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# MICE

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

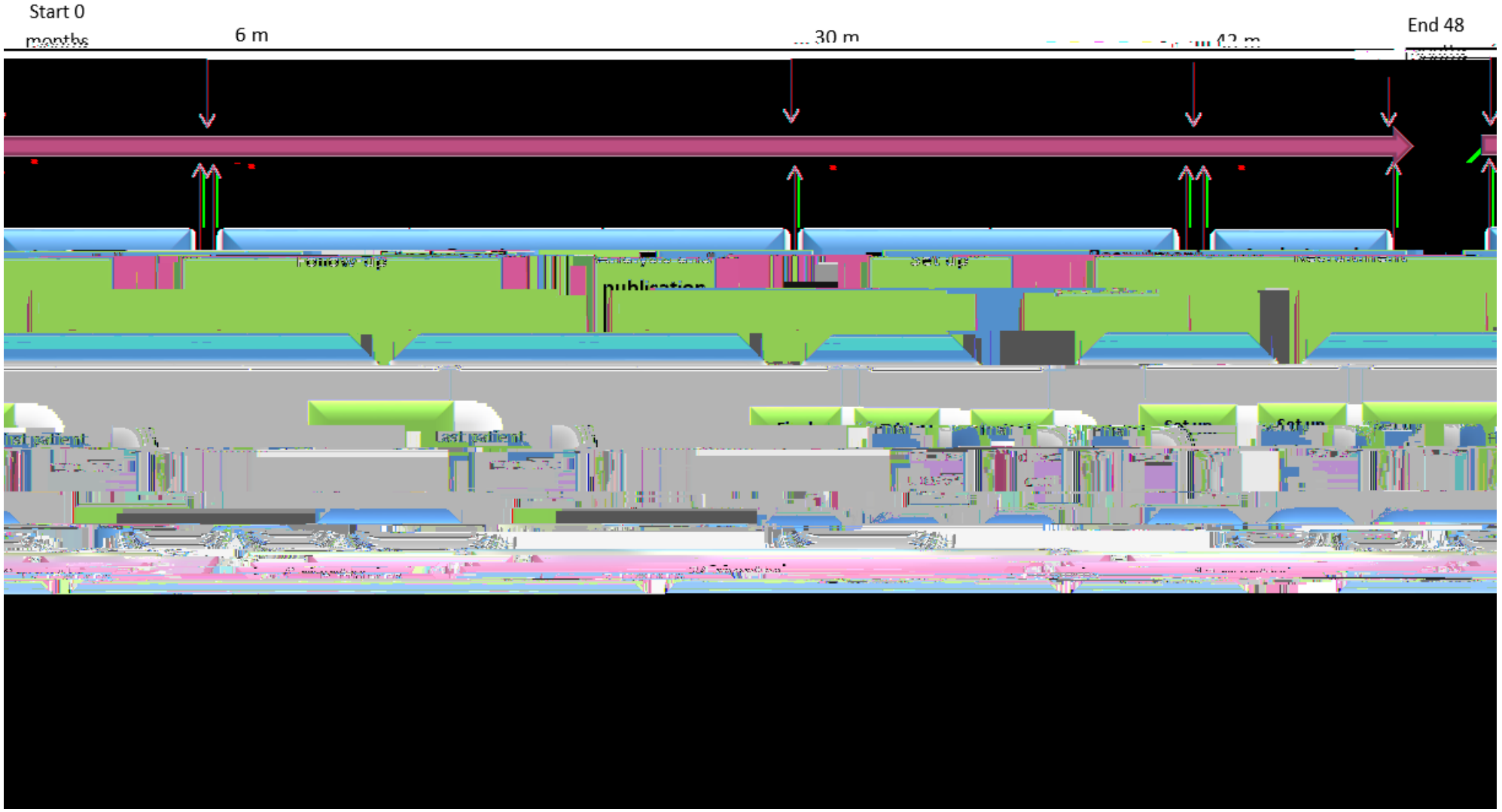
Scientific Title: A randomised controlled, multi-

# Contents

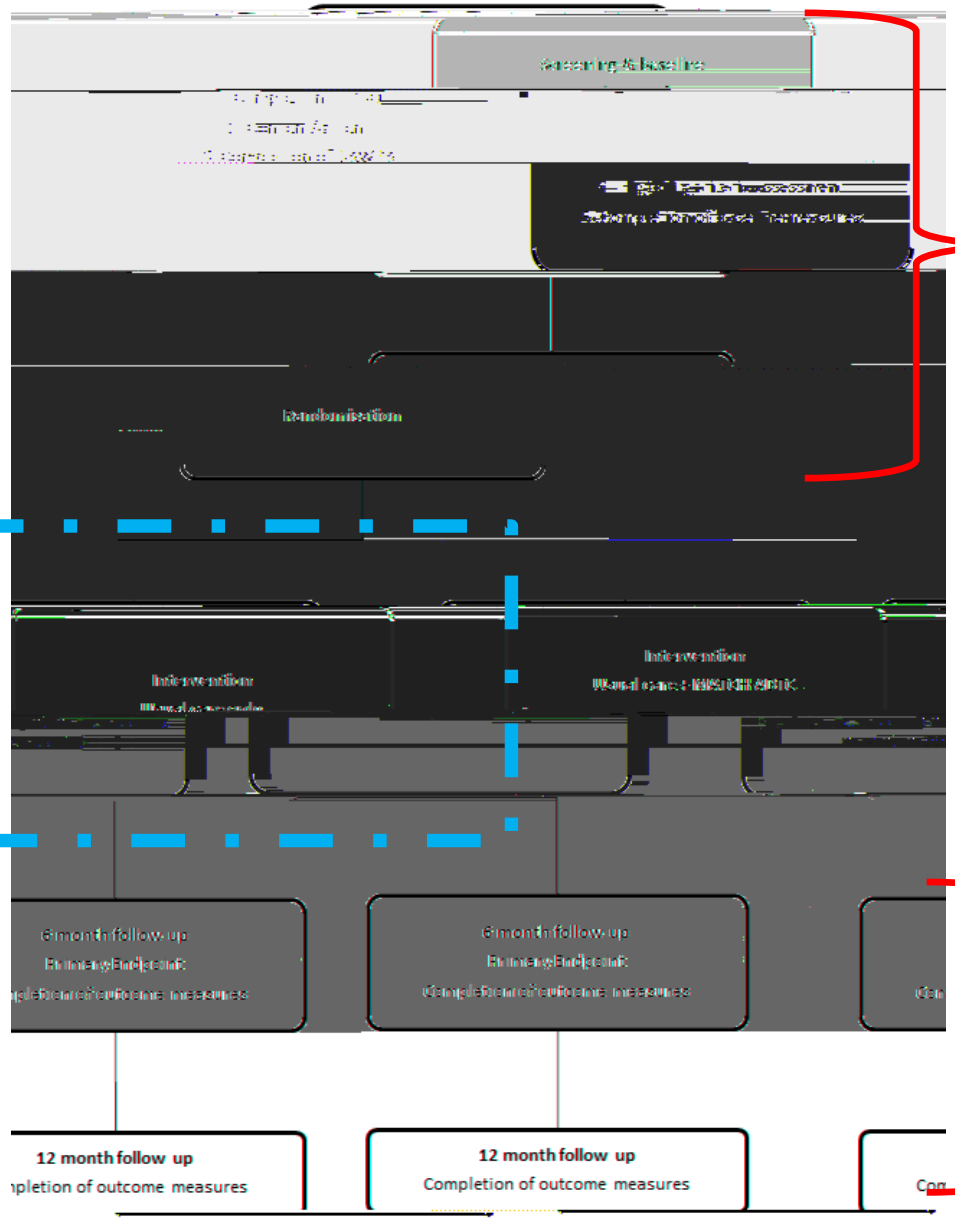
# Trial Summary

- 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



# Screening & baseline




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

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

# 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

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

# 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).

# 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

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

# Eligibility Criteria

Inclusion Criteria:

1. Attending clinics for the treatment of epilepsy.
2. Aged 3-

# Screening & baseline

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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

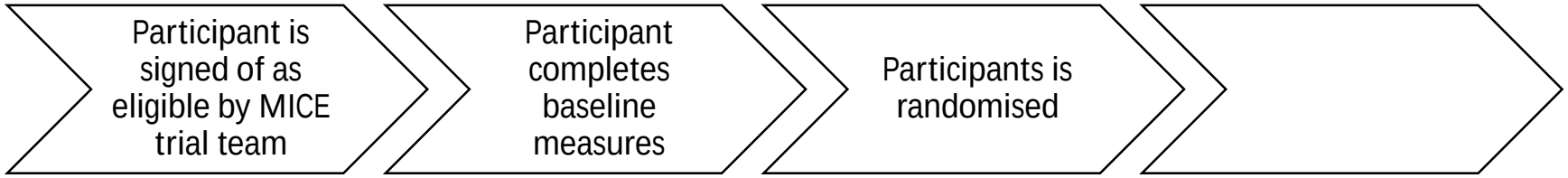
# Measures

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

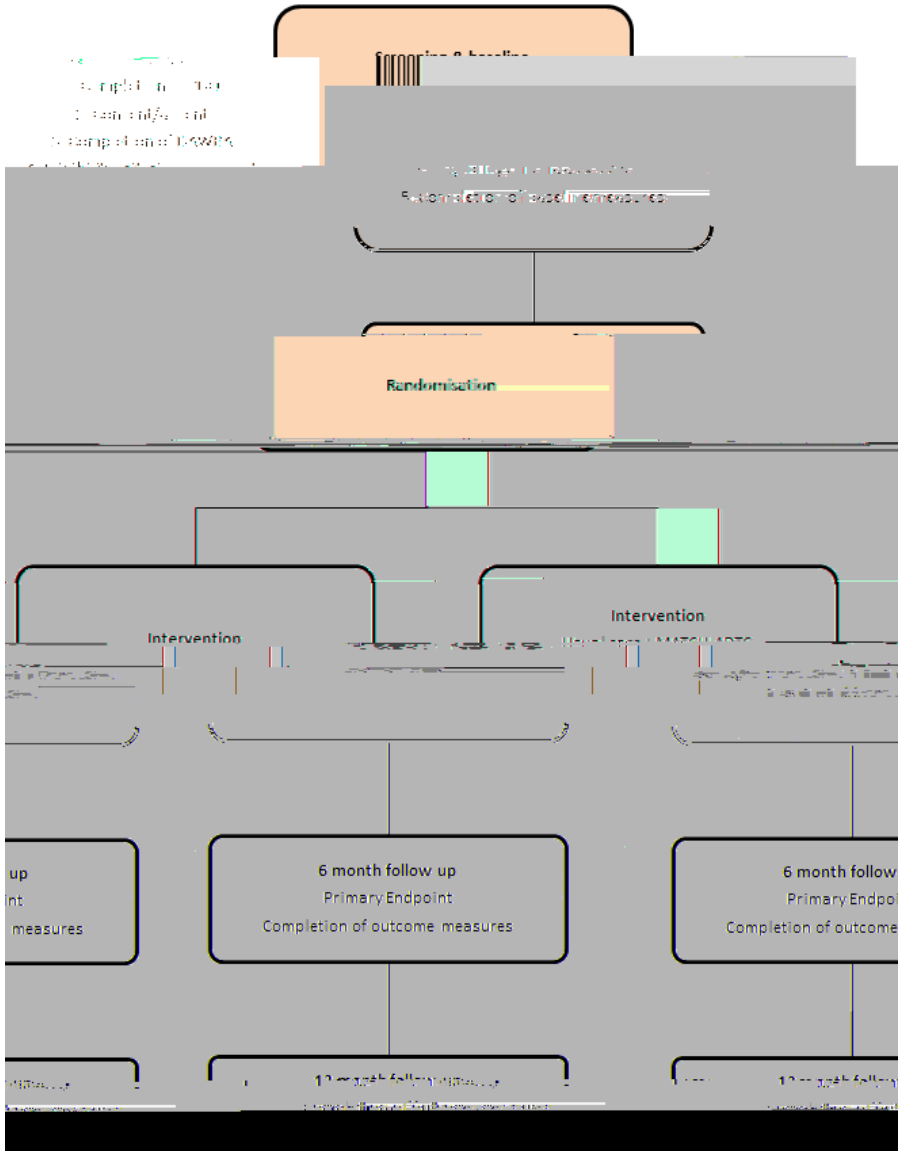
- Key Secondary Outcome Measures:
  - <u>Mental Health Measures:</u>
    - Strengths and Difficulties Questionnaire (SDQ)
    - Development and Wellbeing Assessment (DAWBA)
    - Revised Children's Anxiety and Depression Scale (RCADS ή M ך

# Randomisation

- 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



# Intervention

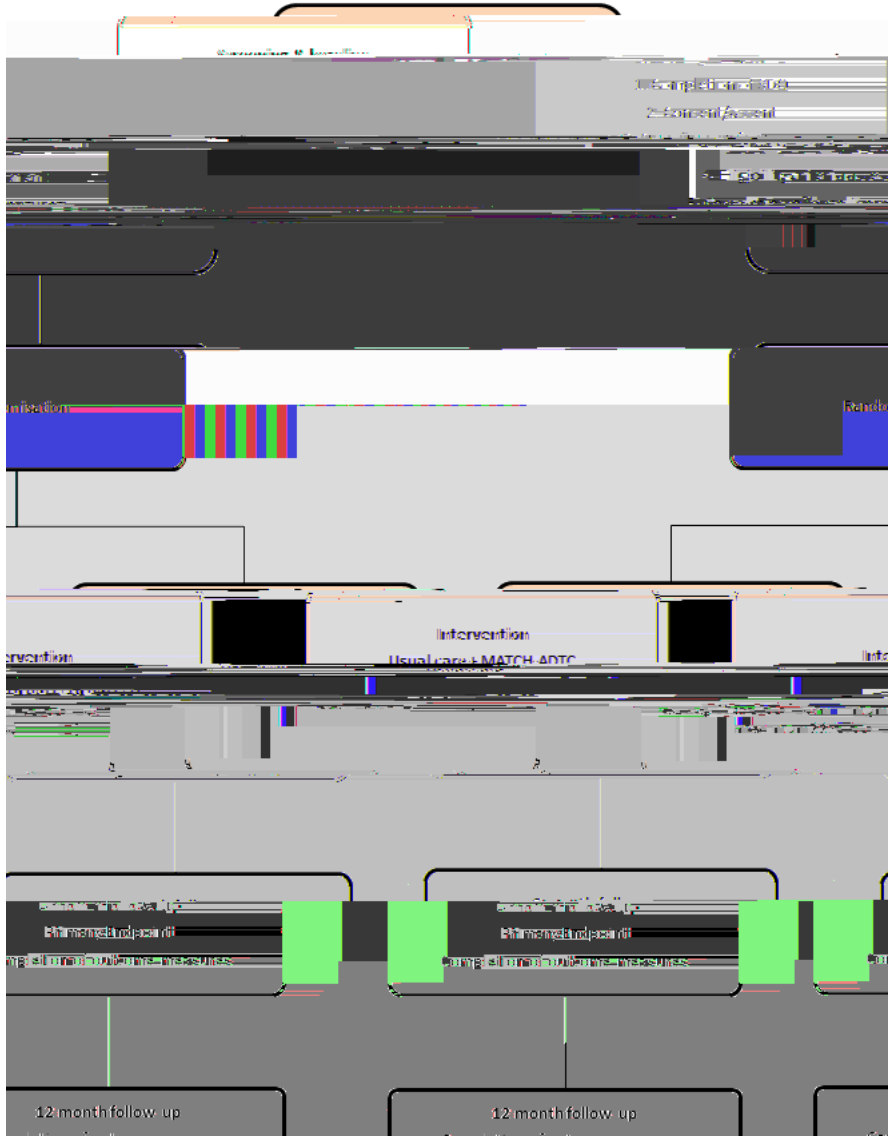
MATCH-ADTC + Usual Care

- 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



# 6 month / 12 month follow up

FYI only –

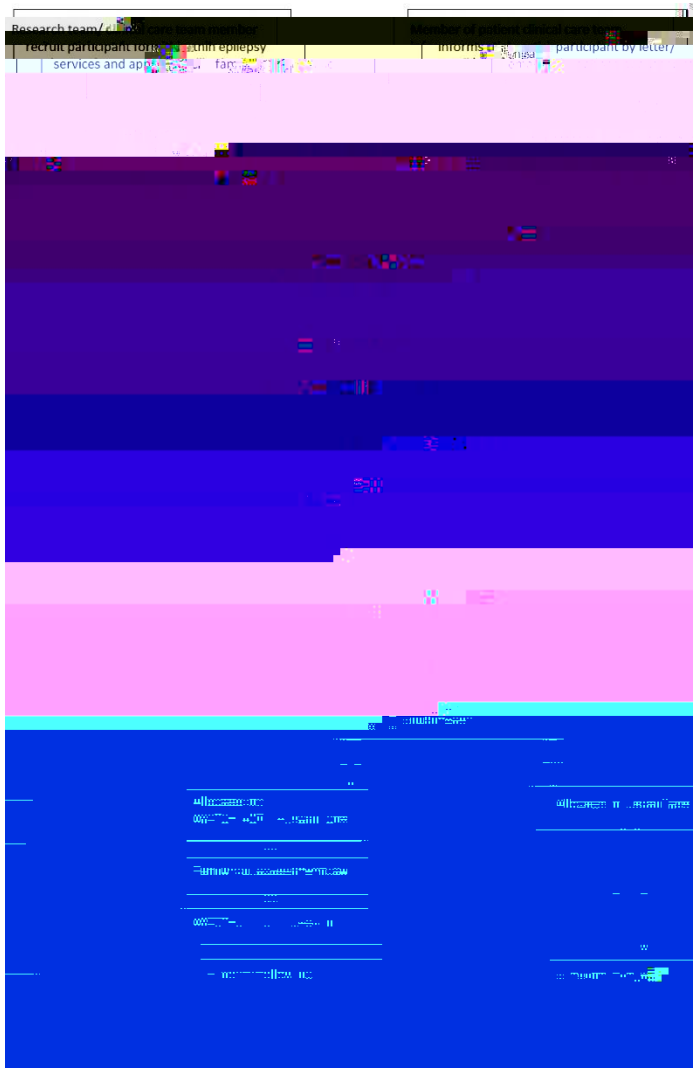
6 month

- 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.

# Contact details

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# Question and Closing Remarks