Moorfields Eye Hospital NHS Foundation Trust

NHS
Moorfields Eye Hospital
NHS Foundation Trust
162 City Road, London EC1V 2PD
Phone: 020 7253 3411

FACE AI: Automated Detection of Oculofacial Parameters Using Artificial Intelligence

Patient Information Sheet

You are being invited to take part in our FACE AI research study. Before you decide it is important for you to understand why the research is being done and what it will involve for you. Please read the following information carefully and discuss it with friends and relatives and other healthcare professionals if you wish. One of our team will also go through the information sheet with you and answer any questions you have. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

Part 1

1. What is the purpose of the study?

There are several eye conditions that can affect the positioning of certain facial features. These can include changes to the position of the eyelid or the eye itself. These changes can give your healthcare team vital information about your eye condition.

Traditionally, your clinical team measure these changes by examination, using rulers, at your adnexal appointment. Whilst this is useful, the process is time-consuming and there can be slight variations in measurements between clinicians.

There are often long waits for appointments in hospital, due to an increasing patient population. In recent years, more people have had their appointments via video-consultations. This saves time and travel expense for the patients, and allows the healthcare team to see more patients, reducing the time patients spend waiting for appointments. So far, it has not been possible to precisely measure the position of facial features via video, so people still need to travel to hospital for this.

The FACE AI study will aim to develop a software programme that uses artificial intelligence (AI) to recognise different facial features from video stills (*see image 1*). AI allows computer programmes to perform tasks that typically require human intelligence. The machine is trained to perform a task, in this case, recognise and measure the distances between certain facial features, and over time it is capable of doing this, with new faces, on its own.

Computer measurements are very precise and fast. This allows the accurate measurement of the positioning of your features, and the ability to accurately monitor changes over time. This can give your clinical team vital clues about your eye condition from a video

consultation, allowing us to closely monitor changes over time and recognise when further treatment is required. Furthermore, this can support the expanded use of video-consultations for patients.

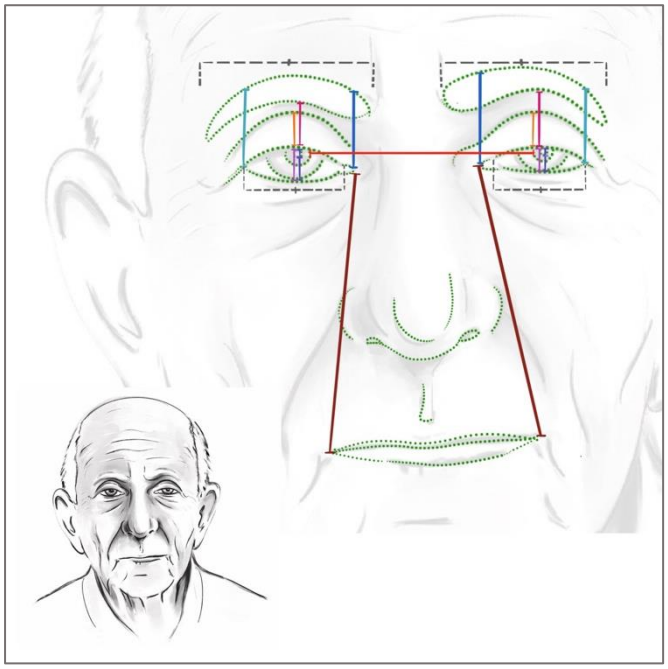

Image 1: illustrated example of the annotation and facial feature measurements taken from a video still for the FACE ID study

2. Why have I been invited?

You have been invited to take part because we need a variety of people to train the FACE AI model to recognise and measure facial features. Some people will have eye conditions that affect the positioning of their features, others will not. We will use a mix of images from people with different eye conditions and some from people with no eye conditions, so that the model learns to recognise the differences.

3. Do I have to take part?

No, your involvement is entirely voluntary. It is up to you to decide to join the study. We will describe the study and go through this

information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw from the study at any time during the recruitment process, without giving a reason. This would not affect the standard of care you receive.

4. What will happen to me if I take part?

The project will last 18 months. Participation will consist of two video-consultations with the research team. These will both be done during your clinic appointment, in different lighting conditions. You do not need to do anything more than this. During the video-consultation, the team will ask you to look in certain directions and take short 20 second clips, from which they will extract the stills (photographs) that make up that clip.

On each still, our research team will annotate (draw around) certain facial features and take measurements This will be used to train the FACE AI to recognise these features and learn to take measurements by itself. Once we have trained the model, we will test it with a new set of people to see if it can recognise features and make accurate measurements.

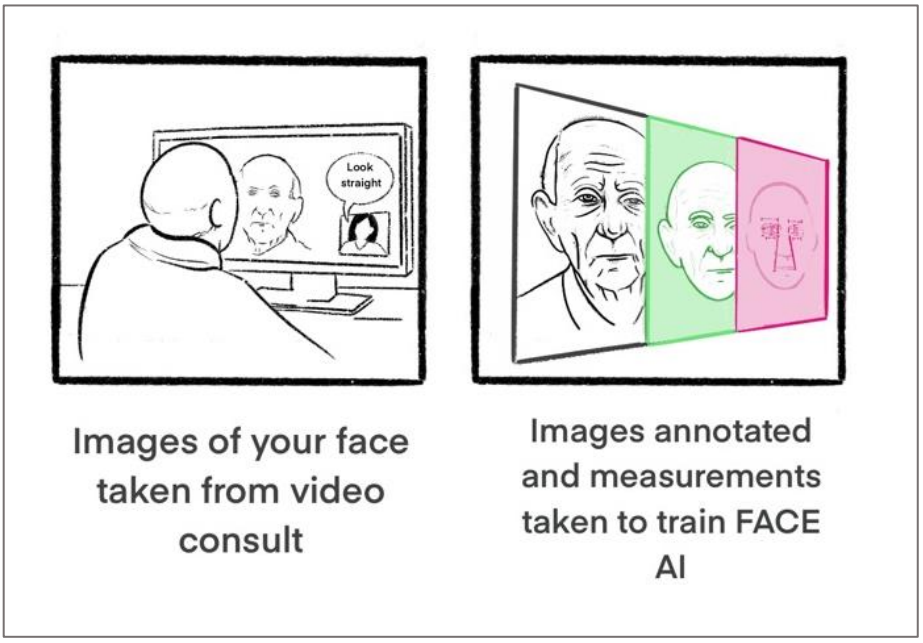

Image 2: Your participation and how your images will be used

5. Expenses and payments

There are no anticipated expenses associated with taking part in this study. The video-consultations will take place at a time and place that is convenient to you. There is no payment offered to those participating in this study.

6. What are the possible disadvantages and risks of taking part?

There are no anticipated risks associated with taking part in this study. There is extremely minimal risk of data security breach in the same way that your usual hospital records are stored. The video stills used to train FACE AI will be collected by the research team and will not be shared beyond that. The team will follow all the information governance guidance regarding the handling of your images, as they would in a clinical context.

7. What happens when the research study stops?

Being involved in the study will not affect your clinical care or the way in which your care is delivered. Therefore, your care will continue as normal throughout the study and beyond. If the study stops, there will be no impact on your care and the stills taken will be deleted.

8. What if there is a problem?

There are no anticipated risks in being involved in the study. Any complaint about the way you have been dealt with during the research project will be addressed. The detailed information concerning this is given in Part 2 of this information sheet. If you

have any concerns or complaints, you should contact your study doctor in the first instance.

9. Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

10. Contact Details

Your Doctor:
Name *Swan Kang* Tel. Number: *+44 7958 585904*

Your Research Fellow :
Name *Laura Ah-Kye* Tel. Number: *+44 7814 480757*

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

11. What if relevant new information becomes available?

As previously mentioned, your clinical care is not affected by being involved in the study. We do not anticipate any new information becoming available that could affect the study. However, should this happen, we will contact you and explain how it will impact your participation, and you can decide if you want to continue with the study.

12. What will happen if I don't want to carry on with the study?

You can withdraw from any point from the study. Please be aware that once we have trained the AI Facial recognition model to recognise features on certain photographs, we cannot untrain it. Therefore, if you decide to withdraw at a later stage, your images that have already been used may still be included in the study, but no new images will be taken or used after that point. Any images that have not already been used to train the model will be deleted.

13. What if there is a problem?

We do not anticipate any problems. We will follow all of the Moorfields Eye Hospital Trust guidance in handling the images of your face as identifiable data.

In the event that something does go wrong and this is due to someone's negligence then you may have grounds for a legal action for compensation against Moorfields Eye Hospital in the same way as exists for when things go wrong in a non-study setting. You may have to pay your legal costs.

14. Complaints

If you have a complaint, your research fellow is usually the first point of contact. However, the normal National Health Service complaints mechanisms will still be available to you via the Patient Advice and Liaison Service (PALS) team.

The PALS team at Moorfields also handles all complaints about our services, ensuring that all are dealt with appropriately and used to improve services for others in future. The service is open at our main City Road hospital from Monday to Friday from 9am to 5pm. The

office is located the ground floor. You can also contact PALS on **020 7566 2324** or by emailing **moorfields.pals@nhs.net**.

15. Will my taking part in this study be kept confidential?

Video stills of your face are classed as identifiable data. We will be using this information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

If you consent to take part in this study, the records obtained while you are in this study will remain strictly confidential at all times. The images collected for this study will be kept anonymous, however may be identifiable.

Your information will be held securely on paper and electronically at your treating hospital and other institutions managing this research under the provisions of the 1998 Data Protection Act and in line with the applicable Trust regulatory framework.

Personal data which may include your name, address and telephone number will be securely stored at the Hospital. Your name will not be passed to anyone else outside the research team at your hospital.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at: www.moorfields.nhs.uk/content/how-we-use-your-information

16. What will happen to the results of the research study?

The results of the study will be available after it finishes and will be included in peer reviewed medical and scientific journals and may be presented at medical meetings. Results will also be published on a publicly accessible trials database. The data will be anonymous and none of the patients involved in the trial will be identified in any report or publication. Should you wish to see the results, or the publication, please ask your study doctor.

17. Will my GP be informed of my involvement?

With your permission, your GP, and other doctors who may be treating you, will be notified that you are taking part in this study. This will not affect your clinical care in any way.

18. Who is organising and funding the research?

Moorfields Eye Charity are funding the study through their Springboard grant. Moorfields Eye Hospital NHS Foundation Trust will be orgnaising and running the study, through the Department of Digital Medicine and The Reading Centre.

19. Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by IRAS (Integrated Research Application System). IRAS is a collaborative initiative providing a single system for applying for the permissions and approvals for health and social care / community care research in the UK.

20. Further information and contact details

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your study doctor or research fellow, who will be able to provide you with up-to-date information.

If you wish to read the research on which this study is based, please ask your study nurse or doctor. If you require any further information or have any concerns while taking part in the study please contact one of the following people:

Your Doctor
Name *Swan Kang* Tel. Number: *+44 7958 585904*

Your Research Fellow
Name *Laura Ah-Kye* Tel. Number: *+44 7814 480757*

In the case of an emergency, only, please contact Moorfields Eye Hospital, 162 City Road, EC1V 2PD. Switchboard telephone: 020 7253 3411.

If you decide you would like to take part then please read and sign the consent form. You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed in your patient notes, one will be filed with the study records and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.