Final Progress Report for Research Projects Funded by Health Research Grants

Instructions: Please complete all of the items as instructed. Do not delete instructions. Do not leave any items blank; responses must be provided for all items. If your response to an item is "None", please specify "None" as your response. "Not applicable" is not an acceptable response for any of the items. There is no limit to the length of your response to any question. Responses should be single-spaced, no smaller than 12-point type. The report **must be completed using MS Word**. Submitted reports must be Word documents; they should not be converted to pdf format. Questions? Contact Health Research Program staff at 717-783-2548.

1. **Grantee Institution:** Wills Eye Health System

2. **Reporting Period (start and end date of grant award period):** 6/1/2010 – 5/31/2014

3. **Grant Contact Person (First Name, M.I., Last Name, Degrees):** Brian Burke, MPH

4. **Grant Contact Person's Telephone Number:** 215-928-3394

5. **Grant SAP Number:** 4100051727

6. **Project Number and Title of Research Project:** Confronting Unequal Eye Care in Pennsylvania

7. **Start and End Date of Research Project:** 6/1/2010 – 5/31/2014

8. **Name of Principal Investigator for the Research Project:** Julia A. Haller, MD

9. **Research Project Expenses**.

   9(A) Please provide the amount of health research grant funds spent on this project for the entire duration of the grant, including any interest earned that was spent:

   $3,365,516.15

   9(B) Provide the last names (include first initial if multiple individuals with the same last name are listed) of **all** persons who worked on this research project and were supported with health research funds. Include position titles (Principal Investigator, Graduate Assistant, Post-doctoral Fellow, etc.), percent of effort on project and total health research funds expended for the position. For multiple year projects, if percent of effort varied from year to year, report in the % of Effort column the effort by year 1, 2, 3, etc. of the project (x% Yr 1; z% Yr 2-3).

Last Name	Position Title	% of Effort on Grant	Cost
Haller	Principal Investigator	10% Yr1-Yr3; 30% Yr4	$ 98,779.98
Hark	Project Director	50% Yr1-Yr3; 75% Yr4	$ 208,075.04
Murchison	Investigator	20% Yr1-Yr3; 50% Yr4	$ 208,837.55
Spaeth	Investigator	10% Yr4	$ 19,970.00
Katz	Investigator	10% Yr4	$ 19,970.00
Waisbourd	Investigator	60% Yr4	$ 24,384.65
Weiss	Project Manager	100% Yr1-Yr4	$ 155,039.94
Fluornoy	Student	100% Yr1	$ 3,551.79
Collymore	Assessor	100% Yr1-2; 50% Yr3-4	$ 39,152.90
Malunda	Research Assistant	100% Yr1-Yr3	$ 73,986.90
Caraballo	Interventionist	100% Yr1-Yr3	$ 96,199.30
Stratford	Interventionist	100% Yr1-Yr2; 65% Yr3; 85% Yr4	$ 124,077.80
Johnson	Assessor	100% Yr1-Yr2; 85% Yr3-4	$ 129,594.51
Aleo	Project Coordinator / Res Assist	95% Yr4	$ 26,359.81
Poole	Interventionist	100% Yr3-4	$ 3,537.00
Tran	Research Assistant	95% Yr4	$ 28,798.05
Hale	Student / Assessor	100% Yr3; 60% Yr4	$ 34,387.21
Fernandez-Ortega	Student	100% Yr1-2	$ 2,932.16
Alston	Student	100% Yr1-2	$ 2,932.16
Neville	Student	100% Yr1-2	$ 2,932.16
Ashford	Student	100% Yr1-2	$ 2,932.16
Samuel	Student	100% Yr1-2	$ 2,932.16
Fuentes	Student	100% Yr2-3	$ 3,039.61
Lambert	Student	100% Yr2-3	$ 3,039.61
Luna-Flores	Student	100% Yr2-3	$ 3,039.61
Batichon	Student	100% Yr2-3	$ 3,077.51
Dominguez	Student	100% Yr3-4	$ 3,080.01
Howard	Student	100% Yr3-4	$ 3,000.00
Kirkland	Student	100% Yr3-4	$ 3,047.50
Marlin	Student	100% Yr3-4	$ 2,990.00
Scozzare	Research Assistant	2% Yr1	$ 94.37
Leiby	Statistician	5% Yr1-Yr4	$ 18,927.24
Thomas	Interventionist	10% Yr2	$ 895.00
Johnson	Interventionist	50% Yr2-3	$ 39,337.26
Collymore	Assessor	2% Yr3	$ 815.80
Payton	Research Assistant	10% Yr3	$ 1,246.45
Ziring	Investigator	3% Yr1-3	$ 10,743.49

Gitlin	Investigator	4% Yr1	$ 2,976.34
Arenson	Investigator	2% Yr1	$ 780.83
Plumb	Investigator	5% Yr1-Yr4	$ 26,244.80
Rovner	Investigator	30% Yr1-Yr4	$ 255,685.57
Jabbour	Investigator	4% Yr2	$ 9,866.24
Casten	Investigator	20% Yr1-2; 30% Yr3-4	$ 118,764.16
Brisbon	Investigator	5% Yr1-3	$ 10,000.52
Salzman	Investigator	10% Yr1	$ 1,708.14
Pizzi	Health Economist	2% Yr3-4	$ 5,071.46
Acquarole	Coordinator	20% Yr3-4	$ 17,105.12
Henderer	Investigator	6% Yr1-4	$ 50,853.98
Gupta	Investigator	5% Yr1	$ 12,041.66
Faust	Research Coordinator	5% Yr1-4	$ 8,330.75
Foster	Research Assistant	3% Yr3-4	$ 8,640.07
Wong	Research Assistant	5% Yr2	$ 1,313.67
Thomas	Assessor	83% Yr2	$ 4,291.60
Schardt	Administrator	40% Yr4	$ 8,003.07

9(C) Provide the names of **all** persons who worked on this research project, but who *were not* supported with health research funds. Include position titles (Research Assistant, Administrative Assistant, etc.) and percent of effort on project. For multiple year projects, if percent of effort varied from year to year, report in the % of Effort column the effort by year 1, 2, 3, etc. of the project (x% Yr 1; z% Yr 2-3).

Last Name	Position Title	% of Effort on Project
None		

9(D) Provide a list of **all** scientific equipment purchased as part of this research grant, a short description of the value (benefit) derived by the institution from this equipment, and the cost of the equipment.

Type of Scientific Equipment	Value Derived	Cost
A1C kits	All subjects have their Hemoglobin A1C's taken at baseline and at the 6-month follow-up assessments.	$8,685.69

Digital Recorders (4)	All assessments, BA sessions, and ST sessions are recorded.	$659.82
Filemaker Pro	Program enables WEIS to store potential participant information in a secure database.	$3,817.00
GPS systems (3)	Systems allow assessors and interventionists to get to and from subjects' homes.	$258.37
SPSS	Program used to organize and analyze data from assessments and process data from treatment sessions.	$1,653.00
Teleform	Converts input data into SPSS file, eliminating the need for a data entry person thereby reducing errors that would result in data entry.	$28,800.00

10. Co-funding of Research Project during Health Research Grant Award Period. Did this research project receive funding from any other source during the project period when it was supported by the health research grant?

Yes_____ No___✓_____

If yes, please indicate the source and amount of other funds:

11. Leveraging of Additional Funds

11(A) As a result of the health research funds provided for this research project, were you able to apply for and/or obtain funding from other sources to continue or expand the research?

Yes___✓_____ No_____

If yes, please list the applications submitted (column A), the funding agency (National Institutes of Health—NIH, or other source in column B), the month and year when the application was submitted (column C), and the amount of funds requested (column D). If you have received a notice that the grant will be funded, please indicate the amount of funds to be awarded (column E). If the grant was not funded, insert "not funded" in column E.

Do not include funding from your own institution or from CURE (tobacco settlement funds). Do not include grants submitted prior to the start date of the grant as shown in Question 2. If you list grants submitted within 1-6 months of the start date of this grant, add a statement below the table indicating how the data/results from this project were used to secure that grant.

A. Title of research project on grant application	B. Funding agency (check those that apply)	C. Month and Year Submitted	D. Amount of funds requested:	E. Amount of funds to be awarded:
Wills Eye Community Intervention to Improve Glaucoma Detection and Follow-up Care	☐NIH ✓ Other federal (specify: CDC) ☐ Nonfederal source (specify: _____)	March 2014	$3,000,000	$3,000,000 October 2014 (Haller, Katz, Hark)
Collaborative Care for Depression in Diabetes	✓NIH ☐ Other federal (specify: _____) ☐ Nonfederal source (specify: _____)	February 2014	$3,450,000	Pending (Rovner)
Improving Medication Adherence in Older African Americans with Diabetes	✓NIH ☐ Other federal (specify: _____) ☐ Nonfederal source (specify: _____)	October 2013	$2, 433, 425	$2, 433, 425 July 2014 (Rovner, Casten)
Patient-Centered, Randomized Controlled Trial to Improve Vision Care in African Americans and Latinos with Diabetes	☐NIH ☐Other federal (specify: _____) ✓ Nonfederal source (specify: PCORI)	August 2013	$1,500,000	Not Funded
Comparison of Follow-up Eye Care Adherence After a Patient-Centered, Community-Based Glaucoma Screening	☐NIH ☐Other federal (specify: _____) ✓ Nonfederal source (specify: PCORI)	August 2013	$1,500,000	Not Funded
Comparison of Follow-up Eye Care Adherence After a Patient-Centered, Community-Based Glaucoma Screening	☐NIH ☐Other federal (specify: _____) ✓ Nonfederal source (specify: Partridge Foundation)	December 2013	$167,000	$167,000 January 2014 (Katz, Hark)

Collaborative Care for Depression and Diabetic Retinopathy in African Americans	✓NIH (National Eye Institute) ☐ Other federal (specify: _____) ☐ Nonfederal source (specify: _____)	June 2013	$478,750	$478,750 (Rovner, Casten)
Improving Access to Eye Care Among High-Risk Persons for Glaucoma in Philadelphia	☐NIH ✓ Other federal (specify: CDC) ☐ Nonfederal source (specify: _____)	May 2012	$1,800,000	$1,800,000 October 2012 (Katz, Hark)

11(B) Are you planning to apply for additional funding in the future to continue or expand the research?

Yes___✓_____ No_____

If yes, please describe your plans:

Wills Eye Hospital has designed a study entitled *Patient-Centered, Randomized Controlled Trial to Improve Vision Care in African Americans and Latinos with Diabetes*. This proposed study will continue our efforts to improve access to and quality of eye care for underserved African Americans in Philadelphia and expand those efforts to younger Latinos and African Americans. This proposed study will utilize a modified 2 session intervention from the current project that can be delivered via web cameras. Like the current project, the objective of the proposed research is to increase rates of dilated fundus exams in at-risk populations with diabetes. This project was scored favorably, but was not funded by Patient-Centered Outcomes Research Institute (PCORI). We are evaluating other grant funding mechanisms to submit this proposal and are considering resubmitting to PCORI.

12. Future of Research Project. What are the future plans for this research project?

Wills Eye Hospital will continue to follow the participants in the current project for their 18-month phone follow-up to determine the long-term efficacy of the intervention. This follow-up will determine if participants have obtained a dilated fundus exam approximately one year after the intervention ended. The 18-month follow-ups will continue until November 2014. In addition, we plan to prepare the following manuscripts based on data collected during this study. No funding source has been secured at Wills Eye Hospital at this time to continue this research beyond the grant.

Additionally, Wills Eye Hospital will seek funding to evaluate the efficacy of the intervention tested in Aim 1 in younger populations as well as Latinos, who are also at high risk of diabetes and diabetic retinopathy. In regards to Aim 2, we have implemented the summer Minority Vision Research Training and Mentoring Program in years 2 - 4 of the grant. Based on the evaluations completed by the students at the end of the program, we have modified and expanded this program. Starting in June 2014, 30 students (including 14 medical students) participated in the Vision Research Training and Mentoring Program, which is designed to provide undergraduate, graduate, and medical students with 9 weeks of clinical research training, experience, and mentorship.

Baseline results from Aim 1 home-based intervention indicated that approximately 15% of the participants suffered from 4 or more depressive symptoms. Depression occurs in 20-25% of older African Americans with diabetic retinopathy (DR) and accelerates progression of DR by compromising diabetes self-management practices and raising hemoglobin A1C levels (HbA1C). Treating depression improves diabetes self-management and lowers HbA1C and may thereby prevent progression of DR. To develop an intervention that simultaneously targets diabetes self-management and depression, Thomas Jefferson University, in collaboration with Wills Eye Hospital, was funded by NIH to conduct a feasibility project entitled *Collaborative Care for Depression and Diabetic Retinopathy in African Americans*.

This project utilizes Behavioral Activation to improve glycemic control and depression in older African Americans who have been diagnosed with diabetic retinopathy. While the aim of the current project was DR screening, the NIH-funded pilot study aims to prevent the progression of DR by treating depression and improving diabetes self-management. The following studies have utilized baseline data from Aim 1 and expand the use of the active intervention, Behavioral Activation, to address depression, medication adherence, and other ocular comorbidities such as glaucoma in at-risk populations.

<u>Collaborative Care for Depression and Diabetic Retinopathy in African Americans</u>
This is an NIH-funded study ($478,750) awarded to Dr. Rovner in 2014 (principal investigator) and Dr. Casten (co-investigator and project director). In this feasibility/pilot study, the investigators will develop, refine, and evaluate the feasibility of a novel mental health/ophthalmologic intervention called, *Collaborative Care for Depression and Diabetic Retinopathy (CC-DDR),* which aims to treat depression and lower HbA1C in older African Americans with mild-to-moderate diabetic retinopathy (DR) and co-morbid depression. The Specific aims are:

1) To develop the CC-DDR treatment protocol. This will involve:
    a. Creating an initial version of the CC-DDR treatment protocol.
    b. Refining the protocol based on input from an expert panel with expertise in DR, depression, and culturally relevant interventions for diabetes in older African Americans.
    c. Developing a tool to assess interventionist treatment adherence and competence.
2) To conduct an open trial of CC-DDR with 40 participants who have poorly controlled diabetes, depression, and mild or moderate DR. During this open trial we will:
    a. Evaluate the feasibility of CC-DDR.
    b. Refine the CC-DDR treatment protocol by incorporating feedback from participants, community health care workers (CHWs), ophthalmologists, and the expert panel.

c. Refine procedures for recruitment and retention, outcome assessment, monitoring treatment fidelity, CHW training and supervision, quality assurance, and study administration, based on input from investigators, CHWs, participants, and the expert panel.
d. Examine CC-DDR's impact on depression severity; diabetes self-management practices; HbA1C level; blood pressure; adherence to the ophthalmologist treatment plan; vision function; quality of life; and satisfaction with CC-DDR.

3) To complete a Manual of Procedures that characterizes all aspects of the planned efficacy trial of CC-DDR.

Improving Medication Adherence in Older African Americans with Diabetes

This an NIH-funded study ($2,433,425) awarded to Dr. Rovner in 2014 (principal investigator) and Dr. Casten (co-investigator and project director). The prevalence of type 2 diabetes (DM) in older persons is increasing rapidly. DM increases the risk for mild cognitive impairment (MCI), which is a transition state between normal cognition and dementia that is often characterized by memory and executive function deficits. These deficits reduce adherence to DM medications, which worsens glycemic control and increases the risk for adverse DM-related health outcomes. Improving medication adherence may prevent these outcomes and reduce health care costs.

This is important to all older persons with DM but particularly to older African Americans (AAs). They have twice the rate of DM, worse cognitive function, lower medication adherence, and worse glycemic control than whites. One million older AAs now have DM and their number will double by 2030. Because 30% also have MCI, low medication adherence is an important problem for them. This necessitates culturally relevant interventions that compensate for their cognitive deficits and improves their medication adherence and glycemic control.

This randomized controlled clinical trial will evaluate the efficacy of a collaborative Primary Care-Occupational Therapy (PC-OT) intervention to lower hemoglobin A1c (HbA1c) levels in older AAs with DM, MCI, HbA1c $\geq$ 7.5%, and $\leq$ 80% adherence to an oral hypoglycemic medication. PC-OT consists of: 1) primary care physician (PCP) - occupational therapist (OT) collaboration; 2) DM education tailored to cognitive impairment; 3) in-home OT cognitive-functional assessment; and 4) OT-delivered Behavior Activation to increase adherence to medications and other diabetes self-management (DSM) practices (e.g., diet). The trial will enroll 100 participants from primary care clinics and randomize them to PC-OT or Enhanced Usual Care (EUC). EUC is usual medical care plus low intensity DM education delivered by community health workers. Participants in both PC-OT and EUC will have 6 initial in-home treatment sessions over 3 months, and then 3 booster sessions during this 12 month study.

The primary outcome is a reduction in HbA1c of 0.5%, which reduces the risk of adverse medical events. The primary efficacy analysis compares the proportion of participants in PC-OT and EUC who achieve this outcome at month 6 (short-term effect) and at month 12 (maintenance effect). Medication adherence will be assessed with an electronic Medication Event Monitoring System, prescription refills, and self-reports. A secondary aim determines if improving medication adherence mediates PC-OT's impact on HbA1c levels. This is the first study to determine if PCPs, collaborating with OTs (who are experts in developing strategies to compensate for cognitive/physical deficits), can improve medication adherence and glycemic

control, and prevent cognitive and functional decline in older persons with DM and MCI. If PC-OT is effective in a high-risk population of older AAs, its benefits may extend to all older persons with DM and have enormous public health significance.

For both of these grants, data from the CURE study were included in the preliminary studies section to demonstrate the efficacy of BA to improve diabetes self-management behaviors, ability to recruit an adequate sample size, the acceptability of the control condition, and participants' satisfaction with study procedures.

Additionally, during 2012 and 2013, Wills Eye was able to secure funding from the National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC) to implement community outreach programs to screen for glaucoma and DR in African Americans.

Community Intervention to Improve Glaucoma Detection and Follow-up Care

The CDC awarded Wills Eye Hospital Department of Research and Glaucoma Research Center $3 million over 5-years (2014-2019) for *Wills Eye Community Intervention to Improve Glaucoma Detection and Follow-up Care*. This cooperative agreement, which builds on our experience from the CURE studies, was awarded to Drs. Haller and Katz (principal investigators) and Dr. Hark (co-investigator and project director).

The specific aims are to:

1) Determine the effectiveness of an innovative, telemedicine, community-based intervention that uses fundus photography of the optic nerve and macula to increase the detection of undiagnosed glaucoma, glaucoma suspect, other eye disease and vision loss in high-risk populations;
2) Evaluate the effectiveness of an evidence-based, enhanced intervention using patient navigators and a social worker to improve eye-care access, utilization, and follow-up care in community settings among those with newly diagnosed glaucoma, glaucoma suspect, other eye diseases and vision impairment;
3) Conduct a comprehensive cost study to estimate the intervention costs and cost effectiveness of detecting eye disease and vision impairment in a high-risk population; and
4) Replicate and disseminate protocols, materials, tools and results with other communities in order to develop a public health repository of interventions/protocols to detect, manage and follow-up patients with glaucoma, other eye diseases and vision impairment.

Improving Access to Eye Care Among High-Risk Persons for Glaucoma in Philadelphia

In 2012, the Wills Eye Hospital Glaucoma Research Center was funded for $1.8 million by the Centers for Disease Control and Prevention to initiate the 2-year demonstration project: *Improving Access to Eye Care Among High-Risk Persons for Glaucoma in Philadelphia.* This cooperative agreement was awarded to Dr. L. Jay Katz (principal investigator) and Dr. Hark (co-investigator and project director). This project mobilized existing community partners to plan, develop, and implement an integrated community-based intervention to improve detection, management, treatment, and follow-up care of individuals at high risk for glaucoma in order to assure access to eye care, and reduce disease burden and related vision loss.

The goals and objectives of the intervention are to:
1) Identify and engage at least 2,000 adults (African Americans age 50+, older adults age 60+) in underserved communities in Philadelphia most vulnerable to glaucoma,
2) Provide on-site educational workshops to at least 2,000 individuals to increase awareness about glaucoma and its risks,
3) Perform 1,500 on-site focused ocular examinations to detect glaucoma in these high-risk individuals, and
4) Provide on-site management, treatment, follow-up examinations, and referrals in individuals diagnosed with glaucoma or glaucoma suspect.

Wills Eye conducted the project in partnership with the Philadelphia Corporation for Aging, Philadelphia Housing Authority, Philadelphia Senior Center, Center in the Park, Health Promotion Council, Southeast Asian Mutual Assistant Associations Coalition, The Council of Spanish Speaking Organizations, Thomas Jefferson University, Temple University, and the Philadelphia Health Department.

The three-phase project consisted of Phase 1 (Program Development and Implementation: 3 months), Phase 2 (Program Implementation and Follow-up: 15 months), and Phase 3 (Program Follow-up and Evaluation: 6 months). The initial focused ocular examination includes 1) ocular, medical and family history, 2) visual acuity, 3) pupil examination, 4) biomicroscopy of the anterior segment, 5) IOP measurement using Goldmann Applanation tonometer, 6) gonioscopy, 7) undilated optic nerve evaluation by indirect biomicroscopy, and 8) visual field testing. Depending on the results of the examination, individuals either required no follow-up, on-site follow-up in 4-6 weeks, and 4-6 months at the same location, or referral for other ocular conditions.

Individuals who were diagnosed with definite glaucoma and required treatment were recommended for selective laser trabeculoplasty, which was performed on the same day on-site or within one week when the intervention team returns. Individuals who were not eligible to, as well as those who did not agree to, receive laser surgery were given a prescription for medications. Wills Eye and its partners, in concordance with the CDC, is implementing a comprehensive process and outcome evaluation plan to monitor, track, demonstrate, and evaluate efforts. The long-term impact of this project is to reduce disability and economic burden from vision loss and reduce ocular health disparities.

13. New Investigator Training and Development. Did students participate in project supported internships or graduate or post-graduate training for at least one semester or one summer?

Yes___✓_____ No_____

If yes, how many students? Please specify in the tables below:

	Undergraduate	Masters	Pre-doc	Post-doc
Male	2	0	3	0
Female	6	4	0	0
Unknown	0	0	0	0
Total	**8**	**4**	**3**	**0**

	Undergraduate	Masters	Pre-doc	Post-doc
Hispanic	4	0	1	0
Non-Hispanic	4	4	2	0
Unknown	0	0	0	0
Total	**8**	**4**	**3**	**0**

	Undergraduate	Masters	Pre-doc	Post-doc
White	0	0	0	0
Black	3	4	1	0
Asian	0	0	0	0
Other	5	0	2	0
Unknown	0	0	0	0
Total	**8**	**4**	**3**	**0**

14. Recruitment of Out-of–State Researchers. Did you bring researchers into Pennsylvania to carry out this research project?

Yes_____ No____✓_____

If yes, please list the name and degree of each researcher and his/her previous affiliation:

15. Impact on Research Capacity and Quality. Did the health research project enhance the quality and/or capacity of research at your institution?

Yes___✓_____ No_____

If yes, describe how improvements in infrastructure, the addition of new investigators, and other resources have led to more and better research.

The health research project has enhanced the capacity to conduct research at the Wills Eye Hospital Department of Research. One of the goals for Wills Eye Hospital is to expand its research portfolio, including the development of more investigator initiated and multi-site research projects. The re-establishment of the Department of Research (under the leadership of Lisa Hark, PhD, RD) has been a major step in the expansion of research activity and securing more federal and foundation funding. While Wills Eye Hospital clinical services have been producing hundreds of scientific research publications annually, it is only in the last few years

that Wills has started to harness independent pieces into a modern, coordinated research enterprise. The health research project has revived translational research efforts by helping establish a Department of Research as well as an invigorated research infrastructure. Wills Eye Hospital now has a new Executive Director who has visionary leadership and enthusiasm for a rejuvenated and redirected research institution, as well as a new Chief of Operations, Finance Director, Research Grants Administrator, and research staff.

The current research project has also facilitated multiple fruitful collaborations (specified in Question 16) that have enhanced our capacity to design and execute larger-scale projects. Since the health research project began, the Department of Research has leveraged over $5 million in the past two years to conduct outreach programs in the Philadelphia community. In addition, with private donor funds, Wills Eye is recruiting candidates for both a Vice Chair for Research position who will oversee all research operations as well as a Senior Biostatistician.

The current health research project has spearheaded the establishment of office space at Wills Eye Hospital to conduct clinical research and facilitate coordination with TU and TJU. Now, with the creation of space for the Department of Research, Wills Eye Hospital boasts approximately 32,000 sq. ft. of clinical research space. With the funds for the health research project, Wills has enhanced its research infrastructure and hired the appropriate faculty/staff to conduct basic science, clinical, translational, epidemiological, and public health research projects.

16. Collaboration, business and community involvement.

16(A) Did the health research funds lead to collaboration with research partners outside of your institution (e.g., entire university, entire hospital system)?

Yes___✓_____ No_____

If yes, please describe the collaborations:

The current project has facilitated collaborations with Thomas Jefferson University (TJU), and Temple University (TU). We enrolled participants from primary care clinics from TJU and TU for Aim 1. These collaborations have improved communication between ophthalmologists at Wills Eye Institute (WEI) and primary care physicians at TJU and TU. As stated in Question 11, WEI is collaborating with TJU to conduct a feasibility study to treat older African Americans with diabetic retinopathy and co-morbid depression. WEI continues to work with TU on the project entitled *Comparison of Follow-up Eye Care Adherence After a Patient-Centered, Community-Based Glaucoma Screening*.

The collaborations with TJU have led to the establishment of the *Wills Vision Research Center at Jefferson*, which has the mission of conducting vision research aimed at preventing and treating eye diseases through collaborative research projects based at both institutions. Recently, the *Wills Vision Research Center at Jefferson*, held its fourth annual symposium, attended by multidisciplinary teams made up of over 100 established basic researchers, scientists, and clinicians from WEI, TJU, TU, and other area universities. These include faculty from Jefferson

Medical College Departments of Ophthalmology, Pathology, Anatomy and Cell Biology, Cancer Biology, Medical Oncology, Neuroscience, Neurology, Psychiatry and Human Behavior, Biochemistry and Molecular Biology, Surgery, the Division of Biostatistics in Pharmacology and Experimental Therapeutics, the Center for Computational Medicine, and Health Educators from the Center of Urban Health at TJUH, as well as faculty from the Jefferson Schools of Population Health, Pharmacy, and Health Professions. The *Wills Vision Research Center at Jefferson* has already spawned strong collaborative research grant applications to the NEI and the NIH, as well as to foundations, industry, and the Department of Defense. Researchers at WEI are eager to continue to expand their vision-related research and collaborate with faculty at TJU and TJUH.

16(B) Did the research project result in commercial development of any research products?

Yes_____ No____✓_____

If yes, please describe commercial development activities that resulted from the research project:

16(C) Did the research lead to new involvement with the community?

Yes___✓_____ No_____

If yes, please describe involvement with community groups that resulted from the research project:

To support recruitment efforts we have established connections with the following community groups: St. Matthew's AME Church, Philadelphia Senior Center, St. Charles Senior Center, Deliverance Evangelical Church, Lutheran Settlement House Senior Center, Peter Bressi Northeast Senior Center, Walnut Park Senior Center, Stiffel Center, Juniata Park Older Adult Center, King Older Adult Center, Spring Garden Senior Center, Opportunity Towers, North Broad Street Senior Center, Scottish Rite House, and Center in the Park.

Our research staff has met with the directors of these community groups and has presented the health research project at various community events including the Senior Healthy Living Expo (as sponsored by State Senator Shirley Kitchen), the Health Fair at Center in the Park, the Health Expo at Deliverance Evangelical Church (also sponsored by State Senator Kitchen), and the Senior Market.

These collaborations have led to partnerships with many of these community groups for our CDC project entitled *Improving Access to Eye Care Among High-Risk Persons for Glaucoma in Philadelphia* which has provided glaucoma evaluations to over 1,500 individuals at risk for glaucoma and has treated over 250 individuals diagnosed with glaucoma. The health research project and the CDC project have demonstrated Wills' ability to work with the community. In January 2014, the Deerbrook Foundation gave Wills Eye Hospital $2.3 million to provide eye screenings to students in elementary schools across Philadelphia.

17. Progress in Achieving Research Goals, Objectives and Aims.

List the project goals, objectives and specific aims (as contained in the grant application's strategic plan). Summarize the progress made in achieving these goals, objectives and aims for the entire grant award period. Indicate whether or not each goal/objective/aim was achieved; if something was not achieved, note the reasons why. Describe the methods used. If changes were made to the research goals/objectives/aims, methods, design or timeline since the original grant application was submitted, please describe the changes. Provide detailed results of the project. Include evidence of the data that was generated and analyzed, and provide tables, graphs, and figures of the data. List published abstracts, poster presentations and scientific meeting presentations at the end of the summary of progress; peer-reviewed publications should be listed under item 20.

This response should be a DETAILED report of the methods and findings. It is not sufficient to state that the work was completed. Insufficient information may result in an unfavorable performance review, which may jeopardize future funding. If research findings are pending publication you must still include enough detail for the expert peer reviewers to evaluate the progress during the course of the project.

Health research grants funded under the Tobacco Settlement Act will be evaluated via a performance review by an expert panel of researchers and clinicians who will assess project work using this Final Progress Report, all project Annual Reports and the project's strategic plan. After the final performance review of each project is complete, approximately 12-16 months after the end of the grant, this Final Progress Report, as well as the Final Performance Review Report containing the comments of the expert review panel, and the grantee's written response to the Final Performance Review Report, will be posted on the CURE Web site.

There is no limit to the length of your response. Responses must be single-spaced below, no smaller than 12-point type. If you cut and paste text from a publication, be sure symbols print properly, e.g., the Greek symbol for alpha (α) and beta (ß) should not print as boxes (□) and include the appropriate citation(s). DO NOT DELETE THESE INSTRUCTIONS.

Aim 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.

Secondary Aim 1: 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.

Secondary Aim 2: 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.

Secondary Aim 3: 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 proposed 5 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.

Exploratory Aim 5: To evaluate the cost-effectiveness of the intervention, as conducted by Dr. Laura Pizzi, an economic evaluation expert at Thomas Jefferson University. (Exploratory Aim 5 was added to the project in response to the Interim Performance Review, which recommended a cost analysis.)

Aim 1 Background: Diabetic retinopathy (DR) is a leading cause of vision impairment and vision loss, affecting approximately 3.3 million people aged 65 and older.[1] African Americans have a higher prevalence of DR than Caucasians.[2] Additionally, older African Americans with diabetes are more likely than older Caucasians with diabetes to develop severe vision loss from diabetic retinopathy, which is a major complication of diabetes.[3] Although the effects of DR can be devastating, DR is often asymptomatic in early stages. As such, detection of disease as early as possible is paramount. Given that early detection with annual dilated fundus exams (DFEs) can prevent severe vision loss resulting from DR, the study aimed to increase rates of DFEs in older African Americans who have diabetes. However, African Americans are less likely to have DFEs than Caucasians.[4] With this obstacle in mind, we created a behavioral intervention to increase older African Americans' utilization of eye care.

Methods: A total of 206 participants with diabetes were recruited from two urban medical centers and community outreach efforts over 2.5 years. Inclusion criteria were (1) age $\geq$ 65 years, (2) self-identification as African-American, (3) diagnosis of type 2 diabetes mellitus, (4) self-report of no DFE in the past 12 months, (5) no medical documentation of a DFE in the past 12 months, and (6) access to a telephone. Exclusion criteria were (1) cognitive impairment

(failure to pass an abbreviated version of the Mini-Mental Status Examination that omits vision-dependent items) (2) current significant psychiatric disorder other than depression or anxiety, (3) current medical disorder limiting life expectancy (≤12 months), (4) need for dialysis, (5) hearing impairment precluding research participation. After a phone screening confirmed eligibility, a race-concordant community health educator performed a home visit to obtain informed consent and to complete the baseline assessment. The baseline assessment captured demographic data and the following:

- Medical status (based on a list of prescriptions)
- Literacy assessment for diabetes (to test health literacy)
- Neuropsychological tests including Clock Drawing, Hopkins Verbal Learning Test, and Animal Naming
- Cultural characteristics (collectivism, religiosity, and time orientation)
- Risk Perception Survey – Diabetes Mellitus
- Depressive symptoms as measured by the Patient Health Questionnaire-9 (PHQ)
- Diabetes Self-Care Inventory – Revised
- National Eye Institute Visual Function Questionnaire (NEI-VFQ-25)
- Hemoglobin A1C levels via finger stick

The 206 participants who completed the baseline assessment were randomized using a fixed scheme with a 1:1 allocation ratio to the two treatment groups. Over a 4-month period, BA or ST was delivered in four, 1-hour sessions by race-concordant community health educators (CHE). A masked, follow-up assessment was performed at 6 months. At this time, participants were asked whether they had received a DFE in the last 6 months. Study staff obtained medical confirmation in the form of a DFE report from participants' ophthalmologists. For participants who reported no DFE, study staff verified by checking medical records from the ophthalmology clinics at the two urban medical centers where patients were recruited. All procedures were approved by the Institutional Review Boards of the two urban medical centers and all subjects signed an IRB-approved informed consent form.

The conceptual model for this intervention draws upon three theoretical frameworks. First, the disablement process model provides an overarching framework that describes the complex relationship between health conditions and contextual factors that may lead to disability.[5] Eye disease is a physiologic dysfunction that impairs vision and personal (i.e., low literacy and inaccurate knowledge) and environmental (i.e., limited access to care) factors increase the likelihood of disability (i.e., blindness).

Additionally, the Health Belief Model guides our understanding of how a person's health beliefs predict one's actions to prevent, screen for, or treat disease[6]. Our intervention addresses concepts of perceived susceptibility, perceived severity (disease consequences), perceived benefits (efficacy of advised action to reduce disease risk), perceived barriers, cues to action, and self-efficacy (confidence to take action).

Finally, this intervention draws more generally from cognitive-behavior theories, which link intentional behaviors (i.e., avoiding difficult situations) with unintended consequences (i.e., vision loss).[7,8] The resulting model directly informed our intervention, Behavioral Activation

(BA), which employed activation strategies to increase diabetes self-management through the optimal use of personal and environmental resources.

BA was designed as a strategy to overcome avoidant tendencies through goal setting, activity scheduling, and graded assignment.[9] Two key components of BA include education related to diabetes and eye care, and the development of an "action plan" aimed at obtaining a DFE. BA interventionists delivered four, 1-hour long, individual sessions to 91 participants.

Two key components of BA were education related to diabetes and eye care and development of an 'action plan' aimed at obtaining a DFE. The BA interventionist provided the following educational materials which have been included in Appendix A:

1) *Steps to Prepare for an Eye Exam,* a document created specifically for the current study which lists activities that people need to address prior to obtaining a DFE,
2) *Four Steps to Control Your Diabetes for Life,* a Centers for Disease Control guide to diabetes,
3) *Diabetic Retinopathy: What You Should Know,* a National Eye Institute publication with large print, color guides to explain diabetic retinopathy in layman's terms.

Supportive Therapy (ST)

Supportive therapy is a structured psychological treatment that controls for the non-specific elements of BA. The ST interventionist was instructed to create a comfortable, non-judgmental environment by demonstrating genuineness, empathy, and acceptance of participants without imposing any judgments on their decisions. Unlike BA, the ST interventionist did not provide educational materials, did not discuss vision-related goals, and did not advise participants to change their behavior. The goals of ST were to facilitate and deepen knowledge of participants' life situations and their relationship to illness. ST interventionists delivered four, 1-hour long, individual sessions to 88 participants.

The primary outcome is medical documentation of a DFE obtained within 6 months of randomization. To calculate the power of this study we estimated the expected rate of DFEs in subjects who receive the control treatment (ST). Similar studies have made it reasonable to estimate a success rate of 25% for the ST group. While there are no reported comparisons of in-home behavioral interventions to increase DFE rates, we estimated the power of this study by identifying a threshold of clinical significance rather than setting a hypothesized effect size. Therefore, we believe a 25% difference (i.e., that 50% of subjects receiving BA will have a DFE within 6 months vs. 25% of subjects in ST) is a clinically meaningful difference. Assuming these rates, 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 in detecting a 25% difference between trial arms using a two-sided Pearson's chi-squared test with α=.05.

Results: Figure 1 depicts the study flow chart. A total of 3,033 African Americans with diabetes over the age of 65 were screened to determine eligibility, resulting in 206 (6.8%) enrolled participants. Of the 2,827 non-participants, 1,040 (34%) did not meet eligibility criteria, 1,136 (37%) refused, and 647 (21%) could not be reached. The most common reason for non-eligibility was self-report of a DFE or medical documentation of a DFE in the past year (703 potential participants or 23% of those who were screened). Of the enrolled participants, 103 were

randomized into the BA group and 103 into the ST group. Completion rates at 6-months for BA and ST subjects were 88% and 85%, respectively.

Table 1 compares the demographic characteristics and baseline measures between BA and ST groups. Overall, there were no significant differences between the two arms with respect to age, education, gender, and marital status. Additionally, there were no significant differences between the two arms with respect to baseline measures, which included the Risk Perception Scale for Diabetes Mellitus, Diabetes Self-Care Inventory, PHQ symptom scores, A1C results, chronic disease scores, Literacy Assessment for Diabetes scores, any of the cultural characteristics subscales, NEI-VFQ-25 composite score, and any of the neuropsychological tests.

Figure 1: Study Flow Chart

DM=diabetes mellitus; DFE=dilated fundus examination; BA=behavioral activation; ST=supportive therapy

JHAP=Jefferson Hospital Ambulatory Physicians; NIS=not in service

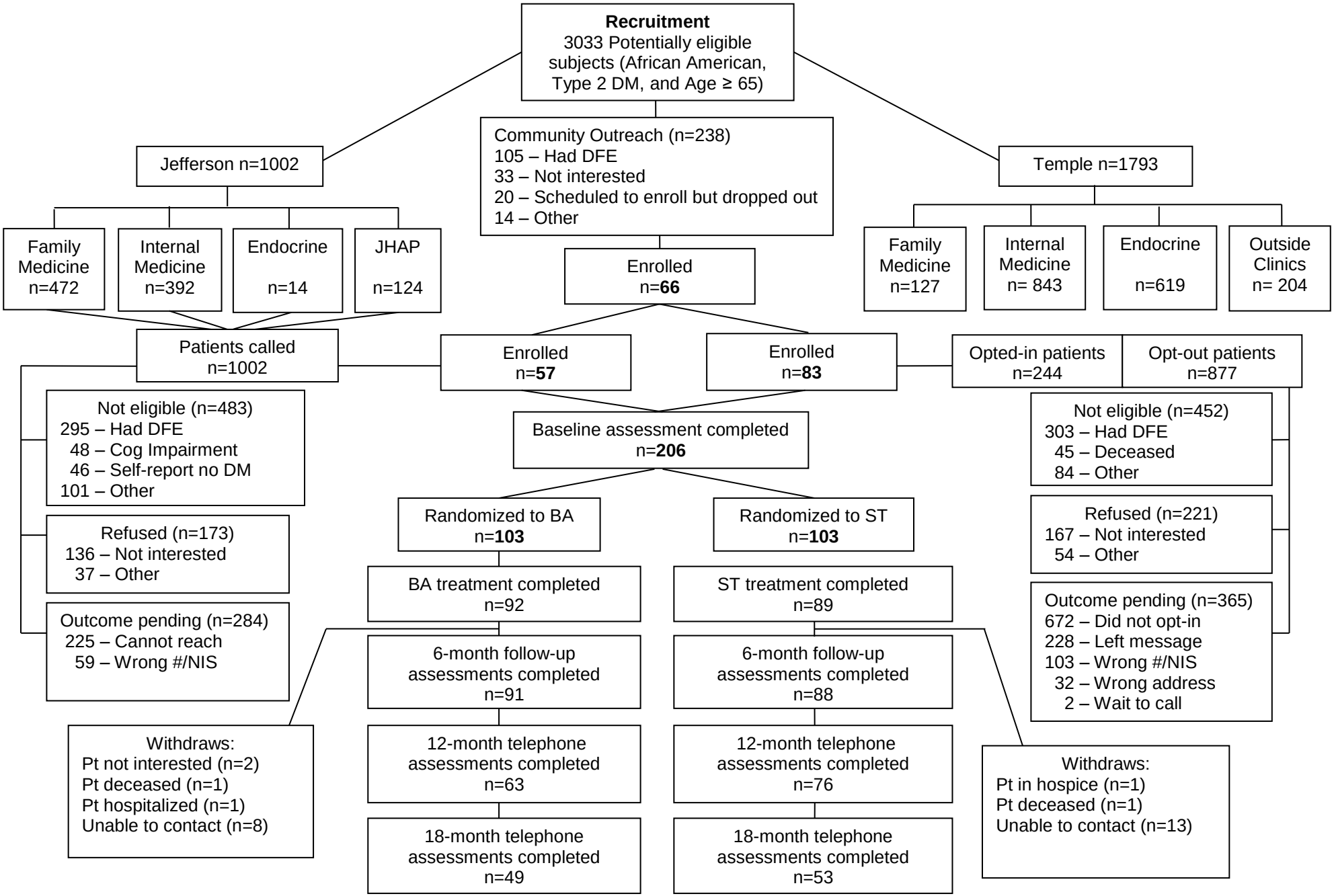

Table 1: Baseline Demographic Characteristics and Measures by Treatment Group

	BA subjects (n=103)	ST subjects (n=103)	p-value
Age (yrs), mean ± SD	73.13 ± 6.79	73.11 ± 6.62	0.983
Education (yrs), mean ± SD	11.67 ± 2.29	12.23 ± 2.79	0.119
Female, n (%)	68 (66)	66 (64)	0.884
Lives Alone, n (%)	42 (41)	48 (47)	0.241
Marital Status, n (%)			
Married	28 (27)	24 (23)	0.199
Widowed	34 (33)	31 (30)	0.199
Divorced	16 (16)	28 (27)	0.199
Other	25 (24)	20 (20)	0.199
Risk Perception Scale Composite[1], mean ± SD	2.71 (0.36)	2.70 (0.31)	0.764
Diabetes Self-Care Inventory[2], mean ± SD	54.15 (14.72)	53.47 (14.53)	0.826
PHQ-9 Symptom Score[3], mean ± SD	5.84 (4.84)	5.53 (5.30)	0.692
A1C, mean ± SD	7.34 (1.62)	7.67 (1.71)	0.177
Chronic Disease Score[4], mean ± SD	6.33 (3.47)	7.10 (3.28)	0.105
Literacy Assessment for Diabetes[5], mean ± SD	48.29 (10.81)	49.58 (8.98)	0.355
Clock Drawing[6], mean ± SD	13.40 (1.84)	13.39 (1.84)	0.970
Animal Naming[7], mean ± SD	15.00 (4.47)	15.87 (5.22)	0.200
Hopkins Verbal Learning Test Immediate Memory[8], mean ± SD	18.76 (4.87)	18.58 (5.05)	0.759
Hopkins Verbal Learning Test Delayed Memory[9], mean ± SD	5.18 (2.91)	5.45 (2.96)	0.505
Cultural Characteristics[10], mean ± SD			
Collectivism	2.52 (0.61)	2.61 (0.48)	0.249
Religiosity	2.42 (0.58)	2.44 (0.51)	0.824
Present-time Orientation	1.25 (0.57)	1.16 (0.56)	0.275
Future-time Orientation	1.90 (0.55)	1.87 (0.45)	0.696
NEI-VFQ-25 Composite Score[11], mean ± SD	82.06 (14.52)	82.77 (13.07)	0.732

1 Scores range from 0-4 with higher scores indicating greater comparative perceived risk
2 Scores range from 0-100 with higher scores indicating better adherence to recommendations
3 Scores range from 0-27 with higher scores indicating more severe depression
4 Higher scores indicate greater medical burden
5 Scores range from 0-60, scores greater than 41 indicate a 9th grade reading level and above
6 Scores range from 0-15, higher scores indicate normal executive functioning
7 Higher scores indicate better cognitive functioning
8 Scores range from 0-36 with higher scores indicating better immediate recall
9 Scores range from 0-12 with higher scores indicating better delayed recall
10 Scores range from 0-3 with higher scores indicating greater endorsement
11 Scores range from 0-100 with higher scores indicating better vision functioning

BA=behavioral activation; ST=supportive therapy
PHQ-9=Patient Health Questionnaire-9
NEI-VFQ-25=National Eye Institute Vision Function Questionnaire

Table 2 shows the primary outcome by treatment group. Participants in the BA group were more likely to report obtaining a DFE compared to participants in the ST group at the 6-month follow-up assessment (85.7% vs. 51.1%, $\chi^2=25.69$, $p \leq 0.001$). Similarly, we were able to confirm a

DFE for a larger proportion of BA participants compared to ST participants (87.9% vs. 35.2%, χ^2=52.71, $p \leq 0.001$).

There was a discrepancy between self-report and actual documentation of DFEs. Specifically, 14 ST participants reported having a DFE that cannot be confirmed by the reported ophthalmologist or eye care provider. Conversely, 3 BA participants reported no DFE but had medical documentation of a DFE compared to 1 ST participant. If the ST participants with undocumented cases of DFE actually obtained exams, rates of DFEs would remain significantly higher in the BA group as shown by "Self-Reported DFE" row in Table 2.

Table 2: Primary and Secondary Outcomes at 6-Months by Treatment Group

	BA Participants (n=91)	ST Participants (n=88)	P-value
	%	%	
Self-Reported DFE	78 (85.7)	45 (51.1)	≤**0.001**
Medical Documentation	80 (87.9)	30 (34.1)	≤**0.001**

BA=behavioral activation; ST=supportive therapy; DFE=dilated fundus examination

Table 3 shows the secondary outcomes by treatment group. There were no significant differences between the two groups in regards to risk perception scale composite score, Diabetes Self-Care Inventory, PHQ-9 symptom score, and NEI-VFQ-composite score (Secondary Aim 2-3). Participants in the BA group had lower A1C levels at the 6-month follow-up compared to participants in the ST group (7.05 vs 7.67, p = 0.01) however this result was no longer statistically significant when controlling for baseline hemoglobin A1C (Secondary Aim 1). Patients with diabetes are generally advised to aim for a hemoglobin A1C below 7% in order to avoid microvascular complications. Forty-four out of the 82 BA participants who allowed their A1Cs to be taken had a result below 7% compared to 31 out of the 85 ST participants (53.6% vs. 36.4%, p = 0.029). While this seems to indicate that a larger proportion of BA participants achieved a recommended A1C result, this result was also not significant when controlling for baseline hemoglobin A1C (Exploratory Aim 4).

Participants in the BA group also had better ratings of their general vision at 6-months compared to the ST group (75.82 vs. 67.29, p = 0.001). However, improved ratings for the BA group for composite VFQ scores was not observed. When examining the neuropsychological tests given at the 6-month follow-up, there were no significant differences between the two groups on the Clock Drawing test or the Hopkins Verbal Learning Test. Participants in the ST group performed better on the Animal Naming Test compared to participants in the BA group (15.67 vs. 14.20, p = 0.02). However, a mean score difference of 1.47 is not a clinically meaningful result.

Table 3: Primary and Secondary Outcomes by Treatment Group

	BA Change from Baseline to 6-months (n=91)	ST Change from Baseline to 6-months (n=88)	BA vs. ST at 6-months	BA Baseline vs. BA 6-months	ST Baseline vs. BA 6-months
	M (SD)	M (SD)	p-value	p-value	p-value
Risk Perception Scale Composite Score	-0.01 (0.42)	0.01 (0.32)	0.926	0.867	0.702
Diabetes Self-Care Inventory	6.18 (13.34)	4.90 (10.87)	0.669	**<0.001**	**<0.001**
PHQ – Symptom Score	-0.05 (5.39)	0.65 (3.91)	0.842	0.937	0.133
A1C	-0.18 (1.07)	-0.09 (1.27)	**0.021**	0.140	0.577
NEI-VFQ Composite Score	0.84 (10.60)	1.22 (8.12)	0.603	0.505	0.224
General Vision	8.44 (15.86)	2.65 (17.32)	**0.006**	**<0.001**	0.167
Clock Drawing	-0.09 (2.11)	0.20 (1.79)	0.574	0.688	0.326
Animal Naming	-1.22 (3.57)	-0.21 (3.74)	**0.049**	**0.002**	0.607
HVLT Immediate Memory	0.88 (4.18)	0.89 (3.61)	0.896	**0.049**	**0.025**
HVLT Delayed Memory	0.54 (2.29)	0.44 (2.43)	0.564	**0.029**	0.103

BA=behavioral activation; ST=supportive therapy; DFE=dilated fundus examination
PHQ-9=Patient Health Questionnaire-9; NEI=National Eye Institute; VFQ=vision function questionnaire
HVLT=Hopkins Verbal Learning Test

Additionally, though there were no between-group differences on the Diabetes Self-Care Inventory, a paired samples t-test was conducted to compare scores at baseline and 6-month follow-up in both the BA and ST group. There was a highly significant difference between baseline and 6-month follow-up Diabetes Self-Care Inventory scores in both the BA group (M=54.46, SD=14.67 vs. M=60.64, SD=13.74) and the ST group (M=54.26, SD=14.34 vs. M=59.16, SD=15.05); $t(89)= -4.40$, $p= < 0.001$, $t(83)= -4.13$, $p < 0.001$. Table 4 provides the ophthalmologic diagnoses based on the reports obtained at the 6-month assessment. Approximately 16% of the participants who received a DFE had a prior history of cataract surgery, 16% had diabetic retinopathy, and 13% had a cataract of Grade 3 or worse.

Table 4: Ophthalmological Characteristics at 6-Months in Participants with DFE

	BA Participants (n=80)	ST Participants (n=30)
Best eye, (logMAR ± SD)	0.17 (0.16)	0.13 (0.12)
History of Cataract Surgery (n, %)	13 (16.3)	4 (12.9)
Diabetic Retinopathy (n, %)		
Mild Non-proliferative	12 (15.0)	2 (6.5)
Moderate Non-proliferative	1 (1.3)	0 (0.0)
Proliferative	1 (1.3)	1 (3.2)
Cataracts (n, %)		
Grade 1	15 (18.7)	7 (22.6)
Grade 2	28 (35.0)	7 (22.6)
Grade 3	8 (10.0)	2 (6.5)
Grade 4	2 (2.5)	2 (6.5)
Hypertensive Retinopathy (n, %)	8 (10.0)	2 (6.5)
Posterior Vitreous Detachment (n, %)	7 (8.8)	5 (16.1)
Drusen (n, %)	6 (7.5)	1 (3.2)
Macular Edema (n, %)	2 (2.5)	0 (0.0)

BA=behavioral activation; ST=supportive therapy; DFE=dilated fundus examination

Discussion: We found that BA successfully increased rates of DFEs in older African Americans with diabetes. Compared to the ST control, BA emphasized education on ocular care, and goal setting to obtaining a DFE. Approximately 23% of participants who obtained a DFE were diagnosed with diabetic retinopathy, although it is not known whether these were newly detected cases. Nevertheless, given the high rate of DFEs in the BA arm, the intervention has the potential to identify new cases so that early treatment can be administered. It should be noted that the DFE rate of 88% observed in the active treatment group substantially exceeds the national goal of 57.8%.

There were no significant differences between the two groups when comparing other secondary outcomes. Participants in both groups reported better adherence to recommended behaviors on the Diabetes Complications Severity Index (DSCI) during the 6-month follow-up assessment compared to the baseline assessment. This indicates that while there may be benefits to participating in the attention control group, these effects do not translate to improvements, at least in the short-term, in biological markers like A1C. Future behavioral intervention studies should consider adding a usual care group, which would provide a means of comparison for the attention-control and intervention arms. Additionally, this shows that there may have been a greater than anticipated effect from the attention control groups, which may have contributed to our inability to find statistically significant results with the secondary outcomes.

Limitations of the study include utilizing a restricted cohort of older (age 65 and over) African Americans with diabetes. The intervention was designed to be culturally-relevant to the targeted population and was delivered by race-concordant community health educators. While the intervention could be adapted to other at-risk populations, it is unclear whether the same type of intervention would yield similar results. There was also a discrepancy between the number of participants who self-reported a DFE compared to the number of medically confirmed DFE reports (BA n=1, ST n=14). Both the rates of self-report of a DFE and actual medical

documentation of a DFE were significantly different between the two groups. The exaggerated discrepancy in the attention-control group could also be explained by the absence of education on ocular care in ST. Myths or misconceptions of what a DFE entails may have persisted in the ST group; participants may have conflated DFEs with refractions for glasses. The benefit of BA over ST on improving DFE rates remained significant whether or not the undocumented exams were obtained.

This study has not examined whether participants with ocular pathology continue to follow-up with eye care providers; it is unclear whether the efficacy of BA extends beyond the intervention (Exploratory Aim 1). Additionally, potential moderators or mediators of BA's efficacy (Exploratory Aims 2 and 3) have not been evaluated.

Conclusion: The current trial demonstrates the value of this psychosocial intervention in improving rates of DFEs in an at-risk population with diabetes. To improve health disparities, interventions like BA can be utilized to increase adherence to recommended self-care.

Research Progress Exploratory Aim 5: Cost effectiveness analysis of behavior activation versus supportive therapy in older African Americans with diabetes to increase rate of annual eye exams (added to the project 7/1/13).

Introduction: While the importance of eye care among diabetics is widely recognized by clinicians, the cost-effectiveness of strategies aimed at improving eye care adherence in this population is not well established.

Objective: A cost-effectiveness analysis was performed alongside a randomized clinical trial comparing Behavior Activation (BA) to Supportive Therapy (ST) (placebo condition) in promoting healthy management of diabetes and encouraging patients to schedule and receive a dilated fundus exam (DFE).

Methods: 103 subjects were enrolled in each of two groups receiving either BA or ST between 2009 and 2013. BA, the active intervention, focused on encouraging subjects to schedule a DFE using a behavioral intervention. ST, a control condition, was used to control for the individualized attention that subjects randomized to active treatment received. The interventions took place over 6 months. The primary measure for the cost analysis was incremental cost effectiveness ratio (ICER) of BA vs. ST at 0-6 months. Costs consisted of total intervention costs for each group: 1) human time costs for screening, intervention, travel, supervision, training, and alerts; 2) materials; and 3) mileage. Effectiveness measures tested in the ICER were 1) incremental cost/% of subjects receiving a DFE, incremental cost/A1C improvement, and incremental cost/NEI VFQ-derived quality-adjusted life years (QALY). Sensitivity analyses were performed by inputting costs and effectiveness parameters into TreeAge Pro decision analytic software.

Results: 80 of 91 subjects enrolled in BA received DFEs, compared with only 30 of 87 in ST. There was no significant difference between groups in either change in hemoglobin A1C or QALY. Total costs for BA and ST per participant were $259.02 and $216.12 respectively. The

ICERs for BA vs. ST were as follows: $89.23/% of subjects with DFE and $476.67/point hemoglobin A1C decrease. In terms of improving DFE rates, BA is more cost-effective than ST.

Discussion: This analysis focused on three different outcome measures, which delineated BA's effect on three distinct aspects of personal health: (1) willingness to schedule and receive a DFE; (2) glycemic control(hemoglobin A1C); and (3) perception of health (NEI-VFQ-derived QALY). BA is an effective method to improve subjects' willingness to assume better control over their health. Nearly 88% of the subjects received a DFE by their 6-month follow-up assessment, compared to 34% of subjects in ST. BA is also cost-competitive with ST, which makes BA more cost-effective as well.

Though the decision tree model found Supportive Therapy preferable to BA for improving hemoglobin A1C, statistical analysis found no significance in the difference between groups for hemoglobin A1C. A possible reason for this is that regardless of any effect either therapy may have had on the measure, the average hemoglobin A1C level for subjects enrolled in the trial is considered low for diabetics, and thus there may be a ceiling effect. In other words, the fairly tight glycemic control observed in this sample limited the power to detect improvement in A1C. It should also be noted that the trial was not designed with the intention of lowering A1C levels. Hemoglobin A1C was included as an exploratory aim, not the primary outcome measure. It is also important to consider the length of the trial. Over the course of six months, it is unlikely to see large physiological changes, especially in a trial that did not include an introduction of new pharmaceutical treatments or surgical procedures.

The NEI-VFQ-derived QALY measure showed no significant treatment group effects. Neither therapy was found to be effective at improving subjects' quality of life. Considering that the trial was not designed to improve NEI-VFQ-derived QALYs, and that the measure was added after the trial began, there is no reasonable expectation for an improvement.

Although ST was a placebo condition, it may have had some nonspecific therapeutic effect as it involved similar amounts of attention from interventionists as BA. In usual care, or a 'do-nothing scenario', it would be expected that subjects' outcome measures remain the same or worsen. Thirty-four percent of subjects received a DFE within 6 months, however, which suggests that ST has some effect on health behavior. Because of this, it is likely that using ST as a control underestimates the cost-effectiveness of BA versus usual care.

The sensitivity analysis suggests that the cost of BA can be further reduced by targeting the travel and intervention time associated with it. If, perhaps, the program were limited to a smaller geographic area, or if subjects were assigned interventionists based on their proximity to an interventionist's location of residence, the travel time cost component would shrink significantly. It is also worth investigating the effect on reducing the number of visitations by interventionists. If subjects are found to schedule a DFE by the first or second visit, subsequent visits may be found unnecessary. This would have a large impact on the therapy cost as well.

Limitations: Most of the limitations of this study stem from its limited scope; it was designed solely to test the effectiveness of BA to increase rates of DFEs. The largest limitation to the cost-effectiveness was a lack of usual care control. As already discussed, comparing BA to ST

underestimates the cost-effectiveness of BA versus usual care. The cost-effectiveness of BA on A1C and NEI-VFQ-derived QALY are also not robust not only due to missing data (due to the measures being added late), but the purpose of BA is not to directly affect these measures.

This trial also had a very short duration. Measures like QALY are not sensitive to change over the short term. The short term also restricted the study from including long term costs of diabetes, diabetic retinopathy, and other associated health care costs. For this reason, our cost-effectiveness calculation of BA in terms of quality of life is severely limited. It may potentially reduce health care costs associated with diabetes, but once again, this was not part of the scope of the study.

Conclusion: The most important result from this analysis is that BA is a cost-effective method of increasing rates of DFE in older African Americans with diabetes. Increased exams and screenings is the first step in reducing vision-related healthcare costs by preventing deterioration of vision. Our study, which compares BA to ST, results in an ICER of $28,600 per QALY, which would be considered cost-effective. This means BA appears to have a positive impact on subjects. Compared to a standard of care, in which no interventionist visits patients, the cost per QALY would be less than 0 – standard care is better than BA in terms of health utility.

Importantly, BA did not aim to treat vision-related complications of diabetes; it sought to encourage subjects to get a DFE. This in itself, especially within a 6-month timeframe, demands no real expectation of improving quality of life. Long-term quality of life studies that include treatment costs of diabetic retinopathy and related vision problems, as well as screening programs, are more effective at estimating the real cost per QALY. Whereas this study did not aim to treat diabetes, it did confirm the cost-effectiveness of BA as a tool to increase rates of DFE in an older African American population. Other studies, previously discussed, have estimated an optimal frequency of eye exams and have suggested the cost-effectiveness is greater if patients begin getting eye exams at a younger age. BA's role, then, is to encourage those patients who have been found to have diabetes to appreciate the importance of eye exams and begin getting them.

Aim 1: Poster Presentations

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<u>Specific Aim 2:</u> To develop and evaluate a Minority Vision Research Training and Mentoring Program at the Wills Eye Institute for undergraduate and graduate minority nursing, pre-health science, and medical students to increase their research skills and promote their interest in pursuing research careers in eye care and health disparities research.

We have successfully accomplished Aim 2 by developing, implementing, evaluating, and disseminating a Minority Vision Research Training and Mentoring Program in the summers of 2011, 2012, and 2013, which consisted of a research internship and individual student mentoring. We selected undergraduate students from Jefferson and TU's School of Nursing, and medical students from Thomas Jefferson University (TJU) and Temple University's (TU) medical schools. The program's goal was to introduce minority students to clinical research. The summer internship provided students with hands-on research experience and active roles in the RCT conducted for Aim 1 (e.g., subject recruitment) and other vision-related research conducted at the WEI. Augmenting the summer internship experience, each student was connected with a mentor who was matched to the students' individual interests.

<u>Recruitment of Students</u>: We recruited students from the undergraduate program at the Jefferson School of Nursing (JSN) and the pre-health undergraduate program at TU. The JSN enrolls undergraduate students after they have completed two years of undergraduate courses; therefore, they enter the nursing program as juniors. At the conclusion of their junior year in April, the nursing students have a 4-month break until they begin their final year. TU undergraduate pre-health science majors were also recruited in the program at the end of their third year. To bring graduate students into the program, we recruited two first year medical students from TJU and one from TU School of Medicine to begin the program in the summer after their first year. We initiated discussions with the Minority Affairs offices and the pre-health advisors at both institutions.

<u>Selecting Students</u>: Our Expert Panel developed the application process and the selection criteria to identify the most qualified applicants. Selection criteria were based on personal essays, extra-curricular activities, previous research experience, and an interview with at least one member of the Expert Panel. The application process highlighted academic accomplishments and focused on students' interests, character, and willingness to increase their research skills and expand their interest in pursuing research careers. The student selection process was developed and initially implemented in January 2011 and completed in May 2011 during the first year. This process was repeated in January 2012 and January 2013.

<u>Summer Research Internship</u>: Each summer, the program provided students with 2 months of clinical research training, experience, and mentorship to gain practical research experience in clinical trials in the field of ophthalmology. Students worked 8 hours per days, 5 days a week for 2 months and were provided with a stipend during the program. Students attended lectures and research meetings, helped to recruit or consent subjects for the RCT, observed telephone intervention calls, analyzed study data, participated in journal club, and completed literature reviews.

The students' research activities included:

- Attending research lectures and seminars
- Conducting literature reviews for grant proposals and manuscripts
- Assisting with writing research grants and manuscripts
- Developing individual research projects
- Assisting in writing IRB protocols
- Conducting chart reviews for research studies
- Surveying patients for research studies
- Meeting with research mentors

Individual Student Mentoring: Faculty mentors play a critical role in guiding students' career choices. Our mentors included the AA and Hispanic faculty on our Panels. The mentors met with the students individually on a regular basis and as a group (i.e., taking the group of five students out to dinner together two times during their summer internship and two times during the academic school year). The mentorship facilitated minority student retention in research, and helped to build networks for future career opportunities. Students were also offered shadowing opportunities.

Syllabi, pre-and post-tests, orientation slides, and lecture series provided during 2011, 2012, and 2013 are described as follows:

1) What is clinical research? (Dr. Casten) This module introduced research design and statistical analysis, focusing on conducting clinical research with minority populations, including human subjects protection, obtaining informed consent, and subject recruitment.
2) What are Populations and Samples? (Dr. Ashton) This module highlighted the elements of populations and samples, focusing on probability sampling (simple and stratified randomization, clustering and systemic research) and non-probability sampling.
3) Measurement and Data Collection: (Dr. Ashton) This module focused on measurement error, levels of measurement, reliability, validity, data collection and measurement.
4) Designing Clinical Research Trials: (Dr. Rovner) This module built on the quantitative research process, including research problem identification, developing hypotheses, purposes, research questions, and outlining the details of a research study. The Association for Research in Vision and Ophthalmology (ARVO) Clinical Trial Series was the model.
5) Clinical Trials: (Dr. Casten) This module reviewed the design of the RCT of Aim 1. It outlined the specific aims and hypotheses, the use of preliminary data, the sample (i.e., inclusion and exclusion criteria), the interventions, outcome measures, power, and the analytic plan.
6) Research Ethics: (Dr. Ashton) This module introduced students to protection of human subject issues, including the rights to self-determination, privacy, anonymity, confidentiality, fair treatment and protection from discomfort or harm, and how to submit an IRB application.
7) Research Funding Opportunities: (Dr. Hark) These workshops highlighted research funding mechanisms available for undergraduate, graduate, doctorate, post-doctorate, and biomedical minority students. Sources of funding include NIH National Institutes of

General Medical Sciences Division of Minority Opportunities in Research (MORE) and Bridges to the Future, National Eye Institute (NEI), ARVO, private foundations (Fight For Sight), and industry support.

8) Grant Writing and Resume Building Workshops: (Dr. Hark) These workshops helped students critically appraise their own as well as their peer's resume in order to improve consistency and interviewing. Grant writing workshops also helped students with important writing skills needed for writing research proposals. Sections of actual vision research grant submissions were assigned to students for the National Eye Institute, Department of Defense, and Centers for Disease Control and Prevention.

Journal Club was conducted weekly for 8 weeks and led by our project manager, Dave Weiss. The journal club article critique checklist was established for students to formulate an evaluation of the merits of a study and evaluate its applicability in clinical practice. The criteria we developed included the following:

- General targeted areas when critiquing a research article:
- Description of the Study
- Literature Evaluation
- Sample
- Method and Design
- Analysis
- Results
- Clinical Significance

Program Evaluation: The Clinical Vision Research Training and Mentoring Program for Minority Undergraduate and Graduate Students provided undergraduate, nursing, and/or medical students with a program of clinical research training, experience, and mentorship. The program was designed to give research scholars the opportunity to gain useful research experience in the field of ophthalmology. This research program aimed to provide students with unique knowledge and experiences to further their education and their careers.

A total of 15 students participated in the summer Vision Research Training and Mentoring Program for Minority Students during 2011, 2012, and 2013 (Table 5). The program evaluation consisted of assessing the development and implementation efforts. We analyzed the implementation of the program, specifically reviewing evaluation data from trainees that have completed the program as well as how they performed on their pre-and post-tests each year. We obtained students' feedback on their perceptions of and satisfaction with each of the research modules, (assessed on a 5-point rating scale), and recorded and synthesize suggestions for improvement each year.

Table 5: Students participated in the Vision Research Training and Mentoring Program for Minority Students during 2011, 2012, and 2013

Student Name	Program Year	College/University	Degree	Current Position
Carlos Fernandez	2011	Thomas Jefferson University Jefferson Medical College	MD Candidate, 2014	Internal Medicine Resident
Lucian Neville	2011	Thomas Jefferson University Jefferson Medical College	MD Candidate, 2014	Internal Medicine Resident
Chanel Alston	2011	Thomas Jefferson University Jefferson School of Nursing	Masters of Science in Nursing, 2014	Currently seeking employment
Regina Ashford	2011	Saint Joseph's University	Bachelor of Science in Biology, 2012	Sales Associate, Follett Higher Education Group
Tia Nelson	2011	Philadelphia College of Osteopathic Medicine	Masters of Science, 2013	Recruiting Assistant, East Coast Executives
Sini Samuel	2011	Temple University College of Science and Technology	Bachelor of Science, Biology, 2013	Temple University School of Nursing
Calvin Lambert	2012	Warren Alpert Medical School of Brown University	MD Candidate, 2015	Medical Student Brown University
Ilsa Lunes-Flores	2012	Thomas Jefferson University Jefferson School of Nursing	Bachelor of Science in Nursing, 2013	Nurse, Wills Eye Glaucoma Service
Jesus Fuentes	2012	University of Pennsylvania	Bachelor of Arts Candidate, 2015	Student, University of Pennsylvania
Nicole Hale	2012	West Chester University of Pennsylvania	Masters of Public Health, 2012	Senior Data Analyst, Health Marketing Sci.
Yvanna Marlin	2013	Temple University School of Public Health	Bachelor of Arts, 2013	Student, Medical Science Preparatory, Drexel University, 2014
Gerome Dominguez	2013	Temple University School of Public Health	Bachelor of Science, Public Health, 2013	Research Assistant, Wills Eye Hospital
Barbara Batichon	2013	Temple University School of Public Health	Bachelor of Public Health, 2015	Office Assistant, Temple University Intergenerational Center
Courtney Kirkland	2013	Drexel University	Master of Public Health, 2013	Epidemiologist, NJ State Department of Public Health
Tynisha Howard	2013	Thomas Jefferson University School of Nursing	Bachelor of Science in Nursing, 2014	Currently seeking employment

To assess knowledge and skills in ophthalmology and basic research, the students were administered a 32-item multiple choice before and after completing the program. Based on test scores during the 3 summers, students demonstrated a 50% increase in knowledge (63.7% average pre-test score vs. 90.3% average post-test score). Figure 2 shows the evaluation results and mean change in test scores for students enrolled during the summer 2011.

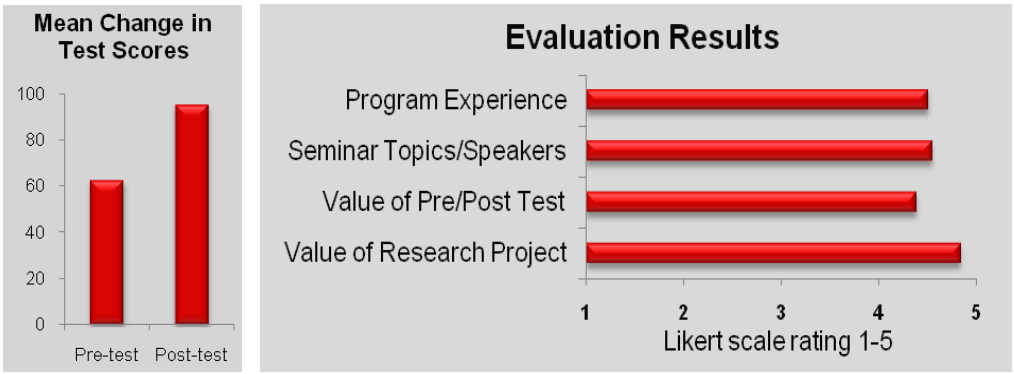

Figure 2: Evaluation results and mean change in test scores in summer 2011 (higher scores indicate greater knowledge/better ratings)

Dissemination: The program was presented at the Association for Research in Vision and Ophthalmology (ARVO) in 2012 and the NIH sponsored Annual Biomedical Research Conference for Minority Students at Thomas Jefferson University. Due to the success of the program, we have been able to continue to recruit students from the targeted population during the summer of 2014.

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<u>Research Progress for Pilot Study #1</u>: Preventing progression of DR in older African Americans with diabetes (added to project July, 2012).

<u>Specific Aims</u>: The purpose of this pilot study was to evaluate the feasibility of administering an in-home behavioral intervention designed to improve diabetes self-management behaviors to older African Americans who have diabetes.

<u>Introduction:</u> Diabetes continues to be a significant source of disability and health care expenditures in the United States. This is a growing problem for African Americans (AAs) in particular. Not only is the prevalence of diabetes higher among AAs, but AAs are less likely to have adequate glycemic control, the consequence of which is a higher rate of diabetes-related complications in this population. Cognitive impairment, which is often a precursor to Alzheimer's Disease (AD), is gaining widespread recognition as a serious consequence of

diabetes. It is estimated that diabetes increases the risk of AD by 30% to 65%. Importantly, there are no effective disease modifying treatments for AD, and efforts to treat AD symptoms are minimally effective at best. Diabetes, on the other hand, can be controlled and thus diabetes related AD can theoretically be prevented. Because AAs are highly likely to have poor glycemic control, targeted disease management interventions are needed to prevent AD in this high risk population. We are in the process of developing a tailored, culturally relevant behavioral/educational intervention to promote glycemic control in older AAs. The intervention will be designed to target multiple factors related to diabetes management (e.g., diet, exercise).

Unlike previous programs, however, it will have a strong educational component regarding the effects of diabetes on cognition and AD. The intervention will contain modules that teach participants strategies for potentially halting the progression of cognitive decline (e.g., activity participation). The NIH grant that we are planning would be a clinical trial to test the efficacy of the intervention to improve glycemic control and thereby slow the progression of cognitive impairment in AAs with diabetes. This pilot study proposed to examine the feasibility of implanting the intervention.

Methods: Prior to pilot testing the intervention, we first conducted a focus group to explore older AAs' views on DSM interventions. The focus group suggested that all participants preferred non-pharmacologic to pharmacologic interventions and to self-select their diabetes management goals (e.g., diet, exercise). Participants also indicated that they would accept in-home treatment delivery. Drs. White and Casten delivered a rigorous 6-hour training program to 3 bachelor's level AA CHWs to pilot test the intervention.

The pilot enrolled 36 older (aged 65+) African Americans who had type 2 diabetes. Unlike participants enrolled in the main study, pilot study participants were not required to be non-adherence to recommendations for annual dilated fundus exams. Participants were recruited from other studies that the PI was conducting, local senior centers, and from referrals from a diabetes support group that was sponsored by Jefferson. All data were collected in participants' homes.

Interventions: Once informed consent was obtained, participants were asked to complete a brief questionnaire that assessed demographic information, frequency with which participants engage in various diabetes self-care behaviors, diabetes knowledge, and cultural characteristics. Study staff tested participants' hemoglobin A1c. The interventionist then delivered 6 in-home treatment sessions over 8 weeks. The intervention consisted of a behavioral intervention to help participants manage their diabetes. The sessions followed a structured protocol. Each session lasted about 90 to 120 minutes. Participants were paid $20 for each of the 6 sessions. Follow-up assessments were administered during at the last treatment session. At this time, we also asked participants to rate their level of satisfaction with the intervention.

Outcomes: Feasibility was assessed as follows.

1) Enrollment: Our goal was to enroll 40 participants. The success of this feasibility indicator was based on whether enrollment goals were on target.
2) Retention: Retention was considered to be successful if 80% of enrolled participants provided follow-up data.

3) Participant Treatment Adherence: We defined treatment adherence by whether or not participants had at least 5 of 6 treatment sessions. Our goal was to have at least 80% of participants meet this milestone.
4) Participant Satisfaction: Participants were asked to rate their level of satisfaction with the intervention.

Sample size: Our target sample size of 40 participants was based on our access to potential participants and budget constraints. Participants were recruited from May 2012 through August 2012. Forty participants agreed to study participation and were consented. Six participants withdrew consent prior to initiating treatment, and 1 participant did not provide follow-up data. We obtained 8-week follow-up data on 23, yielding a retention rate of 68% (23 of 36). Twenty-four participants had at least 5 of 6 treatment sessions (71% of participants were adherent to treatment).

Statistical Methods: We enrolled 85% of our planned sample. The retention and adherence rates fell short of our pre-established goals.

Ethical Aspects: The IRBs at Jefferson and Wills approved all study procedures. Informed consent was obtained in writing in participants' homes.

Participant flow: Since all participants were hand selected from other studies or were referred by study staff, no participants were excluded. That is, we explicitly approached potential participants who were aged 65 and older, African American, did not have cognitive impairment, and who had diabetes.

Recruitment: Recruitment took place from May 2012 through August 2012. Follow-up data were collected from August 2012 through November 2012.

Results: All participants were African American. The mean age was 73.7 years (SD 5.8); 92% were women. All but one participant received all 6 BA treatment sessions. Participants' mean rating of satisfaction with BA was 9.4 (SD .80) on a scale of 1 to 10 (10 = "very satisfied"). At baseline and follow-up at 8 weeks, participants rated the frequency of their adherence to DSM behaviors (1 "never" to 5 "always") on the Diabetes Self-Care Inventory-Revised (DSCI-R). Mean DSCI-R scores improved from 38.9 (9.7) to 44.9 (5.4); $t = -4.5$; $p \leq .001$. Figure 3 depicts increases in mean scores of 5 representative DSM behaviors and the percent of participants who increased adherence by at least one level of frequency (e.g., "sometimes" to "regularly").

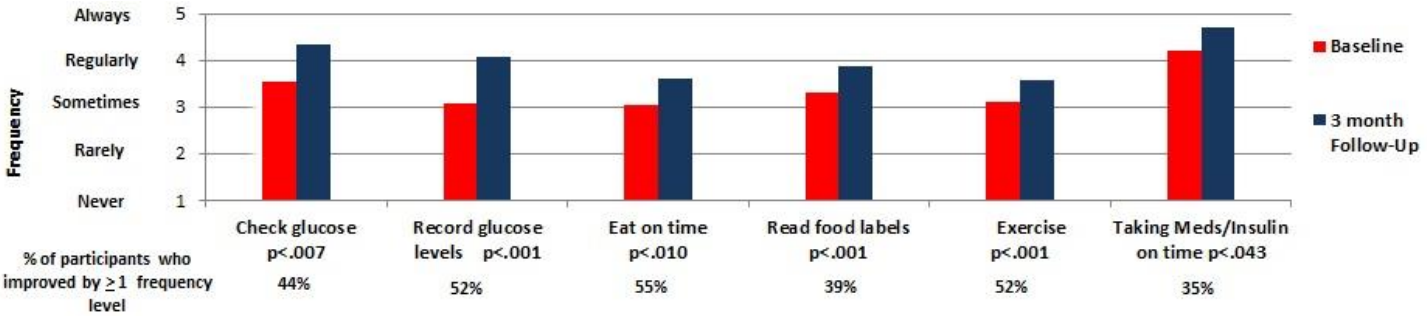

Figure 3: Change in 5 Representative DSCI-R DSM Behaviors (n=23)

Discussion: This pilot study assessed the feasibility, acceptability, and effectiveness of 6 in-home BA treatment sessions to increase DSM practices in older AAs with DM. Drs. White and Casten (Study Co-I's) delivered a rigorous 6-hour training program to 3 bachelor's level AA CHWs to administer BA. We recruited 40 participants (within 2 months) and gathered 6 month follow-up data on 23. All but one participant received all 6 BA treatment sessions. Participants' mean satisfaction rating for BA was 9.4 (SD .80) on a scale of 1 to 10 (10=very satisfied). At baseline and follow-up, participants rated the frequency of their adherence to DSM behaviors (1 "never" to 5 "always") on the Diabetes Self-Care Inventory-Revised (DSCI-R). Mean DSCI-R scores improved from 38.9 (9.7) to 44.9 (5.4); $t = -4.5$; $p \leq 0.001$. Thirteen of 23 participants (56.3%) had a reduction in HbA1c of 0.5%. These data demonstrate our ability to recruit and retain older AAs with DM, and BA's potential to improve glycemic control.

Conclusion: Our recruitment and retention rates are below our pre-established benchmarks. We have since received funding from NIH to test the efficacy of our intervention to improve glycemic control and prevent cognitive decline in older African Americans with diabetes. For this trial, we will modify our recruitment plan to account for greater attrition than anticipated in the pilot study. Moreover, because unlike the clinical trial, participants for the pilot study were hand selected, we will allow additional time for study recruitment. In addition, we will institute measures to boost retention and treatment adherence (study newsletters, send birthday cards to participants, have a designated study hotline for participants to call in with questions and comments about the study).

Research Progress for Pilot Study #2: Improving access to eye care in patients with glaucoma: a prospective, randomized controlled trial (added to project May, 2013).

Specific Aims:

1. To design and develop a prospective, randomized pilot study utilizing information from electronic medical records to address follow-up adherence and reduce the gap between recommended and actual follow-up adherence in patients with glaucoma.
2. To evaluate the impact of a telephone-based intervention on follow-up adherence in patients with glaucoma using a randomly assigned comparison with usual care.

Background and Significance: Glaucoma is a chronic, optic neuropathy with typical optic nerve and visual field defects and progressive vision loss (1). It is the second leading cause of blindness worldwide and the leading cause of irreversible blindness in the United States, causing a major global health problem (2). The prevalence of glaucoma is increasing rapidly. It is estimated that bilateral blindness will be present in 5.9 million people with open-angle glaucoma (OAG) by 2020, resulting in a significant economic and health burden (3, 4). The highest prevalence and morbidity of open angle glaucoma in people of African ethnic origin compared with the European or Asian people is further evidence for the hereditability of glaucoma (5). Glaucoma is distinguished from other optic neuropathies by slow disease progression. Loss of central visual acuity and the temporal visual field typically occurs in the end stage of disease (5).

Follow-Up Guidelines for Glaucoma and Education: Vision loss from glaucoma has a significant impact on health-related quality of life and the overall burden increases as glaucomatous damage

worsens and vision loss progresses. Patients with glaucoma experience problems associated with progressive visual loss, including loss of ability to be gainfully employed, inability to care for oneself, social withdrawal, dependency, and depression. Thus, regular and ongoing follow-up eye exams are needed for all glaucoma patients. The American Academy of Ophthalmology (AAO) recently published follow-up guidelines for patients with glaucoma (Table 6) (6,7). Patients need to be educated about the disease and encouraged to seek appropriate vision management and follow-up exams depending on the factors listed in Table 1.

Table 6: Recommended Guidelines for Follow-up Glaucoma Status Evaluations with Optic Nerve and Visual Field Assessment

Target IOP Achieved	Progression of Damage	Duration of Control (months)	Approximate Follow-up Interval (months)
Yes	No	<=6	6
Yes	No	>6	12
Yes	Yes	NA	1-2
No	Yes	NA	1-2
No	No	NA	3-6

Source: American Academy of Ophthalmology. IOP=Intraocular Pressure

Improving follow-up adherence utilizing a telephone intervention will help patients understand the disease process and ensure better vision. Glanz at all, studied the impact of a health communication intervention to improve glaucoma treatment adherence (8,9). During the study period, patient adherence to glaucoma treatment and keeping appointments improved in both study arms. Strategies that address individuals' barriers and facilitators may increase the impact of telephone calls, especially for keeping appointments and prescription refills. These results show that glaucoma patient care should include reminders about consistent use of medication and the importance of keeping eye exam appointments.

More frequent and personalized telephone contact may be helpful for patients who are known to be non-adherent (8). Lim concentrated on determining whether multiple interventions influence adherence to glaucoma medication. Monthly automated telephone reminders, a single educational session, and increased contact with a physician did not improve adherence rate with glaucoma medications (9). A study by Okeke et al. aimed to understand the impact of the interventions on poor adherence in glaucoma patients. It was a randomized controlled clinical trial with 66 patients with glaucoma being treated with a prostaglandin analog in 1 or both eyes at the Scheie Eye Health System or Wilmer Eye Health System between November 2006 and June 2007. The study found that the multifaceted intervention significantly increased adherence with glaucoma medications (10).

Two studies found that telephone interventions, using problem-solving techniques, increased dilated fundus examination (DFE) rates in low-income African Americans with diabetes. Basch compared a telephone intervention that involved problem-solving to overcome barriers to having a DFE vs. usual care (11). After 6 months, subjects who received the telephone intervention were 4.3 times more likely to obtain a DFE compared to controls (11). In another study, Walker

similarly used a tailored telephone intervention to promote retinopathy screening compared to a standard print intervention over a 6-month period. This intervention influenced risk perceptions about diabetes complications (12). These studies showed that a simple telephone intervention can significantly improve participation in retinopathy screening in a minority, low-income population.

Wills Eye Health System Department of Research Preliminary Data: With funding from the CDC from 2010-2014, the Wills Eye Department of Research is implementing a project entitled: *Overcoming Barriers in Vision Care Utilization of African Americans with Diabetes*. This study has multiple aims including the "Implementation of a telephone-based and educational intervention to improve DFE follow-up adherence in people with diabetes." The purpose of this prospective study is to evaluate the effectiveness of a personalized educational and telephone-based intervention on DFE follow-up in patients with diabetes across all ethnicities. Over 7 months, 522 patients were randomly assigned to "Usual Care" or the "Intervention" group. The usual care group (n=260) received a standard form letter reminding them to make an appointment for their annual DFE and, once an appointment was made, they received an automated reminder phone call one day prior to their scheduled follow-up visit.

Patients in the Intervention group (n=262) received an educational brochure about diabetic eye disease and a personalized letter encouraging them to schedule an eye exam. Two weeks after the letter and brochure were mailed, a research assistant called those in the Intervention group to provide personal assistance to schedule a follow-up eye exam appointment. Barriers to care utilization were also captured. Once an appointment was made, patients in the Intervention group received a reminder letter 3 weeks prior to their appointment and an automated phone call one day prior to the scheduled follow-up visit. All visits were tracked using the electronic medical records system.

Results indicate that patients in the intervention and control groups had similar demographics with regards to gender, race, and age. Overall, the majority of patients were female (66%) and African-American (70%). The mean age was 61 years (range 19-95 years). Patients in the intervention group were more likely to schedule an appointment (68% vs. 44%; relative risk 1.55; 95% confidence interval 1.29-1.79; $p < 0.0001$) compared to the usual care group. Patients in the intervention group were equally likely to keep their appointment once scheduled compared to the usual care group (73.3% vs. 71.3%; $p = 0.71$). Of those who did not make an appointment, common barriers reported included other medical conditions, lack of transportation, busy schedule, being a caretaker for a family member, and lack of health insurance. Our study shows that the combination of a personalized educational and telephone-based intervention can significantly improve follow-up among patients with diabetes. This study was presented at the Association of Researchers in Vision and Ophthalmology in Seattle, WA in May 2013. A follow-up study has been initiated in people with diabetes to determine the impact of each component (letter, brochure, telephone call) separately as well the operational costs of each of these components.

The current pilot project protocol described below in patients with glaucoma is based on this preliminary data. Figure 4 shows the current Usual care procedures in the Glaucoma clinic. Since the vast majority of patients (>80%) schedule a follow-up appointment when they complete their visit, we will focus our intervention on this group of patients. Of those with

scheduled appointments, approximately 30% cancel without rescheduling or simply do not show up for an appointment and are lost to follow-up. Currently Usual care does not consist of any reminder letters or phone calls prior to the patients' scheduled appointment. When patients in the Usual care group do not show up for their appointment, there is no attempt to reach them by letter of phone call.

Conceptual Model Guiding the Study: This study draws on two different theoretical frameworks as described in our initial proposal. First, the Disablement Process Model is used as a broad overarching framework (13). This socio-medical model describes how disease affects the function of specific body systems and leads to disability. The model posits that disability is part of a complex relationship between health conditions and contextual factors, which includes environmental factors (e.g., access to vision care) and personal factors (e.g., motivation, values, beliefs, knowledge of eye disease). In this model, eye disease is a physiologic dysfunction that impairs vision and results in disability (i.e., blindness), where personal (i.e., low literacy, inaccurate knowledge of eye disease) and environmental (i.e., limited access to care) factors may accelerate this core pathway. We propose to improve access to care and thereby slow progression to disability.

The Health Belief Model guides our understanding of how a person's health beliefs predict one's actions to prevent, screen for, or treat disease (14). It invokes the concepts of perceived susceptibility (one's chances of experiencing a disease), perceived severity (the severity of a disease's consequences), perceived benefits (efficacy of the advised action to reduce risk), perceived barriers (practice and psychological costs of the advised action), cues to action (strategies to activate "readiness"), and self-efficacy (confidence in one's ability to take action).

Methods: The Wills Eye Health System Department of Research and the Wills Glaucoma Research Center, under the direction of Drs. Hark, Haller, Katz, Spaeth, Henderer, Weisbourd, Leiby, Pizzi, and Murchison conducted a pilot study to evaluate the feasibility and effectiveness of a telephone-based intervention to improve rates of follow-up exams in patients seen at the Wills Eye glaucoma clinic. The prospective, randomized controlled trial entitled "Improving Access to Eye Care in Patients with Glaucoma" utilized cohort data from 2012-2013 electronic medical record information to reduce the gap between recommended and actual follow-up eye care utilization in glaucoma patients. Patients with glaucoma were recruited from the Wills Eye Glaucoma clinic, and seen between 3/1/13 and 10/31/13 and scheduled for follow-up from 9/1/13 to 11/30/13. All scheduled patients were randomly assigned to Usual Care or Intervention.

Study group procedures are outlined in Figure 4. As described above, Usual Care did not consist of any reminder letters or phone calls prior to the patients' scheduled appointment. When patients in the Usual Care group do not show up for their appointment, there was no attempt to reach them by letter of phone call.

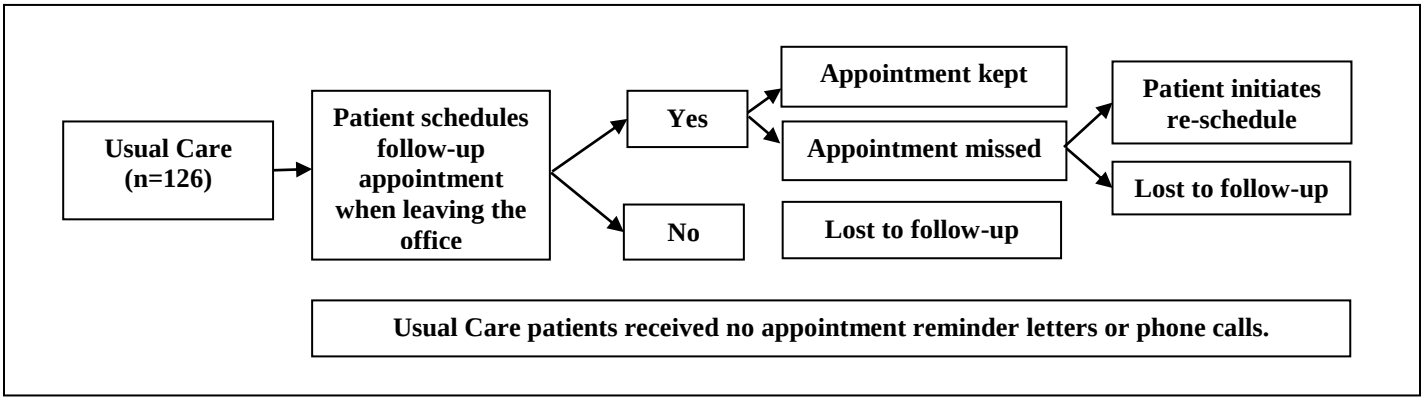

Figure 4: Usual Care versus Intervention Study Flow Chart and Procedures

The initial contact in the telephone-based Intervention included two components that were considered one variable (letter and phone calls). The Intervention group was mailed a customized letter (Dear Mr. John Doe) encouraging them to keep their scheduled appointment with the Glaucoma clinic. The research assistant reviewed the appointment schedule and called patients 2 to 3 days prior to the scheduled appointment. We assessed patients' adherence to keeping their appointments. If the patient did not attend the scheduled appointment, he/she was called up to 2 times in an attempt to reschedule the original appointment

In the event that a patient in the "Intervention" group did not reschedule an appointment with the Glaucoma clinic after the letter is mailed and he/she was called but cannot be reached, another letter encouraging the patient to reschedule their appointment will be mailed. The patient was called up to two times by a staff member to schedule an appointment. If the patient was not reached after two phone calls, the information was noted. If the patient was reached and agreed to schedule an appointment, an appointment reminder letter was mailed. The patient also received a telephone reminder prior to the scheduled appointment.

Recruitment: According to Wills Eye Health System billing records from 2012-2013, there were 256 patients with all types of glaucoma seen each month in the Glaucoma clinic. Roughly 30% of patients who have scheduled appointments cancel, do not reschedule, or do not keep their appointments in a timely fashion. For the pilot study, a total of 256 patients with glaucoma seen between 3/1/13 and 10/31/13, and with scheduled follow-up eye care appointments from 9/1/13 to 11/30/13 were randomized.

Randomization Procedure: Beginning in August 2013, we generated lists of patients scheduled for appointments in two weeks (e.g., on August 15, we will generate a list of patients schedule for the first week of September). Subjects were randomized within strata defined by recommended follow-up at the previous visit (1 month, 2-3 months, 6 months). A randomization schedule was developed by Dr. Leiby using the method of random permuted blocks within strata. See Table 7 for inclusion and exclusion criteria:

Table 7: Inclusion and Exclusion Criteria for Subject Enrollment

Inclusion Criteria:

- As per the glaucoma diagnostic codes; 365.00-365.20
- Attended Wills Eye Glaucoma Clinic from 9/1/12 and 10/31/13
- Age 21 years and above
- Able to understand and speak English

Exclusion Criteria:

- Any medical condition that would preclude the subject from providing reliable and valid data.
- Recommended to f/u in less than 1 month time period.

Specification and Definition of Variables to be Investigated: Baseline characteristics were collected from the electronic medical records at the prior visit (the "index visit") (Table 8).

Table 8: Baseline Characteristics and Study Variables for Data Collection

Clinical Factors	Systems-level Factors	Demographic Factors
Diagnosis	Insurance Type(s) (Private, Medicare, Medicaid, Self-Pay)	Age
Type of glaucoma	Other forms of health insurance	Gender
IOP at index visit	First time seeing this provider	Race/ethnicity
Intervention recommended (change in meds or procedure)	Number of prior visits	Primary language
Past glaucoma surgery	Month of index visit	Distance traveled to clinic
Family history of glaucoma diagnosis	Day of week of index visit	Socioeconomic status (based on home zip code)
Number of active ocular medications	Month of follow-up appointment scheduled	Smoking status
Visual field (VF) test ordered	Day of week f/u apt scheduled	
Mean standard deviation from VF	Recommended f/u (months)	
Number of co-morbid ocular conditions		
Type of co-morbidity		
Existing diagnosis of hypertension or diabetes		

Research assistants collected data related to the outcome of the follow-up appointment from the appointment scheduling software (NextGen EPM). This information included method of scheduling follow-up appointment, (scheduled at index visit, scheduled later), number of cancellations, number of missed appointments, number of patient-initiated re-schedules, and number of office-initiated re-schedules.

The primary outcome was successful attendance at a follow-up appointment within an appropriate time frame (Table 9). Research assistants collected appointment data in the EPM starting from the index visit until the patient either has completed a follow-up appointment or has surpassed the appropriate time frame, whichever comes first.

Table 9: Recommended cut off dates for follow-up intervals

Recommended follow-up interval	Cut-off for appropriate follow-up
1 month	6 weeks
≤ 3 months	4 months
≤ 6 months	8 months

Cost Analysis: A cost analysis was also conducted by Dr. Laura Pizzi, applied health economics researcher at Thomas Jefferson University. The primary measure for the cost analysis was the incremental cost effectiveness of the intervention compared to usual care, where incremental cost effectiveness is defined as the incremental cost of the intervention versus usual care, divided by the incremental difference in the % of participants who were adherent to recommended follow up for intervention vs. usual care. It should be noted that this measure is technically a proxy for cost effectiveness, as true cost effectiveness could only be examined by measuring incremental cost of the intervention in relation to its impact on long term patient outcomes (such as reductions in blindness or delayed blindness, or quality-adjusted life). However, our measure will serve an important purpose of informing what the cost of the intervention is in relation to its follow up yield. In addition, the design of our cost analysis will enable us to explore which aspects of the intervention are most costly, and whether these aspects can be delivered more efficiently in order to promote broader translation. The cost data sources to be collected are shown in Table 10.

Table 10: Cost Data Sources

Name	Description	What needs to be recorded/measured	How to capture
Mailings	Customized letters sent to patients	• Cost of paper and ink for letters • Cost of actual mailing of letters as charged to the Department of Research's account • Time to generate and print customized letters, and stuff envelopes with letters	• Receipts • Printing invoice • Dept mailing account • Time log (Excel)
Calls	All calls performed for telephone-based intervention group	• Calls made to remind about initial appointments and to reschedule missed appointments	• Record length of calls in FileMaker Pro
Training	Training of individual(s) calling patients	• Time to train individual(s) on calling script in FileMaker Pro • Time to train individual in making appointments in NextGen	• Time log (Excel) • Time log (Excel)

Data Analysis Plan and Statistical Analysis:

Sample Size Determination and Power Calculation: We based the sample size calculation on the estimated number of patients who do not attend their scheduled follow-up appointments in a timely fashion (30%). The study aims to reduce this percentage by half to 15%. Therefore, to achieve 80% power for a two-sided test with alpha=0.05, we need a total of 256 patients to be randomized in a 1:1 ratio to the Usual Care versus Intervention Groups.

Outcome Measure: The primary outcome measure will be the percent of patients in each group who attend a follow-up appointment within an appropriate time frame (Table 9).

Analyses: Baseline clinical and demographic characteristics were summarized by randomization assignment using means, medians, standard deviations, and ranges for continuous variables and frequencies and percentages for categorical variables.

The primary analysis compared rates of timely appointments between randomization groups using a stratified Cochran-Mantel-Haenszel test. The stratification variable was recommended follow-up time as defined in Table 9. The Mantel-Haenszel adjusted risk ratio was estimated along with its associated 95% confidence interval. Subjects were analyzed according to their randomization assignment. Since the primary outcome was ascertained from the EMR, no missing data for the outcome should exist.

The intervention had two potential points of patient contact that could improve follow-up adherence. The first was the reminder letter and phone call, which seeks to reduce the cancellation/ no-show rate. The second was the rescheduling phone calls for patients who do cancel or miss their appointments, but do not reschedule on their own. To determine the relative contribution of the initial appointment reminder, we compared arms with respect to missed appointments (canceled/not rescheduled at time of cancellation and no-show) and considered this the effect of the first contact. Any additional increase in adherence was due to the rescheduled phone call(s). We carefully tracked rescheduled phone calls and time of appointment rescheduled to determine the number of timely follow-up appointments due to office-initiated rescheduled following missed or canceled appointments.

As a secondary analysis, we used a log-linear Poisson regression model to adjust the estimated difference in follow-up rates for meaningful differences in randomized groups with respect to baseline characteristics that might impact timely follow-up. We explored whether the effect of the intervention differed by recommended follow-up time (and, thus, distance from the previous appointment) by testing for an interaction between the stratification variable and treatment assignment. We used Kaplan-Meier methods to estimate time to follow-up appointment by recommended follow-up at the index visit. All analyses were performed using SAS version 9.3 (or later) (SAS Institute, Cary, NC).

Results: Two hundred fifty-six subjects were randomized to Usual Care (n=126) or intervention (n=130). Baseline demographic and clinical characteristics are presented in Table 11. Most patients were over the age of 65 years old (68.4%) , African-American (80.5%), had a diagnosis of primary open angle glaucoma (POAG) (79.7%), and were scheduled for a 3-month follow-up visit (71.5%).

Table 11: Baseline Patient Characteristics by Randomization Assignment

Variable	Values	Usual Care (n = 126) n (%)	Intervention (n = 130) n (%)
Age at expected return date	<65	38 (30.2)	43 (33.1)
	>=65	88 (69.8)	87 (66.9)
Gender	Male	67 (53.2)	62 (47.7)
	Female	59 (46.8)	68 (52.3)
Race	African American	105 (84)	101 (78.3)
	White	13 (10.4)	16 (12.4)
	Asian	4 (3.2)	6 (4.7)
	Hispanic	3 (2.4)	6 (4.7)
Glaucoma	POAG	102 (81)	102 (78.5)
	OAG	17 (13.5)	19 (14.6)
	CAC	9 (7.1)	10 (7.7)
	Glaucoma suspect	9 (7.1)	10 (7.7)
	Ocular HTN	3 (2.4)	3 (2.3)
Recall Plan	1 Month	11 (8.73)	12 (9.23)
	3 Month	91 (72.22)	92 (70.77)
	6 Month	24 (19.05)	26 (20)
Primary Insurance	Medicare	58 (46.0)	45 (34.6)
	Vision Plan	27 (21.4)	32 (24.6)
	Private	24 (19.1)	28 (21.5)
	Medicaid	15 (11.9)	20 (15.4)
	Charity/Self-pay	2 (1.6)	5 (3.9)
With secondary insurance	Yes	67 (53.2)	59 (45.4)
	No	59 (46.8)	71 (54.6)

POAG=primary open angle glaucoma, OAG=open angle glaucoma, CAC=chronic angle closure, HTN=hypertension

Follow-up related outcomes are presented in Table 12. Intervention resulted in a significant increase in timely follow-up adherence (P=0.012). Adherence under usual care was 69.0% while adherence under intervention was 82.3%. The relative risk analysis between receiving intervention versus usual care, demonstrated a 19% increase in adherence with intervention.

Table 12: Follow-up Outcomes by Randomization Assignment

Variable	Usual Care (n = 126)	Intervention (n = 130)	Relative Risk (95% CI)	P-value
Attend the original appointment	71 (56.4)	86 (66.2)	1.17 (0.96, 1.43)	0.11
Adherence*	87 (69.1)	107 (82.3)	1.19 (1.04, 1.37)	**0.012**

*Adherence is defined by patient attending a glaucoma follow-up appointment within recall plan window period

As shown in Table 13, significant increase in appointment adherence was associated with older age (>= 65 years at follow-up appointment), recall plan (patients with longer follow up intervals were more likely to attend their visits) and secondary insurance.

Table 13: Baseline Characteristic and Adherence to Follow-Up Appointments

Variable	Values	Adherence		P value
		Yes n (%)	**No n (%)**	
Age at expected return date	<65	53 (65.4)	28 (34.6)	**0.0085**
	>=65	141 (80.6)	34 (19.4)	
Gender	Male	97 (75.8)	32 (24.8)	0.83
	Female	97 (76.4)	30 (23.6)	
Race	African American	162 (78.6)	44 (21.4)	0.21
	Caucasian	18 (62.1)	11 (37.9)	
	Asian	7 (70)	3 (30)	
	Hispanic	6 (66.7)	3 (33.3)	
Glaucoma	POAG (yes)	162 (79.4)	42 (20.6)	0.011
	POAG (no)	32 (61.5)	20 (38.5)	
	OAG (yes)	26 (72.2)	10 (27.8)	0.67
	OAG (no)	168 (76.4)	52 (23.6)	
	CAC (yes)	15 (79.0)	4 (21.0)	1.00
	CAC (no)	179 (75.5)	58 (24.5)	
	Glaucoma suspect (yes)	13 (68.4)	6 (31.6)	0.42
	Glaucoma suspect (yes)	181 (76.4)	56 (23.6)	
	Ocular HTN (yes)	1 (16.7)	5 (83.3)	0.0036
	Ocular HTN (no)	193 (77.2)	57 (22.8)	
Recall Plan	1 Month	12 (52.2)	11 (47.8)	**0.0019**
	3 Month	137 (74.9)	46 (25.1)	
	6 Month	45 (90)	5 (10)	
Primary Insurance	Medicare	81 (78.6)	22 (21.4)	0.18
	Vision Plan	49 (83.1)	10 (17)	
	Private	37 (71.2)	15 (28.9)	
	Medicaid	22 (62.9)	13 (37.1)	
	Charity/Self-pay	5 (71.4)	2 (28.6)	
Secondary Insurance	Yes	104 (82.5)	22 (17.5)	**0.013**
	No	90 (69.2)	40 (30.8)	

POAG=primary open angle glaucoma, OAG=open angle glaucoma, CAC=chronic angle closure, HTN=hypertension

Table 14 shows a multivariable analysis adjusted for recall group, age at expected return date, secondary insurance, and total number of kept appointments at the Glaucoma service before expected return date. The risk ratio between receiving intervention and usual care following multivariable adjustment demonstrates 23% increase in adherence with intervention. . Pending analyses include clinical data and cost analysis results. These results are pending analysis.

Table 14: Multivariable analysis adjusted for recall group, age at expected return date, secondary insurance, and total number of kept appointments at glaucoma service before expected return date

		Risk Ratio (95% CI)	P value
Group	**Intervention vs. Usual care**	1.23 (1.08, 1.41)	**0.0021**
Secondary insurance	Yes vs. No	1.18 (1.03, 1.35)	**0.014**
Age at expected return date	>= 65 vs. <65	1.15 (0.97, 1.35)	0.10
Recall Group	3 month vs. 1 month	1.43 (0.92, 2.21)	0.14
	6 month vs. 1 month	1.70 (1.09, 2.64)	**0.015**
Total number of kept appointment	Increase by 1	1.02 (1.01, 1.03)	**0.0014**

Discussion and Conclusion: An intervention program that consists of a personalized reminder letter and telephone call can significantly improve appointment adherence for patients with glaucoma and may also help to reduce the overall costs for both the patient and the healthcare system. Few studies have examined the effect of a multifaceted intervention system in an ophthalmic setting. In order to determine whether the study's results are generalizable, future studies should be conducted in a larger sample and in other ophthalmic populations.

Future studies should also focus on improving follow-up adherence in patients who are under the age of 65 or patients without health insurance, as these are relatively non-adherent subgroups. While the results of this study are promising with respect to increased follow-up adherence, cost analyses should be conducted in future studies in order to determine whether a multifaceted intervention strategy is feasible in an ophthalmic population.

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18. Extent of Clinical Activities Initiated and Completed. Items 18(A) and 18(B) should be completed for all research projects. If the project was restricted to secondary analysis of clinical data or data analysis of clinical research, then responses to 18(A) and 18(B) should be "No."

18(A) Did you initiate a study that involved the testing of treatment, prevention or diagnostic procedures on human subjects?

___✓_Yes
_____No

18(B) Did you complete a study that involved the testing of treatment, prevention or diagnostic procedures on human subjects?

__✓__Yes
_____No

If "Yes" to either 18(A) or 18(B), items 18(C) – (F) must also be completed. (Do NOT complete 18(C-F) if 18(A) and 18(B) are both "No.")

18(C) How many hospital and health care professionals were involved in the research project?

___54__Number of hospital and health care professionals involved in the research project

18(D) How many subjects were included in the study compared to targeted goals?

__206_Number of subjects originally targeted to be included in the study (Aim 1)
__206_Number of subjects enrolled in the study (Aim 1)

__40_Number of subjects originally targeted to be included in the study (Pilot study #1)
__23_Number of subjects enrolled in the study (Pilot Study #1)

__256_Number of subjects originally targeted to be included in the study (Pilot Study #2)
__256_Number of subjects enrolled in the study (Pilot Study #2)
129 men 127 women. 206 AA, 26 White 10 Asian 9 Hispanic

18(E) How many subjects were enrolled in the study by gender, ethnicity and race?

Gender: (Aim 1)
___72_Males
__134_Females
____0_Unknown

Ethnicity: (Aim 1)
___0 _Latinos or Hispanics
_206__Not Latinos or Hispanics
___0__Unknown

Race: (Aim 1)
___0__American Indian or Alaska Native
___0__Asian
_206__Blacks or African American
___0__Native Hawaiian or Other Pacific Islander
___0__White
___0 _Other, specify:
___0__Unknown

Gender: (Pilot Study #1)
___2_Males
__21_Females
___0_Unknown

Ethnicity: (Pilot Study #1)
___0 _Latinos or Hispanics

_ 23__Not Latinos or Hispanics
___0__Unknown

Race: (Pilot Study #1)
___0__American Indian or Alaska Native
___0__Asian
_ 23__Blacks or African American
___0__Native Hawaiian or Other Pacific Islander
___0__White
___0 _Other, specify:
___0__Unknown

Gender: (Pilot Study #2)
__129_Males
__127_Females
____0_Unknown

Ethnicity: (Aim 1)
___0 _Latinos or Hispanics
_ 247__Not Latinos or Hispanics
___0__Unknown

Race: (Aim 1)
___0__American Indian or Alaska Native
_ 10__Asian
_206__Blacks or African American
___0__Native Hawaiian or Other Pacific Islander
__26__White
___9 _Other, specify: Hispanic
___0__Unknown

18(F) Where was the research study conducted? (List the county where the research study was conducted. If the treatment, prevention and diagnostic tests were offered in more than one county, list all of the counties where the research study was conducted.)

The intervention involves visits in participants' homes. Therefore, our participants were primarily from Philadelphia County. However, there were some participants that lived in Delaware, Montgomery, and Camden Counties.

19. Human Embryonic Stem Cell Research. Item 19(A) should be completed for all research projects. If the research project involved human embryonic stem cells, items 19(B) and 19(C) must also be completed.

19(A) Did this project involve, in any capacity, human embryonic stem cells?

_____Yes
__✓___ No

19(B) Were these stem cell lines NIH-approved lines that were derived outside of Pennsylvania?

_____Yes
_____ No

19(C) Please describe how this project involved human embryonic stem cells:

20. Articles Submitted to Peer-Reviewed Publications.

20(A) Identify all publications that resulted from the research performed during the funding period and that have been submitted to peer-reviewed publications. Do not list journal abstracts or presentations at professional meetings; abstract and meeting presentations should be listed at the end of item 17. **Include only those publications that acknowledge the Pennsylvania Department of Health as a funding source** (as required in the grant agreement). List the title of the journal article, the authors, the name of the peer-reviewed publication, the month and year when it was submitted, and the status of publication (submitted for publication, accepted for publication or published.). Submit an electronic copy of each publication, listed in the table, in a PDF version 5.0.5 format, 1,200 dpi. Filenames for each publication should include the number of the research project, the last name of the PI, the number of the publication and an abbreviated research project title. For example, if you submit two publications for PI Smith for the "Cognition and MRI in Older Adults" research project (Project 1), and two publications for PI Zhang for the "Lung Cancer" research project (Project 3), the filenames should be:

Project 1 – Smith – Publication 1 – Cognition and MRI
Project 1 – Smith – Publication 2 – Cognition and MRI
Project 3 – Zhang – Publication 1 – Lung Cancer
Project 3 – Zhang – Publication 2 – Lung Cancer

If the publication is not available electronically, provide 5 paper copies of the publication.

Note: The grant agreement requires that recipients acknowledge the Pennsylvania Department of Health funding in all publications. Please ensure that all publications listed acknowledge the Department of Health funding. If a publication does not acknowledge the funding from the Commonwealth, do not list the publication.

Title of Journal Article:	Authors:	Name of Peer-reviewed Publication:	Month and Year Submitted:	Publication Status (check appropriate box below):
1. "Depression and risk perceptions in older African Americans with diabetes"	Rovner, Haller, Casten, Murchison, Hark	*Diabetes Spectrum*	5/1/12	☐Submitted ☐Accepted ✓Published

20(B) Based on this project, are you planning to submit articles to peer-reviewed publications in the future?

Yes____✓____ No_____

If yes, please describe your plans:

The research team is developing manuscripts on the cost of the intervention as well as a methodology paper on the active intervention of the health research project, Behavioral Activation. After all 18-month follow-up data is collected, we will examine the long-term efficacy of the intervention and determine whether the results merit a peer-reviewed manuscript.

Title of Journal Article:	Authors:	Name of Peer-reviewed Publication:	Publication Status (check appropriate box below):
1. "Recruitment strategies for older African Americans with diabetes: Opt-in versus Opt-out"	Weiss, Murchison, Hark, Haller	*Sage Open*	✓**Plan to be Submitted** ☐Accepted ☐Published
2. "Feasibility and acceptability of using supportive therapy as an attention-control condition for randomized controlled trials of behavioral interventions"	Stratford, Weiss, Casten, Rovner, Presser, Murchison, Hark, Haller	*Behavior Modification*	✓**Plan to be Submitted** ☐Accepted ☐Published
3. "Behavioral Activation improves rates of dilated fundus examinations in older African Americans with diabetes "	Weiss, Hark, Murchison, Casten, Leiby, Plumb, Brawer, Henderer, Rovner, Stratford, Johnson, Haller	*Ophthalmology*	✓**Plan to be Submitted** ☐Accepted ☐Published

4. "Cost effectiveness analysis of behavior activation versus supportive therapy in older African Americans with diabetes to increase rate of annual eye exams"	Pizzi, Casten, Murchison, Leiby, Hark, Haller	*Applied Health Economics and Health Policy*	✓**Plan to be Submitted** ☐Accepted ☐Published
5. "Multifaceted Intervention System to Improve Access to Eye Care in Patients with Glaucoma"	Shafa, Hark, Tran, Waisbourd, Murchison, Pizzi, Dai, Haller	*Medical Care*	✓**Plan to be Submitted** ☐Accepted ☐Published

21. Changes in Outcome, Impact and Effectiveness Attributable to the Research Project.
Describe the outcome, impact, and effectiveness of the research project by summarizing its impact on the incidence of disease, death from disease, stage of disease at time of diagnosis, or other relevant measures of outcome, impact or effectiveness of the research project. If there were no changes, insert "None"; do not use "Not applicable." Responses must be single-spaced below, and no smaller than 12-point type. DO NOT DELETE THESE INSTRUCTIONS. There is no limit to the length of your response.

The active intervention, Behavioral Activation (BA), successfully increased rates of DFEs in older African Americans with diabetes. Compared to the Supportive Therapy (ST) control, BA emphasized education on ocular care, assessment of barriers to getting an eye examination, and goal setting in obtaining a dilated fundus examination (DFE). We had hypothesized that a 25% difference between the BA and ST groups would be clinically significant. At the primary endpoint, the 6-month follow-up, 88% of BA participants obtained a DFE compared to 34% of ST participants, resulting in 54% difference between the two groups.

Among the 110 participants who obtained a DFE, approximately 15% had some form of diabetic retinopathy and most of these cases were mild non-proliferative diabetic retinopathy. Approximately 70% of participants who obtained DFEs had some form of cataracts. Participants had not obtained a DFE in the preceding 12 months of the study. Therefore, while it is unclear how many of these cases are newly diagnosed, this health research project allowed many participants with ocular disease or ocular conditions to obtain DFEs.

The active intervention, BA, has also been used in a pilot study to increase adherence to recommended diabetes self-care behaviors. That pilot study showed mean increases in 6 diabetes self-care behaviors and half of the 23 participants had a hemoglobin A1C reduction of 0.5%. Another pilot study utilized a telephone intervention to increase adherence to recommended follow-up appointments among glaucoma patients.

We believe that BA can be translated to address other health behaviors as we have shown utilizing BA to address diabetes self-care behaviors, depression and diabetes, medication adherence, and hemoglobin A1C reduction. Though institutions may not have the resources to implement a behavioral intervention such as BA, our telephone intervention illustrates an alternative way to increase adherence or other healthy behaviors.

22. Major Discoveries, New Drugs, and New Approaches for Prevention Diagnosis and Treatment. Describe major discoveries, new drugs, and new approaches for prevention, diagnosis and treatment that are attributable to the completed research project. If there were no major discoveries, drugs or approaches, insert "None"; do not use "Not applicable." Responses must be single-spaced below, and no smaller than 12-point type. DO NOT DELETE THESE INSTRUCTIONS. There is no limit to the length of your response.

Behavior Activation (BA) is a new approach for prevention of diabetes complications such as diabetic retinopathy. BA is a behavioral technique designed to help people overcome avoidant tendencies through goal setting, activity scheduling, and graded task assignment. In this study, the Community Health Worker scheduled and delivered four 45-60 minute in-home sessions within four months of randomization. Previous studies have shown BA is an effective treatment to activate patients to engage in health behaviors. Our results indicate that BA is an effective intervention for increasing rates of dilated eye exams in a population that did not adhere to diabetic eye care recommendations. Ultimately, this new approach for prevention of eye complications due to diabetes may serve as a broad-based, community health model for other medical conditions that disproportionately affect African Americans such as asthma, hypertension, and prostate cancer, where treatment adherence is similarly low.

23. Inventions, Patents and Commercial Development Opportunities.

23(A) Were any inventions, which may be patentable or otherwise protectable under Title 35 of the United States Code, conceived or first actually reduced to practice in the performance of work under this health research grant? Yes_____ No___✓___

If "Yes" to 23(A), complete items a – g below for each invention. (Do NOT complete items a - g if 23(A) is "No.")

a. Title of Invention:
b. Name of Inventor(s):

c. Technical Description of Invention (describe nature, purpose, operation and physical, chemical, biological or electrical characteristics of the invention):

d. Was a patent filed for the invention conceived or first actually reduced to practice in the performance of work under this health research grant?
Yes_____ No___

If yes, indicate date patent was filed:

e. Was a patent issued for the invention conceived or first actually reduced to practice in the performance of work under this health research grant?
Yes_____ No___
If yes, indicate number of patent, title and date issued:
Patent number:
Title of patent:
Date issued:

f. Were any licenses granted for the patent obtained as a result of work performed under this health research grant? Yes_____ No___

If yes, how many licenses were granted?_____

g. Were any commercial development activities taken to develop the invention into a commercial product or service for manufacture or sale? Yes___ No___

If yes, describe the commercial development activities:

23(B) Based on the results of this project, are you planning to file for any licenses or patents, or undertake any commercial development opportunities in the future?

Yes_____ No____x____

If yes, please describe your plans:

24. Key Investigator Qualifications. Briefly describe the education, research interests and experience and professional commitments of the Principal Investigator and all other key investigators. In place of narrative you may insert the NIH biosketch form here; however, please limit each biosketch to 1-2 pages. *For Nonformula grants only – include information for only those key investigators whose biosketches were not included in the original grant application.*