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Mental health intervention for children with epilepsy

Submission date	Recruitment status	[X] Prospectively registered
05/02/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
25/02/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/03/2024	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims

At least half of children with epilepsy also have mental health problems like depression, anxiety and behaviour problems. The mental health problems impact so much on all areas of life including family, friendships and education, that the National Institute for Health and Care Excellence recommends the psychological needs of children with epilepsy should always be considered. However, existing epilepsy services are separate from mental health services, so mental health problems aren't treated as well as they could be. There is an exciting new psychological treatment for childhood anxiety, depression and behavioural problems. This Modular Approach to Treatment for Children – Anxiety, Depression, Trauma or Conduct (MATCH-ADTC) can be given within epilepsy services, by staff without special mental health training and over the phone/Skype, which many families prefer and which reduces costs to the NHS so more children can be treated nationwide. The treatment is flexible so can be given to parents and/or the child according to age and type of problem. The purpose of the first stage of the research programme was to develop a new epilepsy-specific module to include in MATCH-ADTC and to integrate epilepsy-relevant content throughout MATCH-ADTC, so that MATCH-ADTC meets the special mental health needs of children with epilepsy. The purpose of the second stage is to work with staff and patients in epilepsy services to integrate the personalised, modular psychological intervention developed in stage one within existing service models so that it can be delivered with competence, fidelity and flexibility in a sustainable manner. The aim of the third stage is to evaluate the clinical and cost-effectiveness of MATCH-ADTC delivered by the therapists trained in stage two in addition to standard care, compared to standard care alone, for children with common mental health disorders and epilepsy.

Who can participate?

Young people aged 3 – 18 years old who are attending epilepsy clinics and have a common mental health disorder can participate.

What does the study involve?

The study compares MATCH-ATDC in addition to usual care compared to usual care alone. Half of the participants will be randomly allocated to received MATCH-ATDC in addition to usual care, and half of the participants will be randomly allocated to receive usual care alone.

What are the possible benefits and risks of participating?
Participants may benefit by taking part as they may receive additional support for emotional or behavioural difficulties. There are no specific risks from taking part in the study. Participants will not be deprived of any treatment that they would otherwise have received had they not been a part of the study. It is possible that thinking about their life and the effect of having epilepsy could be upsetting for participants. It is possible that the questionnaires and interviews may cause distress as they address sensitive issues.

Where is the study run from?
There are seven centres taking part in this study. These are Great Ormond Street Hospital for Children NHS Foundation Trust (the lead centre), University College London Hospitals NHS Foundation Trust, Royal Devon and Exeter NHS Foundation Trust, North East London NHS Foundation Trust, Lewisham & Greenwich NHS Trust, Royal Free NHS Foundation Trust, Whittington Health NHS Trust.

When is the study starting and how long is it expected to run for?
October 2018 to April 2023

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

Who is the main contact?
Prof. Roz Shafran
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Study website
https://uclpsychmed.wixsite.com/micestudy

Contact information

Type(s)
Public

Contact name
Prof Roz Shafran

Contact details
UCL Great Ormond Street Institute of Child Health
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
18PP14

Study information

Scientific Title
A randomised controlled, multi-centre clinical trial evaluating the clinical and cost-effectiveness of MATCH-ADTC in addition to usual care compared to usual care alone for children and young people with common mental health disorders and epilepsy

Acronym
MICE

Study objectives
The study hypothesis is that MATCH-ADTC in addition to usual care will be more clinically and cost-effective than usual care alone for young people with epilepsy and common mental health disorders.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central - Oxford A Research Ethics Committee, Bristol Research Ethics Committee Centre, Whitefriars, Level 3 Block B, Lewins Mead, Bristol, BS1 2NT, Tel: +44 (0)207 104 8028, Email: nrescommittee.southcentral-oxforda@nhs.net, 15/05/2018, REC ref: 18/SC/0250

Study design
A randomized controlled, multi-centre clinical trial evaluating the clinical and cost-effectiveness of MATCH-ADTC in addition to usual care compared to usual care alone for children and young people with common mental health disorders and epilepsy.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not availabe in web format, plesae use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Children and young people with common mental health disorders and epilepsy

Interventions
Participants will be randomised to one of two treatment groups. Half of the participants will receive MATCH-ADTC in addition to usual care, and half of the participants will be receive usual care alone.

The intervention is MATCH-ADTC (a personalised modular psychological intervention) with epilepsy-relevant content integrated throughout it and an additional epilepsy-specific module added in addition to usual care delivered by non-mental health specialists, over the telephone /Skype, within epilepsy services, for young people with epilepsy who have common mental health disorders.

MATCH-ADTC can be delivered within epilepsy services, by a wide range of health workers, over the telephone/Skype which will facilitate early intervention, maximise access, and minimise stigma, disruption and cost. MATCH-ADTC is an average of 16 sessions of therapy (minimum 10 and maximum 22 sessions) delivered over 4-6 months.

Intervention Type
Behavioural

Primary outcome measure
Total difficulties score from the Strengths and Difficulties Questionnaire reported by the parent /carer measured at baseline, 6 months and 12 months

Secondary outcome measures
1. Mental health diagnosis according to the Development and Wellbeing Assessment (DAWBA) measured at baseline, 6 months and 12 months.
2. Anxiety and depression measured by the Revised Children's Anxiety and Depression Scale (RCADS) measured at baseline, 6 months and 12 months.
3. Number and severity of adverse events measured at baseline, 6 months and 12 months.
4. Seizure severity measured by the Hague Seizure Severity Scale measured at baseline, 6 months and 12 months.
5. Quality of life measured by the EuroQol 5-dimensions measures, five-level version (EQ-5D-5L) measured at baseline, 6 months and 12 months.
6. Quality of life measured by the Paediatric Quality of Life measures (PedsQL) – Epilepsy Module measured at baseline, 6 months and 12 months.
7. Service use measured by the Child and Adolescent Service Use Schedule (CA-SUS) measured at baseline, 6 months and 12 months.
8. Health utility measured by the Child Health Utility 9-dimensions (CHU-9D) measured at baseline, 6 months and 12 months.
9. Intelligence measured by the Peabody Picture Vocabulary Test (PPVT) at baseline
10. School attendance (self-reported) measured at baseline, 6 months and 12 months.
11. School performance (self-reported) measured at baseline, 6 months and 12 months.
12. Session-by-session measures (e.g. goal based outcomes) measured at baseline and after each

therapy session.
13. Measures allowing for therapist self-rating of competence in delivering treatment and adherence to the treatment manual measured at baseline and after therapy is completed

Overall study start date
30/10/2018

Completion date
01/04/2023

Eligibility

Key inclusion criteria
1. Attending clinics for the treatment of epilepsy
2. Aged 3-18 years
3. Meeting DSM-5 diagnostic criteria for a mental health disorder (e.g. depression, anxiety, disruptive behaviour or trauma) identified by the SDQ, DAWBA and clinical assessment
4. Have a parent/carer who is also willing to take part in the study

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
334

Total final enrolment
334

Key exclusion criteria
1. Not speaking/understanding English sufficiently well to access the screening assessments
2. Having an intellectual disability at a level meaning that they cannot access the measures and /or intervention
3. Screening results that indicate a severe mental health disorder not considered suitable for the trial intervention
4. Actively receiving intensive psychological input focused on cognitive and/or behavioural strategies to intervene with emotional or behavioural difficulties at the time of the assessment or due to have such input during the study period
5. Refusing to consent to the research team contacting their GP/other relevant health

professionals about their inclusion in the research
6. Refusing to have the trial therapy sessions audio and/or video recorded
7. Aged 16+ and unable to consent for themselves
8. Unable to complete the measures despite all reasonable efforts being made to assist

Date of first enrolment
30/04/2019

Date of final enrolment
30/04/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Great Ormond Street Hospital
Great Ormond Street
London
United Kingdom
WC1N 3JH

Study participating centre
University College Hospital
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
Royal Devon & Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
North East London NHS Foundation Trust
Marsh Way
Rainham

United Kingdom
RM13 8GQ

Study participating centre
Lewisham & Greenwich NHS Trust
High Street
Lewisham
United Kingdom
SE13 6LH

Study participating centre
Royal Free London NHS Foundation Trust
Wellhouse Lane
Barnet
United Kingdom
EN5 3DJ

Study participating centre
Whittington Health NHS Trust
Magdala Avenue
London
United Kingdom
N19 5NF

Sponsor information

Organisation
Great Ormond Street Hospital for Children NHS Foundation Trust

Sponsor details
30 Guilford Street
London
England
United Kingdom
WC1N 1EH

Sponsor type
Hospital/treatment centre

Website
https://www.gosh.nhs.uk/

ROR
https://ror.org/03zydm450

Funder(s)

Funder type
Government

Funder Name
Programme Grants for Applied Research

Alternative Name(s)
NIHR Programme Grants for Applied Research, PGfAR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The protocol is currently being updated but will be available on request, and may be published in due course. The statistical analysis plan has not yet been finalised.

The results of the trial will be published in peer reviewed scientific journals, and the result disseminated through conference presentations.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
Current IPD sharing plan as of 13/10/2023:
The data is being held in the secure drive at GOSH and/or UCL Data Safe Haven. Participant-level data will not be made available for reasons of confidentiality. Some of the patients have rare forms of epilepsy and sharing their data could identify them.

Previous IPD sharing plan:
Participant-level data may be available on request. Any requests for participant-level data would be carefully considered by the Programme Steering Committee.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		11/02/2021	14/04/2021	Yes	No
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	version 3.0	03/10/2022	12/10/2023	No	No
Results article		07/03/2024	11/03/2024	Yes	No