Participant Information Sheet – Participant Version

Ethical Clearance Reference Number: HR/DP-22/23-34436

Title of project

Exploring the use of smartphone assessment for young adults with Tuberous Sclerosis Complex (TSC): A qualitative analysis.

We would like to invite you to participate in this postgraduate research project. This sheet gives you important information about the study so that you know what is involved before deciding whether to take part. Please take time to read all the information carefully and discuss it with others if you wish. Please contact us if there is anything that is not clear or if you would like more information.

Contact details:
Kate Fifield
PhD Researcher
Email: Kate.fifield@kcl.ac.uk

What is the purpose of this study?

This study aims to understand how a new smartphone app may help monitor mental health and behaviour symptoms in. Young adults with TSC are more likely to face difficulties with mental health symptoms such as low mood and anxiety.

We want to try and develop a new way of monitoring these feelings and experiences using a smartphone app. The app asks an individual to complete several questionnaires throughout the day, over seven days. The questionnaires can ask you many different things such as how you are feeling, what you are doing and who you are with. It can also ask you to complete ‘brain games’ or puzzles.

We think using this app may better reflect the daily life experiences of young adults with TSC. We then hope this information will lead to more personalised, tailored treatment and support.

Before we test out this new smartphone app, we want to understand young adults with TSC thoughts and opinions about using this smartphone app. We want to know what would be useful to measure using this method and how to make it as accessible as possible for young adults with TSC.

Why have I been invited to take part?

You are reading this participant information sheet because you are aged 16-30, have a diagnosis of TSC, and we think you might be interested in taking part. This study will be conducted virtually so there is no need to travel during the study.

What would happen if I take part?

The study consists of two phases.

In phase 1 you will read the study advert and participant information sheet. Then, if you are interested in taking part, you will be asked to provide your contact details. A member of the research team will then contact you and explain what the project is about, answer any questions you have and ask you some questions to see if you are eligible to take part in the study. If you are eligible to take part, you will provide written consent using an online consent form. You will also be sent the phase 1 questionnaire to complete online.
This questionnaire will ask you about your smartphone use such as:

- ‘Do you currently use a ‘smartphone’ (A phone that can access the internet)?’
- ‘For which of the following activities do you ever use your smartphone for?’

The questionnaire will ask some questions about yourself and ask you your preference on whether you want to take part in a focus group or a separate interview for phase 2. It will take around 10 minutes to complete the questionnaire.

If you want to take part in a separate interview, you will also be offered the choice of having a key support person (e.g. a parent) to attend with you at the interview.

You are allowed to take part only in phase 1 if you wish. You can tell the research team this when they contact you.

**In phase two**, once you have completed the phase 1 consent form and questionnaire, you will be contacted by phone by a member of the research team who will explain phase 2 of the study. You can also ask any further questions about the study. If you are still interested in taking part, then you will be asked to provide written consent, using an online form, to take part in the focus group or interview.

You will then attend either an online 1-hour focus group or an online 1-hour interview. At the end of the focus group/interview, you will be asked to complete a short online questionnaire about how confident you would feel using the smartphone app and evaluation form.

In the focus group/interview, you will be asked questions about your experiences as a young adult with TSC. This will include a word cloud ice breaker exercise where you will be asked questions like ‘what words describe your life right now’. You will then be presented with information about the new smartphone app and shown a demo of the proposed app. You will be asked to give your opinions and feedback on the smartphone app. You will also be asked what would be useful to measure using this app and how to make it as accessible as possible for young adults with TSC. At the end of the interview, you will be asked to complete a short online questionnaire about how confident you would feel using the smartphone app and evaluation form.

After the focus group or interview, you may also be contacted with the results of the study and asked to provide feedback on the results. This will be done via an online questionnaire.

**Focus Groups**

The focus group will be run either via Microsoft Teams or Zoom. The focus group will consist of 4-6 participants plus two members of the research team. The focus group will be audio and video recorded.

**Interview**

The interview will be run online either via Microsoft Teams or Zoom and will be attended by the participant, (if requested) a key support person and the interviewer. The interview will be audio and video recorded.

Firstly, you will participate in the interview for 30-40 minutes with your key support person present (if requested). You will then be given the option to be interviewed by yourself (5-10 minutes) to have the opportunity to discuss any sensitive issues you may not have been comfortable discussing in the presence of your key support person.
COVID-19 safety procedures

The research study will take place only by online video call to reduce the risk of spreading COVID-19.

Do I have to take part?

No; taking part is completely voluntary. You should only take part if you want to and choosing not to take part will not affect your clinical care, ability to access clinical care, or disadvantage you in any way. Once you have read the information sheet, please contact us if you have any questions that will help you decide about taking part.

What are the possible benefits of taking part?

Once you have completed phases 1 and 2 of the study, you will also be compensated £25 for your time via a voucher.

What are the possible disadvantages and risks of taking part?

We do not envisage there being any risks, but you should know that it is not always possible to predict what other participants choose to discuss in focus groups. As such, there is a small risk that another participant could say something you find distressing. Support will be signposted to you if this is the case and if further support is required, a debrief telephone call with a clinical psychologist will be organised. Although the researcher will handle the data in a confidential manner, we cannot guarantee that other participants in the group will not disclose what is discussed. As such we urge participants to consider what they disclose to the group. Individuals with TSC may also have learning difficulties or experience mental health difficulties so we have put in a safeguard for this and allow participants to attend an interview with a key support person of their choosing.

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

This research was reviewed by a team with experience of mental health problems and their carers who have been specially trained to advise on research proposals and documentation through the Feasibility and Acceptability Support Team for Researchers (FAST-R): a free, confidential service in England provided by the National Institute for Health Research Maudsley Biomedical Research Centre at King’s College London and South London and Maudsley NHS Foundation Trust.

How will my data be stored and analysed?

To safeguard your rights, we will use the minimum personally identifiable information possible. For instance, your name, email address, and phone number will only be used to remain in contact with you during the study and will not be used after you have completed the experimental visit or after you have withdrawn from the study. Only members of the research team at KCL will have access to identifiable data.
After the focus groups/interview, the video/audio recording will be encrypted and stored in a password-protected folder. This recording will be typed up into a transcript – the researcher will not type any information which may identify you. Once the transcript is checked the recording will be erased to maintain the participant's anonymity. Only the study team will have access to the recording during the study, and this information will not be shared with anyone outside the study team or published anywhere. The anonymised transcript will also be stored in a password-protected folder.

Other data collected from you as a part of this study, such as information about yourself e.g., your age, will be anonymised and stored securely with a participant ID number. Any personal, identifying information we have about you, such as your name, will be stored separately from the anonymised data. Only the study team will be able to link participant ID numbers to the personal, identifying information and only the study team will have access to this data. We will use this data to anonymously describe who took part in our study such as describing the age range e.g., individuals aged 16-30 years old took part in our study.

Any identifiable information will be deleted after 3 years at the end of the research project. Before the study, you will be asked if you would like your contact details to be stored and used to contact you about future similar research. If you consent to this your contact information will be stored securely and, in a password-protected file. The researchers will retain your contact details only for this purpose. If you have consented to be re-contacted for future studies; your contact details will be stored for up to 10 years. As is the case during the timescale of the study, every effort will be made to ensure the confidentiality of the obtained data. If you withdraw from the study, your contact details and other personal information will be deleted.

**Under what legal basis are you collecting this information?**

Your data will be processed under the terms of UK data protection law (including the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018). We will do everything we can to make sure your data is confidential. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is “a public interest task” and “a process necessary for research purposes”.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult the KCL website:

https://www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statementon-use-of-personal-data-in-research

Please also note that individuals from King's College London or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

**What if I change my mind about taking part?**

You are free to withdraw, without having to give a reason. Withdrawing from the study will not affect you or your opportunities to take part in future research or access treatment in any way.

If you have completed the Phase 1 questionnaire you have the right to withdraw without providing any reason, up until two weeks after the completion of the phase 1 questionnaire.
If you choose to withdraw from the study before the focus groups/interviews, we will not retain the information you have given thus far.

Participants who take part in the focus groups will not be able to withdraw after taking part in the focus group due to the nature of focus groups. Focus groups often involve crosstalk or individuals referring back to each other’s prior comments, which can cause difficulties in withdrawing participants’ data. Also, when the data is anonymised into the transcript, it will not be possible to remove a specific person’s data from the project as we will not be able to identify their specific data.

Participants who take part in an interview will be able to withdraw (without giving a reason) up until two weeks after the interview.

If your KSP person withdraws before the interview, you will be given another opportunity to nominate a different KSP or the option to participate by yourself. If your KSP person withdraws after the interview, their demographic data and any data transcribed from the interview will be removed but the data gathered from you (the corresponding individual with TSC who has not withdrawn) will remain in the study.

Who is organising the project?
The study is being organised and funded by the Psychology department at King’s College London

Who has reviewed the research project?
All research at King’s College London is reviewed by a group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by the RESC (Health Faculties Research Ethics Sub-Committee).

Will the outcomes of the research be published?
Findings will be published in peer-reviewed journals and scientific conferences. There will be no way that you could be identified as an individual. No personal identifying information will be published.

What if there is a problem?
If you have concerns about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions:

Dr Sara Simblett. Email: sara.samblett@kcl.ac.uk
Postal address:
Henry Wellcome Building for Psychology,
Institute of Psychiatry, Psychology and Neuroscience,
King’s College London,
De Crespigny Park,
London,
SE5 8AF

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: Institute of Psychiatry, Psychology & Neuroscience and Florence Nightingale School of Nursing & Midwifery Research Ethics Panel: rec@kcl.ac.uk.
Who should I contact for further information?

If you have any questions or require more information about this study, please contact me using the following contact details:

Kate Fifield
PhD Researcher
Henry Wellcome Building for Psychology,
Institute of Psychiatry, Psychology and Neuroscience,
King's College London,
De Crespigny Park,
London,
SE5 8AF
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Thank you for reading this information sheet and for considering taking part in this research.