

A feasibility trial of cognitive behavioural therapy for COVID-related health anxiety: The COVID Anxiety Project

Submission date 23/08/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/09/2021	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/11/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

In addition to risks to physical health, covid-19 is having a major impact on mental health as people struggle to cope with the psychological impact of the disease. Some people develop "health anxiety" and these can have a major impact on a person's life and functioning. The risks and consequences of covid anxiety are not known, and data are needed to help ensure that people with severe covid anxiety receive effective treatment and support.

Cognitive Behavioural Therapy for Health Anxiety (CBT-HA) has been shown to improve the mental health of people with health anxiety. However, the benefit for people with severe anxiety triggered by a pandemic has not been tested. It is possible that repeated public warnings about the dangers of the virus may affect the acceptability, uptake and impact of the intervention. This study aims to examine the impact, course and risk factors for covid anxiety, and to test the feasibility of conducting a randomised trial of CBT-HA for people with covid anxiety.

Who can participate?

People from across the UK who are aged 18 and over who have severe COVID-related anxiety

What does the study involve?

Participants will be asked about their thoughts and feelings, their health and use of health services, occupational and social functioning, and demographic information. They will be invited to answer some of the same questions at 3-month and 6-month follow-up.

Those that score 20+ on the Health Anxiety Inventory at baseline will also be invited to take part in a 1:1 randomised trial of CBT-HA. Those allocated to CBT-HA will receive 5-10 sessions of therapy, delivered remotely by telephone or video-call. We will look at the questionnaire responses of the trial participants over time and compare the groups to see whether people that were given CBT improved when compared to those that were not given CBT.

What are the possible benefits and risks of participating?

Participants may feel that they are contributing to research and a wider understanding of their own difficulties. They may also enjoy the interaction with researchers and an opportunity to explain their thoughts and feelings to someone. They may also benefit from the support on

offer including the self-help booklet and CBT sessions for the group that receive it. Thinking about emotions and worries both when completing the questionnaires and during CBT therapy sessions may be upsetting for some participants. Participants may be inconvenienced by the time required to complete the questionnaires and for the CBT sessions. However, we will accommodate personal preferences for time and day for contact with a member of the research team. Web-based completion of questionnaires can be done at a time to suit the participant. Participants can discontinue their role in the research at any time if they cannot find sufficient time.

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
January 2021 to May 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Dr Verity Leeson, v.leeson@imperial.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Mike Crawford

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
284331

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CPMS 49336, NIHR200185, IRAS 284331

Study information

Scientific Title

COVID anxiety: Risks, consequences and feasibility trial

Study objectives

It is feasible to conduct a randomised trial of Cognitive Behavioural Therapy for Health Anxiety for people with COVID-related health anxiety.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 03/11/2020, East Midlands - Leicester Central (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 972 2568; leicestercentral.rec@hra.nhs.uk), ref: 20/EM/0238

Study design

Observational cohort study and feasibility randomized controlled trial

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mental health issues due to COVID-19

Interventions

Potential participants will be asked to read the information sheet and complete the consent form and screening questions. Those that reach the threshold score for eligibility on the screening questionnaire and do not have a history of psychosis will be invited to take part in the cohort study. Those that take part in the cohort study will be asked to complete a number of questionnaires that take 30-40 minutes to fill in. Some scales will be repeated in a follow-up questionnaire at 3-months and 6-months.

Trial participants will be randomised to either (A) Cognitive Behavioural Therapy for Health Anxiety (CBT-HA) + self help booklet or (B) self-help booklet only. Those allocated to CBT-HA will be offered 5-10 sessions over the telephone or video-call (according to participant preference) with a member of the research team that is trained to deliver CBT-HA. These will usually occur every 1-2 weeks. All CBT-HA sessions will be completed prior to the 6-month follow-up questionnaire is completed by the participant.

Intervention Type

Behavioural

Primary outcome(s)

COVID Anxiety measured using the Coronavirus Anxiety Scale at screening, 3 and 6 month follow up

Key secondary outcome(s)

1. Mental Health measured using the Dependent Personality Questionnaire at baseline and 6-month follow up
2. Use of alcohol and drugs measured using the AUDIT-C at baseline and 6-month follow up
3. Anxiety measured using the Generalised Anxiety Disorder 7-item scale at baseline 3-month and 6-month follow up
4. Health Anxiety measured using the Health Anxiety Inventory at baseline 3-month and 6-month follow up
5. Mental Health measured using the Patient Health Questionnaire-9 at baseline 3-month and 6-month follow up
6. Social Function measured using the Work and Social Adjustment Scale at baseline 3-month and 6-month follow up
7. Behaviour measured using the Unvalidated questionnaire on behaviours intended to reduce the risk of exposure to COVID-19 at baseline 3-month and 6-month follow up
8. Mental Health measured using the Obsessive -Compulsive Inventory at baseline 3-month and 6-month follow up
9. Health-related quality of life measured using the EQ-5D at baseline 3-month and 6-month follow up
10. Resource use measured using the Adult Service Use Schedule at baseline 3-month and 6-month follow up
11. Therapy engagement measured using the Number and length of therapy sessions at 6-month follow up at baseline 3-month and 6-month follow up

Completion date

31/05/2023

Eligibility

Key inclusion criteria

1. Age 18 or over
2. Score 9 or more on the Covid Anxiety Scale

Additionally for the nested feasibility trial

3. Score 20 or more on the Health Anxiety Inventory

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

40

Key exclusion criteria

1. A current or previous diagnosis of a psychotic mental disorder

Additionally for the nested feasibility trial

2. Has had COVID-19 within the last 4 weeks (defined as a positive antigen test or a diagnosis from a clinician)

3. Has been told, either by a doctor or the NHS Test and Trace service, that they should self-isolate due to the possibility that they have been exposed to covid-19

4. Currently in receipt of a psychological treatment

Date of first enrolment

01/03/2021

Date of final enrolment

30/09/2021

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre**Imperial College London**

Centre for Psychiatry

Hammersmith Hospital

7th Floor Commonwealth Building

Du Cane Road

London

United Kingdom

W12 0NN

Sponsor information**Organisation**

Imperial College London

ROR

<https://ror.org/041kmwe10>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK)

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR200185

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Data held by Professor Mike Crawford (contact details above)

- type of data that will be shared: Deidentified participant level data including primary and secondary outcome measures
- When the data will become available and for how long: From 1st August 2022 with no fixed end date
- by what access criteria data will be shared including with whom, for what types of analyses, and by what mechanism: Data may be accessed by researchers who provide a methodologically sound proposal by email to Prof Crawford

All participants gave written informed consent

- comments on data anonymisation: Any data that could potentially be used to identify participants will not be provided in the dataset at the individual participant level e.g. ethnicity, dates of service use
- any ethical or legal restrictions: none
- any other comments: none

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/01/2024	08/01/2024	Yes	No
Results article		03/11/2025	06/11/2025	Yes	No
Protocol article		07/09/2022	24/01/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 1	13/10/2020	07/09/2021	No	Yes
Protocol file			18/08/2022	No	No
Statistical Analysis Plan			17/05/2022	No	No