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START (Systemic Therapy for At Risk Teens): a national randomised controlled trial to evaluate multisystemic therapy in the UK context

Submission date
16/02/2009

Recruitment status
No longer recruiting

Registration date
09/03/2009

Overall study status
Completed

Last Edited
01/05/2020

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
Youth antisocial behaviour is a common and serious problem with costly consequences to young people themselves, their families, and society in general. Antisocial behaviour is associated with higher rates of criminal behaviour, unstable relationships, unemployment, and mental health problems. Multisystemic Therapy (MST) is an intensive family and home-based intervention for young people with serious antisocial behaviour. Although the programme has had some positive outcomes in the U.S., its effectiveness has not yet been assessed in the UK. This study is made up of two parts. The purpose of the first part (START I) is to assess whether Multisystemic Therapy in the UK is more likely to reduce out of home placement compared to management as usual (MAU; i.e., whichever services they would have received in the absence of MST). The purpose of the second part (START II) is to assess whether MST is more likely to reduce criminal convictions compared to MAU.

Who can participate?
Young people who meet three of seven risk indicators, such as history of offending, poor school attendance, and previous episodes of being looked-after.

What does the study involve?
Families which are considered eligible for the study are invited to take part in the research. Each family is randomly allocated to a treatment programme: either MST, or MAU. Research assistants visit the family home with a questionnaire pack at baseline, 6, 12, and 18 months, and (START I), and 24, 36 and 48 months (START II). The questionnaires take about 1-2 hours to complete. Families are also invited to take part in optional qualitative interviews, in which they are asked about their experiences with MST, and about their lives and well-being after taking part in the programme.

What are the possible benefits and risks of participating?
Families taking part in the study are reimbursed £25 per visit. No other direct benefits or risks are anticipated.

Where is the study run from?
The study is run by University College London and takes place in nine NHS sites providing MST services in England (UK)

When is the study starting and how long is it expected to run for?
January 2009 to September 2017

Who is funding the study?
START I: Department for Children, Schools and Families in conjunction with the Department of Health (UK)
START II: NIHR Health Services and Delivery Research Programme (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

START (Systemic Therapy for At Risk Teens): a national randomised controlled trial to evaluate multisystemic therapy for young people at risk of out of home placement as a result of antisocial behaviour in the UK context

Acronym
START

Study objectives
START I:

The aim of this study is to carry out a pragmatic trial that will inform policy makers, commissioners of services and professionals about the potential of Multisystemic Therapy (MST) in a UK context, investigating whether the provision of MST could reduce the incidence of out of home placements for young people at risk of being removed from their homes because of antisocial behaviour, mental health problems, educational problems or unmet need.

START II:

Current study hypothesis as of 27/09/2018:
The primary objective is to compare MST vs. MAU on the proportion of young people who have a criminal conviction at 5-year follow-up.

Previous study hypothesis:
The primary outcome of the study is to determine whether criminal conviction is reduced at 5-year follow-up in the MST arm compared to MAU.

Ethics approval required
Old ethics approval format

Ethics approval(s)
START I: South East Research Ethics Committee, 13/05/2009, ref: 09/H1102/55
Amendment to extend study to 5 years (START II): NRES Committee London – South East, 05/11/2013, ref: 09/H1102/55

Study design
START I: Randomised controlled trial
START II: Observational longitudinal cohort follow up study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Mental health problems and antisocial behaviour in adolescents

Interventions
START I:
MST is offered to families for a period of three to six months, depending on individual family needs. Treatments offered in the MAU arm are widely varied, depending on resources available within the local authority and individual family needs.

Once a referral has been accepted into the study, the research assistant visits the family to confirm participation and complete consent forms. An independent statistician then manages the randomisation and the MST team administrator contacts the Trial Coordinator to find out the results of the randomisation. If the family has been allocated to MAU, the MST supervisor alerts the multi-agency panel for treatment allocation.

MST: Multi-systemic therapy is an integrative, manualised, licensed programme with a substantial evidence base for engaging young people exhibiting anti-social behaviour and their families. Adolescents with severe conduct problems (violence, drug abuse, school expulsion) are treated over a period of 3-6 months with a community-based multi-component treatment programme focused on the family but also engaging schools, neighbourhoods and community resources and administered by specifically trained professionals with relatively low caseloads. Adolescents and their families receive a minimum of 3 and a maximum of 6 months of input from the MST team; it is expected that some families will require briefer periods of treatment or may prematurely terminate treatment unilaterally. MST is delivered by a team of at least 3 specially trained clinicians under the supervision of an MST supervisor, with weekly one hour conference calls for consultation with an MST services staff member. In addition, MST therapists have the support of local consultation from mental health professionals with post-graduate qualifications in disciplines such as social work, psychology or counselling.

MAU: Management As Usual is the standard care offered to adolescents and their families who meet eligibility criteria for the trial. This treatment is likely to be diverse and may involve no therapeutic intervention or individual or family orientated work. It is likely to be delivered by a wide range of practitioners with quite different theoretical orientations. The average duration of these interventions is also likely to vary. It is expected that practitioners will be working in line with best practice as specified in relevant SCIE and NICE guidance. MAU interventions are carefully monitored using a service use schedule designed specifically for the trial that will record contact with all services (health, social, YOT, education, voluntary sector etc), including number of contacts (and possibly average duration of contacts). As this is a pragmatic trial involving a number of collaborating services even within each site, it is not possible to specify in advance what management as usual will be.

Families are followed up to 24 months in START I.

START II:
The study involves the 684 families (young people and parents/carers) recruited into the START I trial. All participants were initially sent an opt-out letter, giving them information on how they could opt-out of being contacted by the research team about START II. If the family does not opt

out, the research team contacts the family to discuss continued participation in the trial. If the family agrees to take part, they are given an updated information sheet, and asked to sign an updated consent form, explaining the extension of the study to 60 months. Participants are then invited to take part in yearly follow-up assessments at 24, 36, and 48 months post randomisation. At each follow-up point, the family is contacted by the research assistant (RA) who schedules a time to visit the family in person. Both the young person and the parent separately complete the questionnaire pack with the assistance of the RA. The questionnaire pack takes approximately 2-3 hours to complete and includes assessments of emotional well-being, mental health, education and work adjustment, physical health, demographic data, antisocial behaviour (e.g., arrests, convictions), family cohesion and parenting. Parents and young people receive £12.50 each for taking part.

Primary outcome data (offending) continues to be collected up to 60 months post randomisation, unless the family does not give consent for this.

Additionally, all families are invited to take part in a qualitative component of the study, comprised of semi-structured interviews with young people and parents about their experiences with MST, their outcomes in terms of offending, emotional well-being, relationships with family and peers, and their outlook on the future. The interviews will be analysed for themes using Framework analysis.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
START I:
Proportion of cases assigned to long-term (3 months+) out of home placements in specialist residential provision at 18 months following randomisation

START II:
Reduction in the number of criminal convictions in the MST arm compared to MAU at 5-year follow-up

Secondary outcome measures
START I
1. Demographic information is measured using the Family Information Form completed by the parent at baseline, and at 6, 12 and 18 months if necessary
2. Antisocial behaviour (time to first criminal offence and the total number of offences) is collected from the Police National Computer and the Young Offender Information System at baseline, 6, 12 and 18 months
3. Antisocial behaviour and attitudes (behavioural problems) and young people's and parental wellbeing are measured by the Strengths and Difficulties Questionnaire (SDQ) completed by the parent and young person at baseline, 6, 12 and 18 months
4. Antisocial behaviour and attitudes (callous and unemotional traits) are measured by the Inventory of Callous and Unemotional Traits (ICU) completed by the parent and young person at baseline, 6, 12 and 18 months
5. Antisocial behaviour and attitudes (conduct problems) are measured by the Self-Report Delinquency measure (SRD) completed by the young person at baseline, 6, 12 and 18 months

6. Antisocial behaviour and attitudes (anti-social beliefs and attitudes) are measured by the Antisocial Beliefs and Attitudes Scales (ABAS) completed by the young person at baseline, 6, 12 and 18 months
7. Antisocial behaviour and attitudes (materialistic values) are measured by the Youth Materialism Scale completed by the young person at baseline, 6, 12 and 18 months
8. Antisocial behaviour and attitudes and young people's adjustment (ADHD symptoms) are measured by the ADHD subscale of the Conners Rating Scale completed by the parent and teacher at baseline, 6, 12 and 18 months
9. Parenting controls are measured by the Alabama Parenting Questionnaire focused on skills for monitoring and supervision (APQ) completed by the parent and young person at baseline, 6, 12 and 18 months
10. Family functioning (parental supervision and involvement) is measured by the Loeber Caregiver Questionnaire completed by the parent at baseline, 6, 12 and 18 months
11. Family functioning (family adaptability and cohesion) is measured by the Family Adaptability and Cohesion Evaluation Scales (FACES-IV) completed by the parent at baseline, 6, 12 and 18 months
12. Family functioning (levels of expressed emotions) is measured by the Levels of Expressed Emotions (LEE) completed by the young person scale at baseline, 6, 12 and 18 months
13. Family functioning (the degree of conflict in the parental relationship) is measured by the Couple Conflicts Tactics Scale (CTS2) completed by the parent at baseline, 6, 12 and 18 months
14. Young person and parental well-being and adjustment (moods and feelings) is measured by the Short Mood and Feelings Questionnaire completed by the young person at baseline, 6, 12 and 18 months
15. Young person and parental well-being and adjustment (screen for minor psychiatric disorders) is measured by the General Health Questionnaire (GHQ) completed by the parent at baseline, 6, 12 and 18 months
16. Educational participation (attendance and exclusions) is collected from the National Pupil Database at baseline, 6, 12 and 18 months
17. Psychiatric disorders are identified by the Development and Well-Being Assessment (DAWBA) completed by the parent and young person at baseline and 12 months
18. Child IQ is measured by the Wechsler Abbreviated Scale of Intelligence (WASI II) - Vocabulary and Matrix Reasoning subtests completed by the young person at baseline
19. Nature of delivery of interventions in MST and MAU arms is measured by the Expectancies Questionnaire completed by the parent at baseline, 6, 12 and 18 months
20. Nature of delivery of interventions in MST and MAU arms is measured by the California Psychotherapy Alliance Scale (CPAS) completed by the parent at baseline, 6, 12 and 18 months
21. Nature of delivery of interventions in MST and MAU arms is measured by the Reason for Termination Checklist (RTC) completed by the parent at baseline, 6, 12 and 18 months
22. Quality of parent-child attachment relationships is measured by the Child Attachment Interview (CAI) completed by the young person at 12 months
23. Data on all other service use and cost effectiveness of treatment was measured using the Child and Adolescent Service Use Schedule (CA-SUS) completed by the parent and young person at baseline, 6, 12 and 18 months
24. Quality-adjusted life years are measured by the EQ-5D completed by the young person at baseline, 6, 12 and 18 months

START II
The outcomes measures collected during the first phase of the START trial will also be collected during the second phase of the trial at 24, 36 and 48 month follow up with the exception of the Development and Well-Being Assessment (DAWBA) and Wechsler Abbreviated Scale of Intelligence (WASI II)
1. Significant life events are measured by the Coddington Life Events Questionnaire - Adult

(CLES-A) completed by the young person at 24, 36, and 48 months
2. Quality of life is measured by SF-36 Health Survey completed by the young person at 24, 36, and 48 months
3. Psychological resilience is measured by Adolescence resilience questionnaire (ARQ) completed by the young person at 24, 36, and 48 months
4. Screening for affective disorders and schizophrenia is measured by Schedule for Affective Disorders and Schizophrenia (K-SADS) completed by the young person if aged 18 or younger at 36 months
5. Behavioural and emotional problems are measured by Adult Self-Report questionnaire completed by the young person at 24, 36, and 48 months
6. Behavioural and emotional problems are measured by Adult Behaviour Check list (ABCL) completed by the parent at 24, 36, and 48 months
7. Materialism is measured by the Adult Materialism Scale completed by the young person if aged 18 or older at 24, 36, and 48 months
8. Screening for personality disorders is measured by the Structured Clinical Interview for DSM Disorders (SCID) completed by the young person if aged 18 or older at 36 months

Overall study start date
01/01/2009

Completion date
01/09/2017

Eligibility

Key inclusion criteria
Candidates (both males and females) will be referred if they meet 3 of the following features indicative of 'risk status':
1. Excluded or at significant risk of school exclusion
2. High levels of non attendance at school
3. An offending history or at significant risk of offending
4. Previous episodes on the Child Protection Register
5. Previous episodes of being looked after
6. Previous referral to Family Group Conference (FGC) to prevent young person from becoming looked after
7. History of siblings being looked after

Referrals considered suitable by the panel will be included in the trial if they meet the following general inclusion criteria:
1. Young person aged 11-17 years
2. Sufficient family involvement for MST to be applied, excluding adolescents already in local authority care or foster accommodation
3. No existing agency involvement (e.g., the family is already engaged with a therapist) which would interfere with MST
4. Meets ONE of the following set of criteria indicating suitability for MST:
4.1. Persistent (weekly) and enduring (6 months or longer) violent and aggressive interpersonal behaviour OR
4.2. A significant risk of harm to self or to others OR
4.3. At least one conviction and three warnings, reprimands or convictions in the last 18 months OR
4.4. Current diagnosis of externalising disorder and a record of unsuccessful outpatient

treatment OR
4.5. Permanent school exclusion

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
700

Total final enrolment
684

Key exclusion criteria
1. History or current diagnosis of psychosis
2. Generalised learning problems (clinical diagnosis) as indicated by IQ below 65
3. Risk of injury or harm to a worker
4. Presenting issues for which MST has not been empirically validated

Date of first enrolment
01/09/2014

Date of final enrolment
01/09/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor information

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ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
Department for Children, Schools and Families (START I)

Alternative Name(s)
DCSF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Department of Health (START I)

Funder Name
Health Services and Delivery Research Programme (START II)

Alternative Name(s)
Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research Programme, HS&DR Programme, HS&DR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The outcomes of START I are currently being prepared for publication in a peer-reviewed journal, with several subsidiary papers planned for publication afterwards.
There are currently no specific plans for dissemination of START II, but publication in a peer-reviewed journal is intended.

Updated 11/07/2018:
The results from the first phase of the trial (baseline to 18 months) have been published (see below). The results from the second phase are currently undergoing the analysis process. The final report will be submitted to the funders on 31/08/2018, and will likely be available towards the end of the year (after undergoing revisions etc).

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from p.fonagy@ucl.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/08/2013		Yes	No
Results article	results	01/02/2018		Yes	No

Results article	results	01/08/2019		Yes	No
Results article	results	01/05/2020	01/05/2020	Yes	No