Evaluating the efficacy of a Behaviour Change Techniques based and linguistically tailored e-mail reminder to increase attendance to diabetic retinopathy screening

ISRCTN Protocol 18167419

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Study Site	*Centretown Community Health Centre*
Sponsor:	*Investigator-initiated*
Funding by:	*Diabetes Action Canada*
Version Date [Day, Month, Year]	04/06/2025

Statement of Compliance

The Principal Investigator (PI) will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Research Ethics Board (REB) of Record, except where necessary to eliminate an immediate hazard(s) to the study participants. All personnel involved in the conduct of this study will have completed the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, PHIPA, and Protocol Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the REB of Record for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is enrolled. Any amendment to the protocol or consent materials will require review and approval by the REB of Record before the changes are implemented to the study. All changes to the consent form will be REB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

Principal Investigator:

Name: Justin Presseau, PhD

Signed:

Date (DD MM YYYY): 05/05/2025

Site Address

The Ottawa Hospital Research Institute

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List of Abbreviations

CCHC	Centretown Community Health Centre
CDEPO	Community Diabetes Education Program Ottawa
DCO	Diabetes Central Ottawa
DESO	Diabetes Eye Screening Ottawa
DR	Diabetic Retinopathy
DRS	Diabetic Retinopathy Screening
BCT	Behaviour Change Technique
EMR	Electronic Medical Record
FSA	Forward Sortation Area
OHRI	Ottawa Hospital Research Institute
OHSN-REB	Ottawa Health Science Network Research Ethics Board
REB	Research Ethics Board
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus
TCPS2	Tri Council Policy Statement
TOH	The Ottawa Hospital

PROTOCOL SUMMARY

Synopsis

Title	**Evaluating the efficacy of a Behaviour Change Technique-based and linguistically tailored e-mail reminder to promote attendance to diabetes retinopathy screening**
Short Title	A BCT Reminder Intervention for Diabetic Retinopathy Screening
Study Description	Following the successful implementation and demonstrated feasibility of a new community-based telemedicine eye screening program in Ottawa for people with diabetes (see 20210426-01H), this project represents the next step in an ongoing research program. This randomized controlled trial will evaluate whether linguistically tailored outreach materials, co-designed with community members and incorporating behaviour change techniques, effectively encourage individuals from linguistic minority groups in Ottawa to attend diabetic retinopathy screening (DRS). Participants registered with the Community Diabetes Education Program of Ottawa (CDEPO) will be randomized to receive an electronic reminder (intervention condition) or no reminder (control condition). The primary outcome is DRS screening attendance.
Objectives	Evaluate the effectiveness of a tailored electronic reminder incorporating behaviour change techniques (BCTs) in addressing documented barriers to DRS attendance among people with diabetes from linguistic minority groups in Ottawa.
Study Design	This two-arm randomized controlled trial will evaluate the effectiveness of a BCT based and linguistically tailored reminder in increasing DRS attendance. Participants (N= 330) will be randomized into one of two groups: a control (no reminder) or the intervention condition (reminder). The reminder will be sent via OCEAN, a secure patient-provider communication platform, linking participants to a tailored reminder available in English, French, Arabic, and Mandarin. To manage workflow and avoid overloading clinic capacity, reminders will be distributed in 2 waves.

Participant Population, Selection Criteria	Eligible participants will be clients of Diabetes Central Ottawa (DCO) at Centretown Community Health Centre (CCHC) who: a) have Type 1 or Type 2 Diabetes Mellitus, b) have consented to receiving virtual communications from CCHC (as indicated in their medical chart), and c) are 18 years or older and d) have engaged with CCHC in the last 2 years (i.e., had an appointment, attended an education session, updated registration).
Study Sites	Centretown Community Health Centre, Ottawa, Ontario
Participant Duration	The trial period, from reminder distribution to data collection closure, is expected to last 120 days. Participation duration will vary depending on condition allocation and the actions taken by each participant. The estimated time required for each action is as follows: - Reading the reminder: ~5 minutes - Booking an appointment: ~20 minutes - Attending a DRS appointment: ~60 minutes - Completing the in-trial debrief: ~5 minutes The minimum participation time is approximately 5 minutes for control group participants who do not receive a reminder, book, or attend an appointment but must read the debrief. The maximum participation time is approximately 90 minutes, for participants in the intervention groups who receive a reminder, book and attend an appointment, and complete the in-trial debrief.
Number of participants	The study will include up to 330 participants, representing a randomly selected sub-group of eligible individuals registered with the Community Diabetes Education Program of Ottawa (CDEPO). Some attrition is expected due to outdated contact information or participant death. Participants will be evenly randomized into two study arms: control (no reminder) and intervention (reminder), with 165 participants in each group. To avoid overburdening clinic resources at Centretown Community Health Centre (CCHC), the intervention group will receive reminders in waves. Control group participants will be matched to these waves to allow for equivalent comparison timing.

Study Phases (Screening, Observation Period, Follow-Up)	• **Screening:** Not applicable. Only eligible individuals identified through the Community Diabetes Education Program of Ottawa (CDEPO) registry will be included. • **Observation Period:** Participants will be randomized into control and intervention groups. The intervention group will receive reminders in two waves, one month apart, to avoid overloading Centretown Community Health Centre (CCHC) resources. Control group participants will be matched to the timing of the intervention waves. Appointment booking and attendance will be tracked for all participants. • **Follow-Up:** Following the observation period, all participants will be debriefed, and follow-up data collection (e.g., withdrawal requests, attendance status) will continue until all participants have been debriefed.
Efficacy Evaluations	The primary outcome is attendance at a diabetic retinopathy screening (DRS) appointment, compared between the intervention and control groups. A secondary outcome is appointment booking, measured by the number of participants in each group who schedule an appointment.
Safety Evaluations	Potential risks include minor inconvenience from receiving the reminder and possible discomfort if participants are reminded of health concerns. These risks are mitigated by the fact that participants are receiving a reminder for a screening service they are already eligible for and can choose to disregard the reminder. Consent in advance of participation participation is being waived because informing participants in advance would introduce bias and compromise the validity of the study. In accordance with the ethical principles and policies outlined by the Tri-Council Policy Statement (TCPS2) related to waiving consent, participants will be debriefed at the end of the trial and given the opportunity to withdraw their data if they choose.

Statistical Analysis	All analyses will follow the intention-to-treat principle. Descriptive statistics will be used to summarize participant characteristics. The primary analysis will compare screening attendance between arms using absolute and relative differences; chi-squared test or Fisher's exact tests will assess significance. Logistic regression will be used to explore moderation effects across subgroups (age, gender/sex, preferred language, prior DRS attendance, and Forward Sortation Area (FSA).
Data and Safety Monitoring Plan	The Principal Investigator (Presseau) and his delegate (Olson) will be responsible for data quality management and ongoing assessment of the study conduct.

Schematic of Study Design

Screening

Day 0

Total N =330

Randomly select eligible participants (N=330) from CDEPO database. Randomize eligible participants to two conditions (n = 165 per condition), divided into two waves. Consent waived.

Active Intervention Period

Days 1

Distribute first wave of electronic reminders to intervention group.

Track number of reminders sent, appointments made, and appointments attended, by intervention condition. Debrief appointment attendees

Day 30

Distribute second wave of electronic reminders to intervention group.

Track number of reminders sent, appointments made, and appointments attended, by intervention condition. Debrief appointment attendees.

Active intervention period concludes

Day 90

Conclude active intervention period – Wave 1 intervention and control groups

Day 120

Conclude active intervention period – Wave 2 intervention and control groups

Post intervention debriefing and reminders

Day 121 (or next business day)

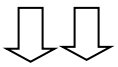
Debriefing information distributed to wave 1 participants who have not yet been debriefed.

Reminder to attend DRS distributed to control group participants in wave 1.

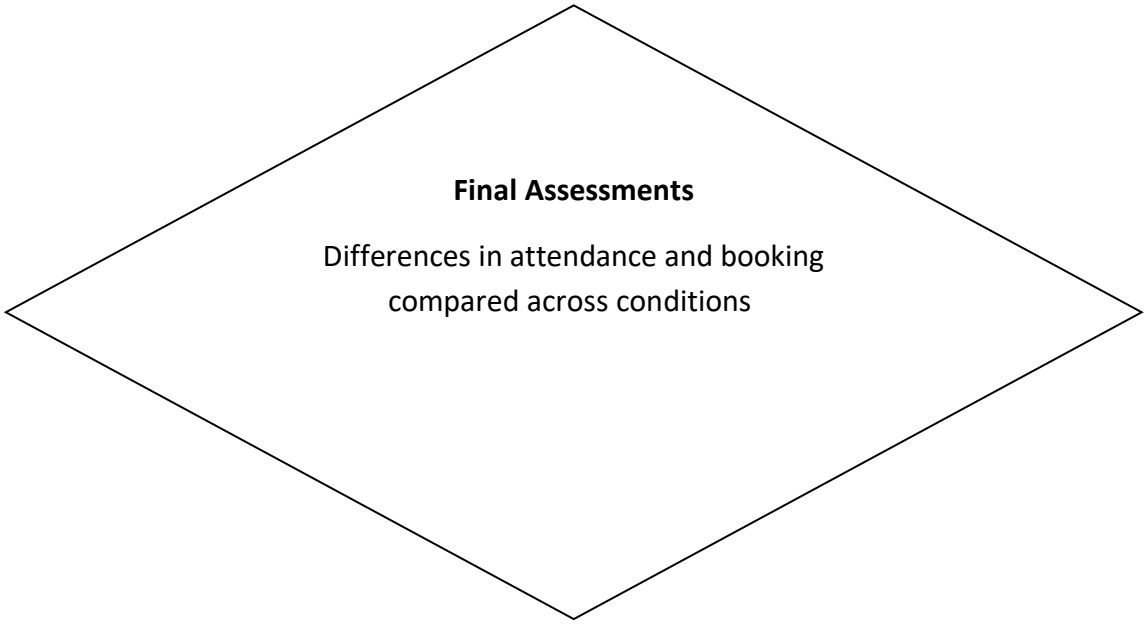
Day 151 (or next business day)

Debriefing information distributed to wave 2 participants who have not yet been debriefed.

Reminder to attend DRS distributed to control group participants in wave 2.



Analysis Period



Schedule of Activities

Activity	Planning Day 0	Intervention Period Day 1	Intervention Period Day 30	Intervention Period **Day 90**	Intervention Period **Day 120**	Post-intervention Day 121	Post intervention **Day 151**	Analysis **Days 121+**
Study team procedures								
Identify eligible participants from CDEPO database	X							
Randomly select 330 participants to take part in the trial.	X							
Randomize participants to conditions.	X							
Waiver of consent	X							
Pilot reminder distribution	X							
Reminder distribution Wave 1		X						
Reminder distribution Wave 2			X					
Intervention period ends Wave 1				X				
Intervention period ends wave 2					X			
Send de-briefing doc Wave 1						X		
Control group reminder distribution Wave 1						X		
Send de-briefing doc Wave 2							X	
Control group reminder distribution Wave 2							X	
Data analysis (Follow-up data collection will continue until all participants have been debriefed)								X

Key Roles

Principal Investigator

Dr. Justin Presseau
Communicates with sponsor and oversees project.

Co-Investigators

Dr. Jen Olson, Senior Methodologist
PI's delegate and study lead – responsible for the day-to-day oversight of the study, statistical analysis, provides feedback on study documents.

Stefanie Linklater, Research Program Manager
Responsible for study continuity in the absence of the study lead. Responsible for arranging contracts and procuring services as needed.

Mackenzie Dowson, Research Assistant
Responsible for day-to-day coordination of the study, creation of study documents, sustaining inter-organizational communications, OHRI – CCHC liaison, preparation for data collection, oversees data collection and is point of contact for any concerns from CCHC

Emily Gibson, Research Coordinator
Responsible for supporting the conduct of study activities including liaising with community partners and supporting the development of research ethics applications.

Monica Taljaard, Research Scientist
Responsible for a priori calculating statistical analyses (e.g., power calculation), trial participant randomization and final analysis of planned comparisons.

Yutong (Betty) Chen, Post Doctoral Fellow
Responsible for a priori calculating statistical analyses (e.g., power calculation), trial participant randomization and final analysis of planned comparisons.

Introduction, Background Information and Scientific Rationale

Background Information and Relevant Literature

Diabetes is among the most common chronic diseases and can lead to serious complications, including diabetic retinopathy,[1–3] a leading cause of preventable blindness in working-aged Canadians[4] and among people living with diabetes worldwide.[5,6] Globally, over 100 million people are affected, with nearly 30 million at risk for vision-threatening diabetic retinopathy, with these numbers projected to increase over the next two decades.[7] Screening is essential for early detection and treatment, yet many people at risk do not regularly have their eyes screened.[8,9]

Several factors contribute to low screening rates, including a lack of understanding of how diabetic retinopathy screening (DRS) differs from routine eye care, the absence of recommendations from

healthcare providers, and limited awareness of available screening programs.[8–10] These barriers are even more pronounced among newcomers to Canada and people from cultural and linguistic minority groups, who face additional challenges such as language barriers, limited healthcare access, and lower awareness to screening services.[10–12] This is particularly concerning as members of these populations have a greater risk of developing diabetes-related complications, compared to the general population of Canada.[5]

To address these challenges, the Ottawa Hospital Research Institute (OHRI), the Ottawa Hospital's Eye Institute (EI), and Centretown Community Health Centre (CCHC) collaborated to develop Diabetes Eye Screening Ottawa (DESO), a community-based tele-retina screening program (see Protocol ID 20210426-01H).[13] DESO was designed to reduce barriers by providing low-cost, linguistically-tailored screening options.

Building on this work, our next step is to explore ways to increase participation in DRS through targeted outreach strategies. Patient reminders can improve health-related behaviours, including attendance at preventive screenings.[14] Different types of reminders – such as telephone calls, automated alarms, electronic medical record (EMR) linked prompts, text-messages, posted mail reminders and emails – have been used to improve screening uptake in areas such as cancer detection and DRS. [15–17] [18] However, not all reminders are equally effective, and tailoring messages to the needs of specific populations is crucial.[14]

Rationale

Reminders are widely used in healthcare settings to encourage preventive screenings, but their effectiveness varies depending on the message design and delivery method. Tailoring reminders to the needs of specific populations – particularly those who face structural barriers to accessing healthcare – may improve their impact. The Theoretical Domains Framework (TDF)[19] and the Behaviour Change Wheel [20,21] provide structured approaches for identifying barriers to health behaviour and selecting appropriate behaviour change techniques (BCTs)[22] to address those barriers. These frameworks have been used in various health behaviour interventions, including those designed to increase screening uptake[18,23,24]. Recent evidence suggests that reminders incorporating BCTs, particularly those addressing knowledge gaps, goal-setting, and social determinants of behaviour, may be effective in encouraging health-promoting actions such as screening attendance[16,18,25].

Therefore, our study will test whether a reminder incorporating a combination of knowledge, social and goal based BCTs effectively increases DRS attendance compared to sending no reminder. By systematically designing and evaluating an evidence informed, linguistically tailored reminder message , we aim to contribute to the growing evidence base on behaviour change in preventive healthcare.

This work will address the following research question:

- How effective are linguistically tailored electronic reminders, incorporating theoretically derived BCTs, in promoting DRS appointment scheduling (secondary outcome) and attendance (primary outcome) among people living with diabetes in Ottawa, compared to sending no reminder?

Potential Risks & Benefits

Potential Risks

This study poses minimal risk to participants. The primary potential risks include minor inconvenience from receiving a reminder and possible mild discomfort if the reminder draws attention to their health status. Participants in the control condition will not receive a reminder to attend DRS during the trial, which may result in a temporary delay in their decision to attend screening. However, these risks are mitigated by the fact that participants are receiving a reminder for a screening service they are already eligible for, can book and attend an appointment without being involved in the intervention, and can choose to disregard the reminder.

Waiving consent introduces the risk that participants will not have the opportunity to make an informed decision about receiving the reminder before it is sent. This could cause confusion or unintended distress. In accordance with the ethical principles and policies outlined by the Tri-Council Policy Statement (TCPS2) related to waiving consent, participants will be debriefed at the end of the trial and given the opportunity to withdraw their data if they choose. Control group participants will receive a reminder to attend DRS at the conclusion of the trial. No additional medical procedures, treatments, or collection of sensitive personal health information are involved.

Potential Benefits

Participants may directly benefit if the reminder encourages them to attend DRS, which can lead to early detection and treatment of diabetic retinopathy. The study may also provide broader community benefits by raising awareness of DRS and improving engagement with screening services. Findings will contribute to the development of effective outreach strategies that can be adapted for other preventive health initiatives, particularly for linguistically diverse populations.

Objectives and Purpose

Primary Objective

The primary objective of this study is to determine whether a linguistically tailored reminder incorporating BCTS to promote DRS increases DRS in participants living with diabetes, compared to not sending a reminder.

Objective	Brief Description / Justification of Outcome Measure	Outcome Measured By	Time Frame
Assess whether a linguistically tailored reminder incorporating BCTs increase DRS *attendance* in participants living with diabetes, compared to not sending a reminder.	DRS is essential for early detection and treatment, yet many people at risk of diabetic retinopathy do not regularly have their eyes screened.	The proportion of participants in each condition who attend a DRS appointment at CCHC.	Assessed at the conclusion of the intervention/ observation period.

Secondary Objectives

Objective	Brief Description/Justification of Outcome Measure	Outcome Measured By	Time Frame
Assess whether linguistically tailored reminders incorporating BCTs increase DRS appointment bookings in participants living with diabetes, compared to not sending a reminder.	Not all participants who book an appointment may attend an appointment. Assessing appointment booking in addition to appointment attendance is important to understand if the intervention is effective in both promoting appointment booking and attendance.	The proportion of participants in each condition who book a DRS appointment at CCHC.	Assessed at the conclusion of the intervention/ observation period.
To examine whether the effect of the intervention on DRS attendance is moderated by participant characteristics, including age, gender/sex, preferred language, prior DRS attendance, and Forward Sortation Area (FSA).	Participant characteristics are likely to influence appointment booking and attendance.	Interaction effects between intervention group and subgroup variables (age, gender/sex, preferred language, prior DRS attendance, FSA) in a logistic regression model predicting DRS attendance.	Assessed at the conclusion of the active intervention period (4 months after first wave of reminders is sent).

Study Design and Endpoints

Description of Study Design

This study is a two-arm randomized controlled trial (RCT) evaluating the effectiveness of a linguistically tailored, BCT based electronic reminder in promoting diabetic retinopathy screening (DRS) attendance. Participants will be randomly assigned to one of two study arms:

- Control group (no reminder)
- Reminder Group (receives reminder incorporating knowledge, social and goal based BCTS).

Participants will be drawn from the Community Diabetes Education Program of Ottawa (CDEPO), registered at Centretown Community Health Centre (CCHC). To avoid overloading clinic resources, reminders will be sent in two waves. Control group participants will be matched to these waves based on distribution timing.

Duration of Study Participation

The study is expected to last approximately 120 days from the start of the intervention to the completion of the active intervention period for participants in wave 2. Final data collection will continue until all participants have been debriefed to ensure accurate documentation of participation status and any withdrawal requests.

Participants' time commitment will vary based on their study condition and actions taken. Estimates of individual participation time by assigned condition and action taken are presented in the table below:

Group	Action taken	Read reminder	Book appointment	Attend appointment	Receive debrief	Total time
Control group	Do not book or attend an appointment	-	-	-	5 mins	5 mins
	Book, but do not attend appointment	-	20 mins	-	5 mins	25 mins
	Book & attend appointment	-	20 mins	60 mins	5 mins	85 mins
Intervention group	Do not book or attend an appointment	5 mins	-	-	5 mins	10 mins
	Book, but do not attend appointment	5 mins	20 mins	-	5 mins	30 mins
	Book & attend appointment	5 mins	20 mins	60 mins	5 mins	90 mins

Total Number of Participants and Sites

This is a single-site study conducted at Centretown Community Health Centre (CCHC). The study will include a randomly selected subsample (N = 330) of eligible individuals listed in the Community Diabetes Education Program of Ottawa (CDEPO) patient database at CCHC. Participants will be randomly allocated 1:1 to either an intervention or control arm (165 per arm). To support clinic capacity, intervention participants will receive reminders in two waves. Control participants will be matched to these waves to ensure comparable observation periods. This sample size achieves 80% power to detect a 10% difference in the primary outcome of screening attendance between the groups (or a proportion of 0.03 in the control arm versus 0.13 in the intervention arm), using a two-sided Z-test with pooled variance at a 5% significance level. Some attrition is anticipated due to outdated contact details or death; thus, our calculation accounts for approximately 10% attrition.

Study Enrollment and Withdrawal

Eligible participants listed on the CDEPO database (i.e., clients with existing medical charts in the CCHC's Electronic Medical Records (EMR), housed on PS Suite v. A-5.24.204, a certified EMR system

hosted by TELUS Health Solutions Inc.) will be identified by CCHC staff. Three hundred and thirty of those eligible will be randomly selected to participate in the study and automatically enrolled.

Participant Inclusion Criteria

Individuals are eligible to participate in the study if they:

a) Are registered to the CDEPO program at CCHC, and
b) have T1DM or T2DM, and
c) have consented to virtual communications from CCHC (as indicated by the inclusion of their email address in the CCHC EMR), and
d) are 18 years of age or older
e) have an active chart (i.e., chart has been updated within the last two years, and
f) have not already attended a DRS appointment with DESO (as indicated in the individual's EMR).

Participant Exclusion Criteria

Individuals are ineligible to participate in this study if they:

a) Are not registered to the CDEPO program at CCHC, or
b) are registered in CDEPO at CCHC but do not:
    - have T1DM or T2DM, or
    - have not consented to virtual communications from CCHC (as indicated by an email address not being listed in the client's EMR), or
    - are not 18 years of age or older
    - Do not have a chart that has a been active in the last two years, or
    - have already attended a DR screening appointment with DESO (as indicated in chart).

Strategies for Recruitment and Retention

As contacting participants in advance would introduce bias, consent for trial participation will be waived. Participants will be debriefed after the trial concludes, either in person or by email, depending on their engagement with the DRS appointment process. Those who attend a DRS appointment will be debriefed in person at CCHC in the eye screening room upon arrival. Those who do not attend will receive a post-study debrief via email, using the OCEAN platform.

Given the passive nature of participation—limited to receiving a reminder and the option to attend a routine DRS appointment—no additional recruitment or retention strategies are necessary.

Participant Withdrawal or Termination

Reasons for Withdrawal or Termination

Participants are free to withdraw from the study at any time upon request. An investigator may terminate participation in the study if:

- An investigator determines continued participation is not in the participant's best interest.
- The study is discontinued.
- The Ottawa Health Science Network Research Ethics Board (OHSN-REB) withdraws study approval.

Handling of Participant Withdrawals or Termination

Participants may withdraw from the study at any time from when they are debriefed about their participation until the study findings are submitted for publication in a peer reviewed journal. No data will be transferred to the research team at OHRI until 2 weeks after all participants have been debriefed, providing ample opportunity for participants to withdraw from the study prior to their data being shared. During this period, data collection by CCHC staff may continue to ensure that any late-stage appointments or withdrawal requests are captured. Requests to withdraw from the study will be made to, and documented by, CCHC staff. When participants withdraw from the study prior to data being shared with the OHRI study team, a note will be placed in the Trial Tracker in the individual's EMR, and the OHRI study team will only receive a summary of the number of participants withdrawn in each condition. If a participant withdraws after data has been shared with the OHRI study team, members of the CCHC team will notify the researchers of the individuals de-identified record number and the individual's data will be deleted and excluded from subsequent analysis.

Study Assessments and Procedures

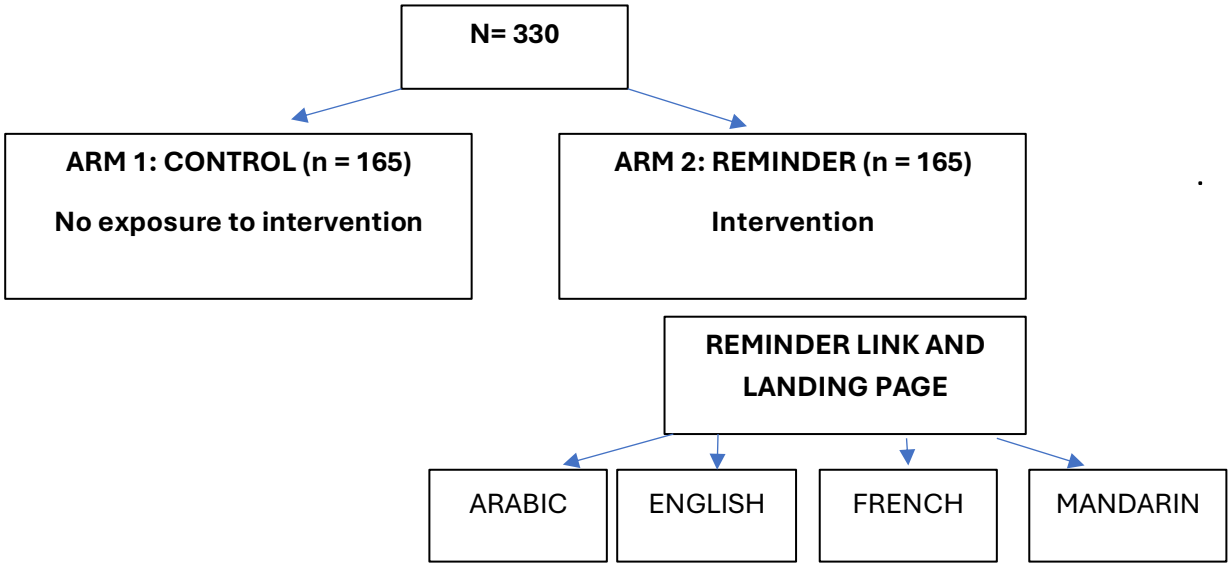
Intervention Preparation Phase

An initial version of the electronic reminder has been developed in English. The research team will collaborate with community partners to tailor the reminder ensuring they are culturally and linguistically appropriate for four linguistic groups that are representative of the linguistic diversity of CCHC clients in Ottawa: Arabic, English, French, Mandarin speaking people. Community partners will include people who are members of these communities, including multi-cultural health navigators or health care providers.

The reminder will then be translated into Arabic, French, and Mandarin with assistance from multilingual collaborators**.** Prior to launching the intervention, reminder distribution procedures will be tested using mock participant files to confirm the correct delivery and functionality of associated links.

Intervention Phase

Reminders will be distributed using the OCEAN secure messaging system integrated with the CCHC electronic medical record (EMR). The reminder will include a unique link to a landing page, where participants can select their preferred language (English, French, Arabic, or Mandarin) to view the tailored content. A schematic of the intervention experience follows, along with a copy of the landing page.



To manage clinic capacity, reminders will be distributed in two waves, each consisting of 80 (+1) participants per condition. Wave 1 participants will receive reminders on Day 1 and will be tracked for 90 days. Wave 2 participants will receive reminders on Day 30 and will be tracked for 90 days (Day 120). Control participants will be matched to these waves to ensure comparable observation periods.

ARM	Wave 1	Wave 2	TOTAL
1 (Control)	83	82	165
2 (Intervention)	83	82	165
TOTAL	166	164	**330**

Wave	Group	Day 1	Days 1-29	Day 30	Days 30-120	Day 90	Day 120	Day 121	Day 151
Wave 1	INTERVENTION	Send reminder	Track booking and attendance					Debrief	
	CONTROL	No reminder	Track booking and attendance					Debrief and DRS reminder	
Wave 2	INTERVENTION			Send reminder	Track booking and attendance				Debrief
	CONTROL			No reminder	Track booking and attendance				Debrief and DRS reminder

Participant Contact and Booking Process

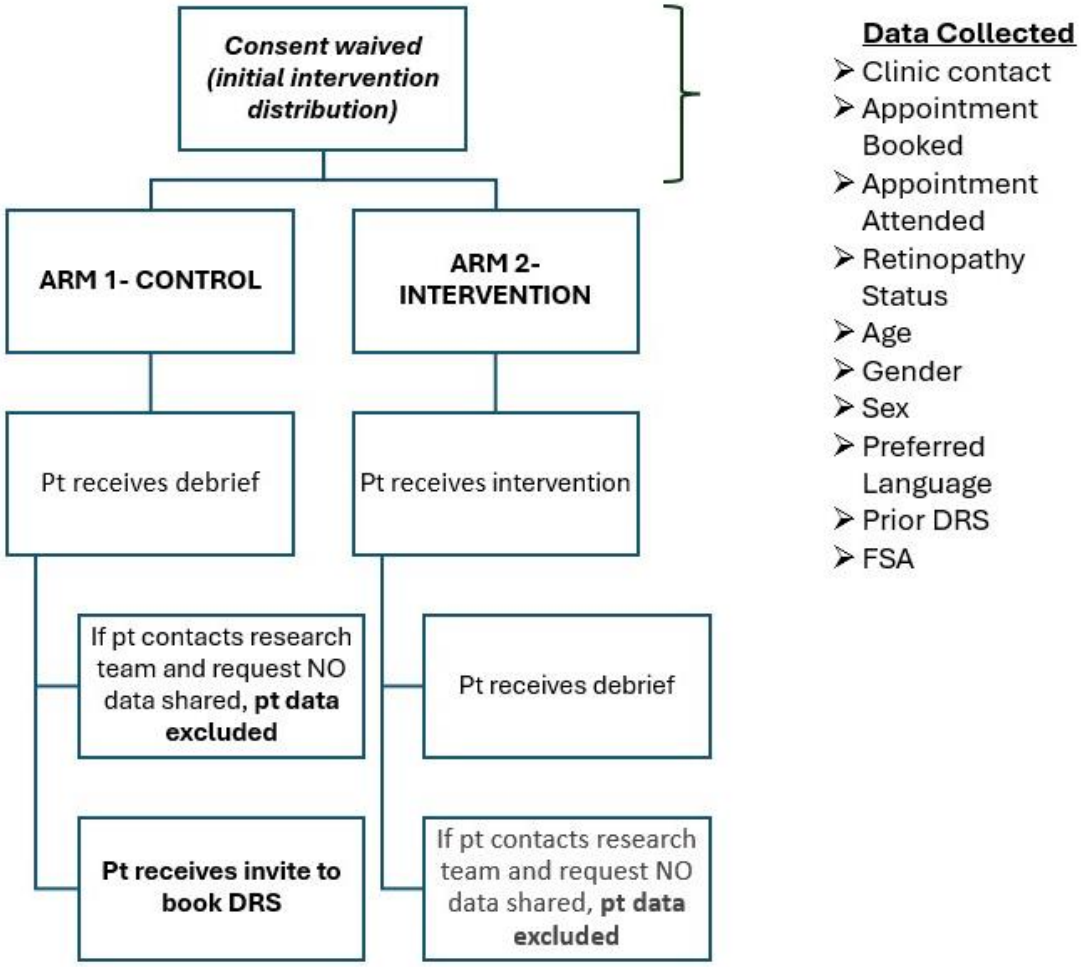
Participants will be able to contact DESO (Diabetes Eye Screening Ottawa) at CCHC via phone, routine CCHC workflow:

1. DESO staff will initiate the booking process by faxing a referral to the participant's primary care provider.
2. Once the referral is received, the administrator will contact the participant to schedule an appointment.
3. If an interpreter is required, one will be arranged unless declined by the participant.

Debriefing Procedures

Debriefing procedures are as follows (and presented in the figure below):

- In-person debriefing: Participants attending a DRS appointment will receive a verbal debrief upon arrival at CCHC.
- Electronic debriefing: Participants who do not attend an appointment will receive a written debrief via the OCEAN EMR system.
- Debriefing materials will explain the study's purpose, data usage, and instructions on how participants can withdraw their data if desired.
- No data will be transferred to the research team until at least two weeks after all participants have been debriefed. Until then, follow-up data (e.g., booking or attendance status, withdrawal requests) may continue to be documented by CCHC staff to ensure complete and accurate records.



Study Procedures / Evaluations

Procedures/Evaluations

When a participant books or attends a DRS appointment, DESO staff will update the DESO Reminder Trial Tracker, which will be maintained within the EMR system (see example below).

Example Reminder Trial Tracker:	
Reminder Received? Client Contacted DESO Date (DD/MM/YY) Client Contact Type ▫ Phone call ▫ Email ▫ Self-Referral Form Online ▫ No contact (default) Language Spoken by Client Age of client in years Forward Sortation Area (first 3 digits of postal code): Has client had a DRS exam before? ▫ Yes ▫ No If yes, approximately what year was last DRS exam	Appointment with DESO Booked ▫ Yes ▫ No ▫ In process If appointment booked- interpretation services booked? ▫ Yes ▫ No Appointment Attended? ▫ Yes ▫ No show Retinopathy Status: Contacted to withdraw data from study? ▫ No (default) ▫ Yes (if yes, DO NOT include this participant's data in the data pull)

After the debriefing period, CCHC staff will extract de-identified trial data and transfer it as a CSV file to a secure OHRI SharePoint folder accessible only to the approved research team. Variables shared with the research team will include all information logged in the Reminder Trial Tracker. The research team will also be advised of the number of participant withdrawals from each group.

Pt ID	**Arm**	**Wave**	**Contact Clinic (Y/N)**	**Book Appointment (Y/N)**	**Attend Appointment (Y/N)**	**Age**	**Gender**	**Sex**	**Prior DRS**	**Spoken Language**	**DR Status**	**FSA**
1												
2												

Example csv data file.

Control of Bias and Confounding

We will use random number generation to assign a condition (control or reminder)to a client at the CCHC. Specifically, the CCHC member responsible for data management will share a CSV file containing unique client ID codes of all eligible individuals. Then the OHRI statistician (MT, BY) will conduct the randomization schedule below, through creating a randomized list of eligible individuals in a spreadsheet containing unique participants IDs. Once the file is prepared, the statistician will lock columns in the document to prevent errors and send the locked document to the CCHC. The document will be stored in an encrypted, limited access folder on the CCHC network. The unlocked columns of the spreadsheet will be used to track whether the client responded to the reminder and other study variables (see below for example spreadsheet). When the data is sent to the OHRI post-

trial, the client ID column will be removed and replaced by “Participant 1- …” before sharing to clear the document of direct identifiers.

RANDOMIZATION SCHEDULE

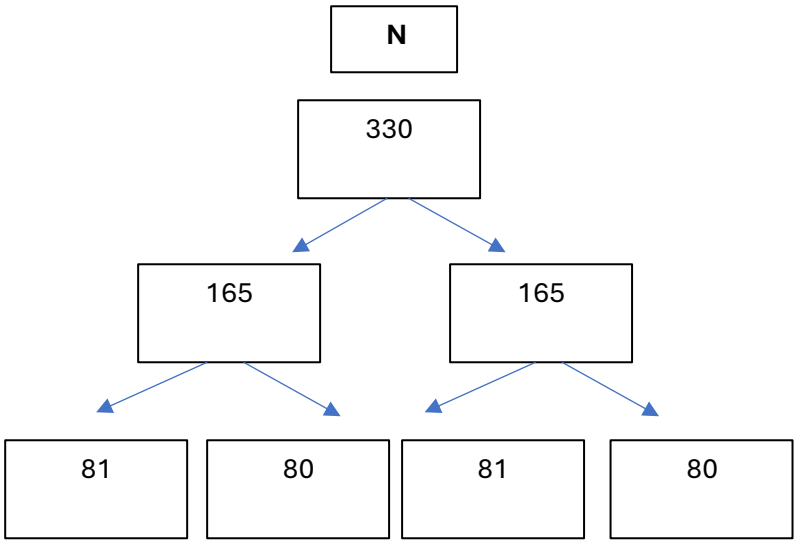
1) 330 participants randomly selected from all eligible individuals listed in the Community Diabetes Education Program of Ottawa (CDEPO), registered at Centretown Community Health Centre (CCHC).

2a) 330 eligible participants randomly assigned to control (n = 165) or intervention (n = 165)

2b) Participants control and intervention groups should be balanced across age and date of last chart update

3a) Control group randomised into wave 1 and wave 2 (n= 80; 81)

3b) Intervention group randomised into wave 1 and wave 2 (n= 80; 81)



Statistical Considerations

Study Hypotheses

- Linguistically tailored reminders will significantly increase DRS appointment attendance (primary outcome) compared to no reminder.
- Linguistically tailored reminders will significantly increase DRS appointment booking compared to no reminder.

Sample Size Determination

Sample size calculations are based on a minimum effect estimate of 10% (based on the effective sizes usually detected in DRS trials[18]) and to achieve 80% power, which requires a total sample of 250 participants. To achieve this sample size, we have estimated we will need to randomize 330

individuals registered to the CDEPO program at CCHC to account for approximately 30% attrition due to outdated contact details or death.

Statistical Methods

Sample characteristics will be described using means and standard deviations for continuous variables and frequencies and percentages for categorical variables. We will also calculate the proportion of those attending screening who test positive for diabetic retinopathy and describe the characteristics of those in the intervention and control groups who (a) booked and attended appointments, booked but did not attend an appointment (i.e., cancelations and no shows), c) did not book or attend an appointment.

To assess the primary outcome, we will compare screening attendance between the intervention and control groups using absolute and relative difference between two proportions with 95% confidence intervals and assess the statistical significance of the difference using a chi-squared test. If the large-sample assumptions are not met, Fisher's exact test will be used. Statistical significance will be assessed at the 5% level.

A similar statistical approach will be to assess the first of the secondary outcomes (i.e., the proportion in each condition who book an appointment). For the final objective of assessing effect modification, we will use logistic regression analysis with the treatment arm, effect modifier and the interaction between treatment arm and effect modifier in the model. Least square mean differences from the model will be used to compare the outcome differences between the subgroup variables: 1) Age, 2) Gender/Sex 3) Preferred Language, 4) Prior DRS Record 5) FSA (Forward Sortation Area).

All analyses will be conducted according to the intention to treat principle. Descriptive statistics (mean and SD for continuous variables or median and IQR for skewed distributions, and frequency and proportion for categorical variables) will be used to summarize participant characteristics in each arm. For the primary analysis of the primary outcome, we will compare screening attendance between the arms using absolute and relative difference between two proportions with 95% confidence intervals and assess the statistical significance of the difference using a chi-squared test. If the large-sample assumptions are not met, Fisher's exact test will be used. Statistical significance will be assessed at the 5% level. A similar statistical approach will be used for secondary outcomes. For the final objective of assessing effect modification, we will use logistic regression analysis with the treatment arm, effect modifier and the interaction between treatment arm and effect modifier in the model. Least square mean differences from the model will be used to compare the outcome differences between the subgroup variables: 1) Age, 2) Gender/Sex 3) Preferred Language, 4) Prior DRS Record 5) FSA (Forward Sortation Area).

Source Documents and Access to Source Data / Documents

Access to study records will be limited to REB-approved members of the study team. The PI will permit study-related monitoring, audits, and inspections by the REB and/or OHRI and compliance and

quality assurance groups of all study related documents (e.g. source documents, data collection instruments, study data etc.). The PI will ensure the capability for inspections of applicable study-related facilities (e.g. pharmacy, diagnostic laboratory, etc.). Please see the data management plan for more information about data access.

Study Oversight

The study will be overseen by the primary investigator, (Presseau) and his delegate (Olson) who will ensure data safety protocols are in place and followed by OHRI and CCHC site data handlers. Data safety during reminder testing phase involves the protection of CCHC client identities when sharing data. No identifying information (i.e., name, health card number, address, phone number or email address) will ever be sent to the OHRI team. If a breach were to occur, the study would stop until the breach was resolved and then restart once there is no question of a second breach.

Those involved in the study will be required to complete a study delegation form.

PROTOCOL NUMBER:	PRINICIPAL INVESTIGATOR (PI): QUALIFIED INVESTIGATOR (QI): (if different from PI)	SITE:
FULL STUDY TITLE	INSTITUTION:	SPONSOR NAME:

Name (N) and Role (R)	Full Signature	Initials	Responsibility (Enter numbers, see list)	Dates of Study Involvement (Y/M/D)	PI/QI Signature to Authorize Delegation of Responsibilities	Date of Signature (Y/M/D)	PI/QI Signature for End of Study or End of Role	Date of PI Signature (Y/M/D)
N				Start				
R				Stop				
N				Start				
R				Stop				
N				Start				
R				Stop				
N				Start				
R				Stop				
N				Start				
R				Stop				
N				Start				
R				Stop				

Ethics / Protection of Human Participants

Ethical Standard

The researchers in the current project will uphold the foundational principles of ethical research outlined in the Tri-Council Policy Statement (TCPS2) including *respect for persons,* promoting autonomy through (continued) informed consent, informed decision making about roles in participation, adaptation and accommodation to meet participant needs, *concern for welfare,* where

no unnecessary risk will be imposed on the participant and participants (and their community) will benefit from the participating in the research as well as the outcomes of the research, and *justice,* where participants treated fairly and compensated for their time and recruitment will focus on identifying a representative and diverse sample with specific considerations in place to encourage people from cultural and linguistic minorities and historically underrepresented groups to participate.

Informed Consent Process and Documentation

Consent for trial participation will be waived in accordance with TCPS 2 (Article 3.7A), which permits such waivers when full disclosure would compromise the research objectives, and the study involves no more than minimal risk.

This study evaluates the effectiveness of Behaviour Change Techniques (BCTs) embedded in an electronic reminder to promote diabetic retinopathy screening (DRS) attendance. Obtaining informed consent in advance would introduce bias, as providing study details could alter participants' natural responses to the reminder, undermining internal validity. Additionally, because the study includes a control group, informing all participants could inadvertently serve as a behavioural prompt, contaminating the control condition.

This design poses minimal risk to participants. All individuals included have previously consented to receive virtual communications—including appointment reminders and provider messages—from Centretown Community Health Centre (CCHC). The reminder used in this study aligns with these routine communications and does not introduce undue influence or burden.

Debriefing will be provided to all participants after the observation period, either in person (if attending a DRS appointment) or via email (if they do not attend). This post-trial communication satisfies TCPS 2 requirements for appropriate safeguards when consent is waived.

Overall, the waiver is justified on methodological, ethical, and practical grounds, with a favourable balance of potential benefits to risks.

Consent / Assent and Other Informational Documents Provided to Participants

Debriefing forms describing in detail the study intervention/observations, study procedures, and risks are given to the participant and is submitted with this protocol:

Debriefing Form

- Participants who attend a DRS appointment during the active intervention period will be debriefed in person by CCHC staff before screening. They will receive the debriefing form and have the opportunity to ask questions or withdraw from the study at that time.
- Participants who do not attend a DRS appointment will be debriefed in writing. The debriefing form will be sent via the OCEAN EMR using the same method as the reminder distribution.
- CCHC staff will document debriefing in each participant's EMR and record any withdrawal requests accordingly.

Research Data Management

Data Management Plan

The following OHRI researchers will have access to the data JP (Principal Investigator), MD, EG, JO. The primary contact/ person responsible for answering any questions about or managing access to the data is Dr Justin Presseau.

Type of Data	Purpose	Data Capture Systems	Data Storage	Accessible by
De-identified clinical and appointment attendance data including variables from the in-chart trial tracker: intervention condition, date of contact, type of contact, appointment booked, interpretation booked, appointment attended, retinopathy detected, spoken language, age, FSA, prior DRS attendance.	To describe sample and observe patterns in appointment attendance by sociodemographic variables and to answer research question of attendance to DRS per arm.	Electronic Medical Record at CCHC	Once exported from the EMR into Excel by the data manager at the CCHC, file will locked for changes and be shared to a secure SharePoint file between OHRI and CCHC.	JP. JO, MD. EG. MT. BY
Web analytics (basic metrics including number of website visits, duration of website visit/ session. clicks on secondary link) No web identifiers (e.g., IP address are to be collected)	To describe website use as this is the platform for the intervention.	Google analytics or website developer analytics	Data will be exported to a secure SharePoint by the Site Owner (CCHC)	JP. JO, MD. EG

Data Collection and Management Responsibilities

De-identified quantitative data will be collected as part of the reminder evaluation. Only the variables specified in the Reminder Trial Tracker will be collected. Final data collection at the site level may continue beyond the active intervention period to allow documentation of any appointments or withdrawal requests that occur before participants are debriefed. This data will be stored in CSV format on a secure OHRI SharePoint site with access limited to study team members responsible for the analysis.

Data Sharing and Reuse

Identifiable data will not be shared. Summaries of analysed data may be shared with relevant partners (i.e., CCHC, Diabetes Action Canada, OHRI research team meetings) prior to the submission of final reports or manuscripts.

De-identified and cleaned datasets, with all direct and indirect identifiers removed, may be uploaded to a secure open-access repository such as the Federated Research Data Repository (FRDR). FRDR is a national platform designed to support the sharing and preservation of Canadian research data.

Study Records Retention

Raw data, data summaries and analyzed data will be stored in a secure file within SharePoint that can only be accessed restricted to members of the study team. Should a researcher leave before the end of the data retention (i.e., 10 years post study completion), they will be removed from the shared folder. JP is responsible for any questions during the retention period.

Protocol Deviations

Any need to deviate from the approved protocol will be reported to the REB and no changes will be made to the approved protocol without informing the REB.

Knowledge Translation

Knowledge Translation (KT) will be integrated throughout the research process. The KT plan will evolve as the study progresses (Barwick, 2022). Early in the project, knowledges users (KUs) will be engaged to provide feedback on the research plan, particularly on outreach and reminder development drawing on their lived experiences. KUs will be consulted again after data collection, to co-develop and review KT strategies and products.

Before participating, all KUs will be fully informed about expectations of collaborators, available participation options, and levels of commitment. The research team will strive to ensure that collaboration is accessible, flexible, and low risk.

The final KT product is not yet determined but will include:

a) development and dissemination of tailored key messages;
b) implementation strategies to promote changes in practice (e.g., improved appointment attendance and outreach); and
c) an evaluation of the KT plan and product for comprehensiveness, alignment, and feasibility (Barwick, 2019).

A potential KT product is a multilingual guide for clinical KUs outlining effective strategies to improve attendance for recommended screening (e.g., annual DRS. This guide would address sociodemographic and structural barriers, include quotes from KUs, and infographics and other accessible materials. It may take the form of online or hardcopy resources, such as a fillable multi-lingual outreach template. Once finalised, appropriate resources will be allocated for its development.

KT will be appraised using Barwick's evaluation criteria (Barwick, 2019). Findings will also be submitted for publication in open access, peer-reviewed journals with high impact.

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