



INFORMATION SHEET FOR PARTICIPANTS

Ethical Clearance Reference Number: HR-19/20-14855

A study examining what makes worry hard to control

We would like to invite you to participate in this research project funded by King's College London. You should only participate if you want to and choosing not to take part will not disadvantage you in any way. 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. If there is anything that is unclear or if you would like more information, please feel free to contact us via the details provided below.

What is the purpose of the study?

The purpose of the study is to help us understand why some people find it difficult to stop worrying. Many people worry from time to time, but some people find that once worry has started, it is very difficult to stop. We know very little about why or how some people can control negative thinking, whilst others find it difficult. In the present study we hope to learn more about why worry persists in the longer term for some people and not others. We will do this by looking at people's responses on different tasks and questionnaires over time.

Why have I been invited to take part?

We are seeking participants who are between the ages of 16-25 and tend to worry about things that might go wrong in the future. Participants must also be fluent in English and have normal, or corrected to normal, vision and hearing.

What will happen if I take part?

Screening Questionnaire

If you choose to take part in the study, you will be asked to complete a brief screening questionnaire.

If you are eligible based on your screening questionnaire, you will be invited to a screening phone call with a member of the research team to discuss the study and address any questions you may have. If the study is suitable for you, you will be invited to take part.

Main Study

The study is set up entirely online, therefore there will be no need for any in-person visits. The sessions and assessments will be completed online within an eight-week period. Although we

use the word “assessments”, there are no right or wrong answers. We are simply seeking to investigate how you are thinking and feeling at that point in time.

After completing the first assessment, participants will be randomly allocated by a computer into either the intervention group or ‘life-as-usual’ control group. Participants in the intervention group will complete assessments and 9 sessions. There will also be some homework exercises to complete outside of the sessions. The ‘life-as-usual’ control group will NOT be participating in sessions, though they will participate in all other parts of the study.

In the study, you will be asked to identify topics that you have been worrying a lot about recently. You will be asked to worry at certain points in the study. After worrying, you will be asked to try and stop worrying. You will also report the types of thoughts you are having at various points. Additionally, you will complete questionnaires and will be required to listen to or watch some things during the task. The researchers will not be able to give you individual feedback on your performance on the tasks, but they will be able to give you an overview of the study and its aims.

Assessments

The three assessments must be completed on a PC, tablet, or laptop. After the first assessment, participants in the intervention group will be granted access to the online sessions. The second assessment will be completed four weeks after the first assessment and the third assessment will be completed eight weeks after the first assessment. The assessments will take around 20 minutes to complete each time.

These assessments will involve completing different questionnaires and tasks. You will complete a task requires you to try to stop worrying and you will be asked to fill out some questionnaires regarding your experiences with worry, anxiety, and low mood. The researchers will not provide feedback regarding task performance, but they can provide an overview of the study and its aims.

Sessions

Participants in the intervention condition will complete nine sessions on an online platform over a 4-week period, which will involve learning a new technique to use when you find yourself worrying. Each session will take around 10 minutes to complete. We ask that you complete the first session on the same day as the first assessment if you can. We encourage you to complete the 9 sessions in two weeks, and then spend two weeks practicing the skills you have learnt. Please make sure that you complete the sessions at a time when you will not be disturbed.

Reminders and Contacting the Team

During the study you will be prompted by the mobile app with reminders to complete your sessions and homework tasks. We may also contact you by email, phone, or text during your time in the study.

You are also welcome to get in touch with the team at any time via email (shiftfocusapp@kcl.ac.uk) to discuss any difficulties that come up to see how we can help change things and if completing all 9 sessions is too difficult.

Exit Interview

A main aim of this research is to find out whether this online intervention does reduce worry and if it is an acceptable approach for young adults. If you are allocated to the intervention group, we may invite you to take part in a 30-minute telephone interview to ask you some questions about your experience of the sessions. This call will be recorded so that we can look at all feedback thoroughly (no identifying information will be included in the recording).

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. Once you have read the information sheet, please contact us using the details at the bottom of the page if you have any questions about taking part. If you decide to participate, we will ask for your consent at all stages of the research.

Reward for taking part

To contribute towards your time, you will be given a £20 Love2ShopVoucher after you complete each assessment. . Therefore, you will receive £60 in total if you complete all three assessments. Those completing the exit interview will be compensated with an additional £20 Love2ShopVoucher.

What are the possible benefits and risks of taking part?

We hope that you find it interesting taking part in the study.

The study involves worrying about current concerns. This procedure may lead to temporary increases in anxiety and low mood. Based on past studies, such mood changes are expected to be temporary and go quickly. If the study brought up any concerns, you would have the opportunity to discuss them with the researcher during and following the study. Hopefully you will find the study interesting, and you will be helping to contribute to research that hopes to find out more about why worry persists in the longer term for some people and not others.

Data handling and confidentiality

Your data will be processed in accordance with the General Data Protection Regulation 2018 (GDPR). Information which is collected about you during the course of the research, including your answers to questionnaires and computer-based tasks, will be kept strictly confidential and pseudonymised during the data collection period. This means you will be given a participant number and that the only way to identify you will be by your numerical ID.

At the end of the study, your personal data and the link between your personal data and your numerical ID, will be deleted to ensure full anonymity. All information will be kept strictly confidential unless any information is disclosed which could seriously affect the welfare of yourself or others, in which case a third party may have to be contacted for legal reasons.

After the data has been archived, it will be stored securely in anonymised form in King's College London for up to ten years, in either a locked filing cabinet or storage facility if in paper format, or on a university drive that can only be accessed via a password protected computer if in electronic format. This information will only be seen by members of the research team and will not be shared with any third parties.

What if I change my mind about taking part?

You are free to withdraw at any point of the study, without having to give a reason. Withdrawing from the study will not affect you in any way. You are able to withdraw your data up until two weeks after completing the study, after which withdrawal of data will no longer be possible due to it having been anonymised. If you choose to withdraw during the study, we will not retain the information you have given up to that point in time.

How is the project being funded?

This study is self-funded.

What will happen to the results of the study?

The findings will be used to improve our psychological understanding of worry. The results of the study will be published in a peer reviewed journal, presented at conferences and discussed at other public events. All the data will be reported in a group level; individual data will not be reported, and you will not be identified in any report or publication. If you would like a copy of the research findings, please let the researcher know, and we will arrange for a copy of the final written report to be sent to you as soon as it is available.

Who should I contact for further information?

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

shiftfocusapp@kcl.ac.uk

Alternatively, you can write to:

Professor Colette Hirsch
Department of Psychology
Henry Wellcome Building, De Crespigny Park
London, SE5 8AF

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:

Chair of the Psychiatry, Nursing and Midwifery Research Ethics Subcommittee
Email: rec@kcl.ac.uk

Data Protection Statement

The data controller for this project will be King's College London (KCL). The University will process your personal data for the purpose of the research outlined on the previous page. The legal basis for processing your personal data for research purposes under GDPR is a 'task in the public interest.' You can provide your consent for the use of your personal data in this study by completing the consent form that will be provided to you.

You have the right to access information held about you. Your right of access can be exercised in accordance with the General Data Protection Regulation. You also have other rights including rights of correction, erasure, objection, and data portability. Questions, comments and requests about your personal data can also be sent to the King's College London Data Protection Officer, Mr Albert Chan, info-compliance@kcl.ac.uk. If you wish to lodge a complaint with the Information Commissioner's Office, please visit www.ico.org.uk.

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