

Feasibility study of an adapted app-based anxiety intervention for autistic people.

Participant Information Sheet

We would like to invite you to take part in our study of Molehill Mountain – an app to help autistic people to better understand and self-manage anxiety. This study is carried out by researchers at King's College London and the South London and Maudsley NHS Foundation Trust, and funded by the Medical Research Council Confidence in Concept Award.

Before you decide whether you wish to take part, it is important for you 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. If you have questions about the study then you can contact the research team by email or phone.

Once you have read this information, and if you decide to take part, you will be asked to sign a consent form.

What is the aim of the study?

Many autistic people experience anxiety, which can impact everyday wellbeing. Cognitive Behaviour Therapy (or 'CBT') approaches that have been specifically adapted for autistic people are a clinically proven technique for managing anxiety. However, accessing in-person CBT appointments can be challenging for some people.

Therefore, the aim of this study is to test whether a new app called 'Molehill Mountain' could help some autistic people to better understand and self-manage their anxiety. We want to know how easy the app is to use, how people choose to use the app, whether it is effective in reducing levels of anxiety over time, and how it can be improved for the future. We hope this study might contribute to improving mental health support and outcomes for autistic people.

Who can take part?

We are inviting autistic people aged 16-years and over who experience anxiety and are registered with a GP to take part in this study. Participants need to be able to use a mobile phone app and should not currently be having therapy (or had 6 or more sessions of therapy in the past 6 months).

Taking part in this study is completely voluntary. You should only take part if you want to. Choosing not to take part will not disadvantage you and will not affect access to your usual health and social care services in any way. If you decide not to take part, we would still like to invite you to complete a short survey to help us to understand who the Molehill Mountain app may, or may not, be helpful for, so we can make it more suitable in the future. This short survey is also optional.



What will happen if I take part?



If you choose to take part in the study, we will first ask a few demographic questions to learn a little bit more about you and understand how representative our sample is. We will also ask some questions about anxiety, autistic traits, and your personal goals. We will then ask you to download the Molehill Mountain app onto a Smartphone, or other Smart device. The research team can support you to do this, if you wish.

You will be invited to use the Molehill Mountain app daily for 13-weeks. We will provide advice on the different ways that you can choose to use the app. We will also check in with you during this time to see how things have been going.

At the end of the 13-weeks, we will invite you to complete a short feedback survey, and optional interview, about your experiences of using the Molehill Mountain app. Finally, we will check in with you up to 3 times after the study to ask some questions about your anxiety and personal goals, and see whether and how these might have changed over time.

We will ask your permission to send a notification letter to your GP so that they are aware of what the study involves for you.

	<p>1. Questions about you. At the start of the study, we will ask you some questions about yourself, your anxiety and personal goals. You can choose whether you prefer to fill this in online a survey platform (Qualtrics), or using pen and paper. We expect this to take around 30-60 minutes, but this may be shorter or longer depending on how you prefer to answer the questions. You do not have to complete them all in one go. If you choose pen and paper, we will provide you with a prepaid envelope so that you can return your forms to us.</p>
	<p>2. Molehill Mountain app. We will help you to download and start using the Molehill Mountain app. . We will then ask you to use the app daily for 13-weeks. We will check in with you during those 13-weeks to see how things are going.</p>

	<p>3. Feedback survey/ interview. At the end of the main study, we will ask you to fill in a short feedback form about your experiences of using Molehill Mountain.</p> <p>If you wish, you may also take part in a feedback interview, which is completely optional.</p>
	<p>4. Follow up with you. If you agree, we will follow up with you up to 3 times after the main study to ask questions about your anxiety and personal goals, and see how these may/ may not have changed since you first started the study.</p>

What are the possible disadvantages of taking part?

As this study focuses on anxiety, the app and surveys include topics related to mental health and wellbeing, which may be potentially sensitive. Please remember that you do not have to answer any questions that you do not wish to. Molehill Mountain provides details of support services and their contact information in case you are experiencing distress. We do not recommend using this app if you are currently experiencing suicidal thoughts or are self-harming. If this is the case, please contact your local care team, your GP, or mental health services. Support is also available from the Samaritans/Shout (call 116 123 or text SHOUT to 85258).

We ask that you do not use the app in situations where using a Smart device is not allowed or may be risky, such as when driving, or crossing the road.

There is a small risk that the technologies used in this study could be hacked. However, this risk is the same as with any Smartphone app. Processes have been put in place to minimise any risk to you in the unlikely event of hacking.

What are the possible benefits of taking part?

There are no direct benefits to you if you decide to take part in this study. The Molehill Mountain app is designed to help with better understanding and self-managing anxiety, but is not a replacement for your usual support services. You will be contributing to a study that aims to improve mental health support and outcomes for autistic people in future. If you choose to take part, you will receive a £15 shopping voucher to say thank you for your time. You can also choose to receive a copy of the results of the study by email after the research has finished, if you'd like to.

How will you use information about me? Will my information be kept confidentially?

We will need to use information from you for this research project. This includes sections of your medical notes that are relevant to this study. Once we have finished the study, we will keep some of the data so we can check the results.

Personal information

Your personal details (e.g., name, initials, contact information) will be stored in a secure file, separate to other data. All paper files will be kept in a locked filing cabinet. People will use this information to do the research, or to check your records to make sure that the research is being done properly. Data will never be shared with anyone outside of the research team without your consent, unless required by law.

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.

Surveys/ interviews

All information from surveys that you fill in will be stored on a password protected secure server at King's College London. If you choose to take part in a feedback interview about your experiences of using Molehill Mountain, we will ask for your permission to audio/ video record this interview so that we don't miss anything you say. The recording will be moved to a secure, password protected server for transcription (where the research team will write out what was said during the interview) and deleted from the recording device. Transcription will be performed internally by the research team, who will remove all identifying information that was said during the interview. Once transcription is complete, we will also delete the recording from the server.

If you agree, we may use direct quotations from your interview in publications, but we will remove any identifying information first. We will write our reports in a way that no-one can work out that you took part in the study. Only if you agree, completely anonymous data from this study may be shared in the public domain to help to speed the rate of scientific and healthcare progress.

Molehill Mountain app

UK autism charity Autistica is responsible for the information that you enter in the Molehill Mountain app. Personal information (e.g., name, email address) is used to create your account and other information to personalise the app so that it works in the right way for you. If you agree, we will also collect anonymous information about your app usage, including your phone details. This helps us to understand how people are using Molehill Mountain, so that we can improve the app in the future. For more information about privacy and your data in Molehill Mountain, please visit: <https://www.autistica.org.uk/molehill-mountain/privacy-and-your-data>

Your safety

Following the BPS code of ethics and conduct and local guidelines, we may breach confidentiality in exceptional circumstances where there is sufficient evidence that you may be a risk to your own or others' safety. We might also encourage you to seek support.

How will my information be processed?

The research information you provide in this study (including consent forms) will be stored confidentially for a minimum of 10 years after the study has ended. 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).

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

- At www.hra.nhs.uk/information-about-patients/
- Our leaflet available from www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research (KCL) or <https://www.slam.nhs.uk/about-us/privacy-and-gdpr> (SLaM)
- By asking one of the research team
- By sending an email to the Data Protection Officer info-compliance@kcl.ac.uk (Albert Chan, KCL) or InformationGovernance@slam.nhs.uk (SLaM)

What if I change my mind about the study?

You can stop the study at any time, without giving a reason. If you stop the study, we will ask your permission to keep some coded information about you that we already have, to make sure that our research is reliable.

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

If you have questions or concerns about this study, please speak to the research team who will do their best to answer them. If they are unable to answer your questions or you have a complaint, please contact the Chief Investigators: Professor Emily Simonoff (emily.simonoff@kcl.ac.uk) or Professor Declan Murphy (declan.murphy@kcl.ac.uk).

If you remain unhappy and wish to complain formally, you can do this through the SLaM Patient Advice and Liaison Service (PALS) on 0800 731 2864, pals@slam.nhs.uk. In the event that something does go wrong, and you are harmed during the research, you may have grounds for legal action for compensation against King's College London and/or SLaM NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Research team contact Information:

Phone: +44 (0) 207 848 0820

Email: molehillmountain@kcl.ac.uk [Contact names: Charlotte, Marianne and Beth]

Health Research Authority: www.hra.nhs.uk/patientdataandresearch



Charlotte



Marianne



Beth

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