Participant Information Sheet

Deep learning for estimation of BMI, age, and sex from cardiac wearable and portable electrocardiograms

Simplified Title: Prospective AI-ECG for BMI, age, and sex

This research study will be undertaken by Dr Ahmed El-Medany as part of his clinical research training fellowship. He will be guided by Dr Fu Siong Ng and Dr Arunashis Sau from Imperial College London.

You are being invited to take part in a research study. Before you decide, you need 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 others if you wish.

Ask a member of the research team if there is anything that is not clear or if you would like more information. Take as much time as you need to decide whether you wish to take part.

If you agree to take part, you will be asked to fill out, sign, and date this information sheet and consent form and to keep it as a useful reference on the study details and research contacts.

Thank you for reading this.

- **What is the purpose of the study?**

This study will look at how artificial intelligence (AI) can predict a person's body mass index (BMI), age, and sex using simple heart monitor data known as electrocardiograms (ECGs) from consumer wearables like smartwatches, and smart portable devices that can obtain ECG data. AI is a type of computer program that helps solve complex tasks. In the past, most studies used old ECG data to see how well AI could predict these things. However, there’s not much information on how AI performs with new, real-time ECG data. Our research group at Imperial College have developed AI models that can predict BMI, age, and sex from ECG data, although we have yet to test it out on real-world ECGs, particularly those from wearable and portable devices.

Our goal is to test the accuracy of our AI models on real-world wearable and portable ECG data. Exploring the application of AI to ECG data from wearables and portable devices could support their use in providing continuous, inexpensive, and non-invasive health monitoring tools.

- **Why have I been invited?**

You have been invited because you meet our inclusion criteria for taking part in this study and have shown interest in becoming a participant. We aim to have 1,000 participants in our study.

- **Do I have to take part?**

It is up to you to decide whether or not to take part. We appreciate that as Imperial College students and staff there may be some perceived pressure to take part, although please be reassured that this is not the case and there are no consequences for refusing to take part or changing your mind at any point. If you decide to participate, you will be given this information sheet to keep and asked to sign a consent form. If you decide to participate you are free to withdraw at any time and without a reason. Data collected up to the point of withdrawal may be used by the research team.

- **What will happen to me if I take part?**

You will only have 1 study visit which will take approximately **10 minutes**. You will not be required to attend any further appointments or visits with us after this.

Firstly, we will obtain your consent to participate in the study and carry out a short health questionnaire. We will ask you about your date of birth, sex at birth, and any relevant past medical and medication history. This will take approximately **2 minutes**. If you have a cardiac implantable electronic device such as a pacemaker or defibrillator this would, unfortunately, exclude you from the study as these devices can affect the reliability of the portable device ECGs we take. As the influence of alcohol or illicit drugs can impact the ECG recording obtained from our devices, and therefore impact the AI's predictive ability, these should not be consumed within 48 hours prior to the study and would exclude you from the study otherwise.

After your health questionnaire, the following will be the sequence of events on the day of your study visit:

Height and weight measurements

i) Attend our research 'kiosk' or designated research room
ii) We will calculate your BMI by taking your weight, using a set of digital scales; and your height, using a height meter. This will take around **2 minutes.** To get

as accurate measurements as possible we will ask you to take off your shoes and empty your pockets.

Apple Watch ECG recording

iii) You will then be seated and an Apple smartwatch will be fitted to your left wrist, regardless of which arm you usually wear your watch. This is to ensure consistency across all our smartwatch ECG measurements. You will be asked to rest your arms on a table or your lap. You will then place your right index finger on the Digital Crown of the watch (Figure 1) for 30 seconds. The ECG app on the Apple Watch will record your heartbeat and rhythm using an electrical heart sensor, and the ECG recording will be automatically uploaded to 1 of our designated study iPhones. If the recording is unsuccessful, it can easily be reattempted. A successful reading should take around **1 minute**

Figure 1: Image showing the Apple Watch ECG function in use. The participant has placed their right index finger on the Digital Crown to start the recording

KardiaMobile 6L® ECG recording

iv) The KardiaMobile® is a small portable device that can record single and 6-lead ECG data (Figure 2 and 3). Single-lead ECG records 1 'view' of the heart's activity, like using a camera to take a picture of your heart's electrical activity from one angle, while 6-lead ECG records 6 'views', or 6 camera angles, of the heart's electrical activity. The device has two electrical heart sensors on the top and a third on the bottom. While seated, we will ask you to lightly place your thumbs on the top electrodes (Figure 2) for 30 seconds – this will collect a single-lead ECG recording. After this, we will take a second recording with your thumbs on the top electrodes, and the bottom electrode on your left ankle (Figure 3) for 30 seconds – this will collect a 6-lead ECG recording. Both

recording will be automatically uploaded to 1 of our designated study iPhones. If any of the recordings are unsuccessful, they can easily be reattempted. A successful pair of recordings should take around **2 minutes.**

Figure 2: Image showing the KardiaMobile 6L device ECG function being used in single-lead mode. Both thumbs are placed on the top electrodes.

Figure 3: Image showing the KardiaMobile 6L device ECG function being used in 6-lead mode. Both thumbs are placed on the top electrodes. The bottom electrode is placed on the left ankle.

Eko Digital stethoscope ECG recording

v) The Eko CORE 500™ digital stethoscope is a device that allows the wearer to listen to heart and lung sounds and can also record 3-lead ECGs. This records 3 'views' of the heart's activity, like using 3 cameras to look at the heart's electrical activity from different angles. While you are seated, the research team will place and hold the chest piece on the skin of the upper left aspect of the breastbone (Figure 4). This allows us to get the best quality signal we can from the device and means you only need to pull down your collar slightly. The recording will take 30 seconds and will be automatically uploaded to 1 of our designated study iPhones. If any of the recordings are unsuccessful, they can easily be reattempted. A successful recording should take around **1 minute**.

Figure 4: Image showing the Eko CORE 500™ digital stethoscope being used to record ECG data. The chest piece has been placed at the right upper aspect of the breastbone. For this study, the chest piece will be placed on the other side.

All information collected about you during the course of the research will be pseudonymised. This means your information will be designated a code to represent it and your linked name and other identifiable information will be hidden and kept strictly confidential. Pseudonymised data and your linked confidential personal information will be stored on secure servers with strict access controls and will not be shared with third parties like insurance companies or employers. Information collected about you during the study will be identified by an allocated study number.

- **What do I have to do?**

As the influence of alcohol or illicit drugs can impact the ECG recording obtained from our devices, and therefore impact the AI's predictive ability, these should not be consumed within 48 hours prior to the study. There are no dietary restrictions required prior to taking part in this study. You can continue to take your regular medication if applicable. Pregnancy does not exclude you from this study, although normal pregnancy can expectedly cause slight changes in the electrical signals of the heart and therefore the ECG recordings we take, so it is important that we document if you are pregnant or not.

- **What are the possible disadvantages and risks of taking part?**

There are no significant possible disadvantages and risks of taking part. All our scales, height meters, and wearable and portable devices will be cleaned between participants. Sometimes incidental findings are uncovered on an ECG. If that happens, the research team will act on the findings and will inform your GP.

- **What are the possible benefits of taking part?**

You will help pave the way in exploring the application of AI to ECG data from wearables and portable devices. This could potentially lead to their use in providing continuous, inexpensive, and non-invasive health monitoring tools for a variety of healthcare conditions.

There will not be any payments or incentives for taking part in the study. The research team also do not receive any payments or incentives, above normal salary, for taking part in the study

- **What if something goes wrong?**

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator:

Dr. Ahmed El-Medany a.el-medany24@imperial.ac.uk

If you are still not satisfied with the response, you may contact the Imperial College Research Governance Integrity Team (rgitcoordinator@imperial.ac.uk).

- **What will happen to the results of the research study?**

The results of the research will be offered for publication in recognised medical journals and presented at appropriate conferences, but you will not be identified in any report, publication or presentation. We will be able to let you know about the results at the end of the study and with your permission send you a copy of the published data.

- **Who is organising and funding the research?**

This study has been made possible through funding from the National Heart and Lung Institute at Imperial College London

- **Who has reviewed the study?**

This study was given favourable opinion by the Imperial College Research Governance and Integrity Team (RGIT) and approval by Professor Barabara Casadei, Head of the National Heart and Lung Institute.

Contact for Further Information

Should you have any further questions about the study

Dr Ahmed El-Medany, Clinical Research Fellow
National Heart and Lung Institute
Imperial College London 4th floor ICTEM building
Hammersmith Hospital
Du Cane Road
London
W12 0HS

Dr Fu Siong Ng, Clinical Lecturer and Consultant Cardiologist
National Heart and Lung Institute, Imperial College London 4th floor ICTEM building
Hammersmith Hospital
Du Cane Road
London
W12 0HS

Tel: 0207 594 3614

Thank you for reading this information leaflet. Please feel free to contact us if you require further information or clarification.

Please keep this copy of the information sheet and a signed consent form.

Transparency Notice

How will we use Information about you?
Research Study Title: Deep learning for estimation of BMI, age, and sex from cardiac wearable and portable electrocardiograms

[Study number - 7411102]

Imperial College London is the sponsor for 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 appropriately. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

The study is expected to finish in December 2025.

For more information/confirmation regarding the end date please contact the study team, see '**WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED'** for contact information.

We will need to use information (including personal data and data created as part of the study) from you for this research project.

This information will include your:

- Name
- Sex at birth
- Date of birth
- Contact details

People within the College and study team (see section 'Sharing your information with others') will use this information to do the research or to check your records (see information to be collected) to make sure that the research is being done properly and the information held (such as contact details) is accurate.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

LEGAL BASIS

As a university we use personally-identifiable information to conduct research to improve health, care, and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

• Imperial College London - "performance of a task carried out in the public interest"; Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), Imperial College London relies on “scientific or historical research purposes or statistical purposes”.

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA. Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

SHARING YOUR INFORMATION WITH OTHERS

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

- Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

POTENTIAL USE OF STUDY DATA FOR FUTURE RESEARCH

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you, used against you, or used to make decisions about you.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have because some research using your data may have already taken place and this cannot be undone.

- We need to manage your records in specific ways for the research to be reliable. This means that we may not be able to let you see or change the data we hold about you if this could affect the wider study or the accuracy of data collected.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED

You can find out more about how we use your information:

- by asking one of the research team
- by sending an email to a.el-medany24@imperial.ac.uk, or
- by ringing us on 0207 594 3614.

COMPLAINT

If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to a.el-medany24@imperial.ac.uk, or by ringing us on 0207 594 3614.

Following our response, if you are not satisfied please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 0207 594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO)- via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.