Original Investigation

Effect of Behavioral Intervention on Dilated Fundus Examination Rates in Older African American Individuals With Diabetes Mellitus
A Randomized Clinical Trial

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IMPORTANCE African American individuals are at high risk of diabetes mellitus and diabetic retinopathy but have suboptimal rates of dilated fundus examinations (DFEs). Early intervention is crucial for the prevention of diabetic retinopathy in this high-risk population.

OBJECTIVE To test the efficacy of behavioral activation for diabetic retinopathy prevention on rates of DFEs in older African American individuals with diabetes mellitus.

DESIGN, SETTING, AND PARTICIPANTS Masked randomized clinical trial at 2 urban medical centers from October 1, 2010, to May 31, 2014. Participants included 206 African American individuals 65 years and older with diabetes mellitus who had not obtained a DFE in the preceding 12 months.

INTERVENTIONS Participants were randomized to either behavioral activation for diabetic retinopathy prevention, a behavioral intervention designed to provide education, facilitate identifying and addressing health care barriers, and promote goal setting to improve rates of DFEs, or supportive therapy, a control condition.

MAIN OUTCOMES AND MEASURES The primary outcome was medical documentation of a DFE at 6 months' follow-up. Secondary outcomes included the Risk Perceptions and Risk Knowledge Survey of Diabetes Mellitus, Diabetes Self-Care Inventory, Patient Health Questionnaire 9, and National Eye Institute Vision Function Questionnaire 25 scores and hemoglobin A_{1c} levels.

RESULTS More participants in the behavioral activation for diabetic retinopathy prevention group (87.9%) obtained a DFE compared with those in the supportive therapy group (34.1%) by the 6-month follow-up assessment ($P < .001$). Overall, participants in the behavioral activation for diabetic retinopathy prevention group were 2.5 times more likely to obtain a DFE compared with those in the supportive therapy group (risk ratio = 2.58; 95% CI, 1.91-3.48; $P < .001$). The intervention had no short-term effect on secondary outcomes of hemoglobin A_{1c} levels, depression, or the Risk Perceptions and Risk Knowledge Survey of Diabetes Mellitus or National Eye Institute Vision Function Questionnaire 25 composite scores; however, both groups had improved adherence to diabetes mellitus self-care behaviors from baseline to 6-month follow-up.

CONCLUSIONS AND RELEVANCE Behavioral activation for diabetic retinopathy prevention significantly increased rates of DFEs in older African American individuals with diabetes mellitus. Behavioral interventions may have the potential to positively affect screening for diabetic retinopathy in at-risk populations.

TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT01179555

JAMA Ophthalmol. 2015;133(9):1005-1012. doi:10.1001/jamaophthalmol.2015.1760
Published online June 11, 2015.

Supplemental content at jamaophthalmology.com

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Diabetic retinopathy (DR) affects approximately 4.2 million Americans older than 65 years[1] and is the leading cause of blindness among adults 20 to 74 years of age.[2] Without treatment and management, the prevalence of DR is projected to increase more than 3-fold by 2050, creating an immense and costly public health problem.[3] In 2004, blindness from DR accounted for approximately $500 million in direct medical costs and substantially more in indirect costs to society.[4]

Diabetic retinopathy is a retinal vascular disorder characterized by microvascular damage leading to retinal ischemia and increased vascular permeability.[5,6] Management of DR includes early recognition and ophthalmic medical and surgical treatments.[7-9] Clinical trials demonstrating the efficacy of various treatments led the American Academy of Ophthalmology and the American Diabetes Association to recommend that individuals with diabetes mellitus have annual dilated fundus examinations (DFEs) to reduce the risk of vision loss.[10] Javitt et al[11] reported that DFE screening saves $2162 per year of visual acuity gained. Sloan et al[12] found that older adults who had regular DFEs had better visual acuity and functional outcomes than those who did not. Each additional year of DFE adherence decreased the probability of developing impaired visual acuity or blindness. Despite the value of early detection, fewer than half of people with diabetes mellitus obtain annual DFEs and an estimated 50% are diagnosed too late for treatment to be optimal.[13,14]

African American individuals have a particularly high risk for DR. The prevalence of DR is higher in African American individuals compared with white individuals (38.8% vs 26.4%) and higher in individuals older than 65 years compared with younger people (6.1% vs 3.1%).[1] Additionally, African American individuals are more likely to develop diabetes mellitus, have worse glycemic control, are 2 to 3 times more likely to present with advanced DR, and are more than 5 times more likely to require immediate intervention compared with white individuals.[15-20] Despite increased risk, African American individuals with diabetes mellitus are less likely to see an eye care physician compared with their white counterparts.[21] These data demonstrate one of the most troubling health disparities in the United States. Older African American individuals are twice as likely to experience preventable blindness from DR compared with white individuals and this disparity is increasing.

Interventions to increase DFE rates in African American individuals have included culturally relevant community screening programs, nurse case management, and telephone-based interventions.[22-24] Several telephone-based intervention studies have increased the rates of DFEs in African American individuals; however, these rates are still suboptimal.[25,26] To address this health disparity, we designed a culturally relevant home-based behavioral intervention that targets specific issues that may prevent older African American individuals from obtaining DFEs. The theoretical basis for our intervention is grounded in the disablement process model, health belief model, and behavioral activation.[27-29] The primary aim of this clinical trial was to evaluate the efficacy of behavioral activation for diabetic retinopathy prevention (BADRP) on rates of DFEs in older African American individuals.

At a Glance

- Early interventions for individuals with diabetes mellitus are needed to prevent blindness and disability owing to diabetic retinopathy.
- Behavioral activation for diabetic retinopathy prevention was 2.5 times more effective in increasing rates of dilated fundus examinations compared with attention control.
- Approximately 23% of participants who obtained a dilated fundus examination were diagnosed as having diabetic retinopathy.

Methods

The design and rationale of this study have been previously published.[30] This study was approved by the Wills Eye Hospital, Temple University Hospital, and Thomas Jefferson University institutional review boards. The full study protocol and list of participating sites and investigators can be found in the trial protocol in the Supplement. A total of 206 participants with diabetes mellitus were recruited from October 1, 2010, to May 31, 2013. The following inclusion criteria included being 65 years or older, self-identification as an African American individual, diagnosis of type 2 diabetes mellitus, no self-report or medical documentation of a DFE in the past 12 months, and access to a telephone. Exclusion criteria included cognitive impairment (based on an abbreviated version of the Mini-Mental State Examination),[31] current significant psychiatric disorder, current medical disorder limiting life expectancy, need for dialysis, and hearing impairment that precluded research participation.

Participants were recruited from the following 2 sources: 1 of 2 academic medical institutions in Philadelphia, Pennsylvania, and community-based programs. Participants from the medical centers were recruited. Research assistants reviewed medical records and identified patients who met demographic and health criteria (ie, had diabetes mellitus). Patients were sent recruitment letters, which were followed up by telephone calls to explain the study. Interested patients were administered a brief telephone screening to determine eligibility. We also enrolled participants from community-based programs, which used advertisements in local newsletters, senior citizen housing centers, and churches. Interested individuals were instructed to call study staff for details and complete the telephone screening to determine eligibility.

Eligible participants had a home-based visit with a race/ethnicity–concordant community health worker (CHW), where written informed consent was obtained and the baseline assessment was administered. The 206 participants who completed the baseline assessment were randomized using random permuted blocks with a 1 to 1 allocation ratio to BADRP or supportive therapy (ST). Randomization sheets were stored in sequentially numbered sealed envelopes that were opened by the project director after each participant completed baseline assessment. The project director notified the appropriate interventionist for the participants' treatment assignments. Across a 4-month period, BADRP and ST were delivered

in four 1-hour sessions by independent race/ethnicity-concordant CHWs. Follow-up assessments were conducted in participants' homes at 6 months' follow-up by CHWs masked to treatment assignment.

Description of Interventions

Behavioral Activation for Diabetic Retinopathy Prevention

The active intervention was a manualized treatment, meaning that content and procedures for each session were prespecified. Behavioral activation for diabetic retinopathy prevention combined the principles of education about diabetes mellitus, behavioral therapy, and the health belief model to assist participants in identifying barriers to obtaining DFEs, problem-solving solutions to surmounting barriers, formulating action plans to facilitate DFEs, and gauging the success of action plans. The educational component consisted of the following 3 printed documents: *Steps to Prepare for an Eye Examination,* a document created specifically for the current study that lists activities associated with scheduling and obtaining a DFE; *Four Steps to Control Your Diabetes for Life,* an easy-to-read National Institutes of Health guide to diabetes mellitus;[32] and *Diabetic Retinopathy: What You Should Know,* a National Eye Institute guide to DR.[33] The action plan involved identifying barriers that may hinder a participant in obtaining a DFE and developing steps to remove those barriers, therefore, reinforcing steps toward goal attainment. The CHW provided participants with the contact information of local ophthalmologists and aided the participants in making appointments, if requested.

Supportive Therapy

Supportive therapy is a structured placebo treatment that controls for the nonspecific elements of behavioral activation (eg, attention). It was administered by a specially trained CHW and was delivered in the home across four 1-hour sessions. Supportive therapy fosters a comfortable nonjudgmental environment where the CHW demonstrates genuineness, empathy, and acceptance of participants without imposing any judgments on their decisions. This was accomplished through the use of open-ended questions (eg, tell me how your life has changed since you were diagnosed as having diabetes mellitus) that allowed participants to reflect on their life situations. Unlike BADRP, the ST interventionist did not provide educational materials and did not use behavioral change or goal-setting strategies. If participants requested information on obtaining a DFE, the ST interventionist supplied them with contact information for local ophthalmologists. Outcome measures were obtained at the baseline and 6-month follow-up by the CHW assessor (masked to treatment group assignment).

Primary Outcome Measure

The primary outcome measure for this study was medical documentation of a DFE by the 6-month follow-up visit. This was obtained as follows: first, participants were asked whether they had received a DFE from an ophthalmologist in the previous 6 months. The assessor was careful to describe the DFE in detail so participants would not mistake another type of eye examination (eg, refraction for glasses) for a DFE. If a participant reported he or she had a DFE, he or she was asked for the name and location of the eye care physician who performed the DFE. Study staff then contacted the named ophthalmologist's office to confirm the DFE and obtain examination results. For participants who reported no DFE, study staff verified by checking medical records from the ophthalmology clinics at the 2 urban medical centers where patients were recruited.

Secondary Outcome Measures

Secondary outcome measures consisted of the following:

Medical Status

The chronic disease score was used to quantify medical comorbidity.[34] Derived from a weighted sum of medications taken for chronic illness, Clark et al[35] validated the chronic disease score on more than 250 000 managed care enrollees and found it predicts health care use, costs, hospitalization, and mortality. Higher scores indicate greater medical burden.

Literacy

The Literacy Assessment for Diabetes is a valid and reliable tool to assess health literacy, specifically in individuals with diabetes mellitus.[36] Scores range from 0 to 60, with higher scores indicating higher reading grade levels.

Risk Perceptions and Risk Knowledge Survey of Diabetes Mellitus

The Risk Perceptions and Risk Knowledge Survey of Diabetes Mellitus is a 31-item survey that assesses risk perceptions and risk knowledge of diabetes mellitus and its complications (eg, DR).[37] Composite scores range from 0 to 4, with higher scores indicating greater risk knowledge and perceived risk owing to diabetes mellitus.

Depressive Symptoms

The Patient Health Questionnaire 9 includes the 9 criteria that comprise *Diagnostic and Statistical Manual of Mental Disorders* (Fourth Edition) diagnoses of depressive disorders. Possible scores range from 0 to 27, with scores of 15 or higher indicative of possible moderate/severe depression.

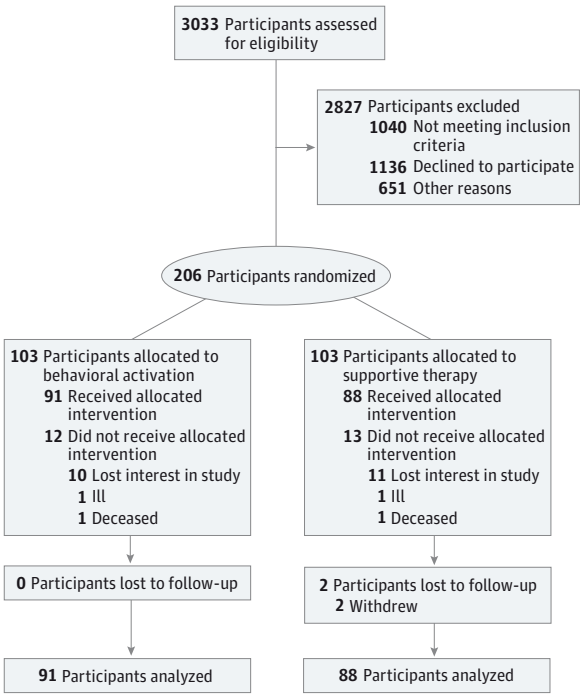
Diabetes Self-Care Inventory–Revised

The Diabetes Self-Care Inventory–Revised is a 12-item self-reported measure of perceived adherence to diabetes mellitus self-care recommendations.[38] Self-care refers to the daily regimen of tasks an individual performs to manage diabetes mellitus. The measure assesses the frequency of blood glucose level monitoring, medication use, eating recommended food portions, etc. Scores range from 0 to 100, with higher scores indicating better adherence to diabetes mellitus self-care recommendations.

National Eye Institute Visual Function Questionnaire 25

The National Eye Institute Visual Function Questionnaire 25 (NEI-VFQ) is a 25-item questionnaire that assess vision-targeted health-related quality of life.[39] Composite scores range

Figure. CONSORT Flow Diagram



from 0 to 100, with higher scores indicating better visual acuity functioning.

Hemoglobin A_{1c} Levels

Glycosylated hemoglobin (HbA_{1c}) levels via finger stick provides a patient's mean plasma glucose level concentration during the previous 3 months and is associated with an increased risk of DR and other microvascular complications of diabetes mellitus. The American Diabetes Association recommends HbA_{1c} levels less than 7.0% for most patients with diabetes mellitus. This study used A1cNow SelfCheck kits (Bayer).

Statistical Analysis

The primary aim of this study was to test the efficacy of BADRP to increase rates of DFEs at 6 months' follow-up in older African American individuals with diabetes mellitus. Based on previous research findings, we hypothesized that 50% of the BADRP group compared with 25% of the ST group would have a DFE by the 6-month follow-up assessment and that a doubling of DFE rates would constitute a clinically meaningful difference.[25] A sample size of 164 participants (82 per group) was needed to have 90% power to detect the hypothesized difference using a 2-sided Pearson χ^2 test, with $\alpha = .05$. Allowing for 20% attrition by 6 months, the target sample size was 206.

The effect of BADRP was estimated by risk ratio and the associated 95% CI. A Pearson χ^2 test evaluated the association between randomization assignment and having a DFE. Secondary analyses evaluated the efficacy of BADRP compared with ST in improving HbA_{1c} levels, depression symptoms, adherence to recommended diabetes mellitus self-care behaviors, diabetes mellitus risk perception and knowledge, and visual acuity functioning. Mixed-effects linear regression was used to analyze these outcomes. Fixed effects included treatment group assignment, time (0 and 6 months), and group × time interaction. A random intercept term was included to account for within-subject correlation. Within the mixed-effects model, we estimated the change in these outcomes from 0 to 6 months for each treatment arm and compared BADRP with ST with respect to this change. Several variables were transformed prior to analysis to better meet assumptions of normality and homoscedasticity of residual variances. The HbA_{1c} level was log-transformed and the Patient Health Questionnaire 9 was square-root transformed. The NEI-VFQ total score was transformed by taking the log of 101 minus the total score. Model-adjusted means were calculated on the transformed scale and then back-transformed to the natural scale.

Results

The **Figure** depicts the CONSORT study flow diagram. A total of 3033 African American individuals older than 65 years with diabetes were screened to determine eligibility. Of the 2827 nonparticipants, 1040 (34%) did not meet eligibility criteria, 1136 (37%) refused, and 651 (21%) could not be reached. Reasons for noneligibility were self-report or medical documentation of a DFE or medical documentation in the past year (67% of those noneligible), cognitive impairment (8.1%), deceased (7.5%), self-report of no diabetes mellitus (6.6%), and illness (3.0%). Of the 206 enrolled participants, 103 were randomized to the BADRP group and 103 to the ST group. Completion rates at 6 months' follow-up for BADRP and ST participants were 88% and 85%, respectively.

Table 1 compares the demographic characteristics and baseline measures between participants in the BADRP and ST groups. The 2 arms were balanced with respect to age, education, sex, recruitment site, and marital status. Differences on the Risk Perceptions and Risk Knowledge Survey of Diabetes Mellitus, Diabetes Self-Care Inventory-Revised, Patient Health Questionnaire 9, Literacy Assessment for Diabetes, and the NEI-VFQ 25 composite scores that may have influenced the primary outcome were not identified. Participants in the BADRP group had lower HbA_{1c} levels and chronic disease scores at baseline.

Table 2 shows the primary outcome by treatment group for the 91 BADRP participants and 88 ST participants who completed a 6-month follow-up assessment. Participants in the BADRP group were more likely to report obtaining a DFE compared with participants in the ST group at 6 months' follow-up (85.7% vs 51.1%; $\chi^2 = 24.9$; $P < .001$). The risk difference between BADRP and ST participants with a self-reported DFE was 0.346 (95% CI, 0.20-0.46; $P < .001$). Similarly, a larger proportion of BADRP participants compared with ST participants had a confirmed medically documented DFE (87.9% vs 34.1%; $\chi^2 = 54.7$; $P < .001$). The risk difference between BADRP and ST participants with a medically documented DFE was 0.538 (95% CI, 0.40-0.64; $P < .001$). Overall, BADRP participants were approximately 2.5 times more

likely to obtain a DFE compared with ST participants (risk ratio = 2.58; 95% CI, 1.91-3.48; $P < .001$). **Table 3** provides the ophthalmologic diagnoses based on the medical reports obtained at 6 months' follow-up.

There was a discrepancy among participants between self-reported and the actual documentation of DFEs. Specifically, 16 ST participants and 1 BADRP participant reported having a DFE that could not be confirmed. By contrast, 3 BADRP participants compared with 1 ST participant reported having no DFE but had medical documentation. We conducted a sensitivity analysis where we assumed ST participants with undocumented DFEs obtained examinations (Table 2). The DFE rate remained higher in the BADRP group, although it reduced the magnitude of the effect.

Table 4 shows the secondary outcomes by treatment group. No differences between groups regarding change in the Risk Perceptions and Risk Knowledge Survey of Diabetes Mellitus composite scores, HbA_{1c} levels, Diabetes Self-Care Inventory-Revised, Patient Health Questionnaire 9, and NEI-VFQ 25 composite scores were identified. Within-group comparisons indicated a significant improvement in Diabetes Self-Care Inventory-Revised scores for both the BADRP (53.9 to 60.7) and the ST (53.6 to 58.9) groups ($P < .001$). Additionally, BADRP participants showed slight improvement in NEI-VFQ 25 composite scores ($P = .03$).

Table 1. Baseline Demographics and Secondary Outcome Measures by Treatment Group

Variable	BADRP (n = 103)	ST (n = 103)
Age, mean (SD), y	72.8 (6.5)	72.6 (5.9)
Education, mean (SD), y	11.7 (2.3)	12.2 (2.8)
Female, No. (%)	68 (66.0)	66 (64.1)
Lives alone, No. (%)	42 (40.8)	48 (46.6)
Marital status, No. (%)		
Married	28 (27.2)	24 (23.3)
Widowed	34 (33.1)	31 (30.1)
Divorced	16 (15.5)	28 (27.2)
Other	25 (24.3)	20 (19.4)
Recruitment site, No. (%)		
Temple University	42 (40.8)	41 (39.8)
Thomas Jefferson University	26 (25.2)	31 (30.1)
Community	35 (34.0)	31 (30.1)
Treatment,[1] No. (%)		
Oral medication, only	60 (58.3)	54 (52.4)
Insulin	14 (13.6)	27 (26.2)
Diet and exercise	13 (12.6)	11 (10.7)
Literacy Assessment for Diabetes score, mean (SD)[a]	48.29 (10.81)	49.58 (8.98)
Chronic disease score, mean (SD)[b]	6.3 (3.5)	7.1 (3.3)
Glycosylated hemoglobin level, mean (SD)	7.3 (1.6)	7.7 (1.7)
NEI-VFQ 25 composite score, mean (SD)[c]	81.3 (15.1)	81.2 (15.0)
PHQ-9 symptom score, mean (SD)[d]	5.9 (4.8)	5.5 (5.3)
Risk Perceptions and Risk Knowledge Survey of Diabetes Mellitus composite score, mean (SD)[e]	2.55 (0.45)	2.54 (0.46)
Diabetes Self-care Inventory score, mean (SD)[f]	53.9 (14.7)	53.6 (14.3)

Abbreviations: BADRP, behavioral activation for diabetic retinopathy prevention; NEI-VFQ, National Eye Institute Visual Function Questionnaire; PHQ-9, Patient Health Questionnaire 9; ST, supportive therapy.

[a] Sixteen participants in the BADRP group and 7 participants in the ST group did not provide medications.

[b] Scores range from 0 to 60, scores greater than 41 indicate a ninth-grade reading level and higher.

[c] Higher scores indicate greater medical burden.

[d] Scores range from 0 to 100 with higher scores indicating better visual acuity functioning.

[e] Scores range from 0 to 27 with higher scores indicating more severe depression.

[f] Scores range from 0 to 4 with higher scores indicating greater comparative perceived risk.

[g] Scores range from 0 to 100 with higher scores indicating better adherence to recommendations.

Discussion

We found that BADRP significantly increased short-term rates of DFEs in older African American individuals with diabetes mellitus. Approximately 23% of participants who obtained a DFE were diagnosed as having DR, although it is unknown whether these were newly detected cases. Nevertheless, because of the high DFE rate in the BADRP arm, this intervention has the potential to identify new cases and allow for early management of DR. Given the efficacy of this intervention, the next step will be to determine the cost-effectiveness of the intervention and its long-term effects on visual outcomes and quality of life.

No differences were identified between the 2 groups on secondary outcomes at 6 months' follow-up, although this may have been too short a follow-up to adequately assess these outcomes. Participants in the BADRP group showed slight improvement on the NEI-VFQ 25 composite score between baseline and the 6-month follow-up, although this change (a mean of 2 points) was not considered clinically meaningful. Additionally, participants in both groups reported improved adherence to recommended behaviors on the Diabetes Self-Care Inventory-Revised. The BADRP intervention encouraged participants to formulate other diabetes mellitus goals and provided overall diabetes mellitus education. While this may have affected Diabetes Self-Care Inventory-Revised improvements for participants in the BADRP group, these elements were absent in the ST group. Future longitudinal studies should assess whether short-term benefits to participating in either group translate to improvements in biological markers, such as HbA_{1c} levels. This is critical because lower HbA_{1c} levels are demonstrably linked to fewer diabetic complications and lower health care costs.[40] Again, it is possible that ST had unanticipated benefits that may have diminished our ability to observe group differences in diabetes mellitus self-management.

Limitations of the study included using a restricted cohort of African American individuals 65 years and older with diabetes mellitus. It is unclear whether the same type of intervention would have yielded similar results in other at-risk

Table 2. Rates of DFEs at 6 Months' Follow-up by Treatment Group

Variable	No. (%) BADRP (n = 91)	No. (%) ST (n = 88)	Risk Ratio (95% CI)	*P* Value
Self-reported DFE	78 (85.7)	45 (51.1)	1.68 (1.34-2.09)	<.001
Medical documentation	80 (87.9)	30 (34.1)	2.58 (1.91-3.48)	<.001

Abbreviations: BADRP, behavioral adaptation for diabetic retinopathy prevention; DFE, dilated fundus examination; ST, supportive therapy.

Table 3. Ocular Characteristics at 6 Months' Follow-up in Participants With DFE

Variable	BADRP (n = 80) Missing	BADRP (n = 80) No. (%)	ST (n = 30) Missing	ST (n = 30) No. (%)
Best eye, logMAR (SD)	1	0.18 (0.19)	4	0.13 (0.12)
History of cataract surgery	9	11 (15.5)	6	5 (20.8)
Diabetic retinopathy[a]	3		5	
Mild nonproliferative		15 (19.5)		2 (8.0)
Moderate nonproliferative		3 (3.9)		1 (4.0)
Proliferative		1 (1.3)		1 (4.0)
Cataracts, grade[a]	6		5	
1		14 (18.9)		7 (28.0)
2		30 (40.5)		7 (28.0)
3		9 (12.2)		2 (8.0)
4		2 (2.7)		2 (8.0)
Hypertensive retinopathy	8	8 (11.1)	6	2 (8.3)
Drusen	8	6 (8.3)	6	1 (4.2)
Macular edema	8	2 (2.8)	6	1 (4.2)

Abbreviations: BADRP, behavioral adaptation for diabetic retinopathy prevention; DFE, dilated fundus examination; ST, supportive therapy.

[a] If both eyes are affected, the grade is the greater of both eyes.

Table 4. Secondary Outcomes by Treatment Group

Variable	BADRP Mean[a] (95% CI)	BADRP *P* Value[b]	ST Mean[a] (95% CI)	ST *P* Value[b]	*P* Value for the Difference Between Groups
HbA_{1c} level					
Baseline	7.2 (6.9-7.5)		7.5 (7.2-7.8)		.37
6 Months' follow-up	7.0 (6.7-7.3)	.09	7.5 (7.2-7.8)	.65	
NEI-VFQ total score					
Baseline	87.0 (84.4-89.2)		85.9 (83.1-88.3)		.32
6 Months' follow-up	89.0 (86.6-90.9)	.03	86.7 (83.9-89.0)	.47	
PHQ-9 symptom score					
Baseline	4.7 (3.7-5.7)		4.3 (3.4-5.2)		.13
6 Months' follow-up	4.0 (3.1-5.0)	.19	4.7 (3.7-5.7)	.42	
Risk Perceptions and Risk Knowledge Survey of Diabetes Mellitus composite score					
Baseline	2.6 (2.5-2.6)		2.5 (2.5-2.6)		.49
6 Months' follow-up	2.5 (2.5-2.6)	.98	2.6 (2.5-2.7)	.34	
Diabetes Self-care Inventory score					
Baseline	53.9 (51.2-56.7)		53.6 (50.8-56.4)		.42
6 Months' follow-up	60.7 (57.8-63.6)	<.001	58.9 (56.0-61.8)	<.001	

Abbreviations: BADRP, behavioral activation for diabetic retinopathy prevention; HbA_{1c}, hemoglobin A_{1c}; NEI-VFQ, National Eye Institute Visual Function Questionnaire; PHQ-9, Patient Health Questionnaire 9; ST, supportive therapy.

[a] Model-estimated analysis for HbA_{1c}, NEI-VFQ total score, and PHQ-9 based on transformed data.

[b] For within-group change from baseline to 6 months' follow-up.

or younger populations. Future trials are necessary to establish generalizability to other age and cultural groups. For example, Hispanic individuals, Native American individuals, and other racial/ethnic groups are disproportionally affected by diabetes mellitus and could potentially benefit from BADRP as well.[41,42]

Per American Diabetes Association guidelines, individuals with diabetes mellitus should be screened every 12 months. This study only examined the immediate effect of BADRP on obtaining a DFE at 6 months' follow-up. It is unknown how durable the effects of BADRP are across time, although participants in the current study will be assessed at

18 months' follow-up. Despite randomization, BADRP participants were healthier at baseline (as indicated by lower chronic disease score and HbA_{1c} levels) and it is not possible to determine how this may have affected whether someone obtained a DFE.

The discrepancy between the number of participants who self-reported a DFE compared with the number of medically confirmed DFE reports is notable (BADRP, n = 1; ST, n = 14). While research showing agreement between self-reported and medical documentation is only moderate, it is possible the actual DFE rate is higher in the ST group.[43] The benefit of BADRP compared with ST on improving DFE rates remained significant whether or not the undocumented examinations were obtained. The exaggerated discrepancy in the attention-control group could be explained by the absence of education on ocular care. Misconceptions of what a DFE entails may have persisted and ST participants may have conflated DFEs with refractions for glasses.

Conclusions

The current study demonstrates the value of behavioral interventions in improving rates of DFEs in an at-risk population. Disseminating similar interventions through collaborative efforts with community programs could significantly affect individuals with diabetes mellitus at risk for DR and improve existing health disparities. Steps to broad implementation may include health care policy initiatives and the funding of related interventions to integrate BADRP in standard patient care.

ARTICLE INFORMATION

Submitted for Publication: February 4, 2015; final revision received April 20, 2015; accepted April 28, 2015.

Published Online: June 11, 2015. doi:10.1001/jamaophthalmol.2015.1760.

Author Contributions: Drs Leiby and Haller had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Casten, Leiby, Hark, Murchison, Rovner, Haller.
Acquisition, analysis, or interpretation of data: Weiss, Casten, Leiby, Hark, Murchison, Johnson, Stratford, Henderer, Rovner, Haller.
Drafting of the manuscript: Weiss, Casten, Leiby, Hark, Murchison, Stratford, Rovner.
Critical revision of the manuscript for important intellectual content: Weiss, Casten, Leiby, Hark, Murchison, Johnson, Stratford, Henderer, Haller.
Statistical analysis: Leiby.
Obtained funding: Casten, Hark, Murchison, Rovner, Haller.
Administrative, technical, or material support: Weiss, Hark, Murchison, Johnson, Stratford, Henderer, Haller.
Study supervision: Weiss, Casten, Hark, Murchison, Rovner, Haller.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

Funding/Support: This work was funded by the Pennsylvania Department of Health.

Role of the Funder/Sponsor: The funder had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

REFERENCES

1. Zhang X, Saaddine JB, Chou CF, et al. Prevalence of diabetic retinopathy in the United States: 2005-2008. *JAMA*. 2010;304(6):649-656.

2. Klein BE. Overview of epidemiologic studies of diabetic retinopathy. *Ophthalmic Epidemiol*. 2007; 14(4):179-183.

3. Saaddine JB, Honeycutt AA, Narayan KM, Zhang X, Klein R, Boyle JP. Projection of diabetic retinopathy and other major eye diseases among people with diabetes mellitus: United States, 2005-2050. *Arch Ophthalmol*. 2008;126(12): 1740-1747.

4. Rein DB, Zhang P, Wirth KE, et al. The economic burden of major adult visual disorders in the United States. *Arch Ophthalmol*. 2006;124(12):1754-1760.

5. Klein R, Klein BE, Moss SE, Davis MD, DeMets DL. Glycosylated hemoglobin predicts the incidence and progression of diabetic retinopathy. *JAMA*. 1988;260(19):2864-2871.

6. Cheung N, Mitchell P, Wong TY. Diabetic retinopathy. *Lancet*. 2010;376(9735):124-136.

7. Frank RN. Diabetic retinopathy. *N Engl J Med*. 2004;350(1):48-58.

8. Rowe S, MacLean CH, Shekelle PG. Preventing visual loss from chronic eye disease in primary care: scientific review. *JAMA*. 2004;291(12):1487-1495.

9. The Diabetic Retinopathy Study Research Group. Photocoagulation treatment of proliferative diabetic retinopathy: clinical application of Diabetic Retinopathy Study (DRS) findings. DRS Report Number 8. *Ophthalmology*. 1981;88(7):583-600.

10. Benson WE, Blodi BA, Boldt HC, et al. The American Academy of Ophthalmology Retina Panel. *Preferred Practice Pattern Guidelines: Diabetic Retinopathy*. San Francisco, CA: American Academy of Ophthalmology; 2008.

11. Javitt JC, Aiello LP. Cost-effectiveness of detecting and treating diabetic retinopathy. *Ann Intern Med*. 1996;124(1, pt 2):164-169.

12. Sloan FA, Picone G, Brown DS, Lee PP. Longitudinal analysis of the relationship between regular eye examinations and changes in visual and functional status. *J Am Geriatr Soc*. 2005;53(11): 1867-1874.

13. Schoenfeld ER, Greene JM, Wu SY, Leske MC. Patterns of adherence to diabetes vision care guidelines: baseline findings from the Diabetic Retinopathy Awareness Program. *Ophthalmology*. 2001;108(3):563-571.

14. Lee PP, Feldman ZW, Ostermann J, Brown DS, Sloan FA. Longitudinal rates of annual eye examinations of persons with diabetes and chronic eye diseases. *Ophthalmology*. 2003;110(10): 1952-1959.

15. Davidson MB. The disproportionate burden of diabetes in African-American and Hispanic populations. *Ethn Dis*. 2001;11(1):148-151.

16. Thackeray R, Merrill RM, Neiger BL. Disparities in diabetes management practice between racial and ethnic groups in the United States. *Diabetes Educ*. 2004;30(4):665-675.

17. Weatherspoon LJ, Kumanyika SK, Ludlow R, Schatz D. Glycemic control in a sample of black and white clinic patients with NIDDM. *Diabetes Care*. 1994;17(10):1148-1153.

18. Baker RS. Diabetic retinopathy in African Americans: vision impairment, prevalence, incidence, and risk factors. *Int Ophthalmol Clin*. 2003;43(4):105-122.

19. Zhang X, Cotch MF, Ryskulova A, et al. Vision health disparities in the United States by race/ethnicity, education, and economic status: findings from two nationally representative surveys. *Am J Ophthalmol*. 2012;154(6)(suppl):S53-62.e1, e1.

20. Kempen JH, O'Colmain BJ, Leske MC, et al; Eye Diseases Prevalence Research Group. The prevalence of diabetic retinopathy among adults in the United States. *Arch Ophthalmol*. 2004; 122(4):552-563.

21. Trivedi AN, Zaslavsky AM, Schneider EC, Ayanian JZ. Trends in the quality of care and racial disparities in Medicare managed care. *N Engl J Med*. 2005;353(7):692-700.

22. Quigley HA, Park CK, Tracey PA, Pollack IP. Community screening for eye disease by laypersons: the Hoffberger program. *Am J Ophthalmol*. 2002;133(3):386-392.

23. Weinberger M, Kirkman MS, Samsa GP, et al. A nurse-coordinated intervention for primary care patients with non-insulin-dependent diabetes mellitus: impact on glycemic control and health-related quality of life. *J Gen Intern Med*. 1995;10(2):59-66.

24. Ellish NJ, Royak-Schaler R, Higginbotham EJ. Tailored and targeted interventions to encourage dilated fundus examinations in older African Americans. *Arch Ophthalmol*. 2011;129(12):1592-1598.

25. Basch CE, Walker EA, Howard CJ, Shamoon H, Zybert P. The effect of health education on the rate of ophthalmic examinations among African Americans with diabetes mellitus. *Am J Public Health*. 1999;89(12):1878-1882.

26. Jones HL, Walker EA, Schechter CB, Blanco E. Vision is precious: a successful behavioral intervention to increase the rate of screening for diabetic retinopathy for inner-city adults. *Diabetes Educ*. 2010;36(1):118-126.

27. Verbrugge LM, Jette AM. The disablement process. *Soc Sci Med*. 1994;38(1):1-14.

28. Glanz K, Rimer BK, Viswanath K. *Health Behavior and Health Education: Theory, Research, and Practice*. Hoboken, NJ: John Wiley & Sons; 2008.

29. Rovner BW, Casten RJ, Hegel MT, et al. Low vision depression prevention trial in age-related macular degeneration: a randomized clinical trial. *Ophthalmology*. 2014;121(11):2204-2211.

30. Casten RJ, Brawer R, Haller JA, et al. Trial of a behavioral intervention to increase dilated fundus examinations in African-Americans aged over 65 years with diabetes. *Expert Rev of Ophthomology*. 2011;6(6):593-601.

31. Rovner BW, Folstein MF. Mini-Mental State Exam in clinical practice. *Hosp Pract (Off Ed)*. 1987; 22(1A):99, 103, 106, 110.

32. National Diabetes Education Program. *Four Steps to Control Your Diabetes for Life*. Bethesda, MD: National Institutes of Health; 2011.

33. National Eye Institute. *Diabetic Retinopathy. What You Should Know*. Bethesda, MD: National Institutes of Health; 2003.

34. Von Korff M, Wagner EH, Saunders K. A chronic disease score from automated pharmacy data. *J Clin Epidemiol*. 1992;45(2):197-203.

35. Clark DO, Von Korff M, Saunders K, Baluch WM, Simon GE. A chronic disease score with empirically derived weights. *Med Care*. 1995;33(8):783-795.

36. Nath CR, Sylvester ST, Yasek V, Gunel E. Development and validation of a literacy assessment tool for persons with diabetes. *Diabetes Educ*. 2001;27(6):857-864.

37. Walker EA, Caban A, Schechter CB, et al. Measuring comparative risk perceptions in an urban minority population: the risk perception survey for diabetes. *Diabetes Educ*. 2007;33(1):103-110.

38. Weinger K, Butler HA, Welch GW, La Greca AM. Measuring diabetes self-care: a psychometric analysis of the Self-Care Inventory-Revised with adults. *Diabetes Care*. 2005;28(6):1346-1352.

39. Mangione CM, Lee PP, Gutierrez PR, Spritzer K, Berry S, Hays RD; National Eye Institute Visual Function Questionnaire Field Test Investigators. Development of the 25-item National Eye Institute Visual Function Questionnaire. *Arch Ophthalmol*. 2001;119(7):1050-1058.

40. Juarez D, Goo R, Tokumaru S, Sentell T, Davis J, Mau M. Association between sustained glycated hemoglobin control and healthcare costs. *Am J Pharm Benefits*. 2013;5(2):59-64.

41. Bressler NM, Varma R, Doan QV, et al. Underuse of the health care system by persons with diabetes mellitus and diabetic macular edema in the United States. *JAMA Ophthalmol*. 2014;132(2):168-173.

42. Centers for Disease Control and Prevention. *National Diabetes Fact Sheet: National Estimates and General Information on Diabetes and Prediabetes in the United States, 2011*. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2011.

43. Beckles GL, Williamson DF, Brown AF, et al. Agreement between self-reports and medical records was only fair in a cross-sectional study of performance of annual eye examinations among adults with diabetes in managed care. *Med Care*. 2007;45(9):876-883.