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YoMeta: A study investigating if metacognitive therapy for children and adolescents with a common mental health disorder is feasible and acceptable to deliver in child and adolescent mental health services

Submission date	Recruitment status	[X] Prospectively registered
22/02/2022	No longer recruiting	[X] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
24/02/2022	Completed	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
05/04/2023	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

One in eight children and young people (CYP) suffer mental health problems needing support or treatment and 5% have more than one such problem. The effects can be major, affecting CYP emotionally and functionally, impacting progress at school, relationships with others and increasing long term risk of mental health problems. The UK Government and the NHS have highlighted the need to improve mental health in CYP.

The most common treatment is cognitive behavioural therapy; however this can be time consuming, needs to be delivered over many weeks, must focus on the most upsetting problem first and is not very effective. One way to overcome this is to evaluate a group therapy that can treat multiple mental health problems at once. This new treatment is called Metacognitive Therapy (MCT).

The aim of the study is to see if participating in a randomized trial of Group MCT is a feasible and acceptable treatment for CYP suffering with anxiety, stress, depression, or a combination in comparison to usual care. This allows us to test key questions about recruitment and drop-out rates, test the protocol, and gain information about MCT including training and supervision needs of clinicians and the experience of patients receiving it.

Who can participate?

We plan to recruit participants aged 18 years or older, with anxiety, stress, depression or a combination.

What does the study involve?

Participants will be randomised to one of two groups; group MCT or treatment as usual. Group MCT will be delivered across 8 sessions lasting 90 minutes. All participants will complete

questionnaires at baseline, 16 week follow up (post treatment), 28 week follow up and 40 week follow up. A qualitative study will explore participants' experience of group MCT and therapist views of MCT and being trained in MCT.

What are the possible benefits and risks of participating?
The information gathered as part of this study will help to inform future care within CAMHS for children and young people experiencing mental health disorders and will provide details to develop further research on MCT for children and young people.

While the risks in taking part are minimal it is possible that answering the questionnaires and/or talking about any difficulties may cause some distress. However, the group MCT is designed to aid in managing negative thoughts and feelings more effectively. The group delivery of this therapy will be facilitated by two trained CAMHS professionals, who will ensure the understanding and maintenance of confidentiality and ease any uncertainty in the situation.

Where is the study run from?
Greater Manchester Mental Health NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2021 to October 2024

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Dr Lora Capobianco. lora.capobianco@gmmh.nhs.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
296079

ClinicalTrials.gov (NCT)
NCT05260060

Protocol serial number
CPMS 50997, NIHR201495, IRAS 296079

Study information

Scientific Title
Youth metacognitive therapy (YoMeta): a single blind parallel randomised feasibility trial

Acronym
YoMeta

Study objectives
The aim is to conduct a two-arm single blind feasibility trial comparing group metacognitive therapy (MCT) vs. treatment as usual for children and adolescents experiencing psychological distress to investigate if a more definitive trial is an acceptable, feasible and potentially effective option

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 11/01/2022, North West - Greater Manchester East Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 2071048199; gmeast.rec@hra.nhs.uk), ref: 21/NW/0329

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anxiety, depression, or both

Interventions
Participants are randomised to the intervention or control condition.

The intervention group will receive six weekly sessions of group-based MCT (with two additional booster session). Group-MCT will be delivered by two trained mental health professionals (i.e. clinical psychologist and high-intensity therapist). Sessions will last approximately 90 minutes. Group MCT will be guided by a treatment manual to maximise treatment adherence and fidelity. Group MCT aims to help participants develop knowledge that can facilitate control of worry, repetitive negative thinking and attention, and to modify the metacognitive beliefs that maintain unhelpful thinking patterns

Control Condition: Treatment as usual (TAU) consist of cognitive behavioural therapies (CBT: behavioural activation, exposure, EMDR, cognitive therapy) and family therapy delivered on a one-to-one or group basis. Participants normally receive up to 12 sessions of TAU.

QUANTITATIVE ASSESSMENTS
Participants will complete quantitative assessments at four time-points: baseline, 20 weeks (end of treatment), 32 weeks (follow up) and 44 weeks (follow up). At the four time-points participants will be asked to complete the following questionnaires:
•Revised Child Anxiety and Depression Scale- Short Version
•Strength and Difficulties Questionnaire (SDQ)
•Metacognition Questionnaire-Adolescent version (MCQ-A)
•Demographic information – including child's age, sex, school, ethnicity, medication, socioeconomic status, parental occupational status. This will be completed by parents/primary caregivers.
•Child Health Utility-9D (CHU-9D)
•EQ-5D-Y
•Health and Social Care Service-Use Interview (SUI). The SUI will include questions about whether the child has used any primary, secondary or community-based health and social care and how often they used the service in the last 16 weeks (baseline study visit) or since the last assessment (follow-up study visits). The SUI will be developed from existing child relevant SUIs held by the co-applicants and through discussion with the PPI representative, parent advisory group and clinical members of the study team. This will be completed by parents/primary caregivers.

QUALITATIVE ASSESSMENTS
A nested qualitative study will be conducted to evaluate patient and clinician perspectives of MCT. We will conduct semi-structured interviews with around 10 patients and 4-6 clinicians. Qualitative interviews with patients will evaluate which aspect of the interventions they liked and disliked. Qualitative interviews with clinicians will evaluate their experience in being trained in MCT and delivering MCT.

Intervention Type
Behavioural

Primary outcome(s)
1. The Revised Child Anxiety and Depression Scale- Short Version is being measured at baseline, 20 weeks (end of treatment), 32 weeks (follow up) and 44 weeks (follow up).
2. Feasibility will be assessed using referral rates, recruitment and retention rates, participant attendance at sessions, their follow up and questionnaire response rates, and willingness to be randomized to treatment

Key secondary outcome(s))
1. Strength and Difficulties Questionnaire (SDQ) is being measured at baseline, 20 weeks (end of treatment), 32 weeks (follow up) and 44 weeks (follow up).
2. Metacognition Questionnaire-Adolescent version (MCQ-A) is being measured at baseline, 20 weeks (end of treatment), 32 weeks (follow up) and 44 weeks (follow up).
3. Child Health Utility-9D (CHU-9D) is being measured at baseline, 20 weeks (end of treatment), 32 weeks (follow up) and 44 weeks (follow up).
4. EQ-5D-Y is being measured at baseline, 20 weeks (end of treatment), 32 weeks (follow up) and 44 weeks (follow up).
5. Health Care Service Use Interview Version is being measured at baseline, 20 weeks (end of treatment), 32 weeks (follow up) and 44 weeks (follow up).

Completion date
31/10/2024

Eligibility

Key inclusion criteria
1. Aged between 11-16 years
2. Consent given
3. Native fluency in English language
4. Seeking treatment for emotional disorder symptoms (i.e. generalized anxiety disorder, panic disorder, agoraphobia, post-traumatic stress disorder, obsessive-compulsive disorder, social anxiety, and/or depression)
5. Medication for mental health problems permitted but participants must be stabilised for 6 weeks

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Presence of significant risk or safeguarding concerns
2. Head injury/organic impairment
3. Autism Spectrum Disorder, Attention Deficit-Hyperactivity Disorder
4. Eating Disorder
5. Non-English speaking children
Note: Only patients with a formal diagnosis or under assessment for one of the exclusion criteria will be excluded from the study.

Date of first enrolment
23/05/2022

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Manchester Children and Adolescent Mental Health Services
Winnicot Centre
Hathersage Road
Manchester
United Kingdom
M13 0JE

Sponsor information

Organisation
Greater Manchester Mental Health NHS Foundation Trust

ROR
https://ror.org/05sb89p83

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Adrian Wells (adrian.wells@manchester.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		12/09/2022	15/03/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes