

Study of Adolescents' Family Experiences

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Registration date 13/05/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/05/2017	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.iop.kcl.ac.uk/departments/?locator=1119>

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

Study of Adolescents' Family Experiences: a randomised controlled trial of functional family therapy with adolescent offenders and antisocial youth

Acronym

SAFE

Study objectives

Aims and hypotheses:

1. Outcomes: The main aim is to evaluate the effectiveness of FFT compared to a dose control condition that includes treatment as usual plus non-specific treatment for young people. It is hypothesised that FFT will be associated with greater improvements in family relationships, parent relationships to the offending youth, youth mental health, and finally, greater reduction in youth re-offending. Effects will be assessed over a one year period.
2. Outcomes across diverse adolescents and their families: The second aim is to assess the effects of the program across the various adolescent, family, and quantity and quality of service provision variables.
3. Mechanisms of change: The third aim is to assess what are the essential 'active' ingredients of the programmes in terms of changes in family, and parent and child behaviours in the domains that FFT explicitly targets for change. It is hypothesised that change in family process variables and the parent relationship with the target youth are necessary conditions for change in ongoing youth antisocial behaviour.
4. Success of service provision in the UK YOT system; suitability for dissemination: Finally, we will assess the total and relative social acceptability, reach, and cost benefits of FFT into the UK YOT system. What proportion of parents can be induced to attend, that is it suitable for a minority or the majority of families? What are the characteristics of those who don't take up the programme? Are there differences across programmes? What is the acceptability of the programmes to parents, frontline practitioners, senior managers and commissioners? How well can practitioners be trained to implement the programme and thus produce change?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Kings College London Research Ethics Committee, 28/03/2008, ref: CREC/07/08-141

Study design

Two-arm randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

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

Conduct disorder, antisocial behaviour

Interventions

1. Functional Family Therapy group:

FFT works by working improving outcomes for families by addressing a number of factors that may contribute to the likelihood of a young person offending. Key amongst these are family circumstances and styles of parenting, which have been shown to be correlated strongly with delinquency and anti-social behaviour.

FFT aims to assist young people and their families to make meaningful changes in their functioning. This is accomplished by reducing negativity in the family and focusing on significant yet obtainable behavioural changes that will have a lasting impact on family relationships. These changes may have the immediate effect of changing a specific functional problem or difficulty and the longer term effect of empowering a family to continue to apply changes to future circumstances. A key duty of the therapist is to assume some of the functional duties of a "family case manager" to assist the family to identify and interact with relevant community resources that will help the family sustain their changes over time.

In this way, FFT aims to increase the family's capacity to manage problems, enabling a reduced reliance on service providers and their resources. It is a home-based assertive outreach model. The intervention process involves, on average, 12 one hour sessions over a period of 3 to 4 months delivered in the family home, with more complex cases requiring up to 30 hours of direct service. Thus young people in the FFT group will receive treatment as usual as normally provided by agencies and FFT.

Experienced family therapists have been hired to provide the intervention. They have been trained to the highest standard by the originator of the programme, Professor James Alexander, and will receive weekly supervision. Given that the SAFE project is an effectiveness trial the therapists will be located within, and will work as part of, the Brighton and Hove Youth Offending Team.

2. Dose Control group:

The use of standard, no-treatment control groups in behavioural intervention research can be problematic for a number of reasons. In addition to ethical and legal considerations of denying treatment to this population, the use of no-treatment control groups may not control for a number of confounding factors. In particular, a treatment group may have improved outcomes, not because of the effectiveness of the intervention, but because they receive additional attention from a therapist. Whilst the use of dose control groups has become more widespread in clinical trials of interventions for depression it has been sorely lacking in evaluation trials of parenting programmes or family therapy.

This study will address these issues by including treatment as usual as normally offered by agencies, and incorporating additional service provision in the control group that matches the

amount of time and attention received by participants receiving FFT. Thus adolescents and their families will receive treatment as usual and an additional 12 hours of additional contact with, and support from, a caseworker not trained in FFT.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Young people's offending and antisocial behaviour:

1. Young Person (YP) offending, reoffending and breach of orders: youth offending service databases and police national database (measured at T1, T3, T4)
2. YP delinquency, conduct disorder and antisocial behaviour:
 - 2.1. Smith and McVie Self-report Delinquency questionnaire (measured at T1, T3, T4)
 - 2.2. Adolescent Parent's Account of Child Symptoms interview (measured at T1, T3, T4)
 - 2.3. Strength and Difficulties Questionnaire (Primary Caregiver [PC] and YP self-report) (measured at T1, T2, T3, T4)
 - 2.4. Antisocial Process Screening Device (parent and self-report) (measured at T1, T3, T4)

Timepoints:

T1: baseline assessment directly before randomisation and treatment

T2: 3 months post-randomisation

T3: 6 months post-randomisation

T4: 18 months post-randomisation

Secondary outcome measures

1. Peer relationships:

- 1.1. Peer delinquency: Smith and McVie Peer Delinquency Self-Report Questionnaire (measured at T1, T3, T4)
- 1.2. YP peer relationship problems: Strength and Difficulties Questionnaire (PC and self-report) (measured at T1, T2, T3, T4)
- 1.3. Child prosocial behaviour: Strength and Difficulties Questionnaire (PC and self-report) (measured at T1, T2, T3, T4)

2. Young peoples mental health:

- 2.1. YP internalising disorders: Strength and Difficulties Questionnaire (PC and self-report) (measured at T1, T3, T4)
- 2.2. YP hyperactivity/inattention: Strength and Difficulties Questionnaire (PC and self-report), Conner's Rating Scale for ADHD (measured at T1, T4)
- 2.3. Child autistic spectrum disorder: the Childhood Asperger Syndrome Test (PC questionnaire) (measured at T1)
- 2.4. Child psychosis: Psychotic-Like Experiences Questionnaire (self-report) (measured at T1)
- 2.5. Child post-traumatic stress disorder: Impact of Events Scale (self-report questionnaire) (measured at T1)

3. Young peoples education attainment and intelligence quotient (IQ):

- 3.1. Child school attendance, exclusions, academic achievement and statements of special educational needs: school records (measured at T1, T3, T4)
- 3.2. IQ: Wechsler Abbreviated Scale of Intelligence (measured at T1)

4. Family relationships and parenting:

- 4.1. Child attachment: Child Attachment Interview (measured at T1, T4)

- 4.2. Parental relationship: the Index of Marital Satisfaction Questionnaire and Conflict Tactics Scales Questionnaire (PC questionnaire) (measured at T1, T3, T4)
- 4.3. Disorganisation and chaos in the home environment: Confusion, Hubbub and Order Scale (PC questionnaire) (measured at T1)
- 4.4. Parenting behaviour: Alabama Parenting Questionnaire (PC [measured at T1, T2, T3, T4] and other parental figures in family [measured at T1, T3, T4], child self-report [measured at T1, T3, T4])
- 4.5. Parental attribution of intent: when interviewing primary caregivers we ask them to imagine their child doing a number of things that could be regarded as positive or negative. We then ask them why they think their child is doing these things. This allows us to assess their attribution of intent: whether they think their child's behaviour is driven by positive or negative motives (PC interview) (measured at T1, T2, T3, T4)
- 4.6. PC self-efficacy: Carer Confidence Questionnaire: 9 item PC questionnaire assessing sense of control and agency (PC questionnaire) (measured at T1, T2, T3, T4)
- 4.7. Reflective functioning: Parent Development Interview (PC interview) (measured at T1, T3, T4)
- 4.8. Expressed emotion: Psychosocial Assessment of Childhood Experiences Coding Scheme (PC interview) (measured at T1, T3, T4)
- 4.9. PC and YP interaction: video observations coded with Problem Solving & Dyad Interaction Coding Scheme (video observation of YP and PC) (measured at T1, T3, T4)
5. Parental mental health:
 - 5.1. PC depression: the Depression, Anxiety and Stress Scales (PC self-report questionnaire) (measured at T1, T3, T4)
 - 5.2. Parental history of antisocial behaviour: Mother's and Father's Antisocial Personality Questionnaire (PC questionnaire) (measured at T1)
 - 5.3. PC alcohol and drug misuse: The Alcohol and Drug Use Disorders Identification Tests questionnaire (PC self-report) (measured at T1)
6. DNA:
 - 6.1. Child DNA: collected with cheek swab (measured at T1)
 - 6.2. PC DNA: collected with cheek swab (if biological parent) (measured at T1)
7. Health economics:
 - 7.1. Service use and demographics: Client Service Receipt Inventory (PC interview) (measured at T1, T3, T4)
 - 7.2. Quantity and type of treatment as usual received by young people: Youth Offending Service and other agency databases (measured at T1, T2, T3)
8. Process variables:
 - 8.1. FFT therapists' adherence to model and competence: assessments undertaken by FFT trainers (measured at T1, T2, T3)
 - 8.2. Client-therapist alliance: standard FFT including questionnaires (measured at T1, T2, T3)

Timepoints:

- T1: baseline assessment directly before randomisation and treatment
 T2: 3 months post-randomisation
 T3: 6 months post-randomisation
 T4: 18 months post-randomisation

Overall study start date

01/07/2008

Completion date

01/12/2011

Eligibility

Key inclusion criteria

1. Young people aged 10 - 17 years (either sex) and their families (mainly primary caregivers but also others with a parental role)
2. Clients of a CYPT agency being seen for offending or antisocial behaviour receiving a casework-based intervention

Participant type(s)

Patient

Age group

Child

Lower age limit

10 Years

Upper age limit

17 Years

Sex

Both

Target number of participants

100 young people and their families

Key exclusion criteria

1. Young people with a major developmental disability
2. Looked after young people (this does not include long term foster placements)
3. Young people not living in the family home

Date of first enrolment

01/07/2008

Date of final enrolment

01/12/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Institute of Psychiatry
London
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Sponsor information

Organisation

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Sponsor type

University/education

Website

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ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

Government

Funder Name

Department of Children, Schools and Families (UK) - The National Academy for Parenting Research

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2017		Yes	No