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Digital cognitive behavioural therapy for anxiety

Submission date
09/01/2019

Recruitment status
No longer recruiting

Registration date
11/01/2019

Overall study status
Completed

Last Edited
19/10/2020

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] 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 involving excessive anxiety and worry that is difficult to control. It is estimated to affect around 5-8% of the population and can have substantial personal and economic impact. Cognitive behavioural therapy (CBT) aims to help people develop coping strategies and change unhelpful thought patterns and behaviours. CBT 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 CBT delivered with extensive involvement of digital means (e.g., computers, smartphones). 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 addressing GAD. This study aims to examine the effects of a new digital CBT intervention, 'Daylight', on symptoms of GAD.

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

What does the study involve?
Participants will be randomly allocated to receive either the digital CBT programme or to a waiting list control group. Participants will be asked to complete surveys at baseline, mid-intervention (3 weeks from randomisation), post-intervention (6 weeks from randomisation), and at follow-up (10 weeks from randomisation). Waitlist control participants will receive access to the programme after completing the follow-up assessment point (after 10 weeks from randomisation).

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 Amazon gift vouchers for their time spent completing questionnaire measures as part of 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 and 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?
The study was reviewed by the ethics committee in December 2018, recruitment will start in June 2019, and the trial is expected to end in January 2020.

Who is funding the study?
Big Health Inc.

Who is the main contact?
Chris Miller (anxiety@ndcn.ox.ac.uk)

Study website
https://bighealth.eu.qualtrics.com/jfe/form/SV_8BRXrMF78IvfSD3

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Efficacy of DigitaL cognitive behavioural Therapy to reduce symptoms of anxiety in adults with generalised Anxiety disorder: a randomised controlled trial

Acronym
DeLTA

Study objectives
Current study hypothesis as of 01/05/2019:
This randomised controlled trial (RCT) examines the efficacy of a novel smartphone-delivered digital Cognitive Behavioural Therapy (CBT) programme to address symptoms of Generalised Anxiety Disorder (GAD) compared with a waitlist control.

Primary aim and hypothesis:
The primary aim is to examine the effects of digital CBT compared to waitlist control on GAD symptom severity at post-intervention (6 weeks from randomisation). The primary hypothesis is that digital CBT will significantly reduce GAD symptom severity compared to waitlist at post-intervention.

Secondary aims and hypotheses:
1. To examine the effects of digital CBT compared to waitlist control on anxiety at 10 weeks (from randomisation) follow-up. Compared to waitlist control, digital CBT is hypothesised to significantly reduce GAD symptom severity at 10 weeks follow-up.

2. To examine the effects of digital CBT compared to waitlist control at post-intervention (6 weeks from randomisation) and 10 weeks follow-up for other salient outcomes: worry, depression symptom severity, insomnia symptoms, wellbeing, and quality of life. Compared to waitlist control, digital CBT is hypothesised to significantly improve these at post-intervention and 10 weeks follow-up: worry, depression symptom severity, insomnia symptoms, wellbeing, and quality of life.

Previous study hypothesis:
This randomised controlled trial (RCT) examines the efficacy of a novel smartphone-delivered digital Cognitive Behavioural Therapy (CBT) programme to address symptoms of Generalised Anxiety Disorder (GAD) compared with a waitlist control.

Primary aim and hypothesis:
The primary aim is to examine the effects of digital CBT compared to waitlist control on GAD symptom severity at post-intervention (6 weeks from randomisation). The primary hypothesis is that digital CBT will significantly reduce GAD symptom severity compared to waitlist at post-intervention.

Secondary aims and hypotheses:
1. To examine the effects of digital CBT compared to waitlist control on anxiety at 18 weeks (from randomisation) follow-up. Compared to waitlist control, digital CBT is hypothesised to significantly reduce GAD symptom severity at 18 weeks follow-up.

2. To examine the effects of digital CBT compared to waitlist control at post-intervention (6 weeks from randomisation) and 18 weeks follow-up for other salient outcomes: worry, depression symptom severity, insomnia symptoms, wellbeing, and quality of life. Compared to waitlist control, digital CBT is hypothesised to significantly improve these at post-intervention

and 18 weeks follow-up: worry, depression symptom severity, insomnia symptoms, wellbeing, and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Oxford Central University Research Ethics Committee, 20/12/2018, ref. R61262 /RE001.

Study design
Interventional parallel-group randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
https://bighealth.eu.qualtrics.com/jfe/form/SV_8BRXrMF78IvfSD3

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

Interventions
Current interventions as of 01/05/2019:
The intervention involves interactive and tailored delivery of digital CBT (cognitive behavioural therapy) for worry and anxiety via a smartphone app using the 'Daylight' programme. The Daylight programme is a voice-led experience, in which a virtual therapist guides the user through the programme. The app provides an interactive and media-rich experience and includes supportive visuals and brief animations to help to illustrate the programme content. 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 Daylight programme was developed in collaboration with leading experts in the area of CBT for anxiety disorders. The content is based on evidence-based CBT techniques for the treatment of GAD, including psychoeducation, stimulus control, applied relaxation, cognitive restructuring, imaginal exposures, and progress monitoring. The programme is designed to be self-paced and includes 4 core modules, each lasting up to 20 minutes. Modules are accessed sequentially, with access to a subsequent module available on completion of the previous module. It is estimated to take approximately 6 weeks to complete the programme. Additionally, modules can be repeatedly accessed (as per the user's preference) for repeated practice of a certain technique.

The programme provides guided exercises of specific techniques, as well as personalised recommendations for how these techniques may be applied in the user's life.

In this study, participants are randomised to one of two groups. Group A will receive digital CBT and group B will be allocated to a waitlist control condition. Outcomes are assessed at 3 (mid-intervention), 6 (post-intervention), and 10 weeks (follow-up) from randomisation. Randomisation (simple randomisation with a 1:1 allocation ratio) will be conducted automatically upon enrolment and completion of the baseline survey, using the randomisation function within Qualtrics Survey Software (www.qualtrics.com). Members of the research team will be unable to influence randomisation and will be concealed from future assignments. Waitlist control participants will receive access to the digital CBT intervention after completing the follow-up assessment point (after 10 weeks from randomisation). This trial will be conducted and findings will be reported In accordance with CONSORT (Consolidated Standards of Reporting Trials) guidelines.

Previous interventions:
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In this study, participants are randomised to one of two groups. Group A will receive digital CBT and group B will be allocated to a waitlist control condition. Outcomes are assessed at 3 (mid-intervention), 6 (post-intervention), and 18 weeks (follow-up) from randomisation. Randomisation (simple randomisation with a 1:1 allocation ratio) will be conducted automatically upon enrolment and completion of the baseline survey, using the randomisation function within Qualtrics Survey Software (www.qualtrics.com). Members of the research team will be unable to influence randomisation and will be concealed from future assignments. Waitlist control participants will receive access to the digital CBT intervention after completing the follow-up assessment point (after 18 weeks from randomisation). This trial will be conducted and findings will be reported In accordance with CONSORT (Consolidated Standards of Reporting Trials) guidelines.

Intervention Type
Behavioural

Primary outcome measure

Current primary outcome measure as of 08/08/2019:
Severity of anxiety symptoms will be measured using the 7-item Generalised Anxiety Disorder questionnaire (GAD-7) (Spitzer et al., 2006) at baseline, mid-intervention (3 weeks from randomisation), post-intervention (6 weeks from randomisation; primary endpoint), and follow-up (10 weeks from randomisation).

Previous primary outcome measure:
Severity of anxiety symptoms will be measured using the 7-item Generalised Anxiety Disorder questionnaire (GAD-7) (Spitzer et al., 2006) at baseline, mid-intervention (3 weeks from randomisation), post-intervention (6 weeks from randomisation; primary endpoint), and follow-up (18 weeks from randomisation).

Secondary outcome measures

Current secondary outcome measures as of 08/08/2019:
1. Worry, measured using the Penn State Worry Questionnaire (PSWQ; Meyer, Miller, Metzger, & Borkovec, 1990) at baseline, mid-intervention (3 weeks from randomisation), post-intervention (6 weeks from randomisation), and follow-up (10 weeks from randomisation).
2. Depression symptom severity, assessed using the 9-item Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer, & Williams, 2001) at baseline, mid-intervention (3 weeks from randomisation), post-intervention (6 weeks from randomisation), and follow-up (10 weeks from randomisation).
3. Insomnia symptom severity, assessed using the Sleep Condition Indicator (SCI; Espie et al., 2014) at baseline, mid-intervention (3 weeks from randomisation), post-intervention (6 weeks from randomisation), and follow-up (10 weeks from randomisation).
4. Wellbeing, assessed using the 14-item Warwick-Edinburgh Mental Well-being Scale (WEMWBS; Tennant et al., 2007) at baseline, mid-intervention (3 weeks from randomisation), post-intervention (6 weeks from randomisation), and follow-up (10 weeks from randomisation).
5. Quality of life, assessed using the Patient-Generated Index (PGI; (Ruta, Garratt, Leng, Russell, & MacDonald, 1994) at baseline, mid-intervention (3 weeks from randomisation), post-intervention (6 weeks from randomisation), and follow-up (10 weeks from randomisation).

Other outcome measures:
1. Treatment credibility and expectancy, assessed using the 6-item Credibility/Expectancy Questionnaire (Devilly & Borkovec, 2000) administered at baseline only.
2. Treatment satisfaction, assessed in participants randomised to the intervention arm by the following questions administered at post-intervention: 1) “How would you rate your overall satisfaction with the programme?” (ranging from 0 (totally dissatisfied) to 10 (totally satisfied)), 2) “What could be better about this treatment programme?”, 3) “What did you like and enjoy about the treatment programme?”, 4) “In what ways did the treatment programme help you to reduce your anxiety?”, 5) “At any point during the treatment programme did you consider stopping using it? When and Why?”, and 6) “Was the content of the treatment programme specific enough to your needs?”.
3. Assessment of safety, assessed using the modified symptom checklist (Kyle, Morgan, Spiegelhalder, & Espie, 2011) at post-intervention only.
4. Concomitant treatment, assessed using the following questions administered at all time points: 1) “How many days in the last week have you taken medications for anxiety that were prescribed by your doctor or not prescribed by your doctor?” (follow up question: “Please list these medications and the dosage”), and 2) “How many days in the last week did you see a treatment provider about your anxiety?”.

Previous secondary outcome measures:
1. Worry, measured using the Penn State Worry Questionnaire (PSWQ; Meyer, Miller, Metzger, & Borkovec, 1990) at baseline, mid-intervention (3 weeks from randomisation), post-intervention (6 weeks from randomisation), and follow-up (18 weeks from randomisation).
2. Depression symptom severity, assessed using the 9-item Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer, & Williams, 2001) at baseline, mid-intervention (3 weeks from randomisation), post-intervention (6 weeks from randomisation), and follow-up (18 weeks from randomisation).
3. Insomnia symptom severity, assessed using the Sleep Condition Indicator (SCI; Espie et al., 2014) at baseline, mid-intervention (3 weeks from randomisation), post-intervention (6 weeks from randomisation), and follow-up (18 weeks from randomisation).
4. Wellbeing, assessed using the 14-item Warwick-Edinburgh Mental Well-being Scale (WEMWBS; Tennant et al., 2007) at baseline, mid-intervention (3 weeks from randomisation), post-intervention (6 weeks from randomisation), and follow-up (18 weeks from randomisation).
5. Quality of life, assessed using the Patient-Generated Index (PGI; (Ruta, Garratt, Leng, Russell, & MacDonald, 1994) at baseline, mid-intervention (3 weeks from randomisation), post-intervention (6 weeks from randomisation), and follow-up (18 weeks from randomisation).

Other outcome measures:
1. Treatment credibility and expectancy, assessed using the 6-item Credibility/Expectancy Questionnaire (Devilly & Borkovec, 2000) administered at baseline only.
2. Treatment satisfaction, assessed in participants randomised to the intervention arm by the following questions administered at post-intervention: 1) “How would you rate your overall satisfaction with the programme?” (ranging from 0 (totally dissatisfied) to 10 (totally satisfied)), 2) “What could be better about this treatment programme?”, 3) “What did you like and enjoy about the treatment programme?”, 4) “In what ways did the treatment programme help you to reduce your anxiety?”, 5) “At any point during the treatment programme did you consider stopping using it? When and Why?”, and 6) “Was the content of the treatment programme specific enough to your needs?”.
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Overall study start date
29/10/2018

Completion date
01/06/2020

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 18/09/2019:
1. Aged 18+ years.
2. A score of 10 or higher on the Generalised Anxiety Disorder questionnaire (GAD-7) indicating at least moderate GAD symptom severity.
3. Screen positive for a GAD diagnosis on a digital version of the MINI International

Neuropsychiatric Interview (MINI) version 7 for DSM-5.
4. Must be either not on psychotropic medication or on a stable dose for at least 4 weeks.
5. Must not be currently receiving or have previously received CBT for anxiety in the last 12 months.

Previous participant inclusion criteria:
1. Aged 18+ years
2. A score of 10 or higher on the Generalised Anxiety Disorder questionnaire (GAD-7) indicating at least moderate GAD symptom severity
3. Screen positive for a GAD diagnosis on a digital version of the MINI International Neuropsychiatric Interview (MINI) version 7 for DSM-5
4. Must be either not on psychotropic medication 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
242

Total final enrolment
256

Key exclusion criteria
1. Past or present seizure disorder or a clinically significant head trauma (e.g. brain damage)
2. Substance use disorder
3. Serious physical health concerns necessitating surgery or with prognosis < 6 months
4. Current bipolar disorder, psychosis, or schizophrenia
5. Severe cognitive impairment that does not allow participants to consent or follow treatment instructions
6. Pregnancy

Date of first enrolment
01/06/2019

Date of final enrolment
07/11/2019

Locations

Countries of recruitment
England

United Kingdom

United States of America

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

Sponsor information

Organisation
University of Oxford

Sponsor details
Nuffield Department of Clinical Neurosciences
Oxford
England
United Kingdom
OX3 9DU

Sponsor type
University/education

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

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Industry

Funder Name
Big Health Inc.

Results and Publications

Publication and dissemination plan
We intend to publish the full trial protocol before completing recruitment. Findings will be written up for publication in a peer-reviewed journal article. We intend to publish findings within one year after the overall trial end date. Findings may also be presented at national and international scientific meetings.

Intention to publish date
01/10/2020

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?
Protocol article	protocol	23/04/2020	27/04/2020	Yes	No
Results article	results	01/03/2021	19/10/2020	Yes	No