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Randomised study to explore the potential effectiveness of multisystemic therapy for child abuse and neglect (MST-CAN) versus usual care for families in contact with children's social care in England and Wales

Submission date	**Recruitment status**	[X] Prospectively registered
23/10/2024	Recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/10/2024	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
28/10/2024	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Multisystemic therapy for Child Abuse and Neglect (MST-CAN) is a licensed, evidence-based intervention working with families with at least one child on a child protection (CP) plan. It was developed to address the key risk factors for child abuse and neglect and for young people developing behavioural problems which may lead to future offending and violence.
As the evidence base for the MST-CAN intervention in Children's Social Care is not well established in the UK we propose a pilot study to:
1. Explore the feasibility of implementing and evaluating MST-CAN versus business as usual in children's social services departments.
2. Explore appropriate methods to maximise recruitment and retention.
3. Explore the appropriateness of parent versus practitioner versus school completion of the primary outcome.
4. Explore the collection of Children's Social Care outcomes.
5. Estimate the parameters needed to conduct a definitive trial.
6. Estimate the potential effect and cost of delivering the intervention.
7. Explore acceptability, implementation, retention, and barriers to participation with a specific focus on equality, diversity, and inclusion.

Who can participate?
Potential participants will be families with one or more children aged 6 to 17 years, subject to a Child Protection Plan for neglect, physical and/or emotional abuse in the participating local authority who meet the specified inclusion and exclusion criteria.

What does the study involve?
Potentially eligible families are referred for MST-CAN by their social worker, following a Child Protection conference or legal planning meeting. The family is assessed for suitability by the

MST-CAN team, the study is explained and the family is provided with an information sheet. If the family is ineligible they receive business as usual. If eligible, the consent forms are signed and they are referred to the evaluation team. If consent is not provided, the family receives business as usual. The evaluation team then make contact with the family and conduct the baseline assessment. The family are randomly allocated to MST-CAN or business as usual. The evaluation team maintain contact with families at 3-month intervals between baseline and 9-month follow-up.

What are the possible benefits and risks of participating?
At this stage, there are no direct benefits of participating. However, the study will provide information about how we work with families in the future. The research staff and organisations involved in this research have a lot of experience and we do not anticipate any risks of participating.

Where is the study run from?
The University of Kent and Teesside University (UK)

When is the study starting and how long is it expected to run for?
May 2024 to April 2027

Who is funding the study?
The Youth Endowment Fund (YEF) (UK)

Who is the main contact?
Prof. Simon Coulton, S.Coulton@kent.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
Project code: 26446

Study information

Scientific Title
Mixed method cluster randomised pilot trial of Multi-Systemic Therapy for Child Abuse and Neglect (MST-CAN) versus business as usual for families with at least one child subject to a child protection plan

Acronym
MST-CAN

Study objectives
Research questions addressed by the pilot trial are:
RQ1. To report on a two-armed cluster randomised pilot trial across three geographical areas in England and Wales.
RQ2. To measure pre-defined progression criteria to assess the feasibility of a definitive randomised controlled trial to evaluate efficacy
RQ3. To report on strategies to maximise recruitment and retention and how they should be implemented in a definitive study
RQ4. To report on the correlation between the primary outcome collected by parents and school to provide an indication of the most efficient method of collecting the primary outcome in a definitive trial for children aged less than 11 years.
RQ5. To report on the feasibility of collecting children's social care outcome data; re-referrals for child abuse and neglect, transitions from child protection to child in need, transitions from child protection to public law outline and/or looked after child, child placed outside the family home, time on child protection register and recommend appropriate children's social care outcomes for a definitive trial
RQ6. To estimate the mean family size and the family intra-class correlation coefficient (ICC) to inform a sample size calculation for a definitive efficacy study.
RQ7. To estimate the pre-post-test correlation of the primary outcome measure to inform a sample size calculation for a definitive trial.
RQ8. To assess the quality of data completion at each assessment point to provide an indication of outcome measure redundancy.
RQ9. To provide an initial estimate of the potential effect of Multi-Systemic Therapy for Child Abuse and Neglect (MST-CAN) versus business as usual (BAU) within 80% confidence intervals.
RQ10. To quantitively assess compliance with planned interventions in MST-CAN.
RQ11. To quantitively assess MST-CAN fidelity.

Success criteria and/or targets
In the pilot stage of the study, the researchers will report on the proportion of families who are eligible, consent, adhere to MST-CAN, are followed up at the primary end point, and complete the primary and secondary outcomes. These proportions will be compared with pre-defined criteria to aid decisions regarding the feasibility of a definitive efficacy RCT.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/07/2024, University of Kent Ethics Committee (Research and Innovation Support, Rutherford Annex, University of Kent, Canterbury, CT2 7NX, United Kingdom; +44 (0)1227 768896; researchculture@kent.ac.uk), ref: 1070

Study design
Two-arm mixed method cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Home, Internet/virtual, School, Telephone

Study type(s)
Other, Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Neglect, physical or emotional abuse

Interventions
Two-arm, mixed method cluster randomised controlled trial comparing MST-CAN versus BAU across three sites (four local authorities) in England and Wales. The unit of randomisation will be the family.

MST-CAN is a licensed, evidence-based intervention working with families with at least one child on a child protection (CP) plan, to reduce risks to children and support safe and effective parenting by addressing underlying barriers. They are introduced to the service by the MST supervisor and an allocated therapist who will work with them intensively for 6 to 9 months.

The control comparison is business as usual in the participating local authorities for a family with a child or children aged 6 to 17 years, subject to a Child Protection Plan for neglect and physical and/or emotional abuse.

Randomisation will employ random permuted blocks of variable size stratified by geographical site, Wrexham and Flintshire, Sandwell and Leeds. Random strings will be created for each site and deployed independently of the research team and each family will have an equal probability of being allocated to MST-CAN or business as usual.

Randomisation will be conducted once a referral has been received and after eligibility has been assessed, informed consent provided, and baseline assessment conducted. The researcher will enter the necessary details into an encrypted database and after the necessary data has been

checked an allocation code will be provided. This code will indicate the nature of the allocated group. The researcher will not be able to access randomisation codes in advance of randomisation. The participant will not be blind to the intervention.

Intervention Type
Behavioural

Primary outcome measure
Externalising behaviours assessed using the Strength and Difficulties Questionnaire (SDQ). The externalising behaviour score is computed as the sum of the conduct and hyperactivity domains of the SDQ. The pilot study will use the self-completed SDQ for those children aged 11 years or more and explore the correlation between parent and school-reported SDQ for those aged less than 11 years. This outcome will be assessed at baseline and again at month 9.

Secondary outcome measures
Child-related secondary outcomes:
1. Emotional symptoms and behavioural difficulties across several domains including conduct, hyperactivity, emotional regulation, peer relationships and prosocial behaviour, assessed using the SDQ
2. For those children aged 10 or more years, current delinquency assessed using the Self-Report Delinquency Scale (SRDS) over the previous 6 months
3. Wellbeing assessed using the short form, 10-item, KIDSCREEN10
4. Psychological health assessed using the Revised Child Anxiety and Depression Scale (RCADS-25)
5. Trauma-related psychological health assessed using the 8-item Child Revised Impact of Events Scale (CRIES-8)
6. For children in school, school belonging assessed using the School Connectedness Scale (SCS)
7. The frequency of school attendance, exclusions and suspensions, and criminal justice involvement over the previous 9 months, assessed using six questions derived from a Client Service Receipt Inventory (CSRI)

Parent-related outcomes:
1. Indicators of future child abuse and neglect following baseline measures including any further referrals, children's social care interventions or out-of-home placements over the 9 months from baseline to follow-up.
2. Family environment (relationships, conflict, and cohesion) assessed using the Brief Family Relationship Scale (BFRS)
3. Potential for child abuse and neglect assessed using the Parent-Child Conflict Tactics Scale (CTSPC)
4. General psychological health assessed using the short-form Depression Anxiety and Stress Scale (DASS-8)
5. Emotional regulation assessed using the Difficulties in Emotional Regulation Scale- Short Form (DERS-SF)
6. Post-traumatic stress symptomology assessed using the 20-item, Post-Traumatic Stress Disorder Checklist for DSM-V (PCL-5)

All child and parent outcomes will be assessed at baseline prior to randomisation and again at 9 months post-randomisation.

Process measures:
Interventions delivered as part of MST-CAN will be derived from weekly case summaries

currently completed by staff involved in delivering MST-CAN. Fidelity will be assessed from two perspectives, a parent-completed rating of therapists, Child Abuse and Neglect-Therapist Adherence Measure (CAN-TAM), which assesses working relationships and completion of overarching goals and a therapist rating of their supervisor's fidelity (Supervisor Adherence Measure (SAM) completed every 2 months that addresses four domains: fidelity to structure and process, adherence to principles of MST-CAN, analytical processes and clinician development.

Overall study start date
01/05/2024

Completion date
30/04/2027

Eligibility

Key inclusion criteria
1. Family has at least one child aged 6-17 years
2. Subject to a Child Protection plan with a report of abuse or neglect in the previous 6 months
3. Usually resident in the local authority
4. One parent and at least one child willing and able to provide informed consent. Consent will be taken from parents for themselves, and any child aged less than 16 years, children aged 16 years or more will provide their own consent

Participant type(s)
Service user

Age group
Mixed

Lower age limit
6 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
72 participants, 36 in each arm, across the 3 sites

Key exclusion criteria
1. A child who has already been placed away from home with no prospect of reconciliation
2. A child living independently
3. Current actual or suspected sexual abuse involving family members
4. Primary referral reason is a child's serious mental health issue
5. Referred child assessed as being actively suicidal or homicidal

Date of first enrolment
01/12/2024

Date of final enrolment
30/11/2025

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Wrexham County Borough Council
The Guildhall
Wrexham
United Kingdom
LL11 1AY

Study participating centre
Sandwell Children's Trust
The Wellman Building Dudley Road
Oldbury
United Kingdom
B69 3DL

Study participating centre
Leeds City Council
110 Merrion Way, Merrion House
6th Floor East
Children's Services Ict
Leeds
United Kingdom
LS2 8BB

Study participating centre
Flintshire County Council
Flintshire County Council
County Hall
Mold
United Kingdom
CH7 6NN

Sponsor information

Organisation
University of Kent

Sponsor details
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t.coleman-581@kent.ac.uk

Sponsor type
University/education

Website
https://www.kent.ac.uk/

ROR
https://ror.org/00xkeyj56

Funder(s)

Funder type
Charity

Funder Name
Youth Endowment Fund

Alternative Name(s)
YouthEndowFund, YEF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. A full report on the design, conduct, analysis, interpretation, and feasibility of progression to an efficacy trial.
2. If an efficacy trial is warranted a revised protocol for the design of that trial.
3. Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
All identifiable data collected will be done with explicit consent and limited to data to allow participants to be contacted for follow-up. Data linkage will employ a unique identifier where the link to identifiable information will be stored on an encrypted secure database. Once the final follow-up is completed, personally identifiable information will be deleted from the dataset held by the university and where consent has been granted for the study encrypted data will be transferred to the Youth Endowment Fund data archive. Data collection and management will be governed by a trial-specific Standard Operating Procedure agreed upon and approved by ethics.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (other)	V1.0	17/05/2024	28/10/2024	No	No