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Telemedicine for diabetic retinopathy screening (Protocol)

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TABLE OF CONTENTS

ABSTRACT	1
BACKGROUND	2
OBJECTIVES	3
METHODS	3
SUPPLEMENTARY MATERIALS	6
ADDITIONAL INFORMATION	6
REFERENCES	8

[Intervention Protocol]

Telemedicine for diabetic retinopathy screening

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ABSTRACT

Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

To evaluate the effectiveness of telemedicine diabetic retinopathy screening versus traditional in-person eye exams in people with type 1 or 2 diabetes mellitus on screening uptake, screening adherence, and referral adherence.

BACKGROUND

Description of the condition

Diabetic retinopathy is the most common complication of diabetes mellitus and is one of the leading causes of preventable blindness in the adult working-age population [1]. The pathophysiology of diabetic retinopathy involves leakage and occlusion of smaller blood vessels in the retina, which can result in permanent vision loss over time, most commonly from advanced diabetic retinopathy complications such as macular edema, vitreous hemorrhage, and tractional retinal detachment.

Within 20 years of diabetes mellitus diagnosis, nearly all people with type 1 diabetes mellitus and over 60% of people with type 2 diabetes mellitus develop diabetic retinopathy [2]. In 2020, 103 million adults worldwide were estimated to have some form of diabetic retinopathy, including 47 million with advanced sight-threatening levels of the disease. By 2045, these numbers are projected to increase to 161 million and 73 million, respectively [1]. Overall, global diabetic retinopathy prevalence in people with diabetes mellitus has been estimated to be over one in five (22%). However, diabetic retinopathy prevalence is disproportionately distributed across global geographic regions, with about one in three people affected in the highest-prevalence regions of Africa (35.90%), North America and the Caribbean (33.30%); and about one in eight people affected in the lowest-prevalence regions of South and Central America (13.37%) [1].

Laser photocoagulation [3] and intravitreal injections or implants of anti-vascular endothelial growth factor therapies [4] are effective treatments to reduce the risk of permanent blindness in diabetic retinopathy [5]. However, the success of these interventions in vision loss prevention is dependent on the effective completion of multiple steps in the diabetic retinopathy screening (DRS) pathway over the lifelong course of a diabetes mellitus diagnosis, in addition to adherence to the indicated course of treatment after acceptance of recommended treatment. These steps include adherence to initial screening (screening uptake); subsequent screening adherence over time (screening adherence); adherence to referrals for treatment after a positive screening (referral adherence); and acceptance of recommended treatment. Despite established evidence supporting the effectiveness of DRS in reducing the risk of vision loss, screening uptake and adherence is consistently below recommended levels in many countries [6, 7, 8, 9], especially in low-and-middle-income countries [10], as well as in most clinical settings globally [11, 12, 13, 14].

Description of the intervention and how it might work

Traditionally, DRS has been conducted via an in-person assessment by a trained healthcare professional performing fundoscopy through dilated pupils, with additional auxiliary testing such as optical coherence tomography (OCT), OCT angiography (OCT-A), and fluorescein angiography (FA) performed to confirm and possibly quantify the presence of diabetic macular edema (DME) or retinal neovascularization. Current clinical practice guidelines recommend DRS at least every one to two years [15, 16], with more frequent screening in advanced stages of the disease to prevent vision loss. Yet as diabetes mellitus prevalence has increased in nearly all settings worldwide, the growing resource demand to implement adequate DRS coverage has outpaced the supply of trained personnel, and has presented further challenges

to maintain optimal DRS coverage. Furthermore, multiple barriers for patients to obtaining traditional DRS from trained healthcare professionals (including geographic, socioeconomic, health literacy, and access barriers) have kept DRS uptake and adherence rates inadequately low. Thus, diabetes mellitus burden increases and barriers have made in-person examinations increasingly impractical and unsustainable for the purposes of adequately maintaining DRS guideline recommendations.

A potentially convenient, streamlined and cost-effective intervention to reduce these DRS challenges is via telemedicine diabetic retinopathy screening (TDRS). TDRS is defined as the use of digital retinal imaging acquired and transmitted for remote evaluation and diagnosis of diabetic retinopathy by a trained grader or evaluated automatically by artificial intelligence-integrated retinal analysis software. Current digital imaging technologies available vary widely, and include desktop fundus cameras (with or without included optical coherence tomography technology) and smartphones with imaging adaptive devices. Regardless of the digital imaging tool, TDRS expands the reach and ease of the DRS process by bringing the digital imaging tool to the patient's clinical point of care, where the patient is more likely to present. For example, in remote or underserved areas with limited access to trained healthcare professionals, a conveniently-placed TDRS program circumvents the need for burdensome travel to specialized clinics by placing the digital imaging tool in a central location. In higher-income areas, where the most frequent and routine diabetes mellitus management takes place in the primary or secondary care setting, a point-of-care TDRS program allows the patient to bypass the additional scheduling and attendance of a separate eye care provider appointment and to participate in a DRS exam with minimal additional time spent, therefore increasing the likelihood of a DRS encounter.

Why it is important to do this review

DRS is an effective screening tool to detect early retinal changes, allowing for timely treatment to prevent vision impairment or blindness. However, DRS screening uptake, screening adherence and referral adherence rates remain suboptimal, with widely-reported geographical variation in DRS coverage and associated inequalities in outcomes, particularly in underserved and rural populations. TDRS potentially provides a quality improvement solution to address these disparities in care.

The technological landscape for TDRS has rapidly evolved over the past decade with significant advancements in digital retinal imaging modalities, quality and portability, as well as artificial intelligence/deep learning algorithms for automated image analysis. These developments have outpaced the evaluation of evidence regarding their clinical effectiveness.

An earlier Cochrane review investigated the effectiveness of a number of quality improvement strategies on DRS screening uptake that targeted patients, healthcare professionals or the healthcare system [17]. Although the use of telemedicine was included in this previous review, given the recent advancements in telemedicine technology and the increased adoption of this screening modality for DRS, a more focused review on TDRS is warranted. Previous non-Cochrane systematic reviews on the use of TDRS have primarily focused on the cost-effectiveness or diagnostic accuracy of this technology [18, 19, 20, 21].

This review aims to provide an updated understanding of the effectiveness of the TDRS model's ability to improve screening uptake, and investigate its effect on screening adherence and referral adherence. To our knowledge, these last two outcomes have not been studied previously in systematic reviews. This information is important to patients in preventing vision loss; to healthcare professionals treating those with diabetes; to communities who may face inequity in a traditional screening system and are burdened by sight-threatening morbidity from diabetes; and to policymakers who use evidence-based medicine to inform policy decisions that could improve early detection of sight-threatening diabetic retinopathy. In addition, our review will have a strong equity focus, an aspect not significantly assessed in prior reviews.

OBJECTIVES

To evaluate the effectiveness of telemedicine diabetic retinopathy screening versus traditional in-person eye exams in people with type 1 or 2 diabetes mellitus on screening uptake, screening adherence, and referral adherence.

METHODS

Criteria for considering studies for this review

Types of studies

We will include all forms of randomized controlled trials (RCTs), such as cluster-RCTs and quasi-RCTs, that were either specifically designed to explore traditional diabetic retinopathy screening (DRS) versus telemedicine diabetic retinopathy screening (TDRS) methods or that reported on the effectiveness of these methods. Cross-over studies will only be included if trial investigators appropriately reported comparison data. We will include eligible studies regardless of their study setting, publication status, language, or year of publication.

Types of participants

We will include studies enrolling individuals of any age with diabetes mellitus of types 1 or 2 who were screened for diabetic retinopathy without any geographical, race/ethnicity, or socioeconomic restrictions. It is possible that studies may include participants outside of the population of interest for this study. We will include these studies if that subset is analyzed separately or if $\geq 90\%$ of participants have diabetes type 1 or 2.

Types of interventions

We will include RCTs that compare TDRS versus traditional eye exams for diabetic retinopathy screening.

We define TDRS as any digital retinal technology (including, but not limited to, fundus photographs and optical coherence tomography (OCT) that produce images that are subsequently interpreted by one or more trained human graders, as defined by the included study, or are interpreted by automated retinal analysis software).

We define traditional eye examinations as an in-person examination by a trained health care provider who performs a retinal exam to evaluate the patient for diabetic retinopathy, including any additional auxiliary testing (including, but not limited to, fundus photographs and OCT).

Outcome measures

Critical outcomes

The critical outcome in this review will be screening uptake, defined as the proportion of participants with diabetes who attend the initial DRS within 12 months of study enrollment.

Important outcomes

The review will also include the following important outcomes.

- Screening adherence, defined as the proportion of eligible individuals who attend subsequent screening(s) within 24 months of the initial screening uptake.
- Referral adherence, defined as the proportion of eligible individuals who attend their referrals for further intervention for their diabetic retinopathy within six months of initial or subsequent screening uptake.
- Adverse events: there are limited adverse events expected from a retinal screening due to the minimal risk and intervention involved in any retinal screening. However, we will report any adverse events reported by included studies, including but not limited to missed retinal pathology, patient-reported issues after DRS, or DRS complications (e.g. technical issues or sequelae from mydriatic eyedrops).

Search methods for identification of studies

Electronic searches

We will limit the search to include studies published from 2000 onward, in order to examine the effectiveness of more current and relevant imaging technologies and DRS pathway processes.

We will search the Cochrane Central Register of Controlled Trials (CENTRAL) (which contains the Cochrane Eyes and Vision Trials Register), Ovid MEDLINE, Ovid MEDLINE E-pub Ahead of Print, Ovid MEDLINE In-Process and Other Non-Indexed Citations, Ovid MEDLINE Daily (January 2000 to present), Embase.com (Elsevier) (January 2000 to present), PubMed (2000 to present), Latin American and Caribbean Health Sciences Literature Database (LILACS) (2000 to present), ClinicalTrials.gov (www.clinicaltrials.gov) and the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (www.who.int/tools/clinical-trials-registry-platform).

We will not use any language restrictions in the electronic search for trials.

See [Supplementary material 1](#) for details of search strategies for CENTRAL, MEDLINE, Embase.com, PubMed, LILACS, ClinicalTrials.gov and the ICTRP.

Searching other resources

We will manually search the reference lists of included trials and any relevant systematic reviews to identify additional potentially relevant trials. We will also contact experts in the field to request information on any ongoing or unpublished studies that would be relevant for this review. All unpublished and ongoing studies will be classified as 'ongoing'.

Prior to data extraction, we will search Ovid MEDLINE and PubMed for retractions, withdrawals, corrections, comments, and replies to comments. Also, we will download the most current Retraction

Watch database as a.csv file and search by study report title [22]. We will follow Cochrane Editorial Policy on managing problematic studies should these be identified [23].

Data collection and analysis

Selection of studies

The Information Specialist will perform the search and remove duplicates. Two review authors will independently screen the titles and abstracts of all records identified in the search using Covidence and the prespecified eligibility criteria based on study type, population, and intervention [24]. Full-text reports will be retrieved for studies classified as relevant or potentially relevant. The two review authors will then independently review the full-text articles and classify each as ‘include’ or ‘exclude’ and document reasons for exclusion in the ‘Characteristics of excluded studies’ table. The unit of interest in the review is each study rather than each report, and we will list multiple reports of the same study under a single study ID. For both initial screening and full-text review, we will resolve any disagreements by discussion and will consult a third review author if discussion does not result in consensus.

If trial registrations of studies that have not yet finished meet the eligibility criteria, we will include them in the review and classify them as ‘ongoing’ studies. If questions arise regarding any study’s eligibility, whether due to incomplete reporting or publications not being obtainable, we will contact the study investigators via email for clarification. If the investigators do not respond within two weeks or if eligibility remains uncertain, we will classify the study as ‘awaiting classification’. We will report the study selection process in detail in order to complete a PRISMA flow diagram [25].

Data extraction and management

Two review authors will independently extract data from the full-text articles using a pre-piloted data extraction form in Covidence [24]. They will collect the following information: study objective, publication characteristics, methods, participants, population characteristics data using the Cochrane PROGRESS-plus framework (place of residence, race/ethnicity/culture/language, occupation, gender/sex, religion, education, socioeconomic status, social capital) [26, 27, 28, 29], an adapted version of the Healthy People 2030 framework (economic stability, education and access, healthcare access and quality, neighborhood and built environment, social and community context) [30, 31], interventions, outcomes, and other information.

We will contact study investigators to request clarification or missing information. If the investigators do not respond within two weeks or information remains uncertain after the last communication before review, we will proceed with the information available. We will complete data extraction using all identified and available sources from any given study. If there are differences in the information presented across sources, we will use the information from the most complete report (e.g. the primary publication) if available, and from the most recent source if not reported in the primary publication. Inconsistencies in data extraction between the review authors will be resolved by discussion, and we will consult a third review author if discussion does not result in consensus.

We will also extract data on the proportion of individuals diagnosed with vision-threatening diabetic retinopathy (VTDR) at screening uptake and screening adherence. VTDR is defined as severe nonproliferative diabetic retinopathy, proliferative diabetic retinopathy, or clinically significant macular edema [32].

Risk of bias assessment in included studies

Two review authors will independently assess the risk of bias in each of the included trials using the risk of bias 2 tool (RoB 2) outlined in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* [33]. We will settle any disagreements in risk of bias assessment by discussion and will consult a third review author if discussion does not result in consensus. We will assess the effect of assignment to intervention for all four predefined outcomes.

We will evaluate the five bias domains in the RoB 2 tool.

- Bias arising from the randomization process
- Bias arising from deviations from intended interventions
- Bias arising from missing outcome data
- Bias in measurements of the outcome
- Bias in selection of the reported result

We will determine an overall risk of bias judgment for each trial using the RoB 2 algorithm [34].

- Low risk of bias if all domains are judged to be at low risk of bias.
- Some concerns if at least one domain is judged to have some concerns without any high risk of bias judgments in any of the domains.
- High risk of bias if at least one domain is judged to have high risk of bias, or the study has some concerns across multiple domains.

If the paper reports insufficient information to assess the risk of bias, we will contact the study investigators and ask for the additional information needed to assess this risk.

As we will include cluster-randomized and cross-over randomized trials, there are some additional considerations for assessing risk of bias in these special trial designs. We will use the Cochrane RoB 2 extensions for cluster-randomized and cross-over randomized trials [35]. For cluster-randomized trials, we will also assess the additional selection bias arising from the timing of identification and recruitment of participants. For cross-over trials, we will also consider bias due to carry-over effects in the ‘Reporting bias’ domain.

Measures of treatment effect

We will conduct data analysis utilizing Chapter 10 of the *Cochrane Handbook for Systematic Reviews of Interventions* [36]. For continuous measures, we will use mean differences (MD) with 95% confidence intervals (CIs). For dichotomous measures, we will use the log odds ratio as there may be greater variance in reported data. We will use data at the longest follow up if there are multiple screening update data within the first 12 months. If outcomes are presented as a continuous outcome measure and cannot be dichotomized, we will present the data as the mean difference (MD) or standardized mean difference (SMD).

Unit of analysis issues

When studies randomize participants, the unit of analysis will be an individual participant. It is unfeasible to randomize diabetic retinopathy screenings to one eye per participant.

We will include cluster-randomized trials in meta-analyses where study comparability permits. In the case that a cluster-randomized trial is included in the review and outcomes are reported at the cluster-level, the unit of analysis will be the cluster. If a cluster-randomized trial does not report cluster-level summary data and instead reports individual-level summary data, we will approximate cluster-level summary data by using the intracluster correlation coefficient (ICC) and number of clusters, as described in Chapter 23 of the *Cochrane Handbook for Systematic Reviews of Interventions* [37].

If there are relevant cross-over trials for this meta-analysis, we plan to only use data from the first period as the intervention arm may bias subsequent outcomes based on previous experience. Additionally, there is a chance that there may be trials with multiple intervention arms and the authors will determine whether all arms are relevant to the meta-analysis. If multiple treatment arms are relevant, we will combine groups where appropriate to create a single pair-wise comparison.

Dealing with missing data

If there are missing data, we will contact the author(s) of the primary trials to request the information of interest. If the study investigators do not respond within two weeks, we will proceed with the available information and assess the impact of the missing data on the overall interpretation of results. We will use imputed data if computed by the trial investigators using suitable statistical methods; we will not impute missing data ourselves.

In dealing with missing data, we will follow the recommendations outlined in Chapters 6 and 10 of the *Cochrane Handbook for Systematic Reviews of Interventions* [36, 38].

Reporting bias assessment

Two reviewers will independently evaluate selective result reporting by studies, utilizing the RoB 2 tool's associated signaling questions. If we have 10 or more eligible trials, we will use funnel plots to detect the presence of small-study effects or to investigate any factors that might lead to asymmetry in the plots, such as publication bias, following the guidelines provided in Chapter 13 of the *Cochrane Handbook for Systematic Reviews of Interventions* [39].

Synthesis methods

If the included studies demonstrate sufficient similarity, we will carry out a quantitative synthesis and conduct statistical analysis in RevMan [40], in accordance with Chapter 10 of the *Cochrane Handbook for Systematic Reviews of Interventions* [36]. If no statistical or clinical heterogeneity is found and fewer than three trials contribute data to a meta-analysis, we will use a fixed-effect model to estimate intervention effects. However, if more than three trials contributed data to a meta-analysis, we will use a random-effects model.

There is the possibility of diversity in the data for this meta-analysis, and we will use the Restricted Maximum Likelihood (REML) estimator to estimate between-trial variance. If statistical

or clinical heterogeneity is greater than zero and there are more than three trials, we will use the Hartung-Knapp-Sidik-Jonkman method to calculate a confidence interval for the meta-analysis effect estimate. In other scenarios, such as no heterogeneity or pooled analyses of two studies, we will employ the Wald-type method.

Investigation of heterogeneity and subgroup analysis

We plan to investigate clinical or methodological heterogeneity among included studies by evaluating differences between participant populations, interventions, and outcome measurements. We will evaluate statistical heterogeneity among outcome data by examining overlap in confidence intervals of forest plots and by using the χ^2 and I^2 statistics, as described in Chapter 10 of the *Cochrane Handbook for Systematic Reviews of Interventions* [36]. In the case that we observe substantial heterogeneity clinically, methodologically, or statistically, we will not conduct a meta-analysis and instead use narrative synthesis to describe the results.

In the event that at least 10 studies provide sufficient data, we plan to perform subgroup analyses on the following characteristics.

- World regions as defined by the World Health Organization [41]: African Region (AFRO), Region of the Americas (AMRO), South-East Asia Region (SEARO), European Region (EURO), Eastern Mediterranean Region (EMRO), Western Pacific Region (WPRO)
- Ethnicity as defined by the US Office of Management and Budget [42]: Asian, American Indian or Alaska Native, Black or African American, Hispanic or Latino, Middle Eastern or North African, Native Hawaiian or Pacific Islander, White
- Socioeconomic status: low, middle, high annual household or personal income brackets
- Geographic classification as defined by the included trials (e.g. rural versus urban)

Equity-related assessment

It is well established that differences exist across multiple health outcomes in certain demographic groups. A higher prevalence of diabetic retinopathy has been found, for example, in the World Health Organization regions of Africa, the Middle East, and the Americas [1, 43], as well as in people of Hispanic, African, and Middle Eastern descent, compared with white populations [1, 44]. Beyond ethnicity, other factors, including lower socioeconomic status, lower household income, lower education and rural geography, have also been associated with reduced access to retinal screening [45].

The modality of telemedicine itself may allow for greater access to retinal screening for these populations, especially in low-income and rural settings [10]. Therefore, it is important to determine how outcome effects differ in these different populations to understand the effectiveness of telemedicine diabetic retinopathy screening (TDRS) in addressing differences in health outcomes. This will be performed in the subgroup analysis described above.

Sensitivity analysis

We plan to perform a sensitivity analysis on critical outcomes by excluding studies with a high overall risk of bias as determined by RoB 2. We plan to perform a sensitivity analysis of our critical

outcome (screening uptake) and important outcomes (screening adherence, follow-up adherence, and adverse effects).

Certainty of the evidence assessment

We will create a summary of findings table following guidance outlined in Chapter 14 of the *Cochrane Handbook for Systematic Reviews of Interventions* [46]. The table will present information regarding population, setting, comparison, and findings on the following outcomes.

- Screening uptake within 12 months
- Screening adherence within 24 months
- Referral adherence, defined as the proportion of eligible individuals who attend their referrals for further intervention for their diabetic retinopathy within six months of initial or subsequent screening uptake
- Any adverse events reported by included studies, including but not limited to patient-reported issues after DRS, or DRS complications (e.g. technical issues or sequelae from dilating drops)

We will use the GRADE approach to determine the certainty of the body of evidence for the predefined outcomes [47]. Two reviewers will independently judge the certainty of evidence as 'high', 'moderate', 'low', or 'very low'.

We will downgrade the certainty of the body of evidence when we identify any of the following.

- High risk of bias in the included studies
- Indirectness of evidence
- Significant heterogeneity or inconsistency of results
- Imprecision of results
- Greater likelihood of publication bias

Any disagreement in assessments will be resolved by a third author.

Consumer involvement

We will not involve consumers in this review due to limited resources.

SUPPLEMENTARY MATERIALS

Supplementary materials are available with the online version of this article: [10.1002/14651858.CD016315](https://doi.org/10.1002/14651858.CD016315).

Supplementary material 1 Search strategies

ADDITIONAL INFORMATION

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- Managing Editor (selected peer reviewers, provided editorial guidance to authors, edited the article): Sue Marcus, Cochrane Central Editorial Service
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Contributions of authors

AS: lead for protocol (conceptualization, project administration, original draft writing, review and editing)

MS: conceptualization, project administration, original draft writing, review and editing

EI: conceptualization, methodology, original draft writing, review and editing

GH: conceptualization, methodology, original draft writing, review and editing

ZK: supervision, conceptualization, review and editing

KH: original draft writing, review and editing

JL: supervision, conceptualization, review and editing

Declarations of interest

AS: none

MS: receives consulting fees from EyePACS

EI: none

GH: none

ZK: none

KH: none

JL: none

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Data, code and other materials

Data sharing is not applicable to this article as it is a protocol, so no datasets were generated or analyzed.

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