

The FFT-EFH study: An evaluation of functional family therapy for child criminal exploitation, county lines involvement and extra-familial harm

Submission date 24/05/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 30/05/2024	Overall study status Ongoing	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 31/03/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

County Lines Drug Networks (CLDNs) represent organised systems for transporting class A drugs from urban to rural areas, initially associated with criminal gangs but now understood as activities of organised crime groups. These networks exploit vulnerable individuals, including children and young people, to transport, store, and distribute drugs, exposing them to risks of violence, exploitation, and criminal conviction. This exploitation falls within the broader definition of child criminal exploitation (CCE) as outlined by the Home Office.

Young people involved in CLDNs and subject to CCE face significant risks, including violent victimisation, sexual exploitation, and criminal conviction, leading to restricted access to legitimate opportunities. Various factors, such as poverty, family breakdown, and school exclusion, elevate the risk of CCE. Unfortunately, there is currently little evidence on what works to tackle CCE/CLDN involvement.

Functional Family Therapy (FFT) has shown promise in addressing severe behavioural problems among adolescents and families. Given the absence of evidence-based interventions for CLDN involvement, adapting FFT to target extra-familial risks presents a promising approach. FFT-Gangs (FFT-G) is a variant of FFT designed to address the specific risk factors associated with gang involvement and has been trialled successfully in the US. It was successfully piloted in the UK for YP with CLDN involvement and exposed to CCE. Moreover, previous trials have demonstrated the feasibility and effectiveness of FFT in engaging high-risk youth and reducing recidivism.

Who can participate?

Children and young people aged between 10–17 years who have been involved with services due to concerns related to CCE, gang affiliation, missing episodes, school exclusion, or other indicators of behavioural issues are eligible. Caregivers and young people willing to engage in family therapy are included.

What does the study involve?

We are seeking participants aged 10 to 17, along with their primary caregivers, from three London areas. These individuals are at risk of involvement in drug networks or criminal exploitation. Inclusion criteria encompass young people aged 10–17 who have experienced concerns in the past year related to sexual or criminal exploitation, going missing, gang involvement, or school problems or violence. Alternatively, they may have encountered issues such as family conflict, association with negative peer groups, or substance use. Participants must primarily reside at home or be in temporary care situations with plans for reunification. Additionally, both caregivers and young people must be willing to engage in family therapy.

What are the possible benefits and risks of participating?

Benefits:

Participating in Functional Family Therapy (FFT) offers potential benefits for young people and their families. FFT is an evidence-based intervention known for its positive outcomes and effectiveness in engaging hard-to-reach individuals, particularly those at risk of criminal exploitation or gang involvement. By participating in FFT, families receive intensive home-based therapy focused on addressing behavioural problems through a structured five-stage model. These stages involve building hope, reducing blame, and developing skills to interrupt problematic relational patterns. The therapy also targets specific risk factors associated with gang involvement, such as impulsivity, substance misuse, and negative peer influences. Through FFT, families learn new communication and negotiation skills, emotional regulation techniques, and strategies to enhance school engagement and pro-social opportunities. Additionally, participating families receive ongoing support and resources tailored to their needs.

Risks:

Participation in the study carries risks as participants may experience psychological distress from discussing their experiences, including exploitation, violence, or criminal involvement. Ensuring confidentiality is crucial due to the sensitive nature of shared information, prompting concerns about privacy and potential consequences. Obtaining informed consent is challenging due to participants' vulnerability and possible coercion from criminal networks, requiring comprehensive explanations of the study's purpose, procedures, and risks.

Where is the study run from?

The University of Greenwich (UK)

When is the study starting and how long is it expected to run for?

August 2023 to September 2026

Who is funding the study?

The Youth Endowment Fund (UK)

Who is the main contact?

Sajid Humayun, s.humayun@greenwich.ac.uk

Study website

<https://youthendowmentfund.org.uk/funding/who-we-fund/family-psychology-mutual/>

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Dr Sajid Humayun

ORCID ID

<http://orcid.org/0000-0003-3849-1629>

Contact details

Old Royal Naval College, Park Row
London
United Kingdom
SE10 9LS
+44 2083319564
s.humayun@greenwich.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

GR2-EVAL-072309

Study information

Scientific Title

Efficacy randomised trial of Functional Family Therapy for Extra-Familial Harm

Acronym

FFT-EFH

Study objectives

Hypotheses:

1. Young People (YP) randomised to receive FFT will have a lower volume of self-reported delinquency 12 months after randomisation than those those randomised to receive Services As Usual (SAU).
2. YP and their caregivers randomised to receive FFT will have lower levels of negative and higher levels of positive secondary outcomes 12 months after randomisation compared to those randomised to receive SAU.

Research Questions:

1. Do any proposed mediators mediate the relationship between intervention arm and self-reported delinquency? Potential mediators include parental supervision and monitoring, family functioning, parental and YP self-efficacy and YP attachment representations.
2. Do any proposed moderators moderate the effect of treatment and are there subgroup

differences? Specific moderators include callous-unemotional traits, temperamental irritability, presence of offending behaviours at baseline.

3. What are the barriers to a successful implementation and efficacy trial of FFT in this setting?

Ethics approval required

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Ethics approval(s)

Approved 22/04/2024, University of Greenwich Research Ethics Board (Old Royal Naval College, Park Row, London, SE10 9LS, United Kingdom; +44 20 8331 8000; researchethics@greenwich.ac.uk), ref: 23.3.5.27A

Study design

Two-armed randomized parallel multi-site efficacy trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Charity/Voluntary sector, Community, Home, Workplace, Other

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

This therapy aims to address severe behavioural problems and offending behaviour in adolescents who are at risk of Child Criminal Exploitation (CCE), gang involvement, County Lines involvement and other Extra-Familial Harm (EFH).

Interventions

Functional Family Therapy (FFT-EFH):

FFT is an intensive home-based family program targeting adolescents and their families with severe behavioural problems and substance misuse problems. This adaptation FFT-EFH is tailored for those at risk of gang involvement or CCE.

Methodology: The intervention follows a phased five-stage model, including engagement, motivation, behaviour change, generalisation, and relapse prevention. Sessions involve all "major players" in the family system and focus on building hope, reducing blame, and developing skills to interrupt problematic relational patterns.

Delivery: Therapists provide several weekly home visits lasting 60-90 minutes in the early stages, reducing to weekly visits during later phases. The typical intervention duration is 3-5 months, with additional support visits available post-intervention, and total number of sessions varies depending on need (mean=11.8 in pilot trial).

Training and Certification: Therapists undergo a three-phase certification process, including training, supervision, and ongoing fidelity monitoring by FFT-LLC.

Duration: The intervention will be delivered to RCT participants between June 2024 and March 2026, with optional booster sessions provided between April and September 2026 to consolidate learning and address new challenges.

Services as Usual (SAU):

SAU consists of the standard services available for youth and families involved with child social care and related agencies, tailored to the specific needs of the youth at risk of CCE.

Methodology: The nature of the SAU intervention is determined by case holding practitioners in consultation with FFT supervisors or supervisors-in-training prior to randomisation. It may include existing services provided by the local authority.

Delivery: SAU interventions are available directly after randomisation and are delivered in parallel with the FFT intervention.

Randomisation process (brief):

Randomisation is conducted by King's College London CTU following informed consent and baseline assessments. It utilises block randomisation with varying block sizes and equal allocation ratio, ensuring blindness of the research team. Stratification by site is employed, and randomisation is done individually. Notification of outcomes is provided to practitioners and families, with families receiving detailed intervention information. Blinding is maintained during baseline assessments but not post-treatment assessments, and families are not blinded to treatment allocation.

Intervention Type

Behavioural

Primary outcome measure

Offending is measured using the International Self-Report Delinquency Study 4 survey offending scale (ISRD4; Marshall et al., 2022), completed by YP at baseline, post-treatment (6 months after randomisation) and follow-up (12 months after randomisation).

Secondary outcome measures

1. YP Mental Health and Adjustment measured using Strengths and Difficulties Questionnaire (Goodman, 2005) at baseline and post-treatment (6 months) and follow-up (12 months) post randomisation. YP and caregiver report.
2. Child Criminal Exploitation measured using SRD4 additional items at at baseline and post-treatment (6 months) and follow-up (12 months) post randomisation. YP report.
3. Substance Misuse measured using ISRD3 substance misuse subscale (Marshall et al., 2013) at baseline and post-treatment (6 months) and follow-up (12 months) post randomisation. YP report.
4. Parental Mental Health measured using DASS-21 (Henry & Crawford, 2005) at at baseline and post-treatment (6 months) and follow-up (12 months) post randomisation. Caregiver report.
5. Parenting Supervision, Knowledge, and YP Disclosure measured using ISRD3 (Marshall et al., 2013) at baseline and post-treatment (6 months) and follow-up (12 months) post randomisation. YP report.
6. Family Functioning measured using SCORE-15 (Fay et al., 2013) at baseline and post-treatment (6 months) and follow-up (12 months) post randomisation. YP and caregiver report.
7. Parental Self-Efficacy measured using BPSES (Woolgar et al., 2023) at baseline and post-treatment (6 months) and follow-up (12 months) post randomisation. Caregiver report.
8. Attachment Representation measured using AAQ (Bodfield et al., 2020) at baseline and post-treatment (6 months) and follow-up (12 months) post randomisation. YP report.
9. YP Self-Efficacy measured using NGSE (Chen et al., 2001) at baseline and post-treatment (6

months) and follow-up (12 months) post randomisation. YP report.

10. Callous-Unemotional (CU) Traits measured using CU Traits MAP (Hawes et al., 2020) at baseline and post-treatment (6 months) and follow-up (12 months) post randomisation. Caregiver report.

11. Temperamental Irritability measured using ODD subtyping DSM items (Stringaris & Goodman, 2009) at baseline and post-treatment (6 months) and follow-up (12 months) post randomisation. Caregiver report.

12. YP School Attendance and Truancy measured using caregiver and YP Report from ISRD4 at baseline and post-treatment (6 months) and follow-up (12 months) post randomisation.

13. Demographic Variables (Age, Gender, Ethnicity, SES, Household Composition, Parent Relationship to YP) at baseline. Caregiver and YP report.

14. Service Being Seen; Days from First Caseworker Contact to Randomization measured using Administrative Data at follow-up.

Overall study start date

21/08/2023

Completion date

30/09/2026

Eligibility

Key inclusion criteria

ONE OR MORE OF:

Known to services due to concerns in the last 12 months around:

1. Child sexual exploitation (CSE)
2. Child criminal exploitation (CCE)
3. Missing (from home or care) episodes
4. Potential or actual gang or CLDN affiliation as identified by police or other statutory service
5. Repeated school exclusion or absence
6. Involvement as a perpetrator or victim of youth violence or criminality

OR

TWO OR MORE OF THE FOLLOWING (OVER THE LAST 12 MONTHS):

7. Family conflict or inadequate supervision
8. Associating with antisocial peers
9. Concerns about alcohol or drug use

AND EITHER

10. Index child/young person is living at home 50% or more each week.

OR

11. Index child/young person is currently in an out of home placement, but with a clear return home plan (discussed on a case-by-case basis).

AND

12. Caregiver(s) and index child/young person are willing to engage in family therapy.

Participant type(s)

Healthy volunteer, Service user

Age group

Child

Lower age limit

10 Years

Upper age limit

17 Years

Sex

Both

Target number of participants

288

Key exclusion criteria

1. Index child/young person is actively homicidal, suicidal, or psychotic.
2. Problem sexual behaviour is the central concern.
3. Presence of organic and/or cognitive conditions that may have prevented family members making use of talking therapy.
4. Key family members, defined as "major players" in FFT-G, refuse family-based therapy.
5. Significant child protection concerns: basic needs of children are not being met.
6. Family have plans to move out of borough, thereby making therapy unfeasible within five months.

Date of first enrolment

03/06/2024

Date of final enrolment

30/09/2025

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

London Borough of Tower Hamlets

London Borough of Tower Hamlets Town Hall

160 Whitechapel Road

London

United Kingdom

E1 1BJ

Study participating centre

London Borough of Redbridge

Lynton House
255-259 High Road
Ilford
United Kingdom
IG1 1NY

Study participating centre**London Borough of Haringey**

Civic Centre
High Road
Wood Green
London
United Kingdom
N22 9SA

Sponsor information

Organisation

University of Greenwich

Sponsor details

Old Royal Naval College, Park Row
London
England
United Kingdom
SE10 9LS
+44 (0)20 8331 8000
compliance@gre.ac.uk

Sponsor type

University/education

Website

<http://www2.gre.ac.uk/>

ROR

<https://ror.org/00bmj0a71>

Funder(s)

Funder type

Charity

Funder Name

Youth Endowment Fund

Alternative Name(s)

YouthEndowFund, YEF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

The study final project report will be published on the YEF website. We also plan at least one publication in a peer reviewed journal.

Intention to publish date

01/07/2027

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository, specifically, the UK Office for National Statistics Secure Research Service. Further details can be found on the YEF website: <https://youthendowmentfund.org.uk/evaluation-data-archive/>.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (other)		01/03/2024	28/06/2024	No	No
Statistical Analysis Plan		24/12/2024	31/03/2025	No	No