THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

INFORMATION SHEET

AI-powered low-cost portable fundus camera to deliver diabetic retinopathy screening at primary health care setting: a pragmatic trial

You are invited to participate in the above project conducted by Dr HE Mingguang, who is a staff member of the School of Optometry in the Hong Kong Polytechnic University (PolyU). The project has been approved by the PolyU Institutional Review Board (PolyU IRB) (or its Delegate) (Reference Number: HSEARS20231218003).

Before deciding whether to participate in this study, please read this information sheet carefully. It will help you understand the nature of this research, why it is being conducted, the procedures and duration of the study, and the potential benefits, risks, and discomforts that may arise from your participation.

You may wish to discuss this with your relatives and friends, or ask the project researchers or physicians to explain any questions you have, to help you make your decision.

If you are currently participating in another study, please inform the researchers.

1. Background and Objectives of the Project

1.1 Current Status of the Disease

Diabetic Retinopathy (DR) is one of the significant health challenges in Hong Kong. It is estimated that approximately 10% of individuals aged 35 to 64 have diabetes, 30% of them develop DR. Timely detection, prevention, and treatment are crucial to control the progression of DR. Retinal photography is a valuable and cost-effective screening tool that can be used to detect the changes associated with diabetic retinopathy. However, traditional fundus photography requires professionals for operation and analysis. The shortage of ophthalmic professionals in public healthcare institutions and the lack of screening equipment in private clinics in Hong Kong hampers the widespread implementation of routine fundus photography screenings.

We plan to integrate a low-cost, portable, self-testing fundus camera with a deep learning AI system to develop an innovative do-it-yourself (DIY) screening model at general practitioner clinics and optometry clinics in Hong Kong. This system integrates fundus imaging technology, artificial intelligence, and automation technology, allowing patients to complete retinal imaging independently with voice prompts, without the need for professional technicians.

This study will be carried out in six representative clinics by clinical research scientists and research assistants, who will identify eligible participants. Patients willing to participate will provide written informed consent voluntarily.

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1.2 Objectives of the Project

The aim of this project is to assess the feasibility and impact of the DIY DR screening system in primary healthcare settings in Hong Kong. This includes evaluating the success rate of the DIY screening system without active assistant help, diagnostic accuracy, screening rate, and referral compliance from the patient's perspective; satisfaction, experiences, perceptions, and confidence in the DIY system from the medical worker's perspective; and assessing cost-effectiveness.

1.3 Study Participants and Expected Number of Subjects

The study is initiated and directly undertaken by The Hong Kong Polytechnic University.

We will conduct a three-month pragmatic trial in two optical stores and one optometry clinic. The total sample size will be 500 subjects.

2. Inclusion and Exclusion Criteria

Participants who meet the following criteria will be included in the study:

(a) Subjects who are 50 years of age or older, or subjects who are 18 years of age or older and have diabetes, and
(b) Have not undertaken an eye examination in the previous 12 months (elevated risk of undiagnosed disease), and
(c) Provide written informed consent.

Subjects will be excluded if

(a) Individuals with physical disabilities that prevent the use of a fundus camera, or
(b) Individuals with speech impairments who are unable to complete telephone follow-ups.

3. Study Procedures

3.1 Pre-Study Procedures: Before you are enrolled in the study, the support staff will ask and record your medical history and examination to confirm your eligibility. After this confirmation, you will sign an informed consent form.

3.2 Consent for DIY AI Screening System: If you agree to use the DIY AI screening system, the support staff will proceed. If you do not agree, the staff will briefly inquire about the reasons for refusal.

3.3 AI Screening: If you opt to use the DIY AI screening system, you will complete the DR retinal screening independently with voice prompts. Our support staff will monitor the process and assist with the retinal photography if needed. Additionally, the staff will collect basic data including gender, age, history of eye disease, satisfaction with the DIY screening system, and other health-related questionnaire responses.

3.4 Screening Report Issuance: You will receive an immediate screening result report generated by

the AI.

3.5 Physician/Optometrist Consultation: A physician or an optometrist will conduct a visual acuity (VA) examination and interpret the retinal photos and AI report, potential diagnosis and, if necessary, providing referral advice.

3.6 Follow-Up: If the screening suggests an ocular disease, we will contact you for a phone follow-up after three months to understand your referral compliance, inform you of the expert's re-diagnosis, and assess your satisfaction with the examination.

3.7 Time required: the AI screening will be around 5 minutes, and the follow-up phone interview will be around 10 minutes.

4. Benefits and Risks

4.1 Benefits

The study involves using an AI-powered fundus camera for screening, followed by an optometrist or ophthalmologist examination and consultation, a survey with questionnaires and a phone interview three months after their baseline assessment. Participants will receive a free automatically graded DR classification report, clarifying the health status of their retina. If any suspected lesions are identified, the report will also include further information such as follow-up recommendations and be re-assessed by an ophthalmology expert.

4.2 Risks and Discomforts

Participating in this study will not affect your regular medical appointments. The risks associated with the examinations in this study are similar to those of standard fundus camera examinations, mainly including temporary glare and afterimages.

We will arrange a follow-up for you after three months to conduct a phone interview, which may take up your valuable time and cause inconvenience.

4.3 Measures to be used to minimize the risks

Not applicable.

5. Related Costs

All examinations in this study do not require you to pay any additional costs beyond your original healthcare plan.

The research methods used are of minimal risk and generally do not cause adverse effects. If participants experience any adverse reactions, the researchers will bear the cost of treating these reactions. However, treatments and examinations for other concurrent diseases you may have, as well as treatments and examinations required based on referral recommendations issued as a result

of participating in the study, are not included in the services.

6. Confidentiality Issues

The information you provide as part of the project is the research data. Any research data from which you can be identified is known as personal data. Personal data does not include data where the identity has been removed (anonymous data). We will minimize our use of personal data in the study as much as possible. The researcher and his team, supervisor, collaborator will have access to personal data and research data for the purposes of the study. Responsible members of The Hong Kong Polytechnic University may be given access for monitoring and/or audit of the research.

All information related to you will remain confidential. The information collected will be kept until 5 years after project completion. The Hong Kong Polytechnic University takes reasonable precautions to prevent the loss, misappropriation, unauthorized access or destruction of the information you provide.

7. Voluntary Participation

Participation is entirely voluntary, and participants can withdraw at any time without any consequences. For your best interest, the researcher may discontinue your participation in this project at any time during its course. If you withdraw from the project for any reason, for safety purposes, you may be asked about your medication usage or undergo necessary laboratory tests and physical examinations.

8. Contacts for Inquiries and Complaints

If you have any questions, you may ask our helpers now or later, even after the study has started.

You may contact Dr CHEN Yanxian (tel. no.: 852-27666111/ email: yan-xian.chen@polyu.edu.hk) or Dr SONG Fan (tel. no.: 852-63657441 / email: fanfan.song@connect.polyu.hk) of PolyU under the following situations:

a. if you have any other questions in relation to the study; or
b. if, under very rare conditions, you become injured as a result of your participation in the study; or
c. if you want to get access to/or change your personal data before 31/12/2024.

In the event you have any complaints about the conduct of this research study, you may contact Secretary, PolyU Institutional Review Board in writing (institutional.review.board@polyu.edu.hk) stating clearly the responsible person and department of this study as well as the Reference

Number.

In case of a serious adverse event[1], please report to the Principal Investigator/Chief Investigator immediately and the Principal Investigator/Chief Investigator will be required to report it to the PolyU IRB within 48 hours upon the receipt of your report.

Thank you for your interest in participating in this study.

Dr HE Mingguang
Principal Investigator/Chief Investigator

[1] SAE is any adverse event that:

- Results in death
- Is life threatening, or places the participant at immediate risk of death from the event as it occurred
- Requires or prolongs hospitalization
- Causes persistent or significant disability or incapacity
- Results in congenital anomalies or birth defects
- Is another condition which investigators judge to represent significant hazards

(Reference: NIA Adverse Event and Serious Adverse Event Guidelines. https://www.nia.nih.gov/sites/default/files/2018-09/nia-ae-and-sae-guidelines-2018.pdf)

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