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Evaluating CBT Bytesize: a mixed-methods feasibility trial of a blended digital CBT intervention for adolescent anxiety and low mood

Submission date
28/05/2025

Recruitment status
No longer recruiting

Registration date
04/06/2025

Overall study status
Completed

Last Edited
08/07/2025

Condition category
Mental and Behavioural Disorders

[ ] 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
Anxiety is common in children and young people and can affect their daily lives, including school, family, and friendships. CBT Bytesize is a new digital mental health programme designed to make therapy more accessible by combining online self-help tools with support from a therapist. The aim of the study is to test whether CBT Bytesize is easy to use and whether it helps reduce anxiety in young people.

Who can participate?
The study included children and young people aged 8 to 17 who had been referred to a mental health service for anxiety-related difficulties. To take part, they needed to have access to the internet, be able to understand and speak English, and be suitable for a short course of CBT. Clinicians who delivered the CBT Bytesize programme were also invited to take part in focus groups to share their experiences.

What does the study involve?
Young people in the study took part in the CBT Bytesize programme, which included short online learning modules and therapist support, delivered either remotely or in person. Their progress was compared to that of similar young people who had previously received standard online CBT. Researchers looked at whether anxiety and low mood improved after completing CBT Bytesize. They also examined how many young people continued using the programme and what they thought about it. Feedback from clinicians who delivered the programme was gathered through focus groups and analysed using thematic analysis.

What are the possible benefits and risks of participating?
The programme may help young people manage anxiety more effectively and provide a more flexible way to access therapy. There are minimal risks, but some young people might find it challenging to engage with digital content or talk about difficult feelings.

Where is the study run from?
The study was coordinated by Manchester Metropolitan University and delivered in partnership with Healios Ltd, a digital mental health service provider.

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

Who is funding the study?
The study was jointly funded by Manchester Metropolitan University and Healios Ltd (UK)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
34434

Study information

Scientific Title
Evaluating CBT Bytesize: a mixed-methods feasibility trial of a blended digital CBT intervention for adolescent anxiety and low mood

Acronym
CBT Bytesize

Study objectives
Current study objectives as of 08/07/2025:

1. Estimating enrolment and uptake:
Measured as the proportion of eligible young people referred by NHS clinicians who were enrolled in the CBT Bytesize programme.
(Target: >30% of those referred engage with the programme)
2. Assessing retention and engagement:
Defined as the proportion of enrolled participants who attended at least 75% of the core intervention sessions (i.e. ≥9 out of 12 sessions).
(Target: >70% session completion rate)
3. Completeness of outcome measures:
Measured by the proportion of participants who completed key clinical outcome measures (RCADS, YP-CORE) at baseline and end-of-study
(Target: >80% data completion across timepoints)

4. Acceptability of the intervention:
Evaluated through qualitative feedback and user engagement data, including self-reported satisfaction and willingness to recommend the programme.
(Target: >80% reporting satisfaction with content and format)
5. Feasibility of trial procedures:
Assessed via clinician and service feedback regarding referral, delivery, and data collection processes.
(Target: majority positive feedback from participating clinicians and low procedural burden)

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Previous study objectives:

Primary hypothesis:
1. CBT Bytesize will be effective in reducing anxiety symptoms in children and young people (CYP) compared to a matched historical control group receiving treatment as usual (TAU) online CBT.

Secondary hypotheses:
1. CBT Bytesize will be feasible and usable for CYP, as demonstrated by adherence to the intervention protocol and positive feedback from participants and clinicians.
2. CYP participating in CBT Bytesize will report positive therapeutic experiences, including perceived support and satisfaction with the hybrid delivery model (app + therapist interaction).
3. Clinicians delivering CBT Bytesize will find the model acceptable and manageable, with insight into its adaptability, potential benefits, and challenges in routine practice.
4. Therapeutic improvements (e.g., anxiety reduction) will be maintained at 6-month follow-up among participants in the CBT Bytesize group.
5. CYP receiving CBT Bytesize will demonstrate improvement on routine outcome measures (ROMs) such as the RCADS, YP-CORE, and GBOs from baseline to post-intervention.
6. Compared to the TAU group, the CBT Bytesize group will show greater gains in specific domains such as engagement, session completion, and goal attainment.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/12/2021, Manchester Metropolitan University REC (Ormond Building, Lower Ormond Street, Manchester, M15 6BX, United Kingdom; +44 (0)161 247 2222; press@mmu.ac.uk), ref: 34434

Study design
Matched mixed-methods feasibility and usability trial

Primary study design
Interventional

Study type(s)
Diagnostic, Other, Prevention, Screening

Health condition(s) or problem(s) studied
Anxiety disorders in children and young people

Interventions

Current interventions as of 08/07/2025:

The intervention group consisted of children and young people who voluntarily opted into the CBT Bitesize programme following identification from Healios' existing waiting list to access mental health support. Clinicians screened potential participants against the inclusion/exclusion criteria.

Those deemed eligible were contacted via telephone by Healios clinicians and offered the option to either remain on the waiting list or begin the CBT Bitesize programme. Comprehensive information about the intervention was also sent to families via email, and only participants who gave informed consent to participate were enrolled.

A matched control group was retrospectively assembled from Healios clinical records, comprising young people who had previously received treatment-as-usual (TAU) online CBT during a comparable period. Participants in the control group were matched to those in the intervention group based on key demographic and clinical characteristics, including age, gender, type and severity of presenting difficulties. If more than one match existed for a CBT Bitesize client, one match was randomly selected. The matched young person was then removed from the sample of clients engaging with TAU to ensure that the same young person could not be a match for multiple CBT Bitesize participants. This matching procedure aimed to enhance group comparability and reduce potential confounding, acknowledging the limitations inherent in non-randomised study designs.

In addition to quantitative outcome measures collected via self-report at baseline, post-treatment, and follow-up time points, the study incorporated a qualitative component to explore participants' and clinicians' experiences of the intervention. Semi-structured interviews were conducted with young people following completion of the programme, and focus groups were held with participating clinicians. These qualitative data were analysed thematically to provide in-depth insights into the feasibility, usability, and perceived value of the CBT Bitesize intervention. This mixed-methods approach was selected to enable a comprehensive evaluation of a novel, digitally delivered CBT programme within a real-world service context, addressing both measurable outcomes and experiential factors relevant to its future scalability and implementation.

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Previous interventions:

Participants were randomised using a computer-generated random number sequence with block randomisation to ensure equal allocation.

The intervention under evaluation is CBT Bytesize, a brief, hybrid-format cognitive-behavioural therapy (CBT) programme designed for children and young people (CYP) experiencing anxiety. It combines digital self-help content delivered through an online platform with therapist-guided sessions, aiming to improve accessibility, engagement, and therapeutic outcomes in routine clinical settings.

CBT Bytesize includes:
1. Structured, brief CBT modules aligned with core CBT principles (e.g., psychoeducation, cognitive restructuring, behavioural experiments).

2. Interactive digital content, such as videos, exercises, and reflective tasks, tailored to a younger audience.
3. Therapist support, provided either face-to-face or via telehealth, to reinforce learning, personalise content, and maintain therapeutic engagement.
4. Typically delivered over 6–8 sessions, the programme is designed to be time-efficient while still therapeutically effective.

The comparator is a matched historical control group that received treatment-as-usual (TAU) online CBT, representing standard care previously delivered by the service. TAU included more traditional CBT protocols without the streamlined, digital–hybrid enhancements of the CBT Bytesize model.

Intervention Type
Mixed

Primary outcome(s)
Current primary outcome measure as of 08/07/2025:

1. Symptoms of various anxiety disorders and low mood, measured using the Revised Child Anxiety and Depression Scale (RCADS) at baseline (T1), mid-intervention (T2) and post-intervention (T3).

Previous primary outcome measure:

Symptoms of various anxiety disorders and low mood, measured using the Revised Child Anxiety and Depression Scale (RCADS) at baseline, post-intervention, and 6-month follow-up

Key secondary outcome(s))
Current secondary outcome measures as of 08/07/2025:

1. Psychological distress and functioning measured using the Young Person's CORE (YP-CORE) at baseline (T1), mid-intervention (T2) and post-intervention (T3).
2. Feasibility, assessed through session attendance and completion rates over the intervention period.
3. Acceptability, evaluated post-intervention using qualitative interviews and satisfaction surveys with participants (young people) and therapists.

Previous secondary outcome measures:

1. Psychological distress and functioning measured using the Young Person's CORE (YP-CORE) at baseline, post-intervention, and 6-month follow-up
2. Progress toward self-identified goals measured using the Goal-Based Outcomes (GBOs) at baseline, post-intervention, and 6-month follow-up
3. Feasibility assessed through session attendance and completion rates over the intervention period
4. Acceptability evaluated using qualitative interviews and satisfaction surveys with participants and therapists post-intervention

Completion date
01/08/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 08/07/2025:

1. Being referred to Healios by contracted NHS trusts supporting young people in the UK
2. Having anxiety symptoms/anxiety disorder(s) and low mood as the primary presentation(s). Young people with comorbidities were not excluded, as long as the primary presentation was 'anxiety'.
3. Access to a smartphone and the Internet
4. Good level of conversational English
5. Aged 11 to 17 years
6. Willing to talk about their experiences and provide feedback on the CBT Bitesize programme

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Previous inclusion criteria:

1. Children and young people (CYP) aged 8 to 17 years
2. Referred to a CAMHS (Child and Adolescent Mental Health Services) team for anxiety-related difficulties
3. Deemed clinically appropriate for brief cognitive-behavioural therapy (CBT) by their care team
4. Able to understand and communicate in English, sufficient to engage with the intervention and complete outcome measures
5. Have access to a device (e.g., smartphone, tablet, or computer) and the internet to engage with the digital content
6. Provided informed consent/assent (with parental/guardian consent as appropriate based on age and service policy)

Participant type(s)
Patient, Service user

Healthy volunteers allowed
No

Age group
Child

Lower age limit
11 years

Upper age limit
17 years

Sex
All

Total final enrolment

Key exclusion criteria
Current exclusion criteria as of 08/07/2025:

1. Presence of sight/hearing problems
2. Suicide attempts within the last three months and/or actively suicidal
3. Current safeguarding concerns, safeguarding investigations or criminal investigations
4. Not able/willing to provide assent to take part in CBT Bytesize, or parents/legal guardians not providing consent to take part in the programme.

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Previous exclusion criteria:

1. Primary presenting difficulties that are not anxiety-related (e.g., severe depression, eating disorders, trauma, or psychosis) and are not suitable for brief CBT.
2. Level of clinical complexity or risk (e.g., high self-harm or safeguarding concerns) that would require more intensive or specialist interventions.
3. Insufficient English proficiency to understand intervention content or complete outcome measures.
4. Significant cognitive impairments or learning difficulties that would prevent engagement with the app-based or self-guided content.
5. Lack of access to a digital device or the internet, preventing full participation in the hybrid model of care.

Date of first enrolment
21/12/2021

Date of final enrolment
01/02/2023

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
Manchester Metropolitan University
All Saints
Grosvenor Square

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Sponsor information

Organisation
Manchester Metropolitan University

ROR
https://ror.org/02hstj355

Organisation
Healios Ltd

Funder(s)

Funder type
University/education

Funder Name
Manchester Metropolitan University

Alternative Name(s)
Manchester Polytechnic, MMU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Healios Ltd

Results and Publications

Individual participant data (IPD) sharing plan

The dataset generated during the current study is not expected to be made available due to the need to protect children and young people's data on sensitive topics such as their mental health. The ethical approval received for this study covers data storage and handling for the purposes of the study, but the participants and their caregivers have not given their informed consent for their personal data to be publicly shared.

IPD sharing plan summary

Not expected to be made available