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Improving accessibility of a digital body-based therapy for anxiety

Submission date
12/06/2024

Recruitment status
No longer recruiting

Registration date
21/06/2024

Overall study status
Completed

Last Edited
23/06/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Many people who experience anxiety do not benefit from standard treatments, such as cognitive behavioural therapy or medication. We developed a novel body-based therapy, called ADIE (Aligning Dimensions of Interoceptive Experience), through which people with anxiety improve awareness of their heartbeats and other aspects of bodily feelings. This type of therapy can be especially helpful for neurodivergent people or people who have a physical health condition that make anxiety harder to control with current treatments. During therapy sessions, patients use a platform called “HeartRater:Clinical”. They wear a sensor that records their heartbeats. They complete different tasks on a tablet computer that gives them information about their heartbeats as part of the therapy. In a previous study, we showed that ADIE can reduce anxiety symptoms in autistic adults and people who experience anxiety and complex physical health conditions. However, the sensor technology that we used does not work well on people with darker skin or poor blood circulation. In this study, we want to use a new sensor technology and test if ADIE can be delivered to patients in NHS Talking Therapies services using HeartRater:Clinical technology. We have designed the technology and software app together with experts by experience to make it inclusive and accessible and want to test if we need to improve HeartRater:Clinical further.

Who can participate?
People who have been referred or self-referred to the participating NHS Talking Therapies services, are over 18 years old, and have a diagnosis of Social Anxiety Disorder, Generalized Anxiety Disorder, or Panic Disorder can participate in the study. Participants also need to have a stable internet connection at home and access to a personal device that has a video chat function. People who are currently pregnant, who experience severe depression or suicidal thoughts, and people who also have a diagnosis of posttraumatic stress disorder (PTSD) or obsessive-compulsive disorder (OCD) cannot participate. If a person takes medication for irregular heartbeats (cardiac arrhythmia) or is very worried about their heart health, they also cannot participate.

What does the study involve?
Every participant first undergoes a screening process to make sure ADIE therapy is the right choice for them. If they decide to take part, we ask people to provide informed consent.

Participants then are randomly assigned one of two study groups. One group receives ADIE therapy together with a therapist, who supports them to use HeartRater:Clinical over video chat in each session. The other group uses HeartRater:Clinical without a therapist to receive ADIE therapy. Every participant is sent a box with all the equipment that is needed, which includes the HeartRater:Clinical sensor technology, tablet computer with the software app, and instructions on how to use everything. Participants then are asked to use the app for a baseline assessment before they start therapy, either with a therapist or self-guided. The therapy itself takes place over 6 sessions, and during each session participants complete tasks to learn how to increase their heartbeat awareness. After the fourth and sixth sessions, we ask participants again to do an assessment, so we can track how they are doing. When a participant has completed all sessions, the equipment is picked up by a mail service from the participant's house. Every participant, whether they completed the therapy with or without a therapist, then meets with a therapist to see if they need further support from their NHS Talking Therapies service. If the participant wishes, they can also take part in a one-hour interview with a member of the research team to share their experience.

What are the possible benefits and risks of participating?
The research is designed to help people with symptoms of anxiety, and will also help us learn more about the treatment of anxiety in the future. Participants are also offered a reimbursement of £10/hour for the time they spend on study assessments. Some people may start to worry about their heart health if they become more aware of their heartbeats, which may make their anxiety worse. The therapy may not help everyone with their anxiety, and we support every participant to find further treatment after they have taken part if needed.

Where is the study run from?
The study is conducted by researchers at the Department of Clinical Neuroscience at the Brighton and Sussex Medical School, together with Sussex Partnership NHS Foundation Trust. We also partner with South London and Maudsley NHS Foundation Trust for this study.

When is the study starting and how long is it expected to run for?
This trial is part of a larger project, which started in 2021 and will end in 2026. The clinical trial will run from October 2024 to September 2026.

Who is funding the study?
This study is funded by the Medical Research Council (MRC) (UK)

Who is the main contact?
Prof Hugo Critchley, H.Critchley@bsms.ac.uk
Dr Lisa Quadt, L.Quadt@bsms.ac.uk

Contact information

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Principal investigator

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Integrated Research Application System (IRAS)
333946

Central Portfolio Management System (CPMS)
61431

Protocol serial number
MR/X030210/1

Study information

Scientific Title
HeartRater:Clinical. Optimizing ADIE therapy for the treatment of anxiety in underserved populations

Study objectives
The primary objective is to test the feasibility of a full-scale Phase 3 randomized clinical trial on ADIE therapy via HeartRater:Clinical within IAPT/TT NHS services.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 04/06/2024, London Dulwich REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8094; dulwich.rec@hra.nhs.uk), ref: 24/LO/0217

Primary study design
Interventional

Study design
Interventional randomized controlled trial with qualitative follow-up

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anxiety

Interventions
Stage 1. Recruitment

Stage 2: Trial entry
a. Randomization
The Brighton & Sussex Clinical Trials Unit (BSCTU) will randomize each participant to either receive therapist- or self-guided ADIE therapy. They will use the randomisation software Sealed Envelope. Participants in the therapist-guided trial arm will have a PWP with them through online video chat (using Microsoft Teams) for each of the following stages of the trial. Participants in the self-guided trial arm will guide themselves through the trial using the materials and support options given by the research team. Participants will be informed of the outcome of the randomization by the RA via their preferred contact method.
b. Baseline assessment
Randomized participants will be sent the HeartRater:Clinical equipment via post, and receive detailed instructions on how to use it. In the therapist-guided trial arm, participants complete the baseline assessment with guidance of the PWP, who will make an appointment for an online video call. The equipment entails the heartbeat sensor (a case with 3 ECG leads, and ECG stickers to be attached to their body), and a computer tablet. They will be instructed to start the baseline assessment. Participants can take a break after each of the components. The baseline assessment includes the following components (also see Assessment Schedule Overview for details):
• Heartbeat tracking task (HBT)
Participants will need to wear the heartbeat sensor for this task. They will be asked to count their heartbeats for a specified amount of time without manually feeling for their pulse. They will then be asked how many heartbeats they counted and how confident they are in their response. Participants can first practice this task and will then be asked to do this six times.
• Heartbeat discrimination task (HBD)
Participants will need to wear the heartbeat sensor for this task. They will hear 10 tones or see 10 flashing lights (depending on their preference), that are either at the same time as their heartbeats, or in between their heartbeats.
Participants will be asked to judge if the tones/lights were at the same time as their heartbeats or not, and to rate how
confident they were in their response. Participants can first practice this task and will then be asked to do this 26
times.
• Questionnaires

Participants will be asked to fill out the following validated questionnaires:
i. 7-item Generalized Anxiety Disorders Assessment (GAD-7)
ii. Beck Anxiety Inventory (BAI)
iii. Spielberger State-Trait Anxiety Inventory (STAI)
iv. Anxiety Sensitivity Index (STAI)
iv. Multidimensional Assessment of Interoceptive Awareness (MAIA)
v. Body Perception Questionnaire (BPQ)
vi. Toronto Alexithymia Scale (TAS-20)
vii. EuroQoL 5 dimensions, 5 levels health survey (EQ-5D-5L)

3. Stage 3: Therapy
a. Therapy sessions 1-4
After completion of the baseline assessment, participants can start the first therapy session at any time. They will be advised to not complete more than two therapy sessions per week. If they are in the therapist-guided arm, they will make appointments with the PWP for each sessions. In the self-guided arm, participants will pace themselves. Each therapy session entails two blocks, between which participants undergo a self-paced physical activity that aims to make it easier to detect heartbeats. Therapy sessions include the following, and each take approximately 30 minutes:
• Block 1
o Heartbeat tracking task
Participants will complete the HBT as described in the baseline assessment. However, in therapy sessions, they will receive feedback on their performance and will be able to see the correct number of heartbeats that occurred during the time they were asked to count them. This way, participants will get a better sense of their performance. They will complete six trials of the task.
o Heartbeat discrimination task
Participants will complete the HBD as described in the baseline assessment. However, in therapy sessions, they will receive feedback on their performance and will be able to see if they were right or wrong about their answer. They will complete 20 trials of this task.
• Physical activity
Participants will then be asked to do 2-3 minutes of self-paced physical activity. We will give them ideas, such as star jumps, briskly walking, or seated exercises. Participants will be encouraged to only be active within their abilities and until they can feel their heartbeats clearly somewhere in their body.
• Block 2
The second block is the same as Block 1.
b. Therapy sessions 5 & 6
After four therapy sessions, participants will complete the Midpoint Assessment. Therapy sessions 5 & 6 are the same as therapy sessions 1-4.
4. Stage 4: Assessments
a. Mid-point assessment after 4 therapy sessions
See Assessment Schedule Overview for details.
b. End-point assessment
See Assessment Schedule Overview for details.
c. Clinical need assessment with PWP
Each participant in both trial arms will meet with the PWP to assess if further therapy is needed. The PWP will discuss with the participant if they wish to be reverted to treatment as usual to receive more support, depending on how each participant feels about their improvement after receiving ADIE therapy.
d. Qualitative assessment (optional)
We will ask a small number of volunteer participants to take part in a qualitative interview with the CRC about their intervention experience. This will be a 1-hour semi-structured interview, in

which the CRC will use a topic guide to loosely structure the interview. This will be done with the preferred communication method. If participants agree to take part, they will fill out a separate consent form.

Intervention Type
Other

Primary outcome(s)
Whether it is feasible to conduct a full randomized controlled trial on ADIE therapy delivered through HeartRater:Clinical within the IAPT/Talking Therapies NHS services.
Primary feasibility outcomes are:
1. Recruitment to target (N=100 in 24 months)
2. Uptake (Patient's willingness to enter the study as an alternative to IAPT/TT offers; i.e., proportion of participant screened who are eligible and participants who consent)
3. Retention (i.e., proportion of consenting participants who are retained after four sessions, six sessions, and at end-point assessment per trial arm)
4. Adherence (i.e., proportion of participants per trial arm completing at least four out of six therapy sessions)

Key secondary outcome(s)
1. Whether a therapist needs to be present for delivering ADIE therapy
2. Establishing the appropriate primary outcome for a full-scale clinical trial.
Candidate primary standardized clinical outcome measures for a full-scale RCT:
2.1. 7-item Generalized Anxiety Disorders Assessment (GAD7)
2.2. Beck Anxiety Inventory (BAI)
2.3. Spielberger State-Trait Anxiety Inventory (STAI)
2.4. Secondary clinical outcome measures:
2.5. Anxiety sensitivity
2.6. Quality of life
2.7. Alexithymia
2.8. General body perception
2.9. Interoceptive abilities
3. Health economic outcome measures:
3.1. EuroQoL 5 dimensions, 5 levels health survey (EQ-5D-5L)
3.2. Client Service Receipt Inventory (CSRI)

Completion date
30/09/2026

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Meets M.I.N.I (7.0.2) criteria for generalized anxiety disorder, social anxiety disorder, or panic disorder
3. Access to stable internet connection in home
4. Access to personal device (smartphone, tablet, (laptop) computer) with video chat function

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
89

Key exclusion criteria
1. Age under 18 years
2. Currently pregnant
3. Current medication for cardiac arrhythmia
4. Health anxiety related to cardiac events
5. Participation in previous trials using ADIE therapy
6. Current severe depression (PHQ9 score >=20)
7. Current risk of suicide
8. Co-occurring Post Traumatic Stress Disorder (PTSD)
9. Co-occurring Obsessive Compulsive Disorder

Date of first enrolment
15/10/2024

Date of final enrolment
31/05/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Brighton and Sussex Medical School
Trafford Centre, University of Sussex
Swandean
Brighton
England
BN1 9RY

Study participating centre
Sussex Partnership NHS Foundation Trust
Trust Hq
Swandean
Arundel Road
Worthing
England
BN13 3EP

Study participating centre
South London and Maudsley NHS Foundation Trust
Bethlem Royal Hospital
Monks Orchard Road
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BR3 3BX

Sponsor information

Organisation
University of Sussex

ROR
https://ror.org/00ayhx656

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
A data sharing agreement will be set up with individuals who are outside of the research team and who request to use the anonymized study data. Prof Hugo Critchley (H.Critchley@bsms.ac.uk) or Dr Lisa Quadt (L.Quadt@bsms.ac.uk) will give approval for data sharing requests. The possibility of data sharing will be made explicit to participants on the study consent form. The Participant's personal details will not be shared with anyone outside of the research team. All data sharing processes will adhere to the 2018 GDPR. The study team will have exclusive use of the data for the first 12 months after the study has ended or until the data is published. Data will be shared with named collaborators during this time.

IPD sharing plan summary
Available on request