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Michigan Screening and Intervention for Glaucoma and eye Health through Telemedicine (MI-SIGHT): Baseline Methodology for Implementing and Assessing a Community-Based Program

Paula Anne Newman-Casey, MD, MS[1,2], **David C Musch, PhD, MPH**[1,2,3,7], **Leslie M. Niziol, MA**[1], **Angela R Elam, MD**[1], **Jason Zhang, MD**[1], **Sayoko E. Moroi, MD, PhD**[1,3], **Leroy Johnson, MD**[4], **Martha Kershaw, MD**[5], **Jinan Saadine, MD, MPH**[6], **Suzanne Winter, MS**[1], **Maria A Woodward, MD, MS**[1,2]

[1]Department of Ophthalmology and Visual Sciences, University of Michigan, Ann Arbor, Michigan

[2]Institute for Healthcare Policy and Innovation, University of Michigan, Ann Arbor, Michigan

[3]Department of Ophthalmology, Ohio State University, Columbus, Ohio

[4]Hamilton Community Health Network, Flint, Michigan

[5]Hope Clinic, Ypsilanti, Michigan

[6]Centers for Disease Control and Prevention, Atlanta, Georgia

[7] Department of Epidemiology, University of Michigan School of Public Health, Ann Arbor, Michigan

Abstract

Purpose: To describe the methodology of the implementation and evaluation of the Michigan Screening and Intervention for Glaucoma and eye Health through Telemedicine (MI-SIGHT) Program.

Methods: The MI-SIGHT Program utilizes community engagement, telemedicine and health coaching to overcome key logistical and psychosocial barriers to glaucoma identification and care among underserved populations. The MI-SIGHT Program will be evaluated in two community clinics: Hamilton Community Health Network, a federally qualified health center in Flint, MI, and the Hope Clinic, a free clinic in Ypsilanti, MI. A Community Advisory Board including the research team and health care providers, administrators and patients from both clinics will guide program implementation. An ophthalmic technician at the community clinics will conduct screening tests for glaucoma and eye disease. The data will be transmitted via electronic health record to be reviewed by an ophthalmologist who will make recommendations for follow-up care. The ophthalmic technician will conduct a return visit to fit low-or no-cost glasses, help arrange follow-up with an ophthalmologist and provide education. Those diagnosed with glaucoma or

Corresponding author: Paula Anne Newman-Casey, MD, MS, University of Michigan, Kellogg Eye Center, 1000 Wall Street, Ann Arbor, MI 48105, Phone: (734) 763-6967, Fax: (734) 232-1957, panewman@med.umich.edu.

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suspected glaucoma will be randomized to standard education or personalized glaucoma education and coaching. Costs will be assessed.

Results: We hypothesize that the MI-SIGHT program will detect a higher prevalence rate of glaucoma than that found in the general population, improve upon presenting visual acuity, enhance vision-related quality of life and demonstrate that personalized glaucoma education and coaching improve adherence to follow-up care.

Conclusion: The MI-SIGHT Program may serve as a model for glaucoma screening and care in high-risk communities.

Precis

The Michigan Screening and Intervention for Glaucoma and eye Health through Telemedicine Program leverages community engaged research, telemedicine and health coaching to overcome key logistical and psychosocial barriers to improved glaucoma screening in underserved communities.

Keywords

community engaged research; glaucoma screening; telemedicine

Introduction:

In the United States (US) the number of people with glaucoma is expected to increase from the 2016 estimate of 2.9 million[1] to 4.9 million by 2030.[2] An estimated 50% of people with glaucoma are undiagnosed,[12,13] resulting in 2.5 million US citizens undiagnosed in 2030 if we continue to use current methods to screen and care for patients.Substantive racial disparities exist. African-Americans are three times more likely to have glaucoma,[3] four times more likely to be undiagnosed with glaucoma,[4] five times more likely to have unilateral blindness from glaucoma,[5] and two times more likely to have bilateral blindness from glaucoma, compared to Caucasians.[6] Worsening glaucomatous vision loss leads to steep declines in health-related quality of life and increased risk of falls and motor vehicle accidents.[7,8,9,10] The National Academy of Science, Engineering & Medicine (NASEM) has issued a call to action to make eye health a population health imperative and address disparities in order to minimize vision loss.[11] As a leading cause of US blindness, with evident disparities in prevalence and care, clinicians and scientists are focusing attention on improving glaucoma detection, diagnosis, and care.

The purpose of the Michigan Screening and Intervention for Glaucoma and eye Health through Telemedicine (MI-SIGHT) Program is to overcome key logistical and psychosocial barriers to glaucoma identification and care. The planned strategy is to implement a telemedicine-based glaucoma screening program partnering with trusted primary care-based community clinics that serve vulnerable, impoverished populations. We hypothesize that the MI-SIGHT program will reach and detect a higher prevalence rate of glaucoma than that found in the general population, improve upon presenting visual acuity, and enhance vision-related quality of life. We also hypothesize that integrating personalized glaucoma education and coaching during the telemedicine visit will improve adherence to follow-up care

appointments with an ophthalmologist compared to standard education. An economic evaluation of both the screening program and the Personalized Glaucoma Coaching program will be performed. The purpose of this manuscript is to detail the the methodology for the MI-SIGHT program evaluation.

Methods

Regulatory Approval

This study was reviewed and approved by the UM Institutional Review Board (HUM00169371) and is registered at Clinicaltrials.gov (NCT04274764) and adheres to the Tenets of the Declaration of Helsinki.

Data Collection

Recruitment sites: Participants will be recruited from two trusted community-based health care facilities, the Hope Clinic, a free clinic in Ypsilanti, MI and the Hamilton Community Health Network, a Federally Qualitifed Health Center in Flint, MI, each who have served their communites for 37 years. Study coordinators will contact patients that have an upcoming appointment to assess interest in participating. Walk-ins and referrals from primary care clinics at Hope and Hamilton will be encouraged. Community members will be recruited using brochures and flyers displayed at the clinics, local churches, and public buses that include study contact information (https://sightstudiesdemo.wesdemo.com/about/university-of-michigan/).

Eligibility Criteria: Participants ≥ 18 years of age will be eligible. Exclusion criteria include: 1. Significant eye pain (likert scale ≥ 8 out of 10); 2. Sudden decrease in vision within 1 week; 3. Binocular diplopia; 4. Cognitive Impairment; 5. Pregnancy; 6. Incarceration; or 7. Moving outside of driving distance to the clinic within 6 months. We will emphasize the recruitment of persons with diabetes mellitus, African-Americans > 40 years, Latinos > 60 years, Caucasians > 65 years, and persons from all ethnic backgrounds with a family history of glaucoma.

Enrollment: Following confirmation of study eligibility, study coordinators will provide informed written consent to participants. The Hope Clinic serves a population where approximately 50% of patients do not speak English and there is no majority second language spoken. Therefore, we will provide full consent forms in English, Spanish, and Arabic, and short form consents in Albanian, Chinese, French, Hindi, Korean, and Tagalog.

Visit 1: Baseline Eye Screening (Table 1)

Assessments: During the initial visit, participants will complete a health and demographic survey, a needs assessment (assessing whether a person needs assistance for adequate food or housing, or identifying a primary care physician), and the National Eye Institute Visual Function Questionnaire-9.[16] Non-English speaking participants will complete the survey with translation support from their English speaking family member/friend attending the appointment. English speaking participants will be asked to complete a Timed Up & Go test, [19] a fall history to assess fall risk, and a Social Determinants of Health survey that includes

the following instruments: Everyday Discrimination Scale (Cronbach's alpha = 0.88),[20] Perceived Stress Scale (Cronbach's alpha = 0.86),[21] UCLA Loneliness Survey (Cronbach's alpha = 0.84),[22] and Flint Water Crisis Lead Exposure Questionnaire (Appendix A).

Ophthalmic Technician Assessment: The ophthalmic technician will then complete the following activities with the patient: 1. Health history; 2. Presenting visual acuity assessment at distance (Snellen acuity with current correction, if any); 3. Refraction measurements (ARK- Autorefractor & Keratometer, Marco Opthalmic, Jacksonville, FL) and refinement with subjective refraction with a table-clamped phoropter; 4. Contrast sensitivity (Pelli-Robson Letter Sensitivity Chart[23]); 5. Eyeglass evaluation including inter-pupillary distance (Essilor Digital Pupilometer, Essilor, Chicago, IL); 6. Eye examination including pupillary response, anterior chamber angle assessment by penlight, extraocular motility and alignment, and intraocular pressure (IOP) measurement (iCare tonometer, Raleigh, NC); 7. Dilation with 0.5% tropicamide only[24] for those without a narrow angle on penlight exam[25] and IOP less than 30 mmHg to mitigate the potential risk of acute angle closure; 8. Mydriatic imaging of the posterior pole by fundus photography (three images focused on the disc, the macula, and the superotemporal arcade[26]) and Retinal Nerve Fiber Layer Optical Coherence Tomography (RNFL OCT) (Topcon, Oakland, NJ). Examination data will be directly entered into the participant's Electronic Health Record (EHR) (EPIC, Verona, WI).

Selecting Free or Low-Cost Eyeglasses: After the examination, ophthalmic technicians will help participants who need eyeglasses select low-cost ($12-$50, ZenniOptical.com) eyeglass frames. The technicians will place the on-line order after the ophthalmologist confirms the eyeglasses prescription remotely, and the glasses will be shipped to the clinic. Following completion of the baseline visit, a follow-up appointment will be scheduled within 4–8 weeks.

Emergent or Urgent Ophthalmic Care: If a participant requires urgent or emergent ophthalmic care, a Univerity of Michigan (UM) ophthalmologist and either the ophthalmologist at the Hamilton Clinic or the Medical Director at the Hope Clinic will be paged and ensure that the participant is offered appropriate care. The social workers at each clinic will help arrange urgent transportation if needed. All participants will be advised to return to the clinic should they experience decreased vision, headache, or nausea following dilation. The ophthalmic technician will re-measure IOP for any participant who returns with a concern following dilation. If the IOP is >21mmHg and has risen >5mmHg from their baseline IOP, urgent care will be offered.

Ophthalmologist Remote Review of Examination: The remote ophthalmologist at UM will review the EHR within 4 business days of the participant's baseline MI-SIGHT visit. All images for review will be stored in the UM Ophthalmic Imaging Platform (CONTINUUM PACS, Integrated Ophthalmic Systems Inc., Woburn, MA). The remote ophthalmologist will assess whether the following vision and eye diseases are present or absent using a template in the EHR: visual impairment (BCVA ≤20/40 in the better seeing eye), refractive error, cataract, glaucoma, macular degeneration, and diabetic retinopathy. For refractive error, the ophthalmologist will refer for gonioscopy for hyperopia >5.0D, refer for topography for

astigmatism >3.0D with inability to refract to 20/20, and refer for peripheral retinal exam for myopia >−5.0D. The ophthalmologist will assess any signs of cataract as requiring or not requiring referral for surgical consultation. Glaucoma or suspected glaucoma will be assessed by the ophthalmologist using the following criteria:[26] 1. Narrow angle on penlight exam; 2. Patient previously treated for glaucoma (e.g. already taking glaucoma medications or previous glaucoma surgery); 3. Cup-to-disc ratio ≥ 0.7;[27] 4. Asymmetry of the cup-to-disc by ≥0.2 where the larger cup is ≥0.6;[27] 5. Abnormal OCT (overall RNFL thickness <80 microns or thinning at <1% certainty (RED-damaged tissue) in the inferior or superior quadrants);[28,29] 6. IOP > 21 mmHg, interpreted according to Table 2.

The ophthalmologist will use their clinical judgement to determine whether the participant's diagnosis is glaucoma or glaucoma suspect. The ophthalmologist will grade macular degeneration using the Age-Related Eye Disease Study (AREDS) criteria[30] and grade diabetic retinopathy and the presence of macular edema using the National Health Service criteria.[31] Any other eye disease will be noted in the EHR. The ophthalmologist will designate the appropriate follow-up interval and type of ophthalmic care and send a template letter to the PCP with the findings. (Appendix B).

Visit 2: Return Visit with Ophthalmic Technician (30–60 days) (Table 1)

Participants without Eye Disease : If the participant has no need for eyeglasses and has no eye disease, the ophthalmic technician will cancel the follow-up appointment. During the follow-up phone call, a three-item Satisfaction Survey[32] will be administered. If the participant cannot be reached by phone after three attempts, they will be given this information at their scheduled follow-up appointment. Participants without eye disease that need glasses will return for their follow-up appointment to have their glasses adjusted and complete the Satisfaction Survey.[32]

Participants with Eye Disease: The ophthalmic technician will review the screening results with the participant, provide and explain the ophthalmologist's diagnosis and recommendations, assist in scheduling a follow-up visit, and adjust the participant's eyeglasses. The ophthalmic technician will provide educational material to participants to explain their diagnos(es), using existing educational materials prepared at less than 8th grade reading level for the most frequent 300 ophthalmologic diagnoses in our UM clinics, following Centers for Disease Control Guidelines for Clear Communication.[33] (UM Health System Patient Education Clearinghouse at https://pteducation.med.umich.edu/kellogg). The ophthalmic technician will offer follow-up care that is scheduled with a provider the participant says they can afford through the Hope Clinic, Hamilton Clinic, and UM where low-cost and no-cost care is available. Participants will be asked to complete the Satisfaction Survey[32] at the end of the visit. For those who do not return for their follow-up visit, a letter will be sent indicating their diagnosis and any follow-up care needed (Appendix B). The study team will call the patient to re-schedule the follow-up visit and three attempts will be made to reach the patient for two additional weeks.

Participants Included in the Personalized Glaucoma Coaching Program Trial: At Visit 2, patients with a diagnosis of glaucoma or glaucoma suspect who speak English will be

included in the randomized controlled trial (RCT) of Personalized Glaucoma Coaching. As the Personalzied Glaucoma Coaching program is available only in English, Non-English speaking patients will be excluded. The counseling session is supported by an eHealth tool that generates personalized content based on the participant's name, age, and screening results (demo available at https://www.glaucomaeyeguide.org, under the "View Follow-Up Coaching Session" link). The personalized counseling and education program will be delivered by a glaucoma coach trained in glaucoma-specific motivational interviewing.[34]

Randomization Process: Trial participants will be randomized in a 1:1 ratio to one of two treatment arms (standard glaucoma education [control] or Personalized Glaucoma Coaching [intervention]). Randomization will occur when the participant returns for their follow-up visit with the ophthalmic technician (Visit 2). A web-based software system, the Treatment Assignment Tool University of Michigan (TATUM), will be utilized to randomize participants. The randomization will be stratified by clinic site, utilize variable block sizes to avoid potential prediction of the next enrollee's assignment, and assure balanced assignment to the treatment arms throughout the study. Assignments will be conveyed to the ophthalmic technician via the TATUM system.

Personalized Glaucoma Coaching Program: The web-based application for the Personazlied Glaucoma Coaching program has two components woven together into a single tool to support the conversation between the participant and the glaucoma coach: 1. an electronic health (eHealth) component and 2. a semi-structured, tailored interview guide to facilitate a motivational interviewing-based conversation. The eHealth component provides an individually tailored explanation of a participant's MI-SIGHT glaucoma test results, what risk the results pose for the participant's vision if untreated, and what risks a participant's family members may have of developing glaucoma. The coach uses the web-based application on a computer tablet, to share engaging audio-visual content about glaucoma and how it can affect vision if it goes untreated. The coach uses a motivational-interviewing based approach to elicit an understanding of what motivates that participant to maintain their vision, and explores what unique obstacles the participant has to engaging in follow-up care. The coach then assesses the participant's motivation to attend the follow-up appointment, and with the participant's input creates an action plan that delineates the short-term steps the participant will take to address any identified barriers to follow-up care.

As the coach walks the participant through the program, the coach helps participants create a list of questions for the ophthalmologist to prepare for their upcoming visit. Research has identified that African-Americans are often less active in asking questions of health care providers,[35] so supporting question-asking during medical visits is a key modifiable patient engagement behavior. Creating a question prompt list for participants can improve information recall after the doctor visit, reduce patients' anxiety about the visit, and improve self-efficacy for question-asking.[36] At the end of the visit, the coach will print out three documents: 1. The participant's written action plan with the time and location of their ophthalmology appointment; 2. A list of questions for the ophthalmologist; 3. Login information to access their education plan remotely if desired.

Glaucoma Specific Motivational Interviewing (MI) Training: The glaucoma coach will attend a 2-day training program in glaucoma-specific MI previously developed by the study team.[37] The program focuses on teaching five core skills of MI: 1. Asking open-ended questions; 2. Affirming; 3. Reflecting; 4. Summarizing; and 5. Asking permission to provide information and advice. These communication skills help counselors elicit and strengthen a participant's own motivation for behavior change. In this case, the behavioral goal is attendace at a follow-up appointment. The program also teaches the coach how to express empathy, which is the key component that underlies the spirit of MI and promotes rapport between the counselor and the patient. After the initial training, the glaucoma coach continues to receive supervision from an MI trainer. The MI trainer will provide weekly supervision for the glaucoma coaches for the first 6 weeks of the MI-SIGHT Program, and then bi-weekly.

Maintaining Fidelity to Treatment Assignment: All counseling encounters for intervention participants and education encounters for control participants will be audio-recorded. The MI trainer will assess a random sample of ≥10% of encounters for fidelity to MI-based counseling and treatment assignment. The MI trainer will be masked to treatment allocation and assess each encounter according to the modified One Pass grading system, a rubric that assesses fidelity to MI counseling techniques.[38] The MI trainer will go over these audio-recorded sessions with the glaucoma coach in their supervision sessions.

Post-Education/Counseling Assessments: Immediately after their respective education sessions, participants in both the control and intervention groups will be asked to complete a survey that includes the following instruments: 1. National Eye Institute Glaucoma Eye-Q test[39] to assess glaucoma knowledge; 2. Satisfaction with Information Scale;[40,41] 3. Clinician and Group Survey of the Consumer Assessment of Healthcare Providers and Systems (CG- CAHPS) questions assessing satisfaction with provider communication;[42] 4. Confidence in Question Asking, which will be assessed with the following question "How confident are you in your ability to know what questions to ask the ophthalmologist?" and will have responses ranging from 1–10 on a Likert scale where 1 is "not confident at all" and 10 is "extremely confident;" 5. Satisfaction Survey.[32] All participants will be provided support for scheduling their follow-up exam with an ophthalmologist within the recommended time frame.

Intervention Group Follow-Up Support: For the intervention group, the glaucoma coach will make at least 3 attempts to contact the participant by phone before their ophthalmology follow-up appointment. During this phone call, the glaucoma coach will remind the participant of their appointment time, asses motivation and confidence in attending the visit and elicit possible obstacles. The coach will help the participant brainstorm possible solutions to identified obstacles and end the conversation by summarizing a new action plan. If needed, the coach will call again to check-in about any outstanding problems. Participants can contact the coach for additional help.

Visit 3: Repeat Eye Screening for Participants Screened in Year 1 (Table 1): Participants enrolled in the MI-SIGHT Program during the first year will be invited back for repeat

screening 2 years later to assess change in vision and vision-related quality of life using the National Eye Institute's Visual Function Questionnaire-9.[16] Participants will go through the same protocol as described for Visit 1 and Visit 2 above, except that if they are newly diagnosed as having glaucoma or suspected glaucoma, they will not be included in the RCT of Personalized Glaucoma Coaching so as not to enroll the same participant twice.

Data Processing

A custom REDCap database, a Health Insurance Portability and Accountability Act (HIPAA) ompliant web-based software system that permits authorized users to view data in real-time, was built for the MI-SIGHT study. Participants will enter survey and demographic data directly into the REDCap database via a computer tablet. All other study data, including ERH data, will be entered directly into REDCap by the research staff. Additionally, double data entry will occur on all data entered by research staff. Any discrepancies found will adjudicated. The REDCap database elements will be archived and stored on HIPAA-secure storage (MiStorage) at the UM.

Data Analysis

Qualitative Analysis

Objective 1: Use community-engaged research strategies to (a) overcome key logistical and psychosocial barriers to accessing glaucoma care for uninsured and under-insured adults, (b) solidify a trusting partnership between the UM, the Hope Clinic, and the Hamilton Community Health Network through the creation of a Community Advisory Board (CAB), and (c) develop a sustainable telemedicine model for glaucoma screening and care in community clinics.

A CAB will be formed that includes key stakeholders from the community clinics including clinicans, administrators, staff and patients. CAB members and additional stakeholders from each clinic will be interviewed to identify the best ways to implement the telemedicine based glaucoma screening proram; all interviews will be audio-recorded and transcribed verbatim. Transcripts will be investigated for major themes using grounded theory, which uses inductive reasoning to categorize data (Dedoose, 8.3.17m Los Angeles, CA). Themes will be interpreted to bring nuanced understanding to what the optimal implementation for the glaucoma care program would look like. Results will be discussed at the quarterly CAB meetings to inform program implementation.

Statistical Analysis

Objective 2: Assess the prevalence of glaucoma and other vision-threatening diseases (refractive error, cataract, diabetic retinopathy, macular degeneration) in two high-risk communities. Assess the impact of the SIGHT program on presenting visual acuity and vision-related quality of life two years after participating in the program. Assess the relationship between social determinants of health and eye care utilization.

Prevalence of glaucoma and glaucoma suspect diagnoses will be calculated as follows: the number of glaucoma diagnoses or glaucoma suspect diagnoses (numerator) divided by the total number screened (denominator). Prevalence (with 95% Wilson confidence interval) of

glaucoma and glaucoma suspect will be reported overall, by site, and by program year. Prevalence of other conditions (refractive error, cataract, diabetic retinopathy, and macular degeneration) will be similarly calculated.

The subset of patients with initial screening and 2-year follow-up screening will be identified. Incident disease (with 95% Wilson confidence interval) will also be estimated by assessing the number of new cases of eye disease among the disease-free participants screened in the first year who returned for repeat screening in the third year. Disease incidence will be associated with demographics and analyzed using chi-square tests, t-tests, and logistic regression. The results of the logistic regression models will be presented with odds ratios and corresponding 95% confidence intervals.

The National Eye Institute Visual Function Questionnaire-9 (NEI VFQ-9) will be scored as described in prior work by Kodjebacheva and colleagues.[16] The composite score will be summarized as a continuous variable. Two-year change from baseline in NEI VFQ and visual acuity will be analyzed using the paired t-test. Differences in demographic characteristics between subjects who returned for 2-year follow-up screening and those who did not will be tested with Student's t-tests, chi-square tests, and non-parametric tests as appropriate. Linear regression models, ANOVA tests, and Student's t-test will be used to assess relationships of the baseline composite score with demographics and baseline disease status. Differences in demographic characteristics and social determinants of health will be explored between those whose last eye exam was >2 years prior and within the last two years using Student's t-tests, chi-square tests, non-parametric tests, where appropriate, and logistic regression analysis.

Objective 3: Assess the impact of a personalized glaucoma coaching program on adherence to follow-up recommendations among those diagnosed as glaucoma suspects or as having glaucoma compared to standard education through an RCT.

The primary outcome of the RCT, attendance to follow-up appointment with a glaucoma specialist within three months, will be summarized with frequencies and percentages by intervention and control groups, overall and stratified by site and will be quantified by the odds ratio (OR) comparing the intervention group to the control group. If the site specific ORs are similar, the common OR will be estimated and tested by the Cochran-Mantel-Haenszel test. The interaction between intervention and site will be investigated. Further logistic regression models will be used to investigate the effect of other factors on the probability of attending follow-up with a glaucoma specialist such as sex, age, race, household net income, distance from appointment location, household income, and visual acuity.

Objective 4: Assess the cost of the screening program per case of glaucoma detected and per case of eye disease detected. Assess the cost of the coaching program per ophthalmologist visit attended.

The cost per case of detected glaucoma and glaucoma suspect disease will require summing all associated program costs (start-up costs for equipment and the annual costs for personnel

and supplies, including the costs of personal protective equipment) and dividing by the number of glaucoma and suspected glaucoma cases. We will use proxy average wage and fringe benefit rates from the Bureau of Labor Statistics to assess staff costs. Cost per case detected will also be stratified by site and divided by the number of years the program was run at each site to estimate the yearly program cost per case detected at each site. Cost per case for all ophthalmic conditions detected in total and in categories (visual impairment, refractive error, cataract, diabetic retinopathy, and age-related macular degeneration) will be summarized similarly.

We will assess the costs to train and supervise the ophthalmic technician to deliver MI-based counseling. We will log the total number of minutes the counselor spends with participants both in-person and over the phone as an estimate of personnel cost to the education and counseling intervention. If the intervention improves follow-up adherence, we will calculate the cost of the intervention per participant who adheres to follow-up recommendations.

Power Calculation: Approximately 5,000 patients access the Hope Clinic per year and 25,000 patients access the Hamilton clinic per year; approximately 20% are new patients annually (80% return patients). A typical day for each technician will include 5 screenings (60 minutes each) and 5 one-month follow-up visits (30 minutes each). Full capacity for enrollment at both sites is 7320 new screenings and 1440 re-screenings. Operating at 80% capacity enrolls 5800 patients for new screenings and 1100 patients for 2-year re-screenings to determine impact on longer term visual acuity and visual function. Based on the anticipated sample size (n=5800), the standard error is at most 1.3 percentage points for the overall prevalence (but could be larger for annual and by-site estimates). The paired-sample t-test has over 80% power to detect a difference in vision-related quality of life and visual acuity (n about 1000) between baseline and two years of follow-up of even just 0.1 standard deviation.

Due to the impact of COVID-19, we have re-estimated anticipated enrollment in the MI-SIGHT Program and given power estimates for each of four different scenarios, where recruitment time is truncated to the worst-case scenario of 2 years at the Hope Clinic and 3 years at the Hamilton Clinic and enrollment per day is decreased to 4 new participants to maintain social distancing. Even with these restrictions (Table 3), we will be able to enroll 3,379 participants and re-screen 960 particpants. This sample size would give us the power to detect the overall prevalence of glaucoma and suspected glaucoma with a standard error of 1.7 percentage points and over 80% power to detect a difference in vision-related quality of life and visual acuity between baseline and two years of follow-up of 0.096 standard deviations. With the most stringent timeline, we would reduce the follow-up duration to one year.

To estimate the necessary sample size for the Personalized Glaucoma Coaching Program RCT, we utilized the fact that our baseline no-show rate is approximately 20% at the Hope Clinic free eye clinic. To detect a 50% improvement (i.e., from 20% to 10%) in the no-show rate, we would need (with alpha=0.05 and power=80%) to enroll n=200 people to each treatment arm for 400 total participants. We estimated recruitment rates for the different

enrollment scenarios (Table 3) under the assumption that the rate of glaucoma and glaucoma suspect detected would be 12% (4% prevalence for glaucoma and 8% prevalence for glaucoma suspect) - double the national average in our high-risk sample, which is a conservative estimate.[15] With the lowest enrollment scenarios we would have between 405 and 675 participants eligible for the RCT in our sample. (Table 4)

Expected Outcomes

We anticipate creating a CAB to serve as the steering committee and communication platform for MI-SIGHT Program implementation and evaluation. The following four outcomes are expected: 1. To develop and implement a model for a comprehensive tele-health glaucoma screening in community clinics, and assess its cost; 2. To have two ophthalmic technicians who are community members fully trained and equipped to manage the local screening program; 3. To establish and evaluate an eHealth- supported personalized glaucoma coaching program on adherence to follow-up recommendations after screening; and 4. To identify methods to sustain the MI-SIGHT program in the two community clinics through the work with the CAB.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1.

Study Activities

Procedures	Visit 1 Day 1	Visit 2 Day 30–60	Phone Contact Day 60–90	EHR Review Day 60–120	Visit 3 2-year Rescreen
Informed consent	X				X
Demographics	X				X
Medical history	X				X
Social Determinants of Health Survey *	X				X
Vision Screening/Refraction/IOP/CCT	X				X
Fundus Photography/OCT	X				X
Eyeglasses Ordered, if needed	X				X
Fit Eyeglasses		X			
Randomization **		X			
Standard or Personalized Education		X			
Satisfaction Survey		X			
Glaucoma Surveys **		X			
Phone reminder for follow up **			X		
Attended Ophthalmologist Appointment.				X	

* Only for English speaking study participants

** English speaking positive for glaucoma or glaucoma suspect

EHR, electronic health record; IOP, intraocular pressure; CCT, central corneal thickness; OCT, optical coherence tomography

Table 2.

Interpreting Intraocular Pressure in the MI-SIGHT Study

IOP Reading in Either Eye	Action
IOP 22–24 mmHg	■ Cup:Disc ratio <0.35 with heavy rim + no other risk factors, * no referral. ■ Cup:Disc ratio 0.4 to 0.65 other risk factors, * refer to eye clinic within 6 months. ■ Cup:Disc ratio ≥0.7, refer to eye clinic within 6 months.
IOP 25–29 mmHg	Refer to eye clinic within 1 month
IOP 30–40 mmHg	Refer to eye clinic within 1 week
IOP >40 mmHg	Refer to eye clinic within 24 hours or immediately

* other risk factors include positive family history of glaucoma, thin (<555 microns) central corneal thickness (CCT), OCT, cup-to-disc asymmetry of ≥0.2 where the larger cup-to-disc ratio is ≥0.6, rim thinning or focal notch, disc hemorrhage

Table 3.

Power Calculations Based on Variable Recruitment Plans due to COVID-19 Delay

Scenario	Recruitment Assumptions	Screenings	80%	Re-Screenings	Standard Error, Margin of Error*	Standard Deviation Difference Detected**
0	Hope: 5 NP/day for 3 years + 3 NP and 2 RS/day for 1 year Hamilton: 5 NP/day for 2.5 years + 3 NP and 2 RS/day for 1 year	7320	5856	1440	1.3, 2.6	0.073
1	Hope: 5 NP/day for 2 years + 3 NP and 2 RS/day for 1 year Hamilton: 5 NP/day for 2 years + 3 NP and 2 RS/day for 1 year	5760	4608	1440	1.5, 2.9	0.083
2	Hope: 4 NP/day for 3 years + 2 NP and 2 RS/day for 1 year Hamilton: 4 NP/day for 2.5 years + 2 NP and 2 RS/day for 1 year	6048	4838	960	1.4, 2.8	0.081
3	Hope: 5 NP/day for 1 years + 3 NP and 2 RS/day for 1 year Hamilton: 5 NP/day for 2 years + 3 NP and 2 RS/day for 1 year	5040	4032	1440	1.6, 3.1	0.088
4	Hope: 4 NP/day for 1 years + 2 NP and 2 RS/day for 1 year Hamilton: 4 NP/day for 2 years + 2 NP and 2 RS/day for 1 year	4224	3379	960	1.7, 3.4	0.096

*Standard error, margin of error for disease prevalence estimate

**standard deviation difference that a paired-sample t-test can detect with 80% power comparing re-screening visual acuity and vision-related quality of life to baseline values; NP, new patient; RS, re-screen patient

Table 4.

Estimated Prevalence of Glaucoma and Suspected Glaucoma in Various Recruitment Scenarios

Scenario	Recruitment Assumptions	Screenings	80%	12% glaucoma/glaucoma suspect	20% glaucoma/glaucoma suspect
0	Hope: 5 NP/day for 3 years + 3 NP and 2 RS/day for 1 year Hamilton: 5 NP/day for 2.5 years + 3 NP and 2 RS/day for 1 year	7320	5856	702	1,171
1	Hope: 5 NP/day for 2 years + 3 NP and 2 RS/day for 1 year Hamilton: 5 NP/day for 2 years + 3 NP and 2 RS/day for 1 year	5760	4608	552	921
2	Hope: 4 NP/day for 3 years + 2 NP and 2 RS/day for 1 year Hamilton: 4 NP/day for 2.5 years + 2 NP and 2 RS/day for 1 year	6048	4838	580	967
3	Hope: 5 NP/day for 1 years + 3 NP and 2 RS/day for 1 year Hamilton: 5 NP/day for 2 years + 3 NP and 2 RS/day for 1 year	5040	4032	483	806
4	Hope: 4 NP/day for 1 years + 2 NP and 2 RS/day for 1 year Hamilton: 4 NP/day for 2 years + 2 NP and 2 RS/day for 1 year	4224	3379	405	675

NP, new patient; RS, re-screen patient