EVALUATION PROTOCOL

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

The University of Kent

Principal investigator: Professor SImon Coulton

YOUTH ENDOWMENT FUND

Pilot trial protocol template (includes a control group)

Evaluating institution: University of Kent

Principal investigator(s): Professor Simon Coulton

Project title[1]	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.
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Evaluation setting	Family
Target group	Families with at least one child, aged 6-17 years subject to a child protection plan.
Number of participants	3 sites, 4 local authorities, 72 families

Protocol version history

Version	Date	Reason for revision
1.0 [*original*]	17/05/24	

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Study rationale and background

Children who are neglected often have low school attendance and attainment, poor mental health, poor physical health linked to missed health appointments and poor nutrition (Lippard and Nemeroff, 2020) (Romano et al., 2014). They may also have experienced trauma and have behavioural difficulties including aggression and engagement in offending behaviour (Heim et al., 2010, Labella and Masten, 2018). Children may experience poor individual and home hygiene and inadequate housing. Limited supervision by parents and community risk factors may lead to contextual risks including criminal or sexual exploitation. Families may experience high levels of physical and emotional conflict, due to current or past domestic abuse, parent to child and young person to parent violence. Parents' own risk factors, such as past abuse and trauma and/or current substance use may impact their ability to attend to their children's emotional and physical needs. Parents often face challenges with inadequate income, unemployment, limited support networks and low community resources.

Multisystemic therapy for Child Abuse and Neglect (MST-CAN) 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. It builds on MST principles and the social ecological framework of Bronfenbrenner (Brofenbrenner, 1979), which recognises strengths and needs across individual, family, community and wider societal domains. The MST-CAN Theory of Change (figure 1) outlines how interventions to improve family functioning and parental mental health impact on improved safety for children, increased social supports for families, and improved engagement in education and relationships with statutory agencies, subsequently leading to reductions in abuse/neglect and improved child and adult functioning.

Studies from the US, UK, Australia, and Switzerland suggest that MST-CAN has a positive impact on both child and adult outcomes in a cost-effective way. A recent meta-analytic study (van der Put et al., 2018) supported the effectiveness of MST-CAN in preventing and reducing child maltreatment. In the UK, the Early Intervention Foundation guidebook gave MST-CAN a rating of 3 out of 5 as at least one RCT or rigorous evaluation showed evidence of a short-term positive impact on child outcomes, indicating some evidence of efficacy. It also noted significant impact of MST-CAN in the areas of child maltreatment prevention, children's health and wellbeing support, and crime, violence, and anti-social behaviour prevention. Since the programme was reviewed by the Early Intervention Foundation, further RCT evidence has been published (Schaeffer et al., 2021) supporting the effectiveness of MST-CAN, specifically for parents with problematic substance use. NICE

guidance on child abuse and neglect also recommends MST-CAN as an evidence-based treatment for families where there is physical abuse and neglect.

MST-CAN was delivered as a pilot in the UK from 2009, initially in Cambridgeshire and then Leeds. The pilot evaluation used a quasi-experimental design (Cottrell et al., 2019) and considered feasibility and subsequent outcomes at month 12 compared to a matched controlled sample. It found that MST-CAN was feasible to implement in the UK with high rates of recruitment and 90% treatment adherence. Positive outcomes were found in relation to reduced PTSD symptoms and improved mental health for children and adults, increased social supports, reductions in inconsistent discipline and psychological aggression by carers. Although there were also fewer days in care for the MST-CAN group, this was not statistically significant. Since then, MST-CAN has successfully expanded in the UK, Australia, Netherlands, Norway, and Switzerland. There is clear evidence that MST-CAN is feasible to implement across different countries and communities and there is emerging evidence of effectiveness, with the need for further evaluation specific to the UK social care environment using scientifically rigorous methods. There is also evidence to suggest that these changes impact longer term outcomes for children, including reductions in youth and family violence (Sousa et al., 2011).

Families referred to MST-CAN have one or more children aged 6 to 17, subject to a Child Protection Plan for neglect, physical or emotional abuse. For some families this may be their 'last chance' before the removal of children into care. MST-CAN is delivered in home, school, and community settings at times convenient for the family, including evenings and weekends and engagement issues are viewed as the responsibility of the MST-CAN team and not the family. There is a 24-hour on-call system to respond to family crises as needed. MST-CAN aims to address risk factors through working intensively to address families' practical and therapeutic needs and create sustainable change in partnership with other services.

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:

- Explore the feasibility of implementing and evaluating MST-CAN versus business as usual in children's social services departments.
- Explore appropriate methods to maximise recruitment and retention.
- Explore the appropriateness of parent versus practitioner versus school completion of the primary outcome.
- Explore the collection of Children's Social Care outcomes.

- Estimate the parameters needed to conduct a definitive trial.
- Estimate potential effect and cost of delivering the intervention.
- Explore acceptability, implementation, retention, and barriers to participation with a specific focus on equality, diversity, and inclusion.

To conduct a scientifically rigorous study we will conduct a randomised controlled pilot trial with randomisation stratified by the three geographical areas participating[2]. As MST-CAN is delivered to families we propose a cluster trial with the family the unit of randomisation.

Intervention

MST-CAN

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. MST-CAN teams include a supervisor, three therapists, a family resource specialist and input from a psychiatrist/nurse to provide an assessment of family mental health needs and support an appropriate treatment plan. Families are referred by their social worker, following a CP conference or legal planning meeting. They are introduced to the service by the MST supervisor and an allocated therapist who will work with them intensively for six to nine months. Therapists meet family members at home to seek both children and adults' views of what they want to change, assess strengths, need, and develop clear safety plans. This then contributes to an analysis of multisystemic factors contributing to abuse and neglect. Goals for treatment are developed in partnership with families and professionals. Sessions take place a minimum of three times weekly, in homes, schools or community settings, with additional contact as needed. Therapists also engage with extended family and friendship networks. An on-call rota provides 24/7 crisis support as needed throughout treatment. The family resource specialist supports families with practical barriers (e.g. finance/housing). Therapy may be individual adult or child-focused, or family-focused, depending on the clinical concern being addressed (individual, family, or community) and the priority concerns for each child and family.

Parents receive parenting and family communications skills training and couples' therapy where appropriate. If anger management is an issue for parents then CBT is provided, for

[2] At this stage the three participating centres are Flintshire and Wrexham, Leeds, and Sandwell .

children their needs are assessed and an appropriate treatment plan developed. When problematic substance abuse is identified as a contributing factor impacting on a parent's ability to safely care for their children, a plan for addressing this is developed in partnership with health providers. The MST-CAN therapist can offer Reinforcement Based Therapy to reduce or eliminate substance abuse and support the parent to replace this dependence with positive activities and an appropriate support network. Where parents or children have experienced past trauma, for example childhood or domestic abuse, and are exhibiting PTSD symptoms, therapists provide 12-20 weeks of Trauma Focused CBT or Prolonged Exposure Therapy. These address underlying trauma and reduce symptoms which impact on parents' ability to safely parent or children's ability to engage in positive relationships and education. Parents are encouraged to take responsibility for their role in the abuse/neglect throughout treatment as research indicates that when parents place responsibility for abuse on the child, the risk for re-abuse is high (Bradley and Peters, 1991). Near the end of treatment, a 'Clarification of Abuse' process is developed (Lipovsky et al., 1998) with parents, which supports them in taking responsibility for their past actions and creates a firm foundation for tackling future issues as they arise. This involves the parent(s), writing a letter of responsibility/apology to their children and reading it to the whole family, supported by the therapist.

Throughout MST-CAN treatment there is a focus on creating sustainable change for children and families in partnership with statutory agencies as well as strengthening families' informal network of supports, including extended family and friends. All teams will be employed by the local authority or Children's Trust and have strong links to a network of statutory services and relevant voluntary and community sector partners. All families will have a social worker during MST-CAN and the therapist will work closely with them and the family in developing a sustainability plan to support sustained change for when treatment ends. This will be planned through joint visits, supervision sessions and clear communication leading up to case closure. Families themselves will have an accessible version of the plan and it will also be uploaded to the social care database. The overall aim for families to safely step down to Child In Need status following MST-CAN where possible. Any referral to other services, will be planned with the family, social worker, and psychiatrist/nurse where appropriate. These could include mental health services for adults or children, special educational needs provision or linking parents to support for training or education. For a small number of families their children may remain on a child protection plan until further concerns are resolved. For some families, social care may end their involvement and families will have continued support from informal networks and universal services.

Teams will receive thirteen days of initial training from MST-CAN consultants covering abuse and neglect, trauma, family conflict and substance use treatments, with supervisors receiving

an additional two days of training. Teams will then receive weekly clinical consultation and quarterly 'booster' training from their MST-CAN Consultant for further skill development. MST-CAN consultants are experienced MST clinicians, qualified to doctoral/master's level in psychology or social work. All training has been adapted to ensure it meets the needs of staff and families from a range of cultures and communities across the UK. This is in addition to local training requirements, for example safeguarding. Supervisors will be professionals qualified in applied psychology, social work, nursing, family therapy or another relevant discipline, with significant relevant post-qualification experience and will provide weekly supervision. Therapists will hold a relevant professional degree and Family Resource Specialists will have relevant professional experience and be recruited from the local community. Mental health input will be provided by a psychiatrist or Nurse Prescriber. The intervention will be delivered between December 2024 and October 2026 The MST-CAN theory of change is highlighted in figure 1.

Business as usual control

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

Our pre-pilot consultation (Green et al., 2023) found that 'service as usual' amongst local authorities aims to establish family needs and provide an individualised, tailored approach. It also found that there is a value for evidence-based provisions of care and support, and a concerted effort to coordinate a multi-agency approach via a range of interventions – including efforts for more evidenced based interventions focused on children, parents, and family support. There are indications that 'in recent years many local areas have made significant progress in how they support families' ((Department for Education, 2023) p. 36); however, 'service as usual' in Wales and England for vulnerable children and their families has been found to vary significantly. Ellison and Renton's (Ellison and Renton, 2018) enquiry into accumulating evidence of English children's welfare systems struggling to meet increasing and more complex demand, highlighted that protecting children has become a postcode lottery. They found that access to support varied across the country with many Directors of Children's Services highlighting variable thresholds for services. Our pre-pilot consultation (Green et al., 2023) also highlighted concerns about a fragmented landscape of service provision which included varying thresholds, limited accessibility of available services, inconsistent multi-agency working, variation in service provision across child, parent, and family-focused interventions, and limited resources or available provision to cover demand. Further supporting a disjointed perception of 'service as usual' in Wales and England, the Department of Education highlights that 'too often the system is not succeeding in providing

the right help at the right point' ((Department for Education, 2023) p. 12) and that 'there is large variation in the amount and quality of support available at a local area level, with varying thresholds to access support' ((Department for Education, 2023) p. 36). Therefore, though there are good intentions to provide effective and timely interventions, limited resources and opportunities limit consistency in the provision of 'service as usual' across England and Wales.

Figure 1: MST-CAN Theory of Change

Population

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Families with child(ren) aged 6-17 years on child protection plan with abuse or neglect reported in the past 6 months. Those not included are children who have been placed away from home or is living independently, current sexual abuse within the family, serious child mental health issue or young person actively suicidal.

Population Need

Estimates indicate 52500 families in England and Wales are subject to child protection plans. Of these, 48% include issues around parental neglect and 45% around neglect. 52% of child abuse and neglect cases include an element of parental substance use.

Inputs

Assess safety and risk of neglect at intake and ongoing

Explore behaviour on referral, treatment success and barriers to treatment progress

Functional assessment of aggression and family conflict. Parenting assessment and beliefs about parenting.

Explore trauma and its impact, child and adult mental health functioning, substance use.

Ensure fidelity to the treatment model.

Activities

Initial safety assessment, practical needs assessment and ongoing monitoring of family conflict.

Case management to address family housing and financial need.

Assessment of factors driving child abuse and neglect to highlight where to focus intervention.

Assessment of factors that act as barriers to intervention compliance.

Functional assessment to identify and recognise the sequence associated with family conflict, identifying where interventions should occur and motivating families to change.

Delivery of evidence-based interventions to address parenting skills, mental health needs and anger management. Including CBT, trauma informed child therapy, substance misuse treatment, family therapy and parenting skills.

Ongoing training and rigorous supervision.

Outputs

Increased capacity of parent/ carers to provide safety for their children. Increased capacity for family members to interact and solve problems without conflict.

Targeting the correct risk factors demonstrates rapid improvement in behaviour and timely treatment completion.

Reduction in inappropriate parenting, verbal and physical aggression and neglectful parenting. Reduction in reabuse.

Improved parent/ carer and child mental health and functioning.

Intensive supervision results in improved clinical competence and fidelity to the MST-CAN model.

Outcomes

Increased safety, wellbeing, and stability for families.

Improved child behaviour.

Completion of treatment with all target goals met.

Reductions in re-referral for abuse or neglect. Reduced out-of-home placements.

Improved family environment. Improved mental health functioning and reduced family conflict.

Improved social support for parents and children. Improved school functioning and behaviour.

Impact

Child(ren) experiences improved wellbeing and more prosocial behaviour.

Child(ren) has improved mental health, greater emotional regulation and fewer externalising behaviours.

Child(ren) reduce their risk-taking behaviour, manages anger more appropriately and reduces their involvement in offending behaviour.

Child(ren) can identify and engage with services that meet their needs.

Child(ren) have a positive future outlook.

Child(ren) develops meaningful relationship with family.

Child(ren) experience a greater sense of belonging.

Preconditions

The focus is on providing treatment to the entire family to overcome parenting challenges. Frontline practitioners and senior managers trained in the MST-CAN model. Ongoing regular supervision. Access to clinical input from therapists and psychiatrist to play a role in delivering the intervention and supporting and supervising staff within the services. Staff are skilled in completing functional assessments, safety planning, and family needs assessment. Provision of services according to need, including parenting training, psychotherapy, anger management, family therapy and substance use treatment.

Research questions.

Research questions for 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 for 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 potential effect of MST-CAN versus 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, we 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.

Table 1: Proposed progression criteria

Criteria			
Proportion of potential families who are eligible.	70%	50%	40%
Proportion of eligible families who consent.	70%	50%	40%
Proportion of consenting families who adhere.	80%	60%	50%
Proportion following up at month 9.	80%	70%	60%
Proportion with complete primary outcomes.	95%	85%	75%
Proportion with complete secondary outcomes.	80%	70%	60%

In addition to proportions we will assess data completeness for each outcome instrument. A threshold of 60% complete will be used to assess whether an outcome instrument should be included in any future efficacy trial.

Methods

Pilot trial design

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.

Randomisation

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 independent of the research team and each family will have 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 necessary details into an encrypted database and after necessary data has been checked an allocation code will be provided. This code will indicate the nature of 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.

Participants

Potential participants will be families with one or more children aged 6 to 17, 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.

Inclusion criteria

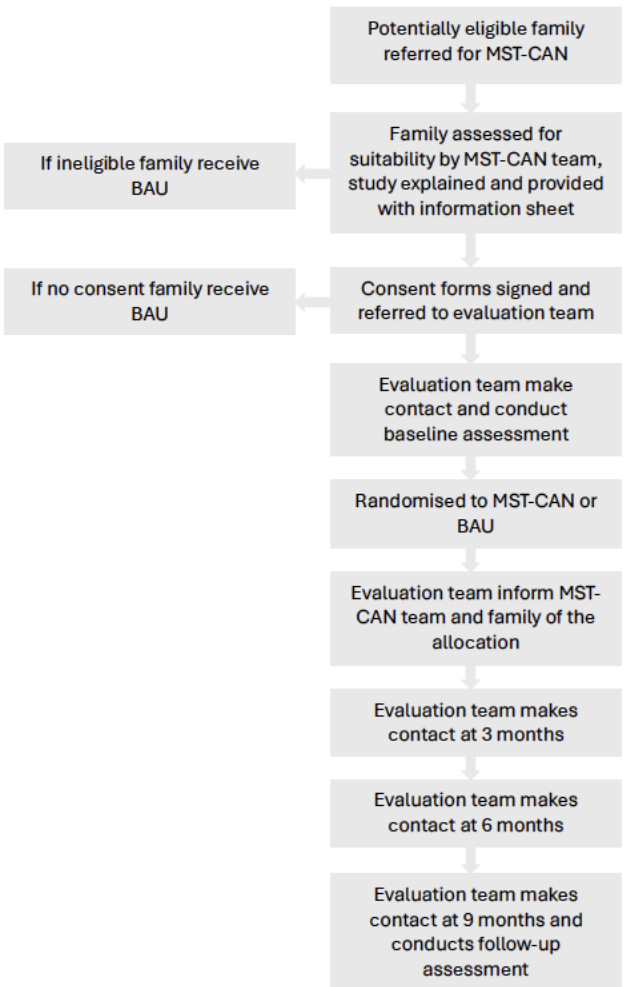
1. Family has at least one child aged 6-17 years.
2. Subject to a Child Protection plan with a report of abuse or neglect in the previous 6 months.
3. Usually resident in the local authority.
4. One parent and at least one child willing and able to provide informed consent. Consent will be taken from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

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.

Participant flow through the trial



Sample size

In the pilot study we will recruit 72 participants, 36 in each arm, across the 3 sites, with the expectation that we will successfully follow-up 58 at month 9. This will allow for exploration of key parameters needed to confirm sample size calculation for the efficacy study. It is

sufficient to allow estimation of two-sided 95% CIs around the proportions of eligible, consenting, adhering and followed-up at month 9 in each arm of the study with half-widths less than 0.15. It exceeds the 30 per group recommended by Lancaster et al (Lancaster et al., 2004) and the 35 per group recommended by Teare et al (Teare et al., 2014) for estimating the SE of a primary outcome with sufficient precision, including accounting for any variation across site, where 12 participants per arm per site is recommended.

Outcome measures

To ensure outcomes are accessible to a wide range of potential participants we will make outcomes available in English and Welsh and provide interpreters and translations for other languages. As we anticipate a higher level of intellectual disability than the general population, we will seek the advice of specialists in how outcome tools can be presented to meet the needs of the target population; this will include using different fonts, colours, and the restriction on the amount of text presented on each page. All outcome tools will be agreed with our advisory panel prior to use and piloted with families already in receipt of MST-CAN.

Key demographic variables will be collected at baseline, these include age, sex, ethnicity, and index of material deprivation (IMD) derived from the participants postcode and converted to IMD using the IMD lookup tool:

https://geoconvert.ukdataservice.ac.uk/help/faq.html.

Primary outcome

The primary outcome will relate to the children within the family. Externalising behaviours will be assessed using the Strength and Difficulties questionnaire (SDQ; (Goodman, 1997)). This outcome is highly correlated with current and future offending behaviour. The externalising behaviour score is computed as the sum of the conduct and hyperactivity domains of the SDQ. The outcome is widely used and has demonstrated excellent validity and moderate reliability in adolescent populations (Goodman, 2001). The SDQ is suitable for self -completion by those aged 11-17 years and those with mild learning disabilities (Law and Wolpert, 2014), in the pilot study we 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.

Child related secondary outcomes

The SDQ will also be used to assess emotional symptoms and behavioural difficulties across several domains including conduct, hyperactivity, emotional regulation, peer relationships and prosocial behaviour.

For those children aged 10 or more years we will assess current delinquency using the Self-Report Delinquency Scale (SRDS; (Smith and McVie, 2003)) over the previous six months. This 19-item questionnaire has established psychometric properties (Fonagy et al., 2018) in this population and has a strong correlation (R = 0.95) with police charges (McAra and McVie, 2007).

Wellbeing will be assessed using the short form, 10-item, KIDSCREEN10 (Ravens-Sieberer et al., 2014), this valid-reliable instrument suitable for completion by children aged 7 years or more demonstrates excellent reliability and validity in the target population (Cronbach's α 0.82).

Psychological health will be assessed using the Revised Child Anxiety and Depression Scale (RCADS-25; (Ebesutani et al., 2017, Ebesutani et al., 2012). This 25-item scale assesses both depression and anxiety and both the child and parent completed version have established reliability and validity. Trauma related psychological health will be assessed using the 8-item Child Revised Impact of Events Scale (CRIES-8; (Perrin et al., 2005). This validated instrument is widely used as a screening tool to identify Post Traumatic Stress Disorder in children and adolescents.

For children in school we will assess school belonging using the School Connectedness Scale (SCS; (Brown et al., 2000)). This 16-item scale assesses school connectedness across three domains: belief, belonging and commitment. The scale has established validity and reliability (Cronbach's α 0.86) and higher school connectedness is associated with greater school attendance and better school outcomes.

We will use six questions derived from a Client Service Receipt Inventory (CSRI;(Coulton et al., 2022)) to assess the frequency of school attendance, exclusions and suspensions, and criminal justice involvement over the previous 9-months. Client Service Receipt Inventory methods are an established and valid form of assessing participant resource use in randomised controlled trials and can be adapted for the target population (Knapp and Beecham, 1990).

Parent-related outcomes

We will collect 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 nine months from baseline to follow-up.

We will include a measure of family environment that assesses relationships, conflict, and cohesion via the Brief Family relationship Scale (BFRS; (Fok et al., 2014)). We will assess the potential for child abuse and neglect using the Parent-Child Conflict Tactics Scale (CTSPC; (Straus et al., 1998). This 22-item questionnaire assesses the frequency of parent to child conflict and includes items on non-violent discipline, psychological aggression, physical assault and neglect.

General psychological health will be assessed using the short form Depression Anxiety and Stress Scale (DASS-8; (Ali et al., 2022) and emotional regulation using the Difficulties in Emotional Regulation Scale- Short Form (DERS-SF; (Hallion et al., 2018)). Post-traumatic stress symptomology will be assessed using the 20-item, Post-Traumatic Stress Disorder Checklist for DSM-V (PCL-5; (Bovin et al., 2016)). This instrument takes 3 -minutes to complete and has established psychometric properties for the screening of probable PTSD and progression of PTSD symptoms over time.

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), that assesses working relationships and completion of overarching goals and a therapist rating of their supervisor's fidelity (Supervisor Adherence Measure (SAM); www.msti.org/sam) completed every two months that addresses four domains; fidelity to structure and process, adherence to principles of MST-CAN, analytical processes and clinician development.

Table 2: Outcomes and time of assessment

Outcome	No of items	Baseline	Nine months
Child Primary			
Strength and Difficulties (SDQ)[1]	25	✓	✓
Child Secondary			
Wellbeing (KIDSCREEN 10)	10	✓	✓
Psychological Health (RCADS)	25	✓	✓
Post Traumatic Stress Disorder (CRIES-8)	8	✓	✓
Receipt Inventory (CSRI)	6	✓	✓
School Connectedness (SCS)	16	✓	✓
Self-reported delinquency (SRDS)[2]	19	✓	✓
Parent Secondary			
Family environment (BFRQ)	16	✓	✓
Psychological Health (DASS-8)	8	✓	✓
Emotional Regulation (DERS-SF)	18	✓	✓
Parent-Child Conflict (CTSPC)	22	✓	✓
Post-Traumatic Stress Disorder (PCL-5)	20	✓	✓
Process measures			
Social Service involvement		✓	✓
Sessions planned and delivered		✓	✓
Supervisor fidelity (SAM)	16	✓	✓
Therapist adherence (CAN-TAM)	18	✓	✓

[1] We will compare the SDQ collected from three sources; parent, practitioner and school.
[2] This will be collected for children and young people aged 10 or more years at baseline

Methods and data collection

Quantitative data will be collected from parents and children at baseline before randomisation and then again at 9-months post-randomisation. In order to maximise retention we will implement a number of retention strategies highlighted in a systematic review of retention strategies in randomised controlled trial (Brueton et al., 2014). We will be flexible in the methods used to collect quantitative data, considering the family's preference; face-to-face or using on-line video conferencing. Trained and experienced research staff will be available to provide support on the completion of questionnaires and where necessary we will provide validated instruments in the family's primary language or provide access to an interpreter. Families will be provided with a £50 pre-paid debit card for the completion of questionnaires at each time-point as a recognition of the time they have spent completing the instruments. Research staff will maintain contact with families at 3-month intervals between baseline and 9-month follow-up.

During the set-up phase of the trial qualitative work will be undertaken with a sample of families involved in child protection proceedings, families involved in MST-CAN and children's service professionals to identify the best methods of presenting the study to potential participants and methods to engage potential participants in the recruitment process and retain them throughout the study. Identified methods will be implemented in and inform the pilot trial design.

To address the research questions in depth, the qualitative aspect of the work will involve the collection of narrative accounts from a range of individuals using semi-structured interviews lasting 45-60 minutes. These will be collected from parents and young people participating and those who withdraw, staff involved in the programme delivery and key stakeholders delivering business as usual. Professionals and families will be sampled purposefully to provide diversity in terms of geographical site, family composition, gender identity and ethnicity.

Data analysis

To address the key questions in the pilot study we will synthesise data from both quantitative and qualitative aspects of the research.

RQ1 -Findings from the pilot study will be presented in accordance with the CONSORT statement for pilot studies.

RQ2 - We will estimate likely proportions of participants who are eligible, who consent, the proportion followed-up at 9-months, the proportion who adhere and the data completeness of primary, secondary outcomes and process outcomes. Each of these will be assessed against progression criteria agreed a priori

RQ3 – We will leverage the qualitative work planned under IPE Q2, specifically targeting retention and barriers. By conducting semi-structured interviews with 5-10 parents who initiated but did not continue the intervention, we aim to identify the underlying reasons for dropout and gather insights that could inform improvements in retention strategies. Additionally, interviews with another 5-10 parents who declined to participate will help us understand barriers to entry into the study. The data collected from these interviews will help refine recruitment techniques to enhance engagement and consent rates. We will report on strategies identified to maximise recruitment and retention from our qualitative work and where appropriate include them in the pilot study.

RQ4 - We will conduct a correlation analysis to explore the relationship between parent and school completed SDQ. First exploring the distribution of the outcome at each time-point and then selecting the appropriate parametric or non-parametric correlation approach. This will inform a decision regarding the relative utility of each approach and the source of the primary outcome for a definitive trial.

RQ5 - We will integrate questions relevant to the feasibility of collecting children's care outcome data into our interviews with 10-15 social service professionals, as planned under **IPE Q1**. These conversations will focus on current data collection practices, challenges faced, and potential areas for improvement regarding the tracking and reporting of outcomes such

as re-referrals for child abuse and neglect, transitions in child protection status, and the time on child protection plan. By tailoring these interviews to include specific questions on data management and reporting, we will gain insights into the practical aspects of data collection, which will help inform the design and implementation of robust data tracking mechanisms for the definitive trial.

RQ6 – We will present descriptive statistics on family composition; number of parents, children, mean age, gender, and ethnicity. We will estimate the harmonic mean (H) of family size to incorporate into a sample size calculation by estimating the design effect.

*Design effect = 1 + (H*ICC)*

The intra-class correlation coefficient (ICC) for the primary outcome will be estimated using the following method.

$$\text{ICC or } \rho = \frac{\text{Between cluster variability}}{(\text{Within cluster variability} + \text{Between cluster variability})}$$

Using statistical notation, this is depicted as:

$$\text{ICC or } \rho = \frac{s_b^2}{(s_b^2 + s_w^2)},$$

s_b^2 = between cluster variance

s_w^2 = within cluster variance

RQ7 - We will present a descriptive analysis of outcomes, including estimates of central tendency and precision, at each time-point broken down by allocated group and site. We will examine the distribution of the primary outcome, externalising behaviours at baseline and month 9 and estimate the pre- post-test correlation using an appropriate parametric or non-parametric correlation coefficient.

RQ8 - We will present the proportion of items on each outcome designated as missing at each time-point to aid an interpretation of data redundancy, if the missing data for any outcome exceeds 40%, we will explore the utility of including the outcome in any definitive trial.

RQ9 - Inferential analysis at the pilot stage will focus on the primary outcome at month 9. After conducting diagnostic plots and selecting an appropriate regression approach, adjusting for baseline values and stratification variables as covariates, we will present the marginal effect, mean difference between the MST-CAN and BAU groups and 80%

confidence intervals. This analysis will provide an estimate of potential effect and aid any decision about whether conducting a definitive study is warranted.

RQ10 - Interventions delivered as part of MST-CAN will be derived from weekly case summaries currently completed by staff involved in delivering MST-CAN, a description of interventions delivered, and adherence will be provided**.**

RQ11 - Fidelity in the MST-CAN group will be assessed from two perspectives, a parent completed rating of therapists, CAN-TAM, that assesses working relationships and completion of overarching goals, and a supervisor rating of fidelity (SAM) completed every two months that addresses four domains; fidelity to structure and process, adherence to principles of MST-CAN, analytical processes, and clinician development. We will present mean scores and 95% confidence intervals for each outcome at each time-point to provide an estimate of intervention fidelity.

Implementation and process evaluation

Research objectives.

A qualitative analysis will be used to address key objectives addressing the implementation, process and equity associated with the pilot. This will focus on assessing the extent to which the intervention has been implemented as intended including factors that facilitate or hinder implementation, the acceptability of the intervention from the perspectives of participants, staff and families and identify positive and negative experiences associated with the intervention and when they occur.

Research questions.

IPEQ1 To qualitatively explore BAU across each site.

IPEQ2 To qualitatively explore barriers, acceptability, implementation, and retention from the perspective of participants, practitioners, and stakeholders.

IPEQ3 To qualitatively explore issues relating to equality, diversity, and inclusion from the perspectives of participants, practitioners, and stakeholders.

Table 3: IPE methods overview

IPE methods overview

IPE Question	Data collection methods	Participants/ data sources (type, number)	Data analysis methods	Research questions addressed	Implementation / logic model relevance
BAU Control (IPE Q1)	Qualitative interviews with relevant stakeholders (i.e., service leads, social workers)	10-15 semi-structured interviews with stakeholders. Purposive sampling to obtain variety by site, gender identity, ethnicity	Transcription and inductive analysis to allow themes to emerge naturally	Explore the nature of and variation in BAU across local authorities	Identify what the comparison control group interventions are comprised of
Barriers (IPE Q2)	Qualitative interviews with parents who do not consent to participate.	5-10 semi-structured interviews with parents who do not consent to intervention. Purposive sampling to obtain variety by site, family composition, gender identity, ethnicity	Transcription and inductive analysis to allow themes to emerge naturally	Explore barriers to participation in the intervention and who this occurs for	To understand how barriers to participation can be lowered or removed
Acceptability (IPE Q2), Implementation (IPE Q2) and EDI (IPE Q3)	Qualitative interviews with parents, young people, and practitioners involved in receiving/providing the intervention	10 parents, 10 young people, and 10 practitioners, involved in the intervention. Purposive sampling to obtain variety by site, family	Transcription and inductive analysis to allow themes to emerge naturally	Examine perspectives on intervention acceptability. Explore implementation successes and challenges.	Identify any potential issues with acceptability. Identify any potential modifications that can be made to

		composition, gender identity, ethnicity		Explore barriers in the reach and significance of the intervention for underrepresented groups	maximise the impact of the intervention. Identify any potential modifications that can be made to improve the reach and significance of the intervention for underrepresented groups
Retention (IPE Q2)	Qualitative interviews with parents who dropped out of the intervention	5-10 parents who began the intervention but dropped out. Purposive sampling to obtain variety by site, family composition, gender identity, ethnicity	Transcription and inductive analysis to allow themes to emerge naturally	Explore barriers to continued participation in the intervention	Identify any potential modifications that can be made to improve the retention of the intervention
TOTAL		**50-65**			

Research Methods

The qualitative component of the study will be purposive and include interviews with 10 parents engaged in MST-CAN, 10 young people engaged with MST-CAN, 10 MST-CAN intervention delivery staff, 10-15 key stakeholders, such as child protection professionals and social care managers involved with BAU, 5-10 parents who declined involvement in MST-CAN as an intervention, and 5-10 interviews with parents who dropped out of MST-CAN intervention. These interviews will answer **IPE Q1**, **Q2**, and **Q3**. Participants will be chosen purposively to provide diversity in terms of service and age and ensure appropriate participation by gender identity and ethnicity. Although a total sample of 50 to 65 interviews

will be the aim, the sample size considerations of the qualitative component are driven by the need to achieve data saturation, and this needs to be judged in practice rather than stated in advance. Semi-structured interviews will be conducted between month 9 and month 25, either online or face-to-face, as appropriate. A research associate will interview each participant once, and within that interview we will explore each of the associated IPE research questions (see Table 3). There will be a focus on sampling diverse voices, including those from multi-agency partners, to explore equity and inclusion.

All interviews will be recorded, with consent and transcribed verbatim. Inductive thematic analysis (Braun and Clarke, 2006) will be performed on the narrative accounts, with the understanding that saturation will guide the requisite sample size, which cannot be predetermined. If saturation is not achieved, an additional 5-10 participants may be recruited. Efforts will be made to incorporate views from those who dropped out or were non-compliant with the intervention, though practical feasibility of this inclusion is a potential limitation.

The interviews aim to capture diverse perceptions of the intervention, utilising Normalisation Process Theory (Murray et al., 2010). This approach will facilitate mapping findings onto NPT's constructs: coherence (how the intervention is perceived and understood), cognitive participation (engagement and commitment of stakeholders), collective action (integration of the intervention into practice), and reflexive monitoring (ongoing assessment and adaptation of the intervention). Bracketing, reflexivity, and member checking will be integral to ensuring research trustworthiness and rigour.

Data will be analysed using NVivo software, employing an inductive approach without the constraint of existing theories, to allow for the natural emergence of findings. This analysis aims to identify critical elements of the intervention, explore implementation issues, and understand ethnicity and equity concerns. It will also focus on identifying perceived barriers or facilitators to implementation in usual practice. This inductive analysis, grounded in the data, will contribute valuable insights into the practicalities of the implementation process.

An aspect of our qualitative work with key stakeholders involves examining participants' positive and negative experiences with different elements within the MST-CAN provision (e.g. support with substance misuse and/or couples therapy). Additionally, we will explore more general points of delivery where there are more negative or positive experiences while considering what steps could be undertaken to ameliorate these experiences to improve the delivery and acceptability of the intervention. This information will be elicited as part of the interviews with the 10 parents engaged with MST-CAN, 10 young people engaged with MST-CAN, 10 MST-CAN intervention staff, 10-15 stakeholders offering BAU, 5-10 parents who declined involvement in MST-CAN as an intervention, and 5-10 interviews with parents who

dropped out of MST-CAN intervention. Inductive applied thematic analysis will be conducted on the transcripts.

Through a detailed exploration of the key dimensions, we plan on stating our theory of change model at the start of the project and revise this again at the end of the pilot stage. The theory of change model will incorporate the qualitative research exploring stakeholder perceptions of acceptability and usefulness, hindrances and facilitators associated with the process and intervention but will also combine quantitative analysis exploring adherence, fidelity, and mediators associated with behaviour change. This mixed methods synthesis will enable us to understand what works, how it works, when it works and for whom it works and provide a detailed elaboration of the mechanisms and processes through which it works.

Outputs

The main outputs of the pilot trial will be twofold:

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.

Cost data reporting and collecting

Cost data will be collected and reported in accordance with YEF guidance. Costs associated with delivering the intervention will be derived using a micro-costing approach accounting for the actual local costs and resources used in delivering the intervention and associated training. This will include salaries, resources, facilities, overheads, and management costs. The cost perspective will be that of the service. We will include any costs associated with supervision and additional training and use the time horizon of the trial to estimate staff turnover. We aim to estimate the cost of delivering the intervention in real practice rather than the cost of delivering the intervention in the trial. The cost data will be provided as mean cost per participant with 95% confidence intervals and be adjusted to occur each year. Data will be collected using activity logs recorded on the administration system of each service, highlighting all activity associated with a single participating case. The main sources of uncertainty in the analysis of costs include within year variations in salary costs, assumptions regarding intervention time and costs associated with non-attendance and lack of clear estimates of staff costs. We will address each of these by using initial salary cost estimates on 1st January 2024, making standard assumptions of the time an intervention takes and assessing the time allocated to missed appointments. Where direct staff salaries are not available, we will establish costs using the median salary for similar staff within the service.

Results will be presented as a table including key assumptions and how costs vary with these assumptions.

Diversity, equity, and inclusion

Ensuring Accessibility and Inclusivity

The evaluation team reflects members from diverse backgrounds all of whom have received training on cultural sensitivity. Based on these experiences, we will adopt a proactive and inclusive approach to ensure materials and activities are accessible to diverse participants. We will provide bilingual study materials to participants in Wrexham and Flintshire, be responsive in producing study materials in other required languages, and ensure all study materials are produced in accessible, easy-read formats suitable for neurodiverse populations. We will invite participants to have the study materials read aloud to them and will not presume that participants can easily read and write. We will ensure that diverse perspectives are considered throughout the evaluation in its entirety (e.g., via input from those with lived experience, and formal qualitative interviews focusing on diversity, equity, and inclusion). We will also ensure that all aspects of the evaluation, from data collection to analysis, respect and reflect the diverse backgrounds of participants. The evaluation team will engage in regular team and individual reflection, to promote cultural sensitivity, encourage self-awareness/evaluation and reduce the influence of personal biases on the evaluation process. The emphasis will be on understanding and appreciating an individual's beliefs and activities in terms of that individual's own culture, rather than judging them by the standards of the evaluator's culture.

Promoting Sensitivity and Support

We will emphasise understanding and mitigate barriers faced by groups disproportionately affected by existing services. This will involve engaging with minority stakeholders local to the recruitment areas to tailor the evaluation in a way that is respectful and supportive of specific needs (Snow et al., 2018). Building on our commitment to understanding and mitigating barriers for groups disproportionately affected by existing services, we recognise the need for a responsive feedback mechanism within our evaluation process. As such, our protocol will incorporate a structured approach to identify families who may not be adequately supported by MST-CAN or might be underserved in some capacity. Our objective is to ensure that these findings are not merely documented but actively utilised to inform and enhance support strategies for these families moving forward. We aim to analyse evaluation data to pinpoint service provision gaps and areas where MST-CAN may not fully address the needs of specific families. This analysis will guide the development of evidence-based, tailored

recommendations designed to enhance support for these families, ensuring they are both practical and aligned with established best practices for engaging and supporting vulnerable populations. We will then proactively share these insights and recommendations with MST-CAN programme administrators, stakeholders, and policymakers, making certain that the information is not only accessible but also actionable, thereby reinforcing our dedication to equity and inclusivity within the MST-CAN evaluation and contributing to meaningful service delivery improvements for all participating families. Our mixed methods design includes the ability to gather a deeper level of insight and understanding with seldom-heard groups (Crown Copyright, 2022), including giving a voice to those who choose not to engage with the service and those who withdraw from the service.

Involving Communities with Lived Experience

The evaluation will actively involve a small steering group of individuals with lived experiences in the design, implementation, and review stages. Their insights will be important to ensuring an equitable evaluation. We will begin our engagement efforts early in the project timeline, dedicating sufficient time for preparatory work to understand the unique needs and preferences of young people and communities with lived experiences. This steering group will guide the evaluation from design through to implementation and review, ensuring that the insights and experiences of those with lived experienced are genuinely considered (Checkoway and Aldana, 2013). We will begin our engagement efforts early in the project timeline, dedicating sufficient time for preparatory work to understand the unique needs and preferences of young people and communities with lived experiences. For example, we will draw on Virtual School Kent which includes young adults with experience in the care system.

Addressing Racial and Diversity Considerations

The evaluation will identify and address key racial and diversity considerations relevant to the project and its context, ensuring that these factors are integrated into the evaluation design and methodology. This includes acknowledging and addressing internalised stigma, shame and discrimination that may affect participation. Our researchers will develop and practice relevant and sensitive strategies to work effectively with individuals from diverse cultures. This involves using communication styles consistent with the life experiences and cultural values of the participants, potentially including the consideration of the researcher's gender or age when appropriate to enhance acceptability and trust (Raque et al., 2021).

Diverse Recruitment Strategies

To recruit a diverse sample of participants, we will employ inclusive and purposive recruitment strategies that reach out to underrepresented groups. Discussions with

practitioners will support identification of representative demographics to support a reflective sampling frame.

Special Requirements and Support

The evaluation design will consider specific requirements and support needs of participants, ensuring that everyone can participate fully and effectively. This includes addressing any accessibility issues and providing support where needed to facilitate participation.

Team Training and Experience

Our team have received training in diversity, equity, inclusion, and cultural competence. We are experienced in working with marginalised communities and therefore committed to conducting an inclusive and equitable evaluation. Dr Judith Eberhardt is experienced in conducting research with ethnic minority communities and has published widely in this area. Professor Theresa Gannon has received numerous trainings regarding cultural competence and conducts research (1) translating westernised research protocols to indigenous persons, and (2) examining the experiences of black and ethnic minority staff within the NHS. Dr Tracee Green successfully worked with vulnerable and diverse families as a registered social worker for over 14 years applying relationship-based and inclusive practices. Professor Coulton and Professor Newbury-Birch have many years of experience of conducting research with marginalised and hard to reach populations who have often been excluded from previous research evaluations.

Through integrating these elements and the practical strategies, the evaluation will adhere to EDI principles and ensure the findings are representative and inclusive.

Ethics and registration

The study will be conducted in accordance with the principles of Good Clinical Practice, the Declaration of Helsinki and Caldicott principles. Participants will only be recruited to the study once independent full ethical approval has been granted by the University of Kent Social Research Ethics Committee and the trial will be registered in a recognised trial registry. Trial methods and data collection instruments will be assessed by our Advisory Board and their recommendations for changes will be incorporated.

We will ensure participants do not feel coerced to participate in the study. Once a participant is referred to the service any consent or assent to participate in the trial is theirs solely to make. Not consenting to the research will not impact on the BAU they receive, and this will be explained verbally and in writing. If a participant does consent it will be made clear that they can withdraw consent at any time during data collection for the study. Participants will

be able to withdraw from any interventions and still provide follow-up data; withdraw, and have data already completed included in the trial analysis but provide no further additional data; or withdraw completely and have data already collected removed from the analysis.

We will minimise the potential for participants and staff to experience any adverse or iatrogenic events. In our experience of conducting similar studies in similar populations the risk of adverse events is low, as is the risk of iatrogenic events. We will implement a standard operating procedure for the reporting of adverse events that involves an independent experienced third-party making recommendations on the severity of any event and whether they are associated with the trial. We will comply with the YEF safeguarding reporting criteria and provide details of any serious offences committed by participants. Staff involved in the study will have enhanced DBS accreditation and will be familiarised with safeguarding practice and procedures.

Data protection

All systems and personnel are approved for the management of clinical and sensitive data and are ISO certified to ISO27001 standard. This includes all physical systems, systems to detect intrusion, encryption of data from point of collection to storage, quality assurance and audit trails associated with any data collected. 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. Researchers will be trained to General Clinical Practice (GCP) standard and will comply with all relevant data protection legislation. Once 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 and approved by ethics.

The basis of processing data is the public task basis to use their personal information. Where the Party is a public body, entity or authority, the applicable lawful basis for the processing of Personal Data under this ISA is provided for in the UK General Data Protection Regulation ("UK GDPR"), article 6 (Lawfulness of Processing), specifically article 6.1 (a) and (e) as well as article 9 (Processing of Special Categories of Personal Data), specifically article 9.2 (a), (h), (i) and (j).

Article 6.1

(a) the data subject has given consent to the processing of his or her personal data for one or more specific purposes.

(e) processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller; […]

Article 9.2

(a) the data subject has given explicit consent to the processing of those personal data for one or more specified purposes, except where Union or Member State law provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject.

(h) Processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3.

(i) Processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy.

(j) Processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

We only use special category information (such as information about health, religion, race, or ethnic origin) if it is necessary for research purposes or statistical purposes which are in the public interest. Potential participants, their carers, and participating staff within services, will be provided with a trial specific privacy notice prior to providing consent. This privacy notice outlines what data will be collected, for what purposes and for how long. In addition to the trial specific privacy notice the evaluation team at the University of Kent, the intervention delivery team at MST-CAN UK and participating local authorities will agree and sign an information sharing agreement highlighting what information will be shared, the reasons for sharing information and the means of sharing information. All communication between the intervention and evaluation team will use encrypted channels secured using a virtual private network.

As the study is being includes sites in Wales only anonymised quantitative data will be transferred from Welsh sites to the YEF data archive at the end of the study.

Stakeholders and interests

Developer and delivery team:

Cathy James, MST UKI, South London & Maudsley NHS Trust.

Anne Edmondson, MST UKI, South London & Maudsley NHS Trust.

Martin Robinson, MST UKI, South London & Maudsley NHS Trust.

Evaluation team:

Professor Simon Coulton, University of Kent, Principal Investigator.

Professor Dorothy Newbury-Birch, Teesside University, qualitative lead.

Professor Theresa Gannon, University of Kent, qualitative and forensic psychology.

Dr Tracee Green, University of Kent, qualitative and child protection.

Dr Judith Eberhardt, Teesside University, qualitative researcher.

Nadine Hendrie, University of Kent, trial management.

Risks

See attached risk register.

Timeline

See attached Gantt chart.

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