Diabetes screening and monitoring using tongue images and self-reported symptoms: a machine learning approach

Informed Consent Form

Project: HMRF 1920081

Project REC Code : REC/21-22/0309

Version: 2 Date: 27/01/2022

Participant Information Sheet

1. STUDY TITLE

Diabetes screening and monitoring using tongue images and self-reported symptoms: a machine learning approach

2. INVITATION

The School of Chinese Medicine, Hong Kong Baptist University (HKBU) is collaborating with Department of Medicine, Queen Elizabeth Hospital to obtain data for the study of diabetes. You are invited to participate in this research, the purpose of which is to study the use of Chinese medicine diagnostics for diagnosis of diabetes with machine learning. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your doctor if you wish. Please feel free to contact us if there is anything that is not clear or if you would like more information. We would be grateful if you can take your time to participate.

3. WHAT IS THE PURPOSE OF THE STUDY?

The incidence of diabetes is about 10%, affecting many people. At present, the detection of diabetes requires blood tests, which is inconvenient and costly. By studying Chinese medicine diagnostics with machine learning, we try to develop a noninvasive method for detection of diabetes using mobile phones. We need to collect tongue images taken with mobile phone, patient symptoms and laboratory tests (HbA1c and Hb) for machine learning. The whole procedure will take about 15 minutes of your valuable time. Each person only need to participate once.

4. WHY HAVE I BEEN CHOSEN?

We will recruit about four thousand subjects (1,500 from QEH) in this study, but each subject only needs to participate once. You are invited to this study because you have a HbA1c test for diabetes. This A1c value will be used as a label for machine learning.

5. DO I HAVE TO TAKE PART?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide not to take part, you don ‘t have to give a reason. You have the right to terminate your participation at any time during the study, and this will not affect the standard of care you receive. If you feel uncomfortable in any way during the session, you may not continue to participate in the study. You can take time to decide whether or not you wish to take part.

6. WHAT WILL HAPPEN TO ME IF I TAKE PART?

We will record your HbA1c reading (and hemoglobin reading as well as other relevant laboratory results if available) from your recent laboratory tests, or from a test that will be

done soon as part of your normal clinical visit. No additional blood test will be required, and no additional amount of blood will be taken from you. After you have decided to join, we will take two pictures of your tongue with a mobile phone using flash, and to fill in the HKBU Diabetic Tongue Questionnaire (DTQ) on the spot. Therefore, no additional visit will be required of you. It is a one-off procedure, which takes about 15 minutes. Please note that the photograph will not include your eyes, and your identity cannot be identified from the photo or the questionnaire in our database. If you are patients in the HKBU clinic who choose to use the free HbA1c test as part of your regular check-up, we will invite you to come back for your HbA1c test results, and collect your tongue images and DTQ data at the same time.

The data will be collected by an online questionnaire service using Qualtrics and then store at a local computer at School of Chinese Medicine of HKBU. A paper version of the questionnaire may be used when necessary, and the filled questionnaire will be kept for 3 years after the study. The collected image will contain no eye features on the photo, and the questionnaire will not include any information for identification of the subject, except a subject ID number for the trial. After completion of the project, data on Qualtrics will be deleted, whereas data on the local computer will be kept for seven years after the study has been published, as per institution requirement.

7. WHAT DO I HAVE TO DO?

There are no lifestyle restrictions. But we prefer you not to scratch your tongue on the day of photo taking, or to drink or eat something that may color stain your tongue 20-30 minutes before photo taking. If any of these applies to you, please let us know. We may still use your data but make a note on the record. During data collection, you need to put your tongue out when requested for photo taking. A research assistant will ask you to fill in an electronic questionnaire, or ask you the questions in the questionnaire and fill it in for you.

8. WHAT IS THE PROCEDURE THAT IS BEING TESTED?

The procedure to be tested is to train a computer algorithm for estimation of HbA1c, which is a laboratory test for monitoring the severity of diabetes. We have already collected several hundred samples and found that the tongue image can detect diabetes with 80% accuracy rate. We hope to improve the accuracy with more images and including clinical symptoms.

9. WHAT ARE THE ALTERNATIVES FOR DIAGNOSIS OR TREATMENT?

At present, the alternative gold standard for diagnosis of diabetes is blood test measuring HbA1c, and not joining the study will not jeopardize your follow-up and subsequent treatments. All follow-ups and examinations subsequently will be conducted in the same manner whether you opt to join the study or not.

10. WHAT ARE THE DISADVANTAGES AND RISKS OF TAKING PART?

It is very unusual that you may have emotional fluctuation during completing the questionnaire and study procedures. If that happened, please report to the study team or clinician on site and

you will be refer back to the treating doctor for assessment and necessary treatment if necessary. Your participation will be terminated.

11. Expected Benefits

There is no immediate clinical benefit to the patient from taking part in this study. However, information we get from this study may help to develop non-invasive methods for diabetic screening and monitoring.

12.NEW INFORMATION

You will be informed if any new information about this study becomes available that may affect your decision to continue participation in the study and you will be contacted for signing a new consent form.

13. WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

As this is a one-off procedure, no more subject will be recruited when the research study stops.

14.Treatment and Compensation

If you feel uncomfortable emotionally or physically during the participation process, researchers will notify the staff of ward to provide support to you or refer you to have appropriate treatment.

If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal health service complaints mechanisms may be available to you. You are not giving up any of legal rights by signing this form.

15. Cost and Payment of the Study

Apart from paying standard hospital fees, you are not required to pay additional fees and will not receive any remuneration.

16. Confidentiality and Privacy

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital/clinic will have your name and address removed so that you cannot be recognised from it. If the information you provide is reported or published, this will be done in a way that does not identify you as its source. To ensure the highest form of confidentiality, we do not fill in your name on the questionnaire. Your signed consent form will be stored separately from your interview notes and personal data to further protect your confidentiality. Access to the data will be restricted to the researchers of this study. Along with this, the audiotapes, interview notes as well as personal data will be stored in the computers which are only accessible by the researchers. Data can be withdrawn and destroyed if requested by you and all data will be destroyed seven years after the completion of the study.

Under the laws of Hong Kong (in particular the Personal Data (Privacy) Ordinance, Cap 486), you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study. For any query, you should consult the Privacy Commissioner for Personal Data or his officer (Tel no.: 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

By signing a written consent form, you are authorizing the Research Ethics Committee (REC) and the regulatory authority(ies) will be granted direct access to your study data for data verification.

17. Expected research result

The results of the research will be published in medical journals in one to two years. A smartphone app for diabetic screening may also be produced. Publications may be accessed from the Hong Kong Baptist University website. No individual participant will be identified in any report/publication.

18. WHO IS ORGANISING AND FUNDING THE RESEARCH?

This study is organized by Dr. Zhang Shi Ping, Hong Kong Baptist University (HKBU); funded by the Health and Medical Research Fund (HMRF). Investigators of this study receive no payment for this study, except the research assistant who are collecting data from you are being employed by HKBU for doing the job.

19. WHO HAS REVIEWED THE STUDY?

Research Ethics Committee (Kowloon Central/Kowloon East) have reviewed this study.

20. CONTACT FOR FURTHER INFORMATION

If you have any questions or concerns regarding the research, please feel free to contact the following investigators,

1. Dr. Zhang Shi Ping, Lead Principal Investigator; School of Chinese Medicine, Hong Kong Baptist University
Phone: 34112466; email: spzhang@hkbu.edu.hk

2. Dr. Jason Ng, PI, (and the designated research assistant) Department of Medicine, Queen Elizabeth Hospital
Phone: 35062076 ; email: ngcm2@ha.org.hk

If you have questions related to your rights as a research participant, please contact Research Ethics Committee (Kowloon Central/Kowloon East) at 3506 8888.

Thank you for your kind support and participation!

SUBJECT INFORMED CONSENT FORM

Centre Number:
Study Number:
Subject code :

Title of Project:Diabetes screening and monitoring using tongue images and self-reported symptoms: a machine learning approach（A Collaborative Study between School of Chinese Medicine, Hong Kong Baptist University and Department of Medicine, Queen Elizabeth Hospital）

Name of Researcher:

		Please initial box
1.	I confirm that I have read and understood the information sheet dated / / for the above study and have had the opportunity to ask questions.	☐
2.	I understand that my participation is voluntary. If the result of my participation in this study caused any physical injury or feel uncomfortable emotionally, the investigator will treat me or refer me for treatment.	☐
3.	I understand that I am free to withdraw from the study at any time, without having to give a reason for withdrawing, and the withdrawal will not affect my present and future medical care.	☐
4.		
5.	If I request to withdraw from this study, I □ agree / □ disagree my research data provided before my withdrawal will be continuously used by the investigator.	☐
6.		
7.	I understand that my identity will be kept confidential. I agree to authorize the Research Ethics Committee (REC) and the regulatory authority(ies) a direct access to my research data for verification of clinical trial data, without violating my confidentiality, to the extent permitted by the applicable laws and regulations.	☐
8.	I agree to take part in the above study.	☐

Name of subject *Date* *Signature*

_____

Name of Impartial Witness (if applicable) *Date* *Signature*

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Name of Researcher	*Date*	*Signature*

Copies to:

- Subject
- Researcher's File
- Hospital Record