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How feasible is it to complete a pilot trial of Multi-Systematic Therapy-Exploitation (MST-E) within existing Multi-Systemic Therapy (MST) services in England?

Submission date
25/01/2021

Recruitment status
No longer recruiting

Registration date
04/02/2021

Overall study status
Completed

Last Edited
01/03/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Multisystemic Therapy (MST) is an intensive family-based intervention designed to support young people with antisocial behaviours. MST-E is an augmented version of MST, adapted specifically for children and young people aged 10 to 15 years of age who are at risk of criminal exploitation.
The aim of this study is to determine whether it is feasible to complete a pilot trial of Multi-Systematic Therapy-Exploitation (MST-E) within existing Multi-Systemic Therapy (MST) services in England. MST-E is a version of Multi-Systemic Therapy that has been augmented by the delivery team for children and teenagers who are at risk of criminal exploitation.

Who can participate?
The families of children and young people aged 10 to 15-years who are at risk of criminal exploitation are eligible to participate. Being at risk of criminal exploitation will be evidenced by disclosure from the family or child, or by the presence of at least two indicators of engaging in antisocial behaviour, such as aggressive behaviour, school exclusion, going missing, involvement with the criminal justice system, or substance misuse.

What does the study involve?
For the pilot, eligible and consenting families will take part in the MST-E intervention for up to six months. For those who are eligible to take part in this study, they will complete outcome measures within 4-weeks before the commencement of treatment, and then 13-weeks (mid-point), 26-weeks (6-months – end of treatment), and 52-weeks (12-months – 6-month follow-up) from treatment commencing.
Before we begin recruiting families to take part in MST-E, we will conduct focus groups with clinicians, families and young people to further refine MST tools. Clinicians and families will also take part in process evaluation interviews at the end of treatment.

What are the possible benefits and risks of participating?
Participating parents and young people will receive a £5.00 shopping voucher for each bank of questionnaires that they complete. Individuals who take part in focus groups will receive £30.00 shopping vouchers. The most likely risk is that parents and children may become distressed during either the treatment or when completing outcome assessments, or while taking part in semi-structured interviews and/or focus groups.

Where is the study run from?
The University of Warwick (UK)

When is the study starting and how long is it expected to run for?
January 2020 to February 2023

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
281902

Protocol serial number
CPMS 45569, IRAS 281902

Study information

Scientific Title
REducing the risk of criminal exploitation using multi-SystEmic Therapy (RESET Study)

Acronym
RESET

Study objectives
The study aim is to determine whether it is feasible to complete a pilot trial of Multi-Systematic Therapy-Exploitation (MST-E) within existing Multi-Systemic Therapy (MST) services in England.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/12/2020, Yorkshire & The Humber - South Yorkshire Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 1048091; southyorks.rec@hra.nhs.uk), 20/YH/0272

Study design
Interventional non-randomised feasibility study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Mental and behavioural disorders due to psychoactive substance use, Behavioural and emotional disorders with onset usually occurring in childhood and adolescence

Interventions

The aim of this study is to determine whether it is feasible to complete a pilot trial of Multi-Systematic Therapy-Exploitation (MST-E) within existing Multi-Systemic Therapy (MST) services in England. This project will form two-phases and take place over 24-months.

Phase 1. There are two complementary workstreams within this Phase.
Workstream 1.1: We have hosted three initial collaborative meetings with the MST delivery team to finalise their logic model which will then be used to formalise the indicators that we will measure within our Process Evaluation. This included, but is not limited to, (i) the impact of additional staff training, (ii) how partnerships with stakeholders are strengthened, (iii) the processes that promote or hinder greater engagement with voluntary and community agencies and other positive activities, and (iv) the processes that increase or hinder engagement in education and school transition. The purpose of these meetings, in addition to finalising the logic model, was to consider the most valid method of measurement associated with each of our key indicators.
Workstream 1.2: We will complete three focus groups with clinicians, stakeholders, families and young people. One focus group will take place with participants from each of the geographical regions of the partner organisations included by the delivery team: (a) Birmingham and Sandwell, (b) Nottingham, and (c) Yorkshire. The aims of these focus groups are to refine MST tools for working with families at risk of criminal exploitation, including adaptations to existing fidelity checklists, and to consider the most appropriate method of measuring outcomes from MST-E. The groups will be of a maximum size of 8 participants, and we aim to include families who have previously received MST and those who are treatment naïve. Within each group, the proposed changes to standard MST will be presented, along with selected outcome measures, and the existing fidelity checklist, the MST Therapist Adherence Measure – Revised (TAM-R; Henggeler, Borduin, Schoenwald, Huey, & Chapman, 2006; Schoenwald & Garland, 2013; Schoenwald, Sheidow, & Chapman, 2009). Participants will be asked to consider each proposed change, outcome measure and the fidelity checklist in turn, and facilitators will encourage discussion about the likely benefits, drawbacks and any associated implementation challenges. Each focus group will be recorded and transcribed. Transcriptions will be coded using thematic analysis, and the results will be considered by the study and delivery team collaboratively, responding to recommendations by making necessary changes as appropriate.

Phase 2. We will complete a single-group modelling study of MST-E with 50 families within existing MST services in order to estimate the parameters necessary to inform the decision as to whether a pilot trial should be completed. We will examine (i) the acceptability and feasibility of MST-E for stakeholders, including families, (ii) patient and clinician satisfaction with the intervention, (iii) the appropriateness of our measures in terms of their use within a future pilot trial, (iv) the appropriateness of an adapted fidelity checklist, (v) the accrual rate and willingness of teams to recruit participants, (vi) therapy completion rate and attrition, and (vii) the within-group effect size. We will also complete in-depth interviews with 12 families (6 who have successfully completed treatment, and 6 who have discontinued treatment, but have consented to take part in our interview) and 12 clinicians as part of our process evaluation, and to further investigate acceptability.

Intervention Type

Behavioural

Primary outcome(s)
Antisocial behaviours will be measured with the Self-Report Delinquency Measure (SRDM; Smith & McVie, 2003), collected at baseline, mid-point, end-point, and six months

Key secondary outcome(s))
1. Crime data will be collected by working with referrers and the police to gain access to arrest, caution, reprimands, warnings and conviction data for participants. We aim to initially collect crime data over the prior 6-month period to the commencement of treatment, during treatment, and the 6-month follow-up period
2. Empathy will be assessed using the parental version of the Griffith Empathy Measure (GEM; Dadds et al., 2008), collected at baseline, mid-point, end-point, and six months
3. Callous and Unemotional Traits will be measured using the 24-item Inventory of Callous and Unemotional Traits – Parent Report and Youth Self-Report Versions (Essau, Sasagawa, & Frick, 2006), collected at baseline, mid-point, end-point, and six months
4. Well-being will be measured by the parent and self-report versions of the Strengths and Difficulties Questionnaire (SDQ, Goodman, 1997), at baseline, mid-point, end-point, and six months
5. Peer Deviance will be measured using the Behavior of Friends Questionnaire (BFQ; Goodnight, Bates, Newman, Dodge, & Pettit, 2006), at baseline, mid-point, end-point, and six months
6. Parenting will be measured using both the parent and child report versions of the The Alabama Parenting Questionnaire (Essau, Sasagawa, & Frick, 2006; Frick, Christian, & Wootton, 1999), at baseline, mid-point, end-point, and six months
7. Satisfaction and acceptability of the intervention will be measured by by asking all children, adolescents and parents to complete a short questionnaire containing 10-items that will be answered using a Likert scale at the end-point
8. Social Deprivation data will be drawn from the English Indices of Deprivation, retrieved using participants' postcodes, which will be collected at baseline
9. Family Functioning will be measured using the Family Adaptability and Cohesion Scales – IV (FACES-IV; (Olson & Gorall, 2006), at baseline, mid-point, end-point, and six months
10. Gang Affiliation will be measured with the Gang Affiliation Risk Measure (GARM; Raby & Jones, 2016; Raby, Jones, Hulbert, & Stout, 2017), at baseline, mid-point, end-point, and six months

Completion date
04/02/2023

Eligibility

Key inclusion criteria
1. Aged between 10 to 15-years
2. Parental consent to take part
3. Child is at risk of exploitation as evidenced by either the child or family having disclosed information to indicate that the child is at risk of another individual or group taking advantage of an imbalance of power to coerce, control, manipulate, or deceive them into any criminal activity in exchange for something the victim needs or wants, for the financial or other advantage of the perpetrator or facilitator, or through violence or the threat of violence, or there is evidence of at least two of the following present which suggests that a children is at risk of exploitation:
3.1. A criminal conviction, or a final warning, cautions or reprimands within the last year
3.2. Exhibiting weekly aggressive behaviour which is of a significant risk to others (e.g. sexually abusive behaviour, physical fighting) outside the home

3.3. At least one period of having gone missing, even for a few hours, within the last six-months
3.4. History of substance misuse (alcohol or drugs)
3.5. History of permanent school exclusion
3.6. Association with peers or adults who are seen by others to have had a negative influence upon the child

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. The family refuse to take part in the study
2. The young person lives independently, or a primary caregiver cannot be identified
3. The child is presenting with symptoms consistent with a psychotic illness
4. Child is at high risk of suicide
5. Documented evidence of a Full-Scale IQ <65
6. There is evidence to indicate that a family member who is living with the child has been sexually abusing them and there continues to be an active and enduring risk
7. The child has previously received a diagnosis of autism spectrum disorder and problematic behaviours as defined within the inclusion criteria have been judged to be associated with having a developmental disability (e.g. self-harm associated with hypersensitivity) by the clinical team assessing the referral

Date of first enrolment
06/08/2021

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Birmingham Children's Hospital NHS Foundation Trust
Steelhouse Lane

Birmingham
United Kingdom
B4 6NH

Study participating centre
Nottingham City Youth Justice Service
Nottingham City Council
29 - 31 Castle Gate
Nottingham
United Kingdom
NG1 7AR

Study participating centre
Kirklees Council
1st Floor South Civic Centre
3 High Street
Huddersfield
United Kingdom
HD1 2NF

Study participating centre
Sandwell Metropolitan Borough Council
Multisystemic Therapy Service
The Wellman Building
Dudley Road
Oldbury
United Kingdom
B69 3DL

Sponsor information

Organisation
University of Warwick

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type

Charity

Funder Name
The Youth Endowment Fund Charitable Trust

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository – the Office for National Statistics Secure Research Service. The data collected as part of this study will first be shared with the Department for Education. The Department for Education will match these data to the children's arrests, cautions, and convictions data. They will then pseudonymise these data, removing any direct or indirect identifiers, before submitting these data to the Office for National Statistics Secure Research Service. We expect that these data will be submitted by 2024. Only researchers with appropriate qualifications who have permission from an ethics committee who have also completed training with the Office for National Statistics will be able to use the data for further research purposes. They will not be permitted to take copies of these data, and their work will be monitored. Consent for the sharing of these data in this way will be obtained from the children's parents before data collection commences.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		27/11/2023	28/11/2023	Yes	No
Funder report results		01/10/2023	01/03/2024	No	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes