University of Bath
Department of Psychology
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PARTICIPANT INFORMATION SHEET

Evaluating the usability and acceptability of a program developed to prevent relapse in OCD

Who are we?

Hi there, my name is Dr Josie Millar I'm a Clinical Psychologist and researcher in the Department of Psychology at the University of Bath. Together with people with personal experiences of OCD we have developed a programme aimed to prevent relapse after people have had Cognitive Behavioural Therapy (CBT) for OCD that helped them. We are now conducting a study to find out what people think of the programme, specifically how acceptable and how usable it is.

Before you decide if you would like to take part, it is important for you to understand why the research is being done and what it would involve. Please take time to read the following information carefully and, if you wish, discuss it with friends, relatives, or anyone else you think would be a good person to advise you.

Please feel free to contact us by email at ocdresearch@bath.ac.uk if there is anything that is not clear or if you would like more information.

What is this study about?

At present, within the NHS, people who have had CBT for OCD do not receive any post-therapy intervention to support them to keep well and maintain their treatment gains. However, research has shown that in the first year after CBT, people are most likely to experience a relapse in their OCD. We understand that people who are experiencing OCD often worry about experiencing relapse after their therapy has ended and that this worry can have a further impact on quality of life.

At present, there are no recommended relapse prevention interventions following the end of CBT for OCD. Therefore, we have developed a blended intervention program. This involves 10 online group sessions combined with the use of a mobile health application (App) which has been developed specifically for use alongside the group sessions. We have developed this program in collaboration with people with personal experience of OCD.

We would now like to find out what people think about this program in terms of how acceptable and how usable it is. We are seeking participants to attend the 10 groups sessions and in between the sessions to try out the App and to provide feedback on their experience of both.

Who can take part?

You are welcome to participate in this study if you are an adult over the age of 18, have had a diagnosis of OCD and have completed CBT for OCD, (which has included some behavioural experiments or exposure

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work), within the last 4 months. Due to the focus of the program being on relapse prevention, to be eligible your OCD symptoms will need to be in the mild-moderate range. This is something we would assess for during an eligibility assessment.

To be eligible, we require participants to either not be taking any psychotropic medication or to have been taking a stable dose of medication for at least 6 weeks. You also need to be fluent in English to participate in the study.

For safety reasons, we advise people who are experiencing active difficulties with thoughts of suicide or are misusing a substance to not consider taking part in this study. Instead, we would suggest you contact your GP if you are not already in contact with local services.

Finally, if you have current involvement in a treatment trial for OCD or are currently receiving another therapeutic intervention or program for OCD or to prevent relapse, you will not be able to participate.

What would taking part involve?

Before the start of the study, you will be invited to take part in an online assessment call (held on Microsoft teams) to find out if the study is the right fit for you. Following this assessment, if the study is a good fit and if you wish to take part, you will be sent a link to the information sheet and consent form.

The study would require you to attend online group sessions and to engage with a mobile app in-between the sessions. The App is designed to support relapse prevention in OCD and is linked to the content of the sessions.

Group Sessions

If you decide to take part, you will be invited to attend 10 group sessions. The groups session will be run by a qualified clinical psychologist and will be carried out online via Microsoft teams over a period of 3-months (specific dates below). Each group session will last 2 hours. These sessions will focus on the following topics:

Session 1: How recovery works	**Session 2:** Tackling fears of relapse
Session 3: Stress and its impact on recovery	**Session 4:** Feelings of responsibility and uncertainty
Session 5: How OCD can change over time	**Session 6:** Tackling low mood
Session 7: Reconnecting	**Session 8:** Building compassion
Session 9: Moving forward	**Session 10:** Future of recovery

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How many sessions do I need to attend?

We would ask that you be able to attend a **minimum of 6** of the group sessions.

Dates

The groups sessions will be run on the **weeks commencing**:

February: 5th, 19th 26th

March: 4th, 11th, 18th, 25th

April: 8th, 15th, 22nd

Mobile App

In-between the sessions you will be asked to make use of the mobile app. This will involve using specific features on the app which relate to the content covered in that week's group session. Before using the app, participants will receive a tutorial in how to use it. After each group session you will be asked to provide anonymous feedback on your experience of the group and the content provided. After each week of using the app, you will be asked to complete some online questionnaires about any symptoms you may be experiencing and to provide anonymous feedback about how acceptable and how usable you found the app.

Your feedback will be anonymous, this means we won't be able to identify who provided which feedback. The feedback you provide will be used to help us to refine and improve the program overall. At the end of the study, and at 3months and 6months following the end of program study a clinical researcher will contact you to conduct a questionnaire with you called the YBOCS (Yale-Brown Obsessive Compulsive Scale) and you will also be asked to complete a short online questionnaire about your symptoms and to provide any further feedback that you may have on the program.

After the end of the 10-session program, you will have access to the mobile app for a further 6 months. After this your user data will be deleted and you will no longer be able to access the app.

End of relapse prevention program – Interview Study

At the end of the 10th session of the program, you will be invited to take part in a follow-up interview with Dr Chelsea Courts who is a clinical researcher and Clinical Psychologist in training. Chelsea will not have previously been involved in any aspects of the program. The aim of this interview will be to find out about your experience of taking part and how you found providing feedback on the program overall. This interview will aim to gain a more in-depth understanding of your experience.

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This interview is optional, and you can decide if you would like to take part at the time, after the program has finished. Before you decide, Chelsea will be available to answer any questions you may have, and she will also seek your informed consent to take part. Chelsea will then arrange a time with you for the interview via Microsoft teams. The interview will be audio recorded and it is expected to last approximately 1 hour. On completion of the interview, you will receive a £20- payment for your time.

If you decide to withdraw from taking part in the relapse prevention program at any point before the 10th session, we would still like to invite you to take part in the end of program - interview study. to understand why this program wasn't right for you. After withdrawal Chelsea will contact you to see if you would like to take part in an interview. Before deciding, Chelsea will be able to answer any questions, and she will seek your informed consent to take part in the interview. The interview will be audio recorded and is expected to last approximately 1 hour. On completion you will receive a £20- payment for your time.

Do I have to take part?

Taking part in any aspect of this research is entirely voluntary, and you are free to make your own choice about whether you want to participate. You will be given a minimum of 24 hours to decide if you would like to take part.

During the course of the study you will be free to withdraw at any time, without having to give a reason, by letting one of the researchers know (please see our contact details below). If you decide to withdraw from the study, please see the section below titled ***'What will happen to the information I provide?'*** for details on what would happen to your data.

If I am interested, how do I sign up for an assessment to find out if this study is the right fit for me?

If you would like to register your interest in the study and be contacted by a researcher for an assessment, you will be able to provide your consent to do this on the next screen. This initial step will involve completing 1 questionnaire about your previous CBT. We will also ask you to confirm if you are experiencing any risk. Following this you can leave your name and email and we will contact you to organise a time to meet via Microsoft teams.

What will happen to the information I provide?

All information you provide will be treated as strictly confidential. Please see the diagram below for a breakdown of what data will be collected, when it will be collected, how it will be stored and what data you can withdraw throughout the study.

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All the below information will be stored securely in a password protected folder on the University of Bath's computer system.

TIME/STAGE	DATA COLLECTED	DATA STORAGE
NOV/DEC 2023 Consent to be contacted by researcher and initial questionnaire.	• Name • Email Address	This will be deleted 10 years after study completion. You **CAN WITHDRAW** this data at any point up until **14 days** after study completion, after this point all data will be anonymised.
	• Previous CBT Questionnaire	This data will be archived. You **CAN WITHDRAW** this data **up to 14 days** after study completion. After this point all data will be anonymised.
DEC 2023 Teams call with researcher to check fit for study.	• OCD Symptoms • Eligibility Criteria	This data will be archived. You **CAN WITHDRAW** this data **up to 14 days** after study completion. After this point all data will be anonymised.
DEC 2023 / JAN 2024Consent to take part in intervention (if eligible)	• Name • Email Address	This will be deleted 10 years after study completion. You **CAN WITHDRAW** this data at any point up until **14 days** after study completion, after this point all data will be anonymised.
	• Baseline Questionnaire	This data will be archived. You **CAN WITHDRAW** this data **up to 14 days** after study completion. After this point all data will be anonymised.

If you are eligible to take part in the study, you will receive a study ID. The information linking you to your study ID will be stored securely and separately from your data. On completion of the study this link will be deleted meaning your data will be anonymous.

TIME/STAGE	DATA COLLECTED	DATA STORAGE
JAN to MARCH 2024 10 Session Relapse Prevention Intervention	• Feedback on group sessions and App • Symptom Measures at week 1,3 and 5	Is anonymous when provided. This data **CANNOT BE WITHDRAWN** as it is anonymous.
	• App Usage data (e.g., Which areas of the app were visited the most-measured in time)	This data will be linked to your 'Study ID' number & stored on the app's secure network. This data **CAN BE WITHDRAWN** up until **14 days** after study completion.
	• Any information you enter the app (e.g., when completing a worksheet or task). • This WILL **NOT** be accessed or used by the therapists or researchers as a part of the study.	After session 10 you will have access to the app and the information you have entered in it for a further 6 months after this point it will be permanently deleted. If you decide to leave the study before week 10, any information you have provided will be deleted at the same time point as mentioned above.
APRIL/MAY 2024 - Post Intervention	<u>Interview (optional)</u> • Recording of interview. • Feedback on Intervention	Interview recordings will be typed up, anonymised, and stored securely. **YOU CAN WITHDRAW** your data **up to 14 days** after the interview. After this point the recordings will be deleted, and the data will be anonymised.
	<u>Post programme follow-up 3/6 months</u> OCD symptoms Continued App usage data	This data will be linked to your 'Study ID' number & stored securely. This data **CAN BE WITHDRAWN** up until **14 days** after the 6-month follow-up.

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What are the possible benefits of taking part?

Participants will be supporting the refinement of a programme which has been developed to prevent relapse for OCD. Following this study, we aim to evaluate the effectiveness of the program in reducing relapse in OCD. The information we obtain from this study will help us to do this, which is needed to evidence the need for relapse prevention program to be part of standard practice. This study is the first step towards this aim.

Although not the primary aim of the study, those taking part may experience benefits of attending a group with other people who have a shared experience. Reviewing content which is aimed at supporting and maintaining gains made in CBT for OCD may be beneficial.

Are there any risks?

The programme that you will be providing feedback on aims to reduce the risk of relapse of OCD symptoms and thus we do not anticipate any risks.

It is not anticipated that taking part should cause any pain, discomfort or distress, nor are there any known risks associated with Cognitive Behavioural Therapy (CBT) which is the therapy underpinning the content of the programme.

What will happen to the results of this research?

What you tell us will inform our research on the acceptability and usability of the new relapse prevention program for OCD. We will use your feedback to modify and improve the program.

The findings of the research may be published in research journals or used in presentations, but you will not be identifiable in any way.

Who is organising and funding the study?

This study has been funded and reviewed by the Academy of Medical Science. The study is being organized by Dr Josie Millar at the University of Bath.

Who has reviewed the study?

All research is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and approved by the University of Bath Research Ethics Committee CODE 0158-1439

What if something goes wrong?

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If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, please contact Dr Josie Millar, via email: jfam20@bath.ac.uk

What do I do if I would like to take part or have more questions?

If you would like to participate, please click to the next page where you will be asked to complete some questionnaires and provide your consent for a researcher to contact you to organise a time to assess if this study is a good fit for you.

If you have a question, you are welcome to contact the researchers directly, and we can provide you with more information.

Our email is: ocdresearch@bath.ac.uk

Many thanks for taking the time to read this. We would be delighted if you would be willing to consider taking part 😊