Manual of Procedures

Preventing and Reducing Emergency Visits in Diabetes through Education and Telehealth (PREVENT)

1. INTRODUCTION

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 this 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 PREVENT (Preventing and Reducing Emergency Visits in diabetes through Education aNd Trust) 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 diabetes, aged 40 years and older, who are recruited from the ED. Note that only 156 participants were randomized due to the pandemic. PREVENT 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). Note that recruitment was terminated early due to the pandemic (156 subjects were randomized). A mediation analysis will determine whether changes in access to care and/or DM self-care explain PREVENT'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.

PREVENT 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 PREVENT 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 PREVENT'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 PREVENT that confer its cultural relevance. If successful, PREVENT 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 PREVENT to reduce the number of incident DM-related ED visits and/or hospitalizations over 12 months (primary outcome) in AAs with DM. Hypothesis: PREVENT 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 PREVENT to increase perceived access to care over 12 months (secondary outcome). Hypothesis: PREVENT will increase Patient Satisfaction Questionnaire-18 scores to a greater extent than EUC over 12 months.

2. Test the efficacy of PREVENT to increase realized access to care over 12 months (secondary outcome). Hypothesis: PREVENT 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 PREVENT to improve DM self-care over 12 months (secondary outcome). Hypothesis: PREVENT 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 PREVENT's reduction of DM-related ED visits and/or hospitalizations. Hypothesis: PREVENT 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 PREVENT 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 PREVENT improves glycemic control (i.e., lowers hemoglobin A1c levels), impacts DM-related health beliefs, reduces depression, and/or improves quality-of-life; 4) identify PREVENT's treatment features that confer its cultural relevance; and 5) estimate PREVENT'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 (PREVENT) 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 40 and older), following an ED visit for a DM-related condition. Note that only 156 participants were randomized.

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 PREVENT (the experimental treatment) or EUC (the control condition).

C. Sample: The sample will comprise 230 older persons (only 156 were randomized) who meet the following criteria:

Inclusion criteria:

1) African American race (self-identified)

2) Age ≥ 40 years

3) Type 1 or 2 DM

4) A recent ED visit

Exclusion criteria:

1) Diagnosis of dementia

2) Anti-dementia medication use

3) Life expectancy less than one year (in the opinion of the evaluating ED physician)

4) DSM-V psychiatric disorders other than anxiety or depression (as per EMR)

5) Intoxicated

6) Suicidal

7) In police custody or currently incarcerated

8) Undergoing medical clearance for a detox center or any involuntary court or magistrate order

9) Lives in assisted living, currently in a rehabilitation facility (other than Jefferson), lives in a nursing home or skilled nursing facility

10) Pregnancy

D. Participant Enrollment: Participants will be recruited from the emergency department (ED) at Thomas Jefferson University and affiliated hospitals.

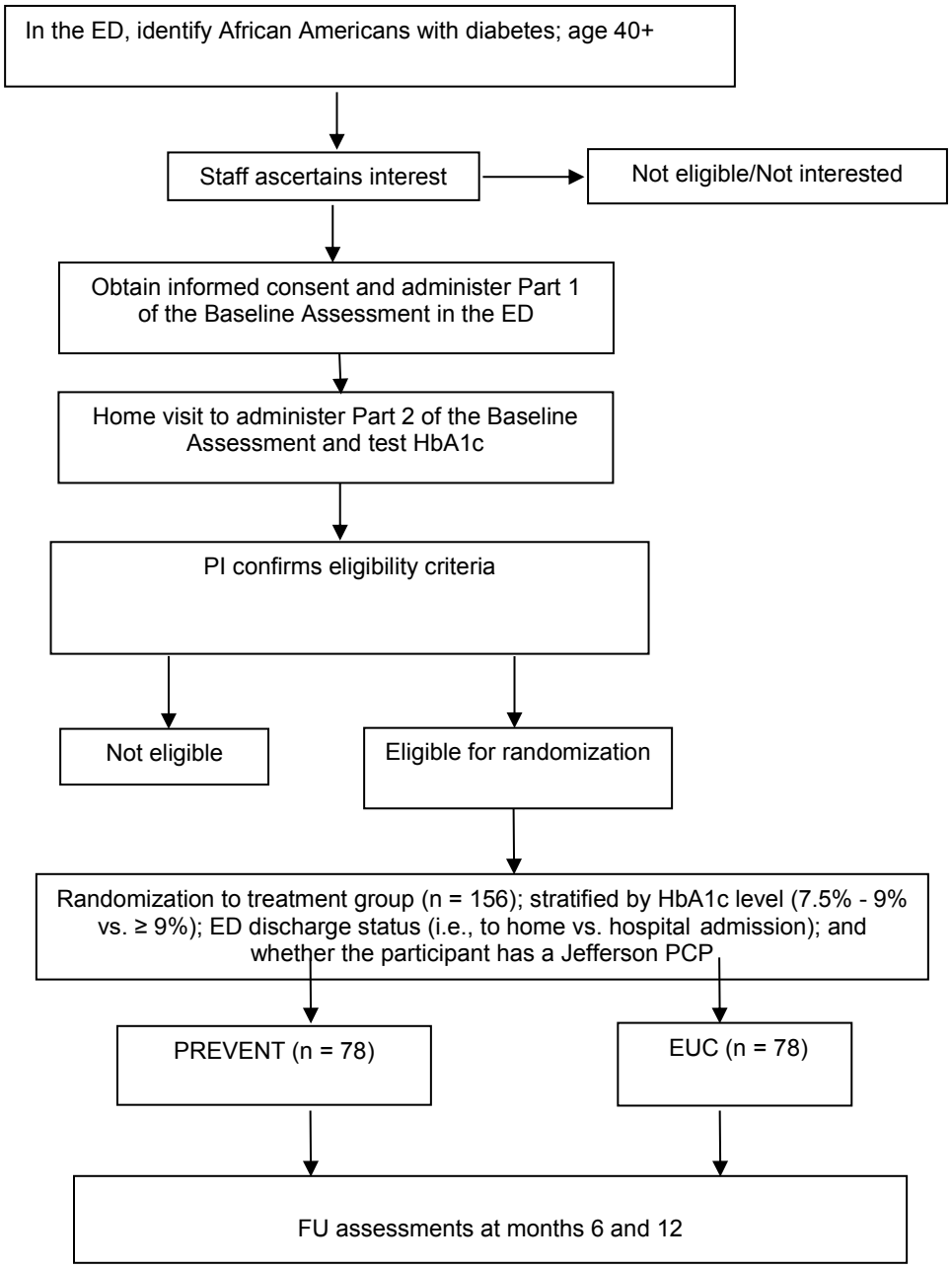
E. Informed Consent: Informed consent will be obtained in the ED by the ED Research Coordinators or in patients' homes by a study assessor.

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

Table 1. Design Summary

Objective	Determine the efficacy of PREVENT to prevent ED visits and hospitalizations among African Americans with diabetes
Major Eligibility Criteria	1) African American race 2) Age ≥ 40 years 3) Diabetes 4) Recent ED visit
Randomization Unit	Person stratified by HbA1c level (7.5% - 9% vs. ≥ 9%), ED discharge status (i.e., home vs. hospital admission), and whether or not the participant has a Jefferson PCP
Treatments	PREVENT (n = 115) EUC (n = 115)
Recruitment Site	Emergency Department
Enrollment Site	Emergency Department or participants' homes
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 (only 156 were randomized due to the pandemic)
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 PREVENT 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 treatments are appropriately implemented; (2) overseeing treatment fidelity procedures and rating recordings of treatment sessions for treatment fidelity purposes; (3) providing supervision for and training the PREVENT CHW interventionist to administer Behavioral Activation and the EUC CHW interventionist to deliver the control condition; (4) overseeing treatment documentation; (5) developing the study data files; (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 (both PREVENT and EUC 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 will be carried out by the ED Research Coordinators (except in cases where patients prefer to have the consent interviews in their homes). The coordinators 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. Chang and Rising will review all ED visits and hospitalizations that occur after randomization to determine whether they are diabetes related.

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 PREVENT intervention. 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 PREVENT 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 a 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 (for both PREVENT and EUC cases). She will also listen to randomly selected audio recordings of CHW treatment sessions (for both treatments) to rate the quality of the diabetes education that they deliver. Dr. White will also provide telehealth visits to participants randomized to the PREVENT 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 PREVENT 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 PREVENT interventionist will complete treatment documentation forms to record details of each PREVENT 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 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 behavioral activation 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. A second CHW interventionist will deliver EUC (the control condition). 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 PREVENT 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 Part 1 of the baseline assessment. 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 Part 2 of the Baseline assessment and follow-up assessments at 6 and 12 months in participants' homes masked to treatment assignment. The Outcome Assessor will obtain informed consent and administer Part 1 of the Baseline Assessment to participants who do not want to be consented in the hospital. 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 PREVENT 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) manage the payment of participant incentives; and (3) send biweekly reports to the Outcome Assessor and CHW Interventionists to inform them of participants who are due for follow-up assessments and intervention visits. Drs. Rovner and Casten will supervise the Research Coordinator.

Research Assistant, To be hired. The Research Assistant will be supported by the Department of Neurology at Jefferson. This person will be responsible for: (1) reviewing participants' medical charts at 6 and 12 months to collect data on current medications, diabetes quality metrics, and recent hospitalizations and ED visits; and (2) listen to audiotapes of data collection visits for quality assurance purposes.

3.3. Study Committees

Data and Safety Monitoring Board (DSMB): The primary responsibilities of the DSMB are to: 1) review and approve the Manual of Procedures (MOP) and the PREVENT 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 staff at participants' index ED visits (i.e., the visit in which recruitment occurs). If the patient is admitted to the hospital, staff will conduct the consent interview in the patient's hospital room (after obtaining permission from the patient's nurse). In either case, patients will only be approached for consent when they are medically stable.

If the patient is not able/does not want to be consented in the ED or when they are an in-patient (for example, if they are not in the hospital long enough for staff to have a chance to consent them), ED staff will ask them to sign a release that permits staff to contact them to schedule an appointment for an in-home consent interview. In this situation, informed consent, and Parts 1 and 2 of the Baseline Assessment will occur in patients' homes.

4.2. Recruitment

Participants will be recruited from the ED at Jefferson or affiliated hospitals.

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, and supplies to assist with the achievement of treatment goals for PREVENT participants (e.g., glucometers and supplies, pedometers, materials to record glucose readings and daily food intake).

4.4. Access to study information

Study documents include: (1) the grant application (excluding the study budget); (2) progress reports to NIH; (3) materials submitted to the IRB; (4) meeting minutes; (5) adverse events reports; (6) the Manual of Procedures (i.e., this document); (7) the PREVENT 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 data collected from screening, blood tests, baseline and follow-up assessments, medical records, 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 (PREVENT and EUC). Note that only 156 participants were randomized due to the pandemic (78 participants to each of the two treatment groups). 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 40+, African American race, in the ED, no diagnosis of dementia); and (2) provides written informed consent. A participant is considered to be eligible for randomization if they meet all eligibility criteria.

Recruitment, enrollment, consent, and the administration of Part 1 of the baseline assessment (to be performed prior to randomization) will be carried out by ED staff or the Outcome Assessor. Staff 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.

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 ≥ 40 years

3) Diagnosis of diabetes

4) A recent ED visit

5.3. Exclusionary Criteria

The following exclusionary criterion will be assessed during screening (i.e., review of EMR while patients are in the ED):

1) Anti-dementia medication use (also assessed by self-report during baseline assessment)

2) DSM-V psychiatric disorders other than anxiety or depression.

3) Medical conditions that preclude participation (e.g., life expectancy ≤ 2 years)

4) Intoxicated

5) Suicidal

6) In police custody or currently incarcerated

7) Undergoing medical clearance for a detox center or any involuntary court or magistrate order.

8) Lives in assisted living, currently in a rehabilitation facility (other than Jefferson), lives in a nursing home or skilled nursing facility.

9) Pregnancy

The following exclusionary criterion will be assessed during Part 2 of the Baseline Assessment and determined by the PI soon after:

1) Diagnosis or evidence of dementia

5.4. Sources of Potential Participants

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

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. ED staff review each triage record and identify patients who are African American, have diabetes, are aged 40 and older, are not taking any anti-dementia medications, and have no excluded medical conditions. Staff 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, staff will maintain a 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 ED staff, 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 intervention 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, staff will record the participant's information (name, contact information). Staff will then proceed with

Part 1 of the Baseline Assessment, which consists of contact information, alcohol use, smoking, medical history, and medications listed in their medical record. Participants are given a signed copy of their consent form. Participants are paid $10 for the consent interview and Part 1 of the 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, staff 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, administer Part 1 of the Baseline Assessment, and schedule a home visit to administer Part 2 of the Baseline Assessment. For patients who are consented in their homes, participants will be paid $30 ($10 for the consent interview and Part 1 of the Baseline Assessment, and $20 for Part 2 of the Baseline Assessment).

After Part 1 of the Baseline Assessment is completed, an ED coordinator enters all collected information into REDCap, which will be stored on the study shared drive. Study staff will collect the participant-signed consent form and hard copies of the completed forms from the ED coordinator to store in the PI's lab. Within 2 weeks of Part 1 of the Baseline Assessment, a study assessor will have a home visit with the patient to conduct Part 2 of the Baseline Assessment. Participants are paid $20 for Part 2 of the Baseline Assessment. Part 2 of the Baseline Assessment consists of HbA1c testing, a cognitive test, and self-report questionnaires. During Part 2 of the Baseline Assessment, the Outcome Assessor will record medications based on a review of the participant's medication bottles. After the audio recordings of Parts 1 and 2 of the Baseline Assessment has been reviewed, the Study Coordinator then logs onto REDCap to retrieve the data. She then completes a Study Eligibility Form that documents the study identifier, the date of the Index visit, the dates of Part 1 and Part 2 of the Baseline Assessment, the results of the HbA1c test, depression score, demographic information, reason for the Index ED visit, any medical or psychiatric illness, and the cognitive test score.

The completed Study Eligibility Form is given to the PI. The PI will review the participant's baseline information to confirm whether the participant has no cognitive impairment, and no other exclusionary medical or psychiatric conditions. 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.

If the participant is eligible to be randomized, the Project Director will randomize the participant in REDCap. Randomization will be stratified by HbA1c level, ED discharge status (home vs. hospital admission), and whether or not the participant's PCP is a Jefferson physician. The Project Director will then enter the participant's baseline assessment disposition in the Study Eligibility file. Possible dispositions are: 0) Eligible for randomization; (1) Not eligible: Cognitive impairment; (2) Not eligible: Psychiatric illness other than depression/anxiety; (3) Not eligible: Severe depression; and (4) Not eligible: Cognitive medication reported at baseline. Other outcomes will be added as needed. If the participant was randomized, the Study Coordinator will enter the treatment group assignment into the REDCap Participant Tracking File. She will then mail a letter to the participant that informs them of the eligibility status. Hard copies of the letter, the signed consent form, 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. Procedures for assessing each inclusionary/exclusionary criterion are presented in Table 2.

5.6. Assignment of study identification numbers

Screening identifiers will be assigned to all patients who are approached for study participation using REDCap. Unique study identifiers will be assigned to all patients who agree to a consent interview. The identification number will consist of the letter "P" (to identify the study), plus the participant's 3 initials, plus a 5 digit number chosen from a consecutive list (e.g., P-BWR10000). If the participant has no middle name, an X will be used. Identifiers must be placed on all study forms and data collection instruments. Blood test results are de-identified. Participant names, contact information, and study identifiers will only be linked in the Recruitment Log (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 PREVENT CHW interventionist to provide participant information to participants' PCPs and the study nurse). 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).

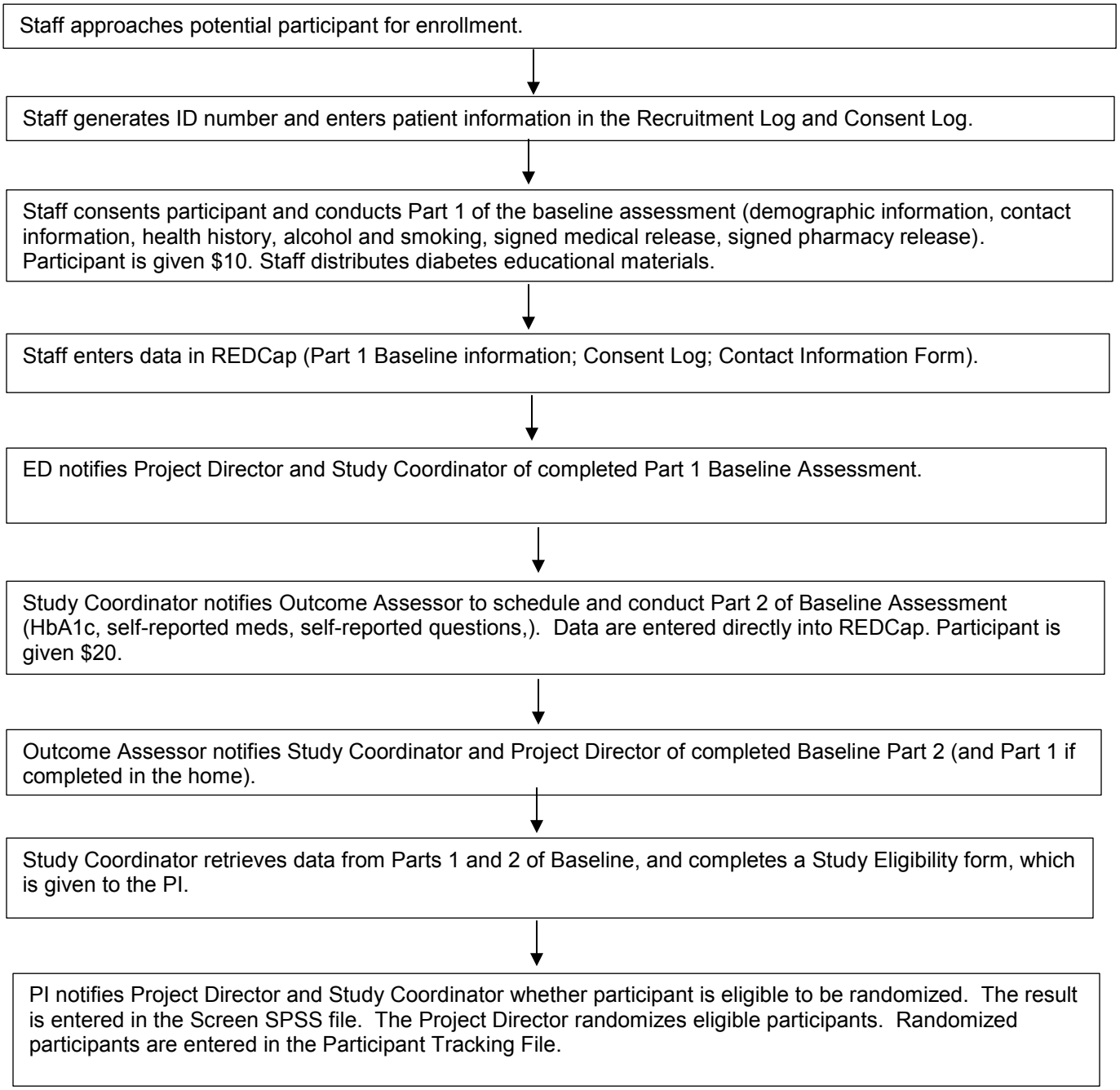
5.7. Randomization to Treatment Group

Randomization will follow a fixed scheme with a 1:1 allocation ratio. Randomization is stratified by HbA1c level (< 9.0% vs. ≥ 9.0%), ED discharge status (discharged home or admitted to the hospital), and by whether or not the participant has a Jefferson PCP. 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 all participants will begin 1 to 2 weeks after randomization. Figure 2 details the work flow for participant enrollment and randomization.

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

African American race	EMR	EMR check by ED staff
Age	EMR	EMR check by ED staff
Diabetes diagnosis	EMR	EMR check by ED staff
Rule out dementia/cognitive impairment	Montreal Cognitive Assessment (MOCA)	Part 2 Baseline assessment conducted by Outcome Assessor; test results interpreted by PI
Rule out suicidal ideation and DSM-V psychiatric disorders other than anxiety or nonpsychotic depression	EMR	EMR check by ED staff
Rule out medical conditions that preclude participation	EMR	ED attending
Rule out anti-dementia medication use	Self-report, EMR	EMR check by ED staff to complete Part 1 of the Baseline Assessment; Self-report of medications during Part 2 of the Baseline Assessment by the assessor
Rule out pregnancy	EMR	EMR check by ED staff
Ineligible disposition (e.g., incarcerated; undergoing medical clearance for detoxification center or any involuntary court/magistrate order lives in assisted living or nursing facility)	EMR	EMR check by ED staff

Figure 2. Workflow for Participant Enrollment/Randomization



6: SCHEDULE AND OVERVIEW OF DATA COLLECTION

6.1. Overview of Schedule and Description of Participant Visits

The ED staff will conduct Part 1 of the Baseline Assessment (pre-randomization) in the ED (or in participants' homes if the participant does not wish to be consented in the ED), and the Outcome Assessor will conduct Part 2 of the Baseline Assessment and follow-up assessments in participants' homes at 6 and 12 months. At part of Part 1 of the Baseline Assessment, staff will have the participants sign a general medical release and a pharmacy release. Data obtained during the Parts 1 and 2 of the Baseline Assessment will be used to determine eligibility for randomization. All participants will receive a cash incentive for each study assessment ($10 for Part 1 of the Baseline Assessment, $20 for Part 2 of the Baseline Assessment, and $20 each for the 6 and 12 month follow-up assessments). Participants will be asked to sign a receipt acknowledging the receipt of the incentives.

At Part 1 of the Baseline Assessment, ED staff will complete the PREVENT Participant Contact Form. 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 have 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.

During treatment Session 1, the CHW interventionist will set up a MyChart account for participants randomized to the PREVENT treatment arm. An account is required so that the PCPs can conduct the telehealth visits. Appendix 1 details Instructions for setting up a MyChart account.

Methods for data collection are described below. Table 6 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, and insurance type. 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 PREVENT's ability to change behavior via better DM self-care and access.

Function: We will administer the Activities of Daily Living–Prevention Instrument, a self-rating scale of ability to carry out multiple complex activities (e.g., shopping, preparing meals).

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. 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. MOCA will be a covariate.

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 status/type will be a potential covariate.

Incident ED Visits and/or Hospitalizations: The primary efficacy analysis will consider the number of incident DM-related ED visits and/or hospitalizations (i.e., an "event") over 12 months. Each ED visit or hospitalization is counted as a single event (although an ED visit that leads to a hospitalization is counted once). A subsidiary outcome analysis will consider "all cause" events. To determine whether an "event" is DM-related or not, Co-I's Chang and Rising (masked to treatment assignment) will independently review the medical records of all "events," and make the determination. For descriptive purposes, we will also classify incident ED visits as "early" (i.e., ≤ 30 days post-baseline) vs. "late" (i.e., > 30 days). The ED physicians will be asked to rate whether each event is "related" (i.e., due to a similar or associated problem) vs. "not related", and "expected" (e.g., suture removal) vs. "unexpected" (i.e., a new medical problem). For discrepant determinations on whether the event is diabetes-related, co-investigator Hollander will render a third determination, and the final classification will be based on the majority rating. When there is not a majority determination among

the 3 physicians, they will be asked to discuss the event and reach consensus.

We will record all ED visits and hospitalizations that occur after consent, and we will code them as occurring: (1) prior to randomization; (2) after treatment begins; or (3) after randomization but before treatment begins. ED visits/hospitalizations that occur after the Index ED Visit will be assessed as follows (if the Index ED Visit results in a hospital admission, that hospitalization will not be counted toward the primary outcome):

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 Research Assistant will verify the details of all ED visits and hospitalizations via EMR. For ED visits/hospitalizations that occur outside of Jefferson, we will obtain clinical information from the outside facility.

2) At 6 and 12 months, for all participants, the Research Assistant will review medical records 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, PREVENT or EUC CHW interventionist) that they had an ED visit or hospitalization, study staff will check medical records to obtain details of the event. Study staff will contact non-Jefferson/Einstein hospitals for events that occurred outside of Jefferson or Einstein. Procedures for processing and coding ED visits and hospitalizations are detailed in the Appendix.

Participants who are permanently placed in a nursing home during the study will be censored (i.e., they will no longer have treatment sessions, follow-up assessments, or chart reviews). This is because: (1) these participants will no longer self-manage their diabetes; and (2) events that may typically require an ED visit may be handled by nursing home staff. Participants who have a temporary nursing home stay during the study will participate in all study activities.

Table 3 indicates the diagnostic codes that will be used to designate ED and hospital visits as being diabetes-related.

Table 3. Diabetes-Related Codes

Code*	Condition
Hyper/hypoglycemic	
250.8	diabetic hypoglycemia
251	hypoglycemic coma
251.1	other specific hypoglycemia
251.2, E16.2, E 16.1	hypoglycemia nos
272.1	pure hyperglyceridemia
790.29, R73.9	hyperglycemia
Skin/soft tissue infection	
680-686, L00-L08	Infections of skin and subcutaneous tissue
686.8	local skin infection nec
686.9	local skin infection nos
Ketoacidosis	
250.1	diabetes w ketoacidosis
250.2	diabetes w hyperosmolar coma
250.3	diabetes w other coma
276.2	acidosis
Diabetes med refill	
v68.1, Z76.0	med refill
Neuropathy	
250.6	DM with neurologic manifestations
357	inflam/toxic neuropathy
357.2	neuropathy in diabetes
357.3	neuropathy in malig dis
357.4	neuropathy in other dis
357.5	alcoholic polyneuropathy
357.6	neuropathy due to drugs
357.82	critical illness neuropathy
377.34	toxic optic neuropathy
337.1	peripheral autonomic neuropathy
UTI/Pyelonephritis	
599	other urinary tract disorder
N39.0	urinary tract infection
590	chronic pyelonephritis
590	chronic pyelonephritis nos
590.1, N10-12, N13.6, N20.9	acute pyelonephritis
590.1	acute pyelonephritis nos
590.3	pyeloureteritis cystica

Code*	Condition
590.8	other pyelonephritis
Chest pain	
786.5, R07.9	chest pain nos
786.59, R07.81, R07.82, R07.89	chest pain nec
Acute renal failure	
584; N17.0, N17.1, N17.2, N17.8, N17.9	acute renal failure
Retinopathy	
362	diabetic retinopathy
362.01	diabetic retinopathy nos
362.02	prolif diabetic retinopathy
362.1	background retinopathy nec
362.1	background retinopathy nos
362.11, H35.039	hypertensive retinopathy
362.12, H35.02	exudative retinopathy
362.2	other prolif retinopathy
362.29	prolif retinopathy nec
* We will also count any ED visit/hospitalization with a code of E08-E13.	

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 PREVENT's efficacy to increase PSQ-18 scores (secondary outcome), and also determine if change in PSQ-18 scores mediates PREVENT'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 medical records 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 PREVENT'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 PREVENT'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. This will be tested at Part 2 of the Baseline Assessment and at follow-up assessments. We will test PREVENT's efficacy to lower HbA1c level (secondary outcome), and whether change in HbA1c mediates PREVENT's effect on ED visits/hospitalizations. The 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 analyzer yields a time-stamped de-identified electronic the test result.

The specifications of the DCA Vantage HbA1c test are as follows:

Table 4. 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, if interfaced
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 (optional):	Serial (9 pin)
Onboard Printer:	54 mm (2 in) width, thermal/label stock
External Printer:	Supports standard PCL printer interface via USB port

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 PREVENT's efficacy to improve DM self-care (secondary outcome), and also determine if change in DSCI-R score mediates PREVENT'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 African Americans. 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 with participants, and the Research Assistant will obtain parallel information from medical records 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 PREVENT 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 PREVENT 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 PREVENT 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 PREVENT 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 (all forms are only for participants randomized to PREVENT unless otherwise noted)

Form	Purpose	Timing
Action Plan Form	Record steps to achieve DSM goal	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 PREVENT 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 via phone calls from study staff
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; both PREVENT 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; both PREVENT and EUC participants
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
Interventionist Adherence Rating Form	CHW's ratings of participant's engagement with the intervention	After 6th initial session and last booster session
Interventionist Communication Log	Record all phone calls and EMR communications	Every time there is an email, phone, or EMR communication regarding the participant; both PREVENT and EUC participants
Master Goal Log	Document progress with treatment goals	Every time a goal is made, revised, or evaluated
Materials Log	Record all materials dispensed to participant (e.g., glucometer, pedometer, divided plate)	Every time materials are given to the participant
Missed Visit Log	Record reasons for missed visit	Every time a visit is missed both PREVENT and EUC participants
Out of Window Visit Log	Record visits that occurred out of window	Every time a visit is out of window both PREVENT and EUC participants
Participant Information Form	Provide background information on newly randomized participants to interventionist	Given to CHW when a participant is randomized to PREVENT
Referral Log	Record any referrals made to study participants	Every time CHW makes a referral to the participant; both PREVENT and EUC participants
Satisfaction with Telehealth visits	Rate participant's perceptions of the telehealth visits	After the 6th session and the last booster session via phone calls from study staff
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; both PREVENT and EUC participants
Telephone Log	Record duration and purpose of all telephone calls to participant	Every phone call between CHW and participant; both PREVENT and EUC participants
Telehealth Documentation Form	To record the date, start time, and end time of each telehealth visit	After each telehealth visit
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 via phone calls from study staff; both PREVENT and EUC participants

Table 5. Conceptualization of Study Measures

Primary Outcome:		
Number of diabetes-specific and other ED visits and hospitalizations over 12 months	- EMR review - Self-report	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, Suicidal ideation suspected
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)	Baseline
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) -Activities of Daily Living -Previous ED use from medical records (self-report and EMR)	Baseline, FU
Cognitive Function	- Montreal Cognitive Assessment (MOCA)	Baseline

[1] FU: Follow-up assessments to take place in participants' homes at 6 and 12 months.

6.3. Participant educational materials

At the conclusion of Part 1 of the Baseline Assessment, staff 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 PREVENT, the CHW interventionists will incorporate the materials into participants' diabetes education during treatment sessions.

6.4. Follow up assessments

Follow-up assessments will be conducted by the assessor at months 6 and 12 in participants' homes. Biweekly, 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 randomization will determine when the follow-up assessments should occur. For example, if the randomization date was 3/1/17, ideally the 6-month assessment should take place on 9/1/17. Follow-up assessments will be timed so as to take place within 7 days of the ideal assessment date. If unforeseeable events prevent the follow-up assessment from occurring on time, an Out of Window Form will be completed. 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 or treatment sessions (both PREVENT and EUC) that occur outside of the time window (i.e., 8 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 or intervention session that is out of window, the ideal date of the visit as well as the actual date of the visit, and the reason that the visit is out of window.

The goal is to have 80% of the visit 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.

6.6. Missed Assessments

If a 6 or 12 month assessment 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. The Project Director and PI reserve the right to make exceptions to this policy (e.g., illness). If any part of an assessment is conducted within the allowable time window but the entire assessment is not completed, it will be designated as an incomplete assessment.

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, the Outcome Assessor will complete a "Missed Visit Form". All attempts and contacts will be documented.

The 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, staff will review participants' medical charts at baseline, 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" 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
Part 1 Baseline assessment:	Within 2 weeks of the Index ED visit
Part 2 Baseline assessment:	Within 2 weeks of the Index ED visit
Review baseline assessment:	1 week after Part 2 of Baseline Assessment
PI confirms eligibility:	1 week after Part 2 of the Baseline Assessment is reviewed
Randomization:	3 days after eligibility is confirmed
PREVENT or EUC treatment begins:	1 to 2 weeks after randomization
6 initial PREVENT or EUC treatment sessions:	To be completed 4 months from baseline
6 month follow-up assessment:	6 to 7 months after randomization
3 booster PREVENT or EUC treatment sessions:	6 to 12 months after randomization
12 month follow-up assessment:	12 months after randomization
Medical chart reviews:	6 and12 months
Pharmacy record reviews:	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 PREVENT in-home intervention sessions
6. Administering the EUC in-home intervention sessions
7. Orienting the PCPs
8. Orienting the ED staff
9. Recognizing and handling of psychiatric and medical emergencies
10. Collecting data from medical charts
11. General research training
12. 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 the MOP prior to the workshop. Finally, all study staff, including the ED staff, will be required to take Jefferson's Cultural Competency training on HealthStream.

7.2. Determining Eligibility/Exclusionary Criteria for Study Enrollment

Participants will be recruited from the emergency department (ED) at Jefferson. Drs. Chang and Rising will be responsible for training the ED staff on identifying potential participants. ED staff are directly supervised by Drs. Chang and Rising. Dr. Chang will be available on pager 24 hours per day, 7 days per week during the study period. On a daily basis, Dr. Chang and the ED Recruitment Coordinator meet informally with the ED staff to monitor the study conduct. The ED staff have formal sessions every 1-2 weeks where project quality assurance is monitored.

7.3. Obtaining Informed Consent

Dr. Casten will train the ED staff to obtain informed consent in writing, and to determine patients' capacity to consent. Written informed consent will be obtained during the index ED visit while patients are in the ED (or in the hospital for admitted patients, or in patients' homes for those who do not wish to be consented in the hospital). Staff will discuss the objectives, procedures, risks, and benefits of the study. The consent form will describe the baseline and follow-up assessments, including hemoglobin A1c testing. The consent form will also describe subsequent procedures for eligible persons, including randomization to one of two treatment groups, details of the study treatments, and the follow-up assessment schedule.

Staff will evaluate potential participant's capacity to provide informed consent, which is especially relevant to persons with low literacy. First, staff will provide the potential participant with a copy of the consent form. Then staff will 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 their ability to control their diabetes and reduce hospitalizations. 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."

Staff 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, staff will document if the person can provide informed consent. We will only enroll participants if staff judges them to have an adequate understanding of the study. We also instruct all participants that the study treatment supplements and does not replace the care that their primary care physicians (PCPs) provide.

7.4. Conducting Study Assessments

Dr. Casten will train the ED staff and the Outcome Assessor on REDCap and procedures for transporting data. Dr. Rovner will train on testing HbA1c. He will also train staff to administer each instrument in the assessments (baseline and follow-up). Training will include a half day of instruction. Staff will then observe Dr. Rovner administer the assessment to Dr. Casten, after which Dr. Rovner will review the assessment. Staff will then administer the assessments to 5 practice participants with Dr. Rovner present. Certification will be granted by Dr. Rovner upon successful completion of 5 practice participants. Dr. Rovner will have regular meetings with the ED staff 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

Staff 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 3 study staff. Certification will be granted by Dr. Rovner upon successful completion of 3 practice administrations.

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

Training for the CHW interventionists will be conducted by Drs. Rovner, White, and Casten. The PREVENT 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 PREVENT 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 Plans 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 PREVENT 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 PREVENT 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 PREVENT or EUC Treatment Fidelity Form (to rate the quality of the delivery of diabetes education, explaining the PREVENT 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 previous diabetes study conducted by the PI. She will explain to these participants that a new 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. Staff will deliver 6 sessions to these practice patients; they 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 PREVENT 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 PREVENT and EUC CHW interventionists). During these meetings, the interventionists will present their active cases, and have the opportunity to ask questions.

7.7. PCP Training

Dr. Powell will act as the liaison between the primary care providers at Jefferson and the study team. All primary care physicians at Jefferson are 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 PREVENT intervention; and (3) instruction on how to administer the intervention to patients randomized to the PREVENT 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; and (3) incorporating information provided by the CHW on diabetes self-management behaviors, goals, and barriers into routine care. 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 may 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 Chang 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 Chang will orient ED staff to the proposed project, including study goals, 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 Outcome Assessor, and the CHW interventionists on the recognition and management of psychiatric and medical emergencies, including procedures for reporting such events. 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 staff to collect data from medical charts, including the primary outcome (number of ED visits and hospitalizations). He will have staff garner medical chart data for the 10 practice participants, 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 for 10 practice participants. 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 staff collects from medical records. In instances in which errors are detected, Dr. Casten will meet with the Research Assistant 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 protected health information (PHI) on study documents); and (4) only using Jefferson email addresses for study communication.

7.11.3. REDCap

All study data will be entered into Research Electronic Data Capture (REDCap). REDCap is a secure web application for building and managing online surveys and databases. While REDCap can be used to collect virtually any type of data, it is specifically geared to support online or offline data capture for research studies. Study staff will receive training on 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 interventionist on the technical aspects of facilitating the telehealth visits. The instructions for the CHW interventionist to conduct the telehealth visits are in Appendix 2. The telehealth visits with Dr. White will be conducted via Bluejeans.

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 maintaining good clinical practice. In conducting an RCT of a behavioral intervention, 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, the Study Coordinator, the CHW interventionists, the diabetes nurse educator, and PCPs treating participants randomized to PREVENT 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 document it 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 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 PREVENT 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 PREVENT 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 staff 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. PREVENT

PREVENT 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, PREVENT 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. For participants who do not have a Jefferson PCP, the CHW will fax the form to the PCP. Dr. White will supervise the CHW during twice monthly meetings. 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 social services 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 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 PREVENT 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. The CHW EUC interventionist 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, function, adherence to diabetes self-management behaviors, and depression

(3) Inconvenience or fatigue associated with the 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 and depression

(2) Evaluation of cognitive functioning

(3) Detection of unstable medical or psychiatric condition, diagnosis of dementia, or unsafe living situation and subsequent action to be undertaken by study staff (e.g., referral to primary care physicians, local memory clinics, acute medical or psychiatric services, social services, and crisis intervention)

(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 Outcome Assessor will also assess depressive symptoms and suicidal ideation. In addition, every 6 months staff 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 phone call or a PREVENT or EUC treatment session.

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 (e.g., Area Agencies on Aging). 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. 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 DSMB. 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 DSMB at designated intervals (e.g., quarterly) as determined by the DSMB during study start-up.

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 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 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 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. For psychiatric emergencies (e.g., suicidal ideation), staff will call PI Rovner, a geriatric psychiatrist. Conditions of special interest include:

a. Suicidal Ideation: To detect suicidal ideation, staff will 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 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 it is detected during the in-home 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. 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, or recommend a course of action to study staff.

b. Cognitive Impairment: If incident 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 appropriate 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 ED staff 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.

10.4. Interim Analysis

PREVENT 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 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 monitor participant safety, evaluate the progress of the study, 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. AEs and Alerts will be reported at regular intervals to be decided upon by the DSMB. The DSMB will meet at least once annually by teleconference call to review study progress, data quality, and participant safety. The DSMB may request teleconference calls if needed.

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 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 PI;
- Protecting the safety of the study participants;
- Making recommendations to the PI concerning continuation, termination or other modifications of the trial based on the observed beneficial or adverse effects of the treatment under study; and
- Ensuring the confidentiality of the study data and the results of monitoring.

11: PSYCHIATRIC EMERGENCY PLAN

To detect suicidal ideation, the Outcome Assessor administers 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, 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 suicidal thoughts, or who express imminent intent with or without a method of self-harm, represent an immediate threat. Staff will contact Dr. Rovner, who will talk with the participant to assess the level of risk and determine an appropriate course of action. 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 call Dr. Rovner ASAP. 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 the PI, the Project Director, and the Study Coordinator. 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, 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 the PI, the Project Director, and the Study Coordinator 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 staff 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, staff 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 staff 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.

Although there will be efforts to minimize missing data, missing data will be handled in the following way: at each time point, participants who complete that assessment will be compared to those lost to attrition on all baseline variables as well as those from previous time points if appropriate. Any variable(s) that emerge as significantly different will be controlled statistically.

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, 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.

12.4. Procedures for Data Checking and Editing

After completing an in-home assessment, the Outcome Assessor should not leave the participant's home until they check REDCap to verify that: (1) that the correct participant ID was selected; (2) all questionnaires are completed; and (3) missing data are properly coded. Once the Outcome Assessor gets back to the office, she will enter in REDCap all data that were collected on paper forms (e.g., LAD, MOCA). The Outcome Assessor should also check to be sure that all hard copies are properly labeled with the date of the assessment, the participant's initials and ID, and the assessment type (e.g., 6 months). Assessments should be marked as "unverified". The assessor will then email the Project Director and the Study Coordinator to inform them that the assessment was completed. The subject line of the email should contain the participant's initials and ID (for example, CRJC0001). The body of the email should contain the following completed table (note example provided). The image of the A1c readout should be attached to the email. The email must be sent the same day that the assessment occurred.

Notification of Completed Assessment Table

Participant ID:	CRJC00001
Assessment date:	9/14/18
Assessment:	Part 2 Baseline
Comments:	

Once the email has been sent, the Outcome Assessor should upload the recording of the assessment to the designated location on the shared drive. All tapes must be uploaded and all hard copies of paperwork must be turned into the Study Coordinator within 1 business day of the assessment. Staff will scan all hard copies and store them on the appropriate location of the shared drive. Staff will download the A1c image and store it in the appropriate location on the shared drive.

The Research Assistant, who is employed by the Department of Neurology at Jefferson and is not paid by this grant, will then review the tape and update the REDCap files as necessary. All data edits made by the Research Assistant must be recorded on the Assessment Check excel file, which will be stored on the shared drive. If additional information is required from the Outcome Assessor (for example, a skipped question), the Research Assistant will email the Outcome Assessor, the Project Director, and the Study Coordinator. The subject line should be the participant's initials and ID. The body of the email should include the following table:

Data Query Table

Participant ID:	CRJC00001
Assessment date:	9/14/18
Assessment:	Part 2 Baseline
Data issue:	PHQ6 is blank and is not asked on the tape

Within 1 business day of receiving this email, the Outcome Assessor should "reply all" with the response to the query. The Research Assistant will then update REDCap as necessary, and will indicate in the Assessment Check excel file that the Outcome Assessor responded to the query. Once all queries have been resolved, the Research Assistant will mark the assessment as "verified" in REDCap.

Data forms (both hard and electronic forms) will be reviewed within 1 week of completion by the Research Assistant. 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 Research Assistant will also check to assure that consent forms are signed appropriately. The Research Assistant will then scan the consent form and store it on the server. The hard copy will be stored in the participant's research chart.

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 9/1/17, 10:00 AM, and I am with CBWR00001 to conduct the Part 2 of the baseline assessment". Within 1 week of an assessment being completed, the Research Assistant will listen to the audio recording of the assessment, and compare it to the corresponding data entered into REDCap.

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) Not Applicable = 9999; (2) Refused = 7777; (3) Missing due to impaired vision = 8888; and (4) Reason for missing data unknown 5555.

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.

13.1. 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 PREVENT 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 PREVENT to reduce the number of incident DM-related ED visits and/or hospitalizations over 12 months (primary outcome). Hypothesis: PREVENT 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, cognitive functioning, 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 PREVENT participants vs. EUC participants who would have been adherent had they been assigned to PREVENT. 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 PREVENT 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 PREVENT to increase perceived access to care over 12 months (secondary outcome). Hypothesis: PREVENT will increase Patient Satisfaction Questionnaire-18 (PSQ-18) scores to a greater extent than EUC over 12 months.
2. Test the efficacy of PREVENT to increase realized access to care over 12 months (secondary

outcome). Hypothesis: PREVENT will increase the number of received Diabetes Quality Metrics to a greater extent than EUC over 12 months.

3. Test the efficacy of PREVENT to improve DM self-care over 12 months (secondary outcome). Hypothesis: PREVENT 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 PREVENT's reduction of DM-related ED visits and/or hospitalizations. Hypothesis: PREVENT 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 PREVENT 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 PREVENT 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 PREVENT which confer its cultural relevance.
Analysis: We will use descriptive statistics to characterize responses on the Cultural Relevance Rating Form in participants assigned to PREVENT. 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 PREVENT'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 PREVENT 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

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.

Year 1						Year 2						Year 3						Year 4					
2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48
START UP																							
			BASELINE ASSESSMENTS																				
			6 INITIAL INTERVENTION SESSIONS OVER 4 MONTHS																				
					3 BOOSTER SESSIONS AT 6, 8, AND 10 MONTHS																			
						6 MONTH FU ASSESSMENTS																	
									12 MONTH FU ASSESSMENTS														
																				DATA ANALYSIS; DISSEMINATION			

APPENDIX 1: SETTING UP MYCHART ACCOUNTS

All participants, regardless of whether or not they have a Jefferson PCP, will need to have a MyChart account. If they are randomized to the PREVENT group, they will need the account to have telehealth visits with their PCP. THE PARTICIPANT DOES NOT NEED TO HAVE AN EMAIL ADDRESS TO SET UP MYCHART.

Please ask the participant if they already have a MyChart account. If they do, ask them for their user name and password, and sign in using your computer to be sure that the account is active. If their user name or password is incorrect, work with them to re-set their account. You may need to call the help desk at 215-503-5700.

If they do not have an account, open the participant's snapshot on EPIC. Then click edit demographics>additional information>sign up. This will proxy you out of EPIC into the sign up website, where the participant will assigned a username and password.

APPENDIX 2: FACILIATING PCP TELEHEALTH VISITS

Web Browers: Please use Internet Explorer, Safari or Firefox.

Step 1: Activate Account from invite received through email or code at office check-out. SSN might be 9999, 1111 or 0000 depending if real SSN was NOT collected in office.

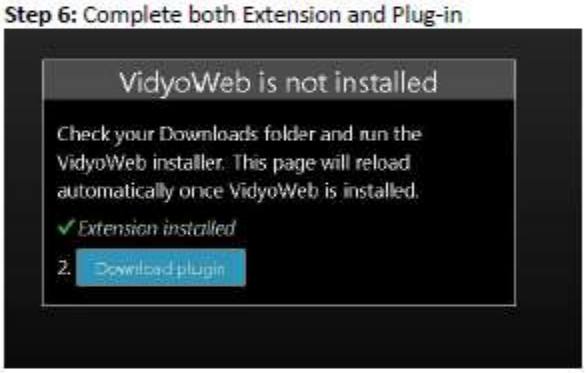
Step 2: Log in (if account active)

Step 3: Select Upcoming Visits

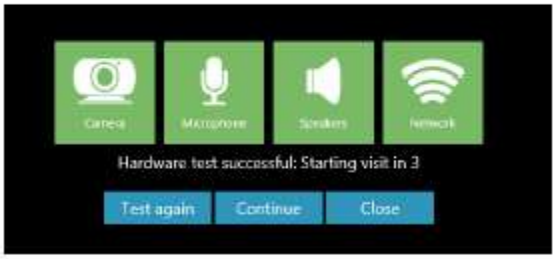
Step 4: Select Time/Date of Visit

Step 5: Begin Visit

Step 6: Complete both Extension and Plug-in



Step 7: Hardware Test



Step 8: You visit will now begin, please make sure your speaker volume are adjusted and that you have not muted your connection.

APPENDIX 3: GENERAL INSTRUCTIONS FOR ALL STAFF

1) To comply with HIPAA, all paperwork that contains PHI must be stored in a locked bank bag. You will be issued a HIPAA compliant bag that contains 2 keys. Robin and Megan will keep 1 key as a back-up. In addition, you will need to put your name and phone number on the outside of the bag. All cash for study incentives must be stored in the bag during transport.

2) Only use your Jefferson-issued devices for study-related purposes. Do not use any personal devices.

3) All communication regarding this study must be conducted through the Jefferson email system. For privacy purposes, Jefferson email accounts may not be forwarded to a personal smart phone or any other mobile device. PHI may only be included in an email if the recipient address is a Jefferson email.

4) All assessments and treatment sessions should be audio taped for quality assurance purposes. When participants are consented, they will be told that all visits will be audio taped. We will be giving you a digital recorder. Since the recordings are not encrypted, please do not ever say a participant's name or any other identifying information (e.g., birth date) on the tape. Please begin each recording with your name, the participant's study ID and initials, the date of the session, and the session type and number. For example, "This is Robin Casten. I am with subject CABC123456 on 12/5/18 for a 6 month assessment". After the session is complete, please upload your tape onto the study shared drive. All files should be named with the participant's initials, ID, type of assessment, staff initials, and date. For example, "CABC123456 Baseline Part 2 RC 08-31-18." All tapes must be uploaded within 24 hours of the session being completed.

5) Schedules for the upcoming week must be sent on Fridays by noon.

6) We are required to report any potentially unsafe situations (e.g., suspected abuse, unsafe living situation, lack of heat/air conditioning, bug infestation) to the appropriate agencies. If you encounter a situation that needs reporting, please contact Robin at 215-713-6786 or Barry at 215-503-1230. They will give you instructions for addressing the situation (e.g., contact Philadelphia Corporation for Aging). Within 24 hours of reporting the event via phone, please send an email to Robin, Barry, and Megan that describes the event, including any instructions given to you regarding the handling of the event.

7) This study requires home visits, and thus you may encounter potentially unsafe situations. If you encounter a situation that makes you feel unsafe (e.g., sexually inappropriate comments, gun in plain sight, bad neighborhood), or if you suspect that there is drug use or any other questionable activity going on in the home, you should leave immediately. You can politely say something like "I left some study materials in my car and I'm going to get them". And then just drive away. If you are in the home for an assessment, and the participant asks you for their incentive, you can give them the money, even if the assessment wasn't completed. You do not need to have them sign the receipt in this circumstance. Your safety is the top priority. Another strategy you can employ is to send a text (even a blank text) to Megan, Alesia, or Robin. They will then call you right away to be sure that you are OK. Alternatively, you can ask Megan, Alesia, or Robin to call you at a designated time when you are in a participant's home to check on you. If such an incident occurs, please email or call Robin or

Megan as soon as you can. Robin or Megan will call the participant and notify them that if they wish to continue participating in the study, all visits must occur at Jefferson. The study will cover the cost of the participant's roundtrip travel to Jefferson. Staff will no longer be permitted to make home visits to the participant.

8) If at any time you suspect that a participant is severely depressed, please email Robin, Barry, and Megan as soon as you can. If you think they are in a severe crisis, please follow the Psychiatric Emergency Plan that is described in the MOP. If the participant has suicidal ideation, please call Barry ASAP. Call Robin if you cannot reach Barry.

APPENDIX 4: GENERAL INSTRUCTIONS FOR THE OUTCOME ASSESSOR

1) Please update the Contact Information Form at the 6 and 12 month assessments.

2) Unmasking:
   - Please ask the participant to NOT tell you what group they are in.

   - If the participant or any staff member discloses a participant's treatment assignment, please email Robin and Megan ASAP.

3) Missing data should be coded as follows:

   - Not Applicable = 9999
   - Refused = 7777
   - Missing due to impaired vision = 8888
   - Reason for missing data unknown 5555

4) Not Applicable (NA):
   - NA is to only be used in 2 circumstances:
     - The question does not apply to the participant.
     - The participant is physically unable to respond to a cognitive question/task.

   - Low literacy is not a reason for using NA. For example, if a participant is not able to read the words on the LAD, the response for each word should be "incorrect". Being wheelchair bound is also not a reason for using "NA" on questions regarding walking. These questions should be coded to reflect the fact that the participant is not able to do the activities.

   - For the Diabetes Self Care Inventory, if a participant indicates that they never have low blood sugar, their response should be "never do it". This scenario also applies to question 6 (carry quick acting sugar for lows).

   - For the questions on hypoglycemia, if the participant responds "No" to the first question (have you had a hypoglycemic episode), the response to the remainder of the questions in this section should be NA. Otherwise, all questions must have a response other than NA.

5) Part 2 of the baseline assessment:
   - Our goal is for all Part 2s to be completed within 2 weeks of Part 1.
   - This is very important to maintain participant interest in the study and to insure integrity of study data.

6) A1c results:
   - Take a photo of the result with your Jefferson-issued iPhone and email to Robin, Megan, and Alesia.
   - Please make sure the proper study ID is on the image.
   - Enter the result in REDCap.

- Megan will verify the result entered in REDCap against the image.

7) Medication lists:
- At Part 1 of the baseline assessment, the ED staff will obtain a list of medications from EMR.
- At 6 and 12 months, staff will obtain medication lists from EMR.
- At the in-home assessments (Part 2 of baseline, 6, and 12 months), the Outcome Assessor will obtain self-reported medications.
    - First, ask to see the participant's medications bottles (or a list of they use a med box), including supplements and over the counter drugs.
    - Second, ask the participant's if they take any other medications that they aren't showing you.
    - Enter the medication names, doses, and number of time per day that they take each medication into REDCap.

8) Patient Health Questionnaire (PHQ 9):
- If the participant seems severely depressed, please email Robin, Barry, and Megan as soon as you can. If you think they are in a severe crisis, please follow the Psychiatric Emergency Plan.
- If the participant responds with anything other than "0" for question 9, please administer the Columbia-Suicide Severity Rating Scale.
- If the participant has suicidal ideation, please call Barry ASAP. Call Robin if you cannot reach Barry.
- If the participant does not have suicidal ideation, please email a description of the participant's responses to the PHQ and the Columbia to Robin, Barry, and Robin.
- Be sure to include your impressions/observations of the participant.

9) After completing an in-home assessment, the Outcome Assessor should not leave the participant's home until they check REDCap to verify that:

(1) The correct participant ID was selected.
(2) All questionnaires are completed.
(3) Missing data are properly coded.

Once the Outcome Assessor gets back to the office, they will enter in REDCap all data that were collected on paper forms (e.g., LAD, MOCA). The Outcome Assessor should also check to be sure that all hard copies are properly labeled with the date of the assessment, the participant's initials and ID, and the assessment type (e.g., 6 months). Assessments should be marked as "unverified". The Outcome Assessor will then email Megan, Robin, and Alesia to inform them that the assessment was completed. The subject line of the email should contain the participant's initials and ID (for example, CRJC0001). The body of the email should contain the following completed table (note example provided). The image of the A1c readout should be attached to the email. The email must be sent within 1 business day of the completion of the assessment.

Notification of Completed Assessment Table

Participant ID:	CRJC00001
Assessment date:	9/14/18
Assessment:	Part 2 Baseline
Comments:	

Once the email has been sent, the Outcome Assessor should upload the recording of the assessment to the designated location on the shared drive. All tapes must be uploaded and all hard copies of paperwork must be turned into Megan within 1 business day of the assessment. Alesia will scan all hard copies and store them on the appropriate location of the shared drive. She will also download the A1c image and store it in the appropriate location on the shared drive.

10) To ensure that in-home baseline assessments are properly conducted, assessors will be notified of new subjects as follows:

A) In the email notification, the subject line will contain the participant ID and type of assessment (B1 and/or B2).

- B1: Consent, med release, pharm release, datasheet
- B2: A1C, vitals, MOCA, self-report questionnaires

Sometimes there were will be specific notes, which will be documented in the below table.

Subject Initials and ID: CXXX00002
Assess type: B1
Consented: Needs consent
Notes: Participant was discharged prior to consent, please consent

B) Instead of having 2 separate folders for each assessment type, there will only be 1 participant folder. Anything that needs to be completed will all be put in the 1 folder. Each baseline packet will have an attached label on it. It will document where in the baseline process each participant is. You will be asked to check, initial and date each item as it is completed.

- For example, if the participant was consented in the ED, Megan will sign off on what was completed, and the Outcome Assessor will mark off when they complete Baseline Part 2.

- It is IMPERATIVE that the Outcome Assessor only use the folder that is assigned to each participant. Do NOT recycle folders or switch out for other participant.

Check, initial and date when completed:

__ Consented: _____

__ Medical Release: _____

__ Pharmacy Release: _____

__ Data Sheet: _____

__ $10 Payment: _____

__ A1C: _____

__ Baseline Part 2: _____

__ $20 Payment: _____

11) Please complete an Assessment Documentation Form in REDCap after each assessment to document the date, start time, end time, and travel time for each assessment.

APPENDIX 5: GENERAL INSTRUCTIONS FOR INTERVENTIONISTS

1) To schedule telehealth visits with the PCPs, call 1-800-JEFFNOW. These visits will be conducted via MyChart. Note that this does not apply if the participant does not have a Jefferson PCP.

2) To schedule telehealth visits with Dr. White, contact her directly.

3) The audio recorder should not be on during the telehealth visits.

4) If you give the participant a mental health referral, please inform the PCP ASAP, and let them know where you sent the participant for care.

5) Please turn in all paperwork from the initial 6 sessions to the Study Coordinator within 2 weeks of the 6th session. Please enter the paperwork in REDCap and turn in any hard copies. Please turn in paperwork from the booster sessions within 2 weeks from each booster session. Tapes should be posted within 1 business day of the session being completed. The Study Coordinator will document that the paperwork was handed in, and it will then be scanned (and stored on the shared drive).

APPENDIX 6: PROCEDURES FOR RECORDING INCIDENT ED VISITS/HOSPITALIZATIONS

1) Whenever any staff learn of a new ED visit or hospitalization, they must complete an Incident Hospitalization/ED Visit Form. If the event was learned of at an assessment visit (baseline or FU), the Outcome Assessor will complete the required fields on the assessment in REDCap AND will complete an Incident Hospitalization/ED Visit Form in hard copy (not REDCap).

2) The completed Incident Hospitalization/ED Visit Form must be emailed to Robin, Alesia, and Megan as soon as possible.

3) If the event occurred at Jefferson, Alesia will go into EPIC and verify (and correct if necessary) the information on the Incident Hospitalization/ED Visit Form (for example, incorrect date).

4) If the event occurred at a non-Jefferson facility, Alesia will fax the release and a request for details about the event to the treating hospital. Once the requested information is received, Alesia will verify (and correct if necessary) the information on the Incident Hospitalization/ED Visit Form.

5) Alesia will enter the verified and corrected data from the Incident Hospitalization/ED Visit Form into REDCap.

6) Alesia will complete Part 1 of the Event Form and email to Barry, Robin, Megan, and Drs. Chang and Rising.

7) Drs. Chang and Rising will separately complete Part 2 of the Event Form, and email back to Robin, Alesia, and Megan.

8) If there is a discrepancy between the responses to Part 2 provided by Drs. Chang and Rising, Megan will email the Event Form to Dr. Hollander to complete. When there is not a majority determination among the 3 physicians, the 3 physicians will be asked to discuss the event and reach consensus.

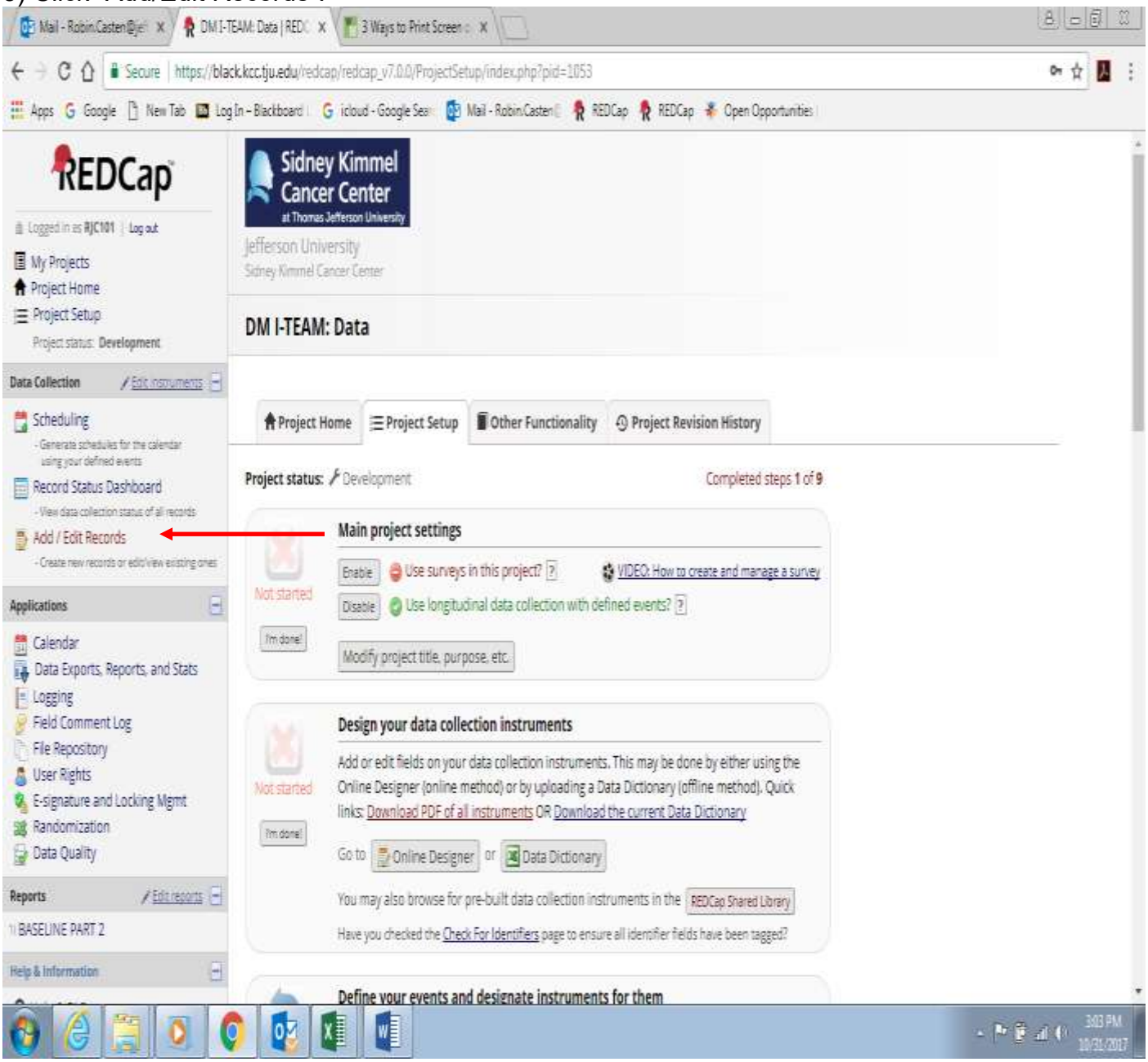
9) Alesia will enter each physician's response to Part 2 of the Event Form in REDCap.

10) Staff will conduct medical chart reviews for all participants at 6 and 12 months. If when reviewing the charts, staff learns of an ED visit or hospitalization that HAS NOT BEEN PREVIOUSLY reported by staff (i.e., an event for which there is no Incident Hospitalization/ED Visit Form), staff will complete an Event Form, and follow steps 6 through 9. In this situation, an Incident Hospitalization/ED Visit Form will not be completed.

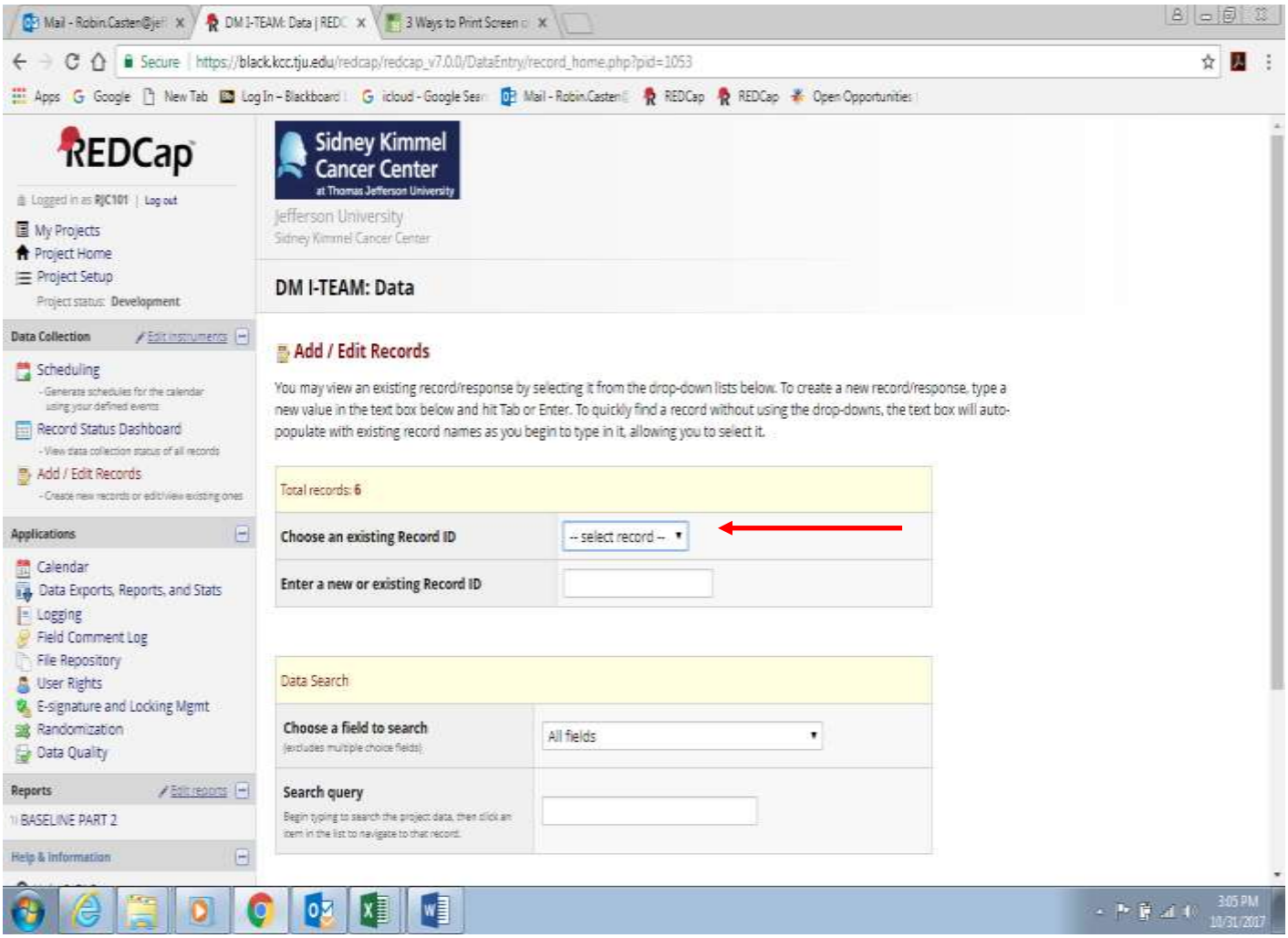
APPENDIX 7: PROCEDURES FOR CHECKING DATA

Alesia will check data via REDCap rather than SPSS. She will also make all edits in REDCap. Robin will download the SPSS files monthly. Procedures for checking data in REDCap are as follows.

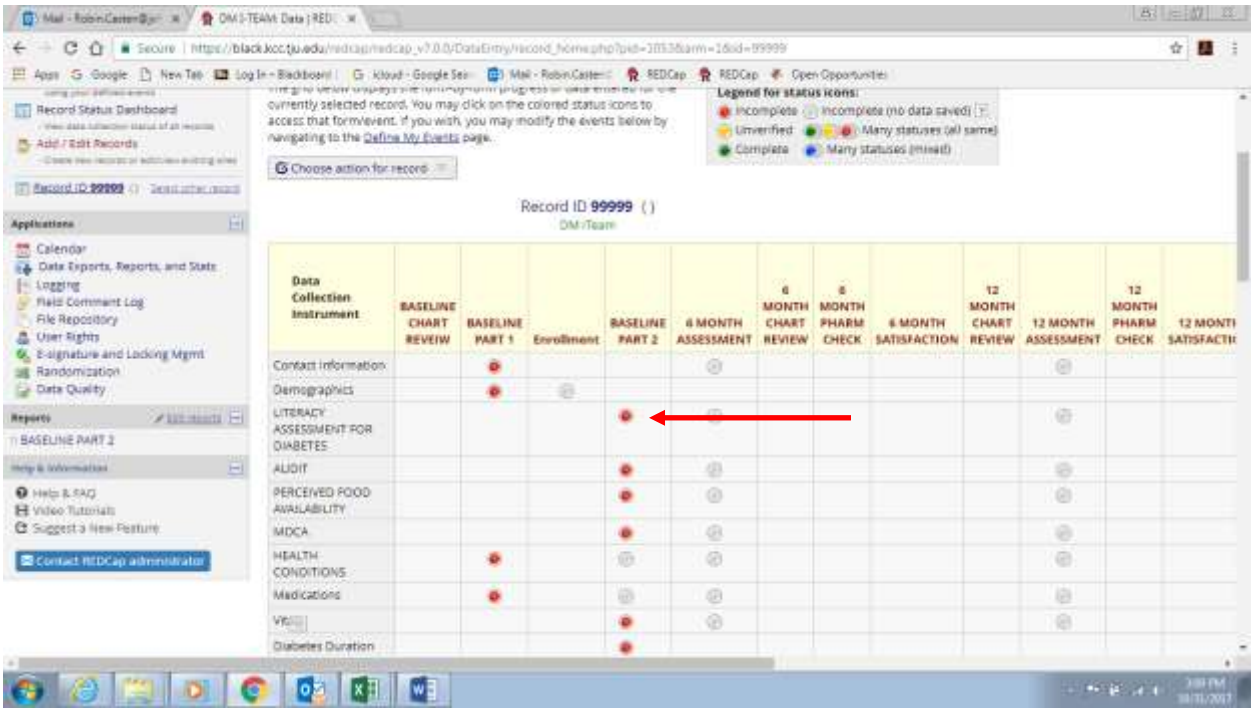
1) Log on to REDCap.
2) Under “My Projects”, click “PREVENT: Data”.
3) Click “Add/Edit Records”.



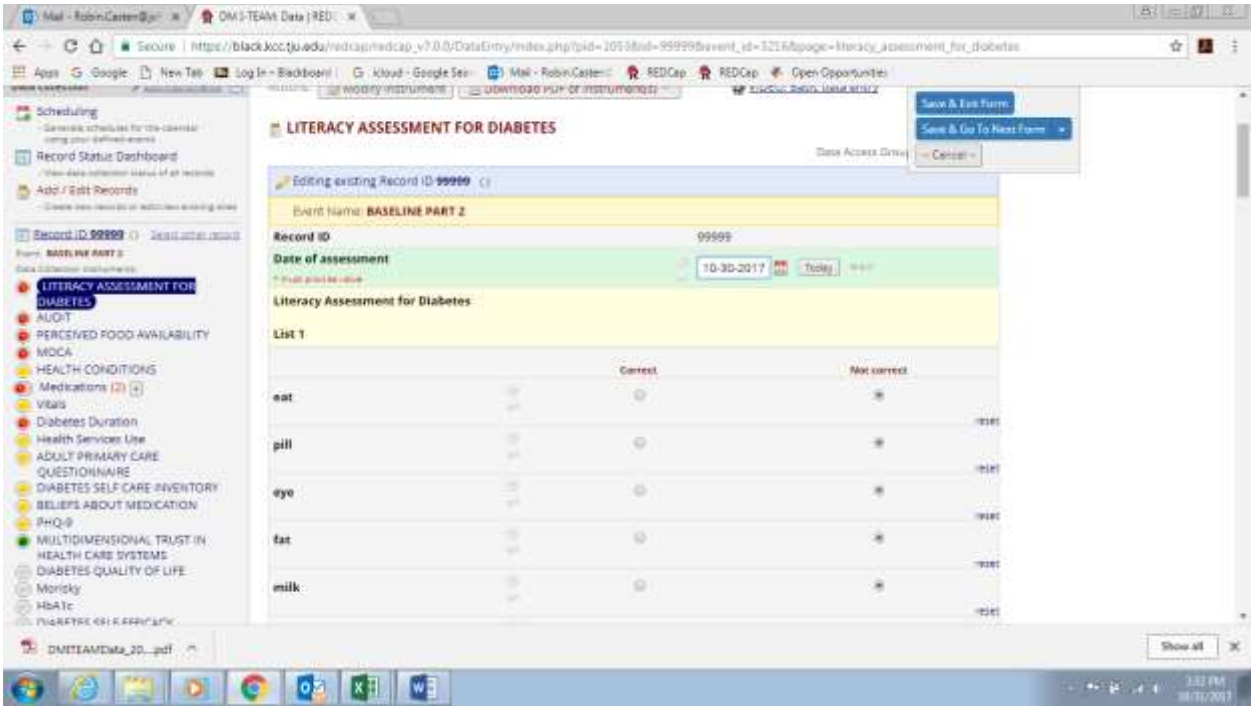
4) Find the subject from the drop down menu under “Choose an Existing Record ID”. You will know when an assessment is complete because the assessor will send you an email, and the A1c print out will be attached to the email.



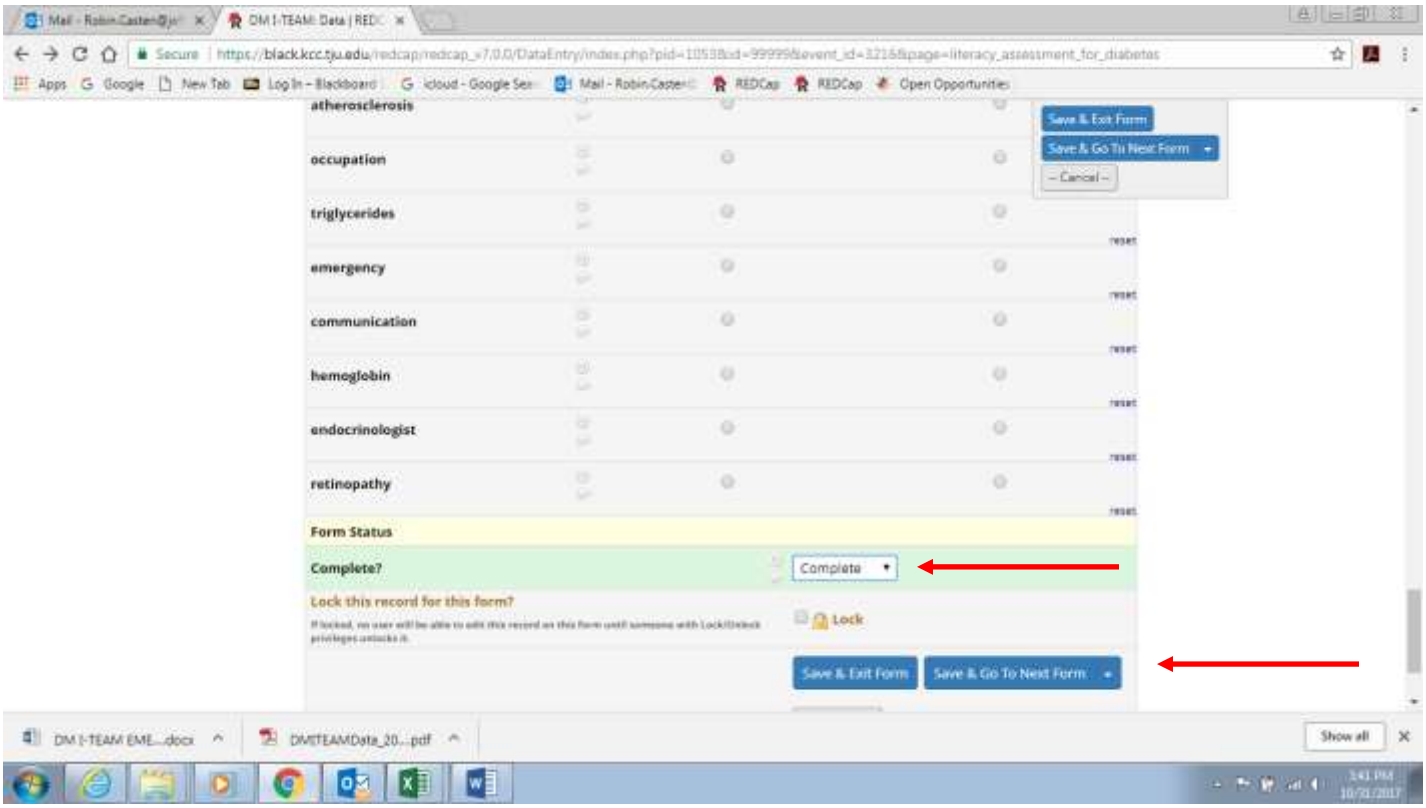
5) Go to the assessment that you want to review. Click on the first instrument for that assessment. Click on the red circle to open it.



6) Here you will see the responses to the first instrument.



7) When you get to the end of the instrument and all errors have been corrected, click “Complete” from the drop down menu. Then click “Save and Go to Next Form”.



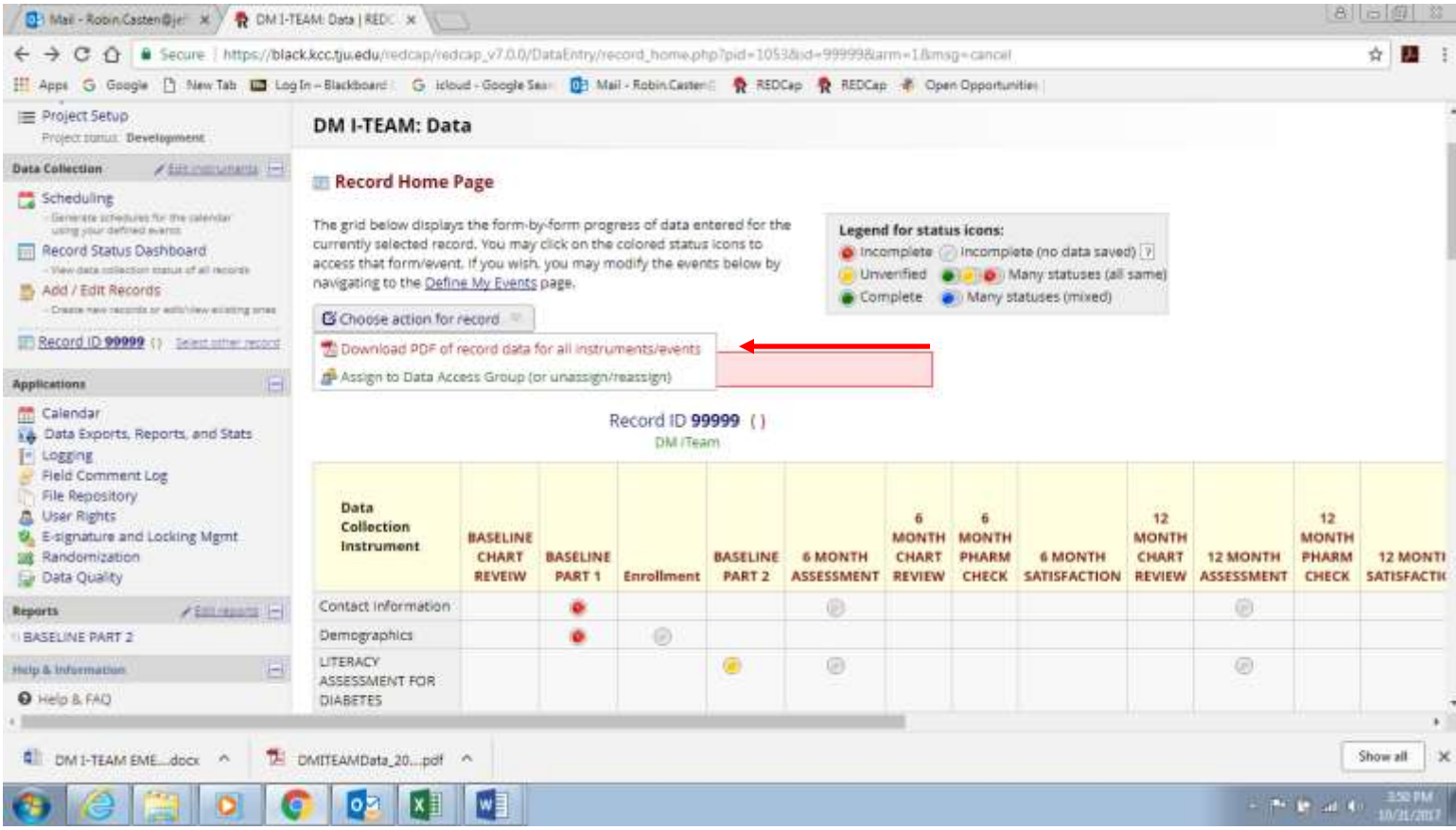
8) If you notice an error in the data, make the change in REDCap before you mark the instrument as "Complete". Log the change in the excel file called "Assessment Check", which will be stored on the shared drive. You can click on the "Instructions" tab in the excel file for instructions on how to complete this file. If there is an error (or missing data) that requires input from the Outcome Assessor, please send a data query to the Outcome Assessor using Data Query Table format depicted below. Please copy Megan and Robin on the email.

Data Query Table

Participant ID:	CRJC00001
Assessment date:	9/14/18
Assessment:	Part 2 Baseline
Data issue:	PHQ6 is blank and is not asked on the tape

Do not mark the instrument as "Complete" until the data query is resolved. Enter all data queries in the "Assessment Check" Excel file.

9) Once the entire assessment has been checked and everything is marked "Complete", download a pdf of the assessment. Label the pdf file with the subject's ID, assessment type, and date (for example, CRJC00001 6 MONTH 10-31-18). Save the pdf to the appropriate location on the shared. Save the image of the A1c result in the same folder on the shared.


DM I-TEAM: Data
Record Home Page
The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the Define My Events page.
Legend for status icons:
Incomplete
Incomplete (no data saved)
Unverified
Many statuses (all same)
Complete
Many statuses (mixed)
Choose action for record
Download PDF of record data for all instruments/events
Assign to Data Access Group (or unassign/reassign)
Record ID 99999 ( )
DM iTeam
Data Collection Instrument
BASELINE CHART REVEIW
BASELINE PART 1
Enrollment
BASELINE PART 2
6 MONTH ASSESSMENT
6 MONTH CHART REVIEW
6 MONTH PHARM CHECK
6 MONTH SATISFACTION
12 MONTH CHART REVIEW
12 MONTH ASSESSMENT
12 MONTH PHARM CHECK
Contact Information
Demographics
LITERACY ASSESSMENT FOR DIABETES

APPENDIX 8: PROCEDURES FOR RECORDING ATTRITION AND MISSED VISITS

1) Study Withdrawal Form: Megan or Robin will complete this form when a participant drops out of the study, expires, or is no longer able to be reached.

2) Missed Visit Log: There will be 2 versions of this form: one for intervention/telehealth visits, and one for assessment visits. This form is to be completed by the Outcome Assessor or CHW interventionist every time a visit is missed, even if the visit is re-scheduled. For example, if there is a visit scheduled for 1/1/18, but the participant calls to request to change the visit to 1/3/19, the visit scheduled for 1/1/9 should be entered in the log. These REDCap forms are the Interventionist Missed Visit Form and the Assessor Missed Visit Form.

3. Out of Window Log: There will be 2 versions of this form: one for intervention/telehealth visits, and one for assessment visits. This form is to be completed every time a visit is out of window as per the schedule of visits provided by Megan. These REDCap forms are the Assessor OOW Log and the Interventionist OOW Log.

To keep track of the number of times that staff are attempting to reach participants, staff will be asked to maintain a call log in REDCap for each participant that tracks the date of each time staff called or attempted to call the participant. The Outcome Assessor will use the Assessor Communication Log, and the CHW Interventionists will use the Interventionist Communication Log.

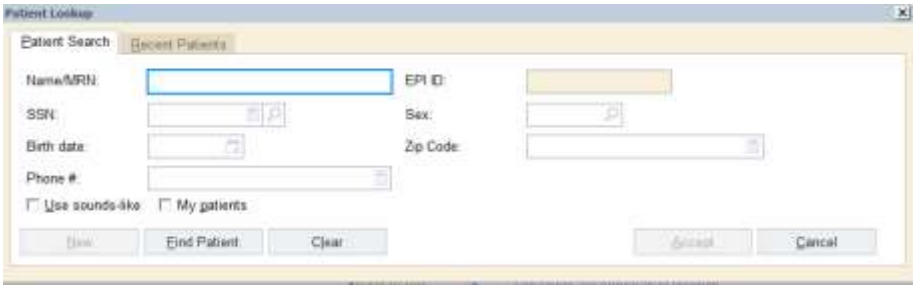
APPENDIX 9: POSTING DOCUMENTS TO EPIC

To Upload Documents

1. Sign into Epic

2. Click on “Pt Research Studies”

3. Enter MRN number for patient and Select “Find Patient”

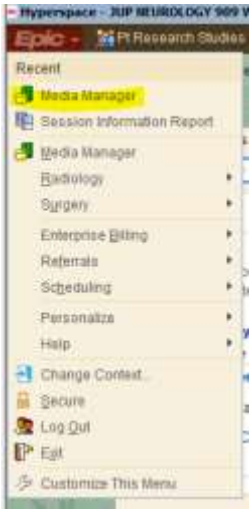


Please note that if you’ve already searched for this patient, they will be listed under the “Recent Patients” tab

4. Confirm that this is the correct patient, and double click on highlighted name

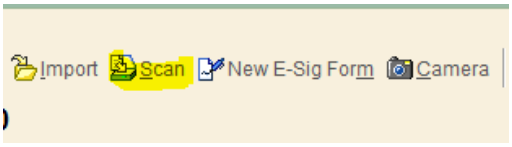
5. Click on Epic button

6. Click on Media Manager

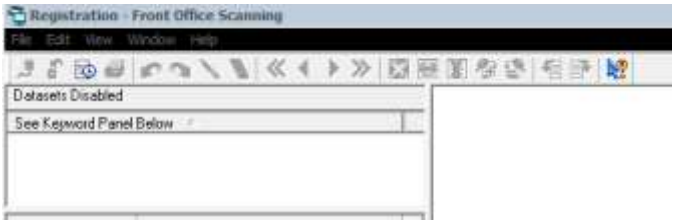


7. Double click on highlighted patient name

8. Click on scan



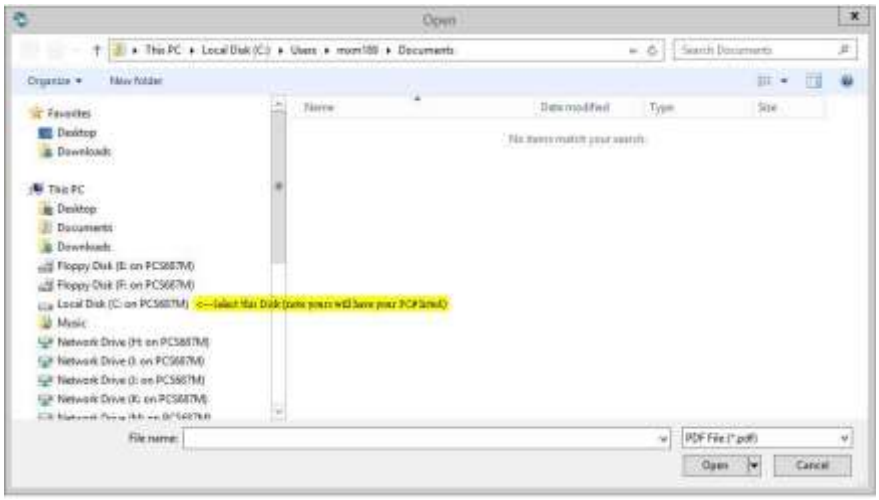
9. Click in top left of black bar and select “File”



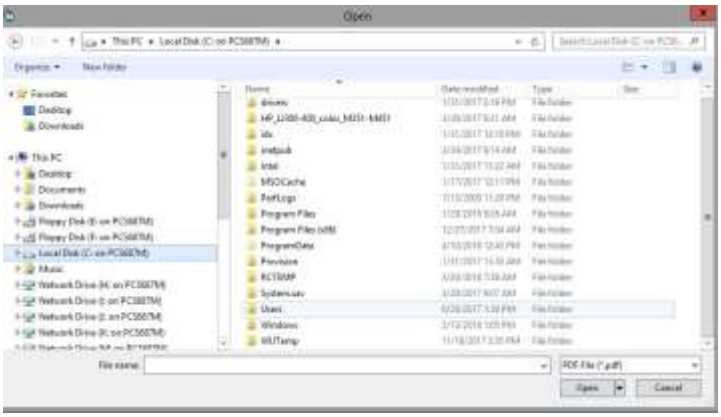
10. Click import file

11. Click on “This PC”

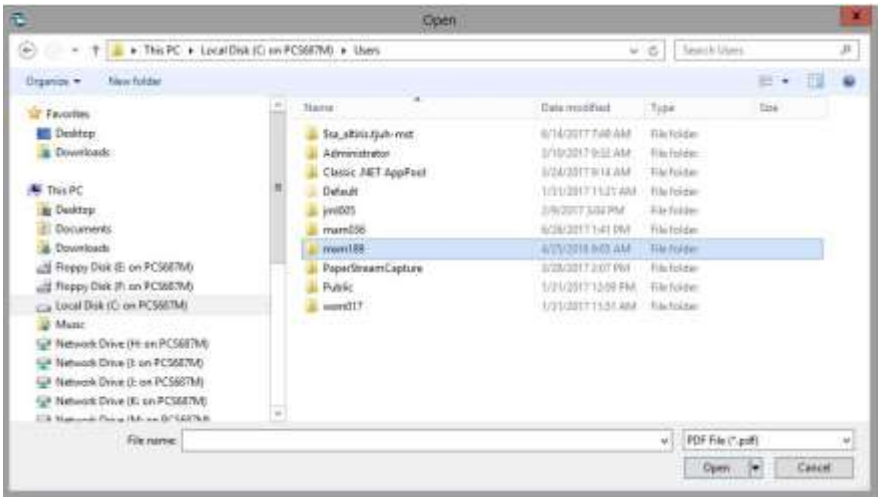
12. Click on Local Disk C: drive (Note: yours will have your PC# listed)



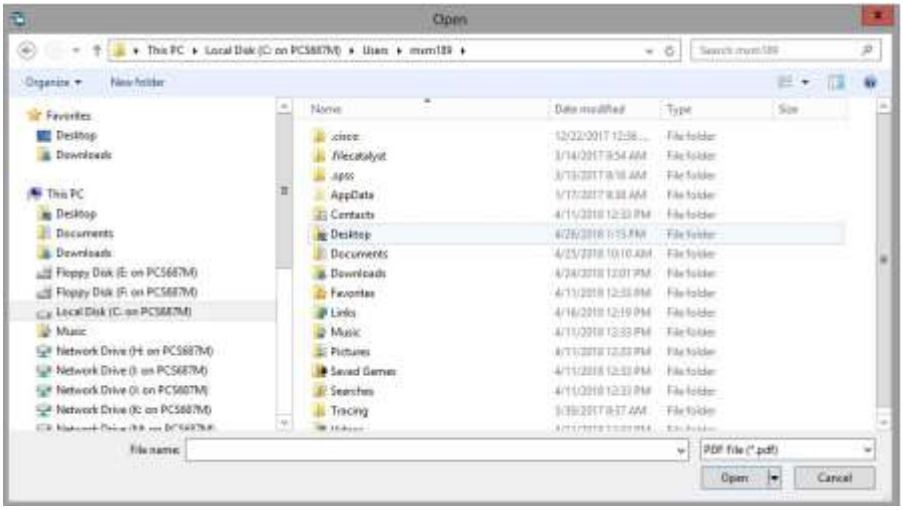
13. Click on “Users”



14. Click on your campus key folder



15. Click on location where you saved your document

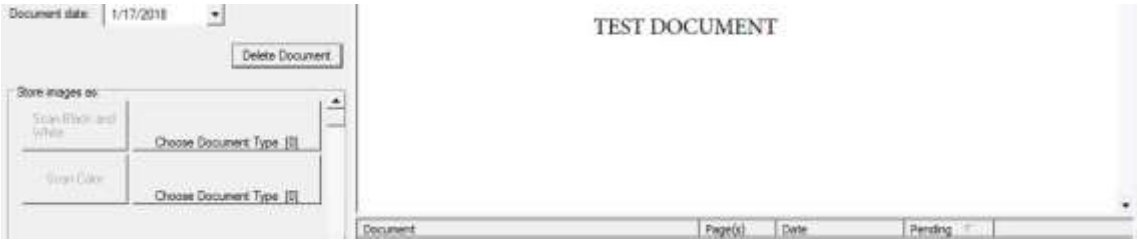


Note: I save any document that I will be posting to Epic on my Desktop for ease of upload

16. Next to file name, make sure that PDF is selected

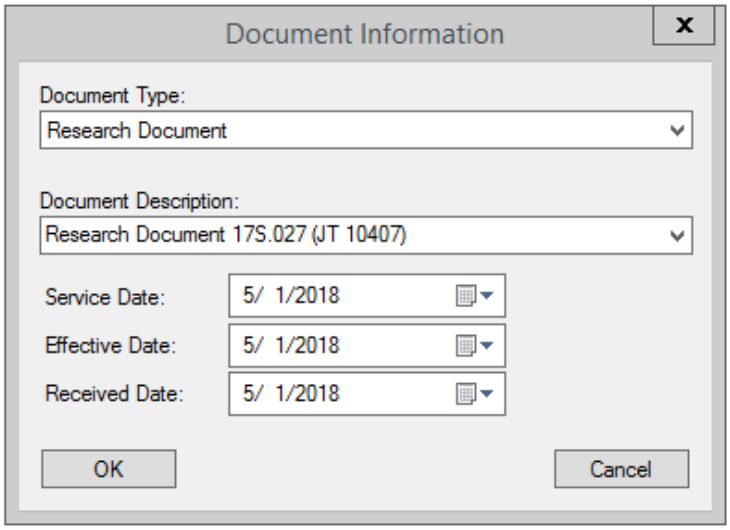
17. Search and select file

18. Form will show up in preview window



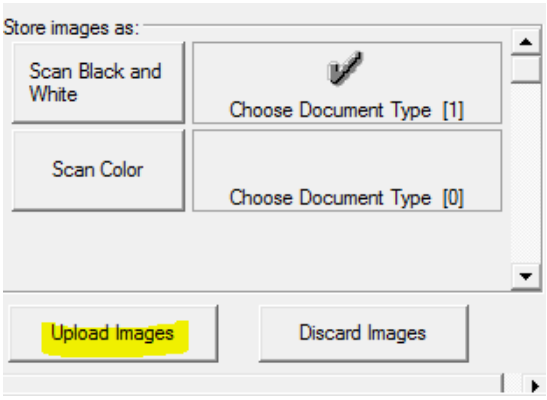
19. Under “Store image as” section click on “Choose document type”
    a. Either scan black and white or scan color

20. Document type: Research Document
21. Document Description: Research Document 17S.027 (JT 10407)



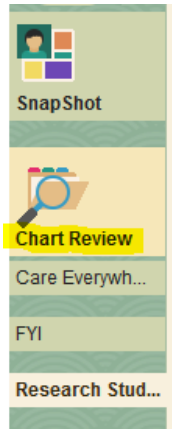
22. Click “OK”

23. Click “Upload Images”

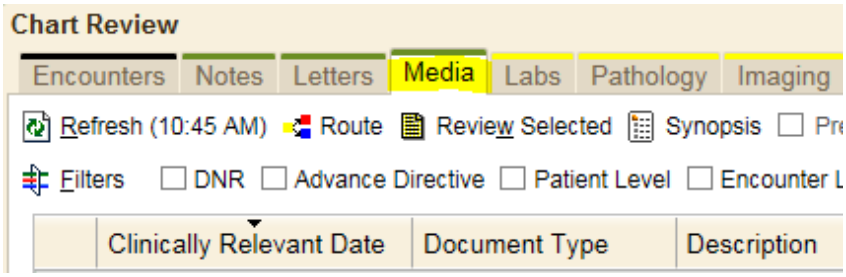


24. Close out of Media Manager

25. Click on “Chart Review”

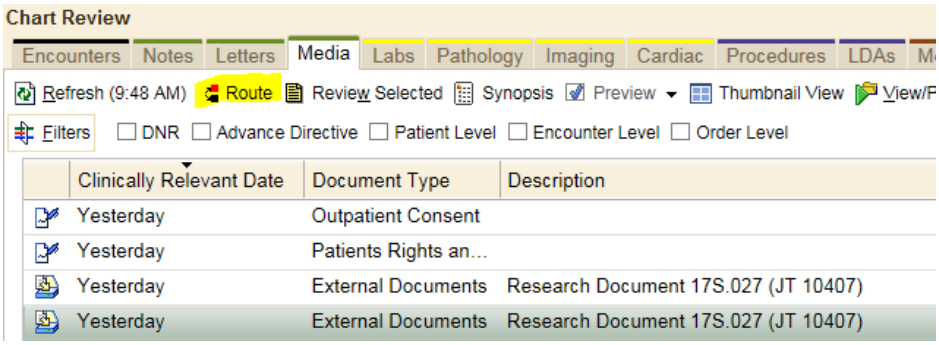


26. Click on the “Media” tab



27. Click on the document that you just uploaded

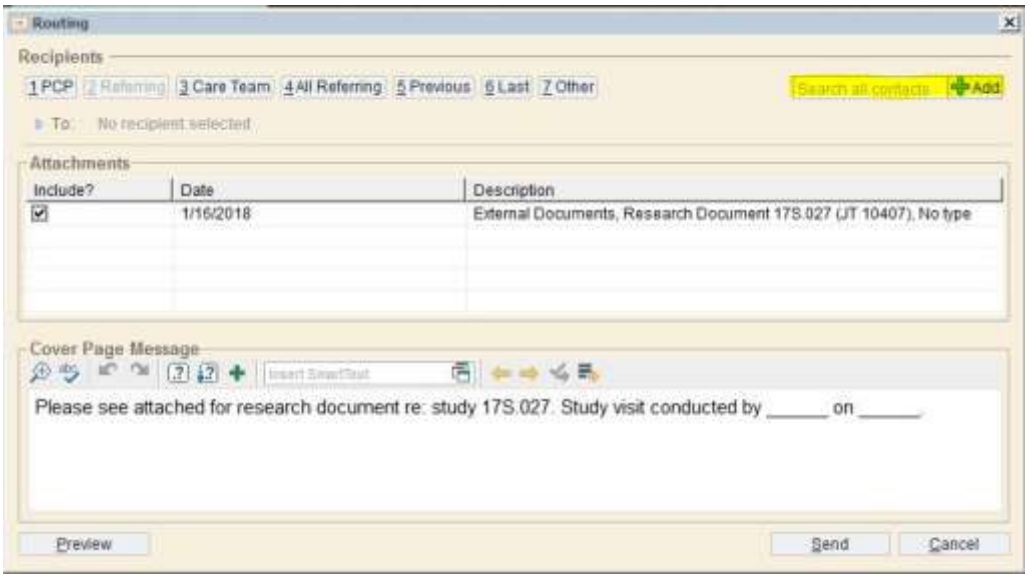
28. Click on “Route”



29. In “Cover Page Message” type:
    a. CHW: Please see attached for research document re: study 17S.027. Study visit conducted by _____ on _____.
    b. Neva: Please see attached for research document re: study 17S.027. Study visit conducted by Neva White, DNP, CRNP, CDE on _____.

30. Click “Add” button

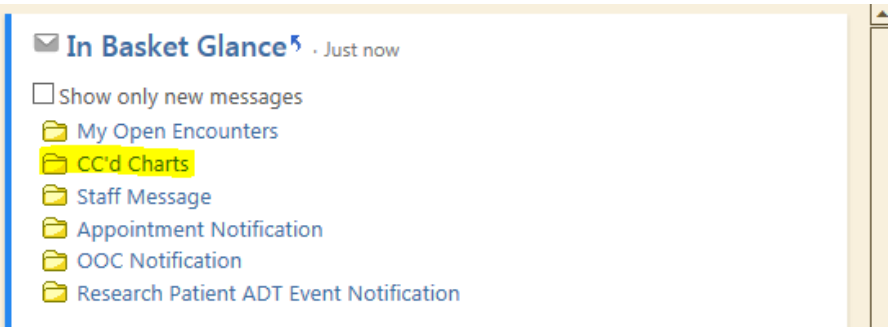
31. Enter Study Team (as applicable: Barry Rovner, Robin Casten, Megan Kelley(these 3 always), PCP, Neva White, CHW (Joann Akpan or Deiana Johnson))



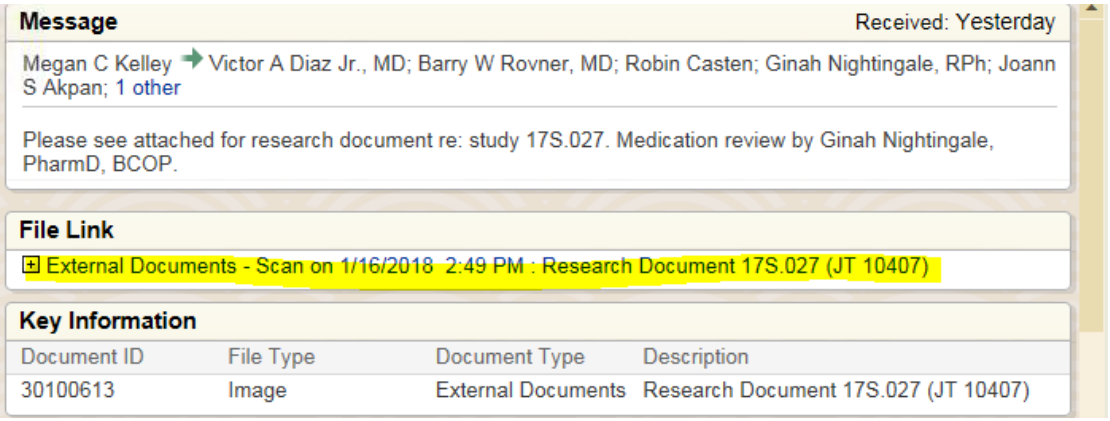
32. Click “Send”

To View Documents Uploaded

1. A message will be sent to the recipients as a CC’d Chart



2. Click on patient name and the message will pop up with a link to the document



3. Click on link to view document

To Delete Documents Uploaded Erroneously

1. Under Media Manager, click on document to be deleted.
2. Double click on the scanned document
3. Click on the blue button “Send to Document Corrections”
4. A window will open where you can indicate what you want done
    a. Ex. Please delete scan”
5. Then click on the save button

This will submit the request to HIM for them to delete.

APPENDIX 10: INTRUCTIONS FOR THE OUTCOME ASSESSOR TO COMPLETE THE DATA SHEET FROM BASELINE PART 1 IN PARTICIPANTS' HOMES

- Prior to the B1 visit, you will receive the participant's:
  - Current medications
  - Current medical conditions
  - Past medical conditions
  - Outpatient visits in past 6 months

- You should take the following with you to confirm with the subject:
  - Current medications
  - Current medical conditions
    - I recommend reviewing before the visit, as the subject may not be aware of some of the medical terms
  - Past medical conditions
    - I recommend reviewing before the visit, as the subject may not be aware of some of the medical terms

- Please fill out the Datasheet as you normally do. You will skip the following questions (Alesia will enter them directly into REDCap Datasheet):

2. AA should identify ED clinician team: Resident _____ Attending _____
5. AA should record patient's (from Epic) Height: _____inches & Weight: ____pounds
6. AA should record intake vitals (from Epic) SBP: _____mmHg DBP:_____mmHg
7. Documented ED Arrival Date and Time: _____(HH:MM):_____
8. Documented ED Triage Date and Time: _____(HH:MM):_____
9. Study Screen Date (MM/DD/YYYY): _____
10. Study Screen Number: _____
16. Patient's health insurance provider and plan (check insurance card):
29. Left Main ED Date & Time (MM/DD/YYYY): ___ (HH:MM):_____
30. Patient disposed to: □Home □Obs Unit □□Inpatient □Transfer □Other:_____
Hospital bed #: _____
31. List ED final diagnoses below:

ED Final Diagnoses	ICD10 Codes

- Document the medication/medical condition confirmation on the Epic print outs. To save time while in the home, you will enter this information directly into REDCap Datasheet when you're back in the office.
  - NOTE: If there is a self-report medication change/addition, this info should be documented in REDCap Baseline Part 2.

- As part of Baseline Part 2, you should ask about any visits in the past 6 months.
-
- Once you're back in the office, you should enter the Epic print out into Datasheet.

- This may seem redundant, but Epic may not capture out of network visits, so any self-reported visits should be entered into Baseline Part 2.

APPENDIX 11: INSTRUCTIONS FOR PHARMACY REFILL DATA

All patients: The assessor will be getting pharmacy information from participants' diabetes medication bottles at each assessment time wave (baseline, 6M and 12M)

a. This information is gathered on the "Vitals/HbA1c" form

*Jefferson Patients

1. *Jefferson Patients- We will also check Epic for Jefferson patients to insure that we have all pharmacies on file
    a. Log into Epic
    b. Search Subject by MRN
    c. Look up pharmacy information indicated in subject's chart.

2. *All Patients- Print out pharmacy refill release form from shared drive

3. Write in pharmacy information
    a. Name
    b. Phone
    c. Fax

4. Print out pharm release cover form from Filemaker
    a. In Filemaker
        i. Click "Find" and search subject's ID
        ii. Change layout (top left) to PHARMACY RELEASE FORM 6M or 12M
        iii. Click "Preview"
        iv. Click "Print Setup"
            1. Select "Landscape"
        v. Click "Save as PDF"
        vi. Will need to edit time frame (in bold)—should be date of baseline assessment (oldest pharm refill doc) through date of 6M or 12M assessment (newer pharm refill doc)
            1. Click "Tools"
            2. Click "Edit Text & Images"
5. Fax both docs to PCP (sub signed release form and release form cover (from FM))
6. Once you receive the records back from the pharmacy, write study ID and save on the shared drive folder: under the subject's folder in the Assessment PDF and tapes folder
7. Enter information into REDCap
8. File paper copies in chart 1.

APPENDIX 12: INSTRUCTIONS FOR CHART CHECKS

Jefferson Patients:

1. Log into Epic
2. Search Subject by MRN
3. Take a screen shot (use Snipping Tool) of the following items:
    a. Outpatient visits
        i. Epic- Chart review- all visits between Recruitment Visit/6M Review Date and 6M/12M Assessment
    b. Problem list
        i. Epic- Snap shot
    c. Medical history
        i. Epic- Snap shot
    d. Medications
        i. Epic- Chart Review- Meds (include all meds taken between Recruitment Visit/6M Review Date and 6M/12M Assessment
4. Convert jpeg docs into PDFs
    a. Add subject initials, ID, date of review and your ID to each page
5. Save the PDFs on the shared drive folder: under the subject's folder in the Assessment PDF and Tapes folder (Neurology_ DM_I-Team -> DM ITEAM-CLINICAL TRIAL -> ASSESSMENT PDFS & TAPES)
    a. Save to subject's folder:
        i. Save file as: SUB INITIALS ID ASSESS CHART CHECK DATE
            1. i.e. EDJMM00002 6M CHART CHECK 6-28-18
6. Print out Medical History and Problem List pages and give to Barry
    a. Barry will circle the conditions to be entered into REDCap
7. Scan these pages and replace the original pages in the chart check PDF
8. Enter information Into REDCap
9. Enter chart check/data entry dates to tracking file on shared drive
    a. Neurology_DM_I-Team -> DM ITEAM-CLINICAL TRIAL -> CHART REVIEW BLANK ->DM I-TEAM CHART REVIEW TRACKING (xls doc)

Non-Jefferson Patients:

1. Send signed med release to subject's PCP
    a. Be sure patient's name and DOB is listed
    b. Write in Physician's name
    c. Under Specific Information to be released
        i. Check off summary of records
        ii. Covering the period(s) of treatment from _(date of med release)_ to _(date of 6M/12M assessment)_
2. Once you receive the records back from the PCP's office:
    a. Add subject initials, ID, date of review and your ID to each page

3. Save the PDFs on the shared drive folder: under the subject's folder in the Assessment PDF and Tapes folder (Neurology_ DM_I-Team -> DM ITEAM-CLINICAL TRIAL -> ASSESSMENT PDFS & TAPES)
    a. Save to subject's folder:
        i. Save file as: SUB INITIALS ID ASSESS CHART CHECK DATE
            1. i.e. EDJMM00002 6M CHART CHECK 6-28-18
4. Give Medical History and Problem List pages and give to Barry
    a. Barry will circle the conditions to be entered into REDCap
5. Scan these pages and replace the original pages in the chart check PDF
6. Enter information Into REDCap
7. Enter chart check/data entry dates to tracking file on shared drive
    a. Neurology_DM_I-Team -> DM ITEAM-CLINICAL TRIAL -> CHART REVIEW BLANK ->DM I-TEAM CHART REVIEW TRACKING (xls doc)