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Feasibility and preliminary efficacy of digital cognitive behavioural therapy for anxiety

Submission date
08/08/2018

Recruitment status
No longer recruiting

Registration date
22/08/2018

Overall study status
Completed

Last Edited
01/10/2020

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims:
Generalised Anxiety Disorder (GAD) is a condition characterised by excessive anxiety and worry that is difficult to control. It is estimated to affect approximately 5-8% of the population and has a considerable personal and economic impact. Cognitive Behavioural Therapy (CBT) is the recommended evidence-based psychological therapy for GAD, but there are substantial barriers to accessing this treatment (e.g., insufficient numbers of trained clinicians, costs, waiting lists, distance from services, and stigma). Digital CBT provides a solution to overcoming treatment accessibility barriers and has the potential to provide both reliable and personalised psychological therapy. More recently, the widespread uptake and use of smartphone technologies in our daily lives has increased interest in the use of these devices to deliver psychological therapies. Recent evidence supports the effectiveness of smartphone-delivered interventions for reducing anxiety, however, there is a lack of smartphone-based digital CBT interventions for treating GAD. The present study aims to examine feasibility and potential efficacy of a novel 6-week digital CBT intervention for GAD.
Generalised anxiety disorder (GAD) is a condition involving excessive anxiety and worry that is difficult to control. It is estimated to affect around 5-8% of the population, and can have personal and economic impacts on sufferers. Cognitive behavioural therapy (CBT), which aims to help people develop coping strategies and change unhelpful thought patterns, is the recommended treatment for GAD. However, there can be substantial barriers in accessing CBT, such as too few trained clinicians, cost, waiting lists, distance from CBT services and stigma. A way to solve this problem is digital CBT, which is delivered online and can be better personalised to the individual. Additionally, the widespread use of smartphone technologies in our daily lives has increased interest in the use of these devices to deliver psychological therapies such as CBT. Recent evidence has shown the effectiveness of smartphone-delivered methods of reducing anxiety, but there is a lack of smartphone-based digital CBT interventions for treating GAD. This study aims to look at the feasibility and effectiveness of a new 6 week digital CBT intervention for GAD.

Who can participate?
Adults with a diagnosis of GAD with at least moderate anxiety severity

What does the study involve?
Participants will be randomly allocated to 1 of 3 baseline periods of either 2, 4 or 6 weeks. After this period, participants will be given access to the digital CBT programme for 6 weeks (treatment period). After this 6 weeks, there will be a 4 week follow-up period where participants will receive no active digital CBT treatment.
During the baseline and treatment periods, participants will be asked to complete a daily online question and weekly surveys. During the follow-up period, participants will be asked to complete online weekly surveys.
Depending on their allocated baseline period, the study will last 12-16 weeks.

What are the possible benefits and risks of participating?
Potential benefits of participating include the opportunity to undertake a programme based on CBT, which has been found to be an effective treatment for GAD. Participants will also be compensated in vouchers for the active duration of time spent in the study. There are no known risks to participants taking part in this study. There is a chance participants may be fatigued or distressed by questionnaire assessments or programme content. Safety will be monitored throughout the study and participants are free to stop taking part at any time, without having to give a reason.

Where is the study run from?
This study will be conducted entirely online, but is run from Nuffield Department of Clinical Neurosciences, University of Oxford

When is the study starting and how long is it expected to run for?
June 2018 to September 2019

Who is funding the study?
Big Health Inc (USA)

Who is the main contact?
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Contact information

Type(s)
Public

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Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Feasibility and potential efficacy of digital cognitive behavioural therapy to reduce symptoms of anxiety in adults with Generalised Anxiety Disorder: A randomised multiple-baseline single-case study

Study objectives
The current study aims to examine the feasibility and potential efficacy of a novel 6-week digital CBT intervention for GAD.
Specific aims:
1. To determine the feasibility of a digital CBT intervention for the treatment of GAD, measured by: retention (number of treatment completers), safety (adverse events), adherence rates (number of digital CBT components completed), and acceptability (participant satisfaction with digital CBT)
2. Examine the potential efficacy of digital CBT to reduce daily levels of anxiety
3. Examine the potential efficacy of digital CBT to improve the following additional outcomes: worry, depression symptom severity, sleep, wellbeing, work productivity, and CBT skills acquisition

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Oxford Central University Research Ethics Committee, 06/08/2018, R58113/RE001

Study design
Interventional randomised multiple baseline single case experimental design

Primary study design
Interventional

Secondary study design
Randomised multiple baseline single case experimental design

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Generalised anxiety disorder (GAD)

Interventions
In this study, participants serve as their own control and are randomised to a baseline period of 2, 4, or 6 weeks (i.e., they will wait for either 2, 4, or 6 weeks before receiving access to the intervention). Randomisation will conducted automatically upon completion of the baseline survey. All participants will receive access to the intervention after their randomly allocated baseline period.
The intervention involves interactive and tailored delivery of digital cognitive behavioural therapy (CBT) for generalised anxiety disorder (GAD) via a smartphone app. The programme is a voice-led experience, in which a virtual therapist guides the user through the programme. The programme is self-paced and includes 5 sessions, with each session lasting up to 20 minutes. Each session can be repeatedly accessed. It is estimated to take approximately 6 weeks to complete and unlock all 5 sessions. Session content is based on evidence-based CBT techniques for treating GAD and was developed in collaboration with leading experts in CBT for anxiety. Core techniques include stimulus control, applied relaxation, cognitive restructuring, imaginal exposures, problem solving, relapse prevention, progress monitoring, and psychoeducation. Guided exercises in the app and recommendations for how these techniques may be applied in the user's life for their own problems are suggested.
The app provides an interactive and media-rich experience and includes supportive visuals and brief animations. Throughout the programme, participants will be asked to complete questions within the app about their anxiety and other aspects of experience (e.g., mood, sleep). Personalisation is built in using algorithms to tailor the intervention based on participants' responses to questions and their progress.
The intervention will last for 6 weeks, after which there will be a 4-week follow-up period.

During this period, participants will be asked to complete weekly assessments of anxiety (GAD-7), depression (PHQ-9) and sleep (SCI), as they will be during both the baseline and intervention periods, and they will not be accessing the intervention.

Intervention Type
Other

Primary outcome measure
1. Feasibility, assessed by the following:
1.1. Number of participants who start and complete the digital CBT intervention, assessed post-intervention by objective usage data
1.2. Number of digital CBT intervention components completed, assessed post-intervention by objective usage data
1.3. Participant satisfaction with the digital CBT intervention, assessed post-intervention using self-reported qualitative and quantitative questions:
1.3.1. “How would you rate your overall satisfaction with the programme - ranging from 0 (totally dissatisfied) to 10 (totally satisfied)”
1.3.2. “What could be better about this treatment program?”
1.3.3. “What did you like and enjoy about the treatment program?”
1.3.4. “In what ways did the treatment program help you to reduce your anxiety?”
1.3.5. “At any point during the treatment program did you consider stopping using it? When and Why?”
1.3.6. “Was the content of the treatment program specific enough to your needs?”
1.4. Safety, assessed by occurrence of the following post-intervention:
1.4.1. Any adverse events related to the intervention throughout the study period, self-reported throughout the study by participants to the study coordinator in response to open-ended questions asked during any telephone correspondence with participants from consent until the final follow-up assessment
1.4.2. Unwanted symptoms related to the intervention, assessed using the Modified Symptom Checklist at the post-treatment assessment
1.5. Treatment credibility, assessed by the self-reported Credibility/Expectancy Questionnaire near the start of the digital CBT intervention
2. Potential efficacy of the digital CBT intervention to reduce anxiety, assessed by the following:
2.1. Self-report question (On average over the past 24 hours, how anxious or fearful have you felt?' answered using a 10-point visual analogue scale), completed daily during the baseline and treatment periods
2.2. Self-reported anxiety severity, measured using the 7-item Generalised Anxiety Disorder questionnaire (GAD-7), assessed weekly during the baseline, treatment and follow-up periods

Secondary outcome measures
Potential efficacy of the digital CBT intervention to improve the following outcomes, which are self-reported online at the baseline, post-intervention and at the follow-up:
1. Worry, assessed using the Penn State Worry Questionnaire (PSWQ)
2. Depression symptom severity, assessed using the 9-item Patient Health Questionnaire (PHQ-9), measured at weekly intervals during baseline and treatment periods in addition to the above
3. Sleep difficulty, assessed using the Sleep Condition Indicator (SCI), measured at weekly intervals during baseline and treatment periods in addition to the above
4. Wellbeing, assessed using the 14-item Warwick-Edinburgh Mental Well-being Scale (WEMWBS)
5. Health-related quality of life, assessed using the Patient-Generated Index (PGI)
6. Work productivity and activity, assessed using the Work Productivity and Activity Impairment (WPAI) questionnaire

7. Cognitive behavioural therapy skills acquisition, assessed using the Cognitive Behavioural Therapy Skills Questionnaire (CBTSQ)

Overall study start date
04/06/2018

Completion date
02/09/2019

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Able to give informed consent
3. Score of 10 or higher on the 7-item Generalised Anxiety Disorder questionnaire (GAD-7), indicating moderate severity of anxiety
4. Screen positive for GAD diagnosis by a digital version of the MINI International Neuropsychiatric Interview (MINI) version 7 for DSM-5
5. Must be either not on prescription medication for anxiety, depression, or sleep, or on a stable dose for at least 4 weeks

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
21

Total final enrolment
48

Key exclusion criteria
1. Past or present psychosis, schizophrenia, bipolar disorder, seizure disorder, alcohol use disorder, or substance use disorder
2. Trauma to the head or brain damage
3. Severe cognitive impairment
4. Serious physical health concerns necessitating surgery or with prognosis < 6 months
5. Pregnancy

Date of first enrolment
03/09/2018

Date of final enrolment
30/04/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Nuffield Department of Clinical Neurosciences
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Sponsor information

Organisation
University of Oxford

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Sponsor type
University/education

Website
https://www.ndcn.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Not defined

Funder Name
Big Health Inc.

Results and Publications

Publication and dissemination plan
Findings will be written up for publication in a peer-reviewed journal article. The intention to publish date is around one year after the overall trial end date. Findings may also be disseminated in presentations at conferences and seminars.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The final anonymised research data containing quantitative questionnaire data will be stored in the Oxford Research Archive (ORA; https://www.bodleian.ox.ac.uk/ora/about) at the University of Oxford for long term storage of seven years after publication or public release of the results. Information on the conditions under which data are shared is given on the ORA website. This process has received ethical approval from the University of Oxford Central University Research Ethics Committee and participants will be informed of and consent to this data storage arrangement.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/09/2020	01/10/2020	Yes	No