ISRCTN14973494 https://doi.org/10.1186/ISRCTN14973494

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

Registration date
09/09/2021

Overall study status
Completed

Last Edited
08/01/2024

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] 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 alth anxiety. However, the benefit for people with severe anxiety triggered by a pandemic have 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

EudraCT/CTIS number
Nil known

IRAS number
284331

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

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

Secondary outcome measures
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

Overall study start date
21/01/2021

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

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
England

United Kingdom

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

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Sponsor type
University/education

Website
http://www.imperial.ac.uk/

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/05/2023

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?
Participant information sheet	version 1	13/10/2020	07/09/2021	No	Yes
Statistical Analysis Plan			17/05/2022	No	No
Protocol file			18/08/2022	No	No

Protocol article	07/09/2022	24/01/2023	Yes	No
HRA research summary		28/06/2023	No	No
Results article	06/01/2024	08/01/2024	Yes	No