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MICE

Short Title: MICE – Mental Health Intervention for Children with Epilepsy

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

Chief Investigators	Roz Shafran & Helen Cross
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Clinical Project Manager	Liz Deane
Sponsor	Great Ormond Street Hospital for Children NHS Foundation Trust

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Trial Summary

- **Intervention:** MATCH-ADTC + usual care, compared to usual care alone
- **Primary Outcome:** SDQ
- **Sample Size:** 334 children aged 3-18 years with epilepsy an mental health disorders + their parent/ carer
- **Centres:** 7 Sites in England

MICE Project Plan

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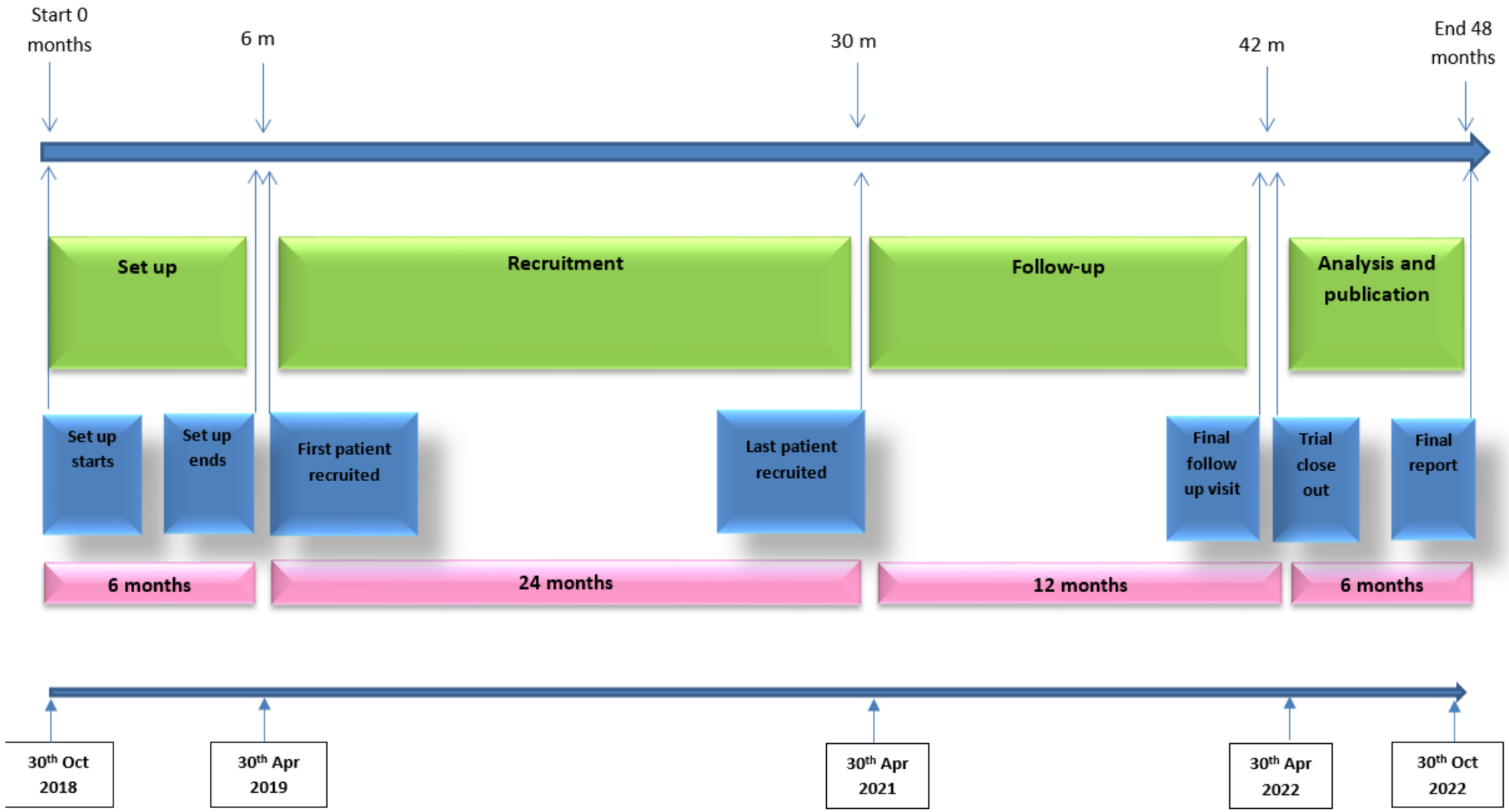

Screening & baseline

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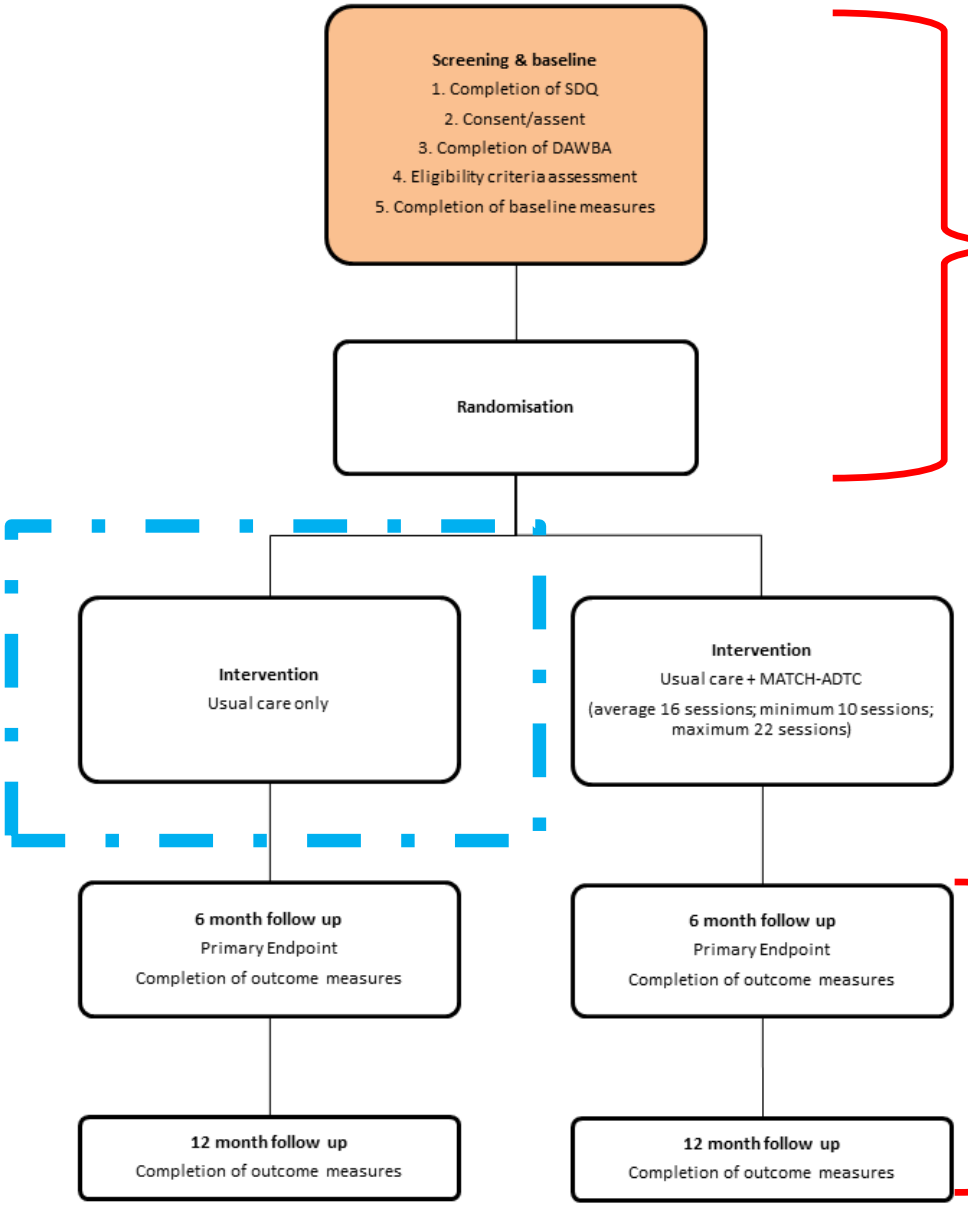

The research team will be screening in clinics – site therapists don't need to be involved until intervention.

Site therapists involved in therapy only. Research team will support with:

- Weekly measures
- Letters
- Booking sessions if helpful

The research team will be completing the follow-up measures with families. Site therapists will not be involved at this point

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Screening & baseline

FYI only – this stage will be completed by the research team. If you identify a patient that you think may benefit, the research team can talk you through the next steps (please do not share identifying details without permission of the patient/family).

Patient Approached + Verbal Consent → SDQ completed → PIS & Consent → DAWBA completed → DAWBA is rated → Participant is signed off as eligible → Baseline measures completed → Participant is randomised

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Informed Consent / Assent

FYI only – this stage will be completed by the research team. If you identify a patient that you think may benefit, the research team can talk you through the next steps (please do not share identifying details without permission of the patient/family).

- Ensure consent / assent is taken before any trial related activity is carried out.
- Children aged 16 to 18 -> CONSENT.
- Children aged 3 to 15 -> ASSENT.
- The participant must be provided with sufficient time to read the PIS and discuss the trial with members of the trial team, prior to consent.
- The participant should be informed of all aspects of the trial, which may be relevant to them making a decision, e.g. the amount of assessments and appointments.
- The consent process should be fully documented including the PIS version and date.
- Photocopies of the signed consent / assent forms should be made; one filed in the patient's medical/trial records, one given to the patient and the original kept in the Investigator Site File (ISF).

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Screening & baseline

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Eligibility Criteria

FYI only – this stage will be completed by the research team. If you identify a patient that you think may benefit, the research team can talk you through the next steps (please do not share identifying details without permission of the patient/family).

Inclusion Criteria:

1. Attending clinics for the treatment of epilepsy.
2. Aged 3-18 years.
3. **Scoring above the threshold in the SDQ for mental health symptoms which is a combination of total difficulty score (≥14) and raised impact score (≥2).**
4. 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.
5. Have a parent/carer who is also willing to take part in the study.

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 screening measures (SDQ and DAWBA) despite all reasonable efforts being made to assist.

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Screening & baseline

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Measures

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- **Primary Outcome Measure:** Strengths and Difficulties Questionnaire reported by the parent/ carer at 6 months post-randomisation

- **Key Secondary Outcome Measures:**
  - Mental Health Measures:
    - Strengths and Difficulties Questionnaire (SDQ)
    - Development and Wellbeing Assessment (DAWBA)
    - Revised Children's Anxiety and Depression Scale (RCADS)
  - Physical Health Measures:
    - Number of Serious Adverse Events
    - Hague Seizure Severity Scale
  - Quality of Life/Health Economic Measures:
    - Child and Adolescent Service Use Schedule (CA-SUS)
    - Child Health Utility 9-dimensions (CHU-9D)
    - EuroQol 5-dimensions, five-level version (EQ-5D-5L)
    - Paediatric Quality of Life measures (PedsQL) – Epilepsy Module
  - Further Measures:
    - Peabody Picture Vocabulary Test (PPVT) as intelligence measure
    - School attendance (self-reported)
    - School performance (self-reported)
    - Session-by-session measures (e.g. goal based outcomes)
    - Measures allowing for therapist self-rating of competence in delivering treatment and adherence to the treatment manual

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Randomisation

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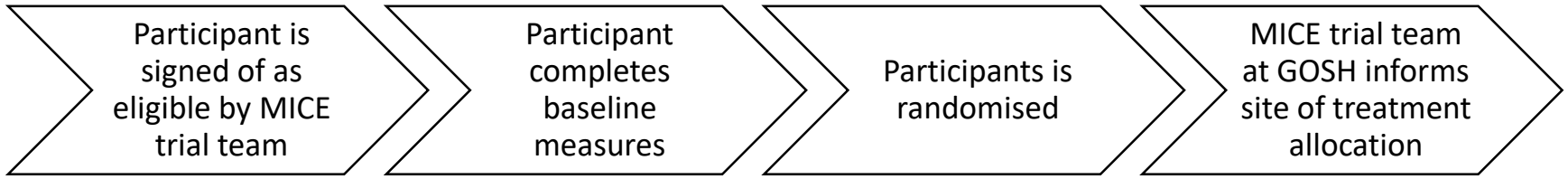
FYI only – this stage will be completed by the research team. If you identify a patient that you think may benefit, the research team can talk you through the next steps (please do not share identifying details without permission of the patient/family).

- Randomisation will be performed by the MICE trial team at GOSH
- 1:1 allocation
- Minimisation Factors:
  - Primary mental health disorder – anxiety/depression/disruptive behaviour/trauma
  - Presence of autistic spectrum disorder or autism – yes/no
  - Age - <11/11+
  - Presence of intellectual disability – yes/no
- MICE trial team at GOSH informs site of allocation



Intervention

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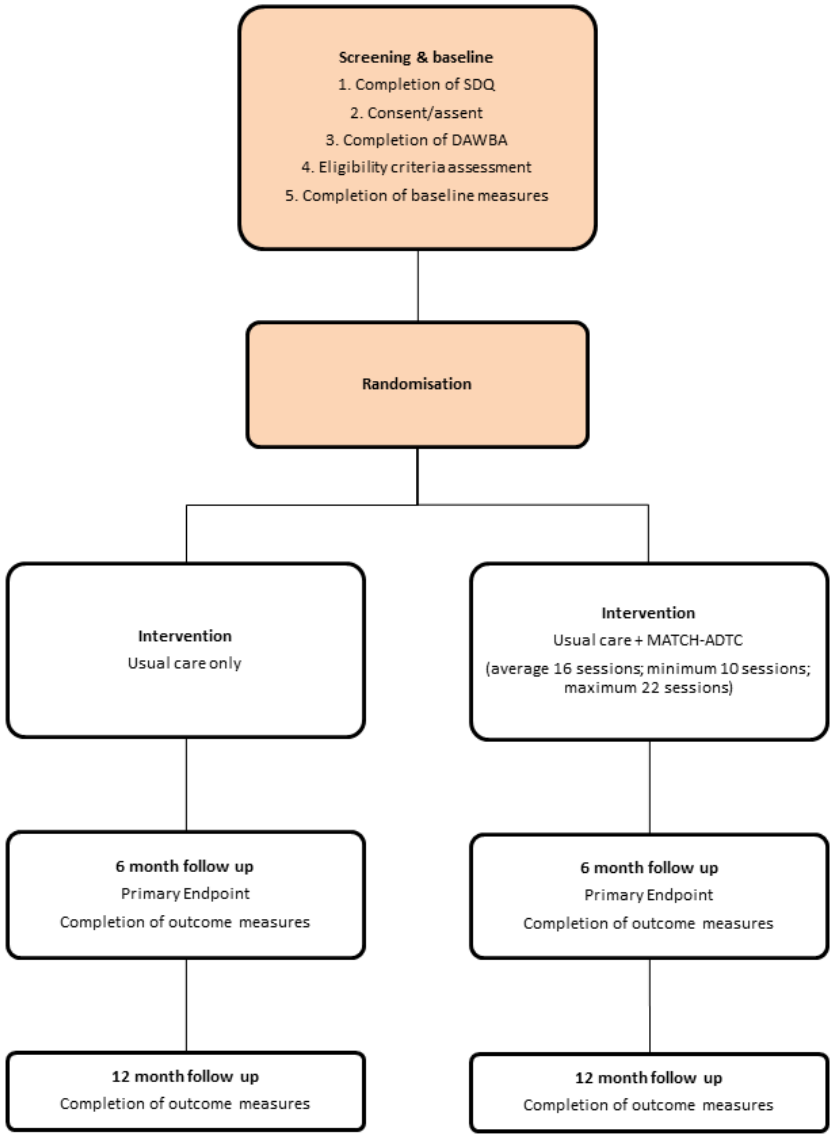

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Intervention

MATCH-ADTC + Usual Care

- 10-22 (Average of 16) sessions over 6 months
- Session-by-session measures (e.g. goal based outcomes)
- Measures allowing for therapist self-rating of competence in delivering treatment and adherence to the treatment manual

Usual Care

- N/A

6 month / 12 month follow up

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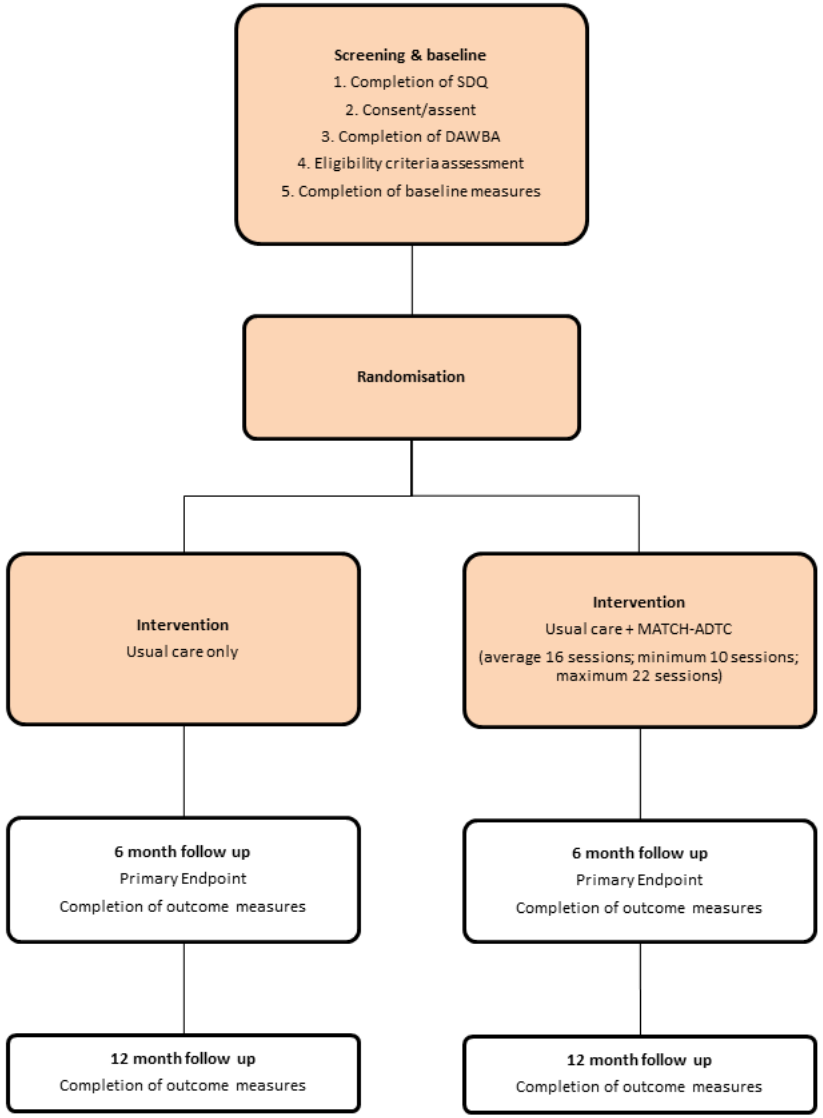

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6 month / 12 month follow up

FYI only – this stage will be completed by the research team. If you identify a patient that you think may benefit, the research team can talk you through the next steps (please do not share identifying details without permission of the patient/family).

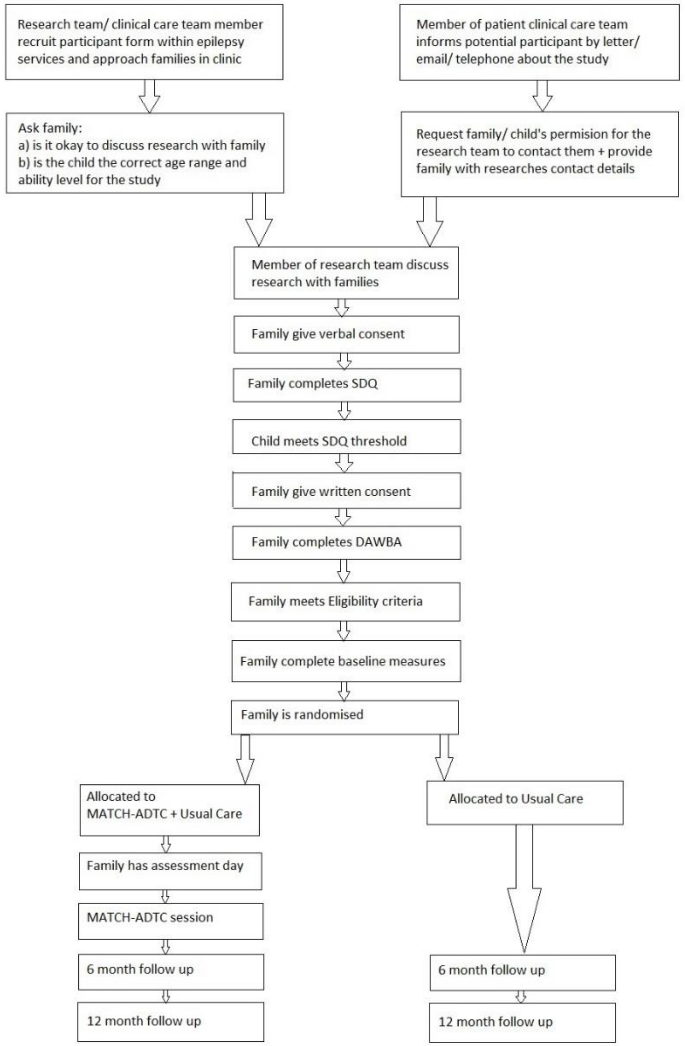
6 month

- Primary endpoint/ End of therapy
- Participants completes outcome measures online

12 month

- Participant completes outcome measures online

6 month / 12 month follow up



FYI only – this stage will be completed by the research team.

Summary table: what happens when?

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Site therapists involved in this column only, with support from research team

	Screening / Randomisation		MATCH-ADTC Session		6 Month Follow-up		12 Month Follow-up	
Therapist Assessed								
SDQ score and DSM-5 diagnosis summary scores	x							
Informed Consent (Main Caregiver), Informed Consent (Child 16+), Informed Assent (Child <16)	x							
DAWBA rated	x							
Inclusion / exclusion criteria review	x							
Epilepsy history	x							
Confirmation of eligibility	x							
Peabody Picture Vocabulary Test (PPVT)	x							
Randomisation	x							
Session-by-session measures			x					
Survey for Therapists (costing MATCH-ADTC)			x					
Survey for Therapist Supervisors (costing MATCH-ADTC)			x					
Therapist self-rating of competence			x					
MATCH-ADTC session audio/video recordings			x					
Number of Serious Adverse Events reported	x		x		x		x	
Participant Reported Questionnaires	Main Caregiver	Child	Main Caregiver	Child	Main Caregiver	Child	Main Caregiver	Child
Demography Questionnaire	x							
Strengths and Difficulties Questionnaire (SDQ)	x	11+						
Strengths and Difficulties Questionnaire (SDQ) Follow-up					x	11+	x	11+
Development and Wellbeing Assessment (DAWBA)	x	11+			x	11+	x	11+
Revised Child Anxiety and Depression Scale (RCADS)	x	8+			x	8+	x	8+
Child Health Utility 9-dimensions (CHU-9D)	x	7+			x	7+	x	7+
Hague Seizure Epilepsy Scale	x				x		x	
EQ-5D-5L	x				x		x	
Paediatric Quality of Life Epilepsy Module (PedsQL)	x	8+			x	8+	x	8+
Child and Adolescent Service Use Schedule (CA-SUS) Brief Main Caregiver	x							
Child and Adolescent Service Use Schedule (CA-SUS) Follow-up Main Caregiver					x		x	
Self-reported school attendance / performance	x				x		x	

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Data collection

FYI only – this stage will be completed by the research team. If you identify a patient that you think may benefit, the research team can talk you through the next steps (please do not share identifying details without permission of the patient/family).

- The MICE trial database is provided by Sealed Envelope
- Many of the trial questionnaires require completion by parents/carers or participants
- Parents/carers and participants will be sent invitations from the Sealed Envelope database to complete these questionnaires online

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Safety Reporting

- SITE THERAPISTS NEED TO REPORT ADVERSE EVENTS – THEY CAN CONTACT THE RESEARCH TEAM FOR ADVICE ABOUT THIS
- An adverse event is any untoward medical or psychological occurrence in a participant which does not necessarily have a causal relationship with this intervention. An adverse event can therefore be any unfavourable and unintended sign, symptom, or disease in any participant (including those in the control group), whether or not considered related to the intervention. Adverse events may include non-medical events such as self-harm.

- Only SAEs needs to be reported, low grade adverse events that are not considered serious do not need to be reported

- A serious adverse event is one that:
  - results in death
  - is life threatening*
  - requires hospitalisation or prolongs existing hospitalisation
  - results in persistent or significant disability or incapacity
  - is a congenital anomaly or birth defect or is another important medical condition

- SAEs should be reported to the CCTU within 24 hours of you becoming aware of the event. An SAE form should be filled out and emailed to cctu.mice@ucl.ac.uk

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Monitoring

Site Monitoring:

- Performed by the CCTU trial team
- Triggered
  - Result of central monitoring
  - Notified in advance of the visit and informed of documents we would like to access
    - Investigator Site File
    - Consent / Assent forms
    - Participants medical/trial records
- Aim to visit each site at least once

Central Monitoring:

- Performed remotely by the CCTU trial team
- Review of data on a per participant and per site basis

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Contact details

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Question and Closing Remarks