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Manhattan Vision Screening and Follow-up Study in Vulnerable Populations (NYC-SIGHT): Design and Methodology

Lisa A. Hark, PhD, RD[1,2], **Yocheved S. Kresch, OD, MS**[1,2], **C. Gustavo De Moraes, MD**[1,2], **Jason D. Horowitz, MD**[1,2], **Lisa Park, MD**[1,2], **James D. Auran, MD**[1,2], **Prakash Gorroochurn, PhD**[3], **Stella Stempel, PhD, LCSW**[2], **Stefania C. Maruri, BS**[2], **Elizabeth M. Stidham, BS**[2], **Aisha Z. Banks, BA**[2], **Jinan B. Saaddine, MD, MPH**[4], **Bianca C. Lambert, MD, MS**[5], **Laura T. Pizzi, PharmD, MPH**[6], **Saloni Sapru, PhD**[7], **Simani Price, PhD**[7], **Olajide A. Williams, MD**[8], **George A. Cioffi, MD**[1,2], **Jeffrey M. Liebmann, MD**[1,2]

[1]Columbia University, Department of Ophthalmology, Vagelos College of Physicians and Surgeons, 630 W. 168th St., New York, NY 10032

[2]Edward S. Harkness Eye Institute, Columbia University Irving Medical Center, 635 W. 165th St., New York, NY 10032

[3]Department of Biostatistics, Columbia University Mailman School of Public Health, 722 W. 168th St., New York, NY 10032

[4]Centers for Disease Control and Prevention, Vision Health Initiative, Division of Diabetes Translation, National Center for Chronic Disease Prevention and Health Promotion, 1600 Clifton Road, Atlanta, GA 30329

[5]Montefiore Medical Center, Department of Surgery, 1055 E. Tremont Ave., Bronx, NY 10461

[6]Center for Health Outcomes, Policy, and Economics, Rutgers University, 160 Frelinghuysen Road, Piscataway, NJ 08854

[7]Westat, Public Health and Epidemiology Practice, 1600 Research Blvd., Rockville, MD 20850

[8]Columbia University, Department of Neurology, Columbia University Irving Medical Center, 710 W. 168th St. New York, NY 10032

Abstract

Purpose: To describe the study design and methodology of the Manhattan Vision Screening and Follow-up Study in Vulnerable Populations, which aims to investigate whether community-based vision screenings can improve detection and management of glaucoma, vision impairment, cataract, and other eye diseases among vulnerable populations living in affordable housing developments in upper Manhattan.

Corresponding Author: Lisa Hark, PhD, RD, Professor of Ophthalmic Sciences (Ophthalmology), Vagelos College of Physicians and Surgeons, Columbia University Irving Medical Center, Edward S. Harkness Eye Institute, 635 West 165th Street, Room 504, New York, NY 10032, lah112@cumc.columbia.edu.

Conflicts of Interest None of the authors have any proprietary interests or conflicts of interest related to this submission.

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Methods: This 5-year prospective, cluster-randomized, controlled trial consists of vision screening and referral for follow-up eye care among eligible residents aged 40 and older. Visual acuity, intraocular pressure (IOP), and fundus photography are measured. Participants with visual worse than 20/40, or IOP 23-29 mmHg, or unreadable fundus images fail the screening and are scheduled with the on-site optometrist. If IOP is ≥30 mmHg, participants are assigned as "fast-track" and referred to ophthalmology. Participants living in seven developments randomized to the Enhanced Intervention Group who fail the screening and need vision correction receive complimentary eyeglasses. Those referred to ophthalmology receive enhanced support with patient navigators to assist with follow-up eye care. Participants living in three developments randomized to the Usual Care Group who fail the screening and need vision correction are given an eyeglasses prescription only and a list of optical shops. No enhanced support is given to the Usual Care Group. All participants referred to ophthalmology are assisted in making their initial eye exam appointment.

Conclusion: This study targets vulnerable populations where they live to ensure improved access to and utilization of eye-care services in those who are least likely to seek eye care.

PRÉCIS:

The Manhattan Vision Screening and Follow-up Study in Vulnerable Populations is a 5-year prospective, cluster-randomized study to improve detection and management of glaucoma and other eye diseases in vulnerable populations living in affordable housing developments.

Keywords

Vision screening; Telemedicine; CDC; Glaucoma; Social determinants of health

INTRODUCTION

In the United States (US), glaucoma is the second leading cause of irreversible blindness and the leading cause of blindness in African Americans.[1,2] Given the rapidly changing demography of the US population, the prevalence of glaucoma is estimated to increase by 270% to 7.32 million persons.[3] Currently, New York State is reported to have one of the highest prevalence rates of glaucoma in the US.[4] Both *Healthy People 2020* and *2030* include objectives specifically aimed at reducing vision impairment due to glaucoma, diabetic retinopathy, age-related macular degeneration, cataract, and refractive error.[5,6] However, studies indicate that half of those with glaucoma are undiagnosed, and this rate is even higher among vulnerable populations.[7,8]

Risk factors for glaucoma include older age (65+ years), family history of glaucoma, ancestry (Black, African American, and Asian), and ethnicity (Hispanic).[9-11] Glaucoma is three times more prevalent in African Americans than in non-Hispanic whites.[12,13] African Americans develop glaucoma at a younger age, progress more rapidly, and are almost seven times more likely to go blind than non-Hispanic whites.[14] Approximately 4.7% of Hispanics have POAG, compared to 1.7% of non-Hispanic whites. Hispanics have the highest rate of undetected POAG at 75% (compared to 58% in African Americans and 50% in non-Hispanic whites).[13,15] In under-resourced communities, social determinants of health,

specifically healthcare access and utilization, poverty, housing, transportation, education level, insurance status, and employment rates contribute to these health disparities.[16]

Community eye care services can improve glaucoma detection by identifying and targeting those at highest risk and linking individuals to follow-up eye care.[17] However, previous community- or hospital-based glaucoma screenings in high-risk populations have yielded only marginal results.[18] Given that African Americans with or without adequate health insurance coverage are less likely than other groups to obtain eye exams, innovation is necessary to address the problem of access to and utilization of eye care and non-adherence to follow-up.[19,20]

Community health workers (CHWs) are knowledgeable frontline health personnel who typically come from the communities they represent and bridge cultural and linguistic barriers, expand access to coverage and care, and improve health outcomes.[21,22] In addition, patient navigators show promise as the missing link between available services and healthcare delivery in vulnerable populations.[23] Training ophthalmology staff to serve in the patient navigator role is beneficial because navigators can provide support by scheduling follow-up eye exams and directly addressing any barriers that inhibit attending these appointments.[24,25]

Therefore, the Columbia University Irving Medical Center Department of Ophthalmology designed a 5-year prospective, randomized, controlled trial to investigate whether community-based vision screenings can improve detection and management of glaucoma, vision impairment, cataract, and other eye diseases among vulnerable populations living in New York City (NYC) affordable housing developments in upper Manhattan. This paper describes the study design and methodology for the Manhattan Vision Screening and Follow-up Study in Vulnerable Populations (NYC-SIGHT) and how the protocol was amended during the COVID-19 pandemic.

MATERIALS AND METHODS

The study protocol, consent form, recruitment flyers and all data collection forms are developed in English and Spanish and approved by the Columbia University Irving Medical Center Institutional Review Board (IRB) (#AAAR9162) and all aspects of the study are conducted in accordance with the Declaration of Helsinki. Verbal informed consent is obtained from all participants prior to enrollment and the study is registered on ClinicalTrials.gov (NCT04271709).

Outcomes:

We plan to follow participants prospectively to evaluate the effects of an enhanced intervention using patient navigators on presenting visual acuity at 1-year (primary outcome), adherence to follow-up eye care and cataract surgery, and health-related quality-of-life (secondary outcome), falls risk and rates of falls (safety outcomes), and participants' satisfaction following on-site vision screenings and eye exams.

Community partners/Advisory Board:

Our primary community partners are New York City Housing Authority (NYCHA) and New York City Department for the Aging. The NYCHA owns and operates 326 public housing developments across NYC's five boroughs.

Target population:

The study targets NYC residents living in upper Manhattan, where a high number of potentially at-risk, vulnerable adults and seniors are living at or below the NYC.gov poverty measure.[25] The 10 NYCHA developments in Harlem and Washington Heights provide access to 6,640 vulnerable residents who live in close proximity to the Columbia University Harkness Eye Institute and Harlem Hospital Ophthalmology. These developments have a high proportion of men and women of diverse race/ethnicity with high rates of inadequate eye care.

Cluster-randomization by housing development:

A cluster-randomized design was chosen to prevent contamination. It would be impossible to provide vision screening and eyeglasses to only some residents living in the same housing development, as crossovers would be common and dissatisfaction in the comparison arm would be likely. The development cluster is therefore the unit of randomization and in order for more people to benefit from the enhanced intervention, a 2:1 randomization scheme was established.

Since there are 6,640 residents living in 10 housing developments, randomization accounted for size within each development. We first randomly selected the development for the Intervention Arm, which resulted in seven developments for Intervention (n=4447) and three developments for Usual Care (n=2193) (Table 1). Each housing development has 5 to 15 housing buildings where residents reside.

Enhanced Intervention versus Usual Care Groups:

Participants living in developments randomized to the Enhanced Intervention Group who fail the screening and need vision correction, receive complimentary eyeglasses. If they are referred to ophthalmology, they receive enhanced support with patient navigators to assist with all aspects of follow-up eye care over one year, specifically scheduling eye exam appointments and arranging transportation to these appointments and ocular surgery, if needed. Participants living in developments randomized to the Usual Care Group who fail the screening and need vision correction are given an eyeglasses prescription only and a list of optical shops. No enhanced support is given to Usual Care Group and those referred to ophthalmology are only assisted with making the initial eye exam appointment.

Recruitment:

A variety of recruitment methods are used to invite adults and senior residents to participate in on-site vision screening. English and Spanish IRB-stamped approved flyers, are distributed to all residents' apartments, posted in elevators and lobbies, sent via email

by NYCHA, and distributed during community and food donation events. Recruitment takes place over a 24-month period from October 2020 to September 2022.

Enrollment and Informed Consent

Verbal informed consent: Eligibility for enrollment is determined when NYCHA residents contact our call center, which is staffed by the study's research coordinators. Inclusion and exclusion criteria for study enrollment are shown in Table 2.

Informed consent: Residents who meet the study's inclusion criteria are consented in English or Spanish over the telephone by the bilingual study coordinators.

Study team and data collection: The trained vision screening team consists of patient navigators (four research coordinators and a research assistant), one community health worker (CHW), one ocular photographer, one optometrist, and two remote study ophthalmologists. Data are collected by the team over the phone and entered into a Research Electronic Data Capture (REDCap) database. After verbal informed consent is obtained, the following intake data are discussed:

Demographics and access to healthcare and technology: To assess social determinants of health, consented participants are asked over the telephone prior to the on-site vision screening about their date of birth, sex, race/ethnicity, education level, employment status, insurance status, preferred transportation, and computer/mobile device accessibility (technology). Best methods of contact including email, text, and telephone, are documented and permission to text and email are included in the informed consent form.

Ocular and Medical History, Vision-Related Quality of Life, and Falls Risk Assessment

Ocular and medical history: Consented participants are asked over the telephone prior to the on-site vision screening about their ocular and medical history, including ocular medications and family history of glaucoma and diabetes. The approximate time of their last dilated eye exam is captured and if they are currently under the care of an eye doctor.

Vision-related quality of life (VRQOL): Consented participants are administered the validated National Eye Institute-Visual Function Questionnaire (NEI-VFQ)-9 over the telephone prior to the on-site vision screening and at the 12-month follow-up visit to assess barriers and the influence of their vision impairment on their health-related quality-of life.[26] The NEI-VFQ-9 has been validated by a large prospective longitudinal cohort study, making it a feasible tool for large scale, community-based studies as it can be completed in less than five minutes.[27,28]

Falls risk assessment: Falls and injuries are a particular problem in visually impaired individuals and those diagnosed with glaucoma.[29,30] Participants are asked over the telephone prior to the on-site vision screening about feelings of unsteadiness when standing or walking, occurrence of falls in the past year, and subsequent emergency department visits or hospital admissions in the past year.

On-site Vision Screening Components

On-site vision screening begins in 2021 and is conducted 1-2 days per week, over a 24-month period in the community centers and senior centers. Vision screening consists of visual acuity, intraocular pressure (IOP) measurements, and fundus images. The definition of vision screening failure prompting referral to the on-site optometrist is shown in Table 3.

Visual acuity: Visual acuity is measured in all participants by a trained community health worker at the initial on-site vision screening and the 12-month follow-up visit with a Snellen eye chart at 20 feet while the participant wears their current eyeglasses (with correction). Any participant with a visual acuity worse than 20/40 in either eye fails the vision screening and is scheduled to see the on-site optometrist within 2 weeks.

Intraocular pressure (IOP): The IOP is measured in both eyes in all participants using the TA01I Icare® rebound tonometer (ICare, Helsinki, Finland). If IOP is ≥23 mmHg, a second IOP measurement is taken of that eye and the average of the two measurements are recorded. If mean IOP is 23-29 mmHg in either eye, the participant fails the vision screening and is scheduled to see the on-site optometrist within 2 weeks. If IOP is ≥30 mmHg, participants are assigned as “fast-track” and immediately referred to Harlem Hospital Ophthalmology, Columbia University Harkness Eye Institute, or their own eye care provider.

Fundus photography: Images are taken by a trained ocular photographer using the non-mydriatic, auto-focus, hand-held fundus camera (Volk Pictor Prestige, Volk Optical, Mentor, OH, USA).. In a darkened space, two non-dilated posterior fundus photographs of each eye are taken for an optimal two-dimensional view of the macula and optic nerve. Within 24 hours, the ocular photographer uploads these images to a HIPAA-compliant cloud-based database (Forum, Zeiss Oberkochen, Germany), which are read and graded by two study ophthalmologists specializing in retina and glaucoma and results are combined.

Grading of each eye includes the image quality of the optic nerve and retina (good, fair, poor, or unreadable) based on image features, specifically color, focus, contrast, and illumination.[31] Glaucoma findings for each eye include abnormal cup:disc ratio, asymmetric discs, and nerve fiber layer defect based on AAO *Practice Pattern Guidelines*®.[32] A comprehensive list of 50 retinal findings for each eye is used and examples include retinopathy, disc neovascularization, vitreous hemorrhage, microaneurysms, and macular edema.[32] Following image grading by the study ophthalmologists, an overall determination is made for each eye as 1) normal or abnormal without significant findings, 2) abnormal with significant findings, or 3) unreadable.

With asymmetric findings, the worse eye is used to categorize participants. Those with an unreadable image in the worse eye are scheduled to see the on-site optometrist within 2 weeks.

STEADI tests: Participants deemed a falls risk during the telephone assessment are administered the CDC’s Stopping Elderly Accidents, Deaths, and Injuries (STEADI) Tool Kit during the vision screening. These tests include the Timed-Up-and-Go (TUG) test,

the 30-Second Chair Stand Test, and the 4-Stage Balance Test, which assess the level of functional mobility and falls risk of participants.

On-site Optometrist Eye Exams at the Housing Developments

All participants living in both Enhanced Intervention and Usual Care developments who fail the vision screening are scheduled with the on-site optometrist for a non-dilated eye exam either the same day or within 2 weeks at the same location. The optometrist assesses refractive error in participants with presenting visual acuity worse than 20/40 in either eye with correction using an autorefractor (QuickSee Autorefractor, Panoptika, Cambridge, MA, USA). The autorefractor provides an objective measurement of a participants' refractive error and guides the optometrist in prescribing eyeglasses. Once an approximate eyeglasses prescription is generated by the autorefractor, the optometrist uses a Trial Lens kit to confirm the participants' eyeglasses prescription.

The optometrist then performs an anterior segment exam using a portable slit lamp and a posterior segment exam using a direct ophthalmoscope (Welch Allyn Panoptic 3.5V, Skaneateles Falls, NY, USA) to assess abnormal ocular signs. The optometrist diagnoses glaucoma and glaucoma-suspect using cup:disc ratio based on the AAO *Practice Pattern Guidelines*®.[32] The optometrist also diagnoses cataract, retinal abnormalities, and other ocular conditions and refers participants to ophthalmology for a dilated eye exam and further ocular testing, such as visual fields and optical coherence tomography (OCT), when deemed necessary.

Enhanced Intervention participants who need vision correction receive complimentary eyeglasses. Usual Care participants who need vision correction are given an eyeglasses prescription only and a list of optical shops.

COVID-19 screening: The study follows Columbia University's IRB and CDC guidelines for all research studies to mitigate the community spread of COVID-19. On the day of the on-site visits, all scheduled participants are screened over the phone about their COVID-19 symptoms, including recent exposure from any household members. Participants that test positive for COVID-19 with the last 2 weeks or have any COVID-19 symptoms are rescheduled.

Referral to Ophthalmology and Patient Navigation

Participants who are referred to ophthalmology, either by the optometrist or because they had an abnormal fundus image or IOP ≥30 mmHg during the vision screening and were "fast tracked" are assisted by the study team with scheduling their first eye exam appointment. Enhanced Intervention participants who are referred to ophthalmology receive enhanced support with patient navigators to assist with all aspects of follow-up eye care over one year, specifically scheduling appointments and arranging transportation to eye exams and ocular surgery.

Study coordinators are trained to serve as patient navigators and schedule eye exams and ocular testing appointments, provide transportation information, and review the electronic medical record (EPIC) to document if participants followed-up with eye exam

appointment(s). The patient navigator documents the appointment(s) in REDCap, confirms the appointment and reschedules if needed. Reasons for not attending the eye exam appointments are captured.

Usual Care participants who are referred to ophthalmology do not receive enhanced support from patient navigators after the initial follow-up eye exam appointment is scheduled, attended, cancelled or missed.

Satisfaction surveys: Participants are asked to rate their satisfaction with the vision screening (duration, convenience, screening staff), and the likelihood of attending a follow-up eye exam if referred to the on-site optometrist. Participants who complete an on-site optometrist exam are also asked to rate their satisfaction and the likelihood of attending a follow-up eye exam if referred to ophthalmology.

12-month follow-up vision check: All enrolled participants will be contacted again in 12-months over the telephone to schedule an on-site follow-up visual acuity check and NEI-VFQ-9 survey. Figure 1 presents the vision screening and eye exam Study Design and Methodology Flow Chart.

Statistical Design and Methods

Sample size determination: As shown in Figure 2, sample-size calculations are based on the Philadelphia Telemedicine Glaucoma Detection and Follow-up Study.[33] The team projects 35% of the 6,640 eligible residents living in the 10 housing developments will participate in the baseline vision screening [7 Intervention developments (n=1,556), 3 Usual Care developments (n=767)]. Based on previous community outreach programs to detect glaucoma and other eye diseases, we estimate that 40% of those screened will fail due to visual acuity worse than 20/40 or IOP ≥23 mmHg, and/or 15% could have an unreadable fundus image due to either cataract, small pupils, or room lighting.[33-35]

Therefore, a total of 55% of those screened (n=1,277) are predicted to fail and will be requested to undergo autorefraction on the same day. It is estimated that 40% of participants' vision will be correctable with eyeglasses and 60% who failed the screening will be referred to ophthalmology (n=766).[36] We estimate 513 participants will be referred to ophthalmology in the Enhanced Intervention Group and 253 participants from the Usual Care Group, which will provide adequate power for analysis for both primary and secondary outcome measures (Figure 2).

Sample size and power analysis for primary outcome: The primary outcome for the study is presenting visual acuity at 1 year, dichotomized as ≤20/40 or >20/40 for those referred to ophthalmology. Power calculations are based on the assumptions that 35% of the total number of residents in both the Enhanced Intervention (Group 1) and Usual Care (Group 2) developments will consent for and complete the vision screening (n=2323). Our analysis shows that power is sensitive to various assumptions of the effect size and intracluster correlation coefficient (ICC). Enrollment sample sizes of 176 residents in Group 1 and 88 residents in Group 2 will achieve 80% power to detect a difference between the group proportions of 15%. The proportion in Group 1 (Intervention) is assumed to be 30%

under the null hypothesis and 15% under the alternative hypothesis. The proportion in Group 2 (Usual Care) is 15%. The test statistic used is the Z test for proportions (α=0.05, two-sided test). The significance level of the test will be targeted at 0.05.

After adjusting for development size in the ICC calculation (assuming ICC=0.05), Enhanced Intervention Group residents increased from 176 to 396 and Usual Care Group residents increased from 88 to 211. We also accounted for 15% of participants to drop out due to attrition, which we believe is realistic since they are aging in place, we know where they live, and NYCHA Tenant Association Leaders will assist with recruitment and retention. Therefore, the sample size requirement to achieve 80% power to detect a difference between the group proportions of 15% is 466 residents in the Enhanced Intervention Group and 253 residents in the Usual Care Group (Figure 2).

Cost Analysis

A robust cost analysis is being conducted alongside the study to estimate the cost of the intervention per case of glaucoma and cost per case of any eye disease detected, as well as the costs of follow-up care of the identified cases of glaucoma, vision impairment, cataract, and other eye diseases. Using a framework of cost measures we employed for a prior study, we will comprehensively capture itemized intervention costs.[37] Use of the framework will allow us to compare the costs of this intervention to prior research in terms of personnel time, equipment, screening and study supplies, and travel to the sites. The cost analysis is critical to understanding the resources required to deliver the intervention, as well as to identifying opportunities to deliver it at a lower cost.

Cost measures inventory: Cost measures will include costs for the on-site vision screening, optometrist eye exams, 12-month follow-up vision check, patient navigation, personal protective equipment (PPE), and travel costs to the sites. We will calculate the cost of delivering the Enhanced Intervention by tracking the time patient navigators spend coordinating appointments and the time they spend arranging transportation for participants referred to ophthalmology to attend these office visits. Patient navigators will record the time (in minutes) they spend delivering the Intervention using a tracking log in REDCap. Patient navigators and their approximate wage rate plus fringe benefits will be costed using the same approach as previously summarized for visit personnel.[38]

DISCUSSION

The Manhattan Vision Screening and Follow-up Study in Vulnerable Populations study design and methodology were amended during the COVID-19 pandemic. To account for social distancing and the safety of our research team and study participants during this extremely challenging time, we created a call center where our staff could easily and safely conduct study eligibility, informed consent, enrollment, intake and demographics, medical and ocular history, and surveys on the telephone prior to scheduling the on-site vision screening and optometrist exam. This potentially reduced the community-based on-site vision screening time from 2 hours to 30 minutes per participant and vision screening was changed to appointment only. No walk-ins are accepted.

Questions about COVID-19 testing were added to the medical history and we are screening participants for COVID-related symptoms by telephone on the day of vision screening and optometrist exam. We initiated recruitment in October 2020 and have started scheduling on-site vision screening in 2021. We aim to develop an innovative model to identify, engage, and improve access and utilization of eye care services among these vulnerable populations most at risk for glaucoma and other eye diseases.

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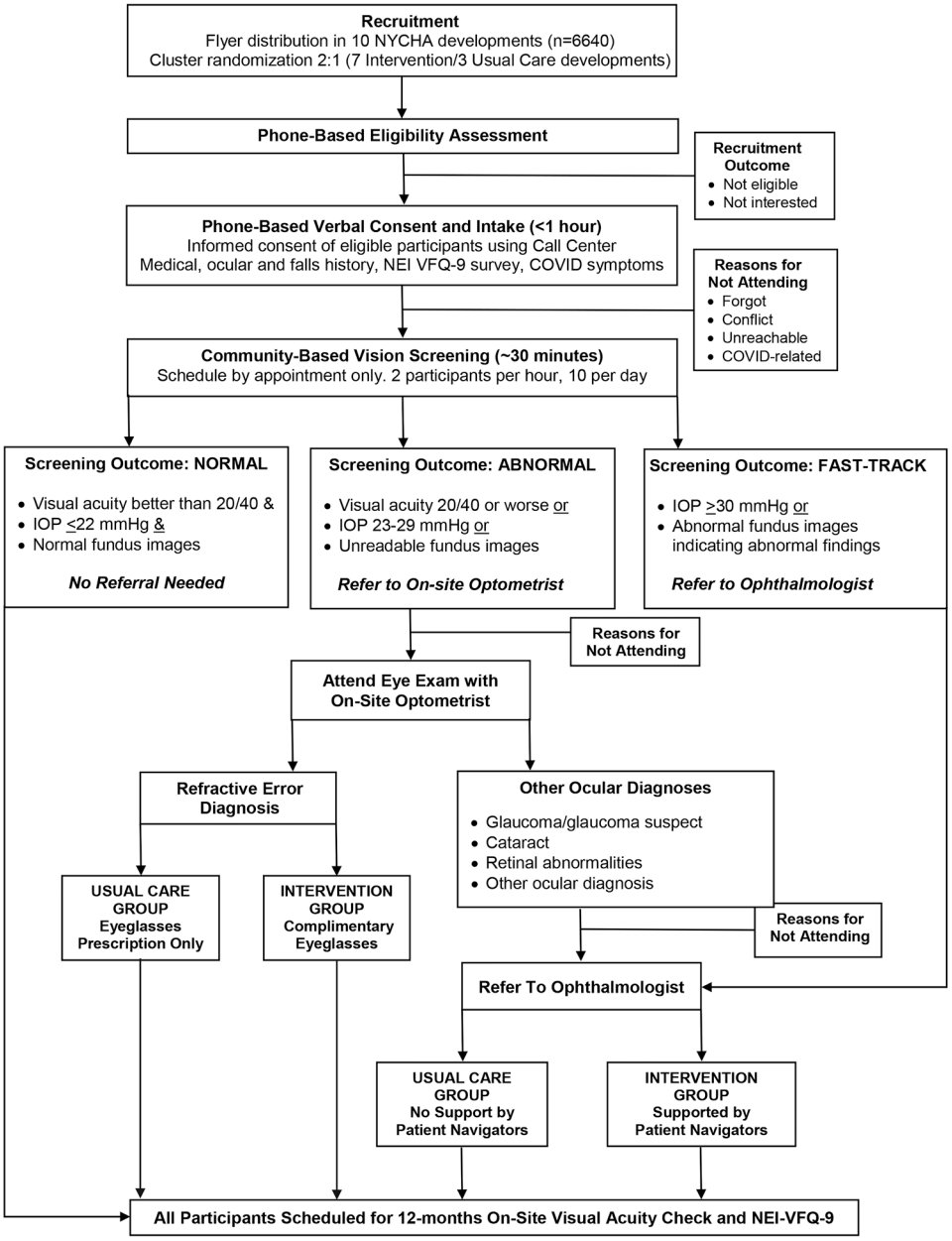

Figure 1. Study Design and Methodology Flow Chart: Manhattan Vision Screening and Follow-Up Study in Vulnerable Populations.

Participants are recruited via flyer distribution (Top center) and eligibility is assessed (Second row center). Verbal informed consent, intake data, and COVID-19 history are obtained via the call center (Third row) prior to vision screening. All enrolled participants are scheduled for vision screenings at the NYCHA development (Fourth row). Vision screening pass/fail criteria and fast track (Fifth row). All participants who fail the vision screening are scheduled with the on-site optometrist (Sixth row). Ocular diagnoses (Seventh row). Usual Care Group receives eyeglasses prescription only, Enhanced Intervention group receives complimentary eyeglasses (Eighth row left). Enhanced Intervention participants referred to ophthalmology are assisted by patient navigators while Usual Care Group is not

provided with ongoing assistance (Tenth row). All enrolled participants will be invited and scheduled for a 12-month on-site visual acuity check and NEI-VFQ-9 survey (Last row).

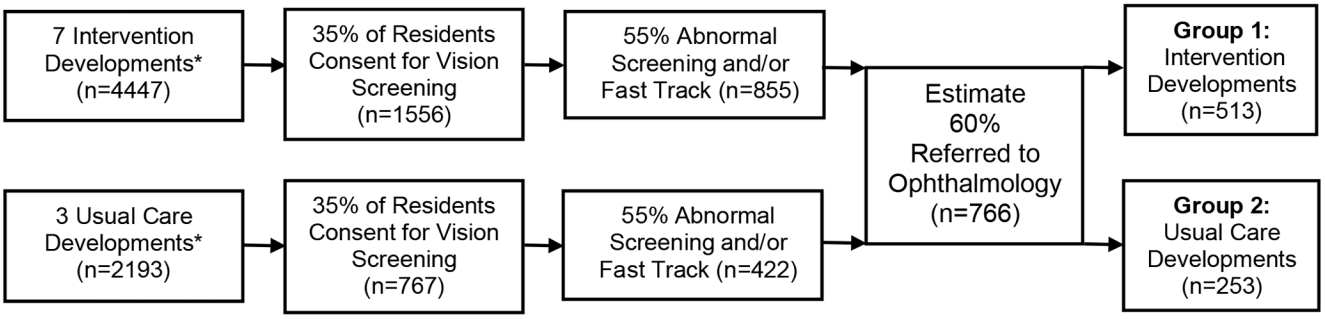

Figure 2: Sample Size Determination (*2:1 Cluster Randomization by Development)

A total of 10 housing developments in Washington Heights and Harlem will give access to 6640 potential participants (First column). We project 35% of the 6640 eligible residents living in the housing developments will consent and participate in the baseline vision screening (Second column). In the third column, 55% of those screened are estimated to have an abnormal and/or fast-track outcome. We estimate 60% who fail the vision screening (n=766) will be referred to ophthalmology (Fourth column). A total of 513 participants are estimated to be referred to ophthalmology in the Enhanced Intervention Group and 253 participants from the Usual Care Group (Fifth column).

Table 1.

Adult and Senior Housing Developments Selected by New York City Housing Authority

1)	Fort Washington Housing 1 & 2	**INTERVENTION**	275 seniors only
2)	St. Nicholas Housing	**INTERVENTION**	1269 adults and seniors
3)	Rangel Houses	**INTERVENTION**	863 adults and seniors
4)	Polo Grounds	**INTERVENTION**	1423 adults and seniors
5)	Drew-Hamilton Housing	**USUAL CARE**	1033 adults and seniors
6)	Lincoln Housing	**USUAL CARE**	1025 adults and seniors
7)	Bethune Gardens	**INTERVENTION**	252 seniors only
8)	Marshall Plaza	**INTERVENTION**	205 seniors only
9)	Public School 139 Conversion	**USUAL CARE**	135 seniors only
10)	Audubon Housing	**INTERVENTION**	160 adults and seniors

Table 2.

Inclusion and Exclusion Criteria for Study Enrollment

Inclusion Criteria: • Individuals over age 40. • Living independently in a NYCHA housing development. • Willing to consent for on-site vision screening and 12-month follow-up vision check. • Willing to report COVID-19 related symptoms on the day of vision screening.
Exclusion Criteria: • Self-reported terminal illness with life expectancy less than 1 year. • Inability to provide informed consent due to dementia or other reasons.

Table 3.

Definition of Vision Screening Failure and Referral to On-site Optometrist

- Visual acuity worse than 20/40 in either eye, **or**
- IOP 23-29 mmHg in either eye, **or**
- Unreadable fundus images

IOP=Intraocular pressure