

INFORMATION SHEET FOR PARTICIPANTS

Ethical Clearance Reference Number: LRS-20/21-20985



YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of study – Echoes, a collective database of heart sounds to help cardiology research

Invitation Paragraph

I would like to invite you to participate in this research project where we want to build a better future for our cardiovascular health. A future of empowered citizens, keen on taking healthy lifestyle choices, and free of stigmas around cardiac disease. A future where well-informed people living with cardiac conditions can monitor their progression from home, avoiding anxiety and visits to the hospital.

This is a collaborative project led by King's College London (from my team, the Cardiac Modelling and Imaging Biomarkers <http://cmib.website/>) and in collaboration with the School for Cardiovascular Diseases in Maastricht (<https://www.carimmaastricht.nl/>) and Cellule Studio (<https://www.cellule.co.uk/>).

Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

The purpose of the study is to check if the microphone of a mobile phone is enough to derive clinically useful metrics about your health inferred from the heart sound. We therefore collect heart sounds to then measure their sound quality and see if we can extract key metrics from them. But be aware, the Echoes app is not a clinical tool, it will never provide you with any clinical information!

Our second aim is to facilitate the development of a better healthcare based on remote heart sound recordings. We hope to record enough sound quality, and we will thus build a database of heart sound recordings that will enable researchers and companies from all over the world to work and advance towards this aim.

Besides, we want to use the Echoes app to engage with you by getting you to know your heart better (look at <https://www.echoesapp.org/>), and the research we are doing to improve the management of cardiovascular conditions. We want to establish a dialogue with society about the future of cardiovascular healthcare – you can have a glimpse at ongoing conversations at <http://cmib.website/public-engagement/>.

Why have I been invited to take part?

You are being invited to participate in this study because we simply want as many people as possible to enrich the database of heart sounds. Please also encourage your friends, relatives and colleagues to use it!

What will happen if I take part?

If you agree to take part you will download the Echoes app, complete a survey to get minimum set of information about you (age, gender, weight, height and cardiac condition, if any) that will take you 20 seconds to fill, and that will enable you to record, re-play and enjoy as much as you want with your mobile handset.

We encourage you to make the best possible quality recordings, and therefore we will provide you with some guidance on how to operate your mobile phone by yourself.

In order to facilitate further research through the Echoes app, each mobile will be given with a unique ID that will allow for data to be traced back. Next studies will thus ask users to provide this ID to the research team, but not in this case!

Do I have to take part?

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in anyway. If you choose to take part you will be asked to provide your consent through the app. To do this you will be asked to indicate that you have read and understand the information provided and that you consent to your data being used for the purposes explained.

You are free to withdraw at any point during the study, without having to give a reason. You are able to withdraw your data from the project, by e-mailing us on echoes@kcl.ac.uk the user ID that will be displayed on the screen of the app, up until the day we make the database open to other researchers, planned to be in Fall 2022, after which withdrawal of your data will no longer be possible due to the lack of control we will have of the copies of the data. Withdrawing from the study will not affect you in any way.

What are the possible risks of taking part?

Using a mobile phone in contact with your bare skin on your chest shall not cause you any discomfort or risk, but it might feel cold, and you definitely would prefer to find a quiet and comfortable place to try out.

If you have any cardiac device (e.g. pacemaker or defibrillator) there might be an interference between your mobile phone and this device. There is not any conclusive scientific evidence of any risk here, but it will be safest if you **use your mobile in flight mode**, and that follow any other advice from your device manufacturer.

What are the possible benefits of taking part?

By sharing your heart sounds with us, you're contributing to research towards a better cardiac healthcare. If you wish to keep up with our progress, or if you want to join the dialogue towards how to build better tools, do contact us!.

By taking part we also hope that you experience your heart in a different and playful way! And remember, Echoes will not provide you with any insight about your cardiovascular

health – do not worry if you don't manage to record your heart sounds, or if they sound poorly or weakly, we expect this will be the case in a lot of the people trying!

Data handling and confidentiality

Your data will be processed in accordance with the General Data Protection Regulation 2016 (GDPR). Nobody, including the researchers, will be aware of your identity, but your data will be linked to a unique ID to your mobile device. This ID will be generated by the Echoes app and be visible on the main screen. By providing this ID there is a way to connect your mobile device to the answers you provide. This will not be required in this project, and you will not be asked to provide your mobile handset ID, but this is a feature that allows us to better train users and identify and solve technical issues.

Your answers will be treated confidentially and no personally identifiable data will be included in any research outputs/publications. Your data will be held securely for ten years in Firebase, a secure cloud server, and we are hoping that researchers could use it to design solutions and achieve the envisioned better future for our cardiovascular health.

The data controller for this project will be King's College London (KCL). Research is a task that the University carries out in the public interest.

How is the project being funded?

This study is being funded by the Wellcome Trust, through my Senior Research Fellowship (g.a. 209450/Z/17/Z), and by the European Commission, through the Personalised In-silico Cardiology project (g.a. 764738, <https://picnet.eu/>)

What will happen to the results of the study?

The results of the study will be summarised in a scientific article that will report the quality of sounds we recorded. We expect to find which mobile devices, which anatomical locations, and which age groups and body characteristics will be enough to record enough quality for a potential future service. And we will provide an open access to the research community, so that many further studies can be enabled through our Echoes platform.

Who should I contact for further information?

If you have any questions or require more information about this study, please contact us on echoes@kcl.ac.uk.

What if I have further questions, or if something goes wrong?

If this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information:

The Chair, Ms Gemma Singleton, rec@kcl.ac.uk

Thank you for reading this information sheet and for considering taking part in this research.