Remote smartphone-based research on mood and behaviour

Participant information sheet – 29/09/22 (Version 3.0)

You are invited to take part in a research study!

We are inviting you to take part in a smartphone-based research project. Our team at UCL have developed a smartphone app containing fun games based on psychological experiments. We hope that data from these games is beneficial in understanding mood and behaviour.

Before you decide whether to take part it is important that you understand why the research is being done and what this study will involve. Please take time to read the following information carefully and discuss it with your relatives, friends, and GP if you wish. Ask us if anything is not clear or if you would like more information. If after reading this information sheet you decide to take part, you can complete the consent form online: https://redcap.idhs.ucl.ac.uk/surveys/?s=JNRE4YXK88RHFFDE

What is the purpose of the study?

We hope that the data we collect from these games will allow us to better understand how neurological and psychiatric illness affects mood and behaviour. We hope to determine whether there are subtle differences in how people make decisions in the games that are related to symptoms of Parkinson's disease, and to anxiety disorder, bipolar disorder, and major depression.

Why have I been invited?

We are recruiting up to 900 volunteers to participate in this study. We are inviting volunteers aged 18-85 who own an iOS or Android smartphone. If you do not have a smartphone, it may still be possible to participate as our app can also be installed on some tablets that have iOS or Android operating systems. Eligible individuals should either 1) been diagnosed with Parkinson's disease or an anxiety or mood disorder, or 2) never have been diagnosed with a neurological or psychiatric illness.

What is included in the app?

The app contains multiple short games that should last between 3-5 minutes each. The games are based on experiments that we have designed at UCL and specially adapted so they can be played on smartphones. We hope each game is fun and interesting to play and will help us understand how neurological and psychiatric illness relates to different aspects of behaviour like learning, risk taking, and motivation.

Do I have to take part?

No, it is up to you to decide to take part. This study is voluntary. It should also be highlighted that saying no to this study will not affect your current or future clinical care. You can withdraw at any time without giving a reason and without penalty or loss of benefits to which you are otherwise entitled. You can delete data you have contributed at any time in the Settings menu on your phone. You can also contact a member of the research team if you wish to delete your data. However, we can only guarantee deletion requests received within 60 days of enrolling in the study. It may not be possible to delete data after that point because the data may be included in completed analyses.

How do I get the app onto my phone?

If you would like to take part, you can download the app from the Apple or Google app stores. Instructions to download the app are included at the end of this document. Once the app is downloaded you will be assigned a unique ID number for your device. Please contact us [contact details provided] if you find that you have any questions about the installation process of the app so that we can help you. A member of the study team can also help you download the app from the Apple or Google app stores over the phone. A member of the study team may contact you to check if everything is working and if you have any additional questions.

What will I have to do in the study?

Study duration: Participation in smartphone tasks will be no more than 10 minutes per day for a duration of 3 weeks.

The games and questionnaires: You will be asked to play the games and complete the brief questionnaires in the app each day for the duration of the study. In some cases, you may be asked to play the games at different times including in the morning. You will be sent a message on your device reminding you when to play the app. Each game is quite short and should last 3-5 minutes, and you do not have to complete all games at the same time. We may send you reminder messages in case you forget.

You may also be asked to complete tasks on your computer or laptop: The tasks will be similar to the games you see on the smartphone application, along with brief questionnaires. Any tasks should take no more than 10 minutes to complete. A member of the study team will email you the link to the computer tasks, which you will be able to open online.

Game, task and questionnaire data: Data collected from the smartphone games and questionnaires will be automatically transferred to our secure server. Data collected from the computer tasks will be stored on the secure online Gorilla platform, which is a service dedicated to hosting online experiments. We will link your data from the computer tasks with your data collected from the smartphone application.

Stopping participation: You can decide to stop further participation at any time by changing your preferences in the Settings menu of the app to stop receiving notifications. You can also delete the app. You can also stop further participation in the computer tasks at any time by closing the browser.

Providing your consent: If after reading this information sheet you decide to take part, you will be asked to complete the consent form online. The consent form will ask you to record your year of birth, and you will also be asked to provide a telephone number and email address so we can contact you to answer any questions you may have. [Information and link for accessing secure online consent form] If you have any questions regarding accessing the online form, please contact the study team using the contact details at the bottom of this information sheet and we can answer any questions that you may have.

What do the games look like?

We've made the games easy and fun to play. Here are a few pictures of what the app looks like:
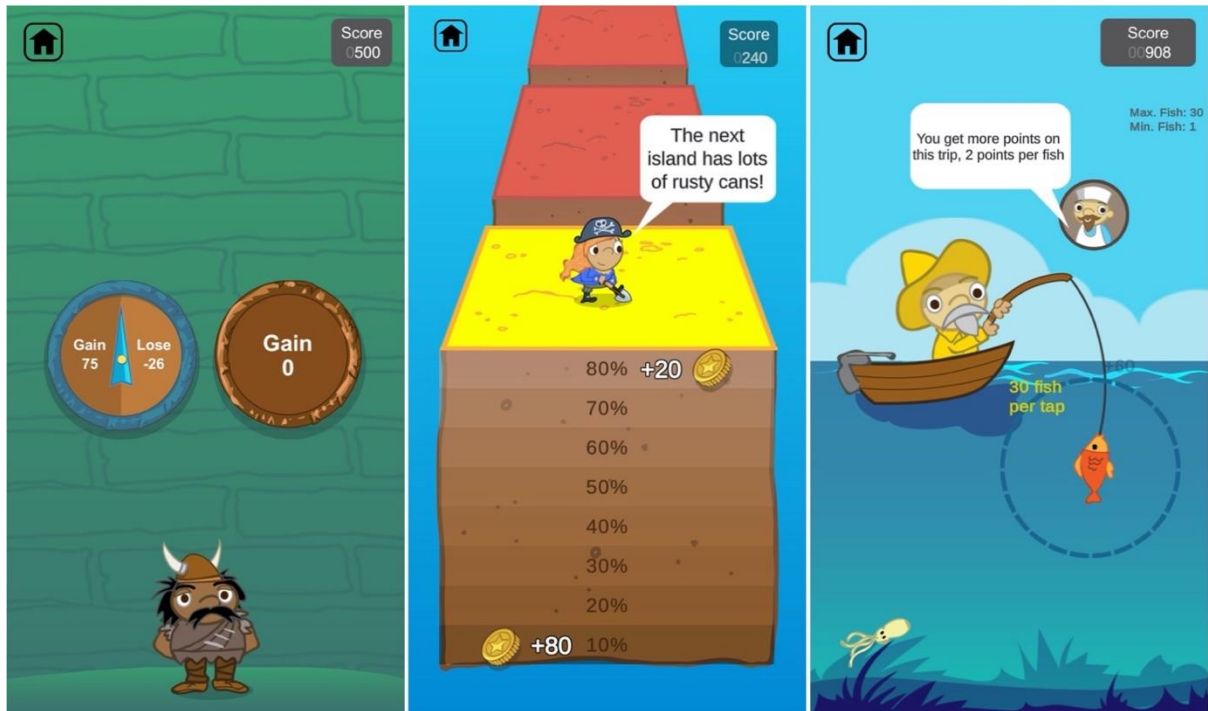
Are there any advantages/benefits from taking part?

While you will receive no direct financial benefit from your participation, you will be contributing to research that aims to better understand mood and decision making and how it is affected in neurological and psychiatric illness. We also hope you enjoy playing the games.

Are there any disadvantages/risks from taking part?

There are minimal risks associated with taking part in this study. Those risks include those associated with everyday use of computers, smartphones, and tablet devices, for the purposes of completing brief surveys and playing brief games. We have designed the games in the hope that they are fun to play repeatedly. Although test scores might be an interesting conversation topic with friends, they do not have direct implications for health or life success. We expect different people to make different kinds of choices, but we do not expect that this will necessarily result in lower scores in people with a neurological or psychiatric illness.

Will my taking part in the study be kept confidential?

Yes. The data collected from your device is transferred only with your unique identifier and stored on secure computer servers based in the UK. The data collected from computer tasks will be stored on the secure online Gorilla platform, which is a service dedicated to hosting online experiments. Identifying information is stored only on secure UCL servers and accessible only to the study team. The app and computer tasks do not collect any identifying information. The data is stored pseudonymously and will be fully anonymised before any data is shared with other researchers outside of the study team.

All the information that we collect about you during the course of the research will be kept strictly confidential. You will not be able to be identified in any ensuing reports or publications. Please note that assurances on confidentiality will be strictly adhered to unless evidence of wrongdoing or potential harm is uncovered. In such cases the University may be obliged to contact relevant statutory bodies/agencies.

At the end of the study we will save some of the data in case we need to check it and/or for future research (depending on whether you consent to being contacted for future studies). Personal data that links your identity to game or questionnaire data will be securely deleted ten years after the completion of the study. Personal data (name, contact details) and the information that you have been a participant in the study will

also be kept for ten years after the completion of the study. We will make sure no one can work out who you are from the reports we write.

This information sheet tells you more about this.

How will we use information about you?

We will need to use information from you for this research project.
This information will include your:
- · Name
- · Year of Birth
- · Email address and telephone number in order to contact you to discuss the study

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

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.

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 unless you ask us to delete it. You can also delete any data sent from your device by going to Settings within the app.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

We may also ask you whether the app can occasionally record other types of passive data (e.g. step count, GPS location at suitable times, and a measure of screen-on time) relevant to mood and behaviour. The app will not collect data about usage of other apps on the device, or any additional personal information about you. Location data will be transformed (no raw location data will be transferred) so that no information can be identifiable. You are free to decline providing any passive data, and doing so would not affect the functionality of the games or questionnaires within the app. All responses and measures will be linked to the unique participant ID only.

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 or by sending an email to the UCL data protection officer Alex Potts data-protection@ucl.ac.uk.

What will happen to the results from the study?

We plan to report our findings in scientific journals and present them to researchers at meetings and conferences. You will not be identified in any reports or publications from the study. If you would like to be informed of the results of this study, please inform the researcher. To make the best use of the data, we may make fully anonymised data available for further research and such data will be kept indefinitely. Shared data will not contain any information that could be used to identify you. Summary of results will be freely available on the Rutledge lab website (www.rutledgelab.org) at the conclusion of the study.

What if I want to stop taking part in this study?

If for any reason, you want to stop taking part in this study you are free to do so at any time. You are able to withdraw from the study or temporarily suspend your participation at any point from within the app itself in the Settings menu. You may be contacted by a member of the research team to verify that you would like to delete your smartphone data to ensure that accidental deletions do not occur. If you stop taking part in this smartphone study, this will not affect your current or future clinical care. You are also able to withdraw from the study but keep playing the games and, in this case, we will not receive your data from the app.

Who is organizing and funding the research?

This study is organised by Dr. Robb Rutledge and colleagues at the Wellcome Centre for Human Neuroimaging at University College London. The study is sponsored by University College London.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the UCL Research Ethics Committee.

Will I be contacted for further studies?

In the consent form, you will be asked whether you agree to be contacted for further studies. You may or may not be contacted. However, if you are contacted, you are under no obligation to participate in a further study if you do not wish to. In addition, you are free to withdraw from a study at any time without giving a reason.

What if something goes wrong?

If something goes wrong, in the first instance the Chief Investigator should be contacted. Dr Robb Rutledge [contact information] can be contacted at Wellcome Centre for Human Neuroimaging, 12 Queen Square, London WC1N 3BG. If you feel that your complaint has not been handled to your satisfaction, you can contact the Chair of the UCL Research Ethics Committee at ethics@ucl.ac.uk.

What if I have any comments or concerns about the study?

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, UCL complaints mechanisms are available to you. In the unlikely event that you are harmed by taking part in this study, compensation may be available. Please make the claim in writing to Dr Robb Rutledge who is the Chief Investigator for the research and is based at Wellcome Centre for Human Neuroimaging, 12 Queen Square, London WC1N 3BG. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions, contact details are at the end of the document.

Local Data Protection Privacy Notice

The data controller for this project will be University College London (UCL). The UCL Data Protection Office provides oversight of UCL activities involving the processing of personal data, and Alex Potts the UCL Data Protection Officer can be contacted at data-protection@ucl.ac.uk. You can provide your consent for the use of your personal data in this project by completing the consent form that has been provided to you. If you are concerned about how your personal data is being processed, please contact UCL in the first instance (data-protection@ucl.ac.uk). If you remain unsatisfied, you may wish to contact the Information Commissioner's Office (ICO). Contact details and details of data subject rights are available on the ICO website: https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/ The UCL General Research Participant Privacy Notice can be found here: https://www.ucl.ac.uk/legal-services/privacy/ucl-general-research-participant-privacy-notice

How have patients and the public been involved in this study?

Service User Research Forum: The design of the smartphone app was presented to a Service User Research Forum group by Chief Investigator Dr Robb Rutledge. This included six current mental health service users with a mix of diagnoses and medication who regularly consult on proposals and applications concerning mental health research. All members were given the opportunity to play a game from the previous smartphone app similar to the Reward and Happiness game and to discuss the design of the app for use in clinical samples. The feedback from the group was that the app was a positive and enjoyable way to engage service users in research. They suggested that users might like being able to easily contribute to further scientific research at times and places that are convenient for them. Researchers listened to concerns on accessibility of game download including that it should be made available for tablet devices and concerns on device memory and data usage, which were considered when developing the app to minimize data storage requirements.

If I have further questions, who I can talk to?

Please send any questions to Millie Lawrence (millie.lawrence@ucl.ac.uk).

If after reading this information sheet you decide to take part, you can complete the consent form online: https://redcap.idhs.ucl.ac.uk/surveys/?s=JNRE4YXK88RHFFDE

Thank you very much for taking the time to consider your involvement in our study. Please keep this copy of the information sheet and do not hesitate to contact us if you have further questions.