

Screening for memory concerns in community-based settings to facilitate early detection of Alzheimer's disease: Can optometry clinics serve as a useful venue?

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BACKGROUND

- Canada faces a critical need to increase screening rates for Alzheimer's disease (AD) given anticipated new treatments for AD. In Ontario, primary care providers (PCPs) are the gatekeepers to medical care; however, primary care settings are not equipped to effectively assess cognition resulting in significant under-diagnosis of AD¹.
- Current AD diagnostics, such as positron emission tomography scans and cerebrospinal fluid analysis, are impractical for scalable and accessible early detection.
- The launch of new AD therapies in 2023 has led to an urgent and unmet need for accessible diagnostics.
- Research shows that retinal hyperspectral imaging can detect biologic signatures of AD given the retina's shared developmental and biological similarities to the brain^{2,3}. RetiSpec's Artificial Intelligence (AI)-based retinal imaging solution may enable an affordable and noninvasive way to enhance real-time clinical decision support at the point-of-care.

To address the rising need for AD screening, novel settings should be explored as an opportunity to enable actionable information for healthcare providers and to provide a pathway to accelerate access to disease-modifying AD treatments.

METHODS

- A cross-sectional, observational study assessed the utility of leveraging novel, communitybased settings to increase rates of cognitive testing (conducted by Alzheimer Society of Toronto [AST] social workers) and assessment of biologic signatures of AD (using RetiSpec's AI-based eye test). Eligible participants were adults aged ≥55 years with selfreported memory concerns.
 - Aim 1: to assess the feasibility of a community-based Alzheimer's screening program to increase rates of cognitive assessments and RetiSpec eye tests
 - Aim 2: to evaluate risks, benefits, facilitators, and barriers to adoption and implementation of these settings to increase rates of cognitive and RetiSpec eye tests
- Dual entry screening: local Alzheimer Society chapter for cognitive assessment or optometry clinics for a RetiSpec scan, plus a brief survey on scan experience (Figure 1)
- Cognitive assessments: included Boston Naming Test (BNT) and Montreal Cognitive Assessment (MoCA), or Mini-Mental State Examination (MMSE) plus Clock Drawing Test (CDT), as per education level. Results were shared with the participant's PCP or studyappointed Nurse Practitioner (NP) and a visit to discuss results was facilitated.
- RetiSpec scan: participants were seated comfortably at a RetiSpec Retinal Imaging System comprised of a commercially available standard fundus camera (Topcon TRC-NW8) and hyperspectral sensor (Cubert FirefIEYE 185) (Figure 2). Bilateral retinal images were acquired over ~10 mins. Dilation drops were administered (per standard clinic practices) for adequate pupil size to ensure high quality imaging.
- RetiSpec AI analysis: ensemble convolutional neural network model of 3-dimensional spectral-spatial architecture that scrutinized multiple retinal regions (Figure 2)
- Utilization focused evaluation⁴: to explore the risks, benefits, facilitators, and barriers to these settings from the perspective of frontline providers via key informant interviews.
- All study activities took place in Toronto, Ontario, Canada over a 9-month period

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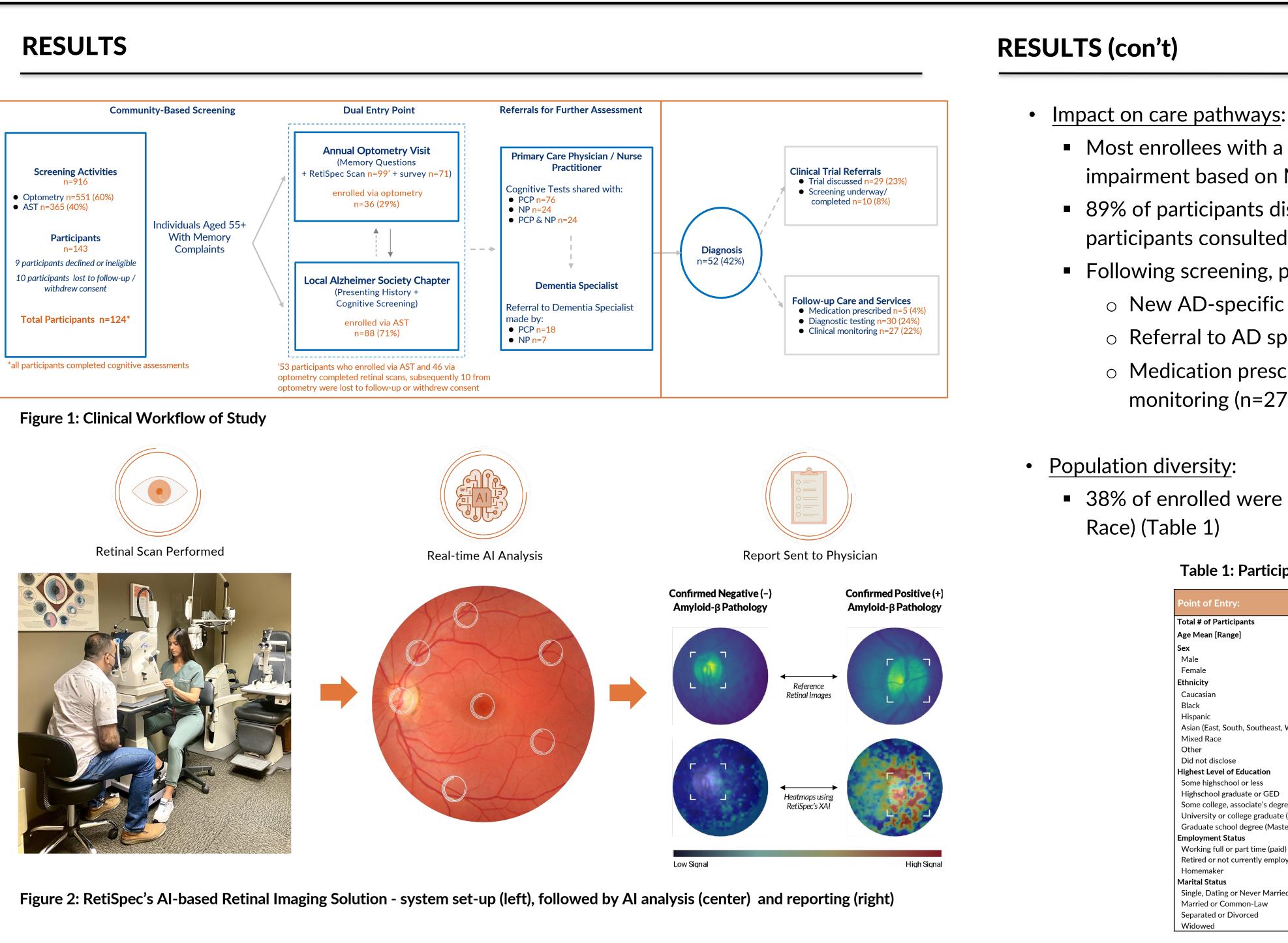
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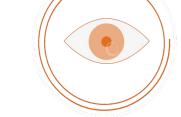
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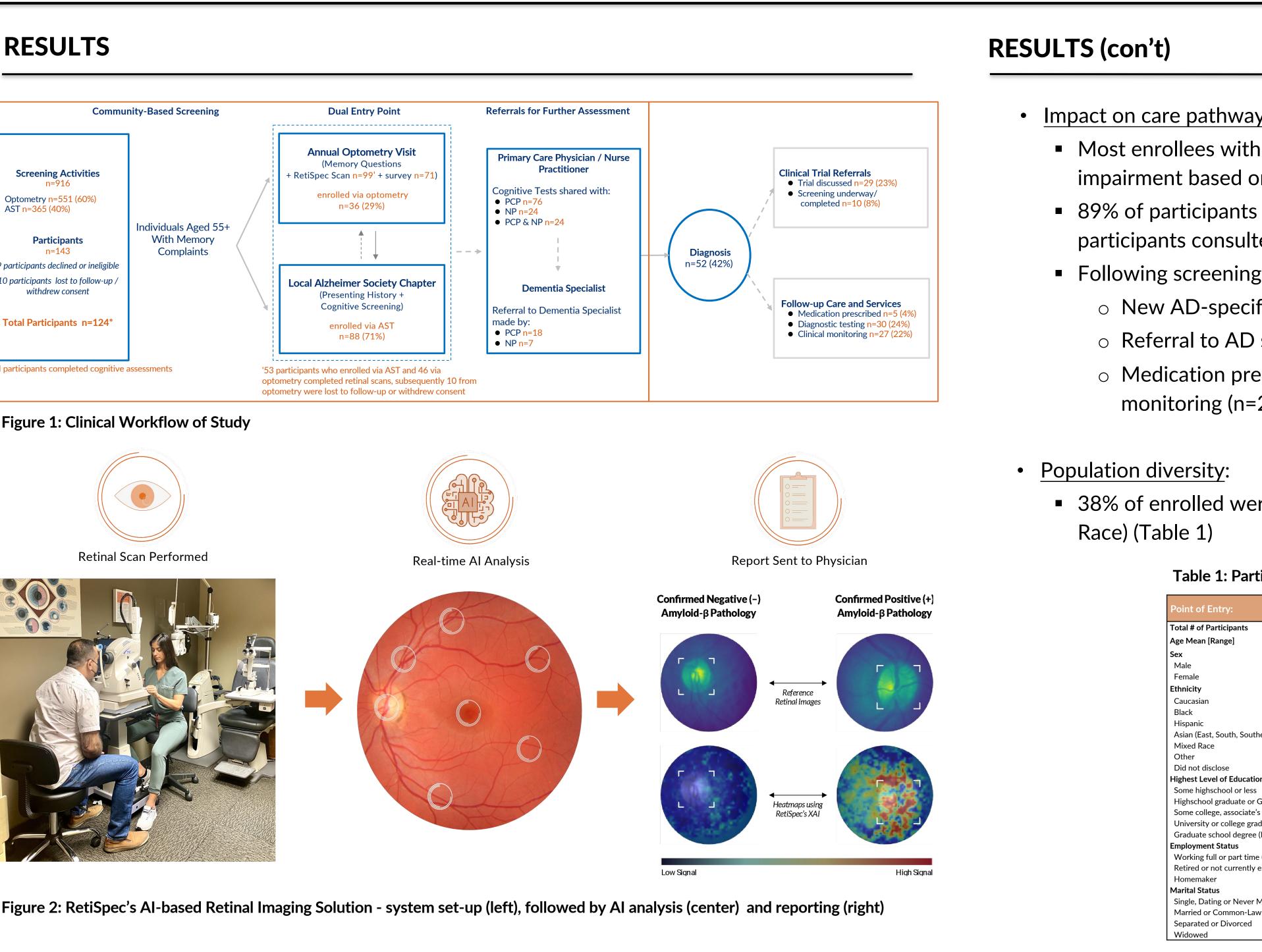




ROGRAM







- Aim 1: RetiSpec eye scans (a) and cognitive testing (b) integrated well into existing clinical workflows where n=916 individuals were screened (Figure 1) (a) 29% of cognitive test referrals originated from optometry compared to the study
- endpoint target of 10% (99/134 participants underwent a RetiSpec scan; 74%) (b) 13.8 cognitive tests/month during study period compared to 1.8 tests/month in the 12-
- month pre-study period (667% increase)
- Aim 2:
 - Benefits: access to screening in comfortable settings, reduced stigma, early detection, patient concerns addressed
 - **Risks:** delays or missed connections for follow-up care, surprising patients with AD screening out of context
 - **Facilitators:** accessible settings for screening, effective training for staff, clear communication pathways with primary care, cost-free screening, Nurse Practitioner closed primary care gaps and enabled timely follow-up
 - **Barriers:** stigma, PCP unresponsive to patient concerns, communication challenges between care partners
- Impact of optometry settings:
 - Screening rates were higher in optometry settings (60% Figure 1)
 - Individuals enrolled through optometry settings showed slightly better cognitive results than those entering through the Alzheimer Society (mean MoCA and BNT scores: 25.0±3.2 and 13.8±1.7 vs 24.5±4.0 and 13.1±2.1, respectively)
 - Results from the RetiSpec post-imaging survey were highly favorable, with positive experiences, willingness to repeat particularly if the cost was covered and unanimous interest in sharing scan results with PCP (Table 3)
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- - Referral to AD specialist (n=25; 20%)
 - Medication prescribed (n=5; 4%), diagnostic testing (n=30; 24%), clinical
 - monitoring (n=27, 22%), or clinical trial referrals (n=29; 23%) were offered

Point of Entry:	Optometry N (%)	Alzheimer Society N (%)	Total N (%)
Total # of Participants	36 (29.03)	88 (70.97)	124 (100
Age Mean [Range]	72.08 [55-87]	75.17 [55-89]	74.26 [55-89
Sex			
Male	14 (11.29)	31 (25.00)	45 (36.29
Female	22 (17.74)	57 (45.97)	79 (63.71
Ethnicity			
Caucasian	20 (16.13)	55 (44.35)	75 (60.48
Black	0	7 (5.65)	7 (5.65
Hispanic	0	2 (1.61)	2 (1.61
Asian (East, South, Southeast, West/Arab)	11 (8.87)	10 (8.07)	21 (16.89
Mixed Race	1 (0.81)	7 (5.65)	8 (6.45
Other	2 (1.61)	7 (5.65)	9 (7.26
Did not disclose	2 (1.61)	0	2 (1.61
Highest Level of Education			
Some highschool or less	1 (0.81)	4 (3.23)	5 (4.03
Highschool graduate or GED	5 (4.03)	7 (5.65)	12 (9.68
Some college, associate's degree or technical training	6 (4.84)	23 (18.55)	29 (23.39
University or college graduate (Bachelor's degree)	11 (8.87)	32 (25.81)	43 (34.68
Graduate school degree (Master's, professional, doctorate)	13 (10.48)	22 (17.74)	35 (28.23
Employment Status			
Working full or part time (paid)	10 (8.06)	15 (12.10)	25 (20.16
Retired or not currently employed	26 (20.97)	72 (58.06)	98 (79.03
Homemaker	0	1 (0.81)	1 (0.81
Marital Status			
Single, Dating or Never Married	3 (2.42)	23 (18.55)	26 (20.97
Married or Common-Law	22 (17.74)	44 (35.48)	66 (53.23
Separated or Divorced	5 (4.03)	10 (8.06)	15 (12.10
Widowed	6 (4.84)	11 (8.87)	17 (13.71

Point of Entry:	Optometry N (%)	Alzheimer Society N (%)	Total N (%)
RetiSpec Assessments	46 (46.46)	53 (53.54)	99 (100
Predicted positive	28 (28.28)	37 (37.37)	65 (65.66
Predicted negative	18 (18.18)	16 (16.16)	34 (34.34
RetiSpec Score Mean [Range]	0.55 [0.36-0.83]	0.59 [0.36-0.90]	0.57 [0.36-0.90
MoCA Assessments	36 (30.51)	82 (69.49)	118 (100
MoCA Score Mean [Range]	24.97 [17-30]	24.5 [14-30]	24.65 [14-30
Normal Cognition	18 (15.25)	40 (33.90)	58 (49.15
Mild Cognitive Impairment	18 (15.25)	35 (29.66)	53 (44.92
Moderate Cognitive Impairment	0	7 (5.93)	7 (5.93
MMSE Assessments	0	6 (100)	6 (100
MMSE Score Mean [Range]	0	18.67 [12-26]	18.67 [12-26
Normal Cognition	0	1 (16.67)	1 (16.67
Mild / Early Impairment	0	1 (16.67)	1 (16.67
Moderate Impairment	0	4 (66.67)	4 (66.67
CDT Assessments	0	6 (100)	6 (100
CDT Score Mean [Range]	0	1.17 [0-3]	1.17 [0-3
BNT Assessments	36 (29.03)	82 (66.13)	124 (100
BNT Score Mean [Range]	13.81 [8-15]	13.08 [5-15]	13.3 [5-15

SUMMARY & CONCLUSIONS

Community-based AD screening facilitated access to cognitive assessments in adults with selfreported memory concerns, which lead to meaningful clinical responses (e.g., specialist referrals, new diagnoses, follow-on care/services) which may have otherwise been missed or delayed

Screening in community-based settings achieved a racially and ethnically diverse population, supporting generalizable results.

Participants reported the RetiSpec scan experience to be positive and would repeat it again. High interest in sharing RetiSpec scan results with their PCP suggests that individuals wish to know their risk of AD and discuss implications with their PCP.

Utilizing community-based settings, including optometry clinics and Alzheimer's Society chapters, demonstrates a promising approach to AD screening. Technology to evaluate amyloid status that leverages existing imaging infrastructure, such as RetiSpec's AI-based eye exam, may offer a pragmatic, affordable, and scalable way to increase AD screening rates via optometry settings.

- Most enrollees with a memory concern were found to have signs of cognitive
- impairment based on MMSE/MoCA evaluations (n=65; 52%) (Table 2)
- 89% of participants discussed their cognitive assessment results with a clinician; 38% participants consulted the study-appointed NP
- Following screening, participants' received a wide range of follow-on care (Figure 1): • New AD-specific diagnosis was given (n=52; 42%)

• 38% of enrolled were from minority groups (including Black, Hispanic, Asian, & Mixed

Table 1: Participant Demographic Characteristics

back from RetiSpec Scan^{*}

Questions	Mean Score*
The RetiSpec scan was difficult to do	Strongly disagree
Was initially nervous/afraid to do the RetiSpec scan	Strongly disagree
The duration of the RetiSpec scan was longer than expected	Disagree
The duration of the RetiSpec scan was reasonable	Agree 4.13
The RetiSpec scan was comfortable for the eyes	Agree 4.17
The RetiSpec seating position and posture were comfortable	Agree 4.21
Level of satisfaction with the RetiSpec scan experience	Very satisfied 4.24
Willingness to undergo a RetiSpec scan again	Very willing
Willingness to undergo RetiSpec scan if covered by OHIP	Very willing 4.63
Interested in providing RetiSpec scan results to clinician	Strongly agree





