COVID Anxiety Project: Clinical Trial Information Sheet

Invitation to take part in a clinical trial

Thank you for answering our questions about how COVID impacts on your mental health. In addition to continuing with the questionnaire study, we are inviting some of the people that reported a lot of anxiety about their health to take part in an additional part of the research.

Because of your responses, we would like to invite you to take part in a clinical trial of a talking therapy. In the trial we allocate some people to treatment over the telephone or video-call with a trained therapist to talk about their worries, working together to improve their mental health and day-to-day functioning.

What is the purpose of the study?

We know that a type of therapy called cognitive behavioural therapy (or CBT for short) is helpful for people that have high levels of anxiety about their health. CBT is used for people that are preoccupied by worries about getting a serious illness, are focussed on bodily feelings that may be symptoms of illness, and may think or act in a way that focusses on illness to the point that it stops them from doing other things that they want to do. However, we do not know whether the treatment is helpful for people that are experiencing similar things about COVID. To see whether CBT benefits people with a lot of anxiety about COVID, we are inviting people to take part in a trial. We will randomly allocate people that take part to one of two groups. People in group 1 will be offered a series of one-to-one sessions of CBT over the telephone or video call whereas people in group 2 will not have CBT. This is a small-scale study to see whether it is possible to do a larger clinical trial in the future.

Do I have to take part?

No, you are free to choose to take part or not. If you agree to take part but decide that you do not wish to carry on, you can stop at any time. If you decide not to take part or withdraw at any time, we will ask you why but you do not have to answer. If you do answer, nothing that you say will affect the care that you are entitled to or the standard of care that you receive.

What will happen to me if I take part?

Firstly, we will ask you to sign a consent form to say that you have read this information sheet and are happy to take part in the trial. This is separate from the consent that you gave to complete our questionnaires because not everyone is invited to take part in the trial. You can still carry on with the questionnaires even if you don’t want to be in the trial of CBT. To answer any questions about the trial and help you to complete the consent form, we will telephone you to talk about it. If you decide to take part, we would like you to complete the consent form whilst on the telephone with us. If you’re not ready to decide, we can arrange a time to call you again.

Allocation to therapy

Each person who agrees to take part in the clinical trial will be put in either group 1 (CBT) or group 2 (no CBT) based on chance. This is done using a list that is randomly generated by a computer. About half of the people that take part in the trial will be put in group 1 and get CBT. We will telephone you to let you know which group you are in, and to arrange your first appointment with one of our therapists if you are in the group that gets CBT.

We will send everyone in the trial a self-help booklet that has been developed to help people cope with anxiety about COVID.

Those that are allocated to CBT will be given between five and ten therapy sessions. If you are offered CBT, you can choose whether it is on the telephone or video call. Each session will last between 30 and

50 minutes. These can be arranged at a time that suits you and we will aim to schedule a session every 1-2 weeks. Please note that further CBT will not be available after the end of the trial.

Like everyone that is taking part in this research, we will ask you to complete questionnaires about your thoughts and feelings at three months and six months after you started taking part in the research.

If you choose to complete these questionnaires with a researcher on the telephone, they won't know whether you were allocated to the group that received CBT or not. That way the information that they record about your thoughts, actions and feelings will not be influenced by knowing that you had the treatment or not. We will look at your responses in the questionnaires to identify any changes in your thoughts, feelings and actions. We will then compare the groups to see whether people that were given CBT improved when compared to those that were not given CBT.

We will ask you for the details of you GP and let them know that you are taking part in the trial.

What is Cognitive Behavioural Therapy (CBT)?

- CBT is based on the idea that your thoughts, feelings, physical sensations and actions are interconnected, and that negative thoughts and feelings can trap you in a vicious cycle.
- CBT aims to help you deal with overwhelming problems in a more positive way by breaking them down into smaller parts.
- You're shown how to change these negative patterns to improve the way you feel.
- Unlike some other talking therapies, CBT deals with what is happening at the moment, rather than focusing on issues from your past.
- It looks for practical ways to improve your state of mind on a daily basis.

During the sessions, you will work with your therapist to break down problems into their separate parts, such as your thoughts, feelings and actions. Together you will analyse these areas to work out if they are unrealistic or unhelpful, and to determine the effect they have on each other and on you. Your therapist will then help you work out how to change unhelpful thoughts and behaviours. After working out what you can change, your therapist will ask you to practise these changes in your daily life and you'll discuss how you got on during the next session.

The therapist will make notes during the sessions and these notes will be used for planning the next session. The session will be recorded on a device for recording audio such as a dictaphone, and the recording saved with password protection. We will use these recordings to make sure that your therapy is good quality, with a senior member of our team listening to some of the recordings to provide feedback to the therapists.

The only information that we will use when writing up the trial is how many sessions of therapy you completed, and how long they lasted. We will also report on the quality of the therapy based on the audio recordings, but nothing to do with what you said in those recordings. We will not quote any of the things you said.

Are there any disadvantages or risks in taking part in the study?

For those people that are allocated to CBT, time for both the therapy and working on planned actions between sessions is needed. Some people may find it difficult to commit their time for this.

During the therapy, thinking about your emotions and worries may be upsetting. However, our therapists will listen to you and adapt the sessions to your needs.

What are the possible benefits of taking part?

CBT has been shown to improve the mental health and everyday functioning of people with health anxiety so we may find a similar benefit in our trial for people that are put in the CBT group. However, it is not certain that it will work for people with anxiety about COVID.

The results of our study will help us to understand whether CBT may be a good treatment for people with significant anxiety about COVID and plan a larger clinical trial in the future.

How will we use information about you?

Imperial College London is the sponsor for this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

We will need to use information from you for this research project. This information will include your name and contact details. 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

Legal basis

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research

International Transfers

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (EC) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

Sharing your information with others

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your personal data with certain third parties. These are other College employees, agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

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. 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.

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 sending an email to covid-anxiety@imperial.ac.uk. Also at www.hra.nhs.uk/information-about-patients.

Complaint
If you wish to raise a complaint on how we have handled your personal data, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

What if something goes wrong?

Imperial College holds insurance policies which apply to this study. If you are harmed due to someone's negligence, then you have grounds for legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study you can contact the Joint Research Office at Imperial College or the Chief Investigator, Professor Mike Crawford [email m.crawford@imperial.ac.uk; tel number 0203 313 4161].

What will happen to the results of this research?

We will publish the results in scientific journals and conferences and also produce a summary to send to those who have taken part.

Who is organising and funding the research?

This study is organised by Professor Mike Crawford at Imperial College. It is funded by the National Institute of Health Research.

Who has reviewed the study?

This research project has been looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Leicester Central Research Ethics Committee.

Contact us

If you would like to talk to a member of the study team before you decide whether to take part or at any other time, please contact us on covid-anxiety@imperial.ac.uk or 020 7594 3253.