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The Support, Educate, Empower personalized glaucoma coaching trial design

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Abstract

Background: Glaucoma is a chronic disease that affects 3 million Americans. Glaucoma is most often asymptomatic until very late in its course when treatment is more difficult and extensive peripheral vision loss has already occurred. Taking daily medications can mitigate this vision loss, but at least half of people with glaucoma do not take their prescribed medications regularly. The purpose of this study is to improve glaucoma medication adherence among those with medically treated glaucoma and poor self-reported adherence using the Support, Educate, Empower personalized coaching program.

Methods/design: This study is a two-site randomized controlled trial enrolling 230 participants with poor self-reported glaucoma medication adherence. The trial has two arms, an intervention arm and a control arm. Participants in the intervention arm receive personalized glaucoma education and motivational interviewing-based coaching over 6 months from a trained non-physician interventionist for three in-person sessions with between visit phone calls for check-ins where current adherence level is reported to participants. Participants also can elect to have visual, audio, text or automated phone call medication dose reminders. Participants in the control arm continue usual care with their physician and receive non-personalized glaucoma educational materials via mail in parallel to the three in-person coaching sessions to control for glaucoma knowledge content. All participants receive a medication adherence monitor. The primary outcome is the proportion of prescribed doses taken on schedule during the 6-month period. The secondary outcome is glaucoma related distress. The exploratory outcome is intraocular pressure.

Discussion: The personalized education and motivational-interviewing-based intervention that we are testing is comprehensive in that it addresses the wide range of barriers to adherence that people with glaucoma encounter. Leveraging a custom-built web-based application to generate the personalized content and the motivational-interviewing-based prompts to guide the coaching sessions will make this program both replicable and scalable and can be integrated into clinical care utilizing trained non-physician providers. Although this type of self-management support is not currently reimbursed for glaucoma as it is for diabetes, this trial could help shape future policy change should the intervention be found effective.

Keywords

Glaucoma, medication adherence, randomized controlled trial, personalized education, tailored education, motivational interviewing, health coaching, multi-pronged intervention, self-management support

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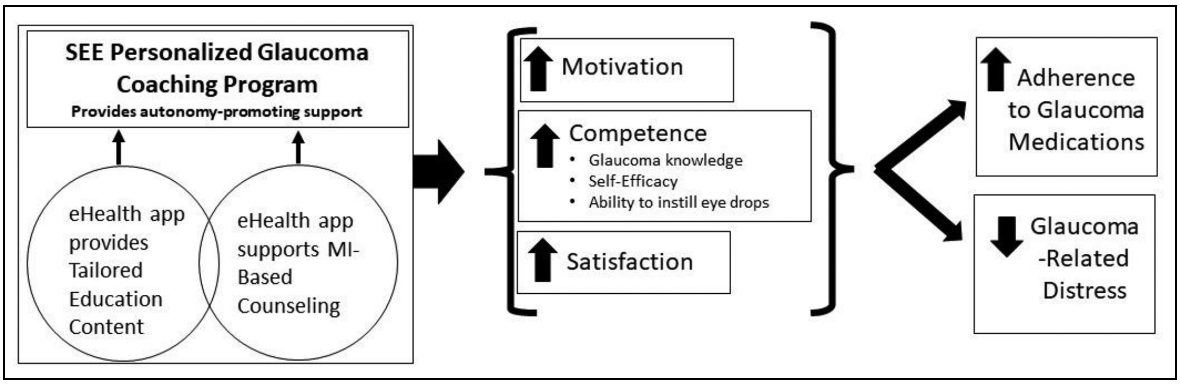

Figure 1. Theoretical model of how the SEE program works through self-determination and empowerment theories to improve medication adherence and decrease glaucoma-related distress.

Background

Although randomized clinical trials have shown that medication reduces vision loss from glaucoma,[1,2] it remains the second leading cause of blindness in the United States.[3,4] A critical barrier to preventing vision loss is medication nonadherence. At least 50% of glaucoma patients are "untreated" because they do not adhere to their medications.[5–7] Poor self-management behaviors and clinical outcomes disproportionately affect people with lower incomes and from minority backgrounds, including Black and Latinx Americans.[5,8,9] Black Americans have both a higher prevalence of glaucoma and of vision loss from glaucoma.[3,4,10] It is essential to develop, test, and implement glaucoma self-management support programs that can engage the diverse population of more than 3 million people living with glaucoma.

There are numerous health-system-level barriers to optimizing self-management support for people living with glaucoma, including limited physician time.[11] Demands on physicians' time will only increase with the increase in glaucoma prevalence as baby-boomers age.[12,13] In contrast to glaucoma, people with chronic conditions such as diabetes have established programs wherein trained paraprofessionals provide disease self-management education and support as standard care.[14] Using health educators or ophthalmic para-professional staff trained as glaucoma coaches to deliver self-management support is one intervention that can overcome the time barrier facing physicians.

A Cochrane Review of interventions to improve glaucoma medication adherence found successful programs included: evidence-based and theory-based interventions; tailored or personalized education; motivational interviewing-based health coaching; and reminder systems.[15,16] We used these elements to create the Support, Educate, Empower (SEE) personalized glaucoma coaching program. The SEE program is an intervention based on Empowerment Theory[17,18] and Self-Determination Theory[19] (Figure 1), behavior-change theories utilized in interventions to improve chronic conditions such as diabetes and tobacco abuse, and includes the following elements: glaucoma education personalized to a patient's gender, race, test results, doctor's recommendations, and unique barriers to adherence, delivered via a web application (www.seeglaucoma.org); glaucoma coaching using motivational interviewing to guide patients to identify their barriers to optimal adherence and brainstorm solutions; personalized daily dosing reminders where the participant can choose between visual or audible alarms, text messages, or phone call reminders. The SEE Program also includes a glaucoma-specific training program in motivational interviewing for ophthalmic para-professional staff and health educators.[20] In the SEE program, a trained glaucoma coach uses a web-based eHealth application to deliver personalized, high-quality counseling and education.

In our feasibility pilot study of the SEE Program,[21] among 39 participants with poor baseline adherence, mean electronically monitored glaucoma medication adherence increased by 21 percentage points, from 59.9% ($\pm$18.5) at baseline to 81.3% ($\pm$17.6) during the intervention.[22] In addition, the SEE Program decreased mean glaucoma-related distress by 30.3% from 6.6 points (standard deviation = 3.1) at baseline to 4.6 points (standard deviation = 2.4) after the intervention. However, this was an uncontrolled cohort study. A randomized controlled trial (RCT) needs to be conducted to evaluate program effectiveness while controlling for potential confounders. Glaucoma is a slowly progressive disease where a person may not notice vision loss for a decade or more and so intraocular pressure control is used clinically as a surrogate for disease control. These are several of the issues guiding the design of the SEE RCT that will be detailed herein. In each section describing the methods of the trial, we detail the considerations and data that informed each decision to make transparent the complexities of each design choice.

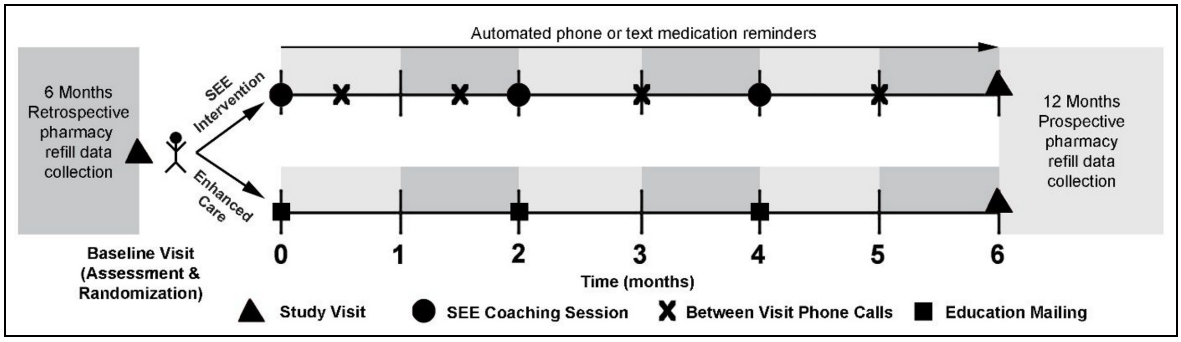

Figure 2. Schedule of SEE trial visits for intervention and control arms. Primary outcome assessment at 6 months.

Methods

Trial overview

The SEE personalized glaucoma coaching program trial will enroll 230 participants with glaucoma and poor self-reported glaucoma medication adherence and randomize them to receive either the intervention or enhanced standard care. Enhanced standard care includes usual care with a physician alongside written educational materials about glaucoma from the American Academy of Ophthalmology, National Eye Institute, and Glaucoma Research Foundation. Participants are being recruited from two medical centers, the University of Michigan, Kellogg Eye Center (Ann Arbor, MI, USA), and the Henry Ford Health System, Department of Ophthalmology (Detroit, MI, USA). Participants randomized to the control arm will have the opportunity to schedule a free coaching session after completing all exit visit assessments. This study was reviewed and approved by the University of Michigan and Henry Ford Institutional Review Boards (the University of Michigan multi-site approval number HUM00188154 and performance site HUM00194281 and the HFHS 14813) and is registered at Clinicaltrials.gov (NCT04735653).

Trial design consideration

We are recruiting from sites that serve low-income and minority populations as these populations have a higher incidence of both poor medication adherence and poor outcomes from glaucoma. The Henry Ford system's main site serves Detroit, a city with a median household income of US$27,838[23] compared with the national median of US$67,521. Detroit is predominantly Black (75%) and Hispanic (8%).[23] We are stratifying block randomization by site as we anticipate that Henry Ford may have a higher proportion of Black and Hispanic participants compared with the University of Michigan to ensure that participants are allocated to the intervention or control groups with consistent balance.

We chose to use standard physician care as the attention control and non-personalized educational content as the content control. Although the other seminal RCT of a complex intervention to improve glaucoma medication adherence chose to use general eye health education as the attention control,[24] we followed the Pragmatic Model for Comparator Selection in Health-Related Behavioral Trials.[25] This NIH Panel recommended that "compatibility with the primary purpose of the trial is the single most important consideration in choosing a comparator."[25] Therefore, because our trial's purpose is to test whether a change in glaucoma care delivery by including a glaucoma coach with structured personalized content improves medication adherence compared with current care, we included only current physician care as the attention control condition.

We anticipated that retention among participants who self-report poor glaucoma medication adherence and are not fully engaged in their glaucoma care could be an issue. Thus, we have devoted resources to participant retention in addition to the usual strategies of study visit reminder calls and texts, distributing materials with study contact information, incentives, travel support, and sending birthday cards. Prior to randomization, participants are shown a 2-min animated video explaining the importance of full participation for the trial to have meaningful results. Participants will have the opportunity not to commit to participation (video link: https://www.youtube.com/watch?v=dC0OJ8Wnbsg). In addition, participants will receive a monthly letter thanking them for their participation and describing the importance to the trial of continued data collection (Supplemental Figure 1) alongside their monthly incentive for using the electronic adherence monitor.

Summary of the intervention

Participants randomized to the SEE Program intervention receive three in-person SEE coaching sessions and four brief between-session phone calls over a 6-month period (Figure 2), starting within 2 weeks of the baseline study visit. During the first in-person coaching session, the glaucoma coach uses a custom-built web-based

application (seeglaucoma.org) to generate tailored glaucoma educational materials and teach eye drop instillation. The education is tailored on the following variables: name, gender, race/ethnicity, type of glaucoma, glaucoma test results (visual field tests, optic nerve photographs, and optical coherence tomography results), previous laser or incisional glaucoma surgeries, recommended glaucoma medications, physician's name, cell phone and Internet usage, social support, and barriers to adherence.[26] The application also generates motivational interviewing coaching prompts to guide the conversation. The coach shows the patient the tailored audio-visual educational materials on a 9" × 12" tablet that can be enlarged as needed for patients who are visually impaired. Text is read aloud and volume is adjustable. During the session, the coach helps the patient identify barriers to optimal adherence and uses the person's strengths and values to guide potential solutions. The coach helps the patient put together a list of questions to ask the doctor at the next visit. At the end of the session, the coach uses the web-application to create a written action plan of the next steps to integrate medication taking into the participant's daily routine.[27–30] The glaucoma coach also activates the adherence monitor reminder function and the participant chooses any or all of their preferred modalities for receiving reminders when a medication dose is missed: an alarm (light or sound) and/or an automated phone call or text message.

During the second in-person coaching session, participants discuss their daily routine for eye drop use, motivation to take care of their vision and strengths they have that they can use to enact their plan, and practice instilling eye drops. In the third session, participants choose what parts of the personalized glaucoma education content they would like to review and discuss, and troubleshoot any new barriers that may have arisen. During the between-session phone calls, the coach gives the participant the adherence score and tailors the discussion as to whether the score is increasing or decreasing. The phone call then focuses on problem-solving issues that arise. Participants can call their coach if questions arise. Participants will receive approximately 160 min of coaching (120 min in-person and four 10-min telephone calls). Coaches share intraocular pressure and adherence metrics with the participant's physician via the electronic health record at each in-person coaching session. Such three-way communication is the backbone of team-based, collaborative care.[31,32]

The glaucoma coach attended a 2-day training program in glaucoma-specific motivational interviewing, previously developed by the study team.[20] The program teaches five core skills of motivational interviewing: Asking open-ended questions; Affirming; Reflecting; Summarizing; and Elicit-Provide-Elicit to ensure that permission is asked before information or advice is provided. These skills help elicit "change talk," through which participants talk themselves into change. The training teaches coaches to express empathy and support autonomy, which promotes rapport between the coach and the participant. Glaucoma coaches will participate in three practice sessions for each of the three SEE Program sessions and one for each follow-up phone call (13 total practice sessions) and attain competence in motivational interviewing before coaching participants.

Intervention design considerations

The intervention's custom-built web-application was created using user-centered design, with content iteratively improved based on participant feedback.[21] The content is displayed on a tablet, and based on interviewed glaucoma patients' preferences, a trained staff member walks participants through the content.[21] The trained staff member also teaches eye drop instillation. The coaches help participants generate a daily medication schedule that is tied to daily routines as this has been shown to improve adherence.[27] Coaches help participants generate questions for their ophthalmologists, as generating question lists has been shown to improve engagement in care.[33] The cadence of the coaching sessions is based on the usual frequency of visits for those with uncontrolled glaucoma which varies from 1 to 4 months based on disease severity, so we chose to have coaching sessions every 2 months. Although glaucoma self-management is not currently reimbursed, as was the case for diabetes self-management training, which is now reimbursed, generating evidence for which types of interventions successfully improve medication adherence could lead to insurance reimbursement.

Recruitment and randomization

Patients with a diagnosis of any kind of glaucoma, suspected glaucoma, or ocular hypertension, taking $\geqslant 1$ ocular hypotensive medication, with poor self-reported medication adherence,[34] and who are $\geqslant 18$ years of age are eligible. Exclusion criteria include Non-English speaking; A diagnosed serious mental illness (defined as schizophrenia, bipolar disorder, or a major depressive episode with psychotic features); Diagnosed cognitive impairment; Do not instill their own eye drops; Laser or incisional glaucoma surgery within the last 3 months or scheduled during the 6-month study period; Active uveitis or ocular infection; Participated in the SEE Program pilot study; and Unable to attend all study visits. Men and women will be recruited equally with an oversampling of Black participants to ensure at least 25% representation.

Potential participant contact information is extracted from the electronic health record based on meeting inclusion criteria. A letter is sent enabling participants to contact the study team to opt out of

Table 1. Study timeline with participant assessment measures.

Participant measures	Baseline	6 months exit visit	12 months post-program
Demographics: age, sex, race, ethnicity, education, income, and self-reported visual function	X		
Medical: glaucoma medications, medical co-morbidities, visual acuity, severity of reliable visual field within 1 year	X		
Self-reported medication adherence	X		
Outcome variables			
Electronically monitored glaucoma medication adherence within specified time windows	X (begin monitoring)	X	
Medication possession ratio for glaucoma medications from pharmacy data	X	X	X
Video recording of eye drop instillation scored for success[39]	X	X	
Glaucoma related distress scale[36,40]	X	X	
Glaucoma knowledge scale[41]	X	X	
Perceived competence scale to self-manage glaucoma[42]	X	X	
Treatment self-regulation scale to measure autonomous motivation to manage glaucoma[43]	X	X	
Glaucoma eye drop medication self-efficacy scale[44]	X	X	
Health care climate questionnaire to measure perceived autonomy support from the eye care team[45]	X	X	
Intraocular pressure[a]	X	X	
Quantitative and qualitative program evaluation[b]		X	

[a]Intraocular pressure is also measured for intervention participants at the three in-person coaching visits.
[b]Quantitative and qualitative program evaluation will be conducted with intervention participants only.

phone-based recruitment. All remaining potential participants are contacted via phone call to confirm eligibility and study interest. Research associates call potential participants and obtain verbal consent for a survey assessing self-reported medication adherence to determine study eligibility. Self-reported medication adherence is measured from a single question asking, "Over the past month, what percentage of your drops do you think you took correctly?" Those who self-report $\leqslant 85\%$ adherence are invited to participate in the study, and those interested are scheduled for a baseline visit.[34] After baseline assessment, participants are given their randomization assignment: SEE Program (intervention) or enhanced standard care (control). Block randomization using blocks of varying sizes (2, 4, and 6) and stratified by site is used to allocate participants to the intervention or control groups with consistent balance.

Recruitment choice considerations

We chose to include only participants with poor self-reported medication adherence. Self-reported adherence of $\leqslant 85\%$ on our single-item question maximized Youden's J statistic for optimization of the sensitivity/specificity of electronically monitored adherence being $<80\%$ in our pilot data.[34] People with glaucoma who are $<80\%$ adherent to their glaucoma medications have a much higher probability of having severe visual field loss[9] and thus will gain clinical benefit from improving their adherence. One limitation of this approach is that some people with poor medication adherence may not report a low metric due to social desirability bias.[35] We thus may exclude some participants who might be eligible for and benefit from the intervention. If electronic medication adherence monitoring becomes more affordable and widespread or prescription fill data become more affordable and available in real time, participants with poor adherence may be easier to identify more objectively in the future.

Outcomes

Our primary outcome, electronically monitored medication adherence, will be assessed with medication monitors from the baseline visit through the exit visit 6 months later. Our secondary outcome is glaucoma-related distress, a measure of difficulties from living with a chronic condition and an important patient-centered outcome measure for glaucoma care.[36,37] Our exploratory outcome is intraocular pressure measured with an iCare tonometer (Tiolat Oy, Helsinki, Finland) that does not require corneal anesthesia but correlates well with gold standard intraocular pressure measurement by Goldmann applanation tonometry.[38] We will obtain three measures of intraocular pressure at each study visit and use the median as the study visit value. We will also collect demographic, medical, and psychosocial data to inform mediator and moderator analyses. At the exit visit, all intervention participants will complete a quantitative program evaluation as well as undergo an exit interview to give qualitative feedback about the SEE program. See Table 1 for details.

In addition to participant measures, we will assess glaucoma coach fidelity to motivational interviewing coaching. The MI trainer reviews a random sample of 10% of all coaching sessions, stratified by glaucoma coach. The trainer uses the modified One Pass grading system, a rubric with 17 items that assesses fidelity to motivational interviewing coaching techniques and has been adapted for the SEE Program.[46] If a glaucoma coach is not meeting One Pass criteria, motivational interviewing supervision levels will be increased to meet motivational interviewing competence.

Outcomes choice considerations

Measuring adherence to eye drop therapy is complex and consists of assessing whether the patients obtained prescribed medication, instilled the medication within the specified time window and successfully instilled the eye drop medication.[47] Electronically monitored adherence is considered the gold standard in assessing medication adherence, but has some limitations. It only tells us whether the medication was obtained and instilled within the prescribed time window. In addition, it has high expense at an approximate annual cost of US$1210 per patient for a single medication.[48] To estimate pre-trial adherence as well as assess longer term adherence after intervention completion, we will collect pharmacy refill data.

To ensure that participants are receiving the intervention as conceptualized, fidelity to motivational-interviewing-based coaching is continuously assessed. If a coach is not meeting criteria, additional supervision is given, with the amount of supervision each coach needs over the trial tallied. One potential failure point for behavioral health interventions that are successful in a trial setting is in how the quality of the intervention is maintained in clinical practice. Building in a way to assess and remediate lower quality coaching will be important for scaling the program.

Data analyses

Sample size considerations. To inform our sample size calculations, brief interviews were conducted with 25 US glaucoma specialists nationwide to gauge expert opinion regarding clinically important effect size for glaucoma medication adherence. Their average recommendation for difference in-group mean medication adherence was 17.7 percentage points.[49] Mean medication adherence increased by 21 percentage points in the SEE Program pilot study from 59.9% (+ 18.5) at baseline to 81.3% (+ 17.6) during the program.[22] With 97 participants in each group, a *t*-test has 80% power to detect a difference as small as 8 percentage points in mean adherence between the two groups if the within group standard deviation is 20 (effect size = difference in means/standard deviation = 8/20 = 0.4, calculated using R "pwr" package).

Primary outcome: medication adherence. We assess medication adherence in three ways. Prior to trial enrollment, medication adherence is assessed by self-report. Participants' glaucoma medication refill information is collected from pharmacies for the 6 months prior to enrollment, during the trial itself and for 12 months after intervention completion. During the trial, medication adherence is assessed via the gold standard of electronic medication monitoring (AdhereTech, New York, NY, USA). Each glaucoma medication eye drop bottle is placed inside the electronic monitors that look like pill bottles. When the monitor cap is removed to access the glaucoma medication, this is considered a "use event" and the time and date stamp is sent via the cellular data network in real time, then aggregated and sent to the study database daily.

An adherent event is defined as using an eye drop medication within a specified time window of a dose on the previous day. For example, for an eye drop medication dosed once per day, an adherent event is defined as taking the medication within 24 ± 4 h of the previous day's single dose with a 3-h window for twice daily dosed medications and a 2-h window for three times daily medications.[21] This dosing window is discussed with all participants to ensure they understand the importance of timing. We compare the current day's doses to the previous day's corresponding doses, ensuring that opening a bottle multiple times does not inflate the adherence metric. Adherence is calculated as the proportion of doses taken on time divided by total doses prescribed over the 6-month study period. Adherence is first measured at the medication-level and then aggregated to the person-level.

We will perform intent-to-treat analysis and per-protocol analysis of all randomized participants. We will compare the primary outcome variable, electronically monitored medication adherence, between the treatment and control groups using analysis of variance (ANOVA), blocking on clinic. We will also analyze the proportion of subjects achieving ⩾80% adherence between the treatment group and control group, with the Cochran–Mantel–Haenszel test for equality of proportions. We will use Student's *t*-test on post-trial, 12-month medication possession ratios to assess long-term effects of the SEE Program compared to enhanced standard care. In addition, we will use pre-trial medication possession ratios from the pharmacy refill data and self-reported adherence in analysis of covariance (ANCOVA) to investigate whether treatment effectiveness is steady across different levels of pre-trial adherence.

Secondary outcome: glaucoma related distress. For our secondary outcome, with 97 participants per arm, we can

detect a 1.1-point difference in mean change in Glaucoma Related Distress (scale range 6–18) between groups if the standard deviation is 2.8, as it was in our preliminary data. We will score the scale according to the measure's documentation at the baseline and exit visits and calculate change. Descriptive statistics and plots will be generated to understand the distribution of scores and change, overall and stratified by treatment group and clinic. The exit glaucoma-related distress score will be regressed on treatment group, adjusted for baseline glaucoma-related distress and clinic.

Exploratory outcome: intraocular pressure. For our exploratory intraocular pressure outcome, we can detect a 1.9-mm Hg difference in mean change between groups if the standard deviation is 4.6 mm Hg, as it was in our preliminary data. Exit intraocular pressures will be analyzed using measures from both eyes. The distribution of intraocular pressure will be assessed with descriptive statistics and plots. The effect of treatment on intraocular pressure will be assessed with a linear mixed regression model, adjusting for baseline values and clinic, and controlling for the correlation between eyes of a subject with a random subject effect.

Moderator and mediator analysis. The primary moderator of treatment effect (income) will be assessed with an interaction term added to a linear regression model of continuous medication adherence, adjusted for known confounders of adherence. Adjusted R^2 will be used to assess the discriminatory power of the model. The secondary moderators of interest, race and sex, will similarly be evaluated but with Bonferroni adjustment for multiple comparisons; significance will be attained at $p < 0.025$. Four proposed mediators of treatment effect on medication adherence (Figure 1), measured at 6 months, will be analyzed independently: Autonomy support;[45] Competence (glaucoma knowledge,[41] perceived competence,[42,43] and self-efficacy);[44] Autonomous motivation;[43] and Satisfaction with the SEE Program.[50] Mediator and outcome models will be constructed and combined[51–53] to measure the average causal mediation effects (i.e. indirect effects), average direct effects, and percent mediation. Models with multiple mediators will be considered, if necessary.

For the secondary moderator analysis, by oversampling African Americans to comprise 25% of the study population, we are powered to detect an increase of the R^2 by 4 percentage points (e.g. if the SEE program versus enhanced standard of care improves mean adherence from 60% to 70% in Whites and from 50% to 75% in African Americans, then the R^2 increase is 4%). For the mediator analysis, the planned sample size provides 80% power to detect mediation when the standardized difference between the mean of the mediator in the treatment group and the mean in the control group is 0.6 standard deviations with a partial correlation of the mediator and medication adherence of 0.25.

Analytic design considerations

Because there was 20% loss to follow-up in our pilot study, we will assume a similar rate of loss to follow-up in this trial. Studying conditions in which a person has to become motivated to maintain behavior change—such as smoking cessation, management of diabetes or managing glaucoma—will encompass people who are both ready and not ready to engage in behavior change, and some of those who are not ready may be more likely to drop out of the study. To account for this, we will enroll 115 participants in each group for a total of 230 participants.

Conclusion

More than 3 million people have glaucoma in the United States.[3] Their treatment relies on access to 23,000 ophthalmologists, 41,000 optometrists, and 48,000 ophthalmic technicians.[4] In light of projected shortages of ophthalmologists in the face of rising rates of glaucoma[6,7] it is essential to create a larger health care team that includes the 58,000 health educators in the United States to better support glaucoma patients with poor adherence.[8] Our study will test the model of using health educators trained as glaucoma coaches to provide personalized education and motivational interviewing counseling to improve glaucoma medication adherence. Should this model be successful, we will study barriers and facilitators to implementation to enable future widescale use.

Declaration of conflicting interests

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Trial registration

ClinicalTrials.gov Registration: NCT04735653

Supplemental material

Supplemental material for this article is available online.

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