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Digital cognitive behavioural therapy for anxiety 2

Submission date
26/05/2021

Recruitment status
No longer recruiting

Registration date
27/05/2021

Overall study status
Completed

Last Edited
31/05/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Generalized anxiety disorder (GAD) is a long-term condition that causes you to feel anxious about a wide range of situations and issues. Cognitive behavioural therapy (CBT) is a first-line recommended treatment for anxiety that is more effective than pharmacotherapy (drug treatment). However, CBT is difficult to access due to systemic barriers preventing access at scale. Digital CBT may overcome these barriers and provide access to standardised, evidence-based care at scale. Digital CBT for worry and anxiety (Daylight) has been examined in two previous studies, showing significant improvements in GAD symptoms in addition to other areas of mental health. The aim of this study is to examine the effects of digital CBT for worry and anxiety compared to a psychoeducation intervention on symptoms of GAD and related anxiety disorders.

Who can participate?
Adults aged 18+ years with a probable diagnosis of GAD and at least moderate anxiety severity.

What does the study involve?
Participants will complete an online screening survey, and if they screen in, they will then undergo a further eligibility assessment conducted over the phone. If eligible following this and once consented, participants will complete a baseline survey and then be randomly allocated to receive either digital CBT or psychoeducation. Participants will then complete further surveys at mid-intervention (6 weeks from randomisation), post-intervention (10 weeks from randomisation), and follow-up (18 weeks from randomisation). Participants will also undergo a phone-based interview at post-intervention (10 weeks from randomisation) and follow-up (18 weeks from randomisation). Participants will also have the option of completing a 1-year post-randomisation follow-up survey.

What are the possible benefits and risks of participating?
There may be no direct benefit to participating in this study. Participants may experience reduced anxiety as a result of taking part. Participants will be compensated in Amazon gift vouchers for their time spent completing questionnaire measures and interviews as part of the study. There are no known risks to participants taking part in this study. There is a chance that 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?
University of Oxford (UK)

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

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

Who is the main contact?
Alasdair Henry
alasdair.henry@bighealth.com

Contact information

Type(s)
Public

Contact name
Dr Alasdair Henry

ORCID ID
https://orcid.org/0000-0003-2217-3052

Contact details
7-12 Tavistock Square
London
United Kingdom
WC1H 9LT
-
alasdair.henry@bighealth.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effects of self-guided digital cognitive behavioural therapy on symptoms of generalized anxiety disorder and related disorders: a randomised controlled trial

Acronym

DeLTA2

Study objectives

Current study hypothesis as of 26/08/2021:
Primary aim and hypothesis:
To examine the effects of digital cognitive behavioural therapy (CBT) compared to psychoeducation on generalized anxiety disorder (GAD) symptom severity at post-intervention (10 weeks from randomisation). Digital CBT for worry and anxiety will be superior at improving symptoms of GAD at post-intervention compared with psychoeducation.

Secondary aim and hypotheses:
To examine the effects of digital CBT compared to psychoeducation on GAD symptom severity at follow-up and other related outcomes at post-intervention and follow-up: assessor-rated anxiety symptoms, depressive symptoms, sleep difficulty, social anxiety symptoms, panic disorder symptoms, post-traumatic stress disorder symptoms, obsessive-compulsive disorder symptoms, worry, stress, workplace presenteeism and absenteeism, acquisition and implementation of CBT skills and health-related quality of life. Digital CBT for worry and anxiety will be superior at improving the above outcomes at post-intervention and follow-up compared with psychoeducational.

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Primary aim and hypothesis:
To examine the effects of digital cognitive behavioural therapy (CBT) compared to psychoeducation on generalized anxiety disorder (GAD) symptom severity at post-intervention (6 weeks from randomisation). Digital CBT for worry and anxiety will be superior at improving symptoms of GAD at post-intervention compared with psychoeducation.

Secondary aim and hypotheses:
To examine the effects of digital CBT compared to psychoeducation on GAD symptom severity at follow-up and other related outcomes at post-intervention and follow-up: assessor-rated anxiety symptoms, depressive symptoms, sleep difficulty, social anxiety symptoms, panic disorder symptoms, post-traumatic stress disorder symptoms, obsessive-compulsive disorder symptoms, worry, stress, workplace presenteeism and absenteeism, acquisition and implementation of CBT skills and health-related quality of life. Digital CBT for worry and anxiety will be superior at improving the above outcomes at post-intervention and follow-up compared with psychoeducation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 27/04/2021, University of Oxford Medical Sciences Interdivisional Research Ethics Committee (University of Oxford, University Offices, Wellington Square, Oxford, OX1 2JD, UK; +44 (0)1865 616577; ethics@medsci.ox.ac.uk), ref: R74886/RE001

Study design

Interventional parallel-group randomized controlled trial

Primary study design

Interventional

Study type(s)
Treatment

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

Interventions
Current interventions as of 26/08/2021:
In this study, participants will be randomised into one of two groups. Group 1 will receive digital CBT and group 2 will receive psychoeducation. Outcomes are assessed at 6 (mid-intervention), 10 (post-intervention) and 18 weeks (follow-up) from randomisation. Randomisation (block randomisation with a 1:1 allocation ratio) will be conducted automatically upon completion of the baseline survey using the randomisation function within Qualtrics. Members of the research team will be unable to influence randomisation and will be concealed from assignments. Participants will receive access to whichever programme they were not randomised to upon completion of the study. Psychoeducation participants will receive access to digital CBT upon completing the survey and interview at follow-up (after 19 weeks from randomisation), and digital CBT participants will receive access to psychoeducation at this time too.

Digital CBT for worry and anxiety (Daylight):
Participants in the digital CBT group will be provided access to Daylight, a fully automated personalised digital CBT program delivered via app on Apple iOS (version 9 and above) or Android (Oreo and above). A virtual therapist guides individuals through the experience, which includes interactive exercises and animations to facilitate learning and implementation of CBT techniques. The app comprises four modules, each approximately 10–20 min in length). Modules can be repeated or shorter practice exercises (approximately 5 min) can be accessed. The program is selfpaced and the app encourages daily use (e.g., practicing techniques in the app) and realworld implementation (e.g., practicing techniques in their daily lives, outside of the app). Daylight users receive reminders and encouragement to use the program in the form of emails, push notifications, and text messages. Users are asked to complete weekly inapp brief assessments of anxiety, depressive symptoms, and sleep. During assessments, users are provided with personalised feedback based on their selfreported anxiety, mood, and sleep, as well as their progress (e.g., users experiencing problems with sleep could receive a suggestion to practice a relaxation exercise before bedtime). The feedback provided in each exercise (e.g., providing additional instructions, troubleshooting, and/or guidance for future practice of the exercise) is tailored based on user inputs during the exercise (e.g., changes in their anxiety level during the exercise, whether they experienced any difficulties doing the exercise).

Psychoeducation:
Psychoeducation participants will receive standardised Psychoeducation information that will cover the following topics: what is anxiety, the prevalence, symptoms, cause, consequences, diagnosis of GAD and lifestyle advice to help reduce symptoms of worry and anxiety. Psychoeducation will be delivered in a pdf format using Qualtrics. All participants randomised to receive Psychoeducation will be provided access to Daylight after completion of the final online followup assessment and phone interview (week 19).

Previous interventions:
In this study, participants will be randomised into one of two groups. Group 1 will receive digital CBT and group 2 will receive psychoeducation. Outcomes are assessed at 3 (mid-intervention), 6 (post-intervention) and 18 weeks (follow-up) from randomisation. Randomisation (block randomisation with a 1:1 allocation ratio) will be conducted automatically upon completion of

the baseline survey using the randomisation function within Qualtrics. Members of the research team will be unable to influence randomisation and will be concealed from assignments. Participants will receive access to whichever programme they were not randomised to upon completion of the study. Psychoeducation participants will receive access to digital CBT upon completing the survey and interview at follow-up (after 19 weeks from randomisation), and digital CBT participants will receive access to psychoeducation at this time too.

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Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 16/08/2022:
Generalized anxiety disorder symptoms measured using the General Anxiety Disorder-7 (GAD-7) at baseline, mid-intervention (6 weeks from randomisation), post-intervention (10 weeks from randomisation) and follow-up (18 weeks from randomisation). A further uncontrolled evaluation will take place 1 year from randomisation.

Previous primary outcome measure as of 26/08/2021:
Generalized anxiety disorder symptoms measured using the General Anxiety Disorder-7 (GAD-7) at baseline, mid-intervention (6 weeks from randomisation), post-intervention (10 weeks from randomisation) and follow-up (18 weeks from randomisation)

Previous primary outcome measure:
Generalized anxiety disorder symptoms measured using the General Anxiety Disorder-7 (GAD-7) at baseline, mid-intervention (3 weeks from randomisation), post-intervention (6 weeks from randomisation) and follow-up (18 weeks from randomisation)

Key secondary outcome(s))

Current secondary outcome measures as of 16/08/2022:
1. Assessor-rated anxiety assessed using the Hamilton Anxiety Rating Scale (HAM-A) at baseline, post-intervention (10 weeks from randomisation) and follow-up (18 weeks from randomisation)
2. Social anxiety symptoms measured using the self-report Mini Social Phobia Inventory (Mini-SPIN) at baseline, mid-intervention (6 weeks from randomisation), post-intervention (10 weeks from randomisation) and follow-up (18 weeks from randomisation). A further uncontrolled evaluation will take place 1 year from randomisation.
3. Panic disorder symptoms measured using the self-report Panic Disorder Severity Scale at baseline, mid-intervention (6 weeks from randomisation), post-intervention (10 weeks from randomisation) and follow-up (18 weeks from randomisation). A further uncontrolled evaluation will take place 1 year from randomisation.
4. Post-traumatic stress disorder (PTSD) symptoms measured by the 8-item version of the PTSD Checklist for DSM-5 (PCL-5) at baseline, mid-intervention (6 weeks from randomisation), post-intervention (10 weeks from randomisation) and follow-up (18 weeks from randomisation). A further uncontrolled evaluation will take place 1 year from randomisation.
5. Obsessive-compulsive disorder symptoms measured by the Yale-Brown Obsessive Compulsive Scale (YBOCS) at baseline, mid-intervention (6 weeks from randomisation), post-intervention (10 weeks from randomisation) and follow-up (18 weeks from randomisation). A further uncontrolled evaluation will take place 1 year from randomisation.
6. Worry measured using the Penn State Worry Questionnaire (PSWQ) at baseline, mid-intervention (6 weeks from randomisation), post-intervention (10 weeks from randomisation) and follow-up (18 weeks from randomisation). A further uncontrolled evaluation will take place 1 year from randomisation.
7. Depressive symptoms measured using the Patient Health Questionnaire (PHQ-8) at baseline, mid-intervention (6 weeks from randomisation), post-intervention (10 weeks from randomisation) and follow-up (18 weeks from randomisation). A further uncontrolled evaluation will take place 1 year from randomisation.
8. Sleep difficulty measured using the 8-item Sleep Condition Indicator (SCI-8) at baseline, mid-intervention (6 weeks from randomisation), post-intervention (10 weeks from randomisation) and follow-up (18 weeks from randomisation). A further uncontrolled evaluation will take place 1 year from randomisation.
9. Stress measured using the Perceived Stress Scale (PSS) at baseline, mid-intervention (6 weeks from randomisation), post-intervention (10 weeks from randomisation) and follow-up (18 weeks from randomisation). A further uncontrolled evaluation will take place 1 year from randomisation.
10. Workplace presenteeism and absenteeism measured by the Workplace Productivity and Activity Impairment index (WPAI) at baseline, mid-intervention (6 weeks from randomisation), post-intervention (10 weeks from randomisation) and follow-up (18 weeks from randomisation). A further uncontrolled evaluation will take place 1 year from randomisation.
11. Acquisition and implementation of CBT skills measured using the CBT skills questionnaire (CBTSQ) at baseline, mid-intervention (6 weeks from randomisation), post-intervention (10 weeks from randomisation) and follow-up (18 weeks from randomisation). A further uncontrolled evaluation will take place 1 year from randomisation.
12. Health-related quality of life (HRQoL) assessed using the 10-item Patient-Reported Outcome Measurement Information System: Global Health (PROMIS-10) at baseline, mid-intervention (6

weeks from randomisation), post-intervention (10 weeks from randomisation) and follow-up (18 weeks from randomisation). A further uncontrolled evaluation will take place 1 year from randomisation.

Other outcome measures:
1. Concomitant prescription and 'over the counter' medication use and other psychotherapy documented using a standardized form at baseline, mid-intervention (6 weeks from randomisation), post-intervention (10 weeks from randomisation) and follow-up (18 weeks from randomisation).
2. Participants will also be asked to specify the number of days they have sought help with their anxiety from a medical professional or therapy in the past 21 days using the question: "How many days in the last 3 weeks did you see a healthcare professional or doctor about your anxiety?". This will be assessed at baseline, mid-intervention (6 weeks from randomisation), post-intervention (10 weeks from randomisation) and follow-up (18 weeks from randomisation).
3. Treatment satisfaction and acceptability assessed using the following questions rated on 5 point Likert scales from Not at all to Extremely: 1) "How easy was it to use the anxiety programme?", 2) "How frustrating was it to use the anxiety programme?", 3) "How convenient was the anxiety programme in your daily life?", 4) "How enjoyable was the anxiety programme?", 5) "How visually appealing was the anxiety programme?", 6) "How satisfied were you with the amount of support you received with the programme?", 7) "How easy was it to fix problems with the anxiety programme?", 8) "Overall, how satisfied are you with the anxiety programme?", 9) "How willing would you be to recommend the anxiety programme to a friend or family member?", and the following open-text response questions: "What was your overall impression of the anxiety programme?"; "What are your main complaints about the anxiety programme, if any?" and "What were the main benefits of the anxiety programme, if any?". These will be measured at post-intervention only (10 weeks from randomisation).

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Completion date
14/03/2023

Eligibility

Key inclusion criteria
1. Adults aged ≥18 years old
2. Score ≥10 on the 7-item Generalized Anxiety Disorder scale (GAD-7)
3. Screen positive for GAD diagnosis against Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria and phone call verification of diagnosis using a modified version of the Structured Clinical Interview for DSM-5 (SCID)
4. Either not on psychotropic medication or on a stable dose for at least 4 weeks before screening assessment
5. Oral and written fluency in English
6. Participant is able and willing to comply with protocol requirements, has been informed of the nature of the study, and has signed the approved informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
224

Key exclusion criteria
1. Currently receiving or be expecting to start CBT for anxiety during study participation, or have previously received CBT for anxiety in the past 12-months (self-report)
2. Self-reported diagnosis of schizophrenia, psychosis, bipolar disorder, seizure disorder, substance use disorder; recent trauma to the head or brain damage; recent inpatient psychiatric admission or crisis team support
3. Cognitive impairment that does not allow participants to consent or follow treatment instructions (self-report)
4. Physical health concerns necessitating surgery or with <6 months to live (self-report)
5. Hearing or vision impairment that prevents effective use of the audio-visual content of digital CBT

Date of first enrolment
22/06/2021

Date of final enrolment
07/03/2022

Locations

Countries of recruitment
United Kingdom

England

United States of America

Study participating centre
University of Oxford
Nuffield Department of Clinical Neurosciences
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Industry

Funder Name
Big Health Inc.

Results and Publications

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 7 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