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Prescheduled Appointments As A Strategy To Improve Follow-Up Rates Among At-Risk Individuals Identified During Community-Based Glaucoma Screenings

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Prescheduled appointments as a strategy to improve follow-up rates among at-risk individuals identified during community-based glaucoma screenings

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ABSTRACT

Purpose: To investigate whether pre-scheduled appointments increase follow-up rates among participants identified as “at-risk” for glaucoma during a community-based glaucoma screening.

Design: Randomized controlled trial.

Methods: Between May 2010 and October 2012 we screened 362 underserved individuals age 40 years or older for glaucoma within the Greater New Haven Area. Screening modalities included visual acuity, automated perimetry, portable tonometry and ophthalmoscopy. Participants with abnormal screening results were randomized to receive either a pre-scheduled appointment for a low-cost complete eye exam within 7-10 days of the date of screening (intervention), or standard counseling (control). Follow-up rates were determined via clinical records and phone surveys and analyzed using Chi-square test with significance set at $p<0.05$.

Results: The overall follow-up rate among positively screened participants was 30% (n=63). Forty-one percent in the intervention group (n=22) successfully followed up compared to 24% of controls (n=41, p=0.173). Ethnicity (p=0.584), gender (p=0.681), age (p=0.792), access to car (p=0.425), living situation (p=0.893), health insurance status (p=565), or tobacco use (p=0.486) did not independently affect follow-up rates, nor did having an established eye care provider (p=0.118) or diabetes (p=0.334).

Among participants lacking access to a car, the follow-up rate among those with prescheduled appointments was 66.7%, compared to 5.3% among controls (OR 36.0; 95% CI 3.1-414.9). Among participants lacking health insurance, the follow-up rate was 46.7% in the intervention group compared to 7.0% among controls (OR 12.3; 95% CI 1.3-118.4). Among those who lived alone or used tobacco, follow-up rates were higher in the intervention group (OR 1.8, 95% CI 0.29-11.2; OR 2.3 95% CI 0.23-22.1, respectively).

Conclusion: Provision of pre-scheduled follow-up appointments to glaucoma suspects at the time of screening does not lead to a significant increase in overall follow-up rates. This intervention may, however, prove both clinically valuable and cost-effective when offered specifically to individuals lacking access to a car and/or health insurance.

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1. INTRODUCTION

1.1 Background

Open-angle glaucoma (OAG), the most common form of glaucoma in the US, affects more than 2.22 million individuals in the US and is projected to affect 3.72 million by the year 2020.[1] OAG is a chronic painless condition leading to optic nerve damage and characteristic mid-peripheral visual field loss in one or both eyes; left untreated, it may progress towards complete, irreversible blindness.[2]

Although the pathogenesis of primary OAG is incompletely understood, it is recognized to be a characteristic form of optic neuropathy among patients with open iridocorneal angles. It is associated with, but not defined by, elevated intraocular pressure (IOP).[3] OAG is distinguished from other optic neuropathies by its slow progression over months to years and also by an array of typical structural and functional defects (**Figure 1**). Typical structural defects include thinning of the nerve fiber layer and optic disc damage characterized by topographical deepening and widening of the cup as a result of both loss of retinal ganglion cell axons and deformation of connective tissues supporting the optic nerve head. Typical functional defects include characteristic visual field abnormalities such as a nasal step scotoma that respects the horizontal meridian, inferior or superior arcuate scotoma, paracentral scotoma or generalized depression. Glaucomatous visual field defects are most often bilateral but asymmetric, and on average the better eye demonstrates only about 50% as much damage as the worse eye.[4]

Demographic, ocular and non-ocular risk factors have been identified from epidemiological studies, with the overall risk of developing glaucoma increasing with the

number and strength of risk factors. There is good evidence, for example, that African descent, Mexican heritage, older age, elevated intraocular pressure (IOP), family history of POAG, myopia, and low diastolic perfusion pressure are risk factors. [5-12] Among patients with elevated IOP, a relatively thin central cornea is another major risk factor for the disease.[13] Other risk factors including DM, elevated systolic pressure, migraine have been investigated, however, the evidence is less consistent **(Table 1).**

1.2 Burden of glaucoma on the individual and society

Progressive, irreversible visual impairment due to glaucoma can be distressing and disabling to patients and has been shown to adversely affect their health-related quality of life (HRQoL). HRQoL is a metric for quantifying a person's physical and social functioning, mental health, and general health perception and can be used to inform decision making about patient management and policy changes.[14] While, predictably, central visual acuity has the greatest impact on HRQoL, measurable and clinically significant reductions in HRQoL have been documented in patients with early glaucomatous field loss.[15,16] This observation was significant even when assessed among those unaware of their diagnosis.[17]

Reading difficulties are among the most common complaints related to reduced HRQoL and are frequently reported in patients with glaucomatous VFL independent of their visual acuity.[18] These difficulties were quantified in a study by Ramulu et al. reporting a significant association between glaucoma and decreased reading speed (12 wpm slower on two separate tests, p=0.002) even when adjusted for multiple variables including age, race, education and visual acuity.[19] In addition to baseline slower rates of

sustained silent reading (16% slower; 95% CI= -24 to -6%, *p*=0.002), glaucoma subjects in this study were also more susceptible to “reading fatigue,” in which their reading speeds declined more rapidly over thirty minutes when compared to subjects without glaucoma.

Many lines of evidence suggest that glaucoma impairs mobility. In the Salisbury Eye Evaluation (SEE) Project, a population-based observational study among community-dwelling individuals, participants with bilateral glaucoma had significantly reduced mobility as measured by walking speed (2.4 meters per minute slower, *p*=0.009), number of bumps (more bumps, *p*=0.03) stair-climbing speed (slower, *p*=0.163), number of orientation errors (more errors, *p*=0.246), and stand failure (more failures, *p*=0.089), compared to those without glaucoma.[20] These findings were significant even after controlling for use of mobility aids, demographics, comorbidities and visual acuity. As highlighted by the authors, factors affecting daily activities such as slower ambulation, higher frequency of bumping into objects, and a generalized reduction in mobility, are likely to promote a more sedentary lifestyle as well as increased dependence on others.

Fear of falling accompanies and potentially underlies to a large extent the reduced mobility observed in patients with visual field loss, and is present even among patients with no prior history of falls.[21] It has also been shown to directly limit activity and promote sedentary behavior.[22] Slower walking speed is an understandable adjustment by any individual in fear of falling, and perhaps even justified in light of multiple studies demonstrating significantly greater rates of falls, and falls with serious injuries, among those with visual field loss.[23-26] Specifically, in a prospective study,

Haymes et al. found that, compared to control subjects, patients with glaucoma were over three times more likely to have fallen in the previous year ($OR_{adjusted}$ = 3.71; 95% CI, 1.14-12.05).[27] In a retrospective cohort analysis amongst Medicare recipients, Bramley et al. found that glaucoma subjects coded as visually impaired were almost twice as likely to have had a fall or accident (OR=1.6) and to have had a femur fracture (OR=1.6) when compared to glaucoma patients not coded to have visual loss.[28] Findings such as these add further gravity to the issue in light of established associations between falls and increased morbidity and mortality.

Individuals with glaucoma and visual field loss also have higher rates of motor vehicle collisions (MVC); Haymes et al. reported that individuals in this group were over six times more likely to have been involved in one or more MVCs in the previous 5 years ($OR_{adjusted}$ = 12.44; 95% CI, 1.08-143.99).[27] A potentially related finding is the higher rate of self-restriction or complete cessation of driving among those with glaucoma.[29] Although driving cessation is undoubtedly safer than driving with visual impairment, this adjustment can exert a profound impact on HRQoL through limitation of independence, especially in areas where driving is an activity critical for participation in daily activities. Evidence supports this conjecture, showing that elderly persons who stop driving are nearly 5 times more likely to move to a long-term care facility[30], have higher rates of depression[31], and report a lower quality of life. Large numbers of subjects with very advanced VF loss continue to drive, even after a previous collision, subjecting both themselves and society at large to increased mortality.[29,32]

1.3 Why Screen for Glaucoma?

In a 1968 monograph for the World Health Organization, Wilson and Junger proposed a set of characteristics shared by diseases or conditions potentially amenable to screening.[33] These characteristics, listed in **Figure 2**, have since served as the foundation for developing new screening criteria in all areas of medicine. In many aspects, OAG fits into the Wilson and Junger paradigm as a disease for which screening could make a significant impact on the burden of disability in the population: glaucoma is a leading cause of blindness and subsequent disability; its prevalence is high; the sparing of central visual acuity and temporal visual field until late-stage disease very often results in asymptomatic progression and it is estimated that nearly half of the people with glaucoma in the United States are not aware that they have the disease.[5,34-36] (UK studies have estimated this rate to be as high as 67%.) [37] Finally, as reported in the OHTS Phase II study after 13 years of follow-up, treatment is likely to be more effective if begun early in the disease process.[38] Glaucoma screening, therefore, offers a potential means to identify affected individuals and encourage them to seek treatment before clinically meaningful loss of visual functioning occurs. Assuming proper follow-up and management, the ultimate outcome would be prevention of visual impairment and preservation of quality of life.

In 2006, the World Glaucoma Association (WGA) subcommittee on screening for OAG published a consensus report addressing the justifications for glaucoma screening programs.[39] In addition to measuring current evidence according to metrics proposed by Wilson and Junger, the report highlighted at least two additional rationales that strengthened in their opinion the justification for glaucoma screening. The first rationale

appealed to the opportunity for screening events to promote public awareness of the disease, especially among physicians and legislators. The second rationale was that glaucoma screening could be beneficial in medically underserved communities, insofar as it could offer an avenue for detecting vision disorders and facilitate access to care for those who needed it.

1.4 Cost Effectiveness of Glaucoma Screening

Whether or not and how glaucoma screening should be implemented remains controversial both at a national and international level. This debate is fueled by the many challenges inherent in screening for and treating glaucoma such as: 1) determining the appropriate setting for screening; 2) determining the appropriate timing of screening, and; 3) determining the most appropriate types of providers to be present the screening. Although the disease to a large degree satisfies the Wilson and Junger checklist—a set of internationally agreed upon criteria as a screenable disease—the question of whether screening for glaucoma offers significant added value compared to usual practice in terms of both overall cost of treatment and effectiveness in preventing visual impairment and blindness is also often debated.

In a systematic review and economic evaluation commissioned by the National Health Service (NHS) to evaluate the clinical and cost-effectiveness of screening for OAG in the UK, Burr et al. concluded that population screening at any age is unlikely to be cost-effective.[37] However, selective screening of groups with higher prevalence, such as black ethnicity or positive family history, was identified as a possibly cost-effective approach. Specifically, the authors found that screening (vs. no screening) was cost-

effective given a willingness to pay threshold of £30,000/QALY if the prevalence of glaucoma reached 4% with a screening interval of 10 years in a 50-year old cohort.

To further explore the cost-effectiveness of screening high-risk populations for glaucoma, Ladapo et al. developed a Monte-Carlo simulation model using data from the Eye Diseases Prevalence Research Group and Baltimore Eye Study to project the clinical impact of routine glaucoma screening on visual outcomes in African Americans aged 50-59 years—in which the prevalence is estimated at 4.7%—compared to opportunistic case finding.[40] In this group, the number needed to screen (NNS) in order to diagnose 1 person with glaucoma was 58. At a cost of $80 per individual screened, the total estimated cost of diagnosing one case of glaucoma was $4750. Upon extending their analysis beyond glaucoma diagnosis as an end-point and instead assessing for functional outcomes such as visual impairment or blindness, however, the investigators found that associated costs of glaucoma screening rapidly increased. For example, the NNS to prevent one case of visual impairment in their high-risk cohort was 785 (ranging from 425 to 5330 depending on the effectiveness of treatment and frequency of screening studies built into the model) and the NNS to prevent one case of blindness was 1220. These values translated to a total cost of $71 130 to avoid one case of visual impairment and $98 970 to avoid one case of blindness through screening and subsequent treatment according to preferred practice patterns.

Although to a large extent the above NNS figures for glaucoma are on par with other screened diseases, including breast and colorectal cancer†, arguments to justify or reject their associated costs remain complex and continue to be grappled with. Only by integrating the multiple dimensions of benefits associated with avoiding a case of visual impairment or blindness into a unified economic model of screening versus no screening could a study comprehensively inform decisions about the true cost-effectiveness of glaucoma screening.

1.5 Glaucoma screening programs

Despite uncertainties about its cost- and clinical- effectiveness, screening for glaucoma has a long history and is a well-established activity for a variety of voluntary health agencies and service organizations. The Friends of the Congressional Glaucoma Caucus Foundation (FCGCF) is the largest organization in the US committed to provision of free glaucoma screening nationwide, often in collaboration with the Lions Club. Since April 2001 the FCGCF has conducted both independent and collaborative screening events in community-based settings such as seniors' centers, office buildings, malls and houses of worship, among others.[42] More recently, the FCGCF established a Student Sight Savers program with chapters organized by medical students at over

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† The NNS for mammography to prevent one breast cancer death for 5 years among women aged 50-59 has been estimated at 2451; the NNS for fecal occult blood testing to prevent one colon cancer death in 5 years has been estimated at 1374.[41]

thirty US universities, including Yale School of Medicine. Until recently, it received most of its funding from the federal government.

In the absence of defined guidelines for glaucoma screening, considerable variation exists regarding its implementation. In terms of screening methods, there are many potential tests or combinations of tests available, including ophthalmoscopy, tonometry and automated perimetry; to date, none have been identified as being superior as a screening test for glaucoma.[43] Staff members conducting glaucoma screening events comprise multiple different backgrounds and may be volunteering as trained laypersons or medical assistants, ophthalmic technicians, optometrists, ophthalmology residents in addition to ophthalmologists. Criteria to refer for full exam are also not standardized, but most often include a combination of IOP threshold, cup-to-disc ratio, visual field test results, and presence of risk factors.

1.6 Importance of Follow-up after Positive Screening

The benefits of screening for glaucoma cannot be realized without receipt of appropriate follow-up care for abnormalities identified via screening. Failure of an individual to obtain appropriate follow-up care and treatment, if necessary, not only puts him or her at risk for disease progression and future disability; it also carries cost implications for both the individual and the health care system. First and foremost, the efforts and expenses dedicated by staff members, volunteers and funding organizations to the screening program are essentially negated by a participant's failure to follow-up. Second, in a scenario of poor follow-up rates among those with abnormal screening results, any projected benefits calculated by a cost-effectiveness analysis will have

been greatly overestimated. Finally, given that disease- and treatment-related costs to the individual and society directly correlate to severity, delaying follow-up until onset of symptomatic visual impairment is substantially more costly than obtaining follow-up promptly after a positive screening result during asymptomatic stages.

All in all, regardless of existing controversies regarding the place for glaucoma screening in the public health arena, maximizing follow-up rates among those who screen positive remains essential for both cost- and clinical effectiveness.

1.7 Barriers to follow-up after screening

An individual found positive for OAG or OHT at screening should have the disease confirmed or excluded as quickly and efficiently as possible. For those in whom OAG is confirmed, a management plan should be formulated and implemented. Despite awareness of these established next-steps, participants who screen positive often face substantial barriers to obtaining adequate follow-up care.

Barriers to follow-up commonly identified in the screening literature include: no recollection of screening result; unawareness of the purpose of follow-up examination; lack of social support; being uninsured or underinsured; socioeconomic status; lack of perceived urgency; and inadequate education about the condition being screened for.[44-49] Among African Americans screening positive for glaucoma at a community-based screening, Gwira et al. identified smoking, lack of access to a car for eye examinations and living alone as being associated with noncompliance to follow-up after glaucoma screening. [50]

Long scheduling intervals also represent barriers to follow-up care. A retrospective study across various clinic types within the VA Health System by Whittle et al. identified a significant relationship between scheduling interval and nonadherence to follow-up. [51] For appointments made within 13 days, the rate of no-show visits increased from 12.0% to 20.3%, but remained stable thereafter. In contrast to the plateauing of no-show rates, cancellation rates beyond the 2-week scheduling interval continued to rise proportionally such that follow-ups scheduled within 8-months were cancelled at a rate of 40% and those within 12 months at 50%. Given that both cancelled and missed appointments are considered failures to follow-up, these findings support efforts to limit scheduling intervals to 2 weeks, if possible, in order to preempt appointment cancellations and ultimately maximize rates of successful follow-up.

1.8 Interventions to improve FU rates

Maximizing follow-up rates among groups of individuals screening positive is an important issue common to all of the screened diseases. Various interventions to address this issue have been explored in the literature, most commonly in the realm of cancer screening and in particular among women with abnormal Pap smears, mammograms or clinical breast examinations.[45,52-54] Interventions to increase follow-up rates after findings of polyps or positive fecal occult blood tests (FOBTs) for colorectal cancer screening have also been studied.[55,56] These studies have investigated mostly patient-level interventions such as mail and telephone reminders, telephone counseling, or printed educational materials, all of which were shown to have modest effectiveness.

Interventions involving financial assistance and transportation services to overcome economic or structural barriers have also been associated with increased compliance.[46]

Within the glaucoma screening literature, direct investigations into the efficacy of specific interventions to improve rates of successful follow-up care after positive screening results have not been examined to our knowledge. Potential barriers to follow-up are, however, often preemptively addressed and incorporated into screening programs so as to minimize loss to follow-up and maximize sample size if future investigations are planned. The Hoffberger program, a community-based vision screening program funded by three charitable organizations in Baltimore, MD, is a good example.[57] This program identified and addressed multiple potential cultural, structural and financial barriers to follow-up in the predominantly African-American community of East Baltimore. To address cultural barriers rooted in distrust of the medical profession, organizers trained members of the community to work with neighborhood health workers and conduct initial vision screenings in churches, senior housing complexes, and other community venues. To address structural barriers, program organizers offered pre-scheduled appointments at the affiliated General Eye Service clinic at Wilmer Eye Institute to all positive screenees with availability both during business hours as well as nights and weekends for a comprehensive eye examination free of charge. Transportation was provided if needed. Finally, to address financial barriers, the exams were offered free-of-charge. Despite all of the above measures, Quigley et al. reported low rates of follow-up (<50%) over a 4-year period. Anecdotally, however, it was noted that this follow-up rate was higher than the typical rate of appointment-

keeping at the Wilmer General Eye Clinic, where similar ancillary support systems are not in place.

The only recent study identified in the ophthalmology literature to directly examine the comparative effectiveness of interventions to promote successful follow-up was conducted by Saine and Baker at a multi-specialty ophthalmology practice in New Hampshire.[58] In a controlled, staggered, prospective study, the authors investigated the comparative effectiveness of two reappointment methods aimed at increasing appointment compliance. Patients with a variety of different ophthalmic diagnoses leaving clinic without having made an appointment were sent either a postcard reminder with the clinic's phone number or a letter notification of a prescheduled appointment. The scheduling interval included in the study was within three months of the last appointment. Of the 1062 patients who were sent postcard reminders, 56% successfully scheduled and 54% completed appointments within the 3-month scheduling window (2% no-show rate). Of the 1045 patients notified by letter of their prescheduled appointments, 74% successfully completed their appointments, 19.5% rescheduled for a time outside the study window, and 6.5% were no-shows. The success rates between intervention groups were significantly different, yielding a *P* value of <0.0001. The 3-fold higher no-show rate in the appointment letter group was also significant; however, as the authors point out, unlike the patients in the postcard group who did not schedule appointments and thereby remained anonymous, the no-show patients in the letter group remained in the system and could subsequently be contacted to reschedule the appointment they missed.

Although the Saine and Baker study population consisted of established patients who would likely follow-up at higher baseline rates than a screening population, the significant effect of implementing an inertia-lowering structural intervention (i.e. prescheduled appointments) on increasing follow-up rates seems likely to be transferrable.

2. PURPOSE AND AIMS OF CURRENT STUDY

The purpose of the current study is to examine follow-up rates among at-risk individuals identified at a glaucoma screening and directly assess, in a controlled fashion, the effectiveness of a structural intervention designed to maximize those rates compared to an established standard procedure.

3. METHODS

3.1 Study approval

The Institutional Review Board of Yale University approved this randomized controlled study. All participants volunteered for screening and signed written informed consent to participate in the study, which included the initial screening event and a possible follow-up phone interview within 3-6 months of the event.

3.2 Description of screening events

Between May 2010 and October 2012, the Yale Sight Savers Program conducted 12 glaucoma screenings in the Greater New Haven area. The screenings took place in community-based settings such as neighborhood health fairs, senior's fairs and public

libraries. Screenings were targeted to those over 40 years of age, but turned no one away. On average, the events were 2 to 4 hours long and were attended by 20 to 60 participants.

Each screening event consisted of registration, measurement of visual acuity, automated perimetry, tonometry and ophthalmoscopy through an undilated pupil performed by a Yale ophthalmology resident. The first three steps of the screening process were administered either by trained undergraduates, medical students or technicians from the FCGCF; either a trained medical student or the resident performed tonometry.

3.3 Data collection and Measurements

At registration, participants were asked to complete a brief questionnaire requesting contact information, demographic information and a signed statement of consent to be screened and potentially contacted by phone for a follow-up survey. Factors previously reported in the literature to influence likelihood of follow-up after a positive screening result, including smoking status, access to car, and living situation (alone or not), were also assessed at the time of registration. Visual acuity was tested at distance with a Titmus 2s Vision Screener in the two eyes separately with habitual eyeglasses. Finally, a screening visual field test was performed with a Humphrey®FDT in each eye with better than 20 out of 200 vision.

3.4 Outcome variables

Participants were classified by the on-duty resident ophthalmologist into categories A, B or C, with A representing a positive screen for possible glaucoma and B representing a positive screen for risk of another ophthalmic condition, such as cataract or diabetic eye disease. Those with either a normal screening exam or isolated refractive error were classified into category C. Those in category A had one or more of the following: IOP>20, cup-to-disc ratio >0.5, cup-to-disc asymmetry >0.2, abnormal FDT result on a reliable test, or a first-degree relative with glaucoma.

3.5 Statistical Analysis

Data were recorded in a Microsoft Excel file and evaluated biostatistically using IBM SPSS v.19. A chi-square test was used to examine the association of successful or failed follow-up with the socio-demographic characteristics and barriers assessed at registration. Variables considered in this analysis included age, race, sex, health insurance status, availability of a car, and a history of diabetes. Since no confounders were identified in bivariate analysis, no multivariable analysis was performed.

4. RESULTS

4.1 Screening Participant Characteristics

Three hundred and sixty-two individuals in total were screened. The average age of all screening participants was 56.7 years (± 14.6 years; range, 30-94); females predominated (52.3%), as did those of African American and Hispanic ethnicity (40% and 35%, respectively).

Approximately 40% of all screening participants were classified into either category A or B, i.e. they were found to have evidence of at least one ophthalmic condition that could benefit from further assessment **(Figure 3)**. The two most frequent conditions noted by resident physicians during screenings, apart from possible glaucoma, were possible cataract (10.8%) and need for diabetic eye exam (10.8%). Other, less common, conditions noted were pterygium (0.3%), exotropia (0.8%) and strabismus (0.3%). Refractive error was also very common (31.8%) and was noted in participants ultimately classified into all three categories based on the presence or absence of other findings.

Sixty-three individuals, or 17.4% of screening participants who met the eligibility criteria for this study, were classified as being at risk for glaucoma. The average age in this group was 55.1 years (± 14.6 years; range, 30-71), with a female preponderance (54%) and ethnic distribution similar to that of the entire screened population. Specifically, the group consisted of 40% African American, 35% Hispanic, 14% Caucasian, with the remaining 11% individuals self-identified as Other **(Table 2)**.

In accordance with a 1:2 randomization strategy, 22 of 63 individuals in category A were assigned to the intervention group and therefore received prescheduled appointments at the time of screening **(Figure 4)**. As shown in table 2, randomization was effective with respect to age, gender and ethnicity, as well as all other pertinent characteristics with the exception of health insurance status. A greater proportion of those in the intervention group were uninsured compared to the control group (68% compared to 41%, p=0.017).

4.2 Association of follow-up with patient characteristics

Among 63 participants who screened positive as being at risk for glaucoma, 19 completed successful follow-up within 3-6 months, resulting in an overall follow-up rate of 30%. The follow-up rate among those receiving prescheduled appointments was 41%, compared to 24% among controls, although this difference did not reach statistical significance (p=0.173) **(Table 3)**.

Demographic characteristics such as ethnicity (p=0.584), gender (p=0.681), and age (p=0.792) did not independently affect follow-up rates, nor did other characteristics previously identified as potential barriers to completing follow-up care. Specifically, overall follow-up rates were not affected in a statistically significant manner by access to car (p=0.425), living situation (p=0.893), health insurance status (p=565), or tobacco use (p=0.486). Having an established eye care provider ("eye doctor") (p=0.118) or diabetes (p=0.334) also exerted no significant impact on overall follow-up rates.

We performed subgroup analysis to determine whether prescheduled appointments improved follow-up rates among participants sharing particular characteristics previously associated with lower follow-up rates, i.e. living alone, tobacco use, having no access to car, and being medically uninsured **(Table 4)**. Among participants lacking access to a car, those receiving prescheduled appointments followed up at a rate of 66.7%, compared to a rate of 5.3% among those receiving standard counseling (OR 36.0; 95% CI 3.1-414.9). Among participants lacking health insurance, the follow-up rate was 46.7% in the intervention group compared to 7.0% in the control group (OR 12.3; 95% CI 1.3-118.4). Among those who lived alone or used tobacco, follow-up rates were higher in the intervention group (OR 1.8, 95% CI .29-11.2;

OR 2.3 95% CI .23-22.1, respectively), but not to a statistically significant degree. No further significant associations were identified in the other subgroups.

4.3 Perceived barriers to follow-up among study participants

We attempted to contact by phone all glaucoma suspects who were non-compliant with follow-up, regardless of whether they were assigned to the intervention or control group. A standard interview was administered to determine whether they had followed-up elsewhere, and, if not, assess the reasons behind their failure to obtain follow-up care. Ten of the 44 participants (22.7%) in this group were successfully reached by phone and surveyed; none had obtained follow-up care elsewhere. Among the three participants who had received pre-scheduled appointments, two cited financial barriers (i.e. expected cost of the appointment) and the third participant disagreed with the recommendation and believed there was no reason to follow-up. Among participants in the control group, three participants (42.9%) cited cost as a barrier; six (85.7%) admitted to forgetting to call to make an appointment and two (28.6%) stated they could not obtain time off work to seek follow-up care. All ten participants who were contacted described obtaining follow-up as a non-urgent (versus urgent) issue.

5. DISCUSSION

In this study, we examined the effect of a patient-level structural intervention, i.e., prescheduled appointments, as a strategy to improve follow-up rates among participants screening positive at a community glaucoma screening. Given the choice of a variety of established interventions, we chose this particular intervention for multiple reasons. First, it offered the potential to ameliorate a range of barriers relating to financial, transportation-, work-, or childcare reasons rather than simply removing a

single one. Second, unlike other more labor- or time-intensive interventions, this one required a relatively low upfront investment. Finally, it carried the recognized advantage of an opt-out versus opt-in scenario, in that the latter is associated with overcoming a higher level of inertia to achieve the same outcome (i.e. successful follow-up).

In contrast to our original hypothesis, the chosen intervention did not increase overall rates of follow-up as compared to standard counseling. Follow-up rates were, in fact, very low in both study groups (41% and 24%, respectively) yet quite consistent with findings from the Hoffberger program in Baltimore, MD. (41%)[57]. These findings are strikingly lower than those of a similar study that examined follow-up rates among patients in Oregon (69%),[59] most likely explained by the demographic and cultural similarities between Hoffberger program and the Yale Sight Savers Program, and their mutual difference compared with the Oregon study. This contrast in outcomes highlights the importance of implementing interventions appropriate to one's target population.

The average rate of referral for follow-up at a screening event in our study was 17.4%. Undoubtedly, not unlike other screening scenarios[60], the number of true positives within this event group is likely very low. This is due to both limitations in terms of sensitivity and specificity of currently used screening methods, as well as a natural inclination to lower the threshold for "abnormal," especially in a charitable, public service-oriented atmosphere. Combined with a low follow-up rate among those referred for full examination, the number needed to screen in order to identify one case of glaucoma or OHT could rapidly exceed justification. This is important to recognize, as most cost- and clinical-effectiveness models do not adjust for follow-up rates below 100%. Consequently, when numbers generated by such models indicate borderline

effectiveness, this may in fact be an overestimation, underlying the idea that modeling can sometimes extend and clarify evidence but should not be considered evidence in itself.

The potential harms of any screening program cannot be ignored. Even glaucoma screening is associated with potentially harmful effects on participating individuals. Practically, those who are screened and found to be at minimal risk for glaucoma may misinterpret the findings as indicating a normal eye exam and thereby be falsely reassured. Conversely, the psychological burden associated with any positive screening result is a tangible harm that would affect a large proportion of those with no disease but who are referred based on conservative criteria. Finally, the opportunity cost of attending a follow-up eye examination and the financial burden associated with chronic ocular hypotensive use can also be conceived as a possible harm to the screening participant, especially if the impact on functional vision loss turns out to be very slight.

Along similar lines, the US Preventive Services Task Force (USPSTF) issued a statement of recommendations in 2005 (an updated version of its 1996 statement) for OAG screening. Based on a thorough review of the literature on the effectiveness of screening and treatment for early primary OAG, it found insufficient evidence to determine the extent to which screening – leading to earlier detection and treatment of individuals with elevated IOP or OAG – would reduce impairment in vision-related function or quality of life. In light of this uncertainty it was unable to recommend for or against glaucoma screening.

Expert groups, in contrast, recommend screening programs leading to early detection because of a large and growing burden of suffering from glaucoma and its complications, the existence of accurate screening tests, and strong evidence that interventions can prevent onset of progression of the disease. However, the evidence is much less convincing that early detection and treatment lead to lower rates of visual field loss than treatment after clinical diagnosis.[40]

A possible option that addresses both cost issues and risk/benefit issues is a combined screening for multiple asymptomatic yet vision-threatening conditions, such as diabetic retinopathy in addition to glaucoma. With rapidly advancing technology, more accurate and portable devices are sure to become available and they will likely amenable to either operation by laypersons or interpretation at a centralized reading center via teleophthalmology.

An intriguing solution to the cost-effectiveness conundrum surrounding glaucoma screening has been proposed by Wittenborn et al. in a recent study.[61] The authors' idea involved the addition of a screening component to another healthcare assessment that is already paid for or conducted for other reasons, namely the Welcome to Medicare health evaluation. Using conservative parameters within a comprehensive, previously established model, they demonstrated that a new policy of reimbursement for Welcome to Medicare dilated eye evaluations would be highly cost-effective.

6. LIMITATIONS

There are several limitations to this study. First, the outcome measure we employed was successful follow-up of all participants—regardless of group assignment—at our

study-specific eye clinic, as opposed to follow-up at any eye clinic. In calculating follow-up rate, we therefore relied on appointment records in our clinic database to determine who in our study had successfully completed a follow-up eye exam. Names found in the database were recorded as successful follow-ups; names not found in the database were recorded as failed follow-ups. It is therefore possible that individuals who screened positive but failed to follow-up at the study clinic did in fact obtain follow-up elsewhere. We attempted to address this contingency during the follow-up phone interviews by confirming follow-up status; however, since only 27% of all participants could be reached by phone, we could not confirm a large proportion of these cases. Reassuringly, among those successfully contacted, none contradicted our original assessment of their state of follow-up.

Another limitation of our study is that certain population characteristics assessed were self-reported and not verified independently in a rigorous way. For example, in an effort to use language accessible to all participants, we asked whether they had an “eye doctor” rather than “ophthalmologist.” Because of the broadly defined term, it is possible that many respondents who indicated that they had an eye doctor were in fact referring to one of multiple possible eye care professionals including opticians and optometrists in addition to ophthalmologists. This may explain why we found no significant difference in follow-up rate at the study clinic among those with eye doctors compared to those without; in contrast to what was observed, we may have expected those with established doctors to have lower rates of follow-up at the study clinic by virtue of presenting instead to their own outside clinic.

A third limitation is that we did not collect data beyond the first stage of the screening process and can therefore not evaluate the sensitivity or specificity of our referral rate, i.e., what proportion of positive screenees would, upon comprehensive examination, receive a diagnosis of either glaucoma suspect or glaucoma. Without this data, we cannot directly estimate the clinical- or cost-effectiveness of our screening program in terms of how many individuals were newly identified and treated.

Another limitation is the sample size of our desired population. Although the total number of study participants was 362, the relatively low event rate (representing positive screenees) resulted in a limited subpopulation of 63 individuals qualifying for intervention and subsequent analysis. While this sample size allowed for determination of overall effect of the intervention on follow-up rate and highlighted a couple characteristic subgroups in which it was particularly effective, it is possible that it was underpowered to detect the presence of other significant characteristics.

7. FUTURE DIRECTIONS

In future studies, data collection could be extended to include results from the comprehensive examinations of positively screened individuals who successfully followed up at the study clinic. This would validate the screening technique and allow for determination of its sensitivity and specificity, thereby providing further insight into its clinical- and cost-effectiveness.

Another direction might entail offering follow-up examinations free of charge to referred participants. This could potentiate meaningful investigations in several ways. First, by eliminating a known barrier to follow-up, i.e. cost, it would better isolate the barrier being addressed by the chosen intervention and increase the likelihood that

changes in follow-up rates between groups are traceable to the intervention. Second, free follow-up examinations could potentially raise the follow-up rate across both the control and intervention groups, leading to a greater sample size for further data collection of extended end-points, as proposed in the previous paragraph. Finally, free follow-up examinations would offer an avenue to investigate whether glaucoma screening programs could offer benefits beyond the immediate problem being screened for by connecting participants to social work resources and offering them an entry point to seek evaluation and management of other chronic issues such as diabetes mellitus or hypertension.

8. CONCLUSION

According to a large body of literature, general population screening for glaucoma is unlikely to be cost-effective, whereas targeted screening of those in higher risk groups may be cost-effective. Targeted screening will never be cost-effective, however, if follow-up rates after a positive screening consistently fall below 40%. Therefore, carefully selected evidence-based interventions designed for increasing follow-up rate comprise an equally important component of delivering a cost-effective program. We examined whether providing prescheduled appointments to participants screening positive for possible glaucoma would increase their likelihood of following up and found that it did not. In certain subsets of patients, however, such as those lacking access to a car or health insurance, the intervention did result in statistically significant higher follow-up rates. Faced with the reality that not all positive screenees can be provided with appointments at the time of screening, these results may help inform optimal allocation of appointments to those who would likely benefit most.

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10. FIGURES & TABLES

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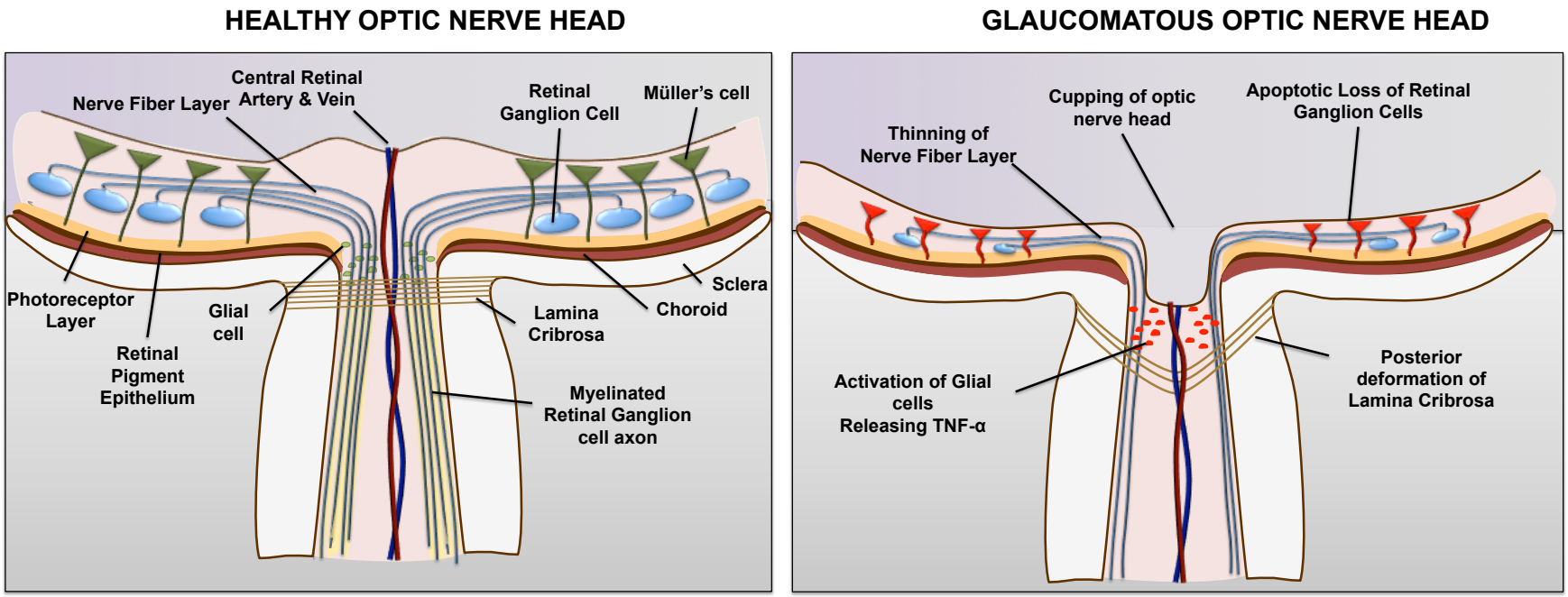
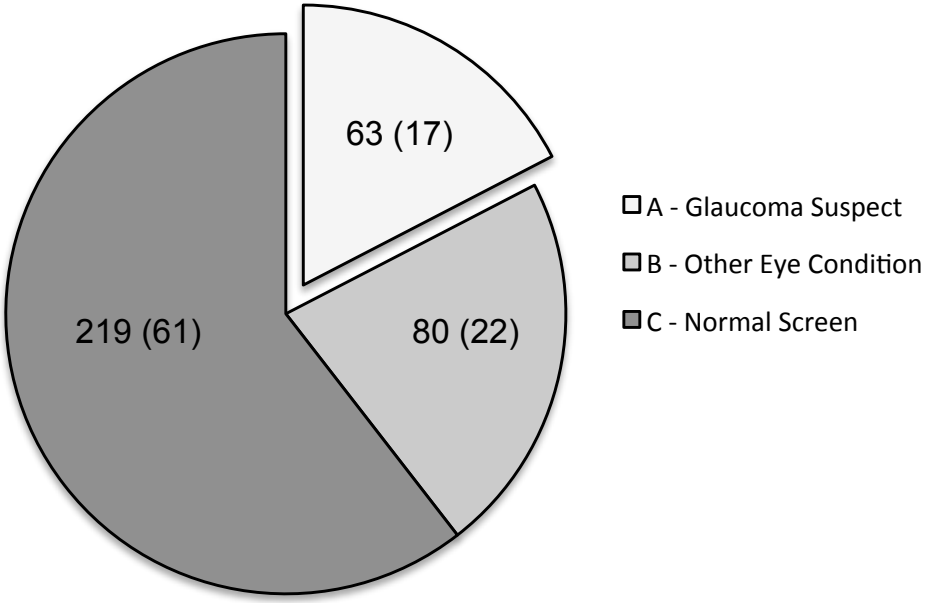


Figure 1. Characteristics and mechanisms of optic nerve damage due to glaucoma.

1. The condition sought should be an important health problem.
2. There should be an accepted treatment for patients with recognized disease.
3. Facilities for diagnosis and treatment should be available.
4. There should be a recognizable latent or early symptomatic stage
5. There should be a suitable test or examination.
6. The test should be acceptable to the population.
7. The natural history of the condition, including development from latent to declared disease, should be adequately understood.
8. There should be an agreed policy on whom to treat as patients.
9. The cost of case-finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole.
10. Case-finding should be a continuing process and not a “once and for all” project.

Figure 2. Wilson and Junger’s Principles for Early Disease Detection.

A



Presented as n (%)

B

Condition	No. (%)
Refractive Error	115 (31.8)
Glaucoma	63 (17.4)
Cataract	39 (10.8)
Diabetes	39 (10.8)
Exotropia	3 (0.8)
Pterygium	1 (0.3)
HTN	1 (0.3)
Other	19 (5.2)
Normal	82 (22.6)
Total	362 (100.0)

Figure 3. (A) Classification of screened participants. (B) Conditions noted on screening exam.

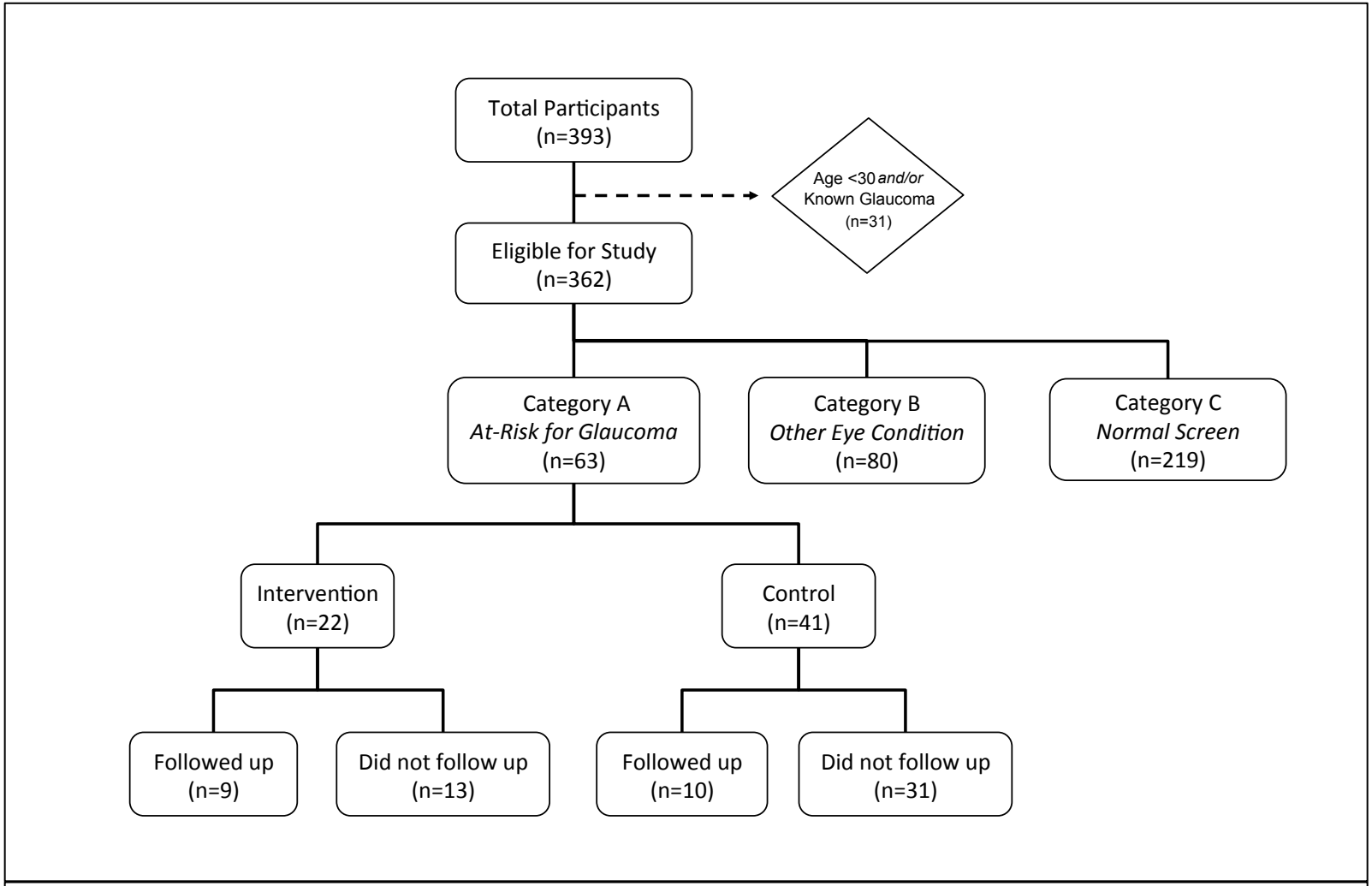


Figure 4. Summary of study design & outcomes

Table 1. Major Risk Factors Associated with Primary Open-Angle Glaucoma.

Risk Factor		Prevalence of Glaucoma (%)	Relative Risk of Glaucoma*	Source of Data
Race				
	Overall (>40 yrs)	1.86		Friedman[1]
	Black	4.97		Tielsch et al.[5]
	Hispanic (Mexican heritage)	4.74		Varma et al.[6]
	Non-hispanic White	1.69		Friedman[1]
	Asian	1.41		Rudnicka et al.[6]
Older age (odds ratio per decade increase)				Rudnicka et al.[6]
	Black		1.61	
	White (including Hispanic)		2.05	
	Asian		1.57	
Elevated intraocular pressure				Sommer et al.[8]
	<15 mm Hg		1.0	
	16-18 mm Hg		2.0	
	19-21 mm Hg		2.8	
	22-29 mm Hg		12.8	
	30-34 mm Hg		39.0	
Diastolic perfusion pressure† (adjusted odds ratio)				Tielsch et al.[11]
	>=50 mm Hg		1.0	
	40-49 mm Hg		1.7	
	30-39 mm Hg		2.1	
	<30 mm Hg		6.2	
Family history in first-degree relative (adjusted odds ratio)			2.9	Tielsch et al.[9]
Myopia (adjusted odds ratio)			1.6-3.3	Mitchell et al.[10], Wong et al.[12]
Thin central cornea (hazard ratio per 40μm decrease)			1.7	Gordon et al.[13]

Table 2. Characteristics of study population

**Presented as N(%)*		**Total (n=63)**	**Intervention (n=22)**	**Control (n=41)**	***P* Value**
Race					0.51
	AA	25 (40)	11 (50)	14 (34)	
	H	22 (35)	6 (27)	16 (39)	
	C	9 (14)	2 (9)	7 (17)	
	O	7 (11)	3 (14)	4 (10)	
Gender					0.26
	M	34 (54)	14 (64)	20 (49)	
	F	29 (46)	8 (36)	21 (51)	
Age					0.16
	30-39	11 (17)	7 (32)	4 (10)	
	40-49	14 (22)	6 (27)	8 (20)	
	50-59	15 (24)	4 (18)	11 (27)	
	60-69	10 (16)	2 (9)	8 (20)	
	70+	13 (21)	3 (14)	10 (24)	
Access to Car					0.68
	Yes	35 (56)	13 (59)	22 (54)	
	No	28 (44)	9 (41)	19 (46)	
Lives Alone					0.84
	Yes	24 (38)	8 (36)	16 (39)	
	No	39 (62)	14 (64)	25 (61)	
Insurance					0.02
	Yes	33 (52)	7 (32)	26 (63)	
	No	30 (48)	15 (68)	15 (37)	
Tobacco use					0.97
	Yes	17 (27)	6 (27)	11 (27)	
	No	46 (73)	16 (73)	30 (73)	
Eye care provider					0.45
	Yes	18 (29)	5 (23)	14 (32)	
	No	45 (71)	17 (77)	27 (68)	
Diabetes					0.22
	Yes	12 (19)	6 (27)	6 (15)	
	No	51 (81)	16 (73)	35 (85)	

Table 3. Unadjusted association between follow-up status and sub-group

**Presented as N(%)*		**Follow-up (n=19)**	**No Follow-up (n=44)**	***P Value***
Group				0.17
	Intervention	9 (41)	13 (59)	
	Control	10 (24)	31 (76)	
Race				0.58
	AA	6 (24)	43 (76)	
	H	6 (27)	36 (73)	
	C	4 (44)	5 (56)	
	O	3 (43)	9 (57)	
Gender				0.68
	M	11 (32)	23 (68)	
	F	8 (28)	21 (72)	
Age				0.79
	30-39	3 (27)	8 (73)	
	40-49	6 (43)	8 (57)	
	50-59	4 (27)	11 (73)	
	60-69	2 (20)	8 (80)	
	70+	4 (31)	9 (69)	
Access to Car				0.42
	Yes	12 (34)	23 (66)	
	No	7 (25)	21 (75)	
Lives Alone				0.89
	Yes	7 (29)	17 (71)	
	No	12 (31)	27 (69)	
Insurance				0.56
	Yes	11 (33)	22 (67)	
	No	8 (27)	22 (73)	
Tobacco use				0.49
	Yes	4 (24)	13 (76)	
	No	15 (33)	31 (67)	
Eye care provider				0.12
	Yes	8 (44)	10 (61)	
	No	11 (24)	34 (77)	
Diabetes				0.33
	Yes	5 (42)	7 (16)	
	No	14 (27)	37 (84)	

Table 4. Effect of intervention on subgroups with barriers (subgroup analysis)

		Follow-up Rate (%)	OR	95% CI	*P Value*
Lives Alone			1.8	.29 - 11.2	0.528
	Intervention (n=8)	37.5			
	Control (n=16)	25.0			
Smokes			2.3	.23 - 22.1	0.487
	Intervention (n=6)	33.3			
	Control (n=11)	18.2			
No Access to Car			36.0	3.1 - 414.9	0.004
	Intervention (n=9)	66.7			
	Control (n=19)	5.3			
No Insurance			12.3	1.3 - 118.4	0.030
	Intervention (n=15)	46.7			
	Control (n=15)	7.0			