Confronting Unequal Eye Care in Pennsylvania:

Manual of Procedures

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MOP Modification Log

Chapter #	Version	Date	Page	Brief Modification Summary

CHAPTER 1: SPECIFIC AIMS

Blindness and vision impairment due to diabetic retinopathy (DR) are highly prevalent and disabling conditions of older adults in the United States.[3,8-10]. Although medical services to diagnose and treat DR are available to all U. S. citizens, African Americans (AAs) are less likely to access these services and are almost twice as likely to go blind from DR as Caucasians. [1-7,11-14] Data from the 2006 Behavioral Risk Factor Surveillance System (BRFSS), which is a collaborative effort of the Centers for Disease Control and Prevention (CDC) and the U.S. States, found that AAs compared to Caucasians in Pennsylvania (PA) have greater difficulty seeing friends across a street (18% vs. 13%) and reading (42% vs. 34%), and are less likely to have a dilated fundus examination (45% vs. 51%), which is necessary to diagnosis DR. [15] The 2005 BRFSS data reveal that AAs in PA are less likely than AAs in other five other States (i.e., OH, TN, TX, IA and LA) to visit an eye-care professional (56% vs. 67%) or have a dilated fundus examination in the preceding year (45% vs. 53%).[16] These data suggest that in PA unique factors operate to account for these disparities. The consequences are well known: AAs are at high risk to lose vision from DR because they do not access preventive and therapeutic care. As a result, DR in this population will impose substantial clinical and economic burdens as the population ages in PA.

Although genetic factors may contribute to AAs' increased risk of DR, cultural and socioeconomic barriers to care amplify the consequences of that risk. [11-14, 17] The socioeconomic barriers include difficulty affording medications and physician visits, the debilitating effects of poverty, and the polarizing ways that health services are organized and financed. The cultural barriers arise from differences in language, religion, views of health, perceived harm from treatment, and historical and personal experiences of discrimination.[18-21] These cultural and socioeconomic barriers explain in large part why, despite the availability of effective interventions for DR, the vision of older AAs with diabetes is worse than that of Caucasians. Cultural barriers can be surmounted. Recent studies demonstrate that culturally relevant interventions can increase AAs' use of cancer screening programs, diabetes and hypertension self-management, and preventive eye care.[22-26]

The Eastern Pennsylvania Center of Excellence for the Study of Eye Disease (the COE) seeks to build on these studies and test new interventions to increase older AAs' access to eye care and thereby reduce existing health disparities in vision. We will conduct the project entitled, "Confronting Unequal Eye Care in Pennsylvania", the primary goal of which is to improve eye care for underserved older AAs with diabetes in Philadelphia. To meet this goal, the COE proposes the following Specific Aims:

1. To test the efficacy of Behavior Activation, which is a culturally relevant home-based intervention, to increase rates of dilated fundus examinations (DFE) in older AAs with diabetes in a randomized clinical trial (RCT).

> Hypothesis: A greater proportion of subjects who receive Behavior Activation will have a DFE by 6 months than subjects who receive Supportive Therapy, which is a placebo treatment that controls for attention.
>
> 1a. Secondary Aim: To compare the effectiveness of Behavior Activation vs. Supportive Therapy to increase risk perceptions and risk knowledge of diabetes and its complications (e.g., DR).
>
> Hypothesis: Behavior Activation will increase risk perceptions and risk knowledge of diabetes and its complications to a greater extent than Supportive Therapy at 6 months.

1b. Secondary Aim: To compare the effectiveness of Behavior Activation vs. Supportive Therapy to increase adherence to diabetes self-care recommendations.

Hypothesis: Behavior Activation will increase adherence to diabetes self-care recommendations to a greater extent than Supportive Therapy at 6 months.

1c. Secondary Aim: To compare the effectiveness of Behavior Activation vs. Supportive Therapy to reduce depressive symptoms.

Hypothesis: Subjects who receive Behavior Activation will have lower levels of depressive symptoms than subjects who receive Supportive Therapy at 6 months.

We also propose 4 Exploratory Aims:

Exploratory Aim 1: To examine the long-term efficacy of BA to increase rates of annual DFEs one year after the treatment intervention.

Exploratory Aim 2: To examine whether changes in knowledge of the risk of diabetes complications, adherence to diabetes self-care recommendations, and/or depression mediate the relationship between treatment assignment and obtaining a DFE.

Exploratory Aim 3: To examine whether differences in cultural characteristics at baseline moderate the relationship between treatment assignment and obtaining a DFE.

Exploratory Aim 4: To examine whether a higher proportion of subjects who receive Behavior Activation will have a 1% reduction in hemoglobin A_{1C} levels from baseline to 6 months than subjects who receive Supportive Therapy.

Successful achievement of these Specific Aims will help to reduce health disparities by developing and testing culturally relevant interventions to bring AAs' closer to the Healthy People 2010 goal of 75% of all older persons with diabetes having an annual dilated eye examination.[27]

CHAPTER 2: RESEARCH DESIGN SUMMARY

A. Purpose of Study: The purpose of this study is to determine the efficacy of Behavioral Activation (BA) to increase rates of dilated eye exams in older African American patients who have diabetes. Patients with diabetes have an increased risk of diabetic retinopathy (DR) and subsequent vision loss. Vision loss due to DR is minimized it is detected and treated early in the disease process. Patients with diabetes therefore are advised to have annual DFEs to screen for DR. The active intervention (BA) will help subjects to identify and address barriers to obtaining annual DFEs (i.e., lack of transportation, lack of awareness of DR risk, not knowing where to get a DFE). BA will be delivered during 4 in-home visits over the course of 4 months. Control subjects will have 4 in-home Supportive Therapy (ST) visits. ST in a placebo control condition that controls for the attention that BA subjects receive. Intervention visits for both treatment conditions will occur after randomization, which takes place after the baseline assessment.

B. Study Design: We will recruit eligible subjects (African American, aged 65+, diabetic, no documented DFE in the proceeding 12 months) from primary care practices at Thomas Jefferson University and Temple University. Informed consent will be obtained in subjects' homes (or at another location such as Jefferson if preferred) by the study assessor. At the same visit, the assessor will obtain baseline data (demographic and background information, diabetes-related literacy, current medications, current health conditions, cultural characteristics, visual acuity, diabetes self-care behaviors, perceived risk of complications related to diabetes, perceptions and satisfaction with medical care, depressive symptoms, hemoglobin A_{1C}). After the baseline assessment, subjects will be randomized to the treatment condition (BA) or to the attention control condition (ST). Each treatment will be delivered over the course of 4 sessions (about 45 minutes to 1 hour each), and will take place in subjects' homes (or another location if the subject prefers). Both treatments will be delivered by specially trained Community Health Worker (CHW) interventionists. The study assessor will be masked to treatment assignment. The primary endpoint is whether or not subjects had a DFE by month 6 (the primary analysis will compare the DFE rates between subjects receiving BA versus those receiving ST). This will be ascertained by having the assessor interview subjects a second time in person at 6 months. Self-reports of DFEs will be verified by chart review at the ophthalmology clinics at Wills Eye Institute or Temple University. For subjects who had a DFE, we will also record the extent and severity of eye pathology. Subjects will be paid $25 for each of the 2 in-person assessments (baseline and 6 months). In addition, at 12 and 18 months the assessor will call subjects to inquire by phone whether they have had a DFE since the 6 month assessment point. Subjects will not be paid for telephone assessments.

C. Sample: The sample will comprise 206 African American patients with diabetes for more than one year who are at least 65 years old and have not had a DFE in the past 12 months.

D. Patient Enrollment: Subjects will be recruited from their primary care office. Project staff will screen for eligibility criteria by chart review and telephone screening.

E. Informed Consent: Informed consent will be obtained in writing by the study assessor in subjects' homes immediately prior to the baseline assessment.

F. Patient Follow-Up. Patients will be assessed in person at baseline and 6 months, and by telephone at 12 and 18 months. The primary efficacy analysis will be based on 6-month data; the 12 and 18 month data will assess BA's long-term effects.

G. Data Analysis. The primary analysis will address study group differences in the incidence of DFEs at 6 months. Secondary analyses will address the effect of BA on: (1) perceptions of risk for diabetes-related conditions; (2) adherence to diabetes self-care recommendations; and (3) depression. Exploratory analyses will investigate: (1) the long terms effects of BA on DFE rates; (2) mechanisms linking BA to increased DFE rates; (3) whether cultural characteristics moderate the effect of BA on study outcomes; and (4) the effect of BA on HBA_{1C} levels,

H. Data Monitoring. Data monitoring will consist of: (1) having research staff (a person other than the study assessor) check all completed instruments for errors of omission; (2) running frequency distributions to check for out of range values; and (3) carefully documenting all edits made to the data sets.

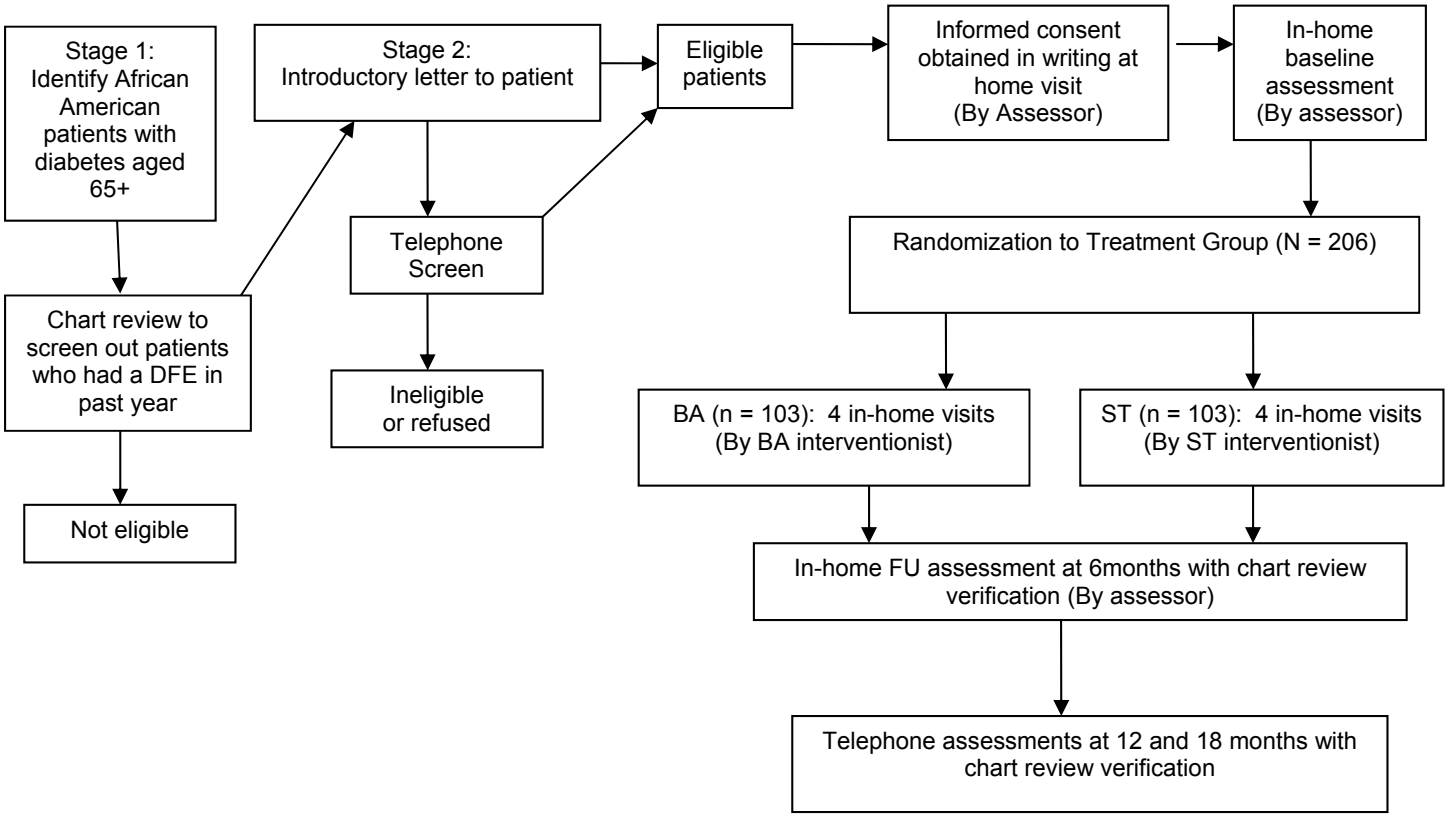
I. Quality Assurance Procedures: Both the BA and ST interventionists will undergo extensive training for their respective interventions. Training for both will consist of a didactic component, as well as an experiential one whereby the interventionists will be required to administer their respective interventions to practice subjects. These practice sessions will be audio taped and reviewed by Drs. Casten, Rovner, Hark, or Brawer. The interventionists will be certified to administer their respective treatments after the successful completion of working with 5 practice patients. All of the practice patient sessions will be recorded and reviewed. Treatment fidelity for both interventions will be accomplished by having study investigators review a random sample of treatment sessions.

The study assessors will receive extensive training on administering all assessments. As with the interventionists, all of the assessments for the practice patients will be recorded and reviewed. Subsequently, rater drift will be minimized by having Drs. Casten, Rovner, Murchison, Brawer, or the Project Coordinator review a random sample of 10% of in-home assessments. This process will indicate the extent to which the study assessor will require additional training throughout the study.

Table 1. Design Summary

Objective	Determine the efficacy of BA to increase rates of Dilated Fundus Exams (DFEs)
Major Eligibility Criteria	1) African-American race (self-identified) 2) Age ≥ 65 years 3) Type II Diabetes Mellitus (physician diagnosis) for at least 1 year 4) No medical documentation of a DFE by an ophthalmologist or an optometrist within the past 12 months 5) Self-report of no DFE within the past 12 months
Randomization Unit	Person
Treatments	BA (n = 103) ST (n = 103)
Recruitment Site	Primary care clinics at Thomas Jefferson University and Temple University
Enrollment Site	Subjects' homes
Outcome Measures	Primary: whether or not the subject had a dilated fundus exam Secondary: 1) risk perceptions of diabetes-related complications 2) adherence to self-care recommendations 3) depressive symptoms
Sample Size	206
Enrollment Timeline	Months 7 through 26
Masking Procedures	This is a single blind study in which the assessor will be masked but subjects and interventionists will not. Subjects will be given frequent instructions to avoid disclosing treatment assignment.
Study Visit Schedule	Assessments: Baseline and 6 months, phone assessments at 12 and 18 months Interventions: 4 in-home sessions of either active treatment or control treatments.
Length of Follow-up	18 months

Figure 1. Flow Chart of Study Design



CHAPTER 3: ORGANIZATIONAL STRUCTURE

1. STUDY PERSONNEL

PI: Julia A. Haller, MD

Dr. Haller is the Principal Investigator, and as such is responsible for the overall conduct of the study. She will provide the necessary oversight for all aspects of the trial, and will serve as the liaison between Wills Eye Institute, Jefferson Medical College, and Temple University. Dr. Haller will not be masked to treatment assignment and will have access to preliminary results and study data.

Thomas Jefferson University Site PI: Barry Rovner, MD

Dr. Rovner is the primary investigator of the clinical trial, and in this capacity he will be involved in the overall management of the clinical trial. He will also coordinate trial activities across all study sites. He will oversee the integrity of the study interventions; supervise procedures to ascertain the sample, obtain informed consent, train and supervise research staff; ensure the integrity of data collection and management; and conduct data analyses and disemnate study findings. Dr. Rovner will also guide the administration of study questionnaires, treatment manuals, subject materials, and procedures for patient safety and confidentiality. Dr. Rovner will not be masked to treatment assignment and will have access to preliminary results and study data.

Temple University Site PI: Jeffrey Henderer, MD

Dr. Henderer will oversee and manage all study activities to be conducted at Temple University, including subject recruitment, preparing IRB documentation, and overseeing study staff at Temple University. Dr. Hendrer will not be masked to treatment assignment and will have access to preliminary results and study data.

Co-I: Robin Casten, PhD

Dr. Casten will coordinate the daily operations of the trial, and will oversee data collection and management. Dr. Casten will also be responsible for supervising training and treatment fidelity for both Behavioral Activation (BA) and Supportive Therapy (ST). She will conduct training workshops for the CHW interventionists, supervise the interventionists' training cases, and provide the interventionists with ongoing supervision and support as part of the treatment fidelity process. She will also attend biweekly case review meetings. Dr. Casten will also develop the BA and ST treatment manuals, perform statistical analyses, and disseminate study results. Dr. Casten will not be masked to treatment assignment and will have access to preliminary results and study data.

Co-I: Lisa Hark, PhD, RD

Dr. Hark will oversee the administrative aspects of the trial, including supervising the Project Coordinator, the Research Assistant, the Study Assessors, and the Community Health Worker (CHW) interventionists. Dr. Hark will also: (1) assist with the development of the treatment manuals; (2) be responsible for IRB documentation; (3) participate in the training workshops; (4) perform treatment fidelity activities including supervising the CHW assessors and interventionists at biweekly case review meetings; (5) direct the Minority Research Training and Mentoring Program and (6)

disseminate study results. Dr. Hark will not be masked to treatment assignment and will have access to preliminary results and study data.

Co-I: Ann Murchison, MD, MPH

Dr. Murchison will also oversee the administrative aspects of the trial, including supervising the Project Coordinator, the Research Assistant, the Study Assessors, and the Community Health Worker (CHW) interventionists. Dr. Murchison will also: (1) assist with the development of the treatment manuals; (2) be responsible for IRB documentation; (3) participate in the training workshops; (4) perform treatment fidelity activities including reviewing the tapes of the CHW assessors and interventionists; (5) co-direct the Minority Research Training and Mentoring Program and (6) disseminate study results. Dr. Murchison will be masked to treatment assignment and will have access to preliminary results.

Co-I: Laura Gitlin, PhD

Dr. Gitlin will provide guidance on issues related to subject recruitment, retention, and treatment documentation. She will also assist in the development of study materials. Dr. Gitlin will not be masked to treatment assignment and will have access to preliminary results.

Co-I: Christine Arenson, MD

Dr. Arenson will not be masked to treatment assignment and will have access to preliminary results.

Co-I: James Plumb, MD, MPH

Dr. Plumb will participate in staff training, provide supervision to the BA interventionist, and assist with the development of study materials, particularly those related to diabetes. Dr. Plumb will also be available to handle emergent medical situations that may arise with study subjects (for example, elevated hemoglobin A_{1C}). Dr. Plumb will not be masked to treatment assignment and will have access to preliminary results.

Co-I: Rickie Brawer, PhD

Dr. Brawer will provide ongoing training and supervision to the CHWs, review audiotapes of treatment sessions for treatment fidelity purposes regarding diabetes education, and attend biweekly CHW case review meetings. Dr. Brawer will not be masked to treatment assignment and will have access to preliminary results.

Diabetes Educator: Neva White

Ms. White will provide training regarding diabetes education to the study interventionists. She will also be available to study staff to address diabetes-related issues as needed and attend biweekly CHW case review meetings. She will not be masked to treatment assignment and will have access to preliminary results.

Co-I: Brooke Salzman, MD

Dr. Salzman will supervise patient recruitment at the Family Medicine and Internal Medicine clinics at TJU. Dr. Salzman will be masked to treatment assignment and will have access to preliminary results.

Co-I: Omesh Gupta, MD

Dr. Gupta will be responsible for providing clinical care for the Temple University patients enrolled in the study.

Co-I: David M. Barclay, MD

Dr. Barclay will supervise patient recruitment at the primary care clinics at Temple University. Dr. Barclay will be masked to treatment assignment and will have access to preliminary results.

Statistician: Benjamin Leiby, PhD

Dr. Leiby will generate the randomization schedules and will oversee quality control procedures for ensuring that randomization is being carried out correctly. He will also advise on all data analysis issues. Dr. Leiby will not be masked to treatment assignment, and will have access to preliminary results and study data.

Brandon Johnson, MD
Dr. Brandon Johnson is a ophthalmology resident at the Wills Eye Health System/Jefferson Medical College and is mentoring the Minority Research Training and Mentoring Program students. He will meet with students during orientation, group meetings and individual as-needed basis.

Project Coordinator: David Weiss

Mr. Weiss will coordinate the daily operations of the study including data collection and entry; recruitment activities; randomization; and preparing study reports. Mr. Weiss will not be masked to treatment assignment and will have access to preliminary results and study data.

Research Assistants

This project will employ 2 Research Assistants. The Temple University Research Assistant will assist with subject recruitment at the Temple University primary care sites. The Wills Eye Institute (WEI) Research Assistant will be involved with subject recruitment at the Jefferson primary care sites. For both research assistants, recruitment activities will include identifying potentially eligible patients, mailing letters to introduce the study, and screening patients by phone for study eligibility. The WEI Research Assistant will also assist the Study Assessor in verifying whether or not subjects had dilated fundus exams at 6, 12, and 18 months by reviewing ophthalmology charts. This individual will also provide administrative assistance as needed for all study activities. The WEI Research Assistant will not be masked to treatment assignment, and will have access to preliminary results and study data. The Temple Research Assistant will be masked to treatment assignment, and will not have access to preliminary results or study data.

BA Interventionist

The BA interventionist will be responsible for administering 4 in-person treatment sessions to subjects randomized to BA. In this capacity the BA interventionist will: (1) adhere to the protocol for administering the active treatment; (2) maintain detailed records of subjects' progress including compliance with treatment plans; and (3) audio tape intervention sessions for treatment fidelity purposes. The BA Interventionist will not be masked to treatment assignment, and will not have access to preliminary results or study data.

ST Interventionist

The ST interventionist will be responsible for administering 4 in-home treatment sessions to subjects randomized to the control condition. In this capacity the ST interventionist will: (1) adhere to the protocol for administering the control treatment; and (2) audio tape intervention sessions for treatment fidelity purposes. The ST Interventionist will not be masked to treatment assignment, and will not have access to preliminary results or study data.

Study Assessor

One full time and one part-time CHW Assessor will conduct all in-person assessments at baseline and 6 months, and will administer the telephone assessments at 12 and 18 months. The Study Assessor will also obtain informed consent in writing. The assessors will be masked to treatment assignment, and will not have access to preliminary results or study data.

2. STUDY COMMITTEES

1. Executive Committee This internal committee will consist of Drs. Haller, Rovner, Casten, Hark, and Murchison. The function of this committee is to: (1) prepare the final draft of the Manual of Procedures (MOP); (2) direct all activities of the trial; (3) advise on the preparation of reports and documents for the Data and Safety Monitoring Committee (DSMC); (4) prepare research findings for dissemination for both primary outcome manuscripts and methodological papers; (5) ratify major changes to the protocol; (6) resolve any problems that may arise; and (7) monitor performance and take corrective action. The committee will convene monthly with more frequent meetings if needed.

2. Data and Safety Monitoring Committee. Barry, are we still having a DSMC? The committee consists of XXX. The functions of the DSMC are to: (1) monitor and advise on the study quality; (2) monitor and advise on study progress including enrollment and attrition; (3) monitor data quality; (4) assure the scientific integrity of the study; (5) monitor the treatment of study participants (including a review of serious adverse events); and (6) review and approve the study protocol. The DSMC will meet in person once a year. Telephone meetings will occur every 6 months. Minutes of each meeting will be recorded and distributed. More frequent meetings may be requested in the following circumstances: (1) numerous serious adverse events; (2) to solicit advice on possible protocol modifications; and (3) to discuss the dissemination of study findings.

CHAPTER 4: STUDY POLICIES

1. PATIENT CONSENT

Written consent will be obtained from all subjects prior to the baseline assessment. The consent protocol will be conducted in subjects' homes by the CHW assessor prior to administering the baseline assessment. Since cognitive impairment will be screened out, all potential subjects will have the capacity to provide informed consent. The study assessor will provide the subject with a copy of the consent. The assessor will read the statement that appears below to potential subjects. To ensure understanding (and avoid misunderstandings due to low literacy), the assessor will read aloud the consent form, stopping after key components to ask a series of questions to be sure that the patient understands to content of the consent.

"You are being asked to take part in a research study to help people manage complications from diabetes. To make an informed decision about whether to participate, it is important for you to 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 this by yourself, and then we can discuss it."

2. PATIENT COSTS

All patient costs will be covered by the study, and thus there will be no financial burden on study participants. Subjects are responsible for any costs associated with obtaining a DFE, as well as any treatment recommended by the treating ophthalmologist.

3. PUBLICITY

All publicity related to the trial will be submitted to Lauren Lavine, Director of Marketing and Public Relations at the Wills Eye Health System, for review and approval

4. EDITORIAL POLICY

Manuscripts and conference presentations must be approved by the Executive Committee prior to submission/presentation.

4.1 Publication of study design, methods, and findings

The Executive Committee will approve all publication of design, methods, and findings.

4.2 Authorship

The Pennsylvania Department of Health will be acknowledged on all manuscripts. All of the study investigators will have the opportunity to co-author study papers. Authors will be listed in the order that accords with their contributions.

5. ACCESS TO STUDY INFORMATION

5.1 Study documents

Study documents include: (1) the grant application; (2) progress reports to the PA Department of Health; (3) materials submitted to the IRB; (4) minutes from Executive Committee meetings; (5) minutes from DSMC meetings; (6) reporting of adverse events; (7) the MOP; (8) treatment manuals; and (9) manuscripts and presentations. Study information will be released to staff and committee members on an as needed basis. No persons whose responsibilities include the application or evaluation of the treatments will have access to results prior to the completion of the trial.

5.2 Study data

The identity of individual subjects may not be revealed in any public report or presentation. The PIs and relevant Co-Is are responsible for assuring that the integrity and confidentiality of study records are maintained. Study data include raw data files as well as hard copies of completed data collection forms.

CHAPTER 5: ELIGIBILITY CRITERIA

1. ELIGIBILITY CRITERIA

Age. Patients must be at least 65 years old to be considered for study participation. Age will be ascertained from patients' medical charts.

Medical Criteria. Eligible patients must have a diagnosis of Diabetes Mellitus documented in their medical charts, and patients have had DM for at least 1 year. In addition, study participation requires that patients have not had a DFE in the proceeding 12 months. Medical charts at the primary care clinics will be reviewed, and patients who have had a DFE from either an ophthalomologist or optometrist in the past year are ineligible for study participation. During the telephone screening we will also ask potential subjects whether they've had a DFE in the past year. The DFE will be described to the subject as an exam where the doctor will use drops to make the black part of your eyes (the pupil) more visible. This exam allows the ophthalmologist to see the back of the eye with a large bright light which he/she wears on their forehead. The subjects vision will be blurry and will be light sensitive for about 3 hours after the dilated eye exam.

Ethnicity: African-American

2. EXCLUSION CRITERIA

Cognitive Impairment: Cognitive functioning will be evaluated by project staff during the telephone screen. Patients with cognitive impairment will not be eligible to participate.

Psychiatric Disorder: Patients that have any psychiatric disorder other than depression or anxiety will not be eligible for this study. This information will be obtained from patients' medical charts.

Health. Patients with life-threatening illness (e.g., terminal cancer, need for oxygen) or any other health conditions that interferes with study activities will not be eligible to participate. Initial information regarding heath status will be obtained from patients' medical charts.

Hearing Impairment: Any patient with hearing impairment that interferes with study activities (i.e. telephone screening) will not be eligible to participate.

CHAPTER 6: PATIENT ENROLLMENT AND RANDOMIZATION

1. PATIENT RECRUITMENT

This study will enroll 206 patients, at a rate of 10-11 per month. We will recruit subjects from Thomas Jefferson University at Family Medicine, Internal Medicine, and Geriatric Medicine. We will recruit subjects from Temple University at Internal Medcine, Family Medicine, and Endocrinology. Patient recruitment procedures will differ slightly at both institutions.

1.1 Thomas Jefferson University Recruitment

Patient recruitment will be a 4-stage process. During stage 1, study staff will review electronic medical records from participating primary care practices to identify patients who meet inclusion/exclusion criteria. During stage 2, for those patients who meet stage 1 eligibility, we will obtain permission from the subject's primary care physician to contact the patient for possible study participation. At this time, an introductory letter will be sent to the patient and signed by the PCP. This letter will include an opt-out clause that instructs the patient to call project staff if they wish to decline further contact. We will make every effort to obtain updated contact information for patients whose recruitment letters are returned due to an invalid/out of date address. During stage 3, approximately one week after mailing the letter (and if the patient did not opt out), project staff will telephone the patient to: (1) explain the study in more detail; (2) ascertain patient interest; and (3) assess eligibility criteria. We will attempt to obtain updated telephone numbers for patients whose numbers are out of date or disconnected.

1.2 Temple University Recruitment

Patient recruitment will be a 3-pronged approach. The first prong of the recruitment approach is similar to the one employed by TJU. Study staff will review the IDX list which will contain patients who meet inclusion/exclusion criteria. At this time, an introductory letter will be sent to the patient and signed by the PCP. Different from Jefferson, this letter will include an opt-in clause that instructs the patient to call project staff if they wish to participate in the study. Considering that this could result in a lower-yield of potential patients, we will use alternative procedures to recruit patients. We will use flyers to advertise the study at the Temple Recruitment site. Additionally, we will cross-reference the master IDX list with the schedule at each of the Temple Clinics. For those patients that are eligible, we will talk with each patient individually after they are precepted for their appointment.

1.3 Following Patient Recruitment at TJU and TU

For interested patients, a race concordant assessment community health worker (CHW) will schedule an in-home visit within the next 2 weeks to obtain written informed consent and complete the baseline assessment. For each patient we will record the number of times the patient was called prior to conducting the telephone screen. As well, we will record the whether the patient dropped out of the study prior to the initial consent visit.

Patients will be considered enrolled in the study after he or she gives informed consent, which will occur soon after the phone screening. All randomized subjects, regardless of whether or not they received their respective intervention, will be included in all intent to treat analyses. We will replace enrolled subjects who decided against study participation prior to randomization.

An electronic Recruitment Outcome Form (ROF) will be completed for all patients who meet medical and demographic criteria. This information will be used to track the number of patients who: (1) opt out of the study; (2) refuse to participate; and (3) do not meet cognitive functioning criteria, and/or have had a DFE in the last 12 months. We will also use this data to obtain an estimate of the population that is unreachable due to outdated or incorrect contact information. The ROF will also document the patient's PCP. This information will be abstracted from the patients' medical charts.

2. ASSIGNMENT OF STUDY IDENTIFICATION NUMBERS

Study identification numbers will be assigned by the Project Coordinator immediately after enrollment. The identification number will consist of a 3 digit number chosen from a consecutive list. All data forms will also contain the subject's 3 initials (the first letter of the first, middle, and last names). If the patient has no middle name, an X will be used. Identification numbers and initials will be used to cross reference subjects in the data bases. Patient names, corresponding identification numbers, address, and phone numbers are then entered into the subject log (to be maintained by the Project Coordinator).

3. RANDOM ASSIGNMENT TO TREATMENT GROUP

After the baseline assessment, randomization will follow a fixed scheme with a 1:1 allocation ratio to the 2 study groups. The study biostatistician, will use a random numbers table to assign subjects to treatment groups and base the schedule on a permuted random block design to ensure balance between treatment groups on enrollment time. Use of randomly chose block sizes (2, 4, and 6) will hide the blocking process. We will use sealed, opaque, serially numbered envelopes containing the treatment allocations. The envelopes will be stacked in the order in which they will be opened. The resulting stack of envelopes will be given to the Project Coordinator, who in turn will store them in a locked box.

Immediately after completing the baseline interview, the CHW assessor will call the Project Coordinator to inform him that the consented subject is ready for randomization to one of the two intervention groups. After the randomization is performed for a given subject, the Project Coordinator will send through inter-departmental mail a photocopy of the randomization sheets to the biostatistician, who will store them in a locked file. The original will be stored in the subject's chart.

Exhibit 1. Sample Randomization Documentation for Treatment Assignment:

Diabetic Retinopathy Study
Treatment and Interventionist Assignment

Sequence #

Date of Randomization: ____/____/____
month / day / year

Patient Initials: _____

Study ID #_____

ASSIGNMENT: Treatment Group: BA

Completed by: _____

Please complete this form. Keep original.
Mail a copy to: Benjamin Leiby, Ph.D.

CHAPTER 7: SCHEDULE AND OVERVIEW OF PATIENT FOLLOW-UP AND DATA COLLECTION

1. OVERVIEW

Assessments will take place at screening, baseline, and 6 months post-baseline. Screening will be conducted by phone, and the baseline and 6 month assessments will take place in the subjects' homes. Telephone follow-up assessments will take place at 12 and 18 months. The following chart provides an overview of the type of data collected.

Study Variables, Corresponding Measures, and Study Occasion

Variable	Name of Measure and how Quantified/Qualified	Study Occasion
Outcome Measures		
DFE: Primary Outcome	- Self reported - Confirmed by ophthalmology chart review. The following information will also be collected from ophthalmology charts (if applicable) 1) DR stage 2) Visual acuity 3) Intraocular pressure 4) Diagnoses other then DR 5) Optic nerve appearance 6) Recommendations for follow-up care/treatment 7) Itemized checklist of information provided to patient by ophthalmologist	6, 12, and 18 months
Risk perceptions of diabetes: Secondary Outcome	- Risk Perception Survey-Diabetes Mellitus (RPS-DM): 5 subscales: 1) Personal Control 2) Optimistic Bias 3) Personal Disease Risk 4) Comparative Environmental Risk 5) Risk Knowledge	Baseline, 6 months
Diabetes self-care behaviors: Secondary Outcome	- Diabetes Self-Care Inventory-Revised: Yields a global scale that summarizes self-care behaviors	Baseline, 6 months
Depressive Symptoms: Secondary Outcome	- Patient Health Questionnaire-9 (PHQ-9)	Baseline, 6 months
Exploratory Outcomes		
Hemoglobin A_{1c}	- Blood obtained by finger stick	Baseline, 6 months
Potential Covariates		
Demographic information	- Age, education, marital status, SES	Baseline
Health	- Chronic Disease Score: continuous measure that quantifies severity of medical burden - Self-reported health conditions: Multilevel Assessment Inventory Health Conditions Check List	Baseline, 6 months
Literacy	- Literacy Assessment for Diabetes	Baseline
Neuropsychological Measures	- Animal Naming, Clock Test, CERAD verbal learning test	Baseline, 6 months
Cultural Characteristics	- Collectivism - Religiosity - Racial Pride - Time Orientation	Baseline
Process Variables (to be collected by the BA and ST interventionists)		
Dose	- Number of treatment sessions	Intervention

	- Length of each treatment session	visits
Treatment Goals (BA interventionist only)	- Description of each goal worked in during the course of the intervention - Plan for achieving each behavior activation goal - Compliance with Action Plans - Family Involvement	Intervention Visits
Screening: These variables will be used to determine study eligibility criteria and will be obtained by various study staff		
Cognition	Modified Mini Mental Status Exam : Continuous measure of cognitive functioning	Screening
Self-reported DFE in past year		Screening

Unless noted, all data will be obtained by the Assessment CHW.

2. SCREENING

The screening assessment will be administered over the telephone by project staff. TJU patients will be called approximately one week after the introductory letter is mailed. TU patients will be screened only if they call to opt-in. Patient interest, self-report of a DFE, cognitive functioning, and hearing impairment will be determined during this contact. If the patient is interested and meets eligibility criteria, project staff will explain that the CHW assessor will call the patient within 1 week to make an appointment for an in-home visit.

3. BASELINE ASSESSMENT

The following will occur at the baseline assessment. (1) The CHW assessor will explain the details of the study to the subject. (2) The CHW assessor will obtain informed consent in writing. (3) The CHW assessor will obtain contact information (names, phone numbers, addresses) of up to three friends/relatives who can be contacted in the event that the patient is unreachable. (4) The CHW assessor will distribute to the subject Wills Eye Health System's, Thomas Jefferson University's, and/or Temple University's HIPAA policy in writing. (5) The CHW assessor will perform the baseline assessment.

4. FOLLOW-UP ASSESSMENTS

The 6-month assessment will be administered by the CHW assessor. Each week the Project Coordinator will generate a list of subjects who are due for their 6-month assessment within the upcoming 14 days. Included on the list will be the date of the last assessment for each subject as well as the ideal date that the assessment should take place. The date of the baseline in-home assessment will determine when the follow-up assessments should occur. For example, if the baseline assessment date was 2/1/01, ideally the 6-month assessment should take place on 8/1/01. Follow-up assessments should be timed so as to take place within 30 days of the ideal assessment date. For example, in the above example, the 6-month assessment needs to occur anywhere from 5/27/01 through 6/27/01. If unforeseeable events prevent the follow-up assessment from occurring on time, an "Out of Window" form will be completed by the Project Coordinator and stored in the subject's chart.

5. TIMING OF EVENTS

Table 3: Timing of Events

ACTIVITY	IDEAL TIME	TIME WINDOW
Screening telephone call	2 weeks after recruitment letter is mailed	3 weeks after recruitment letter is mailed
Informed consent and baseline assessment	Within 2 weeks of screening call	Within 4 weeks of screening call
Randomization to intervention group	Within 2 days of the baseline assessment	Within 1 week of the baseline assessment
First session with BA or	Within 2 weeks of the baseline	Within 4 weeks of the baseline

ST CHW	assessment	assessment
Last session with BA or ST CHW	Within 4 months of the baseline assessment	Within 5 months of the baseline assessment
6-month assessment	6 months after the baseline assessment	30 days within the date that is 6 months after the baseline assessment
12-month phone follow-up	12 months after the baseline assessment	13 months after the baseline assessment
18-month phone follow-up	18 months after the baseline assessment	19 months after the baselineassessment

6. OUT OF WINDOW POLICY

For any of the above described events that occur outside of the time window, an "Out of Window" form will be completed. The following information will be recorded on this form: Subject's name and ID, the event that is out of window, the ideal date of the event as well as the actual date of the event, and the reason that the event is out of window.

Our goal is to have 80% of the assessments and treatments occur within the ideal time frame as specified above. We will produce monthly reports that delineate the percent of assessments and treatments that are occurring within the desired range. We will closely monitor these figures and develop corrective strategies as needed.

CHAPTER 8: QUALITY ASSURANCE AND MONITORING PROCEDURES

In conducting an RTC with older people that involves multiple follow-up assessments, several issues can compromise the integrity of the data. These include: (1) unmasking; (2) treatments not being delivered as intended; (3) data not being obtained in a standardized manner; (4) enrolling an inadequate number of subjects; and (5) attrition and missing data. Plans for addressing each of these issues are discussed below.

1. PRESERVATION OF MASKING

Several measures will be undertaken to preserve the integrity of masking. First, the CHW assessor, who performs the baseline and 6-month assessments, will have no knowledge regarding anyone's treatment assignment. Second, prior to performing any assessment, the CHW assessor will emphasize to subjects the importance of not revealing their treatment assignment to the CHW assessor. They will be instructed to call the Project Coordinator should they have any questions about this. Third, the CHW assessor and the interventionists will be instructed to never discuss any of the subjects with each other, either generally or specifically. All staff meetings will have a closed session that is only open to unmasked staff. Fourth, for quality control purposes, after each assessment, the CHW assessor will be asked to indicate her best guess of which study group the subject is in, as well as her reasons for this estimate. If at anytime the CHW assessor learns of a subject's treatment group, she will notify the Project Coordinator immediately. The Project Coordinator will record this information in a tracking file so that statistical analyses can be adjusted accordingly. If unmasking occurs in greater than 20% of subjects, the PI will convene a meeting of the Executive Committee to trouble shoot ways of minimizing unmasking.

2. TREATMENT FIDELITY

To insure treatment fidelity throughout the study, we will audiotape all treatment sessions during the study. We will randomly select 30% of subjects in each treatment group for treatment fidelity ratings. Two recorded sessions (of the possible 4 sessions) will be selected for ratings (the first session and a random selection of sessions 2 to 4). Drs. Casten, Rovner, Murchison, or Brawer will evaluate the extent to which the CHW interventionists adhere to the BA and ST protocols, respectively, and Ms. White will rate the quality of the diabetes education in BA. Standardized rating forms will be used to evaluate each session. Supervision of the CHW interventionists (with review of the taped sessions) will take place at a minimum of once per month. If ratings are below the "satisfactory" rating on the scales, supervision will focus on necessary techniques to improve the score to satisfactory or higher.

3. DATA MANAGEMENT

We will manage and clean data throughout the study. Inconsistencies and missing data will be reconciled (e.g. call subject for missing data; verify data with medical records). We will create a separate database for each time wave. On a monthly basis, the project manager will run frequency distributions for all variables to check for accuracy. Although we will make every effort to minimize missing data, we will handle missing data in the following way: at each time point, subjects who complete that assessment will be compared to those lost to attrition on all baseline and available follow-up variables. We will control for any that are significantly different statistically.

4. PREVENTING ATTRITION AND MISSED VISITS

We will take the following steps to minimize attrition:

1) The CHWs who deliver the study interventions will reinforce the importance of completing the study and its potential value to others with diabetes
2) We will ensure the cultural relevance and acceptability of our retention procedures and the brochures and scripts that we use
3) We will schedule intervention sessions and baseline and follow-up assessments at times that are convenient to subjects
4) We will hire staff that is race concordant with subjects and experienced working with older persons
5) We will build rapport by mailing an informative "Question-and-Answers" letter to subjects to maintain positive, personalized contact. The letter will review the importance of the project and reinforce subjects' sense of altruism and community involvement. All communications will include a change of address card
6) We will ask subjects to identify a contact person as a back-up means to reach a subject, given the possibility of intermittent phone usage
7) We will send thank you notes and reminders and maintain flexibility when scheduling follow-up appointments. We will call subjects 2 days prior to intervention sessions and clinical assessments to assure their convenience, and call subjects who miss an intervention appointment within 24 hours to reschedule
8) We will update addresses and telephone numbers at each study visit
9) We will give subjects $25 for completion of the baseline and the 6 month follow-up assessment visits
10) All study personnel will be selected on the basis of interpersonal sensitivity and the ability to convey a warm and friendly demeanor. To increase our understanding of the sample, we will conduct telephone "exit interviews" with subjects who discontinue participation. For subjects who cite disinterest, we will mail a handwritten "refusal conversion letter" describing the importance of study participation after a 2-week "hold" period to avoid undue pressure.

CHAPTER 9: CERTIFICATION PROCEDURES

1. OVERVIEW

The study assessor will require certification in: (1) administering the self-report instruments; and (2) testing blood glucose hemoglobin A_{1c} via a fingerstick test. The interventionists will obtain certification to conduct their respective interventions. All study staff will be trained in recognizing and responding to signs of severe depression, including suicidal ideation. Training will take place over a 4 week period and include information on diabetes, pertinent study information, and specifics regarding their role in the study.

2. SUBJECT SELF-REPORT ASSESSMENTS

All self-reported assessments will be administered verbally by the CHW assessor. All data will be entered directly onto the laptop. Drs. Rovner and Casten will train the assessment CHW to administer the consent and the self-reported assessments. Dr. Brawer and Ms. White will train the assessor on how to perform the fingerstick test. The assessor will administer the assessments to 10 practice patients. Drs. Rovner or Casten will review audio tapes of assessments with these 10 practice patients. Certification will be granted upon successful completion of the 3 practice patients. As well, the CHW assessor will obtain informed consent on these practice patients and Drs. Rovner or Casten will review tapes of these practice consent sessions.

3. BEHAVIORAL ACTIVATION (BA)

BA training is a 2-part process that begins with an intensive 1-day workshop led by Dr. Casten. During the first half of the workshop, the BA CHW will receive didactic instruction in BA theory, efficacy data, and Session 1 introductory procedures. He/she will have an opportunity for supervised role play of Session 1 introductory procedures. During the second half of the workshop the BA CHW will learn the additional BA treatment procedures and then role-play treatment sessions. After completing the workshop, the BA CHW will administer the intervention to 5 practice patients. These sessions will be audio taped and reviewed by Dr. Casten. Upon satisfactory completion of this 2-step training program, the BA CHW will be certified to deliver the BA intervention.

4. SUPPORTIVE THERAPY (ST)

ST training will be similarly structured to the BA training, except that the didactics and role-play will focus on the principles of ST rather than BA. ST specifically equates the two in-home conditions with respect to the time and quality of the therapist contact. The training program, to be administered by Dr. Casten, consists of a one-day workshop, a treatment manual, and supervision of 5 training cases. The training consists of reviewing the manual, listening to audiotape examples, and role-playing. After the workshop, the ST CHW will conduct 5 training cases of ST. Dr. Casten will review the first and third audio taped sessions during the training. Trainee follow-up will include monthly 2-hour meetings and weekly telephone consultation to discuss concerns and provide ongoing support

CHAPTER 10. DESCRIPTION OF INTERVENTIONS

1. BEHAVIOR ACTIVATION

Behavior Activation (BA) is a behavioral technique to help people overcome avoidant tendencies through goal setting, activity scheduling, and graded task assignment. At the first session subjects will be asked whether they would like to have a family member/friend attend the treatment sessions. There are 3 components to this intervention.

1. Educational Materials: Diabetes health education is a prerequisite to acting to improve health. To that end, the BA interventionist will review the materials listed below.

a. "Steps to Prepare for an Eye Exam" is a document created specifically for this study. It lists key activities that patients need to address prior to having a DFE. It includes steps such as: knowing if a referral or co-pay is required, arranging transportation or supervision of a dependent relative, being prepared for long waiting room times, and receiving eye drops that dilate the pupil and cause temporary visual distortion and light sensitivity, preparing a list of questions to ask the ophthalmologist, a list of current medications and health problems, and requesting the ophthalmologist to send the DFE results to the subject's primary care physician.

b. "Taking Charge of Your Diabetes" is a Centers for Disease Control and Prevention (CDC) publication that is an easy to read, large print comprehensive guide for patients with diabetes. It provides an overview of diabetes and its management, including treatment, complications, and strategies for tracking health indicators such as hemoglobin A1C levels.[121]

2. Referral Procedures to Eye Clinics: We have designated 1 ophthalmologists at WEHS (Drs. Haller) and at TU (Gupta) to conduct comprehensive ophthalmologic evaluations (i.e., DFEs) on subjects who wish to be evaluated at these sites. The interventionists will give subjects the names and contact information of these ophthalmologists. The ophthalmologists will see subjects within 2 weeks of their phone call to increase adherence. We anticipate that most subjects will wish to be evaluated at the ophthalmology practices affiliated with their primary care clinics. This is because they: are familiar with the locations; will receive a referral to a specific ophthalmologist; and will have the opportunity to schedule a future primary care appointment on the same day as the ophthalmology appointment if desired. Some subjects may nevertheless prefer to have an eye exam by a community ophthalmologist. In all instances, the interventionist will discuss the necessary steps to make an appointment (e.g., arrange transportation, allocate sufficient time, check insurance status and need for referrals or co-pays) and assist subjects as needed. Assisting them might include role playing how the subject would make the phone call to schedule an appointment (in the in-home intervention) or rehearsing the steps required to make the appointment (in the telephone intervention). The Project Manager will be the contact person to make appointments for Dr. Haller and Chirstina Maisenoff at TU will be the contact person to make appointments for Dr. Gupta.

3. BA Treatment Sessions: In session 1, the CHW interventionist will establish rapport and review the structure of the intervention and the educational materials. The CHW will specifically discuss how diabetes affects the eye and the importance of DFEs to preserve vision. The BA CHW will provide a comprehensive list, worded in culturally relevant language, of potential barriers to obtaining a DFE. Drawing from this list, we will inquire about all types of barriers such as: 1) transportation (e.g., not sure which bus to take, need to take paratransit due to trouble walking, need

relative to drive subject to appointment); 2) financial (e.g., cannot afford co-pay); 3) misperceptions of DFEs (e.g., drops may make vision worse); 4) misunderstanding of risk (e.g., no current vision problems so no need for DFE); 5) mistrust of physicians; 6) caretaking responsibilities (e.g., need day care for grandchildren); and 7) inconvenience (e.g., already have too many medical appointments).

If, for example, the subjects states, "my vision is fine now, I don't need to see an eye doctor", the CHW will help the subject to develop an "Action Plan" related to gaining a more realistic perspective of their risk. This will involve goal selection (e.g., getting a DFE or not), and the formulation of specific goals (e.g., learn more about DR, what happens during an eye exam). The CHW will ask the subject to identify a reason for wanting to preserve their vision (e.g., to continue to meet family needs), and develop an action plan to carry out the desired behaviors (e.g., read study materials on DR tonight, ask PCP at upcoming appointment, talk to friend who has diabetes at Church this week).

In session 2, the subject and CHW will evaluate whether the action plan is working (i.e., a self-assessment of knowledge about DR). Assuming that the subject agrees to obtain a DFE, the CHW and subject will develop a stepped plan to obtain the DFE. This "Action Plan" will formulate steps to help the subject to schedule, correctly carry out, and monitor their progress towards obtaining a DFE. The steps for the upcoming week will be written in a schedule on the "Action Plan Form". Each day the subject will check off what steps they have completed. For example, Monday: "ask daughter what day she can drive to ophthalmology appointment"; Tuesday: "find a neighbor to watch grandkids"; Wednesday: "call primary care physician for ophthalmology referral"; Thursday: "left message with receptionist at ophthalmology office"; Friday: "ask a friend who has diabetes what DFE is like".

In session 3, the subject will compare the steps that he or she completed with the plan that was developed in the previous session. The CHW will review the subject's progress and devise new steps as needed. This process of recording progress for each step is positively reinforcing and, we believe, will increase adherence to other diabetes self-management tasks. If the subject is making progress to obtain the DFE, in sessions 3 and 4 the subject will target another self-care task (e.g., diet, exercise). The CHW will encourage the subject to: 1) select a reasonable, observable, behavioral goal (e.g., walking 3 times/week); 2) address its duration (15 minutes at a time), its timing (after breakfast), and its frequency (3 days/week); 3) list reasons for wanting to change (improve blood sugar), the steps needed to enact the plan (map the route), ways others can offer support (walk with subject), potential barriers (bad weather), and ways to evaluate the outcome (lower blood sugars); and 4) rate their level of confidence in carrying out the plan.

Session by Session Description of the BA Intervention

Session 1
▪ Establish rapport; Introduce BA and the structure of treatment sessions. ▪ Discuss educational materials. ▪ Provide general diabetes education. ▪ Discuss complications of diabetes and how these can be minimized. ▪ Provide education about diabetic retinopathy (DR). ▪ Identify barriers to diabetes management.
Session 2
▪ Review basic information on DR. ▪ Discuss barriers to obtaining DFE.

▪ Discuss how to talk to ophthalmologist and questions to ask. ▪ Assess subject's willingness to schedule DFE. ▪ Provide ophthalmology referral information (Wills, TU, community). ▪ Review "Steps to Prepare for an Eye Exam" ▪ Discuss steps to make DFE appointment. ▪ Formulate "Action Plan" to obtain DFE.
Sessions 3 and 4
▪ Determine whether subject made DFE appointment. If yes, formulate action plan for other diabetes management activities. ▪ If not, review and discuss continuing barriers. ▪ Discuss solutions to overcome barriers to obtaining DFE (e.g., obtain bus schedule, ask daughter to help make appointment, schedule a pleasant activity for the day after the exam). ▪ Review the "Action Plan" from session 2 and revise accordingly. ▪ If appropriate, review "Action Plan" with family member. ▪ Preparing for an Eye Exam ▪ Work with subject to formulate an additional "Action Plan" to engage in other diabetes management behaviors. Provide educational materials specific to the "Action Plan" (i.e., on diet, medication and monitoring adherence, exercise).

2. SUPPORTIVE THERAPY (ST)

ST controls for the nonspecific elements of the BA CHW's contact with subjects. It is a fully-structured, nondirective, supportive psychological treatment that facilitates personal expression and conveys empathy, respect, and optimism. Unlike BA, ST contains no active elements beyond its nonspecific components. Its techniques include active listening, open questioning, reflecting back, and summation. Although social attention itself may have benefits, we nevertheless consider ST a placebo because it has no theoretical basis or lasting effects. Our experience has been that subjects accept ST as a credible intervention. To parallel family member/friend involvement in the BA intervention, the CHW will similarly ask ST subjects if they wish to include a family member/friend in the ST sessions.

ST Treatment Sessions: In the first session, the CHW discusses ST's purpose, which is to explore the impact of aging and diabetes on the subject's life. In contrast to the BA intervention, the CHW does not discuss the importance of DFEs or make any attempt to increase them. In subsequent sessions, ST facilitates and deepens knowledge about the subject's life situation in relation to his or her health and other life difficulties. The ST therapist encourages this process and creates an accepting, nondirective, and supportive opportunity for discussion. Although ST is an activity during the time that is delivered, its effects are transient and not associated with meaningful improvement in health behaviors.

CHAPTER 11. HUMAN SUBJECTS

1. ALERTS AND SERIOUS ADVERSE EVENTS

In providing oversight to human subject safety we distinguish between an Alert and a Serious Adverse Event. We consider an Alert to be a dangerous situation discovered to exist by a member of the research team (e.g., either the CHW assessors or the interventionists) 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 subject in a home. An example of an Alert may be a hazardous home condition (e.g., no fan or air conditioning and windows unable to open in summer where the home reaches temperatures over 100 degrees). See Table below for a list of possible alerts and how they will be dealt with.

We will report Serious Adverse Events (SAE) (study related or otherwise) to the IRB within 48 hours of learning of an event. Examples of SAEs include in-patient hospitalization, emergency room visits, or any other event that significantly impacts a patient's health status.

2. DOCUMENTATION

For an alert, documentation involves notifying designated members of the research team (PI and Project Coordinator) and completing an Alert Event Reporting Form within 24 hours of occurrence of the event. The reporting of alerts to the IRB is not required.

For a serious adverse event, documentation involves notifying the PI and Project Coordinator immediately, completing the IRB Serious Adverse Event form and notifying the IRB within 48 hours of occurrence. Although this is a minimal risk study, all study personal are trained in these alert and serious adverse event procedures.

The PI will be informed of alerts, actions taken, and resolution at weekly staff meetings. For a serious adverse event, the PI will be notified as soon as the event occurs, either by telephone from the person's home or immediately there after.[1]

[1] Adapted from Laura Gitlin, PhD, Center for Applied Research on Aging and Health, Thomas Jefferson University

Alert	Action Take
Medical emergency: -Chest pains - Excessive bleeding - Fall and can not get up - Difficulty breathing	The staff person will call 911 immediately, and stay with subject, until help arrives. Project Coordinator and PI are informed within 24 hours of the event. Project Coordinator then contacts subject as a follow-up within two days. Research staff member completes alert form and gives to Project Coordinator(or designate)
Suicidal ideation, threats to hurt self, major clinical depression that is not responding to the intervention	If a research staff person encounters a situation in which the subject threatens to hurt self immediately, Dr. Rovner, Co-PI will be notified, who will then contact the subject with a plan of action (e.g., recommendation of ER visit). If subject is not an immediate threat to self, then staff person will call Co-PI, a geriatric psychiatrist, who will administer crisis intervention. Staff person fills out Alert form and gives it to Project Coordinator.
Evidence of abuse	Evidence of physical abuse or neglect is as follows: • Subject states to staff that abuse occurs • Staff observes physical evidence (black eye, black and blue marks on CR arms/legs) Staff informs subject that a senior member of the research team will be contacting him/her later that day. Staff informs PM immediately upon completion of interview. Project Coordinator (or designate) contacts subject to obtain further information about situation. Based on this phone call and consultation with PI, the Philadelphia Corporation for Aging Protective Services Department at 215-765-9040 Project Coordinator (or designate) completes Alert form.
Environmental Hazards	Staff notifies Project Coordinator within 24 hours. Project Coordinator contacts subject and refers subject to local Area Agency on Aging (AAA). Project Coordinator (or designate) completes Alert form).

Monitoring Alerts - There are two levels of monitoring of study participant safety concerning alerts that will occur in this study. The first level of monitoring occurs on a weekly basis and involves the following staff meetings; a) the PI is notified of all non-emergency alerts at staff meetings; and b) alerts are reviewed weekly to assure that each has been managed appropriately and follow-up and resolution obtained. The second level of review involves entering alert data collection forms in a timely fashion and generating aggregate data reports that are provided to the PI and statistical consultant on a quarterly basis for review and evaluation. Data entry and an aggregate review facilitate a double check that alerts are resolved.

Monitoring Serious Adverse Events -. In the rare case in which more than one serious adverse event occurs, the project staff will meet to review the severity and cause and determine next study steps.

CHAPTER 12: OTHER ISSUES

1. DEPRESSION AND SUICIDAL IDEATION

Diabetes poses a risk for depression, and thus Dr. Rovner will train all project staff to recognize the symptoms of major depression. If during any of the assessments, project staff determines that a subject meets criteria for major depression, they will make the patient aware of the diagnosis and offer choices for treatment. This includes educating the patient with respect to: (1) what depression is; (2) the dangers of untreated depression; and (3) the availability of safe and effective treatments for depression. They will advise the subject to contact his/her primary care physician for advice on where he/she can get treatment. Dr. Rovner will provide psychiatric referrals if requested.

If it is determined that a subject has suicidal ideation, they should ascertain whether the subject is in fact at risk for suicide. This includes asking the subject whether he/she has a plan in mind, and if the subject has the ability to carry out the plan (e.g., does the patient own a gun or have a supply of potentially lethal medications on hand). If it is determined that there is in fact an immediate risk of suicide, then they will call Dr. Rovner, M.D. immediately. Dr. Rovner will administer crisis intervention.

2. SUBJECT WITHDRAWAL

If a subject indicates to project staff that he/she wants to withdraw from the study, the Project Coordinator will complete a subject withdrawal form. This form will document the date and reason for withdrawal. If the subject is withdrawing during an intervention session, the interventionist will ask the subject if he/she would be willing to continue to participate in the follow-up assessments, either in person or by phone.

CHAPTER 13: DATA MANAGEMENT

1. GENERAL ISSUES

All assessment forms will be created in Teleform, which is a tool whereby data collected in the field are entered directly into a computer. This will be accomplished as follows. The CHW assessor will take a laptop computer with her to all in-home assessments. The computer will prompt her to ask each question and enter the subject's response directly into the computer. Immediately after the assessment, she will send an electronic copy of the completed assessment to the project coordinator, who will store the computerized copy on the hard drive, adding it to the ongoing database of the subject's completed assessments. Data will be backed up in triplicate daily. The advantages of this method are: 1) it eliminates the need for a data entry person; 2) it builds skip patterns into the program, minimizing this type of data entry error; and 3) the computer signals the CHW assessor when questions are skipped or out-of-range values are entered. The CHW assessor will bring a back-up computer battery to all assessments. He/she will also bring a blank hard copy of the assessment should the computer malfunction. All computers used for data collection, including the project manager's computer will be password protected.

2. DESCRIPTION OF COMPUTING ENVIRONMENT

2.1 Hardware

Computers will be purchased for project staff, and they will be password protected.

2.2 Software

All data will be managed and analyzed with SPSS. Teleform will be used to create all data forms. It will also be used for direct data entry and scanning hard copies of data. Both the Project Coordinator and the CHW assessor will have individual licenses.

3. DISTRIBUTION OF BLANK FORMS

All assessment data will be entered directly onto the CHW assessor's laptop, eliminating the need for blank forms. The CHW assessor will, however, bring blank hard copies of assessment forms to all assessment visits should her laptop malfunction. Electronic copies of all forms are stored on the Project Coordinator's computer, and he will distribute them as needed. Intervention visit forms will be distributed by the Project Coordinator to the interventionists as they are needed.

4. PATIENT IDENTIFICATION AND CONFIDENTIALITY

Subject identifiers will be assigned immediately after enrollment, and will be used on all data forms. Neither subject names, nor any other identifying information other than the identifiers, will ever be on the data forms. All hard copies of subject information (data forms, contact information, signed informed consents, randomization sheets, etc.) will be stored in locked file cabinets stored in the Project Coordinator's office. Each subject will have 2 charts, and each will be stored in separate file drawers. The following will be stored in the subject identification chart: the subject's contact information, the recruitment outcome form, the signed consent form, the randomization sheet, and serious adverse event/alert documentation. The following will be stored in the subject data chart: all

hard copies of assessment forms, therapy notes, withdrawal forms, and out of window forms. None of the documents contained in the data chart will have the subject's name. A master list linking subject name with identifier will be stored in a password protected file on the Project Coordinator's computer. All project staff will receive human subjects protection training through Thomas Jefferson University and/or Temple University (Wills Eye Institute uses TJU's training). This training places a strong emphasis on the importance of confidentiality in research.

5. LINKING SUBJECT RECORDS

The only data base that will contain both subject names and identifiers is the tracking list which will be stored on the Project Coordinator's computer. All other data bases will identify individual subjects by their unique identifiers. Assessments completed at different time points will be stored in separate data bases. Unique identifiers will be used to link data obtained from subjects at different time points.

6. IDENTIFYING PROJECT STAFF IN THE DATA BASE

All project personnel will be assigned a unique personnel identifier. Personnel will be required to supply their identifier on all data forms that they complete.

7. PROCEDURES FOR DATA CHECKING AND CORRECTIONS

Data forms (screens, all assessment batteries, therapy notes) are reviewed within 1 week of completion by the interviewer using a Check Code Form. 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. Staff also checks to assure that each page of the IRB subject consent form is initialed and the subject's signature is obtained on the final page of the consent.

All changes to data are submitted via a data edit request form for review and signature by the PI. Data edits are entered directly into the respective data bases. The data edit request form will be stored in the subject's chart. A data base will be maintained that documents each data edit, including the date of the edit as well as the type of change that was made.

8. DESCRIPTION OF DATA EDITS

Each month the Project Coordinator will generate a report documenting the number and type of data edits performed for the previous month. We expect few data edits as data entry errors will be minimal due to direct entry and data scanning. Most edits will consist of changes in subject contact information.

9. INTERNAL DATA QUALITY MONITORING

Data quality monitoring will be minimal, owing to the use of Teleform. Since all data will be entered directly into the computer or scanned, there will be no data entry errors. To insure data integrity, weekly, the Project Coordinator will produce frequency distributions on all assessment data. This will highlight out of range values. In the event that this occurs, the Project Coordinator will inform the CHW, and a data edit request form will be completed accordingly.

10. COMMUNICATIONS RELATED TO DATA COLLECTION

Weekly, the Project Coordinator will generate assessment schedules for the CHWs that will indicate which subjects are due for follow-up assessments in the upcoming 2 weeks. On a monthly basis, the Project Coordinator will produce reports that will indicate the number of subjects who: (1) were sent recruitment letters; (2) had a telephone screen; (3) were enrolled in the study; (4) had an assessment at each time point; and (5) withdrew from the study (and the reason for withdrawal). This report will also indicate the number of assessments that occurred out of window, the number and type of protocol deviations, the number of subjects who became unmasked, and the percent of missing data.

11. MISSING DATA

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

12. BACKUP AND DISASTER RECOVERY OF DATA

Data files are entered and stored on the hard drive of the Project coordinator's PC, as well as memory sticks. All data files are backed up daily in duplicate on memory sticks. An additional full-drive backup is completed monthly. This third memory stick is stored off-site by the Project Coordinator so that a copy of the data always remains secure in the rare event of fire or computer damage at the central research office.

13. DATA COLLECTION AND TRANSMISSION

All in-home assessments will be entered directly on a laptop computer. The CHW assessor will always bring an extra laptop battery as well as a blank hard copy of the assessment form to the subjects' homes. This will enable all data to be collected should the computer malfunction. It is very important that all fields on all assessment forms are filled in (unless otherwise noted). If the subject is unable to respond to a particular item, or if it is not applicable, the CHW assessor should check NA for forced choice questions, or write "NA" for open-ended questions. Immediately after completing the in-home assessment, the CHW assessor will check the assessment forms to insure that all information is complete. If there is any missing data, the CHW assessor should call the patient in order to obtain complete information. Wherever possible, the CHW assessor should try to obtain the missing data from alternative sources. For example, if the subject is unable to supply a list of current medications, the CHW assessor can obtain this information from a subject's spouse.

After assuring that the assessment is complete, the CHW assessor will back up the assessment in duplicate on 2 memory sticks. Once a week, she will give the memory sticks to the Project Coordinator.

14. EQUIPMENT PROTECTION

All study computers will be maintained by the Technical Assistance Center at Wills Eye Health System. The Technical Assistance Center assumes responsibility for the installation and repairs if all computers. All data are backed up in triplicate every day, so in the event of a malfunction, all data will be preserved.

CHAPTER 14: STATISTICAL ANALYSES

1. GENERAL CONSIDERTIONS

A subject is considered enrolled in the study after informed consent is obtained. A subject will be included in the intent to treat analysis ONLY if they are randomized to a study group (to take place after the second clinic based low vision optometry visit). The first level of randomization (to occur after the baseline assessment) is to assign subjects to treatment group.

We will begin data analysis with descriptive statistics and bivariate comparisons of subjects by treatment group to characterize the sample, assess the success of randomization and the impact of attrition, and serve as a final data quality check. Based on analysis of residuals from estimated models (using Q-Q and box plots), we will transform dependent variables prior to analysis as needed to improve normality of the residuals. We will use an intent-to-treat approach for all analyses in that we will include all subjects with follow-up data regardless of the extent to which they received treatment. We will also control statistically for any variables (e.g. attrition, treatments outside the study protocol) which are related to the study outcomes. The primary efficacy outcome, rate of DFE will be a categorical variable based on medical documentation. . The secondary outcomes are depressive symptoms (using the PHQ-9), perceptions of risk of diabetes-related complications (using the Risk Perception Survey-Diabetes Mellitus (RPS-DM)), and self-reported adherence to diabetes-related self-care behaviors (using the Diabetes Self-Care inventory)

2. ANALYSIS OF AIMS

Primary Aim: ***To test the efficacy of Behavior Activation, which is a culturally relevant home-based intervention, to increase rates of dilated fundus examinations (DFE) in older AAs with diabetes in a randomized clinical trial (RCT).***

Hypothesis: *A greater proportion of subjects who receive Behavior Activation will have a DFE by 6 months than subjects who receive Supportive Therapy, which is a placebo treatment that controls for attention.*

a. General Considerations: We will begin data analysis with descriptive statistics and bivariate comparisons of subjects by treatment group to characterize the sample, assess the success of randomization and the impact of attrition, and serve as a final data quality check. Based on analysis of residuals from estimated models (using Q-Q and box plots), we will transform dependent variables prior to analysis as needed to improve normality of the residuals. We will use an intent-to-treat approach for all analyses in that we will include all subjects with follow-up data regardless of the extent to which they received treatment.

b. Testing of the Primary Hypothesis: *A greater proportion of subjects who receive BA will have a DFE by 6 months than subjects who receive ST.* The effect of BA will be estimated by the risk ratio and its associated 95% confidence interval. The primary analysis for this aim will be a Pearson's Chi-square test for association of randomization assignment and having a DFE. Subjects on whom we have no follow-up data at 6 months will be excluded from the analysis under the assumption that they are missing at random.

c. Secondary Hypotheses:

1a. Secondary Aim: *To compare the effectiveness of Behavior Activation vs. Supportive Therapy to increase risk perceptions and risk knowledge of diabetes and its complications (e.g., DR).*

> ***Hypothesis:*** *Behavior Activation will increase risk perceptions and risk knowledge of diabetes and its complications to a greater extent than Supportive Therapy at 6 months.*

1b. Secondary Aim: *To compare the effectiveness of Behavior Activation vs. Supportive Therapy to increase adherence to diabetes self-care recommendations.*

> ***Hypothesis:*** *Behavior Activation will increase adherence to diabetes self-care recommendations to a greater extent than Supportive Therapy at 6 months.*

1c. Secondary Aim: *To compare the effectiveness of Behavior Activation vs. Supportive Therapy to reduce depressive symptoms.*

> ***Hypothesis:*** *Subjects who receive Behavior Activation will have lower levels of depressive symptoms than subjects who receive Supportive Therapy at 6 months.*

We will use mixed effects linear regression to test each of these hypotheses. The dependent variables corresponding to the individual hypotheses are (1) the Composite Risk Perception score of the RPS-DM; (2) the SCI-R score; and (3) the PHQ-9 score. For each model, we will include fixed effects for treatment group, time (baseline and 6 months), and their interaction. We will include a random intercept term to account for correlation among the baseline and 6 month values from the same individual. Within this model, our primary test will be for the equality of treatment group mean scores at 6 months. The mixed effects model will also allow us to estimate the change from baseline to 6 months for each group and test for a difference in the change scores.

d. Exploratory Aims:

1) Exploratory Aim 1: *To examine the long-term efficacy of BA to increase rates of annual DFEs 6 months and one year after the treatment intervention.*

The effect of BA will be estimated by the risk ratio and its associated 95% confidence interval. The analysis for this aim will be a Pearson's Chi-square test for association of randomization assignment and having a DFE.

2) Exploratory Aim 2: To examine whether changes in risk perceptions and risk knowledge of diabetes complications, adherence to diabetes self-care recommendations, and/or depressive symptoms mediates the relationship between treatment assignment and obtaining a DFE.

We will analyze mediation effects using the approach of Baron and Kenny (1986).[138] First, using logistic regression, we will regress the primary outcome (documented DFE) on treatment assignment (see analysis for primary hypothesis). Second, we will test whether treatment assignment impacts the change in risk knowledge, adherence to self-care recommendations, or depression within the mixed effects models specified for the secondary hypotheses. Finally, we will fit two logistic regression models where we regress the primary outcome on treatment assignment and change in: 1) risk knowledge, 2) adherence, and 3) depression. If the effect of treatment on outcome is removed or significantly reduced after adjustment for these variables, then there is evidence that these variables are mediators of the relationship between treatment and outcome.

3) Exploratory Aim 3: To examine whether differences in cultural characteristics at baseline moderate the relationship between treatment assignment and obtaining a DFE.

We will use logistic regression to model the probability of obtaining a DFE as a function of treatment assignment, cultural construct, and treatment x construct interaction. The 4 cultural constructs are: collectivism, religiosity, racial pride, and time orientation. Each construct is separately defined as a continuous measure and each will be examined individually, based on previous research which found that these constructs are associated with health-related behaviors in urban residing AAs. We will assess evidence of effect moderation using the estimated coefficient for the interaction term and its confidence interval.

4) Exploratory Aim 4: *To examine whether a higher proportion of subjects who receive BA will have a 1% reduction in HBA_{1C} levels from baseline to 6 months than subjects who receive ST. For this analysis, we will use the same statistical approach for testing the primary hypothesis of Aim 2.*

3. POWER CONSIDERATION

The primary outcome is medical documentation of a DFE obtained within 6 months of randomization. To power this study we first estimated the expected rate of DFEs in subjects who will receive the control intervention. In Basch et al's (1999) study, the DFE rate in usual care controls was 27.3% within 6 months.[25] In Walker et al (2008)'s study, the DFE rate in controls who received print education materials was 19.5% within 6 months.[73] Subjects were drawn from primary care clinics that served predominately minority patients and had not had a DFE in the preceding 12 months. *Given the similarity of those study samples to our sample, we think it reasonable to estimate a success rate of 25% for the control group in this study.*

There are no reported comparisons of in-home behavioral interventions to increase DFE rates to our knowledge. Thus, we estimated power for this study by identifying a threshold of clinical significance rather than setting a hypothesized effect size. *We believe that a 25% difference (i.e., that 50% of subjects receiving the in-home intervention will have a DFE within 6 months vs. 25% of controls) is a clinically meaningful difference (i.e., large enough to guide future treatment of older patients with diabetes).* Assuming a success rate of *25%* in the control group and a true success rate in the in-home group of at least *50%*, enrolling **206** subjects into the clinical trial (allowing for 20% attrition by 6 months) will yield a sufficient number of subjects (i.e., 164) to provide 90% power to detect a 25% difference between trial arms using a two-sided Pearson's chi-square test with alpha=0.05. Power for various assumptions about control/intervention success rates are depicted below:

Control	Intervention	Power
.35	.60	90.1
.40	.65	90.1
.45	.70	90.7
.50	.75	91.8
.40	.60	73.0
.45	.60	48.5
.50	.60	25.0

Power for the **secondary analyses** (i.e., comparing the effectiveness of the interventions to: 1) increase risk perceptions and risk knowledge of diabetes and its complications; 2) increase adherence to diabetes self-care recommendations; and 3) reduce depressive symptoms) is calculated using a two-sided, two-sample t-test. We treat each outcome separately and assume a type-I error rate of 5% for each outcome. With a sample size of 82 per arm, we will have 80% power to detect an effect size (difference in means/standard deviation) of 0.44 or greater. The Table below shows the difference in means for each outcome corresponding to an effect size of 0.44. Our estimated standard deviations are taken from data reported on the relevant instuments.[112-114] For SCI-R and PHQ-9, we provide mean differences for a range of possible standard deviations. We expect the distribution of PHQ-9 to be skewed and require transformation. Thus, we estimate the standard deviation for a natural log-transformed score using the delta method assuming a mean score of 6.[115]

Outcome	Measure	Estimate Standard Deviation	Difference in Means for Effect size of 0.44
Knowledge of Diabetes Risk	**RPS-DM**	**1.55***	**0.7**
Adherence to Diabetes Self-care	**SCI-R**	**11+**	**4.8**
Depressive Symptoms	**PHQ-9**	**0.55^**	**0.24†**

***** Based on data in Walker et al (2008);[114] + Based on data from Wenger et al (2005);[115] **^** Based on data from Kroenke et al (2001);[116] † Equivalent to a mean ratio of 1.3.

CHAPTER 15: STUDY TIMELINE

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	
June 2010 – May 2011						June 2011 – May 2012						June 2012 – May 2013						June 2013 – May 2				
START UP																						
			SUBJECT ENROLLMENT																			
			IN HOME BASELINE ASSESSMENTS																			
			INTERVENTION DELIVERY																			
						6 MONTH IN-HOME ASSESSMENTS																
									12 MONTH ASSESSMENTS													
												18 MONTH ASSESSMENTS										

This timeline assumes we will enroll 10-11 subjects per month

IRB# 10-003

WILLS EYE INSTITUTE
THOMAS JEFFERSON UNIVERSITY
INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY AND AUTHORIZATION FOR LIMITED USE AND DISCLOSURE OF HEALTH INFORMATION FOR THIS RESEARCH STUDY

Department: Clinical Research Organization (CRO)

Principal Investigator: Julia Haller, MD **Telephone**: (215) 928-3073

Co-Investigator:
James Plumb, MD
Thomas Jefferson University, Department of Family and Community Medicine

Medical Title: Confronting Unequal Eye Care in Pennsylvania

Lay Title: Evaluation of a program to educate patients with diabetes about the importance of having yearly eye exams

What Is an Informed Consent?

You are being asked to take part in a clinical research study. Before you can make an informed decision whether to participate, you should understand the possible risks and benefits associated with this study. This process is known as *informed consent* and means that you will:

1- Receive detailed information about this research study;

2- Be asked to read, sign and date this informed consent, once you understand the study and wish to participate. If you don't understand something about the study or if you have questions, please be sure to ask for an explanation before you sign this form.

3- Be given a copy of this signed and dated form to keep for your own records.

4- Be aware that your relationship with the research physician bears

certain differences from your relationship with your personal physician. Your personal physician individualizes the treatment of your specific problem with the expectation of a benefit to you. The research physician treats all subjects under a specific protocol to obtain generalizable knowledge and on the premise that you may or may not benefit personally from your participation in the study. Be sure to ask questions of the study physician if you want further clarification of this relationship.

Introduction and Study Purpose:

We are conducting a research study to evaluate a program designed to educate patients with diabetes about the importance of having an eye exam every year. Patients who have diabetes are at an increased risk of getting diabetic retinopathy, a serious eye problem related to diabetes. Diabetic retinopathy is the most common diabetic eye disease and a leading cause of blindness in adults. It is caused by changes in the blood vessels of the retina, a layer of cells inside the eyeball. If you have diabetic retinopathy, at first you may not notice changes to your vision. But over time, diabetic retinopathy can get worse and cause vision loss. Diabetic retinopathy usually affects both eyes.

This is why it's important for people with diabetes to have their eyes checked each year. Only an ophthalmologist, a medical doctor who specializes in diagnosing eye diseases, can tell for sure if you have diabetic retinopathy.

The purpose of our research study is to see whether a special in-home educational program is effective in increasing people's awareness of diabetic retinopathy.

Procedures/Treatment:

There are 4 parts to this study.

Part 1: In the first part, one of our research staff will meet with you to test your vision and ask you questions about your health (such as what medications you take and how you manage your diabetes). If you agree, the research staff may also take a small amount of blood from your finger at the beginning and end of the study to check your blood sugar. This gives us an indication of how well your diabetes is controlled. This will be

very similar to blood checks that you may do yourself to monitor your sugar and will involve 1-2 drops of blood (less than 0.1 cc)

If your results indicate a potential medical problem, we may notify your primary care physician. If we are not able to reach him/her, we may contact Dr. James Plumb. Dr. Plumb is a physician at Thomas Jefferson University who specializes in providing care for people who have diabetes. You don't have to have this blood test to be in the study.

I agree to have my blood drawn (please sign your name next to your choice):

Yes (signature and date) _____

No (signature and date)_____

Part 2: In the second part of the study, you will be randomized (determined by chance) to 1 of 2 in-home programs: Behavior Activation or Supportive Therapy. You will have a "50-50" chance (like a flip of a coin) of receiving Behavior Activation. Behavior Activation is designed to help you make a step-by-step plan to reach a goal. If you are not assigned to the Behavior Activation program, you will receive the Supportive Therapy program which gives you the opportunity to discuss how your diabetes is affecting your life. You may benefit from being in either group but you will not discuss the step-by-step plan to reach a goal if you are receiving the Supportive Therapy Program.

In both programs the study staff will meet with you 4 times in your home over 2 months and you are welcome to have a family member present. Each of these visits will take about 45 minutes. We will schedule these visits at your convenience. There is no charge for these visits.

With your permission, we would like to audio-tape these sessions. The purpose of this is to train staff members on how to educate patients about their diabetes and vision health. Your name will not be associated with these tapes. We will use a code number to protect your privacy.
You can chose to not be audio-taped and still be in this study.

I agree to have my study visits audio-taped (please sign your name next to your choice):

Yes (signature and date) _____

No (signature and date)_____

Part 3: In the third part of the study, the research staff will meet with you about 6 months from now. At this visit the research staff will ask you questions about your health and your diabetes. If it is OK with you, the research staff will do another blood test at this time. If during this visit you indicated that you visited an ophthalmologist in the past 6 months, we will review your medical records to see if you have any eye problems.

Part 4: In the fourth part, the research staff will call you on the phone twice: both at 12 and 18 months from now. During these phone calls you will be asked whether you visited an ophthalmologist. If you did, we will review your medical records to see if you have any eye problems.

Inclusion Criteria:

To be in this study, you must:

1) be African-American
2) be aged 65 or older
3) have type II Diabetes
4) not have had a dilated eye exam in the past year
5) have access to a telephone

Number of Patients and Length of Study:

The entire length of the study is 48 months. Individual patient participation will last 18 months and will begin in the first year. 206 patients from the Thomas Jefferson University and Temple University

Primary Care offices are expected to enroll in the study. To recruit and retain this many patients, we plan to identify at least 1000 patients via patient medical records.

Risks/Discomforts:

There may be three minor risks associated with participating in this study.

The first is the potential loss of confidentiality. This means that the information that you provide us may be accidentally revealed to people who are not part of this study. We will take special precautions to make sure that this doesn't happen. We will post your confidential information on a secure password protected computer and only our research staff will be able to access this information for the purposes of the study. All of our research procedures are designed to ensure subjects' confidentiality. You will be assigned a unique identification number and this ID number will be the only identifying information on data forms. Your name will not appear on data collection forms. A list linking ID numbers to names will be kept in a password-protected computer file accessible only to research staff. We do not anticipate any circumstances in which medical or professional program will be needed.

Second, some people may feel uncomfortable when discussing their health or attitudes about their health care. You may chose to not answer any question that you may find objectionable.

Third, drawing blood from your finger may cause pain, bruising, lightheadedness, and, on rare occasions, infection.

Alternative Treatments:

Your alternative is not to participate in this study. There may be other alternatives that could be considered in your case. These alternative treatments would include: discussing diabetic retinopathy with your doctor.

Protecting Your Health Information:

The Wills Eye Institute and Thomas Jefferson University are required by law to holding your health information in confidence and protect it from unauthorized use and disclosure. Your health information includes, but is not limited to, your name, address, social security number, and other

personally identifiable information as well as diagnosis, treatment, and other documentation. By signing this informed consent form, you are authorizing the Wills Eye Institute, its Institutional Review Board, the principal investigator, and any other research staff at the Wills Eye Institute to use your protected health information for purposes of this research study. In addition, you authorize these persons to disclose your protected health information to:

1) Study investigators at the Wills Eye Institute.
2) Study investigators at Thomas Jefferson University.
3) The sponsor of this study, the Pennsylvania Department of Health.
4) The Institutional Review Board (IRB) at the Wills Eye Institute and Thomas Jefferson University.
5) Your primary care physician.

Specifically, the following kinds of protected health information may be used or disclosed:

1) Information regarding your diabetes and eyes will be obtained from your primary care physician.
2) Background information, such as your age and marital status.
3) The research staff will ask you about your educational background, medical history, how you are feeling, your past experiences with eye doctors, your diabetes, and about your satisfaction with your medical care.
4) Results of your blood tests, if you agreed, to see how good or bad your diabetes is.
5) If you have your eyes examined during the study, we will gather information about the exam from your eye doctor.

Your name, address, and social security number are not included in disclosed research data and will not be published.

This authorization has no expiration date; however, you may revoke this authorization at any time, except to the extent that action has been taken in reliance on this authorization, by contacting the principal investigator at the telephone number on the front page of this form or the Privacy Director of the Wills Eye Institute. Since the use and disclosure of your protected health information is necessary for the conduct of this research study, revocation of this authorization will result in your withdrawal from this research study.

If you decide not to sign this authorization, you will not be allowed to participate in this research study or receive any research related treatment that is provided through the study. However, your decision to not sign this authorization will not affect your normal course of treatment at the Wills Eye Institute or Thomas Jefferson University.

It is possible that information disclosed under this authorization might be re-disclosed by the persons who receive it and no longer be protected. You may not be allowed to review the information collected for this study, including information recorded in your medical record, until after the study is completed. When the study is over, you will have the right to access the information again.

Compensation in the Case of Injury:

In the event of physical injury or illness resulting to you as a direct result of the experiments, treatment(s), and/or procedure(s) used in this investigation, comprehensive medical and/or surgical care (including hospitalization) to the extent needed and available will be provided. However, the Wills Eye Institute cannot assure that this comprehensive medical and/or surgical care will be provided without charge, and the costs incurred for this care may ultimately be your responsibility.

This study is very low risk because it does not involve any medical procedures. Therefore you are highly unlikely to be injured as a result of participating in this study.

Benefits to Subject:

You may not benefit from being in the study, but a possible benefit from being in either group will be that you will be able to discuss your diabetes care with a health care professional and more frequent monitoring of your diabetes compared to usual care. No matter which group you are assigned to, you will receive a visit from the study staff for 4 visits to talk about your diabetes.

In addition, there may also be a benefit to society, in general, from the knowledge gained in connection with your participation in this study. Any information obtained from this research study, and which may be important to your health or disease progression, will be shared with your personal physician. Additional benefits from your participation in this study may include:

1) Learning about diabetic retinopathy
2) Receiving a referral to an ophthalmologist

Payment:

You will receive payment for your participation in this study. You will be paid $25 for the first assessment visit and $25 for the assessment in 6 months from now, or a total of $50.

Additional Information:

If you have any questions or concerns about this research, you are free to ask questions about these treatments/ procedures and to ask for additional information from the doctor identified on this consent form as the Principal Investigator, his/her designated representative, or any other doctors involved in your care. You may contact the Principal Investigator(s), Dr. Julia Haller, MD at telephone: (215) 928-3073. Should you have any questions regarding your rights as a research participant, you may contact the Wills Eye Institute's Institutional Review Board, which is concerned with the protection of participants in research studies, at telephone: (215) 440-3145. You are not presently enrolled in any other investigational study.

Significant New Findings:

As the research progresses, any significant new finding(s), beneficial or otherwise, will be told to you and explained as they relate to the course of your treatment.

Disclosure of Financial Interest:

The sponsor of this clinical study, The Pennsylvania Department of Health, is paying the Wills Eye Health System to conduct this study.

Certain Costs:

There are no costs associated with participating in this study.

Voluntary Consent and Subject Withdrawal:

You voluntarily consent to participate in this research investigation. You have been told what your participation will involve, including the possible risks and benefits. Your participation in this research project may be terminated by your doctor without your consent from participation at any time, at the study physician's discretion, for any reason(s) he/she deems appropriate. You may refuse to participate in this investigation or withdraw your consent and discontinue participation in this study without penalty and without affecting your future care or your ability to receive alternative medical treatment at the Wills Eye Institute or Thomas Jefferson University.

If you withdraw from this study, you may seek treatment from another physician of your choice. In the event that you withdraw from the study, the study physician will ask your permission to continue study follow-up, and if you agree, all clinical data, as it relates to the study, will continue to be collected from your medical records.

Non-Waiver of Legal Rights Statement:
By your agreement to participate in this study, and by signing this consent form, you are not waiving any of your legal rights.

I have read and received a signed copy of this page informed consent form.

Signatures:

_____(Date) _____(Date)
Your Name *(please print or type)* Signature of Next of Kin /Patient's Surrogate

_____(Date)_____(Date)
Your Signature Witness Signature
(*Only required if subject understands and speaks English, but cannot read English)*

_____(Date)
Name of Person Conducting Consent Interview

_____(Date)_____(Date)
Signature of Person Conducting Consent Interview Signature of Principal Investigator or Co-Investigator