EVALUATION PROTOCOL

Efficacy Randomised Trial of Functional Family Therapy – Gangs

University of Greenwich

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YOUTH ENDOWMENT FUND

Project title[1]	**Efficacy Randomised Trial of Functional Family Therapy – Gangs**
Developer (Institution)	FFT-LLC
Evaluator (Institution)	University of Greenwich
Principal investigator(s)	Sajid Humayun, Claire Monks, and Darrick Jolliffe
Protocol author(s)	Sajid Humayun, Claire Monks, and Darrick Jolliffe
Trial design	Two-armed randomised parallel multi-site efficacy trial with randomisation at the level of the Young Person
Trial type	Efficacy RCT
Evaluation setting	Family, child social care and associated agencies in three Local Authorities in London
Target group	10 to 17 year olds at risk of criminal exploitation
Number of participants	288
Primary outcome and data source	Offending: Self-reported delinquency - International Self-Report Delinquency Study 4 survey offending scale (ISRD4; Marshall et al., 2022).
Secondary outcome and data source	Young People's (YP) mental health and adjustment measured by Parent and YP report: Strengths and Difficulties Questionnaire (Goodman, 2001)

[1] Please make sure the title matches that in the header and that it is identified as a randomised trial as per the CONSORT requirements (CONSORT 1a).

	Child Criminal Exploitation measured by YP report: International Self-Report Delinquency (ISRD) 4 additional items. Substance Misuse measured by YP report: ISRD3 substance misuse subscale[2]. Parental mental health measured by parent report: Depression, Anxiety and Stress Scale (DASS-21; Henry & Crawford, 2005) Parenting supervision, knowledge and YP disclosure measured by YP report (ISRD4). Family Functioning measured by YP and parent report: SCORE-15 Index of Family Functioning and Change (Fay et al., 2013) Parental self-efficacy measured by parent report: Brief Parental Self-Efficacy Scale (BPSES; Woolgar et al., 2023) Attachment representation measured by YP report: Adult Attachment Questionnaire (AAQ; Bodfield et al., 2020) YP self-efficacy measured by YP report: New General Self-Efficacy Scale (NGSE; Chen et al., 2001) Callous-Unemotional traits measured by YP and parent report: Callous-Unemotional Traits Maximum A Posteriori Scale; (CU Traits MAP; Hawes et al., 2020) Temperamental irritability measured by YP report: Oppositional Defiant Disorder (ODD) subtyping Diagnostic and Statistical Manual (DSM) items (Stringaris & Goodman, 2009) YP School attendance and truancy measured by parent report; and YP report from ISRD4: E2/3

[2] http://www.northeastern.edu/isrd/general-isrd-3-publications/

	Age; sex; gender; ethnicity; Socio-Economic Status (SES); household composition; parent relationship to YP measured by parent and/or YP report (this includes some demographic data). Service being seen; days from first caseworker contact to randomisation measured by administrative data

Protocol version history

Version	Date	Reason for revision
1.2 [latest]	4/12/2023	Revised after peer review
1.1	13/10/2023	Updated from trial proposal
1.0 [*original*]	06/2023	

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Study rationale and background

County Lines Drug Networks (CLDNs) are organised networks involving the transportation of primarily class A drugs from urban to rural areas (Home Office, 2022). CLDNs were originally conceptualised as the activity of criminal gangs (National Crime Agency [NCA], 2016) but are now understood to also be an activity of organised crime groups[3] (OCGs; Home Office, 2022). Gangs and OCGs establish a network between an urban hub and rural areas where drugs are sold using a branded mobile telephone line through which orders are placed. Vulnerable children (under 12), young people (YP) and adults are exploited in order to transport, store and distribute drugs (ibid.). They are also likely to be encouraged or coerced into engaging in a range of other criminal activities, including violence against other YP. CLDNs are subsumed

[3] See https://www.local.gov.uk/sites/default/files/documents/tackling-serious-and-orga-44a.pdf

under the broader definition of child criminal exploitation (CCE), as defined by the Home Office (2022).

YP who are being criminally exploited are typically vulnerable and are at high risk for violent victimisation and Child Sexual Exploitation (CSE). CLDN violent crime can involve kidnapping and robbery, scalding victims with the use of boiling water or corrosive materials and sexual violence, with the latter being used more commonly against girls (Coliandris, 2015; NCA, 2017; Robinson et al., 2019; Williams and Finlay, 2019). While YP are often groomed using the offer of 'brotherhood' and gifts (e.g., expensive trainers), the use of debt bondage is common to maintain control. YP involved in CLDNs are at high risk of criminal conviction (Sturrock and Holmes, 2015), which restrict access to legitimate opportunities (e.g., schools, employment) thereby increasing their vulnerability to subsequent exploitation. As noted in the pilot FFT-G report, various factors (including poverty, ethnic minority background, family breakdown, in the care of social services, being missing from home and school exclusion) all appear to increase the risk of child criminal exploitation. Furthermore, the YEF's Children, Violence and Vulnerability (CVV) report[4] noted that overrepresentation of Black children in the youth justice system was increasing and that children from ethnic minority backgrounds were not being given access to the early support from services that they needed. Evidence of effective practice for tackling involvement in CLDNs and CCE in child social work (CSW) and other services is rare (Child Safeguarding Practice Review Panel, 2020). This is likely to be, at least in part, due to limited understanding of the risk factors and mechanisms involved in CLDN exploitation, thereby limiting the development of effective intervention approaches. A key mechanism to reduce the risk of CCE is likely to be a family's ability to support the YP to make those safe choices, with family breakdown a likely risk factor (ibid.).

Evidence-based parenting and family interventions have demonstrated effectiveness in reducing antisocial behaviour, conduct problems and offending and improving parent–youth relationships and family functioning (Humayun and Scott, 2015). Therefore, given the lack of evidence-based interventions for CLDN involvement, interventions based on these approaches may be among the most promising candidates for tackling CLDN involvement and CCE.

However, as most of these approaches are designed to target risk factors within the family, variants which also target extra-familial risks are clearly needed. Interventions designed to improve family protective factors (e.g., clear communication) to reduce the risk of gang involvement are probably the most promising starting point. Unfortunately, evidence-based gang prevention programmes are equally rare. For example, there are no gang prevention interventions with strong evidence of effectiveness listed on Blueprints for Healthy Youth

[4] https://youthendowmentfund.org.uk/reports/children-violence-and-vulnerability-2022/

Development.[5] An alternative to adapting a gang-prevention intervention is to adapt an existing evidence-based family intervention to target extra-familial risk. There are two examples of this approach. First, Boxer and colleagues (Boxer et al., 2011; 2015; 2017) adapted Multisystemic Therapy (MST; Henggeler, 2012) for gang-involved youth with mixed results. Second, Thornberry and colleagues (Gottfredson et al., 2018; Thornberry et al., 2018) trialled an adapted version of Functional Family Therapy (FFT; Alexander et al., 2013) called Functional Family Therapy-Gangs (FFT-G).

FFT (Alexander et al., 2013) is a promising evidence-based intervention that possesses evidence of delivering positive outcomes and engaging and retaining hard-to-reach YP and their families (Hartnett, Carr and Sexton, 2016), a clear challenge when working with those who are gang-involved or at risk of CCE. Contextual factors such as economic disadvantage, structural racism and inequity, play a key part in tackling the root causes of youth crime and violence. Experiences of racism, for example, from professionals and offending/social care systems, may lead to feelings of mistrust towards a new intervention, such as FFT-G. Therapists are trained on recognising and validating experiences of marginalisation and offer a "context-driven and family-specific intervention rather than a unitary or standard protocol approach applied uniformaly to all families" (Alexander et al., 2013). Furthermore, one of the immediate goals of FFT-G is replacing negativity, blame and hopelessness with a strength-based and relational focus - which are often unexpected by families who are more accustomed to problem-focused interventions from service providers or systems.

A variant of FFT, FFT-Gangs, was found to be effective at engaging YP at high risk of gang involvement and was more effective in reducing recidivism at 18-month follow-up for high-risk youth (but not for low-risk youth) when compared to services as usual (SAU; Thornberry et al., 2018). We subsequently tested the feasibility of evaluating this intervention with YP at risk of CCE in UK child social care[6]. The results of this pilot RCT demonstrated that it was feasible to both implement FFT-G with this population and to evaluate it. The key results that informed the design of this efficacy study were:

1. Close alignment and shared recruitment systems between the project and evaluation team were key to successful recruitment of participants.
2. FFT-G therapists require a training period prior to randomisation starting in order to develop clinical skills and establish referral pathways. This should be a minimum of 6 months.

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[5] https://www.blueprintsprograms.org/

[6] See https://youthendowmentfund.org.uk/wp-content/uploads/2023/01/FFT-G.-YEF-Feasibility-and-Pilot.-Jan-2023.pdf.

3. Information on risk factors is not captured and recorded reliably enough on agency systems in order to identify eligible YP (see p.65 of pilot study report). Further screening by the FFT-G supervisor/supervisor-in-training is required.
4. Between 10 and 11 eligible YP were identified per month. Randomisation rates were significantly higher when the FFT-G supervisor/supervisor-in-training screened agency systems for eligible cases rather than when they waited to receive referrals. Therefore, when screening of agency systems is conducted by the FFT-G supervisor/supervisor-in-training, we would expect 6 randomisations per site per month (see pp.56-59 of pilot study report).
5. Attrition was 20%. Missing data rates were very low but, as noted below, there were significant problems with some measures.
6. The upper end of the sample size projection (see sample size calculation section below) indicated a required sample size of 248, adjusted to 288 to account for 10% attrition at post-treatment and another 10% attrition at long-term follow-up (12 months post-randomisation). Therefore, an efficacy trial will most likely need to recruit across 3 sites over 16 months.
7. Available administrative data were not suitable to measure CCE and instead we were forced to use proxy primary outcomes (conduct problems, family functioning). There were significant challenges to measuring the outcome directly, but these would need to be addressed in an efficacy study. Self-report delinquency is very difficult to measure in this population (most likely due to minimisation), with 80% of YP reporting little or no offending. We propose a solution to this problem below.

Intervention

Functional Family Therapy (FFT; Alexander et al., 2000) is a promising evidence-based intervention delivering positive outcomes and engaging and retaining hard to reach YP and their families (Hartnett, Carr, & Sexton, 2016). Retention is a clear challenge when working with those who are gang involved or at risk of child criminal exploitation (CCE).

FFT is an intensive home-based family programme for adolescents and their families with severe behavioural problems. It is a phased five stage model with the engagement (stage 1) and motivation phase (stage 2) designed to recruit the young person and parent into the process of change by building hope for change, reduce blame and hostility and focusing on family strengths. The model requires the participation of all "major players" in sessions to maintain a balanced alliance and a relational focus of any problem behaviour (stage 3). In FFT, "major players" are defined as (a) family members seen as part of the "problem" according to referral sources; (b) family members considered likely to "shut the process

down"; (c) family members considered necessary to begin change; (d) important larger family system members (e.g., grandmother) or involved support systems (e.g., mother's best friend and neighbour) who will participate and are "appropriate" participants retaining an influential role with the young people and/or family. Once engagement is secured then the behaviour change phase (stage 4) can begin, where new skills are learned and practiced in the session and in between sessions via homework. These new skills are theorised (or demonstrated) to interrupt the relational patterns that family members have been involved in that lead to aggression and other risky behaviours. In the third phase of generalization (stage 5), these learned skills are practiced in other contexts such as school, community or in relationships with other professionals. In this final phase a relapse prevention and sustainability plan is developed to secure lasting positive outcomes.

The risk analysis process that takes place in FFT-G provides greater focus on certain individual, family, peer and community factors that increase contextual risk. This includes – at an individual risk level – impulsivity/risk taking behaviours, "neutralisation" (viz. justifying/excusing behaviour or externalising blame), anti-social tendencies and attitudes and substance misuse. This includes also mental health problems, neurodevelopmental problems and low academic aspirations and disruptions at school. At a peer level, therapists address negative peer influences (associations with friends that condone illegal activity or the referred young person minimising involvement with prosocial peers) and peer delinquency (association with friends involved in illegal activity). At a family level, consideration is given to the quality of parental supervision (not knowing their peers) and significant life and family events (e.g., loss of friendship groups, family moves, death of family members, etc.). Parental mental health problems, substance abuse and offending behaviours are considered risks factors as well as low attachment to the adolescent with ongoing conflict with blame and negativity. Community risk factors include disadvantaged neighbourhoods with availability of drugs, lack of pro-social activities and unsafe environments and school disruptions with negative school climate which can increase families' hopelessness.

The FFT-G intervention follows the same FFT phase goals to upskill the family and young person to address and overcome these specific constellations of risk. In the motivation phase the therapist will increase hope and bonding by addressing negativity and blame and some negative attributions and beliefs. The goal is to build empowerment and self-efficacy to reduce the impact of environmental risks on the family. In the behavioral change phase, the family members will learn new skills and strategies to reduce exposure or mitigate influence of risk factors. This includes better communication skills, negotiations and advocacy skills and emotional regulation along with some parental monitoring skills that fit with the relational pattern of the family and, for the adolescent, some drug refusal skills. In the generalization phase more focus is given to school engagement and generation of pro-social opportunities. This can already start in the behavioral phase too if appropriate. To achieve this, additional

support systems and resources are identified to sustain improvements that have been achieved.

All interventions are planned within the relational pattern and function of the presenting problems and alternative behaviours are matched accordingly.

FFT-Gangs (FFT-G) is a variant of FFT where the typical risk factors associated with gang involvement are targeted and skill training with the family are aimed to reduce these risks. The characteristics of YP receiving FFT and the method of recruitment to trials varies depending on setting. In the one previous trial of FFT-G in Philadelphia (Gottfredson et al., 2018; Thornberry et al., 2018) YP were referred to the trial by a family court judge on the basis of 'gang risk', consisting of current or prior gang activity or having a family member or close friend in a gang. In the YEF-funded pilot RCT of FFT-G, YP were either referred by practitioners (typically early help, Youth Offending Service [YOS]and social workers) or identified on agency data systems on the basis of presence of contextual risk factors. Furthermore, in contrast to the Philadelphia trial, participation is voluntary, not court-mandated.

In the early stages the contact between the practitioner and the family will be several times a week with home visits lasting 60-90 minutes and requiring all family members defined as major players to be present – sessions take place when families are available, e.g. sometimes after or before working hours. This reduces to weekly contact through the second and third phases. The typical intervention length is 3-5 months. Post intervention the family may receive additional (up to 4) support visits as required.

FFT-LLC set out a three-phase certification process. In the first phase, FFT-G therapists will receive training in the model and will receive weekly supervision with the USA FFT-G consultant remotely. This training is supported by the FFT CSS data management system where therapists describe the content and FFT techniques they used in a session with a family and outline their preparation for the next session. The local supervisor in training will also hold weekly risk meetings to have a local oversight of all safeguarding and engagement risks and the teams will have bi-weekly skills training in FFT techniques, overseen by the experienced FFT programme manager.

By the end of Phase I, FFT's objective is for the FFT workers to demonstrate strong adherence and high competence in the FFT model. Assessment of adherence and competence is based on data gathered through the FFT Clinical Service System CSS, through FFT weekly consultations and during phase one FFT training activities. It is expected that Phase One be completed in one year, and not last longer than 18 months. Periodically during Phase I, the FFT supervisor on site provides the site feedback to identify progress toward Phase I

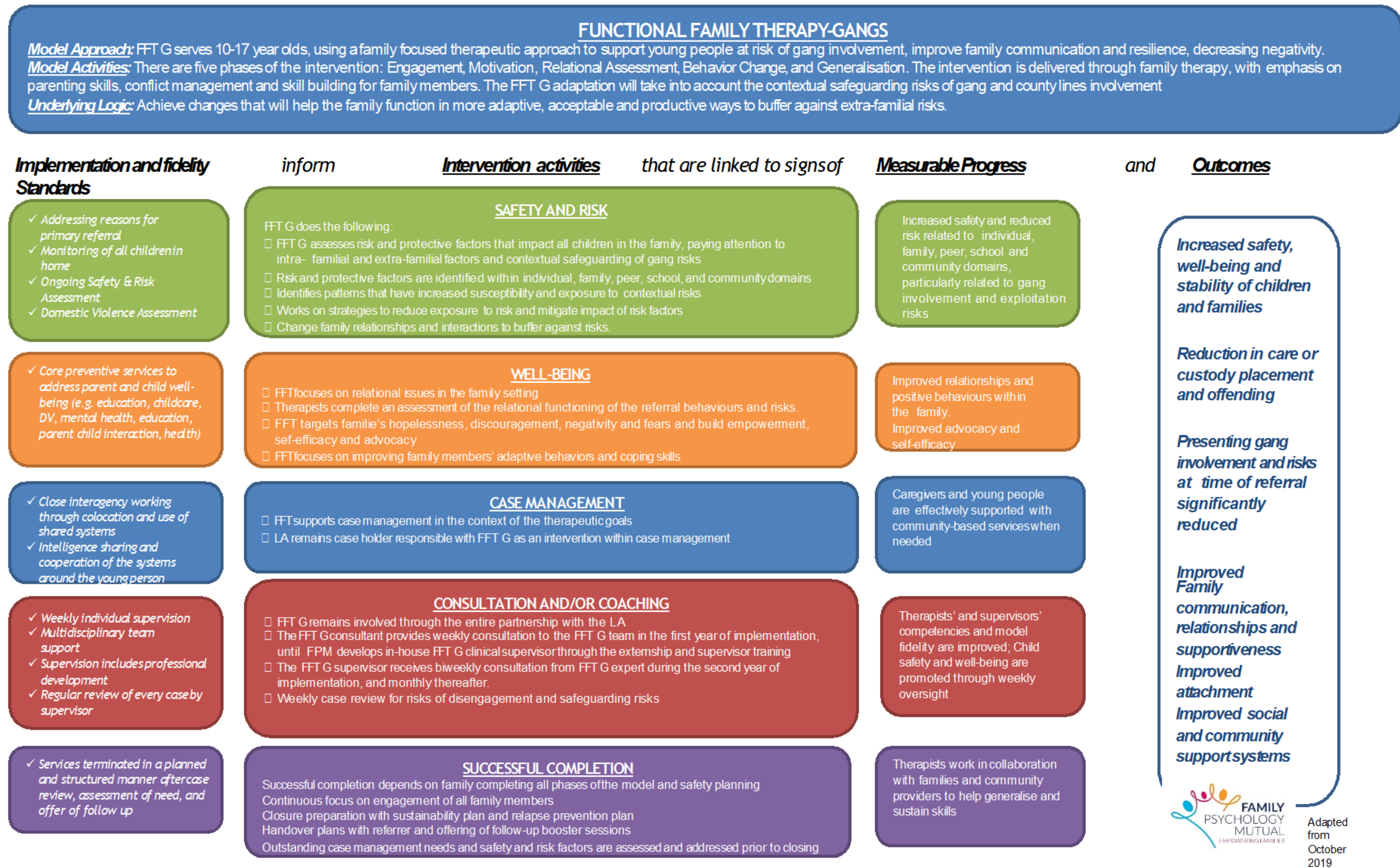
implementation goals. By the eighth month of implementation, FFT-LLC will begin discussions to identify steps toward starting Phase 2 of the Site Certification process.

During Phase II, FFT trains a site's extern (for these teams, the supervisor in training) to become the on-site supervisors. They will attend an externship in the USA and a 2-day supervisor trainings. Following this the supervisors will provide the group supervision for the teams supported by FFT-LLC through monthly phone consultation, some additional training and oversight of the FFT CSS database to measure site/therapist adherence, service delivery trends, and outcomes. Phase II is a yearlong process.

The goal of the third phase of FFT certification process is to move into a partnering relationship between the provider and FFT-LLC to assure on-going model fidelity, as well as impacting issues of staff development, interagency linking, and program expansion.

For this efficacy study, the control condition will be the usual services that would available for the YP and their family delivered to YP in child social care and related agencies. Prior to recruitment and randomisation a potential SAU intervention will be identified and selected by the caseholding practitioner in a consultation with the FFT-G supervisor/supervisor-in-training. The nature of the intervention will vary depending on availability in each site and the particular needs of the YP but there will be existing services in the local authority that are available for cases with contextual risk. This will be decided by caseholders prior to randomisation to ensure that an SAU intervention is available directly after randomization. All YP and Primary Caregivers (PCG) will be reimbursed for each assessment with a £30 shopping voucher. The intervention will be delivered to RCT participants between June 2024 and March 2026, with 6 month boosters provided to some families between April and September 2026. Booster sessions are follow-up sessions intended to consolidate the family's learning and knowledge especially to help resolve or overcome setbacks and new challenges. A caseholder or family member can request boosters directly from the FFT-G service.

Figure 1: FFT-G logic model



Impact evaluation

Research questions or study objectives

1. What is the difference in the volume (or variety) of self-reported delinquency between YP randomised to receive FFT-G and those randomised to receive SAU?
2. What is the difference in secondary outcomes between YP randomised to receive FFT-G and those randomised to receive SAU?
3. ~~What mediates~~ 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.
4. ~~What moderates~~ Do any proposed moderaters moderate the effect of treatment and are there subgroup differences? Specific moderators include callous-unemotional traits, temperamental irritability, presence of offending behaviours at baseline.
5. What are the barriers to a successful implementation and efficacy trial of FFT-G in this setting?[7]

Study design, randomisation, sampling considerations and recruitment

Design

Table 1: Trial design

Trial design, including number of arms		Two-arm randomised, stratified, parallel group, multi-site efficacy trial
Unit of randomisation		Young person
Stratification variables (if applicable)		Site
Primary outcome	variable	Offending
	measure (instrument, scale, source)	Measured by YP report: International Self-Report Delinquency Study 4 survey offending scale (ISRD4; Marshall et al., 2022)
	variable(s)	YP mental health and adjustment; Child Criminal Exploitation; substance misuse; parental mental health; parental

[7] Whilst implementation issues were largely addressed in the pilot trial, this trial will be delivered in two new sites and with entirely new FFT teams. Therefore, we will assess any ongoing barriers to implementation.

		monitoring and supervision; family functioning; parental self-efficacy; attachment representation; YP self-efficacy; Callous-Unemotional (CU) traits; temperamental irritability; school attendance and truancy; age; gender; ethnicity; SES; household composition; service being seen; parent relationship to YP; days from first caseworker contact to randomization (this includes some demographic data).
Secondary outcome(s)	measure(s) (instrument, scale, source)	YP mental health and adjustment measured by Parent and YP report: Strengths and Difficulties Questionnaire (Goodman, 2005) Child Criminal Exploitation measured by YP report: SRD4 additional items. Substance Misuse measured by YP report: ISRD3 substance misuse subscale (Marshall et al., 2013). Parental mental health measured by parent report: DASS-21 (Henry & Crawford, 2005) Parenting supervision, knowledge and YP disclosure measured by YP report: ISRD3 (Marshall et al., 2013). Family Functioning measured by YP and parent report: SCORE-15 (Fay et al., 2013) Parental self-efficacy measured by parent report: BPSES (Woolgar et al., 2023) Attachment representation measured by YP report: AAQ (Bodfield et al., 2020) YP self-efficacy measured by YP report: NGSE (Chen et al., 2001) CU traits measured by YP and parent report: CU Traits MAP; (Hawes et al., 2020) Temperamental irritability measured by YP report: ODD subtyping DSM items (Stringaris & Goodman, 2009) YP School attendance and truancy measured by parent report; and YP report from ISRD4 Age; gender; ethnicity; SES; household composition; parent relationship to YP measured by parent and/or YP report Service being seen; days from first caseworker contact to randomisation measured by admistrative data

Baseline for primary outcome	variable	Delinquency
	measure (instrument, scale, source)	Measured by YP report: International Self-Report Delinquency Study 4 survey offending scale (ISRD4; Marshall et al., 2022)
Baseline for secondary outcome	variable	YP mental health and adjustment; Child Criminal Exploitation; substance misuse; parental mental health; parental monitoring and supervision; family functioning; parental self-efficacy; attachment representation; YP self-efficacy; Callous-Unemotional (CU) traits; temperamental irritability; school attendance and truancy; age; gender; ethnicity; SES; household composition; service being seen; parent relationship to YP; days from first caseworker contact to randomisation.
	measure (instrument, scale, source)	YP mental health and adjustment measured by Parent and YP report: Strengths and Difficulties Questionnaire (Goodman, 2005) Child Criminal Exploitation measured by YP report: SRD4 additional items. Substance Misuse measured by YP report: ISRD3 substance misuse subscale. Parental mental health measured by parent report: DASS-21 (Henry & Crawford, 2005) Parenting supervision, knowledge and YP disclosure measured by YP report: ISRD3. Family Functioning measured by YP and parent report: SCORE-15 (Fay et al., 2013) Parental self-efficacy measured by parent report: BPSES (Woolgar et al., 2023) Attachment representation measured by YP report: AAQ (Bodfield et al., 2020) YP self-efficacy measured by YP report: NGSE (Chen et al., 2001) CU traits measured by YP and parent report: CU Traits MAP (Hawes et al., 2020) Temperamental irritability measured by YP report: ODD subtyping DSM items (Stringaris & Goodman, 2009)

		YP School attendance and truancy measured by parent report; and YP report from ISRD4 Age; gender; ethnicity; SES; household composition; parent relationship to YP measured by parent and/or YP report Service being seen; days from first caseworker contact to randomisation measured by administrative data

Design

This will be a parallel, two-armed, multi-site, efficacy randomised controlled trial of FFT-G compared to Services as Usual (SAU) interventions, in child social work, youth offending and early intervention services for YP at risk of Child Criminal Exploitation (CCE). The YP will be the unit of randomisation with an allocation ratio of 1:1, stratified by recruiting site. All study participants will have an allocated caseworker and will receive statutory or other services provided or organized by child social care and other agencies (e.g., early help, Youth Offending Services). In addition, the intervention arm will receive FFT-G and the SAU arm will receive additional specialist services identified prior to recruitment by child social care and early help service managers or caseworkers in collaboration with Family Psychology Mutual (FPM), the grantee who will deliver FFT-G.

Randomisation

Randomisation will be undertaken by the King's College London Clinical Trials Unit (CTU) after informed consent/assent is given and baseline assessment is complete. This will use block randomisation with randomly varying block sizes of 4 or 6 with equal allocation ratio in order to ensure the research team are blind to the randomization outcome. We will use small block sizes to ensure full caseloads for the clinical teams. We will stratify by site and randomisation will be conducted individually rather than in batches. When randomisation is complete, the researcher informs the referring practitioner and the FFT-G supervisor/supervisor-in-training of the outcome. Families are then informed of the outcome of randomisation by the referring practitioner and then are informed in more detail about the relevant intervention. The researcher is blind to treatment allocation during the baseline assessment but cannot be blind to allocation during post-treatment assessment. Families are not blind to treatment allocation.

Participants

Participants will be YP between 10-17 at risk of CLDN involvement or CCE being seen by child social care or related agencies in three London local authorities and their primary caregiver (PCG).

Inclusion criteria – YP and families

We use broader criteria identified by the Child Safeguarding Practice Review Panel (2020) for CCE/CLDN involvement, with a view to further screening undertaken subsequently in consultation:

Child/ young person aged between 10–17 years

AND

ONE OR MORE OF:

- Known to services due to concerns in the last 12 months around:
    - Child sexual exploitation (CSE)
    - Child criminal exploitation (CCE)
    - Missing (from home or care) episodes
    - Potential or actual gang or CLDN affiliation as identified by police or other statutory service
    - Repeated school exclusion or absence
    - Involvement as a perpetrator or victim of youth violence or criminality

OR

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

- Family conflict or inadequate supervision
- Associating with antisocial peers
- Concerns about alcohol or drug use

AND EITHER

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

OR

- 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

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

Exclusion criteria – YP and families:

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

Screening for eligibility

i) The embedded FFT-G supervisor/supervisor-in-training examines all new referrals to child social care and associated agencies for cases that meet eligibility criteria on the basis of reports produced from agency systems. These reports include all cases with the following categories of need: missing episodes (from home or care) reported to the Multi-Agency Safeguarding Hub (MASH), gang activity, criminal activity and sexual exploitation. If a case is identified as potentially eligible, it proceeds to consultation.

ii) The FFT supervisor/supervisor-in-training attends internal meetings (e.g., with junior Family Intervention Team, Common Assessment Framework (CAF) coordinators and Youth Offending Service [YOS]) to discuss cases and proceeds to consultation (if potentially eligible).

Given that data on CCE, gang and CLDN involvement are not consistently recorded on case records, the aim of the screening conducted by the FFT-G team leader is primarily to identify if contextual risk is present.

Consultation

If a case is deemed potentially eligible, the FFT-G supervisor/supervisor-in-training will have a meeting or call with the practitioner who holds the case and determines eligibility after further discussion with the practitioner. They will also record if the referring practitioner believes that the YP is exhibiting offending behaviour. If the case is deemed eligible, an SAU service is identified (if it had not already been by the agency), should the case be randomised to SAU. SAU services in the FFT-G pilot included the following and we would expect these to be typical in this trial:

- Specialist exploitation social work interventions
- Parenting programmes
- One-on-one mentoring
- Activity-based community interventions
- Diversionary group-based work
- One-on-one counselling provisions (e.g. school-based, CAMHS, etc.)
- Gang-exit interventions

Towards the end of the call, the FPM referral and data officer is invited to join the call and i) explain the study to the practitioner in more detail, ii) provide their contact details, iii) ask the practitioner to provide an information sheet to and request consent from the family for their contact details to be shared with the research team and then iv) set up a first call with the family.

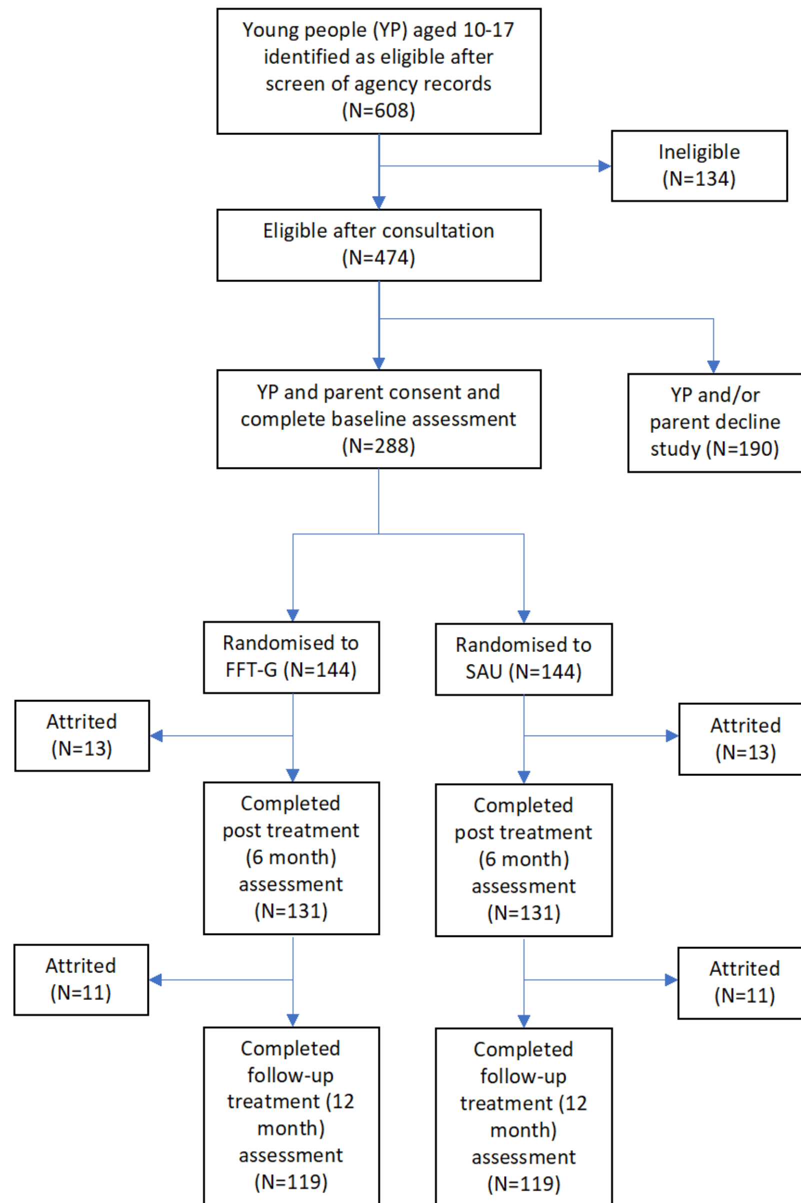
Consent and assessment

The Greenwich Research Assistant (RA) meets the YP and PCG either via a Microsoft Teams video call, on the telephone or in a face-to-face meeting (in the family home or neutral venue), and explains the study to the family (PCG and YP) and obtains consent[8]. Typically, this will take place over a number of calls/meetings. If consent is given the RA will then conduct the baseline research assessment with the YP and their PCG separately. This will be in the form of an interview for the majority of cases. If the participants wish to complete the measures online on their own, then the link to a Redcap survey is provided (please also see description of primary outcome below). Translated study materials and/or interpreters will be used when required to enable informed consent and to complete the research tools.

The intervention is typically delivered in the family home or in a neutral venue if that is preferred by the family.

[8] When it is only possible to obtain verbal consent, participants will subsequently be contacted to attempt to obtain written consent.

Figure 2: CONSORT diagram



n.b. example CONSORT diagram with anticipated numbers.

Sample size calculations

Sample size calculations are not determined on the basis of a priori MDES but rather data from the pilot RCT. [note difference from primary outcomes and direct to outcomes section for full explanation].

Sample size estimates for a full efficacy RCT were calculated using clincalc.com and checked against G*Power calculations. Estimates used 80% power and p = 0.05 with an enrolment ratio of 1. Power calculations used one-sided tests because there is no recorded case of FFT having iatrogenic effects.

Two co-primary outcomes were used: PCG reported family functioning (total scale score) and YP reported conduct problems (CP; subscore of the SDQ). Based on the effect size for PCG-reported Family Functioning outcome (g = 0.36 (-0.32,1.03)), clincalc.com returned 238 participants, increased to 288 to account for up to 10% loss to follow-up at each assessment time point. Based on the effect size for YP-reported CP (g = 1.15 (0.13,1.52)), clincalc.com returned 42 participants, increased to 51 to account for 10% loss to follow-up at each assessment time point. After discussion with the YEF Assistant Director of Evaluation, the decision was taken to use the upper end of this sample size calculation range (N=288). Any harmful effects will be monitored through serious incident reporting.

Table 2: Sample size calculation

		PARAMETER
Pilot study Effect Size		*g* = 0.36 [-0.32,1.03]
Pre-test/ post-test correlations	level 1 (participant)	0.523
Alpha[9]		0.05
Power		0.8

[9] Please adjust as necessary for trials with multiple primary outcomes, 3-arm trials, etc., when a Bonferroni correction is used to account for family-wise errors.

		PARAMETER
One-sided or two-sided?		One sided
Number of participants	Intervention	144
	Control	144
	Total	288

Outcome measures

Details on primary and secondary outcomes and other variables are provided below. Table 3 provides contextual information on the outcomes relating to offending and CCE.

Outcome data collection points

There are three data collection points: at baseline prior to randomisation; post-treatment: six months after randomisation; follow-up: twelve months after randomisation.

Unless specified below, all measures will be collected by a University of Greenwich researcher at all time points.

Table 3: Outcome terminology

Terminology	
Offending behaviours	Offending behaviours refer to behaviours that break the law. The YEF refer to three types of offending behaviours: (a) non-violent crime (viz. that do not involve violence against another person such as shoplifting, graffiti, using illegal drugs); (b) sexually violent crime; and (c) violent crime against another person (e.g., assault, robbery using threat or force, homicide)
Child Criminal Exploitation (CCE)	Child Criminal Exploitation occurs where *"an individual or group takes advantage of an imbalance of power to coerce, control, manipulate or deceive a child or young person under the age of 18. The victim may have been criminally exploited even if the activity appears consensual"* (Home Office, 2022). Child Criminal exploitation is

	broader than just county lines and includes for instance children forced to work on cannabis farms, to commit theft, shoplift or pickpocket, or to threaten other young people. Currently there is no statutory definition for Child Criminal Exploitation. However, it is covered within the Modern Slavery Act 2015 which sets out the offences of slavery, servitude and forced and compulsory labour in section 1, and human trafficking in section 2. Potential victims can be exploited in a number of ways, including sexual exploitation (CSE), forced labour, domestic servitude and criminal exploitation. As a result, they are likely to be both forced to engage in offending behaviours and experience victimisation.
County lines	County Lines involvement is subsumed under the category of CCE. Some have argued that YP involved in county lines have some sense of agency (Moyle 2019), but it is broadly acknowledged that as a form of exploitation, county lines involvement takes place within the context of the limited set of choices available to YP within their social fields (Firmin, 2020). Coercion and control are commonplace.
CCE and offending behaviours	*"Young people are often used in county lines as they are less likely to alert police attention, or be susceptible to stop and search by police, which would disrupt the criminal activity. If they are encountered by police, they are unlikely to have a criminal record ('clean skins'), and therefore likely to be let off in view of being minors. If they happen to get arrested, they are too low down the hierarchy to be able to identify those at the top of the chain, and threats and coercion by the gang ensure they divulge nothing about their activities to police or professionals."*[10]

Baseline measures

Self-reported delinquency - International Self-Report Delinquency Study 4 survey offending scale (ISRD4; Marshall et al., 2022).

Primary outcome

Offending: Self-reported delinquency (SRD) - International Self-Report Delinquency Study 4 survey offending scale (ISRD4; Marshall et al., 2022). Baseline, post-treatment, follow-up. Follow-up is the primary outcome.

This was not the primary outcome in the pilot study. Whilst a number of trials of FFT have been conducted with offending as a primary outcome, and a previous trial of FFT-G did include delinquency as a primary outcome, it recruited court mandated youth who were offending. The focus of the pilot was instead YP at risk of criminal exploitation recruited from social care.

[10] Founder of Stop & Prevent Adolescent Criminal Exploitation (SPACE), *County lines and criminal exploitation – what, why and what does it look like?* https://www.researchinpractice.org.uk/children/news-views/2019/july/county-lines-and-criminal-exploitation-what-why-and-what-does-it-look-like/#:~:text=Children%20are%20used%20in%20county,would%20disrupt%20the%20criminal%20activity.

Therefore, the anticipated primary outcome in the pilot study was CCE as recorded on agency systems. During the pilot study, it became clear that this was not recorded reliably and so two co-primary outcomes collected directly from participants were used instead (see sample size calculation section above). As a result, power calculations for this efficacy trial did not make use of SRD data from the pilot study.

However, as requested by the YEF, this trial will use self-reported delinquency as the primary outcome. The rationale for this is:

- A core YEF strategic aim is to understand what works to reduce crime and violence, so YEF aims to select offending as the primary outcome in all YEF studies where it is plausible that the intervention will reduce it, e.g. it is included in the theory of change
- The primary outcome must be measured using a valid and reliable measure and there were no valid and reliable measures of other relevant outcomes that are highly connected to crime e.g. child criminal exploitation.
- The mitigations included since the pilot study to increase the chance of seeing impact on offending (e.g. screening YP, introducing anonymous reporting of outcomes by YP)
- The co-primary outcomes from the pilot study will be included as secondary outcomes so that it will still be possible to test for intervention effects on these.

Additional subscales, and some additional items on CCE that we will add will be used as secondary outcomes (see below). We will not use the weapon carrying, assault, intimate posting or hacking follow-on questions that were added to the ISRD4 as these are not required for calculating the primary outcome. The total number of delinquent acts will be used as the primary outcome measure.

Method of collection for offending and CCE data

There were significant problems with the SRDS measure (Smith & McVie, 2003) used in the pilot RCT. It was both highly positively skewed and the number of respondents admitting to criminal behaviour was very low. For 10 of the 15 questions, 80% or more of respondents said they had never engaged in these activities in the last six months (90%+ for six of the questions). There were only two questions to which at least half of YP admitted to engaging in at least once: truancy (52%) and fights (66%; although this includes fights with siblings). Furthermore, our limited examination of Protocol case files suggested that these responses were not honest.

We believe that this is due to characteristics of this population (minimisation, denial, fear of reprisal). It is likely that YP will fear reprisal from gangs or OCGs if it is discovered that they have told someone about their engagement in criminal activities. This is likely to be exacerbated by the need for us to include a disclaimer describing the conditions under which we would break confidentiality and disclose because if we are aware that YP are at risk of

being victimised then we have a duty of care to make a referral. The result is likely to be an unwillingness to provide honest responses to the questions in a self-report delinquency measure.

Our proposed solution is to keep primary outcome data and some secondary outcome data entirely anonymous until the end of the study. We will do this by explaining to YP that we will not look at the data until July 2026 and will facilitate this by adding a different ID number to these data than the main study ID used for other data. The study team will not have access to these data and they will stored by another research team at the University of Greenwich, who will not have access to the main study ID. That study team will check for completeness of data but will not look at YP responses and will not be able to identify the YP from this data. Only at the end of the study will we link the two IDs.

Thus, YP will complete either a hardcopy or online version of these outcome measures that will not be linked to any identifying information on our systems and will therefore be completely anonymous. Researchers will provide support to YP in answering questions as requested without having full access to participant response. We will also collect some secondary outcomes using this method, including data on CCE. We will include a paragraph at the end of the measure saying that they can talk to the researcher or to their caseworker if they are being hurt, criminally exploited or feel at risk of being so. We will then make a referral but the data for the primary outcome measure will remain anonymous.

Secondary outcomes

YP mental health and adjustment (25 items) and impact items (5 items) (Both parent and YP report: Strengths and Difficulties Questionnaire; Goodman, 2005). This measure is associated with FFT-identified risk factors situated within the individual domain (i.e., index young person) and with proximal outcomes, e.g., reduction in internalizing and externalizing behaviours. We will total SDQ score and each five item subscore (conduct problems, ADHD, emotional problems, peer problems, prosocial behaviour) and collect the impact score. Taken together, these will measure YP mental health and adjustment. This will be done separately for parent report SDQ and YP report SDQ.

The impact supplement provides additional information on any difficulties a child or young person displays in emotions, concentration, behaviour or social relationships, including information on chronicity, distress, social impairment and burden to others.

Child Criminal Exploitation (YP report: ISRD4; Marshall et al., 2022: 2 additional questions and up to 3 follow-on questions). For each of the ISRD4 offending scale items we will add follow-on questions to each of the 14 items:

Have other people in your life tried to involve you in this behaviour? [CCE lifetime prevalence]
Who tried to involve you? [checklist]

Your friend(s)
A sibling
Other young people you know
An adult in your family
Another adult
Other [Please explain their relationship to you]
If yes [to each of the above], how many times in the last 6 months? [CCE 6 month incidence]

We will also add three additional questions which will be used to prompt for CCE/CSE information (as above) and will not contribute to the primary outcome: ISRD offending scale:

Have you been away from home for at least 24 hours without your parents knowing where you were?
Have you stored or transported (e.g., by train or car) drugs or weapons?
Have you ever had to do any sexual activity in exchange for money, goods or something else?

We also aim to use a short measure currently being developed as part of an ONS funded study (Co-I: Claire Monks) developing a new screening tool for child maltreatment including a CCE subscale. This is not currently available but we would expect it to be available prior to this trial starting.

FFT-G seeks to create a safe, functioning and protective family unit to buffer external influences and pressures associated with CCE. So these follow up questions may be considered distal outcomes as shown in the logic model.

Substance Misuse (YP report: ISRD3 substance misuse subscale: 5 items, 7 potential follow-on questions). Substance use (in terms of frequency, severity and impact) is distinguished in terms of "use" as a goal or as a vehicle for other relational and intrapersonal outcomes (e.g. status, income). The FFT-G intervention seeks to create alternatives for income and alternative paths to meet relational needs.

Parental mental health (Parent report: DASS-21: 21 items, parent report; Henry & Crawford, 2005). The measure will help identify impact on risk/protective factors in the individual domain (caregiver/s) – FFT-G seeks to address parental mental health and impact of trauma through skills training in the BC phase and in the generalization phase in linking caregiver/s to community mental health services.

Mediators[11]

[11] References to phases in this section are provided to improve specificity rather than reflecting claims about changes being made in those specific phases. Please see the intervention section above for more detail on phases.

Parenting supervision, knowledge and YP disclosure (YP report: ISRD3: 12 items, 3 subscales). This is seeking to measure the impact of the FFT-G intervention on risk and protective factors in relation to the parental domain and are addressed in the model primarily in the Behaviour Change (BC) phase.

Family Functioning (YP and parent report: 15 items: SCORE-15; Fay et al., 2013). Family conflict, negativity and poor communication are identified risk factors that required focused attention in all phases of the model. In FFT-G, all major players of the family are required to attended sessions. We will only use the total score.

Attachment representation (YP report: AAQ: 9 items; Bodfield et al., 2020). Loss of connection with caregiver/s is identified as a risk factor in the FFT-G process of analysis and addressed in Motivation phase by tackling negativity and blame and seeing the problems relationally. In BC Phase, there is also, where required, a focus on family bonding activities to increase connection and belonging between the young person and primary caregiver/s at home and siblings.

Parental self-efficacy (parent report: BPSES: 5 items; Woolgar et al., 2023). In the Motivation phase, hope is instilled through application of specialized clinical skills. Then in BC phase, therapists focus on upskilling parents with communication, negotiation, problem-solving to enable them to advocate better for themselves and their child in school and community contexts.

YP self-efficacy (YP report: NGSE: 8 items; Chen et al., 2001). This is associated with the Motivation phase's emphasis on the increase of hope and upskilling of the young person in skills (such peer refusal) to increase their sense of agency to deal with extra-familial risks.

Moderators/Covariates

*Callous-Unemotional (CU) Traits** (4 items; YP and parent report: CU Traits MAP; Hawes et al., 2020). A number of clinical trials of evidence-based family interventions have shown that CU traits are a marker for lower responsivity to treatment (e.g., Hawes & Dadds, 2005). Collected at baseline and follow-up assessment.

*Temperamental irritability** (3 items; YP report: ODD subtyping DSM items; Stringaris & Goodman, 2009). This is viewed as a marker for emotional lability and has been shown to be associated with greater improvements after intervention (Scott & O'Connor, 2012). Collected at baseline.

YP School attendance and truancy (parent report: 1 item 'Has your child been attending school during the last 6 months of school?'; and YP report from ISRD4: E2/3, 2 items). In the

pilot study school attendance was the only reliable predictor of attrition. Collected at each timepoint.

*NB: These scales are partly calculated using some items from the SDQ. As a result, they add a total of 4 extra items rather than 7. No analyses will be conducted using both the SDQ and these scales.

Covariates/Demographic Data

Age of YP (parent report)

Gender of YP (PCG report)

Ethnicity of YP (PCG report)

Age of PCG (parent report)

Gender of PCG (PCG report)

Ethnicity of PCG (PCG report)

SES (PCG report)

Number of adults in the house (parent report)

Number of children/YP in the house (PCG report)

Service the YP was seeing (administrative data)

PCG relationship to YP (PCG report)

Number of days from first contact with a caseworker (typically consultation) and 27andomization (administrative data)

All collected at baseline only.

Compliance[12]

Data on treatment compliance is captured as routine clinical monitoring on the FFT CCS system and will be provide by FFT LLC (the developers) and FPM (the grantee delivering the FFT-G). This will include:

[12] Compliance here is equivalent to the broader term adherence.

Number of sessions received

Phases completed

Critical dose (8 session or more) delivered or not

Fidelity to the intervention model

FFT-LLC therapist and client outcome measures

Therapeutic alliance

Analysis

We will test the effect of FFT-G on primary and secondary outcomes on an intention-to-treat basis using hierarchical linear mixed modelling, with post-treatment and baseline outcomes, trial arm and trial arm by time interaction term as explanatory variables (included in power calculations). Linear mixed models allow repeated measures from each participant to be correlated by fitting random intercepts varying at the level of the individual, thereby improving precision of estimates. We will analyse differences in treatment outcomes in subgroups (e.g., by gender, age, temperamental irritability, CU traits and presence of offending behaviour at baseline identified by caseworker by using interaction terms). We will calculate effect sizes for primary and secondary outcomes. We will use structural equation modelling to test for mediators of treatment (see measures above). Please see IPPE section below for planned analysis of compliance data.

Longitudinal follow-ups

The effect of treatment will be assessed both 6 months after randomisation (at the end of treatment) and 12 months after randomisation (6 months after treatment ends). We will use the latter timepoint as the main assessment of treatment effects. See above for analytical models.

Implementation and process evaluation

Overview

This section presents information about the implementation and process evaluation (IPE). We would aim to deliver a mixed-methods IPE alongside of the Efficacy Study.
The rest of this section covers:

- Research questions
- Research methods

- Approach to analysis

Research questions

This IPE has been designed in line with YEF guidance on IPEs.

The primary objectives of this IPE are to:

- Understand the association between aspects of the FFT-G programme's implementation and successful outcomes.
- Gather data to help guide the successful implementation of FFT-G programmes in future.

The key research questions will be:

1. **Aspects of implementation:** How effectively has the FFT-G programme been implemented?
    a. *Fidelity:* To what extent has delivery been in line with the FFT-G theory of change?
    b. *Dosage:* How much of FFT-G has been delivered and how many families completed all phases? Is it possible to determine how much of FFT-G needs to be delivered to have a desirable impact?
    c. *Quality:* How well have the different parts of FFT-G been delivered?
    d. *Reach:* Has FFT-G reached who it was intended to reach?
    e. *Responsiveness:* Is there evidence that young people and their families have engaged with FFT-G?
    f. *Intervention differentiation:* Is FFT-G sufficiently different from existing practice?
    g. *Adaptation:* Would any changes be needed to accommodate different contexts or needs?

2. **Factors influencing implementation:** What are the facilitators or barriers to the implementation of FFT-G?
    a. *Locality factors:* Are there issues that have influenced implementation at a locality level? For example, identification of suitable young people, family engagement, level of need?
    b. Organisation level factors: Are there factors that may have impacted implementation at the organisational level?
    c. Unexpected factors: Are there factors that unexpectedly had an impact on implementation?

3. **Experiences of support:** What are young people's actual experiences of receiving FFT-G?

a. What were the components of FFT-G that were related to positive outcomes?
b. Have there been any differences in how FFT-G was experienced by those having protected characteristics? In particular we will examine gender in relation to experiences of FFT-G as it is likely that male and female YP may have risks for different patterns of involvmenet in County Lines and thus may have different experiences of FFT-G. We will also explore differences by racial and ethnic background to examine the experiences of YP from different backgrounds.

4. **Guidelines for future implementation:** In their totality, what might the implications of the above be for future implementation of FFT-G in different contexts?

Research methods

This IPE will use a mixed methods approach. The qualitative evidence captured from the interviews will be compared with the evidence of the results from the RCT and this will be ~~martialled~~ used to identify clear recommendations for how FFT-G could be improved in the future and also key issues for future implementation of FFT-G.
Table 4 shows the data capture methods that we would propose to address the research questions posed.

Table 4: IPE methods overview[13]

Research methods	Data collection methods	Participants/ data sources (type, number)	Data analysis methods	Research questions addressed	Implementation/ logic model relevance
Data analysis	Activity from agency systems on SAU and dosage data collected by FFT-G delivery staff	Young people who received FFT-G (n=144) and those in the services as usual group (n=144)	Descriptive statistics of basic measures of dosage	RQ1. Association between aspects of the FFT-G programme's implementation and successful outcomes.	Aspects of implementation.
Semi-structured interviews	Interviews with young people and their families	A total of 10 interviews (5 with young people and their families together who received FFT-G and 5 who did not) to assess how families received the intervention.	Thematic analysis	RQ1: How effectively has the FFT-G programme been implemented? RQ2: What acted as facilitators or barriers to the implementation of FFT-G? RQ3: What are young people's actual experiences of receiving FFT-G? RQ4: In their totality what might the implications of the above be for future implementation of FFT-G in different contexts?	Aspects of implementation; Factors influencing implementation; Experiences of support; Guidelines for future implementation

[13] More detail is provided in subsequent sections.

Research methods	Data collection methods	Participants/ data sources (type, number)	Data analysis methods	Research questions addressed	Implementation/ logic model relevance
Semi-structured interviews	Interviews with FFT-G delivery staff	5 programme staff will be interviewed.	Thematic analysis	RQ1: How effectively has the FFT-G programme been implemented? RQ2: What acted as facilitators or barriers to the implementation of FFT-G? RQ3: What are young people's actual experiences of receiving FFT-G? RQ4: In their totality what might the implications of the above be for future implementation of FFT-G in different contexts?	Aspects of implementation; Factors influencing implementation; Experiences of support; Guidelines for future implementation
Semi-structured interviews	Interviews with wider stakeholders	5 wider stakeholders will be interviewed. These will include social workers, VRU members and police.	Thematic analysis	RQ1: How effectively has the FFT-G programme been implemented? RQ2: What acted as facilitators or barriers to the implementation of FFT-G? RQ3: How did FFT-G fit into the ecosystem of	Aspects of implementation; Factors influencing implementation; Experiences of support; Guidelines for future implementation; Mobilisation and setup activities

Research methods	Data collection methods	Participants/ data sources (type, number)	Data analysis methods	Research questions addressed	Implementation/ logic model relevance
				services delivered in agencies? RQ4: In their totality what might the implications of the above be for future implementation of FFT-G in different contexts?	

Interviews with young people

We will conduct in-depth interviews with 5 young people and their families who received FFT-G towards the end of the efficacy evaluation. The results of these interviews will assist in developing an understanding of how FFT-G might be having its impact.

FFT-G practitioners will help to identify young people and their families who may be interested in being interviewed using a method that minimises bias and informed consent will be obtained for them to take part in the interviews. We will aim to obtain interviews with those who are representative of the sample within the RCT in terms of ethnicity, age, gender and family composition. FFT-G practitioners will help to organise the most appropriate place, time and venue for the interview. If a young person and their family would like an interview to be conducted in a language that is not English we will provide an interpreter so that this does not prevent participation.

The interviews will be conducted by a UoG researcher who will be a member of the evaluation team who has experience of conducting confidential interviews with vulnerable young people and families. With the support of the FFT-G team we will decide whether face to face, online or telephone interviews will be best for each individual young person and their family.

We will design the topic guides for all interviews based on attempts to examine the key implementation and process research questions identified above. We will pilot trial these tools and refine these before using them for the actual interviews. We will ensure that we consult with FFT-G delivery colleague's knowledge of the young people and their families that they are working with to make sure that the topic guides are accessible and easily understood for those who may be neurodiverse. We will also test these for ethnic and cultural sensitivity. We will be mindful of any safeguarding issues which may arise in these interviews. These will be discussed with FFT-G practitioners.

Interviews with FPM and wider stakeholders

We will also interview 5 FFT-G programme delivery staff and 5 wider stakeholders upon completion of the delivery of the intervention. We will agree the sample with FFT-G colleagues based on their likely level of knowledge and embeddedness within the delivery team. Once the potential interviewee has been nominated the individual will be contacted by the research team and provided with more information about the reason for the proposed interview. The potential interviewee will be provided with an information sheet, and we will obtain informed consent before organising a time for the interview.

We would propose to conduct the interview online and would anticipate that this would take around 45 minutes. The topic guides will be designed and agreed with the FFT-G delivery team and YEF. These interviews will examine the views of delivery colleagues on how well FFT-G

was implemented and embedded. The results of these interviews will allow us to answer the research questions posed.

We would propose to record these interviews if the interviewee provides consent to do so. These recordings (or our notes if consent for recording is not given) will be stored securely at the University of Greenwich.[14]

Analysis

Interview analysis

Thematic analysis using Braun & Clarke's (2006) eight-stage framework will be employed to analyse the qualitative data. Following familiarisation with the transcribed interview data codes will be applied; codes will be reviewed to identify patterns with cross comparison occurring, from which themes will arise. Analysis will be both inductive and deductive.

Activity data analysis

The qualitative data collected as detailed above will be compared to the quantitative data available about the delivery of FFT-G to understand more about the dosage and activity that has taken place. Activity data is an important aspect of FFT-G's internal data recording mechanisms.

Cost data reporting and collecting

Cost data will be provided by FPM. We will provide cost estimates in the final project report. Staff costs will follow the submitted FPM budget. Non-staff costs captured can be found in Appendix B: FPM delivery costs. We will collect and report cost data in line with the YEF's cost guidance.

Diversity, equity and inclusion

Accessibility will be ensured by high levels of training and support given to the researchers who conduct the interviews with families.

Contextual factors such as economic disadvantage, structural racism and inequity, play a key part in tackling the root causes of youth crime and violence and CCE. Experiences of racism, for example, from professionals and offending/social care systems, may lead to feelings of mistrust towards a new intervention and an evaluation of it. Thus, participants in this trial are

[14] See https://docs.gre.ac.uk/rep/vco/data-protection-policy

likely to be from populations with high levels of risk and those who maybe resistant to service involvement.

The materials chosen for the interviews have been designed to be accessible, inclusive, and culturally sensitive. They have been piloted with this population and have been found to be acceptable and interviews in the pilot study indicated that participants did not regard the level of assessment burdensome. Researchers will be trained to conduct assessments appropriately and will be able to support participants with any queries. We will use translators and interpreters for recruitment and assessment activities. We successful trialled this approach in the pilot RCT.

The evaluation has been informed by the pilot study where we received feedback from young people and their families (also, see above re: likely sample). This evaluation has also been informed by the expertise of the intervention team.

We will ensure that demographics related to diversity are recorded such that we are able to consider these within the evaluation analyses.

The intervention serves a diverse group of young people and we will ensure that recruitment to the evaluation reflects this.

No specific requirements or support needs have been identified other than that identified in the pilot (e.g., interpreters). The interviewer will be available during the interview to clarify any questions, but the measures have been designed to be accessible for the target groups.

It is a requirement of the University of Greenwich that all members of staff receive regular EDI training.

All members of the team have extensive experience of working with marginalised communities, and with young people. The PI and one of the Co-Is conducted the pilot RCT.

Ethics and registration

We will submit an application for ethical approval in January 2024 to the University of Greenwich Research Ethics Board with a view to obtaining ethical approval for the full RCT in February 2024. The trial will be registered on the ISRCTN registry.

Data protection

After participants have agreed to participate, they will be allotted identification numbers (and pseudonyms will be used for interview recordings and transcripts). Data and contact information will be securely stored, in accordance with GDPR, using the identification numbers, with access limited to the research team only (except for the purposes of data archive; see below). Participants will be informed that all information about them will be stored in this way. Data obtained from participants through questionnaires and interviews will be kept separate from identifying information and available only to the trial team. All identifying information will be stored securely and in accordance with the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, for the purpose of correspondence with participants and only members of the research team will have access to it (other than for archiving). Published reports will not identify the research participant at any time. All data will be encrypted and stored securely in password protected files on password protected computers using University OneDrive and Microsoft Teams storage and using a minimum of two factor authentication and only members of the research team will have access to it.

At the end of the study, all study data as well as limited identifiable information on YP and families will be provided to the ONS and DfE to facilitate data archiving and assessment of long-term effectiveness of the intervention.

We will access data held on agency systems which will be facilitated by Information Sharing Agreements.

Stakeholders and interests

Developer: FFT LLC. The team will be trained and supervised by a consultant from FFT-LLC who will provide clinical oversight and be responsible for the quality of the intervention and adherence to the model.

Delivery team: The FPM senior management team consists of Brigitte Squire (Project Director/FPM CEO) who will oversee the implementation and clinical quality assurance and Raphael Cadenhead (FFT-G Programme Manager) who will be the main contact person for the project. Tom Jefford (FPM CEO/Business Director) will provide back-up support, implementation advice and monitoring feedback reports. FPM Data Analyst, Marco Branco, will be involved throughout the project, especially during the mobilisation period to ensure the development of efficient data systems (e.g. study consultation tracker, case management spreadsheets, joined research and provider tracker), which proved indispensable for the successful delivery of the pilot RCT.

Each Borough will have a designated FFT-G team consisting of one clinical supervisor/supervisor-in-training and two therapists with dedicated admin support. In this

first year the supervisor in training will act as the operational manager of the team and will provide case management oversight of therapist activities and promote adherence to the model whilst holding their own (reduced) caseload of two families. They will also be responsible for identifying eligible cases through data retrieval and review processes and in offering consultations to allocated workers. They will be trained in this process and supported by the Programme Manager.

In addition, we will include a floating/peripatetic FFT-G therapist who can work across all three Boroughs to (a) ensure sufficient coverage in cases of therapist illness/maternity leave/annual leave/turnover; (b) manage capacity in demand. This will need to be a therapist with some prior FFT experience. We consider that this post will provide assurance against workflow fluctuations and also as a mitigation against staff sickness and turnover.

In the second year, supervisors will then also be doing the weekly supervision of the clinical work with training of the supervisor provided by FFT-LLC as we move the second stage of the FFT licence.

The size of the FFT teams was decided upon the capacity needed to work with 144 families over the randomisation period. To generate this capacity we considered 3 teams, each with 2 therapists and 1 supervisor. This will give a capacity of 14 cases over 5 months for each team. Each team will be able to recruit 3-4 new families over 15 months (cycles of 5/6 months to allow completion of cases) for the RCT. There will of course be some attrition which will create some flexibility, but we need to aim for full capacity on completion.

The 3 teams will each be supported by a part time business officer. We will allocate one day a week of input from the Data Analyst and ongoing oversight from the Programme Manager. Leadership will be provided by the full time Programme Manager and part time (three days a week) Programme Director for general oversight. The Programme Manager and Data Analyst will be the main contact points to liaise with the Greenwich research team and to ensure the collection of all necessary data from the teams. To this central FPM administration team, we also propose adding a Data and Referral Officer. The postholder will set up the initial meeting between the family and research team (and all other associated administrative tasks), but will remain blind to research data and will only have access to the FPM/University of Greenwich case tracker spreadsheet to ensure oversight of recruitment and throughput issues. They will have no role in the administration of research questionnaires or consent forms although may collect them in a sealed envelope.

Evaluation team:
The senior evaluation team will consist of some the same team that led the YEF funded pilot feasibility trial of FFT-G, namely, Dr Sajid Humayun (PI; University of Greenwich), and

Professor (Co-I) Darrick Jolliffe (Co-I; Royal Holloway, University of London). In addition, Professor Claire Monks (Co-I; University of Greenwich) will also be a Co-I. The team will also consist of a research team consisting of one Research Fellow and up to three research assistants.

Dr Humayun will have oversight of overall and day to day trial management, of trial setup, of trial protocols, obtaining ethical approval, analysis and write-up, and management of the project Research Fellow. Profs Jolliffe and Monks will both contribute to trial setup, management, analysis and write-up and discussion and negotiation with stakeholders. They will have a key role in the development of the assessment battery and primary outcome measure. Professor Monks will also contribute to staff recruitment and management. The research fellow will be responsible for day-to-day management of the trial and will also conduct recruitment and assessment activities. Research assistants will conduct the majority of recruitment and assessment activity as well as data entry and cleaning. Employment of research assistants will be on a staggered basis to align to recruitment and assessment activities.

Randomisation (but not data management) will be conducted by King's College Clinical Trials Unit.

LA stakeholders: The project partners are three London Local Authorities: Tower Hamlets, Haringey and Redbridge. We already have established contact and they have each appointed a designated lead in their Local Authority who will be the main point of contact between FPM and the Local Authority. These leads will be instrumental in forming and chairing a local steering group in each Authority which will meet monthly and will ensure operational issues are addressed in a timely fashion during the project.

Advisory Group: We are planning the establishment of an Advisory Board consisting of members from FPM, the University of Greenwich, representatives from each participating Local Authority and other external members with specific knowledge to advise the group. This is likely to be held on a quarterly basis to offer cross-Borough opportunities for problem-solving and to unite the different stakeholders to this RCT project.

No conflicting interests.

Risks

Please Appendix C: Risk Register.

Timeline

Dates	Activity	Staff responsible/ leading
July-Dec 2023	Mobilisation	FPM
February-March 2024	Protocol finalised following ethics review	UoG
January – June 2024	FFT-G training phase	FPM/FFT LLC
May-June 2024	Statistical analysis plan and protocol published on ISRCTN	UoG
May 2024	RCT referrals start	FPM
June 2024 – September 2025	Randomisation and baseline data collection	UoG/CTU
July 2024 - March 2026	Delivery of intervention	FPM
December 2024 – March 2026	Post-treatment data collection	UoG

June 2025 – September 2026	Follow-up data collection	UoG
November 2025	Update SAP on YEF website	UoG
April 2026 - September 2026	FFT-G boosters	FPM
July 2026 – May 2027	Data cleaning, analysis and write-up	UoG
April 2027 – May 2027	Data archiving	UoG

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Appendix 1: Changes since the previous YEF evaluation[15]

Appendix Table 1: Changes since the previous evaluation[16]

Feature		Pilot to efficacy stage
Intervention	Intervention content	Addition of floating FFT-G therapist
	Delivery model	None
	Intervention duration	None
Evaluation	Eligibility criteria	None
	Level of randomisation	None but stratification by site introduced
	Outcomes and baseline	Primary outcome changed to ISRD offending scale. Some secondary outcomes changed.

[15] Please delete this section if it is not applicable.

[16] Delete columns from the table if they are not applicable or adjust titles as relevant.

	Control condition	No changes.

Appendix 2

Data protection statement

What will happen to the information collected?

The information you give us and that we collect is confidential and we will not share it with anybody during the study but if you tell us something that makes us worried for you or someone else, we might have to tell someone.

- We will write a report about what we find out for Youth Endowment Fund and articles in academic journals. We will not use your name or any information that could identify you.
- After the study is finished, all the questionnaire/interview answers and information about who took part will be given to the Youth Endowment Fund and stored indefinitely for future research. The Youth Endowment Fund have provided additional information that you can access here.
- The data may also be linked to government datasets, including education, criminal justice and other systems to research the long-term outcomes of the Families Are Forever Service. This data will be used for research purposes only and it illegal for it to be used to identify you. Only approved researchers will be able to access this data and the identities of young people will not be known by anyone accessing this data in future.
- Any information the University of Greenwich keeps will be destroyed in July 2027.

Under the General Data Protection Regulation (GDPR), we have to explain to you which lawful basis we rely on for processing your personal data. This is:

We need it to perform a public task, in the area of research.

The research is for scientific and statistical purposes in the public interest and will be subject to technical and organisational safeguards. The information we collect from you will be stored securely in accordance with the General Data Protection Regulation (GDPR) the Data Protection Act (2018). This means that that the information you give us will be stored under an identification code number only – it will be kept completely separate from any identifying information (names, addresses etc.).

If you have any questions, would like to know more, you can call [RF] on 0208 331 [RF extension] or email him/her (RF email@greenwich.ac.uk) for further advice and information.

Your data protection rights

Under data protection law, you have rights including:

Your right of access - You have the right to ask us for copies of your personal information.

Your right to rectification - You have the right to ask us to rectify personal information you think is inaccurate. You also have the right to ask us to complete information you think is incomplete.

Your right to erasure - You have the right to ask us to erase your personal information in certain circumstances.

Your right to restriction of processing - You have the right to ask us to restrict the processing of your personal information in certain circumstances.

Your right to object to processing - You have the the right to object to the processing of your personal information in certain circumstances.

You are not required to pay any charge for exercising your rights. If you make a request, we have one month to respond to you.

Please contact us at compliance@gre.ac.uk if you wish to make a request.

How to complain

If you have any concerns about our use of your personal information, you can make a complaint to us at

Name: Peter Garrod, Data Protection Officer

Address: University of Greenwich, Old Royal Naval Campus, 30 Park Row, London SE10 9LS

Email: compliance@gre.ac.uk.

You can also complain to the ICO if you are unhappy with how we have used your data.

The ICO’s address:

Information Commissioner’s Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF
Helpline number: 0303 123 1113
ICO website: https://www.ico.org.uk

youthendowmentfund.org.uk

hello@youthendowmentfund.org.uk

@YouthEndowFund

The Youth Endowment Fund Charitable Trust

Registered Charity Number: 1185413