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Study title**: Open Band Cyclist Study**

PARTICIPANT INFORMATION SHEET

CENTRAL UNIVERSITY RESEARCH ETHICS COMMITTEE APPROVAL REFERENCE:
R79660/RE001

Introduction

You are invited to participate in a research study to develop and validate new hardware approaches to measure heart rate related data. The purpose of this form is to help you decide if you want to join this research study. Please read the information carefully.

You should not join this research study until all of your questions are answered.

If you consent to take part in the study you will be given a copy of this form for your records.

Why is this research being conducted?

Most hardware tools that measure activity – often called wearables – are “closed source.” Closed source means that only the company that makes them knows how these wearables work, and only that company can make changes to these wearables. The data that comes off the wearables is also closed, so we don’t know how they come up with the results we get back as users.

This study uses an app to test a new open source wristband (the CRI Open Band) that measures your body’s reaction to activity. The data from the CRI Open Band will be checked against the data from the Polar H10 chest strap for comparison. We can then verify that the CRI Open Band works as well as the Polar strap, which means we can start to use it for research.

Why have I been asked to take part?

You are being invited to participate in this study because you are a member of a local Oxford based cycling club. If you are over 18 years old, have and use a personal iPhone (iPhone 8 or newer (iOS 12.1 and above), have a Polar H10 chest strap already or are willing to use one, and are able to complete the study activities you can join the study.

Who is conducting this study?
This study is a partnership between the department of Psychiatry at the University of Oxford, and the charity companies (non-profit) 4YouandMe and Sage Bionetworks, located in the United States. 4YouandMe is the study sponsor and provides the study digital devices and apps, and is responsible for your study data under the supervision of the Co-Principal Investigator, Co-founder and President of 4YouandMe, Prof Stephen Friend. Your study data will be securely sent to and stored at Sage Bionetworks where your data will be accessed and analysed.

How long will I be in the research study?
Your participation in the study will last for approximately 4 weeks.

How many people will take part in this study?
We expect about 100 people will take part in the study.

Do I have to take part?
No. It is up to you to decide whether to take part. You can withdraw yourself from the research, without giving a reason, by advising the study PI of this decision.

If you do join the study, you may quit at any time. Your decision will not result in any penalty or loss of benefits. If you want to quit the study, there are two ways to withdraw. You can do so directly from your app profile page. Or you can contact the Study Representative Dr. Karen Mansfield at karen.mansfield@psych.ox.ac.uk.

Although you can quit at any time, you cannot take back the coded study data that was collected before you quit. By default, your coded study data provided prior to your withdrawal will remain in the Study. However, your identifiable information will be destroyed after the study is complete.

The study team may also withdraw you from the study at any time for any reason. One reason we might withdraw you is if we feel it is in your best interest. Another reason is if you do not consent to continue in the study after being told of changes in the research. We may also withdraw you if you are not fulfilling the study requirements. We would withdraw you if the study was cancelled.

What will I be asked to do?
If you decide to join the study, you will need to download the COB-APP study app onto your phone. The app is free from your phone's app store.

You will need to contact a study representative whose contact information can be found at the end of this form to discuss the study, and arrange for your preferred method of study device pick up.

You will either pick up a CRI Open Band and Polar H10 chest strap (if you don't own one) from your local cycling club lead or another study representative at your place of work, or the devices will be mailed to you if needed.

After you register, agree to participate in the study and digitally sign the consent form in the study app, we will ask you to connect your Polar H10 chest strap and your CRI Open Band to the app. You will be asked to wear the 2 devices at the same time during different activities including cycling, walking, sitting and sleeping for specific amounts of time. The measurements from these devices during your activities are your study data.

Weekly Tasks:

- You will be asked to wear the CRI Open Band and PolarH10 and complete 4 different activities at least 6 times each during your 4 week study participation. These activities include:
    - Cycling (at least 6 cycle rides for a minimum of 30 minutes)
    - Walking (at least 6 walking periods for a minimum of 5 minutes)
    - Sitting (at least 6 sitting periods for a minimum of 2 minutes)
    - Sleeping (at least 6 nighttime sleeping periods)

Before and after you complete study activities, you will be required to go into the app, select the activity type, and indicate the start time and end time of activities. Other than the sleeping activity that requires you to wear the devices while sleeping for a whole night, you can complete these activities anytime during the duration of the study. You can participate any time during the day and any day of the week you choose.

Do NOT operate the study app while conducting the activities, especially while cycling to reduce the risk of an accident. You can indicate the start time in the app before you get on your bike and the stop time after you get off your bike.

What are the possible disadvantages and risks in taking part?

The following risks and disadvantages should be considered:

- There is a possible risk of irritation or rash on the skin where the CRI Open Band is worn. Please let the study PI know if you encounter any discomfort in wearing the device.
- Other people may glimpse the study app on your phone and realise you are enrolled in this study. This can make some participants feel self-conscious.
- Data collected in this study will count against your phone's data plan. Please do not configure the app to only use WiFi to limit the impact data collection has on your data plan, as that may make the app unable to collect data while on an outdoor bike ride. You can ensure your phone is connected to WiFi while at home to limit the impact data collection has on your data plan. We anticipate <6 gigabytes of data per month (<15% of most data plans) will be used to participate in this study.
- We take great care to protect your privacy. However, if there is a data breach it may be possible to identify you. This risk is low but it is not zero.
- Participation may involve risks that we don't know about yet. We will tell you if we learn anything that might change your decision to be in this study.

Are there any benefits in taking part?
The main goal of this study is to validate the CRI Open Band so we can use it in future research. You will not directly benefit from volunteering for this research study.

Compensation
You will not be paid for participating in this study. You will not be reimbursed for any data costs associated with using the study app.

What information will be collected and why is the collection of this information relevant for achieving the research objectives?
Your privacy is important to us. We will make every effort to protect your privacy. Except as required by law, you will not be identified by name or by any other direct personal identifier.

The data we collect from you only includes the information you provide in the COB-app (name, email address and phone number) and the passive data collected from the two study wearable devices that includes the following: heart rate, resting heart rate, heart rate variability, respiration rate, breathing variance, and activity data (sense of step count and cycling activity). We need to collect this information in order to validate the accuracy of the CRI Open Band.

We use a hosted computing environment, also known as a "cloud server," to store your study data. This cloud server is based in the United States, hosted by

Sage Bionetworks - a non-profit study partner. By participating in the study, you consent to the transfer of your encrypted study data to countries outside of your country of residence, including to the United States. Your data will be transferred in a secure way with a similar level of data protection as required under UK law.

For both devices your study passive data is stored on your phone and then streams to the study cloud server. Data coming from the PolarH10 chest strap will also stream straight to the study server, and will not be stored or processed on any Polar-related server.

Any identifiable data we collect from you, including your signed consent form will also be stored at Sage Bionetworks, but in a separate server location from your other coded research data.

The data we collect through the app will be encrypted on your phone. This means your data is protected. Unauthorised people will not be able to access the data on your phone easily. We will NOT access other apps on your phone. We will NOT access your contacts, photos, texts, email, or browsing history.
We will process your data electronically. We will separate your study data from the account information that identifies you (i.e., your name, phone number and email address). Your account information will not be stored with your survey responses or activity measurements.

Instead of using your name, we will use a code to label your study data. The code is random. Information about the code will be stored in a separate database on a secure server. Only key people from our study team will be able to link your identity to your study data.

How is my coded study data used in research?
We will combine your coded study data with the coded study data of other participants. We will use this combined pool of data for our research. The results of our research will be made public. When results are made public, only coded study data will be used. Your identity will not be shared.

A component of this study involves a DREAM challenge that Sage Bionetworks hosts. DREAM challenges consist of a call to researchers to access publicly available coded (de-identified) study data to perform a specific analysis challenge. For this study, we will host a DREAM challenge so that others can access the study coded data and see if they can validate the CRI Open Band's accuracy. This means your coded study data will be made available via the Synapse at Sage Bionetworks, so that other researchers can conduct research that meet the current study's objectives using it. This means that your coded study data will be stored indefinitely at Sage Bionetworks. However, your identifiable data, including the datafile that links your name to your unique study

ID will be destroyed after the study is complete and your stored signed consent forms after three years post study publication.

This study has received ethics approval from a subcommittee of the University of Oxford Central University Research Ethics Committee. (Ethics reference: xxxxx).

Who do I contact if I have a concern about the research if I wish to complain?
If you have a concern about any aspect of this study, please contact the study representative, [name], at [email, and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Research Ethics Committee at the University of Oxford who will seek to resolve the matter as soon as possible:

The Chair, Medical Sciences Interdivisional Research Ethics Committee;

Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Boundary Brook House, Churchill Drive, Headington, Oxford OX3 7GB

Further information and Contact Details
Should you have any other questions please contact the study representative: karen.mansfield@psych.ox.ac.uk or the study PI, Prof John Geddes: Email: john.geddes@psych.ox.ac.uk, phone: +44 (0)1865 618202