Original Investigation | CLINICAL TRIAL

Assessing the Effect of Personalized Diabetes Risk Assessments During Ophthalmologic Visits on Glycemic Control
A Randomized Clinical Trial

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IMPORTANCE Optimization of glycemic control is critical to reduce the number of diabetes mellitus–related complications, but long-term success is challenging. Although vision loss is among the greatest fears of individuals with diabetes, comprehensive personalized diabetes education and risk assessments are not consistently used in ophthalmologic settings.

OBJECTIVE To determine whether the point-of-care measurement of hemoglobin A1c (HbA1c) and personalized diabetes risk assessments performed during retinal ophthalmologic visits improve glycemic control as assessed by HbA1c level.

DESIGN, SETTING, AND PARTICIPANTS Ophthalmologist office–based randomized, multicenter clinical trial in which investigators from 42 sites were randomly assigned to provide either a study-prescribed augmented diabetes assessment and education or the usual care. Adults with type 1 or 2 diabetes enrolled into 2 cohorts: those with a more-frequent-than-annual follow-up (502 control participants and 488 intervention participants) and those with an annual follow-up (368 control participants and 388 intervention participants). Enrollment was from April 2011 through January 2013.

INTERVENTIONS Point-of-care measurements of HbA1c, blood pressure, and retinopathy severity; an individualized estimate of the risk of retinopathy progression derived from the findings from ophthalmologic visits; structured comparison and review of past and current clinical findings; and structured education with immediate assessment and feedback regarding participant’s understanding. These interventions were performed at enrollment and at routine ophthalmic follow-up visits scheduled at least 12 weeks apart.

MAIN OUTCOMES AND MEASURES Mean change in HbA1c level from baseline to 1-year follow-up. Secondary outcomes included body mass index, blood pressure, and responses to diabetes self-management practices and attitudes surveys.

RESULTS In the cohort with more-frequent-than-annual follow-ups, the mean (SD) change in HbA1c level at 1 year was −0.1% (1.5%) in the control group and −0.3% (1.4%) in the intervention group (adjusted mean difference, −0.09% [95% CI, −0.29% to 0.12%]; P = .35). In the cohort with annual follow-ups, the mean (SD) change in HbA1c level was 0.0% (1.1%) in the control group and −0.1% (1.6%) in the intervention group (mean difference, −0.05% [95% CI, −0.27% to 0.18%]; P = .63). Results were similar for all secondary outcomes.

CONCLUSIONS AND RELEVANCE Long-term optimization of glycemic control is not achieved by a majority of individuals with diabetes. The addition of personalized education and risk assessment during retinal ophthalmologic visits did not result in a reduction in HbA1c level compared with usual care over 1 year. These data suggest that optimizing glycemic control remains a substantive challenge requiring interventional paradigms other than those examined in our study.

TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT01323348

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Multiple randomized clinical trials\textsuperscript{1-4} have established that intensive blood glucose control can reduce the onset and progression of microvascular complications in persons with diabetes mellitus. The Diabetes Control and Complications Trial and the Epidemiology of Diabetes Interventions and Complications study underscored the benefit of closely monitored intensive glycemic control in type 1 diabetes on retinopathy and other diabetic complications.\textsuperscript{5,6} Preventative therapy is a fundamental tenant to reduce ocular and systemic complications of diabetes.

Despite the benefits, optimal glycemic control, as assessed by measuring hemoglobin A\textsubscript{1c} (HbA\textsubscript{1c}) level, is notoriously difficult to achieve, especially long term.\textsuperscript{7,8} Forty-one percent of US adults with diabetes who participated in the 2005-2010 National Health and Nutrition Examination Surveys did not have an HbA\textsubscript{1c} level of less than the American Diabetes Association suggested goal of 7\% (to convert to proportion of total hemoglobin, multiply by 0.01).\textsuperscript{9} Obstacles to achieving optimal glycemic control include a lack of awareness of potential organ damage, a mistrust of the medical system, cultural beliefs, financial constraints, poor access to care, depression, denial, a lack of motivation, and a lack of perseverance.\textsuperscript{10}

One potential strategy to improve glycemic control is to leverage factors known to be highly motivating for people with diabetes, including fear of vision loss. Results from a nationwide poll by the American Foundation for the Blind demonstrated that Americans fear blindness more than human immunodeficiency virus/AIDS, cancer, stroke, or heart attacks.\textsuperscript{11} Other studies have shown similar results in which fear of vision loss even exceeds fear of dying prematurely.\textsuperscript{12} Studies suggest that when patients with diabetes received personalized assessments of their retinal images during an endocrinologic visit, their HbA\textsubscript{1c} levels over the following 3 months were reduced more than when they received an endocrinologic evaluation only.\textsuperscript{13}

An annual dilated eye examination is the minimum recommendation for persons with diabetes. At this type of ophthalmologic visit, physicians have an opportunity to personalize the glycemic control and eye disease education to suit the individual. With knowledge of current key factors for an individual, the risk for onset or progression of retinopathy and kidney disease can be estimated. Although not performed in most ophthalmologic practices, obtaining and tracking point-of-care HbA\textsubscript{1c} levels over time and recording blood pressure, in addition to retinopathy status, can allow for personalized education and can potentially provide patients with the motivation they will need to achieve improved systemic control. Individualized risk reports might have a greater impact than recommendations based on population averages. Assessments may also be shared with primary care physicians.

Given the large and growing worldwide diabetic population,\textsuperscript{14} closing the gap between the known benefits of intensive glycemic control and the ability to achieve this goal is of great public health importance. Thus, a trial to ascertain whether combining personalized risk assessments and diabetes education at an ophthalmologic visit can improve glycemic control for persons with diabetes was warranted.

Methods

This randomized, multicenter clinical trial (NCT01323348) was conducted by the Diabetic Retinopathy Clinical Research Network at 42 clinical sites in the United States. Our study adhered to the tenets of the Declaration of Helsinki. The protocol and Health Insurance Portability and Accountability Act-compliant informed consent forms were approved by multiple institutional review boards, and study oversight was provided by an independent data and safety monitoring committee. Each study participant gave written informed consent prior to participation in the study. Key aspects of the protocol pertinent to this article are summarized herein. The trial protocol can be found in Supplement 1.

Study Population

Eligible participants were older than 18 years of age with type 1 or type 2 diabetes and with an expected routine follow-up with a retina specialist at least annually. Principal exclusion criteria were (1) a known HbA\textsubscript{1c} level of less than 7.5\% within the prior 6 months (reported by the participant or obtained from available records at the time of enrollment), (2) prior complete panretinal photocoagulation, (3) initiation of insulin treatment within 3 months from the date of enrollment, (4) loss of visual acuity in both eyes (which prohibits the ability to read study materials), and (5) significant renal disease (including use of erythropoietin or a history of chronic renal failure requiring dialysis or kidney transplant). Participants with a known HbA\textsubscript{1c} level of less than 7.5\% were excluded because these better-controlled patients would have less chance for a reduction in HbA\textsubscript{1c} level, less risk overall for diabetes complications, and a reduced diabetic retinopathy progression.

Synopsis of Study Design

Sites chose to be randomized by site (34 sites [88 ophthalmologists]) or by ophthalmologist (8 sites [35 ophthalmologists]) to “usual care” or “intervention”; participants were assigned according to the enrolling site or ophthalmologist. Our study included private practices (57\%) and institutions (43\%). Randomization was stratified by site-reported race/ethnicity. Follow-up was planned for 2 years with the primary outcome at 1 year. However, based on the 1-year results, after data and

At a Glance

- Optimization of glycemic control is critical to reduce diabetes mellitus-related complications.
- Our objective was to determine whether the point-of-care measurement of hemoglobin A\textsubscript{1c} level and personalized diabetes complication risk assessments performed during retinal ophthalmologic visits improve glycemic control.
- Individually customized education during retinal ophthalmologic visits, as provided in our study, did not result in a reduction in hemoglobin A\textsubscript{1c} level compared with usual care over 1 year.
- Optimizing glycemic control remains a substantive challenge requiring interventional paradigms other than those examined in our study.
safety monitoring committee approval, our study ended prior to the planned 2-year follow-up.

The participants who received usual care were only required to complete an annual study visit, although if they returned for a standard care visit 9 to 17 weeks after their baseline visit, a 3-month study visit was documented. Participants in this group did not receive any additional education regarding diabetes beyond the ophthalmologist’s standard visit approach. Participants in the intervention group received the following at each standard-of-care visit, but not more often than every 12 weeks: (1) a point-of-care measurement of HbA1c level, blood pressure, and retinopathy severity; (2) a graph showing personalized risk for worsening retinopathy based on the participant’s HbA1c level and diabetes type (eFigures 1 and 2 in Supplement 2); (3) a report summarizing a personalized risk assessment for renal disease and retinopathy based on the participant’s HbA1c level (eFigure 3 in Supplement 2); (4) a graph plotting the participant’s previous and current HbA1c levels (eFigure 4 in Supplement 2); (5) an email with instructions for accessing individualized risk assessment findings; and (6) supplemental diabetes management education materials (baseline only). Materials were reviewed by the ophthalmologist via a script, given to the participant, and mailed to their primary care physician (eFigure 5 in Supplement 2). Each participant completed an assessment of their understanding of key diabetes control issues, and immediate feedback and supplemental education were provided if the assessment was not answered 100% correctly (eFigure 6 in Supplement 2).

Examination Procedures
Baseline testing included determining visual acuity (from a usual-care assessment within the past 3 months), an ocular examination of both eyes (including a dilated fundus examination), measurement of blood pressure, collection of a blood sample for central laboratory HbA1c measurement, measurement of HbA1c using the DCA Vantage point-of-care device (Siemens Medical; intervention group only), measurement of height and weight, and completion of the Problem Areas in Diabetes (PAID) questionnaire and the Self-Care Inventory 2 (SCI-2) questionnaire. The PAID questionnaire is a validated self-administered questionnaire consisting of 20 items scoring from 0 to 4 (from “not a problem” to “serious problem”) covering a range of emotional problems frequently reported in persons with diabetes.16,17 The SCI-2 questionnaire is a validated self-administered questionnaire that consists of 17 items scored from 1 to 5 (from “never” to “always”) that measure perceived adherence to diabetes self-care recommendations.18–20 Testing at the 1-year visit included all of the tests performed at the baseline visit.

Diabetes and ophthalmic management was left to the participant in partnership with the participant’s medical care professionals. Adverse-event reporting was limited to severe hypoglycemia, as defined by the Diabetes Control and Complications Trial criteria.21

Statistical Methods
Our study was designed to evaluate intervention vs control participants within 2 separate cohorts. Participants were included in the cohort with more-frequent-than-annual follow-ups if at least 1 ophthalmologic visit occurred between baseline and 1 year, otherwise they were included in the cohort with annual follow-ups. Assuming a difference between treatment groups in 1-year change in HbA1c level of 0.5% for each cohort, a standard deviation of change of 1.8%, an intraclass (ie, within site) correlation coefficient of 0.03, a type 1 error rate of 0.05, and a power of 90%, we found that the sample size was estimated to be 800 participants with a baseline central laboratory HbA1c level of 6.0% or higher for each cohort for a total of 1600 participants equally distributed among 25 cluster units per treatment group. To account for a potential 10% loss to follow-up, the target sample size was increased to 900 participants per cohort. The recruitment goal was met in the cohort with more-frequent-than-annual follow-ups; however, the recruitment goal in the cohort with annual follow-ups could not be met in a timely manner, and thus recruitment was discontinued after 756 participants were enrolled.

All analyses included only participants with a baseline central laboratory HbA1c level of 6.0% or higher. The primary outcome was the change in HbA1c level from baseline to 1 year. Treatment group comparisons were made within each cohort using a repeated-measures analysis of covariance model to adjust for the baseline HbA1c level and the correlation of participants within the same site. The primary analysis included only participants with baseline and 1-year central laboratory values and was an intent-to-treat analysis with study participants analyzed in their assigned group (intervention or control) regardless of whether the education intervention was actually received.

Secondary outcomes of body mass index (calculated as weight in kilograms divided by height in meters squared), blood pressure level, and PAID and SCI-2 composite scores were compared between intervention groups within each cohort using linear mixed analysis of covariance to adjust for the baseline value and the correlation of participants within the same site. For the PAID and SCI-2 questionnaires, 0- to 100-point composite scores were calculated for each participant at each visit.17,20 Data on history of medical conditions (including occurrence of severe hypoglycemic episodes, myocardial infarction, stroke, and renal failure) were collected at baseline and annual visits. There were no identifiable relationships between these events and treatment group, for either cohort (data not shown).

Parallel analyses were performed on all outcomes for the data collected at 3 months and 2 years. The results were similar to those at 1 year and are not included in this report. All P values are 2-sided. SAS version 9.4 (SAS Institute Inc) was used for all analyses.

Results
There were 25 clusters (ophthalmologists or sites) randomly assigned to each group. The control group included 502 participants in the cohort with more-frequent-than-annual follow-ups (range, 11-31 participants per cluster) and 368 participants in the cohort with annual follow-ups (range, 1-25
participants per cluster), and the intervention group included 488 participants in the cohort with more-frequent-than-annual follow-ups (range, 7-29 participants per cluster) and 388 participants in the cohort with annual follow-ups (range, 3-24 participants per cluster). Enrollment in our study was from April 2011 through January 2013.

The participant flowchart is presented in Figure 1. The 1-year visit completion rates (excluding deaths) were 88% and 89% in the control and intervention groups, respectively, for the cohort with more-frequent-than-annual follow-ups and 82% and 85% in the control and intervention groups, respectively, for the cohort with annual follow-ups. Baseline characteristics were similar when comparing 1-year completers with noncompleters (data not shown), with the exception of a higher mean central laboratory HbA1c level in the noncompleters of the subset of 1-year data occurring within the ±1-month period of-care value) (Figure 2B).

Baseline characteristics by patient were similar between treatment groups and between cohorts (eTable 1 in Supplement 2). The mean central laboratory HbA1c levels were 8.3% and 8.6% in the control and intervention groups, respectively, for the cohort with more-frequent-than-annual follow-ups and 8.3% and 8.4% in the control and intervention groups, respectively, for the cohort with annual follow-ups. The correlation between participant’s last known HbA1c level and baseline central laboratory HbA1c level was $r = 0.71$ (among the 631 participants across both cohorts and both treatment groups for whom the last known date was within the prior 6 months) (Figure 2A). The correlation between point-of-care HbA1c level and baseline central laboratory HbA1c level was $r = 0.96$ (among 867 participants across both cohorts in the intervention group, excluding 9 participants whose laboratory HbA1c levels were >14%, the maximum possible point-of-care value) (Figure 2B).

Outcomes for Cohort With More-Frequent-Than-Annual Follow-ups
Among the participants who completed a 1-year visit in the cohort with more-frequent-than-annual follow-ups, the median number of ophthalmologic visits was 3 for the control group and 2 for intervention group (Table 1). Prior to the annual visit, only a single follow-up visit occurred in 34% and 40% of participants in the control and intervention groups, respectively, while 35% and 24% of these participants, respectively, had 5 or more follow-up visits. Within the intervention group, 22% of participants received no interventions after baseline.

The 1-year mean (SD) change in HbA1c level was $-0.1\%$ (1.5%) in the control group and $-0.3\%$ (1.4%) in the intervention group (mean difference adjusted for baseline HbA1c level, $-0.09\%$ [95% CI, $-0.29\%$ to $0.12\%$]; $P = .35$; $P = .29$, adjusted for additional potential confounders [race, income, and education level]) (Table 2). Results were similar when the cohort with annual follow-ups was pooled with the cohort with more-frequent-than-annual follow-ups. A significant effect with regard to the number of interventions was not detected (eTable 2 in Supplement 2).

The results of other sensitivity analyses were consistent with the results of the primary analysis, including the use of all available measurements (point-of-care measurement or primary care physician-reported values) when the central laboratory value was not available, excluding 48 participants (3%) whose central laboratory values indicated that an abnormal hemoglobin variant was observed, evaluating only the subset of 1-year data occurring within the ±1-month protocol window or imputing for missing 1-year data (data not shown). Results were also consistent when stratified by predefined baseline subgroups of interest (based on HbA1c level, last known HbA1c level, annual income, type of diabetes, dia-

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Figure 1. Participant Flowchart

![Participant Flowchart](https://example.com/flowchart.png)

- **1875** Participants enrolled
- **129** Excluded because of missing baseline HbA1c level or because it was >6%
- **990** Were in the cohort with more-frequent-than-annual follow-ups
  - **502** Were in the control group
    - **61** Dropped out
      - **6** Died
    - **434** Completed 12-mo visit
      - **1** Missed 12-mo visit
  - **488** Were in the intervention group
    - **50** Dropped out
      - **9** Died
    - **428** Completed 12-mo visit
      - **1** Missed 12-mo visit
- **756** Were in the cohort with annual follow-ups
  - **368** Were in the control group
    - **59** Dropped out
      - **4** Died
    - **300** Completed 12-mo visit
      - **5** Missed 12-mo visit
  - **388** Were in the intervention group
    - **54** Dropped out
      - **11** Died
    - **320** Completed 12-mo visit
      - **3** Missed 12-mo visit

Of 42 sites, 34 were randomized on the site level (at 17 sites, all investigators were assigned to the intervention group, and at another 17 sites, all investigators were assigned to control group), and 8 were randomized on the investigator level. HbA1c indicates hemoglobin A1c.
Scatterplots showing the correlation between participant’s last known HbA1c level and baseline central laboratory HbA1c level among 631 participants across both cohorts and both treatment groups for whom the last known date was within the prior 6 months (A) and the correlation between point-of-care HbA1c level and baseline central laboratory HbA1c level among 867 participants across both cohorts in the intervention group (B). The solid lines represent the equality of the x- and y-axes.

Outcomes for the Cohort With Annual Follow-ups
For the cohort with annual follow-ups, the 1-year mean (SD) change in HbA1c level was 0.0% (1.1%) in the control group and −0.1% (1.6%) in the intervention group (mean difference adjusted for baseline HbA1c level, −0.05% [95% CI, −0.27% to 0.18%]; P = .63) (Table 2). Results were consistent when evaluating parallel sensitivity analyses as performed for the cohort with more-frequent-than-annual follow-ups (data not shown) and when evaluating secondary outcomes (including arterial blood pressure, body mass index, and survey data) (Table 3 and eTable 3 in Supplement 2).

Discussion
In our randomized, multicenter clinical trial, individualized assessments of the risk of diabetes-related complications during ophthalmologic visits based on point-of-care HbA1c level, blood pressure, and retinopathy severity, combined with personalized and standardized education delivered directly by each participant’s ophthalmologist, did not alter either short- or long-term glycemic control among participants with diabetes compared with participants who received usual care. Although the evidence supporting the beneficial effects of improved diabetes control is overwhelming, our results emphasize the difficulty of changing personal behavior and treatment paradigms through...
education, even when the participant is motivated by fear of possible future ocular and renal complications.

In our study, the control group received standard care that likely varied between sites. Thus, the similarity of HbA1c levels between intervention and control groups at 1 year should not be interpreted to imply that educational interventions aimed at improving systemic control are not worthwhile. Rather, it emphasizes the enormous challenge and the critical need for additional approaches other than those used in our study to identify effective strategies to improve glycemic control. Possible alternatives include (1) personalized retinal imaging and review to directly visualize an individual's current eye disease; (2) displaying images of severe diabetic complications such as blinding stages of eye disease, dialysis, or amputations; (3) exposure to persons who have experienced these debilitating complications; (4) more frequent educational interaction; or (5) additional communication with primary diabetes care professionals. Although results of the personalized assessments were mailed to each participant’s primary care physician, the protocol did not require further communication to ensure nonophthalmologic follow-up. Whether such attempts to improve communication between treating ophthalmologists and primary care physicians helps reinforce a participant’s behavior remains unknown.

Only 36% of intervention participants in the cohort with more-frequent-than-annual follow-ups and only 40% of intervention participants in the cohort with annual follow-ups provided an email address to receive intervention materials, which suggests that many of the participants did not use computers for communication or were uncomfortable providing this information. Of the 277 participants who provided an email address, 72% never accessed the web link, and 16% accessed it 2 or more times. Such limited use highlights the need for other novel approaches to engage persons with diabetes.

The lack of an intervention effect in our study could reflect the standard care given by this specialized investigator group, which is highly attuned to evidence-based retinal care for individuals with diabetes and possibly already providing patient education at a level where the prescribed intervention would not add incremental benefit. Nevertheless, in our study, 13% to 18% of participants had poorly controlled diabetes (with a baseline HbA1c level of >10%) and approximately half of the participants had a HbA1c level of higher than 8.0%, suggesting that there was room for improvement. The enrollment of the cohort of participants with annual follow-ups did not meet the calculated sample size, and thus a negative finding must be interpreted with caution. However, the cohort of participants with more-frequent-than-annual follow-ups did meet the sample size requirements, and there was no intervention difference despite the potentially greater effect in this cohort. There was also no evidence of a dose-response effect in a secondary analysis pooling both cohorts.

### Conclusions

Of potential importance for future studies, these data demonstrate excellent correlation between point-of-care HbA1c level and a personal diabetes risk assessment given by an investigator or a primary care physician. Of potential importance for future studies, these data demonstrate excellent correlation between point-of-care HbA1c level and a personal diabetes risk assessment given by an investigator or a primary care physician.

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**Table 2. Primary Analysis of HbA1c Levels at 1 Year**

<table>
<thead>
<tr>
<th>Data on HbA1c</th>
<th>Cohort With More-Frequent-Than-Annual Follow-ups</th>
<th>Cohort With Annual Follow-ups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control (n = 424)</td>
<td>Intervention (n = 423)</td>
</tr>
<tr>
<td>Baseline level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>8.0 (7.2-9.0)</td>
<td>8.2 (7.3-9.3)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>8.3 (1.6)</td>
<td>8.5 (1.7)</td>
</tr>
<tr>
<td>Level at 1 y^a</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>7.9 (7.0-9.0)</td>
<td>8.0 (7.0-9.1)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>8.2 (1.7)</td>
<td>8.2 (1.6)</td>
</tr>
<tr>
<td>Change from baseline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>−0.1 (−0.6 to 0.5)</td>
<td>0.0 (−0.6 to 0.5)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>−0.1 (1.5)</td>
<td>0.0 (1.1)</td>
</tr>
<tr>
<td>Difference (intervention-control), mean (SE)^b</td>
<td>−0.09 (0.09)</td>
<td>−0.05 (0.09)</td>
</tr>
<tr>
<td>95% CI^c</td>
<td>−0.29 to 0.12</td>
<td>−0.27 to 0.18</td>
</tr>
<tr>
<td>P values^d</td>
<td>.35 and .29^d</td>
<td>.63 and .44^d</td>
</tr>
</tbody>
</table>

Abbreviations: HbA1c, hemoglobin; IQR, interquartile range.

^a From central laboratory measurements.

^b Data missing for 10 control participants and 5 intervention participants in the cohort with more-frequent-than-annual follow-ups and for 8 control participants and 8 intervention participants in the cohort with annual follow-ups.

^c From a repeated-measures model adjusting for baseline HbA1c level and correlation between participants within a site, assuming that the correlation is the same for any pair of participants at a given site and that the within-site correlation is the same at all sites.

^d The second P value is from the same model but is adjusted for additional potential confounders (race, education level, and income).

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obtained in a retina specialist office and HbA1c level obtained in a central laboratory. We are unable to assess whether the intervention group in the cohort of participants with more-frequent-than-annual follow-ups became desensitized to the intervention over time. National trends suggest that glycemic control has improved among Americans with diabetes over the last few decades.10 However, our study and other recent epidemiologic assessments demonstrate that, despite improvements in educational efforts and greater awareness of the importance of health status, there still exists a sizable population of persons with diabetes whose condition remains poorly controlled.

Evidence supporting the multiple beneficial effects of systemic control of diabetes is overwhelming, and there is a critical need to encourage intensive blood glucose control among persons with diabetes in order to prevent long-term development and progression of vasculopathy across multiple organ systems. Although the addition of personalized education and risk assessment during ophthalmologic visits in our study did not improve glycemic control, long-term optimization of glycemic control is still a cornerstone of diabetes care. These results suggest that optimizing glycemic control requires more extensive interventional paradigms than were examined in our study and further research into new technologies and models of behavioral change. In the meantime, ophthalmologists and all other diabetes care professionals should continue their efforts to maximize education, assessment, systemic control, and treatment of complications for patients with diabetes.

### Table 3. Secondary Outcomes at 1 Year

<table>
<thead>
<tr>
<th>Data</th>
<th>Cohort With More-Frequent-Than-Annual Follow-ups</th>
<th>Cohort With Annual Follow-ups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control</td>
<td>Intervention</td>
</tr>
<tr>
<td>Change in ABP, mm Hg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants, Total No.</td>
<td>432</td>
<td>428</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>−1 (−8 to 6)</td>
<td>−1 (−8 to 6)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>−1 (12)</td>
<td>−1 (12)</td>
</tr>
<tr>
<td>&lt;140/80 at baseline, No. of participants</td>
<td>282</td>
<td>276</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>2 (−5 to 9)</td>
<td>3 (−5 to 9)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>3 (11)</td>
<td>2 (11)</td>
</tr>
<tr>
<td>≥140/80 at baseline, No. of participants</td>
<td>150</td>
<td>152</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>−8 (−13 to 0)</td>
<td>−7 (−15 to 0)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>−7 (11)</td>
<td>−8 (11)</td>
</tr>
<tr>
<td>Change in BMI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants, Total No.</td>
<td>419</td>
<td>424</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>0.0 (−1.1 to 1.1)</td>
<td>−0.1 (−1.3 to 0.9)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>0.0 (3.8)</td>
<td>−0.1 (3.6)</td>
</tr>
<tr>
<td>&lt;25 at baseline, No. of participants</td>
<td>40</td>
<td>57</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>0.2 (−0.7 to 1.3)</td>
<td>0.3 (−0.4 to 1.8)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>0.7 (2.3)</td>
<td>0.9 (2.1)</td>
</tr>
<tr>
<td>≥25 at baseline, No. of participants</td>
<td>379</td>
<td>367</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>0.0 (−1.3 to 1.1)</td>
<td>−0.3 (−1.3 to 0.9)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>0.0 (3.9)</td>
<td>−0.2 (3.8)</td>
</tr>
</tbody>
</table>

Abbreviations: ABP, arterial blood pressure; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); IQR, interquartile range.

* Data missing for 2 control participants in the cohort with more-frequent-than-annual follow-ups and for 3 control participants in the cohort with annual follow-ups.

* Data missing for 13 control participants and 4 intervention participants in the cohort with more-frequent-than-annual follow-ups and for 7 control participants and 1 intervention participant in the cohort with annual follow-ups. Two control participants in the cohort with more-frequent-than-annual follow-ups were excluded because they were extreme outliers.

## ARTICLE INFORMATION

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Effect of Personalized Diabetes Risk Assessments on Glycemic Control

Original Investigation Research

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