrenia) that would preclude study participation in the opinion of the ED physician

2) Clinically significant cognitive impairment

D. Participant Enrollment: Participants will be recruited from the ED at Thomas Jefferson University.

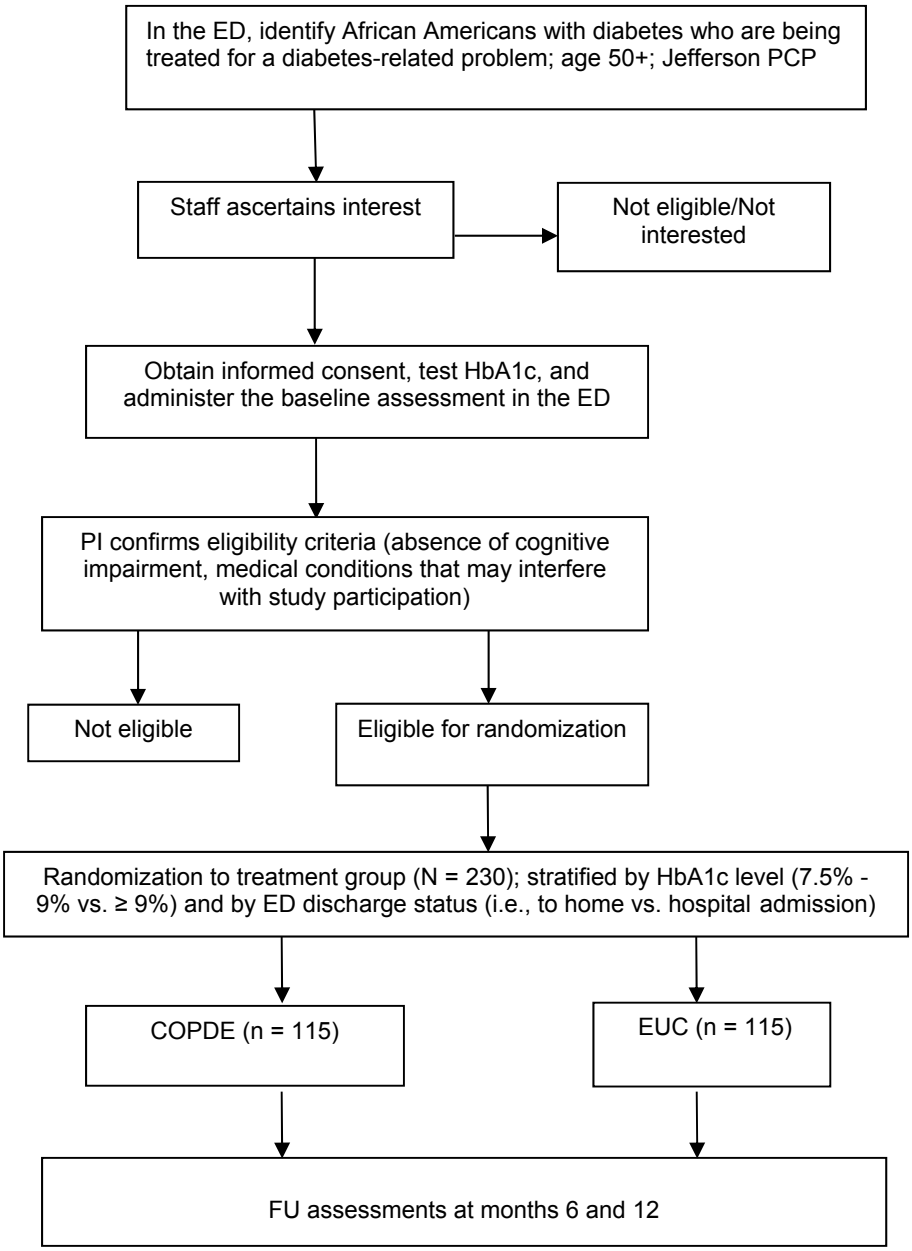
E. Informed Consent: Informed consent will be obtained in the ED by the ED Research Coordinators.

F. Participant Follow-Up. Participants will be assessed at baseline, 6, and 12 months.

Table 1. Design Summary

Objective	Determine the efficacy of COPDE to prevent ED visits and hospitalizations among older African Americans with diabetes
Major Eligibility Criteria	1) African American race 2) Age ≥ 50 years 3) Diabetes 4) ED visit for a diabetes-related problem in the past month 5) Has a PCP at Jefferson
Randomization Unit	Person stratified by HbA1c level (7.5% - 9% vs. ≥ 9%) and by ED discharge status (i.e., to home vs. hospital admission)
Treatments	COPE (n = 100) EUC (n = 100)
Recruitment Site	Emergency Department
Enrollment Site	Emergency Department
Outcome Measures	Primary: Number of diabetes-related ED visits and hospitalizations over 12 months Secondary: Scores on Patient Satisfaction Questionnaire; number of received diabetes quality metrics; scores on Diabetes Self-Care Inventory Exploratory: depression; diabetes health beliefs; all cause incident ED visits/hospitalizations; glycemic control; quality of life
Sample Size	230
Enrollment Timeline	Months 7 through 26
Masking Procedures	This is a single blind study in which the Outcome Assessor will be masked but participants, interventionists, and Primary Care Physicians (PCPs) will not
Study Visit Schedule	Assessments: Baseline, 6, and 12 months Interventions: 6 in-home sessions of COPDE or EUC, followed by booster sessions at months 6, 8, and 10
Length of Follow-up	12 months

Figure 1. Flow Chart and Study Design



3: ORGANIZATIONAL STRUCTURE

3.1. Investigators

PI: Barry Rovner, MD. Dr. Rovner is a geriatric psychiatrist and Principal Investigator of this project. He will be responsible for the overall conduct of the trial. He will assure the integrity of the study intervention, provide oversight on participant recruitment and consent, train and supervise research staff, ensure the quality of data collection and management, interpret study results, and prepare and disseminate research findings. Dr. Rovner will also hold case review meetings with the CHW interventionists for supervisory purposes.

Co-I and Project Director: Robin Casten, PhD. Dr. Casten is a Research Psychologist, and is a Professor in the Department of Psychiatry at Jefferson. Dr. Casten will oversee day to day study activities of the clinical trial. Her responsibilities will include: (1) assuring that the study treatment is appropriately implemented; (2) overseeing treatment fidelity procedures and rating recordings of treatment sessions for treatment fidelity purposes; (3) providing supervision for and training the COPDE CHW interventionist to administer Behavioral Activation and the EUC CHW interventionist to deliver the control condition (EUC); (4) overseeing treatment documentation; (5) developing the study data bases; (6) overseeing data collection, management, and quality, including the collection of data for the primary efficacy analysis; (7) preparing IRB documents; (8) randomizing participants; (9) assisting in the preparation and dissemination of research findings; (10) preparing reports for the DSMB; and (11) attending case review meetings to provide ongoing supervision to the CHW interventionists.

Co-I: Anna Marie Chang, MD, MS. Dr. Chang is faculty in the Department of Emergency Medicine at Jefferson. Together with Dr. Rising, Dr. Chang will be responsible for supervising participant recruitment and collection of baseline data. Recruitment, enrollment, consent, and the collection of baseline data (to be performed prior to randomization in the ED) will be carried out by the ED Research Coordinators. They are stationed in the ED at Jefferson where they identify all patients who enter the ED. They prospectively monitor patient care by review of the computerized medical records to ascertain whether or not patients meet criteria for enrollment in the proposed trial. Dr. Chang will also be responsible for orienting ED staff to the study. Drs. Hollander and Rising will review all ED visits and hospitalizations that occur after randomization to determine whether they are diabetes related. In instances in which Drs. Hollander and Rising disagree, Dr. Chang will be asked to review the event.

Co-I: Judd Hollander, MD. Dr. Hollander is Associate Dean for Strategic Health Initiatives at Jefferson and an Emergency Medicine physician. For this trial, he will contribute his expertise in emergency care clinical trial design and data collection. Dr. Hollander will be responsible implementation and quality assurance of the telehealth component of the COPDE intervention. Dr. Hollander will be asked to review all ED visits and hospitalizations that occur during the study to determine whether or not they are diabetes related. Dr. Hollander will also be involved with the interpretation of study data and the dissemination of study results.

Co-I: Benjamin Leiby, PhD. Dr. Leiby is the study biostatistician. His responsibilities will include creating the randomization schedules, consulting on questions of study design and execution, analyzing the data, and assisting with manuscript preparation.

Consultant: Laura Pizzi, PharmD, MPH. Dr. Pizzi will oversee the cost effectiveness aim of the trial.

She will provide ongoing consultation regarding cost measures and the proposed cost-benefit analysis, and will specifically work with Drs. Rovner and Casten to implement variables measured for cost effectiveness study. Dr. Pizzi will lead the development and refinement of measurement strategies to capture all cost-related information including training, materials, mileage, interventionists' time, supervision time, healthcare and other diabetes-related service utilization.

Co-I: Rhea Powell, MD. Dr. Powell is a physician in the Division of Internal Medicine at Jefferson. Dr. Powell's primary responsibility will be to serve as a liaison between the primary care practices at Jefferson and the study team. She will orient the Jefferson PCPs to the trial, and will train them on delivering the primary care component of the COPDE intervention. Dr. Powell will also assist in the dissemination of study results.

Co-I: Kristin Rising, MD. Dr. Rising is an Emergency Medicine physician at Jefferson. She has extensive experience with enrolling and engaging African American patients with diabetes in an acute care setting. On this study, she will work with Dr. Chang to oversee participant selection and enrollment, and the collection of baseline data in the ED. She will also conduct in-service meetings with ED staff to orient them to the trial. She will also review all ED visits and hospitalizations that occur during the study to determine whether or not they are diabetes related. Dr. Rising will play a major role in coordinating and implementing dissemination of project findings, including publications in scientific journals.

Co-I: Neva White, DNP, RN, MSN, CRNP, CDE. Dr. White is an African American certified diabetes nurse educator with extensive experience conducting diabetes self-management education programs in the African American community. For this study, she will provide diabetes education training and ongoing supervision to the CHW interventionists on the provision of diabetes education. Dr. White will attend the CHW case review meetings. She will also listen to randomly selected audio recordings of CHW treatment sessions to rate the quality of the diabetes education that they deliver. Dr. White will also provide telehealth visits to participants randomized to the COPDE intervention.

3.2. Other Staff

2 Community Health Care Worker (CHW) Interventionist: To be hired. We will hire a CHW interventionist to deliver the in-home of component of the COPDE intervention to participants randomized to active treatment. The in-home visits will include providing comprehensive diabetes education, strengthening the patient/PCP relationship, and using Behavioral Activation (BA) to facilitate diabetes-related care goals. The CHW interventionist will also facilitate telehealth visits between study participants and their PCPs and the study nurse (Dr. White). The CHW interventionist will complete treatment documentation forms to record details of each COPDE participant's treatment goals and progress, the length and date of each treatment session, obstacles to diabetes management, referrals provided, supplies dispensed (e.g., glucometer, pedometer), participants' perceptions of the intervention (e.g., cultural relevance, satisfaction with telehealth), and EMR communication between the CHW and the PCP and nurse. The CHW interventionist will audio record each treatment session. Drs. Casten and White will review the recordings to rate the quality of the diabetes education provided and to insure that BA is being delivered according to protocol. The CHW interventionist will also attend regular case review meetings with Drs. Rovner, Casten, and White for supervisory purposes. We will hire a second CHW interventionist to deliver EUC. Drs. Casten and White will review audio recordings of EUC treatment sessions to rate adherence to the EUC protocol and the quality of the diabetes education provided. The EUC interventionist will attend case review meetings with Drs. Rovner, Casten, and White. The EUC case review meetings will be separate from

the COPDE meetings.

4 ED Recruitment Coordinators, To be hired. The ED Recruitment Coordinators will work closely with Drs. Chang and Rising to implement the recruitment protocol in the ED. The ED Research Coordinators will screen the ED computerized medical records to monitor study enrollment and identify potential study participants. They will explain the study to potential participants, obtain informed consent, and administer the baseline assessments, including testing hemoglobin A1c. Drs. Chang and Rising will supervise the ED Recruitment Coordinators. Having two ED physicians performing this role will optimize the number of hours that there is direct supervision in the ED.

Outcome Assessor, To be hired. The Outcome Assessor will administer follow-up assessments at 6 and 12 months in participants' homes masked to treatment assignment (note that the baseline assessments will be performed in the ED by the ED Research Coordinators). The follow-up assessments will include questionnaires (e.g., self-reported diabetes self-management behaviors, depressive symptoms, access to primary care) and finger stick hemoglobin A1c testing. The Outcome Assessor will also review participants' medical charts at 6 and 12 months to collect data on current medications, diabetes quality metrics, and recent hospitalizations and ED visits (the primary outcome). Dr. Casten will supervise the Outcome Assessor.

Study Coordinator, Megan Kelley. Ms. Kelley will be responsible for providing assistance to Dr. Rovner with the overall conduct of the COPDE trial. In addition, she will assist Dr. Casten in managing study data. Specifically, she will: 1) maintain administrative data bases (e.g., participant contact information); (2) assist with the preparation of IRB documentation and DSMB reports; (3) manage the payment of participant incentives; (4) send weekly reports to the Outcome Assessor and CHW Interventionists to inform them of participants who are due for follow-up assessments and intervention visits; and (5) prepare weekly reports to monitor participant accrual. Drs. Rovner and Casten will supervise the Research Coordinator.

3.3. Study Committees

Data and Safety Monitoring Board (DSMB): Members of the DSMB will be appointed by the NIH. The primary responsibilities of the DSMB are to: 1) review and approve the Manual of Procedures (MOP) and the COPDE treatment manual; 2) periodically review and evaluate the accumulated study data for participant safety, study conduct and progress, and, when appropriate, efficacy; and 3) make recommendations to the NIH concerning the continuation, modification, or termination of the trial.

4: STUDY POLICIES

4.1. Consent

Written consent will be obtained by the ED Research Coordinators in the ED at participants' index ED visits (i.e., the visit in which recruitment occurs).

4.2. Recruitment

Participants will be recruited from the ED at Jefferson.

4.3. Participant costs

All patient costs directly related to study participation will be covered by the trial, and thus there will be no financial burden on study participants. This includes costs associated with HbA1c testing at baseline and follow-up assessments, DM educational materials, supplies to assist with the achievement of treatment goals (e.g., glucometers and supplies, pedometers, materials to record glucose readings and daily food intake), and telehealth visits.

4.4. Access to study information

Study documents include: (1) the grant application (excluding the study budget); (2) progress reports to the NIH; (3) materials submitted to the IRB at Thomas Jefferson University; (4) meeting minutes; (5) adverse events reports; (6) the trial protocol (i.e., this document); (7) the COPDE and EUC treatment manuals; (8) data collection forms; (9) DSMB reports; and (10) manuscripts and presentations. The study PI and Co-Is will have access to all study documents. Other study staff and the DSMB will have access to study documents on an as needed basis. The IRB is permitted access to all study materials.

The data collected from screening, blood tests, baseline and follow-up assessments, EMR, and intervention sessions will be de-identified. The identity of individual participants will not be revealed in any public report or presentation. The PI is responsible for assuring that the integrity and confidentiality of study records are maintained. Study data include raw data files, hard copies of completed data collection forms, blood test results, data collected from EMR, and intervention notes and forms. The PI (Barry Rovner, MD), Dr. Casten, and the Study Coordinator will have access to identified study data throughout the trial because they will not be involved in the direct administration of the treatments. No other study personnel will have access to raw data or identified data.

5: PARTICIPANT ENROLLMENT AND RANDOMIZATION

5.1. Introduction

This study will randomize 230 participants; 115 will be randomly assigned to each of the two treatment arms (COPDE and EUC). A participant is considered to be enrolled in the study (i.e., eligible for a baseline assessment) when all of the following conditions are met: (1) the participant meets screen criteria (aged 50+, African American ethnicity, in the ED for a diabetes-specific problem, has a Jefferson PCP; no medical conditions that preclude study participation); and (2) provides written consent. A participant is considered to be eligible for randomization when it is determined that they meet all inclusionary and exclusionary criteria.

Recruitment, enrollment, consent, and the administration of the baseline assessment (to be performed prior to randomization) will be carried out by ED Research Coordinators. The 4 ED Recruitment Coordinators are currently on staff in the ED, and their primary responsibility is to recruit, screen, and enroll ED patients for various studies. Collectively, they provide 160 hours per week of ED coverage. These 4 individuals will work on the proposed study. Based on an analysis of the ED census at Jefferson, we estimate that each ED Recruitment Coordinator will need to devote 20% to 30% of their shift to the proposed study.

The ED Research Coordinators are stationed in the ED where they identify all patients who enter the ED. They prospectively monitor patient care by review of the computerized medical records to ascertain whether or not patients meet criteria for enrollment in the proposed trial. ED Research Coordinators routinely perform this function for various studies in the ED at Jefferson. In other studies, they have consistently maintained screening, identification and assessment of greater than 90% of patients who meet eligibility requirements while they are present in the ED. Their shifts will be scheduled to maximize coverage. These hours cover more than 85% - 95% of patient presentation times to the ED. Since the average ED length of stay for patients with diabetes-related complaints (triage to discharge or hospital bed transfer) is at least 5-6 hours, patients presenting before midnight who are discharged before 7:00 AM can be identified by the same screening methods.

5.2. Inclusion Criteria

The following eligibility criteria will be assessed via EMR while patients are in the ED:

1) African American race

2) Age ≥ 50 years

3) Diagnosis of diabetes

4) A DM-related cause for the ED visit (i.e., hyperglycemia/hypoglycemia, diabetic ketoacidosis, chest pain, skin or soft tissue infection, diabetic neuropathy, retinopathy, urinary tract infection/pyelonephritis/acute renal injury, requesting DM medication refill)

5) Under the care of a Jefferson PCP

5.3. Exclusionary Criteria

The following exclusionary criterion will be assessed during screening:

1) Medical or psychiatric morbidity (e.g., acute stroke, schizophrenia) that would preclude study participation in the opinion of the ED physician

The following exclusionary criterion will be assessed during the baseline assessment and determined by the PI soon after:

1) Clinically significant cognitive impairment (i.e., scoring below age- and education-adjusted norms on the Montreal Cognitive Assessment)

5.4. Sources of Potential Participants

All potential participants will be patients presenting for care at the ED at Jefferson.

5.5. Identifying Potential Participants

The ED at Jefferson has acute ED rooms used for evaluation and treatment of patients, rooms for ED fast track assessment, and at all times is staffed with multiple full-time Emergency Medicine physicians, Emergency Medicine nurses, and Emergency Medicine resident physicians. All patient examination rooms are private cubicles which allow privacy during enrollment, consent, and administration of the baseline assessment.

The procedure for identification and recruitment of potential participants is as follows. Patients arrive to the ED by one of 3 methods: private vehicle, ambulance, or as walk-ins. All patients who present to the ED are assessed on arrival by a triage physician according to their chief injury or complaint. The date and time of the triage assessment are electronically documented. Also entered into the computer record are the date and time that patients are taken into a treatment cubicle in the ED as well as the nature of the presenting complaint. An on-duty ED Research Coordinator reviews each triage record and identifies patients who are African American, have diabetes, are presenting with a diabetes-related complaint, and are aged 50 and older. The ED Research Coordinator then approaches potentially eligible patients while they are awaiting discharge from the ED (or transfer to an in-patient unit) to briefly explain the study and ascertain study interest. For patients who are not interested, the ED Recruitment Coordinators will maintain a de-identified log to track the diagnosis, age, and gender of patients who refuse.

Interested patients will be escorted to a private exam room (if not already in one) by an ED Research Coordinator, who will then explain the study in detail to the patient and conduct the consent interview. The consent form informs participants that that all assessment and treatment sessions will be audio recorded for quality control purposes, and that information from participants' medical charts will be obtained for research purposes. The consent interview contains open-ended comprehension questions to insure that the patient fully understands the research study. For patients who agree to a consent interview, the ED Research Coordinator will enter the participant's information (name, contact information) into a REDCap data file to generate a Participant Identification number. The ED Research Coordinator will then proceed with the baseline assessment, which contains self-reported instruments (questions will be read out loud by the ED Research Coordinator and responses will be entered into REDCap), and a finger stick test to measure hemoglobin A1c. Participants are given a

copy of their consent form.

Participants are paid $20 for the consent interview and baseline assessment. Participants who agree to a consent interview are paid if they are not eligible to be in the study (i.e., unable to comprehend the consent form).

For potentially eligible patients who are admitted to the hospital (about 20%), the ED Research Coordinator will monitor the patient's hospital course, with the goal of approaching the patient one day prior to or on the day of discharge to briefly explain the study, ascertain interest, obtain written informed consent as appropriate, and administer the baseline assessment.

After the baseline assessment is completed, the ED Research Coordinator returns the participant-signed consent form and the results of the HbA1c test to the Study Coordinator. After the audio recording of the assessment has been reviewed, the Study Coordinator then logs onto REDCap to retrieve data collected during the baseline assessment. She then completes a Participant Eligibility Form (to be created during Study Start-Up) that documents the study identifier, the date of the assessment, the results of the HbA1c test, any medical/psychiatric illness, current medications, and results of the cognitive test.

The completed Participant Eligibility Form, along with the participant-signed consent form, is given to the PI. The PI will sign the consent form and review the participant's baseline information to confirm whether the participant meets all inclusionary/exclusionary criteria. The PI will indicate whether the participant is eligible for randomization, or the reason(s) for ineligibility. He will sign and date the form, and then pass it on to the Project Director (along with the PI-signed consent form).

If the participant is eligible to be randomized, the Project Director will randomize the participant in REDCap. Randomization will be stratified by HbA1c level and ED discharge status (home vs. hospital admission). The Project Director will then enter the participant's baseline assessment disposition in the "Baseline Tracking File". Possible dispositions are: (1) Eligible for Randomization; (2) Not Eligible---Possible Dementia/Cognitive Impairment; (3) Not Eligible---Medical Illness; (4) Refused to Sign Consent; and (5) Signed Consent but Refused Study Participation. Other outcomes will be added as needed. If the participant was randomized, the Study Coordinator will enter the treatment group assignment into the REDCap Treatment Assignment File. She will then mail a copy of the PI-signed consent form and a letter indicating study eligibility/ineligibility status to the participant (the letter will be created during Study Start-Up). Hard copies of the randomization result, the letter, the consent form (signed by both the participant and the PI), and the signed Participant Eligibility Form will be filed in the participant's research chart (located in a locked file cabinet in the PI's lab). The Study Coordinator will then complete a Participant Information Form, and send an electronic copy to the appropriate CHW interventionist. A hard copy will be printed and in the participant's research chart.

Procedures for assessing each inclusionary/exclusionary criterion are presented in Table 2.

Table 2. Summary of Procedures for Determining Inclusionary/Exclusionary Criteria

Inclusionary/Exclusionary Criterion	Source of Data	Method
African American ethnicity	EMR	EMR check by ED Research Coordinator
Age	EMR	EMR check by ED Research Coordinator
Diabetes diagnosis	EMR	EMR check by ED Research Coordinator
Diabetes-specific cause for ED visit	EMR	EMR check by ED Research Coordinator
Under the care of a Jefferson PCP	EMR	EMR check by ED Research Coordinator
Rule out cognitive impairment	Montreal Cognitive Assessment	Baseline assessment conducted by ED Research Coordinator; test results interpreted by PI
Medical or psychiatric morbidity (e.g., acute stroke, schizophrenia) that would preclude study participation	ED physician	ED physician

5.6. Assignment of study identification numbers

Unique study identifiers will be assigned using REDCap to all enrolled participants who agree to a consent interview. The identification number will consist of the letters "ED" (to identify the study), plus the participant's 3 initials, plus a 5 digit number chosen from a consecutive list (e.g., ED BWR00001). If the participant has no middle name, an X will be used. Identifiers must be placed on all study forms, data collection instruments, and blood samples. Blood test results are de-identified. Participant names, contact information, and study identifiers will only be linked in the Recruitment File (e.g., an electronic REDCap file that contains lists of potentially eligible patients and their recruitment outcomes), the Participant Contact file (REDCAp file), and the Community Health Worker Encounter Form (used by the COPDE CHW interventionist to provide participant information to participants' PCPs and the study nurse via EMR). The Participant Contact File links contact information and study identifiers for all enrolled participants. Access to identified files is limited to staff who need this information (e.g., Study Coordinator, Project Director).

5.7. Randomization to Treatment Group

Randomization will follow a fixed scheme with a 1:1 allocation ratio. Randomization is stratified by HbA1c level (7.5% - 9% vs. ≥ 9%) and ED discharge status (discharged home or admitted to the hospital). The study statistician (Dr. Leiby) will use a random numbers table to assign participants, and will base the schedule on a permuted random block design (with randomly chosen block sizes) to ensure balance between treatment groups on enrollment time. Randomization assignments will be loaded into a REDCap database and participants will be randomly assigned using the REDCap randomization facility. The Project Director will randomize participants once Dr. Rovner confirms eligibility criteria. Treatment sessions for participants will begin 1 to 2 weeks after randomization.

6: SCHEDULE AND OVERVIEW OF DATA COLLECTION

6.1. Overview of Schedule and Description of Participant Visits

The ED Research Coordinators will conduct baseline assessments (pre-randomization) in the ED, and the Outcome Assessor will conduct follow-up assessments in participants' homes at 6 and 12 months. All follow-up data are collected masked to treatment assignment. Data obtained during the baseline assessment will be used to determine eligibility for randomization. All participants will receive a $20 cash incentive for each of the 3 study assessments. Participants will receive the incentive at the baseline assessment even if they do not meet eligibility criteria or complete the baseline assessment. Participants will be asked to sign a receipt acknowledging the receipt of the incentives.

At the baseline assessment, the ED Research Coordinator will complete the COPDE Participant Contact Form (to be developed during the Start-Up Phase). The Outcome Assessor will update this form if necessary at the 6 and 12 month follow-up assessments. This form will contain the participant's contact information (name, address, phone number), name and phone number of the participant's PCP, and the names and contact information for emergency contacts. This form will help insure that study staff has up to date contact information on all participants. The consent form will inform participants that study staff may contact their emergency contacts if staff are unable to contact the participant.

Methods for data collection are described below. Table 5 describes how each measure will be used to assess the study aims.

6.2. Description of Study Measures

Personal Characteristics: Collected data will include age, sex, education, marital status, duration of DM, household composition, financial status, insurance type, and height and weight. We will obtain insurance status at baseline and months 6 and 12 to detect changes in coverage. We will examine these personal characteristics variables as possible treatment covariates. In separate analyses, we will examine age, sex, and health literacy as treatment modifiers. We will also assess previous ED use as an index of care-seeking behavior, which will enable us to assess COPDE's ability to change behavior via better DM self-care and access.

Community Need Index (CNI): CNI scores represent economic and structural barriers related to income, culture, education, insurance, and housing that affect overall health. CNI scores are available for every zip code in the U.S. Each barrier (e.g., percent living in poverty, percent uninsured or unemployed) is assigned a score; scores are aggregated across barriers and averaged for a final score (higher scores reflect greater community need and correlate with a higher number of hospitalizations). We will supplement the CNI by asking participants about aspects of the "built environment" (i.e., neighborhood safety, transportation difficulties, and access to healthy foods) as additional indicators of access. Access to healthy food will be measured with a 3-item instrument that asks whether stores that stock produce and low fat foods are located within a mile of participants' homes. We will also ask participants if they have missed medical appointments due to transportation issues, and whether they limit daily activities due to feeling unsafe. CNI will be examined as a potential treatment modifier.

Cognition: We will use the Montreal Cognitive Assessment (MoCA) to assess cognition, and screen for the exclusion criterion of significant cognitive impairment (i.e., scoring below age- and education-adjusted norms on the MoCA). The MoCA is a brief cognitive screening tool that assesses multiple domains of cognition (e.g., executive function, memory, language) and has known validity in AAs. After the baseline assessment, the PI will evaluate participants' performance on the MoCA to determine their cognitive function.

Health Literacy: To assess health literacy, we will use the Literacy Assessment for Diabetes (LAD)**.** The LAD tests pronunciation of DM-related terms, and correlates highly with other literacy tests. Literacy will be considered as a potential covariate and treatment modifier.

Alcohol Use: Alcohol use will be assessed at baseline with the 3-item short form of the Alcohol Use Disorders Identification Test (AUDIT). The AUDIT has adequate sensitivity and specificity to identify potential alcohol abuse. Alcohol will be evaluated as a potential covariate.

DM-Specific Health Beliefs Model Scale: We will use this instrument as an exploratory outcome to assess change in DM-specific health beliefs (i.e., perceived benefits, side effects and general barriers to DM care (e.g., *"I worry about the long term effects of my DM medication."*), perceived susceptibility to DM complications, and perceived severity of DM.

Insurance Status and Type**:** We will classify insurance type as: government (Medicare, Medicaid, other government), private (Blue Cross/Blue Shield, other commercial, managed care), self-pay, other (industrial and worker's compensation, unclassified), unknown insurance, and no insurance. insurance will be a potential covariate.

Incident ED Visits and/or Hospitalizations: The primary outcome is the number of incident DM-related ED visits and/or hospitalizations that occur over 12 months. Each ED visit or hospitalization counts as a single event (an ED visit that leads to hospitalization counts once). An exploratory analysis will consider all ED visits and/or hospitalizations regardless of cause. To determine if an ED visit/hospitalization is DM-related or not, ED Co-I's Hollander and Rising (masked to treatment assignment) will independently review medical records to make the determination. For discrepant views, Co-I Chang will make the deciding determination. For descriptive purposes, we will classify incident ED visits as "early" (i.e., ≤ 30 days post-baseline) vs. "late" (i.e., > 30 days); "related" (i.e., due to an associated problem) vs. "not related"; and "expected" (e.g., suture removal) vs. "unexpected" (i.e., a new medical problem). To identify incident ED visits/hospitalizations we will use two complementary approaches:

1) At the 6- and 12-month follow-up assessments, the Outcome Assessor will ask about ED visits and/or hospitalizations during the previous 6 months. For each event, data on presenting symptoms, diagnostic code(s), event date(s), facility, and length of stay will be collected. The Outcome Assessor will verify the details all ED visits and hospitalizations in EMR. For ED visits/hospitalizations that occur outside of Jefferson, we will seek participants' permission (i.e., sign a medical release form) to obtain clinical information from the outside facility.

2) At 6 and 12 months, for all participants the Outcome Assessor will review the EMR to detect ED visits and/or hospitalizations that participants may fail to report. Details regarding each event will be recorded.

In addition, at any time that participants inform study staff (e.g., Outcome Assessor, CHW interventionists) that they had an ED visit or hospitalization, study staff will check EMR to obtain

details of the event. Participants will be asked to sign a medical release form for events that occurred outside of Jefferson. Study staff will contact the non-Jefferson facility for details about the event.

Whenever staff learns of an ED visit or hospitalization (e.g., via routine EMR checks at 6 and 12 months, 6 and 12 month follow-up assessments), the Study Coordinator will enter the details in REDCap, including the diagnostic codes. Drs. Hollander and Rising will be notified, and will be asked to independently rate whether or not the event is diabetes-related. In cases where their ratings are discrepant, the Study Coordinator will ask Dr. Chang to rate the event, and the majority rating (i.e., 2 out of 3) will be the final determination. Drs. Hollander, Rising, and Chang will enter their ratings in REDCap.

Subjective Access to Care**:** We will use the Patient Satisfaction Questionnaire-18 (PSQ-18) to measure subjective perceptions of access to care (higher scores reflect better access). We will test COPDE's efficacy to increase PSQ-18 scores (secondary outcome), and also determine if change in PSQ-18 scores mediates COPDE's treatment effect (PSQ-18 as a mediator). This 18-item instrument has demonstrated reliability and validity, and includes 7 subscales: 1) General Satisfaction (e.g., "*I'm dissatisfied with some things about the medical care I receive."*); 2) Technical Quality *("I have some doubts about the ability of the doctors who treat me."*); 3) Interpersonal Manner *("My doctor treats me in a very courteous and friendly manner."*); 4) Communication (*"Doctors are good about explaining the reasons for medical tests."*); 5) Financial Aspects (*"I have to pay for more of my medical care than I can afford."*); 6) Time Spent with Doctor (*"Doctors usually spend plenty of time with me."*); and 7) Accessibility (*"It's hard to get an appointment right away."*). Responses are scored (1 to 5) in a "strongly agree/strongly disagree" Likert format. We will also examine change in the individual subscales.

Objective Access to Care: We will measure participants' receipt of up to five American Diabetes Association-recommended DM Quality Metrics as an objective indicator of realized access to care. The 5 metrics will be: twice yearly HbA1c testing (outside the research protocol), annual blood pressure check, urine protein testing, foot exam, and influenza vaccination. We will review the EMR to identify receipt of these 5 metrics. Scores will range from 0 to 5, with higher scores reflecting better achieved access to the health system. We will test COPDE's efficacy to increase the number of received DM Quality Metrics (secondary outcome), and also determine if change in number of received DM Quality Metrics mediates COPDE's treatment effect (DM Quality Metrics as a mediator). For each indicator, we will count them as having occurred if the date of the event is within 30 days in either direction of the due date.

Hemoglobin A1c (HbA1c): HbA1c level reflects glycemic control over the preceding 3 months. We will test COPDE's efficacy to lower HbA1c level (exploratory outcome). The ED Research Coordinators and Outcome Assessor will use the DCA Vantage point-of-care device to measure HbA1c (results correlate 0.96 with central laboratory testing). Staff will be trained and certified to obtain and handle the samples following standard operating procedures. HbA1c will be a secondary outcome and a potential mediator. The specifications of the DCA Vantage HbA1c test are as follows:

Table 3. Specifications of the DCA Vantage HbA1c test

System Description:	Point-of-care immunoassay analyzer
Quantitative Tests:	Hemoglobin A1c (whole blood): Range: 2.5% to 14% (4mmol/mol to 130 mmol/mol)
Test Format:	Self-contained immunoassay cartridges
Formulas for Calculated Results	% HbA1c = (HbA1c/Total Hemoglobin) x 100 eAG* mg/dL = (28.7 x HbA1C) – 46.7 eAG* mmol/L = (1.59 x HbA1C) – 2.59
Formulas for Dual Reporting From IFCC to % HbA1c:	NGSP = (0.09148 x IFCC) + 2.152 JDS = (0.09274 x IFCC) +1.724 Mono-S = (0.09890 x IFCC) + 0.884
Formulas for Dual Reporting From % HbA1c to IFCC mmol/mol	IFCC = (10.93 x NGSP) – 23.50 IFCC = (10.78 x JDS) – 18.59 IFCC = (10.11 x Mono-S) – 8.94
Test Measurement:	Automatic, optional transmission
Test Method:	HbA1c and Albumin: monoclonal antibody agglutination reaction
Time to Test Results:	HbA1c - 6 minutes; A:C Ratio - 7 minutes
Sample Volume:	HbA1c - 1µL whole blood
Sample Preparation:	No pretreatment; no pipetting required
Sample ID/Operator ID Entry:	Optional; via touch screen or bar code reader
Calibration:	Lot-specific calibration card provides automatic calibration with every cartridge Traceable to International Federation of Clinical Chemistry (IFCC) reference materials and test methods for measurement of HbA1c
Storage Capacity/Memory:	4000 patient and/or control records ip to 1,000 operator IDs
Display:	Color touch screen with 1/4 VGA resolution
Data Export:	Via USB flash drive to PC or direct to LIS/HIS or data manager
Flexible QC Scheduling:	None, Automatic Reminders or Required
QC Testing:	Optional lockout if schedule not followed or QC fails
User/Operator Access:	Restricted, if desired, to protect patient and QC data and prevent unauthorized use
Matching Lab Results/ Reference Method:	Adjustable correlation to reference methods
Reference Ranges:	User-definable reference ranges available for HbA1c
Serial Port:	RS232, ASTM
Ethernet Connection:	ASTM or POCT1-A2
Bi-Directional Capabilities:	ASTM: Remote computer can be set up to lock out patient tests POCT1-A2: Remote computer can be set up to lock out patient tests, and send operator list to analyzer
USB-Port:	Standard USB 2.0
External Bar Code Reader	Serial (9 pin)
Onboard Printer:	54 mm (2 in) width, thermal/label stock
External Printer:	Supports standard PCL printer interface via USB port

The analyzer yields a time-stamped de-identified printout of the test result. The result will not be shared with the participant. The printout will be placed in a bank bag. Immediately after the visit is completed, the ED Research Coordinators and Outcome Assessor will give the data to the Study Coordinator. The Study Coordinator will enter the test result in the REDCap HbA1c Data File. This file will be de-identified. After the Study Coordinator enters the test result, she will give the print out to the Project Director, who will verify that the result was correctly entered in the data file. There will be a field for each of the HbA1c results obtained at baseline and follow-up assessments for the Project Director to indicate that she verified that the test result was correctly entered. Incorrectly entered results will be corrected. Hard copies of the print out will be stored in participants' research charts.

Diabetes Self-Care: The Diabetes Self-Care Inventory-Revised assesses self-reported adherence to 12 DM self-care behaviors (e.g., medications, glucose monitoring, exercise, diet). Total scores on this reliable and valid instrument correlate with HbA1c and are sensitive to treatment effects. We will test COPDE's efficacy to improve DM self-care (i.e., increase DSCI-R scores) (secondary outcome), and also determine if change in DSCI-R score mediates COPDE's treatment effects on ED/hospitalization rates (DM self-care as a mediator).

Depression: Clinically significant depressive symptoms occur in 25% of persons with DM. Depression impairs DM self-care and worsens glycemic control. We will assess depressive symptoms using the Patient Health Questionnaire-9 (PHQ-9), which has known reliability and validity in older AAs. The PHQ-9 yields a continuous measure of depressive symptoms based on their number, duration, and clinical significance. Depression is an exploratory outcome. For participants who respond with anything other than "Not at All" to the question on suicidal ideation, staff will administer the Columbia-Suicide Severity Rating Scale to assess risk for harm.

DM-Specific Quality-of-Life (QoL): We will use the Diabetes Quality of Life Brief Clinical Inventory to assess QoL. This 15-item scale yields a total health-related QoL score that predicts DM care behaviors and satisfaction with DM control. Diabetes quality of life will be an exploratory outcome.

Medical Comorbidity and Medication Use: We will use the Health-Related Quality of Life Comorbidity Index (H-RQLCI), which assesses 20 medical conditions (e.g., dyslipidemia, hypertension), and provides a valid index of overall medical comorbidity. The Outcome Assessor will review current health conditions and medications (e.g., opioids) with participants, and will obtain parallel information from the EMR to ensure completeness and accuracy. We will use all sources of information to score the H-RQLCI, which will serve as a treatment covariate that captures overall medical comorbidity as well as changes in health status.

Intervention Costs: As an exploratory aim, we will conduct a cost-benefit analysis based on best practices in applied health economic methods. The CHW interventionists will log their time spent preparing for, scheduling, documenting, traveling, and delivering each COPDE or EUC session. We will capture supervision and screening costs using time-logs maintained by the study coordinator. Other direct costs will include ED, inpatient, outpatient, and medication costs.

Treatment Process Measures: The COPDE CHW will document: 1) the number and duration of sessions; 2) the extent and quality of participant adherence to treatment goals; 3) participants' satisfaction with the COPDE treatment; 4) Action Plan content (and successful and unsuccessful strategies utilized), 5) participants' satisfaction with the telehealth visits; (6) number and content of EMR contacts; 7) participants' perceptions of the cultural appropriateness of the COPDE intervention;

8) educational topics discussed at each treatment session; and 9) the extent to which family/friends participated in each visit. The EUC CHW will document: 1) the number and duration of sessions; and 2) the extent to which family/friends participated in each visit. Table 4 depicts the forms we will use to document treatment process variables.

Study Process Measures: We will query PCPs, ED staff physicians, and ED administrative staff to inquire about study implementation, engagement, concerns (e.g., impact on work flow), and acceptability of CHW collaboration. For the CHW - PCP communication via the EMR, we will measure: 1) number of PCP responses/CHW queries; 2) timeliness of PCP responses (i.e., none, or within 1, 2, or ≥ 2 days); and query type (e.g., check medication dose, administration time, or side effect). These data will be analyzed descriptively to explore the relationship between PCP communication and study outcomes.

Table 4. Treatment Process Data

Form	Purpose	Timing
Action Plan Form	Record steps to achieve DSM goals	Every time a goal is made or revised
Booster Session Form	Record goal progress during booster sessions	After each booster session
Community Health Worker Encounter Form	Document content of COPDE sessions	At every session
Cultural Relevance Rating Form	Participants rate the cultural appropriateness of the intervention	At the end of session 6 and the last booster session
ED Visit Form	Record participant's perception of their recent ED visit	Session 1
EMR Check Form	To find out about medication changes and new health problems	Prior to each booster session
Family/Friend Involvement Form	Record whether family/friend was involved in the treatment	After each session; completed for COPDE and EUC participants
Goal Satisfaction Form	Rate participant's level of satisfaction with goals	The session following the one in which a new goal was formulated or revised
Incident Hospitalization/ED Visit Form	To gather information on hospitalizations and ED visits that occurred after the index ED visit	Any time that the CHW learns of a hospitalization/ED visit after the index visit
Initial Team Contact Form	To inform the PCP and nurse that the participant was randomized to active intervention and to collect preliminary information about the participant	Prior to session 1
Master Goal Log	Document progress with treatment goals	Every time a goal is made or revised
Materials Log	Record all materials dispensed to participant (e.g., glucometer, pedometer, divided plate)	Every time the CHW gives the participant any materials
Participant Information Form	Provide background information on newly randomized participants to interventionist	Given to the CHW when a participant is randomized to COPDE
Referral Log	Record any referrals made to study participants	Every time the CHW makes a referral to the participant; completed for COPDE and EUC participants
Satisfaction with Telehealth visits	Rate participant's perceptions of the telehealth visits	After the 6th session and the last booster session
Session Documentation Form	To record the date and length of each visit, and the length of time spent traveling to and from each visit	After each session; completed for COPDE and EUC participants
Telephone Log	Record duration and purpose of all telephone calls to participant	Every phone call between CHW and participant; completed for COPDE and EUC participants
Treatment Note	Record any notes relevant to the participant's treatment	After each session
Treatment Satisfaction Form	Rate participant's level of satisfaction with the intervention, and how much they felt the intervention respected their cultural beliefs	At the end of session 6 and the last booster session

Table 5. Conceptualization of Study Measures

Number of diabetes-specific and other ED visits and hospitalizations over 12 months	- EMR review - Self-report - Medical record request for ED visits and hospitalizations that occur outside of Jefferson	FU[1]
Secondary Outcomes and Potential Mediators:		
Diabetes Self-Management	- Diabetes Self-Care Inventory-Revised (DSCI-R)	Baseline, FU
Subjective access to care	- Patient Satisfaction Questionnaire-18	Baseline, FU
Objective access to care	- DM Quality Metrics	Baseline, FU
Exploratory Outcomes:		
Glycemic Control	- Hemoglobin A1c	Baseline, FU
Depression	- Patient Health Questionnaire (PHQ-9) - Columbia Suicide Severity Rating Scale (for participants who express suicidal ideation)	Baseline, FU, Anytime for suicidal ideation
Quality of Life	- Diabetes Quality of Life Brief Clinical Inventory	Baseline, FU
Diabetes Health Beliefs	- DM-Specific Health Beliefs Model Scale	Baseline, FU
Intervention Costs	- CHW interventionist time - Time spend supervising the CHW interventionists - Medical costs	
Potential Treatment Modifiers		
Built Environment	- Community Needs Index (CNI) - Access to healthy food, neighborhood safety, transportation to medical appointments	Baseline
Health Literacy	- Literacy Assessment for Diabetes (LAD)	
Demographics	- Age, sex	Baseline
Potential Covariates		
Demographic and Background Characteristics	-Age, sex, education, duration of DM, marital status, household composition, financial status, insurance status -Literacy -Alcohol Use Disorders Identification Test (AUDIT)	Baseline
Medical Comorbidity	-Health-Related Quality of Life Comorbidity Index (HRQL-CI) -Current medications (taking more than 5 medications; opioid use) -Height/weight -Previous ED use from medical records (self-report and EMR)	Baseline, FU
Screening		
Cognitive Function	- Montreal Cognitive Assessment (MoCA) to rule out cognitive impairment	Baseline

6.3. Participant educational materials

At the conclusion of the baseline assessment, the ED Research Coordinators will give all participants a packet of educational materials (regardless of whether participants are eligible for randomization). This packet will contain the following documents:

- 4 Steps to Control your Diabetes for Life
- Celebrating life: A guide to Depression for African Americans
- What I Need to Know about Physical Activity and Diabetes
- The A1c Test and Diabetes
- Diabetes and Healthy Eating
- My Plate Planner
- Is the Plate Method of Eating Right for You
- Talking with your Doctor

These patient-friendly educational materials are written in lay language, and are culturally relevant for African Americans. For participants randomized to COPDE, the CHW interventionist will incorporate the materials into participants' diabetes education during treatment sessions.

6.4. Follow up assessments

Follow-up assessments will be conducted by the Outcome Assessor at months 6 and 12 in participants' homes. Weekly, the Study Coordinator will generate a computerized list of participants who are due for their follow-up assessments within the upcoming 2-week period. Included on the list will be the date of the last assessment for each participant as well as the ideal date that the assessment should take place. The date of the baseline in-home assessment will determine when the follow-up assessments should occur. For example, if the baseline assessment date was 4/1/18, ideally the 6-month assessment should take place on 10/1/18. Follow-up assessments will be timed so as to take place within 14 days of the ideal assessment date. If unforeseeable events prevent the follow-up assessment from occurring on time, an Out of Window Form (to be created and finalized during the Start-Up phase) will be completed by the Study Coordinator. We will not attempt to conduct follow-up assessments on participants who are more than 30 days past due for their follow-up assessment. If a participant misses their 6 month assessment, we will attempt to contact them when they are due for their 12 month assessment.

6.5. Out of window policy

For any assessments that occur outside of the time window (i.e., 15 to 30 days past the ideal assessment date), an Out of Window form will be completed. The following information will be recorded on this form: Participant's name and ID, the assessment that is out of window, the ideal date of the assessment as well as the actual date of the assessment, and the reason that the assessment is out of window.

The goal is to have 80% of the assessments occur within the ideal time frame as specified above. The Project Director will produce monthly reports that delineate the percent of assessments that are

occurring within the desired range. These figures will be closely monitored, and corrective strategies will be implemented as needed.

6.6. Missed Assessments

If a visit is not conducted within the allowable time window, which is 30 days on either side of the target date for the follow-up assessments, it will be designated as a missed visit. If any part of a visit is conducted within the allowable time window but the entire visit is not completed, it will be designated as an incomplete visit.

If a participant misses a scheduled assessment, the Outcome Assessor will contact the participant to reschedule the assessment prior to the end of the visit window. If the participant is unable to complete an assessment within the acceptable visit window, he/she will complete a "Missed Visit Form" (to be created during the Start-Up phase). All attempts and contacts will be documented.

The Outcome Assessor should collect what information they can by telephone. If the assessment is conducted over the telephone, any adverse experiences, hospitalizations, or other information available are recorded on the appropriate assessment forms.

6.7. Medical chart review

Once a participant is randomized, the Outcome Assessor will review participants' medical charts at 6 and 12 months, and will complete a standardized form to document current medications, medical diagnoses, health visits, lab tests and screens, and ED visits and hospitalizations.

6.8. Attrition

The Study Coordinator will complete an "Attrition Form" (to be created during Start-up) that details the date and reason for attrition (e.g., no longer wants to participate, death, illness).

6.9. Schedule of Study Activities

Study activities will conform to the following schedule:

Screening:	At the Index ED Visit
Baseline assessment:	At the Index ED Visit
Review baseline assessment:	1 week after baseline assessment
PI confirms eligibility:	1 week after baseline assessment is reviewed
Randomization:	3 days after eligibility is confirmed
COPDE or EUC treatment begins:	1 to 2 weeks after randomization
6 initial treatment sessions:	To be completed 4 months from baseline
6 month follow-up assessment:	6 to 7 months after randomization
3 booster treatment sessions:	6 to 12 months after randomization
12 month follow-up assessment:	12 to 13 months after randomization
Medical chart reviews:	Baseline, 6, and 12 months

7: CERTIFICATION PROCEDURES

7.1. Introduction

This chapter describes the study activities that require certification and/or training.

Certification and/or training are required for the following study activities:

1. Determining eligibility/exclusionary criteria for study enrollment
2. Obtaining informed consent
3. Conducting study assessments
4. Measuring HbA1c level
5. Administering the COPDE and EUC in-home intervention sessions
6. Orienting the PCPs
7. Orienting the ED staff
8. Recognizing and handling of psychiatric and medical emergencies
9. Collecting data from medical charts
10. General research training
11. Conducting the telehealth visits

All study team members will attend a 2-hour workshop at Jefferson at the beginning of the study. During this workshop the PI will present an overview of the study, including the role of each team member. All team members will be required to read this protocol prior to the workshop.

7.2. Determining Eligibility/Exclusionary Criteria for Study Enrollment

Participants will be recruited from the emergency department (ED) at Jefferson by ED Research Coordinators. Drs. Chang and Rising will be responsible for training the ED Research Coordinators on identifying potential participants.

7.3. Obtaining Informed Consent

Dr. Casten will train the ED Research Coordinators to obtain informed consent in writing. Each ED Research Coordinator will conduct 5 mock consent interviews with the Study Coordinator. These interviews will be audio tapped and reviewed by Drs. Rovner and Casten. Feedback is provided, and if necessary, additional mock interviews will be requested. Certification is granted by Drs. Rovner and Casten when errors are minimal.

7.4. Conducting Study Assessments

Dr. Casten will train the ED Research Coordinators and the Outcome Assessor on REDCap and procedures for transporting data. Dr. Rovner will train on testing HbA1c, and measuring height, and weight. He will also train staff to administer each instrument in the assessments (baseline and follow-up). Training will include a half day of instruction. The ED Research Coordinators and the Outcome Assessor will then observe Dr. Rovner administer the assessment to Dr. Casten, after which Dr. Rovner will review the assessment. The Outcome Assessor and the ED Research Coordinators will

then administer the assessments to 5 practice participants. Study staff will take turns acting as practice participants. Certification will be granted by Dr. Rovner upon successful completion of 5 practice participants. Dr. Rovner will have regular meetings with the ED Research Coordinators and the Outcome Assessor throughout the study to review assessments and coding decisions, and address any questions that may arise. All assessments will be audiotaped, and Dr. Rovner will review a random 10% for quality assurance purposes. He may increase the number of assessments selected for review if error rates exceed 5%.

7.5. Measuring HbA1c level

The ED Research Coordinators and the Outcome Assessor will be required to pass the blood borne pathogen training course at Jefferson. Dr. Rovner will train staff to measure HbA1c using the DCA Vantage point-of-care device. Staff will practice testing HbA1c and obtaining samples on 5 study staff each. Certification will be granted by Dr. Rovner upon successful completion of 5 practice administrations.

7.6. Administering the COPDE and EUC in-home intervention sessions

Training for the CHW interventionists will be conducted by Drs. Rovner, White, and Casten. The COPDE and EUC CHW interventionists will attend a 2-day workshop that will cover the following: (1) instruction on providing DSM education to participants (e.g., providing general education using lay language, advising on appropriate nutritional and exercise goals, correct use of glucometers, handling high and low glucose, incorporating the participant educational materials into the diabetes education); (2) instruction on recognizing cognitive impairment and discussing depression with participants (e.g., defining and de-stigmatizing depression, links between depression and diabetes, depression treatment, relationship between depression and activity engagement); (3) supportive psychological techniques (e.g., conveying empathy); and (4) cultural and social influences on DM self-care.

After the workshop, the CHW interventionists will be asked to take the Diabetes Knowledge Test.

Dr. Casten will train the COPDE CHW interventionist on the principles and administration of Behavioral Activation (e.g., theoretical basis and practical implementation, incorporating BA into DSM education, instruction on completing Action Plan and other treatment documentation forms). She will also provide instruction for the completion of process data and administrative forms. In addition, the CHW will attend a half-day workshop on procedures for communicating information to participants' PCPs via EMR. This aspect of training will be conducted by a staff person from the Information Technology Department at Jefferson. At the completion of the training, the COPDE interventionist will be assigned 5 training cases to be treated consecutively for 6 sessions over 8 weeks. The EUC interventionist will be assigned 3 training cases. Drs. Casten and White will review audiotapes of sessions, and will meet weekly with the interventionists to answer questions, provide feedback, and problem-solve the administration of intervention as needed.

The CHW interventionists must meet preset requirements of competence before being certified to administer the COPDE or EUC treatments to randomized participants. These requirements are:

- Scoring ≥ 80% on the revised Diabetes Knowledge Test, which will be administered at the conclusion of the training workshop. If the CHW interventionist's score is < 80%, Dr. White will meet with them to review key aspects of diabetes education. The EUC interventionist will also be required to take this test. The CHW interventionists will be given the test a second time after meeting with Dr. White.

- Achieving favorable ratings on audio recorded treatment sessions of practice participants. Drs. Casten and White will rate all practice sessions using the COPDE or EUC Treatment Fidelity Form (to rate the quality of the delivery of diabetes education, explaining the COPDE treatment to participants, applying principles of Behavioral Activation, and formulating and evaluating Action Plans).

If ratings on any of the above instruments are unsatisfactory, Dr. Casten may assign additional practice participants.

Practice participants will be recruited as follows. After obtaining IRB approval to enroll practice participants (including an informed consent form specific to practice participants), the Study Coordinator will contact participants who participated in a diabetes pilot study. She will explain to these participants that a large trial is now being conducted, and that they are being offered the opportunity to receive 6 sessions of either study intervention to be delivered over 8 weeks. Participants will also be told that their HbA1c will be tested at the first and last sessions (for COPDE participants only). We will deliver 6 sessions to these practice patients; we will not administer booster sessions. If a participant is agreeable, the CHW interventionist will make a home visit to obtain informed consent. Dr. Casten will train the interventionist to obtain consent for practice participants. At the first visit, after consent is obtained, the interventionist will proceed with the first treatment session. Five additional treatment sessions will occur within 8 weeks of the first session. There will be 3 telehealth visits for COPDE participants: 1 with the participant's PCP and 2 with Dr. White (the diabetes nurse). There will be no telehealth visits for EUC participants.

During the CHW interventionist training workshop, Dr. Casten will review procedures to maintain treatment fidelity, including the handling of session recordings. The interventionists will be informed that they will receive feedback for each session that is reviewed, and that corrective training may be implemented if necessary. Ongoing supervision during the course of the study will be accomplished by holding biweekly case review meetings with Drs. Rovner, Casten, and White, and the interventionists (separately for the COPDE and EUC CHW interventionists). During these meetings, the interventionists will present their active cases, have the opportunity to ask questions, and problem-solve treatment issues.

7.7. PCP Training

Dr. Powell will act as the liaison and channel of communication between the primary care providers at Jefferson and the study team. All primary care physicians at Jefferson are already trained on using JeffConnect, Jefferson's telehealth platform. During study start-up, Dr. Powell will present the study at 3 monthly consecutive departmental meetings for both Family Medicine and Internal Medicine faculty. These presentations will include: (1) an overview of the study goals; (2) a description of the study design and the COPDE intervention; and (3) instruction on how to administer the intervention to

patients randomized to the COPDE intervention. The presentation on administering the intervention will include training on: (1) collaborating with the diabetes nurse and the CHW via EMR; (2) the content of the telehealth visits provided to participants; (3) working with the diabetes nurse to modify medication regimens; (4) incorporating information provided by the CHW on diabetes self-management behaviors, goals, and barriers into routine care; and (5) completing study forms. For faculty who are not able to attend all or some of the meetings, Dr. Powell will contact these physicians personally to discuss the study and to provide them with relevant information. In addition, after the initial training sessions, Dr. Powell will attend faculty meetings on a quarterly basis to provide study updates (e.g., recruitment progress), trouble shoot any issues that arise, and answer questions from the PCPs. Throughout the study, she will be available by phone and email to physicians who have questions or concerns about the study. In an ongoing trial that involves PCP/study staff collaboration via EMR, we have not encountered any situations whereby the PCPs are not responsive to the collaborative process. To maintain this level of PCP involvement in the proposed study, study staff will notify Dr. Powell of situations whereby a PCP is unresponsive. Dr. Powell in turn will reach out to the PCP, re-educate them about the study, and stress the importance of team collaboration.

7.8. ED staff

Drs. Rising and Change routinely conduct regular in-services regarding research projects being conducted in the ED. These in-services are attended by ED faculty, residents, nursing and ancillary staff. Since there are >20 ED faculty, 39 Emergency Medicine residents, and approximately 100 nursing and ancillary staff members who work different shifts, each set of in-services must cover the day, evening, and nighttime and weekend staff. The ED typically in-services each shift twice to attempt to capture staff who was not working during the first session, in addition to having ongoing re-orientation sessions 3 times per year. This amounts to 24 orientation/in-service sessions annually for the ED staff. Most (75%) occur during the off hours. During these in-services, Drs. Rising and Chung will orient ED staff to the proposed project, including study goal, and methods for identifying, enrolling, and consenting potential participants.

7.9. Recognizing and handling of psychiatric and medical emergencies

Dr. Rovner will train the Study Coordinator, the ED Research Coordinators, the Outcome Assessor, and the CHW interventionists on the recognition and management of psychiatric and medical emergencies, including procedures for reporting such events to Drs. Rovner and Casten. He will also train staff on the protocol for managing suicidal ideation. This will include training on recognizing and inquiring about potential suicidality, and how to handle it when suspected. Procedures for managing suicidal ideation are designed so that there is a low threshold for alerting Dr. Rovner. This approach will insure that all cases of potential suicidal ideation are appropriately evaluated.

7.10. Collecting data from medical charts

Dr. Rovner will train the Outcome Assessor to collect data from medical charts, including the primary outcome (number of ED visits and hospitalizations). He will have the Outcome Assessor garner medical chart data on 10 practice charts, and he will then review the completed forms for accuracy. Certification will be granted by Dr. Rovner upon successful completion of obtaining medical chart data from 10 practice charts. During the course of the study, Dr. Casten will review a 20% random sample

of completed forms for quality control purposes. Dr. Leiby will create a randomization schedule for this purpose. Dr. Casten will specifically verify completeness and accuracy of the data that the Outcome Assessor collects from EMR. In instances in which errors are detected, Dr. Casten will meet with the Outcome Assessor to review errors and to provide additional instruction as necessary. The PI may decide to increase the number of charts selected for review if the error rate becomes excessive (i.e., greater than 5%).

7.11. Basic training for all staff

7.11.1. Human Subjects Protection

As per the regulations of the Institutional Review Boards (IRB) at Thomas Jefferson University, all study staff are required to be trained and certified in the practices of human subjects research. The training is done through the Collaborative Institutional Training Initiative (CITI).

7.11.2. Handling of Study Data

Dr. Casten will train all staff on the handling and transport of study data. This will include procedures for: (1) transporting hard copies of data (e.g., all hard copies will be transported using IRB-approved locked bank bags and stored in locked file rooms at Jefferson); (2) handling electronic data (e.g., data can only be accessed and stored on IRB-approved password protected encrypted devices); (3) de-identifying data (e.g., the use of study identifiers rather than PHI on study documents); (4) only using Jefferson email addresses for study communication; and (5) not using personal cell phones to communicate study information.

7.11.3. REDCap

All study data will be entered into Research Electronic Data Capture (REDCap), and when appropriate, will be exported to SPSS or SAS. Study staff will receive training on using REDCap. During the start-up phase, the Project Director will produce a manual to orient staff to all study data bases, and to provide step-by-step instructions for using REDCap.

7.12. Conducting the telehealth visits

The PCPs are already trained in conducting and facilitating the telehealth visits. Dr. Hollander will train Dr. White and the CHW interventionists on the technical aspects of facilitating the telehealth visits.

8: QUALITY ASSURANCE AND MONITORING PROCEDURES

8.1. Introduction

The PI assumes responsibility for insuring that all study staff are adhering to the treatment protocol and maintain good clinical practice. In conducting clinical research that involves multiple follow-up assessments, several issues can compromise the integrity of the data. These include: (1) unmasking; (2) treatments not being delivered as intended; (3) data not being obtained in a standardized manner; (4) attrition and missing data; and (5) handling of crisis situations. Plans for addressing each of these issues are discussed below.

8.2. Preservation of masking

This is a single-masked trial. The Outcome Assessor will be masked to treatment assignment. The PI, Participants, the Project Director, Study Coordinator, the CHW interventionists, the study nurse, and PCPs treating participants randomized to COPDE will be unmasked. Since this study is testing a behavioral intervention and there are no anticipated risks associated with study participation, there are no circumstances in which there will be unmasking based on untoward medical events.

An unavoidable aspect of behavioral intervention research is that participants are aware of their treatment assignments. Several measures will be undertaken to preserve the integrity of masking. First, the Outcome Assessor, who assesses all outcomes, will have no knowledge regarding treatment assignment. Masked staff will not have access to any data files or charts that contain information on treatment assignment. Hard copies of data will be stored in a locked, secure file room at Jefferson. Electronic copies will be stored on an encrypted, password protected server. Second, prior to performing any assessment, the Outcome Assessor will emphasize to all participants the importance of not revealing their treatment assignment. They will be instructed to call the Study Coordinator should they have any questions about this. Third, the Outcome Assessor and the CHW interventionists will be instructed to never discuss any of the participants with each other, either generally or specifically. Fourth, for quality control purposes, after each follow up assessment, the Outcome Assessor will be asked to indicate his/her best guess of which study group the participant is in, as well as his/her reasons for this estimate. If at any time the Outcome Assessor learns of a participant's treatment group, he/she will notify the Study Coordinator immediately, and she will complete an "Unmasking Form' (to be developed during Start-Up). The Study Coordinator will record this information in a data file so that statistical analyses can be adjusted accordingly. The biostatistician will specifically examine whether unmasking leads to the introduction of treatment-related biases in all reporting of study results. In addition, a research assistant who is works in the PI's lab and is employed by the Department of Neurology at Jefferson, will be trained to conduct the follow-up assessments. If a participant's treatment assignment is revealed to the Outcome Assessor, the research assistant will conduct that particular participant's subsequent follow-up assessments.

8.3. Treatment Fidelity

To monitor treatment fidelity, all treatment sessions (both COPDE and EUC) will be audio recorded, and Drs. Casten and White will review one third of all recordings. The first session, 1 recording randomly selected from sessions 2 through 6, and 1 randomly selected booster session will be

reviewed. Drs. Casten and White will listen to the recordings and rate the CHW interventionists' adherence to the treatment protocol using the COPDE or EUC Treatment Fidelity Rating Form in which the quality of interventionist rapport, delivery of diabetes education, and the delivery of intervention components are rated. Drs. Casten and White will discuss their ratings with the respective CHW interventionist for supervisory purposes.

To determine which participants and intervention sessions will be selected for treatment fidelity review, Dr. Leiby will create a randomization schedule. The schedule will determine: (1) which participants will be selected for treatment fidelity; and (2) which sessions from those participants will be reviewed. The PI will regularly review the interventionists' progress to insure that each he/she is meeting the standard of performance.

8.4. Quality Control for Assessments

The quality of the assessments (both baseline and follow-up) will be evaluated by having Dr. Rovner review a random sample of 10% of all assessments. All assessments will be audio recorded. Dr. Rovner will review the recordings and discrepancies in the interpretation of participant responses will be discussed and reconciled. The ED Research Coordinators or the Outcome Assessor may be referred for additional training at Dr. Rovner's discretion if there are many discrepancies.

8.5. Attrition

The following strategies will be implemented to maximize retention. 1) All participants (in both treatment groups) receive diabetes educational materials. 2) All participants receive $20 and certificates of completion for all outcome assessments. 3) Established relationships with PCPs will convey credibility to participants and sustain research engagement. 4) We will mail birthday cards and a quarterly "Question-and-Answers" newsletter to all participants to maintain positive, personalized contact. 5) We will make reminder calls the day before in-home appointments, and maintain flexibility when scheduling them. 6) We will have a dedicated telephone line for participants to call for study-related questions.

9: DESCRIPTION OF INTERVENTIONS

9.1. COPDE

COPDE is a collaborative intervention of PCPs, a DM nurse educator, and CHWs that aims to reduce the need for DM-related ED visits in AAs with DM. To achieve this goal, COPDE uses culturally tailored strategies to improve DM self-care and access to care. Within 2 weeks of discharge from the ED or hospital, a CHW will begin to deliver six 90-minute in-home treatment sessions (during the 1st four months) and three booster sessions (over the next 8 months). The CHW will: 1) deliver culturally relevant DM self-care education; 2) use DM-specific Behavioral Activation to reinforce DM self-care skills, and 3) facilitate a telehealth visit with the participant's PCP (session 2), and three telehealth visits (sessions 3 and 5, and the 8-month booster session) with a DM nurse educator (Co-I Neva White, DNP, CDE). At every treatment session, the CHW will complete the Community Health Worker (CHW) Encounter Form. This brief standardized form characterizes CHW treatment activities and participant DM self-care practices. The CHW will upload the Form to the EMR (Epic) for the PCP's review after sessions 1 and 6 (at 4 months). This will enable the PCP to better engage the participant during the telehealth visit (session 2) and in subsequent office visits. Dr. White will supervise the CHW during twice monthly meetings and after each booster session. The CHW will make no treatment recommendations unless previously discussed with Dr. White.

● Session 1*:* The CHW will establish rapport and describe the collaboration with the PCP and DM nurse educator. She will discuss the reasons for the participant's recent ED visit, experiences with DM self-care (e.g., adherence to medications, diet, glucose monitoring), and barriers (e.g., unhealthy family diet). The CHW will then review culturally relevant educational materials to build DM knowledge and skills according to national standards. The CHW will also rehearse and record a participant's questions (e.g., *"Do I skip medications when traveling?"*) and health beliefs (e.g., *"Sometimes I think prescription medications are addictive"*) to build confidence to discuss these issues with the PCP. The CHW will contact the JeffConnect scheduling office to schedule the PCP telehealth visit (session 2). The CHW will also refer participants (as needed) to the Area Agency on Aging to ensure that basic needs are met (e.g., safe housing, financial counseling, food security).

● Session 2: This session will begin with the telehealth visit (on an iPad) with the PCP (about 20 minutes). The PCP will explain the collaboration with the CHW, and will assess the participant's current health status, answer questions about the recent ED visit, address relevant health beliefs, and review current medications (i.e., purpose, dosing, side effects). If the participant's most recent HbA1c is at target, the PCP reinforces the participant's current DM self-care strategies, and may consider a medication dose reduction. If the HbA1c level is not at target, the PCP will ask about treatment obstacles, and discuss ways to surmount them that are acceptable to the participant (e.g., diet modifications, medication change). After the telehealth visit, the CHW will review the PCP's recommendations with the participant. The CHW might say, *"You've been taking metformin only when you thought your glucose was high. Dr. __ advises taking it daily to stay healthy. Let's talk about how metformin works and find a way to take it every day."* They may then discuss how to integrate medication-taking into daily routines or a participant's personal values (e.g., trust in God). Taking medications might be linked to the message, *"God has given us these medicines to live a healthy life*." At the end of session 2, the CHW and participant will schedule a telehealth visit with the DM nurse educator for session 3.

● Session 3: This session will begin with the telehealth visit with the DM nurse educator, who will discuss the participant's current experiences with DM self-care and will target a participant-selected DM self-care goal. Using DM-Specific Behavioral Activation, the DM nurse educator, CHW, and participant will devise an Action Plan for that activity. For diet, an Action Plan might target healthy food choices, food portions, timing meals, and discussing dietary needs with family. The CHW will provide skills training as needed (e.g., plate method to organize meals, using a glucometer). The Action Plan goal might be to reduce soft drink consumption or eat 3 vegetables daily. The Action Plan steps specify the "how, when, and where" of the plan, and are observable, quantifiable, integrated into daily routines, and attainable (to provide positive reinforcement). An Action Plan for exercise (e.g., *"walk with a friend"*) might be: 1) call a friend; 2) pick a date/time; and 3) use a pedometer (supplied) to track distance walked. These steps are recorded on a large print calendar to provide cues to action. Over the next week, the participant will record the number of times the Action Plan is completed, and will rate their sense of accomplishment (to enhance reward salience). The CHW will also anticipate negative perceptions (e.g., *"I can't do this"* or *"This will never work"*) and encourage the participant to "make room" for these thoughts while still following the Action Plan (i.e., *"Follow the plan instead of the feeling"*).

● Sessions 4-6*:* The CHW and participant will review previous Action Plans. The CHW will reinforce attained DM self-care goals, help set new ones, and facilitate access to upcoming PCP clinic visits [e.g., discuss barriers (e.g., transportation) and health beliefs (e.g., *"check-ups aren't really necessary."*); rehearse questions for PCP; and mark upcoming appointments on a calendar]. If a participant has an ED visit and/or hospitalization during treatment, Dr. White and the CHW will identify modifiable predisposing or precipitating factors, and develop an Action Plan to address them. Session 5 will include the 2nd telehealth visit with the DM nurse educator to answer questions, identify treatment barriers, and set new DM self-care goals. After session 6, the CHW will upload the current CHW Encounter Form for the PCP's review.

● Booster Sessions (Months 6, 8, and 10): These 3 booster sessions will sustain treatment engagement and reinforce DM self-care. A telehealth visit with the DM nurse educator will occur at month 8. During the booster sessions, the CHW and participant will discuss current medical care and upcoming PCP visits, and review and modify previous Action Plans to accommodate changes in health or social circumstances.

9.2. EUC

EUC is comprised of usual primary care that is enhanced with individualized DM self-care education. EUC is a credible intervention that matches COPDE in treatment intensity, educational materials, delivery characteristics, and referral to community resources as needed, but does not include DM-specific Behavioral Activation or telehealth. The EUC control: 1) ensures that all participants will receive DM self-care education; 2) reduces risk of unmasking (i.e., all participants will have in-home visits; and 3) reduces attrition (all participants will have attention to their DM). Interventions like EUC accord with the American Association of Diabetes Educators' position statement on CHWs. In EUC, the CHWs will deliver an accurate, culturally relevant understanding of DM, and use supportive techniques (e.g., encourage personal expression, convey empathy) to create an accepting treatment environment. In two of our RCTs with AAs with DM, CHWs maintain fidelity to this education-only treatment condition. Low attrition rates indicate that participants have reasonable expectations of improvement and value this treatment. We will document: 1) the number/duration of sessions; 2) the extent/quality of participant adherence; 3) treatment satisfaction; and 4) friend/family involvement.

10: DATA AND SAFETY MONITORING PLAN

10.1. Potential Risks and Benefits for Participants

Potential Risks:

The potential risks to study participants form the study assessments include:

(1) Breaches in confidentiality

(2) Psychological discomfort associated with answering questions about health beliefs, quality of life, adherence to diabetes self-management behaviors, and depression

(3) Inconvenience or fatigue associated with the 60 to 90 minute baseline and follow-up assessments

HbA1c will be measured with a fingerstick. Although highly unlikely, there is a remote possibility that there will be pain, brushing, or infection at the site of the finger stick.

Potential Benefits:

The potential benefits to all study participants include:

(1) Receipt of culturally relevant education on diabetes

(2) Evaluation of cognitive functioning

(3) Detection of cognitive impairment or unsafe living situation and subsequent action to be undertaken by study staff (e.g., referral to primary care physicians, local memory clinics, social services, and crisis intervention through the Philadelphia Office of Adult Protective Services)

(4) Sense of altruism from participating in a study that may lead to effective ways to manage diabetes

10.2. Adverse Event and Serious Adverse Event Collection and Reporting

10.2.1. Alerts and Serious Adverse Events

An adverse event (AE) is any unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease which either occurs during the study, having been absent at baseline, or if present at baseline, appears to worsen. Adverse events will be reported regardless of their relationship to the study intervention.

A serious adverse event (SAE) is any adverse event that results in death, is life threatening, or places the participant at immediate risk of death, requires or prolongs hospitalization, causes persistent or significant disability or incapacity, or any other condition which the PI or DSMB judges to represent significant hazards.

All AEs and SAEs will be reported regardless of their relationship to the study intervention.

Solicited AEs and SAEs will be detected at the follow-up assessments to occur at 6 and 12 months. The Outcome Assessor will use a structured questionnaire to inquire about hospitalizations, emergency room visits, surgeries, and physician visits. The ED Research Coordinators and the Outcome Assessor will also assess depressive symptoms and suicidal ideation (when indicated). In addition, every 6 months the Outcome Assessor will review participants' medical charts to identify new medical diagnoses, emergency department visits, and hospitalizations.

Unsolicited AEs and SAEs will be detected when participants spontaneously report a medical event during a COPDE or EUC treatment session. They may also be reported during a phone call to schedule a visit.

10.2.2. Alerts

In providing oversight to human subject safety, an Alert is distinguished from an AE and an SAE. An Alert is considered to be a dangerous situation discovered to exist by a member of the research team that is not related to the conduct of the research study. Alerts are not specific to or consequences of the study but represent situations that may be encountered in any interaction with a participant. Examples of Alerts include hazardous home conditions (e.g., no heat, no electricity, insect infestation), inadequate food supply, potential abuse/neglect, or inability to access health care/medications. The PI will train study staff on the recognition and handling of common alerts. Study staff will be required to report all alerts to the Project Director immediately, who will maintain a log of all reports, the plan of action, and the outcome of the plan. Staff will be given a Resource List that contains a description of and contact information for local agencies that are equipped to provide assistance for Alert situations. The provision and outcome of all referrals will be tracked.

10.2.3. Reporting of AEs, SAEs, and Alerts

All AEs, SAEs, and Alerts will be reported to the IRB as per Jefferson regulations. The Study Coordinator will prepare the appropriate IRB documentation, and will forward it to the PI. The PI will review the event, and will rate its severity and determine whether it is related to study participation.

All AEs, SAEs, and Alerts will be reported to the NIH and the DSMB using an Adverse Event form or a Serious Adverse Event Form (to be developed during study start-up and submitted to the NIH and DSMB for approval). All will be classified along the following dimensions: (1) severity; (2) whether it was expected or not; and (3) the extent to which it was related to study participation. The PI will rate the seriousness of the event. A report detailing AEs and Alerts will be submitted to the NIH and DSMB at designated intervals (e.g., quarterly) as determined by the DSMB during study start-up. SAEs will require expedited reporting (i.e., within 24 hours of the PI becoming aware of the SAE), and will thus be emailed to the NIH and DSMB as the PI learns of them.

For events that are judged by the PI to be ongoing, the Study Coordinator will make weekly calls to the participant to collect updated data regarding the event. This process will continue until the PI determines that the event is terminated, at which time a follow-up report will be submitted to the IRB, the NIH, and the DSMB.

10.3. Protection Against Study Risks

10.3.1. Protection Against Risks

We will minimize the risk of hypoglycemia by having primary care physicians (PCPs) carefully review participants' current medication regimens, previous HbA1c levels, and risk of hypoglycemia based on previous hypoglycemic episodes and other risks. For enrolled participants, PCPs will adjust hypoglycemic medications (e.g., reduce dose of a sulfonylurea) if they are concerned that increased adherence may cause hypoglycemia. We will encourage participants to regularly check their blood glucose, particularly if they feel light-headed, shaky, or weak.

We will minimize the risk of discomfort during assessments and treatment by selecting staff based on their interpersonal sensitivity and capacity to communicate with older persons. We will train staff to recognize signs of distress and fatigue and will terminate testing or treatment if indicated. The assessment instruments have been well-tolerated in our previous studies with older African Americans.

We also train the staff to recognize medical events (e.g., hypoglycemia) that warrant intervention at all stages of this project, including screening and follow-up assessments. Since screening will occur in the Emergency Department, medical assistance will be available if needed. For in-home assessments and treatment visits, staff will be instructed to call the PI or a designated Co-I if they encounter a situation that may warrant medical attention. Events of concern include suicidal ideation, hypoglycemia, HbA1c levels ≥ 10.0%, and participant-reported recent blood glucose level over 300, foot ulcers, and any other symptomatic medical condition that the participant reports or that staff observe. The consent form will state that we will alert PCPs to any unsafe medical situations, regardless of participants' treatment assignment. Dr. Powell will oversee medical and safety procedures related to diabetes. For psychiatric emergencies (e.g., suicidal ideation), staff will call PI Rovner, a psychiatrist. Conditions of special interest include:

a. Suicidal Ideation: To detect suicidal ideation, the ED Research Coordinators and the Outcome Assessor administer the Patient Health Questionnaire-9, which includes a question asking if the participant has thoughts that he/she would be better off dead, or has had thoughts of hurting him/herself. If a participant endorses suicidal ideation, staff will be trained to follow a protocol that we have developed for at-risk participants.

For individuals who express suicidal ideation at any time during the study, staff will administer the Columbia Suicide Severity Rating Scale, which distinguishes passive from active suicidal ideation, and includes specific questions on level of intention and controllability, and any specific plans of self-harm. Staff members are instructed that participants who state that they have considered suicide, have a plan, and either intend to harm themselves, or may not be able to prevent themselves from self-harm, represent an immediate risk. If this is detected while patients are in the ED, staff will be instructed to notify the attending physician ASAP so that a psychiatric consult can be ordered. If it is detected during the in-home follow-up assessments or intervention visits, staff will be advised to contact Dr. Rovner ASAP, who will then talk with the participant to assess the risk, and determine an appropriate course of action. In our ongoing, "Preventing Cognitive Decline in African Americans with Mild Cognitive Impairment" RCT, this situation arose in 2 participants. Dr. Rovner was reached immediately, and evaluated both participants. If the participant does not pose an immediate risk, staff

will nevertheless notify Dr. Rovner, who will contact the participant within 24 hours to assess the participant and devise a plan of treatment.

b. Cognitive Impairment: If cognitive impairment and/or functional disability (e.g. difficulty managing medications) is detected, staff will contact Dr. Rovner to identify diagnostic/treatment steps to ensure adequate evaluation, treatment, and safety.

c. Abuse or Neglect: If staff determines that a participant is a victim of abuse or neglect, after discussion with Dr. Rovner, we will file a report with the local agency that services the area in which the participant lives.

All research procedures are designed to ensure participants' confidentiality. We will assign each participant a unique identification number; this ID number will be the only identifying information on data forms. Participants' names will not appear on interview forms. A list linking ID numbers to names will be kept in a password-protected computer file accessible only to project staff. Audiotapes of interview and/or intervention sessions to monitor treatment fidelity will be identified by the unique identifier and will not contain participants' names or any identifying information.

Because this study is testing a low risk behavioral/educational intervention, there are no circumstances in which participants will be involuntary discontinued from the study.

10.3.2. Informed Consent Process

We will follow the informed consent guidelines of Jefferson's Institutional Review Board. The Informed Consent document will be developed when the NIH requests "Just In Time" information. The ED Research Coordinators will obtain informed consent in writing from all participants. They will discuss the objectives, procedures, risks, and benefits of the study. The consent form will describe the baseline assessment and the possibility of not being eligible for further study participation. The consent form will also describe subsequent procedures for eligible persons, including randomization to one of two treatment groups and the follow-up assessment schedule.

The ED Research Coordinators will evaluate potential participant's capacity to provide informed consent, which is especially relevant to persons with low literacy. First, they will provide the potential participant with a copy of the consent form. They will then read aloud the statement that appears below, and then will read aloud the consent form, stopping after key components to ask questions to be sure that the participant understands the content.

> "You are being asked to take part in a research study for people with diabetes, which aims to improve your ability to control your diabetes. To make an informed decision about whether to participate, it is important that you understand the study's purposes, risks and benefits. To evaluate this, we will read the consent document together and, after certain sections, I will ask you a few questions about what we've read. If any section is unclear, we can go over it again. Or if you prefer, you may read it by yourself, and then we can discuss it."

The ED Research Coordinator will then ask the participant open-ended questions about key points about the study (e.g., What is the main purpose? What are the benefits? What are the risks? Are you able to withdraw from the study at any time?). Based on the responses, the ED Research

Coordinators will document if the person can provide informed consent. We will only enroll participants if the ED Research Coordinator believes that the participant understands the study.

We also instruct all participants that the study treatments supplement and do not replace the care that their primary care physicians provide.

10.4. Interim Analysis

COPDE is not expected to pose any special risks for the participants, and no safety issues are expected that would prompt early termination of the trial. The DSMB will monitor safety, study outcomes and performance data on an ongoing basis. If the DSMB identifies any safety or ethical concerns during the conduct of the trial, it is still possible that they could recommend and interim analysis and/or early termination.

10.5. Data Safety and Monitoring

The Principal Investigator (PI) will be responsible for ensuring participants' safety on a daily basis. The DSMB will act in an advisory capacity to the NIH Director to monitor participant safety, evaluate the progress of the study, to review procedures for maintaining the confidentiality of data, the quality of data collection, management, and analyses.

10.5.1. Frequency of Data and Safety Monitoring

The PI will be informed of serious adverse events as soon as they occur and will notify the NIH and DSMB within 24 hours of notification. AEs and Alerts will be reported to the NIH and DSMB at regular intervals to be decided upon by the DSMB. The DSMB will meet twice annually by teleconference call to review study progress, data quality, and participant safety.

10.5.2. Content of Data and Safety Monitoring Report

The content of the data and safety monitoring report will include information on: SAEs, AEs, and Alerts; participant accrual (actual accrual vs. expected accrual, reasons for non-eligibility); participant activities (e.g., percent of participants who provided follow-up data at each assessment point, percent of participants who completed initial treatment and booster sessions, percent of participants who withdrew from the study); protocol deviations; descriptive data on baseline characteristics, and any other information requested by the DSMB. Specific requirements for these reports will be defined by the DSMB.

10.6. DSMB Membership and Affiliation

DSMB members will be selected by the NIH Program Official in consultation with the PI. Membership will consist of individuals who have no financial, scientific, or other conflict of interest with the trial. Collaborators or associates of the investigator are not eligible to serve on the DSMB. Written documentation attesting to absence of conflict of interest is required. The DSMB will include experts in or representatives of the fields of relevant clinical expertise, clinical trial methodology, and biostatistics.

10.6.1 Conflict of Interest for DSMB

DSMB members should have no direct involvement with the study investigators or intervention. Each DSMB member will sign a Conflict of Interest Statement which includes current affiliations, if any, with pharmaceutical and biotechnology companies (e.g., stockholder, consultant), and any other relationship that could be perceived as a conflict of interest related to the study and/or associated with commercial interests pertinent to study objectives.

10.6.2. Protection of Confidentiality

Data will be presented in a blinded manner during the open sessions of the DSMB or in DSMB reports. At DSMB meetings, data and discussion are confidential. Participant identities will not be known to the DSMB members.

10.6.3. DSMB Responsibilities

The DSMB responsibilities will include:

- Reviewing the research protocol, informed consent documents and plans for data safety and monitoring;
- Recommending that participant recruitment be initiated after receipt of a satisfactory protocol;
- Evaluating the progress of the trial, including periodic assessments of data quality and timeliness, recruitment, accrual and retention, participant risk versus benefit, and other factors that can affect study outcome;
- Considering factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the trial;
- Reviewing study performance, making recommendations and assisting in the resolution of problems reported by the Principal Investigator;
- Protecting the safety of the study participants;
- Reporting to NIH on the safety and progress of the trial;
- Making recommendations to the NIH and the PI concerning continuation, termination or other modifications of the trial based on the observed beneficial or adverse effects of the treatment under study;
- Ensuring the confidentiality of the study data and the results of monitoring; and,
- Assisting the NIH by commenting on any problems with study conduct, enrollment, sample size, and/or data collection.

11: PSYCHIATRIC EMERGENCY PLAN

To detect suicidal ideation, the ED Research Coordinators and the Outcome Assessor administers the Patient Health Questionnaire-9, which includes a question asking if the participant has thought that he/she would be better off dead or has had thoughts of hurting him/herself. If a participant endorses suicidal ideation, intent, or plan, staff is trained to follow a protocol. The protocol entails a specific determination of the suicidal risk and prescribes a set of actions.

For individuals who express suicidal ideation at any time during the study, staff will administer the Columbia Suicide Severity Rating Scale. Staff members are instructed that participants who have difficulty controlling suicidal thoughts, or who express imminent intent with or without a method of self-harm, represent an immediate threat. If this is detected during the baseline assessment (which will take place in the ED or the hospital), the ED Research Coordinator will notify the attending physician ASAP so that a psychiatric consultation can be ordered. If it is detected in participants' homes, staff will page Dr. Rovner, who will talk with the participant to assess the level of risk and determine an appropriate course of action. If Dr. Rovner cannot be reached, the staff member will call 911, and will remain with the participant until help arrives. If the participant does not pose an immediate threat, staff will nevertheless notify Dr. Rovner, who will contact the participant within 24 hours to assess the participant and devise a plan of treatment.

All staff will be trained to implement the study Psychiatric Emergency Plan when indicated. The plan is as follows:

If at any time severe depression is detected, or if a participant expresses thoughts of death or suicide, staff need to assess their risk for self-harm, and initiate the study Psychiatric Emergency Plan. Signs of severe depression include: poor hygiene or grooming, house in disarray (compared to previous times that the staff has interacted with the participant), weight loss, flat or sad affect, slowed speech, or statements of not wanting to live anymore. If severe depression is suspected, staff will say the following to the subject:

From what you're saying and from what I'm seeing, I suspect you are severely depressed and I'm concerned about this.

If the participant indicates (or you suspect) that they don't want to live anymore, you will need to do a suicide risk assessment by administering the Columbia Suicide Severity Rating Scale. When you are finished administering this scale, please go somewhere private (e.g., another room or your car) and page Dr. Rovner ASAP. His pager number is XXXXX. Have the participant's responses to the rating scale with you. Please do not leave the participant's home until you speak with Dr. Rovner. He will provide guidance on how to handle the situation. He will likely ask to speak with the participant to further assess their risk of self-harm, and he will provide you with instructions for handling the situation immediately after he speaks with the participant.

If Dr. Rovner determines that the participant is not suicidal, you can say *"I'd like to know if you are receiving help for depression. Have you ever talked to a doctor or counselor or social worker about how you are feeling? Are you taking any medication for depression or nerves?"* If the participant is currently being treated for depression, encourage them to keep up with the treatment and to let the treating physician know that their depression is not getting better.

If they are not being treated you can say: "*It is not uncommon for people with diabetes to become depressed. In fact, it is a known complication of diabetes. But you don't have to feel this way. There are many different kinds of safe and effective treatments for depression. Some people prefer to be treated with medications and other people decide to talk to a counselor.*

Depending on the situation, for participants who have severe depression or a significant worsening of depression, Dr. Rovner may recommend that you encourage the participant to discuss their depression with their primary care physicians, or that you offer the participant a mental health referral. After you talk to Dr. Rovner, you can convey his recommendation to the participant. You can say something like (based on Dr. Rovner's recommendation):

It seems like you're quite depressed, and it is a good idea to receive treatment. I recommend that you contact your primary care doctor to let them know how you are feeling. Alternatively, I can give you a referral for community-based mental health treatment."

When you get back to the office, please send an email ASAP to Drs. Rovner and Casten. In the email, please describe the situation in detail and the actions that were taken (e.g., Dr. Rovner talked to participant and determined that the participant was not in imminent harm, Dr. Rovner advised me to call 911, I recommended that the participant contact their PCP). If you recommended to the participant that they contact their PCP or if you made a mental health referral, please contact the participant within 2 to 3 days to determine the outcome of that action (e.g., PCP prescribed medication, participant has upcoming mental health appointment). Please send a follow-up email to Drs. Rovner and Casten to inform them of the outcome of the referrals/recommendations.

12: DATA MANAGEMENT

12.1. General issues

All assessment forms will be created in REDCap, and all data files will be housed on the study server, which is secure and encrypted. The ED Research Coordinators and the Outcome Assessor will use a laptop to administer all assessments. The computer will prompt staff to ask each question and enter the participant's response directly into the computer. Staff will have hard copies of the assessment available at all times should the computer malfunction.

Prior to each assessment, the Study Coordinator will prepare an assessment folder. The folder will contain all necessary forms and instructions (e.g., Informed Consent documents, receipts for dispensing incentives, worksheets for the neuropsychological test), money for incentives, and the educational materials.

All assessments will be audio recorded. All computers used for data collection and storage will be encrypted and password protected. The following data will be collected via hardcopies, which will be entered by hand by the Study Coordinator into REDCap: (1) intervention notes; (2) intervention forms; and (3) HbA1c results.

Data management and cleaning will be ongoing throughout the study. Inconsistencies and missing data will be reconciled (e.g. call participant or check EMR for missing data). There will be separate database for each time wave. Study identifiers will be used to link data from multiple time points for longitudinal analyses. On a monthly basis, the Project Director will run frequency distributions for all variables to check for accuracy.

12.2. Description of computing environment

12.2.1. Hardware

Computers will be purchased for project staff, and they will be password protected and encrypted. All computers will be serviced by the Information Technology (IT) department at Thomas Jefferson University.

12.2.2. Software

All data will be managed and analyzed with SAS, SPSS, or Mplus, TreeAge Pro, and Excel. REDCap will be used to create all data forms.

12.3. Participant identification and confidentiality

Study identifiers will be used on all data forms except when absolutely necessary (e.g. Community Health Worker Encounter Form). Neither participant names, nor any other identifying information other than the unique identifiers, will ever be on the data forms. All hard copies of participant information (e.g., signed informed consent forms) will be stored in locked file cabinets stored in the PI's lab. Each participant will have 2 charts: an identified chart and a de-identified chart, and each will be stored in separate file cabinets in the PI's lab. The following will be stored in the identified chart: the participant's contact information, the signed consent form, serious adverse event/alert documentation, and any other documentation that contains identifying information (e.g., documents uploaded to EMR that require identifying information). The following will be stored in the de-identified chart: all hard copies of assessment forms, intervention forms, de-identified treatment notes, and administrative forms. None of the documents contained in the de-identified chart will have the participant's name. A master list linking participants' names with their study identifiers will be stored in an encrypted password protected file on the study server, and will be restricted to specific staff. Only specified staff will have access to the file cabinets.

12.4. Procedures for Data Checking and Editing

Data forms (both hard and electronic forms) will be reviewed within 1 week of completion by the Study Coordinator. This review is performed to check that all information is accurate, check marks or circled answers are clearly demarcated (if completed on a hard copy), and that each item is completed. The Study Coordinator will also check to assure that consent forms are signed appropriately.

All assessments will be audiotaped using a digital audio recorder. This is explained to participants in the consent form. The recorder is not turned on until after the consent form has been signed by the participant and the person conducting the consent interview. Staff will be instructed to refrain from mentioning any identifying information (e.g., the participant's name) during the recording. Staff will begin each recording by stating the participant's unique identifier, the date, the time, and assessment type. For example, "My name is XXXX. Today is 4/1/18, 10:00 AM, and I am with ED BWR00001 to conduct the baseline assessment".

Within 1 week of an assessment being completed, an experienced research assistant will listen to the audio recording of the assessment, and compare it to the corresponding data entered into REDCap. Dr. Rovner's research lab employs a research assistant whose primary job responsibility is to perform quality control activities for participant assessments on all of his studies. The research assistant is supported by the Department of Neurology at Jefferson, and is supervised by Dr. Casten (the Project Director). She has listened to approximately 800 recordings of assessments for Dr. Rovner's various studies. She is trained on the correct administration of all assessments that will be used in the COPDE study.

When the research assistant identifies data entry errors (e.g., incorrect response are entered in REDCap, missing data), she completes a "Data Error Form" (to be developed during Start-Up) which details the type of assessment (i.e., baseline, 6, or 12 months), the participant, the data field in question, and a description of the error. The Project Director reviews all Data Error Forms to determine whether a data edit is warranted. Once a baseline assessment is verified and incorrect data is rectified, the Project Director will notify the Study Coordinator that a participant is ready to be evaluated for study eligibility.

All changes to data are submitted via a Data Edit Form (to be created during the Start-Up phase) for review and signature by the Project Director. Data edits are entered directly into the respective data bases. The Data Edit Form will be stored in the participant's chart. A data base will be maintained that documents each data edit, including the date of the edit as well as the type of change that was made.

Data quality is maintained through a variety of analyses that target anomalies, delinquent data, and key-entry errors. A part of this process is to analyze the frequency of errors according to type to determine if certain types of errors are recurrent. Modifications to the data forms are made if the same types of errors occur frequently. If the PI deems necessary, steps are taken to resolve the problems by providing additional training for staff and/or modifying the study forms. In addition, random audits of the data collected on the forms may be performed by the Project Director by checking for accuracy and completeness.

12.5. Missing Data

Missing data will be entered according to the following established coding scheme: (1) NA = 99; and (2) refused = 88.

12.6. Data back up

Data files are entered and stored on a secure, encrypted network maintained by Jefferson that is backed up twice daily.

13: STATISTICAL ANALYSES

13.1. Data Analyses

We will use descriptive statistics to characterize the sample, assess randomization success, and as a final data quality check. We will analyze survey metrics (e.g., treatment satisfaction with COPDE and EUC) by summing responses across items and reporting means and SDs. For outcome analyses, we will use an intent-to-treat approach (i.e., all participants with any follow-up data are included as randomized). Any missing data are considered missing at random (MAR); we will apply models that yield valid estimates under this assumption. For analyses of continuous outcomes, we will check assumptions of normality and homoskedasticity of errors using checks of model residuals. We will transform outcomes as appropriate prior to analyses and will use SPSS, SAS, TreeAge Pro, and Mplus software as indicated.

13.1.1. Primary Aim

Test the efficacy of COPDE to reduce the number of incident DM-related ED visits and/or hospitalizations over 12 months (primary outcome). Hypothesis: COPDE will halve the number of incident DM-related ED visits and/or hospitalizations relative to EUC over 12 months.

Primary Statistical Approach: The primary outcome measure is a count of DM-related ED visits and/or hospitalizations. We will use Poisson regression to model the number of outcome events as a function of randomization assignment, adjusting for the stratification variables and using follow-up time as the offset term. We will consider baseline variables (e.g., age, sex, education, insurance, polypharmacy (i.e., taking ≥ 5 medications), and medical comorbidity) as possible covariates if they relate to outcome events at the bivariate level with $p<0.2$. Negative binomial regression will be considered if there is evidence of over- or under-dispersion of the data.**]** From the model, we will calculate estimates of annual rates of the primary outcome and the adjusted estimate of the rate ratio. We will evaluate the primary hypothesis by testing the null hypothesis that the rate ratio for randomization assignment equals 1.

To examine the impact of treatment adherence on outcomes, we will calculate the Complier Average Causal Effect (CACE) and compare it to the intent-to-treat estimate. We will define adherent participants as those who: 1) receive ≥ 4 of 9 treatment sessions, and 2) have a telehealth visit with the PCP, and 3) achieve ≥ 2 DM self-care treatment goals. CACE will estimate treatment effects by comparing the outcomes in adherent COPDE participants vs. EUC participants who would have been adherent had they been assigned to COPDE. The adherence status for EUC participants, however, is not observable. Through the use of a latent class model, the CACE is estimable under certain assumptions. Part of the model includes using baseline covariates and adherence status in COPDE participants to predict adherence status in EUC participants. This analysis will enable us to estimate the impact of adherence on study outcomes.

13.1.1. Secondary Aims

1. Test the efficacy of COPDE to increase perceived access to care over 12 months (secondary outcome). Hypothesis: COPDE will increase Patient Satisfaction Questionnaire-18 (PSQ-18) scores to a greater extent than EUC over 12 months.

2. Test the efficacy of COPDE to increase realized access to care over 12 months (secondary outcome). Hypothesis: COPDE will increase the number of received Diabetes Quality Metrics to a greater extent than EUC over 12 months.

3. Test the efficacy of COPDE to improve DM self-care over 12 months (secondary outcome). Hypothesis: COPDE will improve Diabetes Self-Care Inventory (DSCI) scores to a greater extent than EUC over 12 months.

Analyses: For Secondary Aims 1 – 3, we will model PSQ-18 scores, number of received Diabetes Quality Metrics, and DSCI scores as continuous variables to estimate average change in each of these three variables over time by treatment group. We will use mixed effects linear regression with fixed effects for time (baseline, and months 6 and 12), randomization assignment, and time by randomization interaction. A random intercept term and an appropriate covariance structure will be used to account for correlation among repeated measurements. Within this model we will estimate the average change in PSQ-18 scores, number of received Diabetes Quality Metrics, and DSCI scores, respectively, by treatment group, from baseline to 6 months, from 6 to 12 months, and from baseline to 12 months. For each of these 3 Secondary Aims, the primary hypothesis will be tested by comparing the groups with respect to change from baseline to 12 months.

4. Determine if increasing subjective and/or objective indicators of access to care and/or DM self-care mediates COPDE's reduction of DM-related ED visits and/or hospitalizations. Hypothesis: COPDE will reduce DM-related ED visits and/or hospitalizations to the extent that it increases subjective and/or objective indicators of access to care and/or improves DM self-care.

Analysis: We will use structural equation modeling (SEM) to evaluate this aim, and will simultaneously model the DM-related ED visit/hospitalization count and each proposed mediator separately (i.e., PSQ-18 scores, number of received Diabetes Quality Metrics, and DSCI scores). The model will have paths from treatment to ED visit/hospitalization count (direct effect), treatment to mediator, and mediator to ED visit/hospitalization count. Using MPlus software, we will fit the SEM model and calculate the total indirect effect for the mediator. Mediation of the treatment effect on reduced incidence of DM-related ED visits and/or hospitalizations will be considered present if there is a significant path from treatment through the mediator to the primary outcome (i.e., an indirect effect). Standard errors will be calculated using bootstrapping. If there is evidence of mediation for more than one of the proposed mediators, we will fit a model that simultaneously considers the effect of the multiple mediators.

13.1.3. Exploratory Aims

1. Determine whether COPDE reduces "all cause" ED visits/hospitalizations relative to EUC. Analysis: We will use the Poisson regression approach described in the analysis of the primary aim.

2. Determine if Community Need Index score, literacy, age, and/or sex moderate treatment effects. Analysis: We will explore moderation effects by extending the models above to include randomization assignment by moderator interaction terms, and estimating treatment effects for different levels of the moderator. We will consider treating the moderators as continuous variables under a linear assumption, and as categorical variables categorized in clinically meaningful ways, by quartiles, or at the median. As the literature on sex differences on ED use in AAs is scant, we are unable to formulate specific hypotheses regarding the relationship of sex to study outcomes. If our

data suggest differences by sex, we will conduct supplementary analyses to delineate potential mediators of these differences. We will also examine whether "built environment" indicators (i.e., neighborhood safety, transportation difficulties, and access to healthy foods) moderate treatment response.

3. Determine if COPDE improves glycemic control (i.e., lowers HbA1c levels), impacts DM-related Health Beliefs, reduces depression, and/or improves quality-of-life.
Analyses: For these continuous outcomes we will use the mixed effects approach described above.

4. Identify the treatment features of COPDE which confer its cultural relevance.
Analysis: We will use descriptive statistics to characterize responses on the Cultural Relevance Rating Form in participants assigned to COPDE. If ≥ 75% of participants rate an item ≥ 7 [from 1 to 10 (more valued], that aspect of treatment will be considered to be culturally relevant.

5. Evaluate COPDE's costs and net financial benefit.

Analysis: Intervention costs will be calculated using wage rates multiplied by time in preparation, documentation, delivery, training, and supervision. Fringe benefit costs will be added to staff member costs by application of prevailing rates. Material costs will include study documentation forms and educational materials. Travel expenses to/from participant homes will be captured per visit, and will be costed using current government reimbursement rates. We will estimate direct medical costs using published reimbursement rates (e.g., Medicare) for inpatient and outpatient care. The costs of DM-related ED visits and hospitalizations will be captured at baseline and months 6 and 12 for both treatment groups. Costs for DM outpatient services will be based on Medicare reimbursement rates using relevant CPT codes. We will define net financial benefit as the difference between total costs of COPDE vs. EUC. We will conduct sensitivity analyses to determine the robustness of this calculation. The results will reveal ways to improve the efficiency of treatment delivery and to facilitate translation to practice. The sensitivity analyses will include those variables where we anticipate "real-world" uncertainty, and will include modification of key cost variables (e.g., inpatient and outpatient medical costs, based on 25th and 75th percentiles of Medicare reimbursement.)

14: STUDY TIMELINE

Pre-start up activities will take place upon notification from the NIH that the study will likely be funded. During this phase, IRB approval will be obtained. This includes formalizing the recruitment letter and script, and finalizing the consent form and procedures. The Start-Up phase will take place during the first 6 months of the trial. The following will occur during the Start-Up phase: (1) hiring and training of study staff; (2) refining and implementing procedures for study recruitment; (3) creating study data files and exporting all data collection instruments into REDCap; (4) creating the randomization schedules; (5) updating the Resource List (to provide social service referrals to participants if needed); (6) creating administrative forms and study letters (e.g., to inform participants of eligibility status); and (7) convene a meeting with the DSMB and have the DSMB review and approve relevant study materials. Recruitment will take 20 months (months 7 through 26). We will expect to conduct 15 baseline assessments per month, and randomize 11 to 12. The initial 6 treatment sessions will be administered during months 7 through 32. The 6 month follow-up (FU) assessments will take place months 13 through 32, and the 12 month assessments will be completed months 19 through 40. Months 41 through 48 will be devoted to data cleaning and analysis, and dissemination of study findings.