Functional Family Therapy - Gangs

Statistical analysis plan

Evaluating institution: University of Greenwich
Principal investigator(s): Sajid Humayun, Darrick Jolliffe, Claire Monks

YOUTH ENDOWMENT FUND

YEF statistical analysis plan

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

[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).

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) 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)

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

	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 Age; sex; gender; ethnicity; Socio-Economic Status (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

SAP version history

Version	Date	Changes made and reason for revision
1.2	07.08.2024	Revised following additional YEF comments
1.1	14.06.2024	Revised following YEF comments and peer review
1.0 [*original*]	15.04.24	

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Introduction

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 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). 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.

Functional Family Therapy (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.

We tested the feasibility of evaluating FFT-Gangs (FFT-G), an adaptation of FFT designed to reduce gang affiliation and related criminal behaivour, with YP at risk of CCE in UK child social

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

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

care[5]. The results of this pilot RCT demonstrated that it was feasible to both implement FFT-G with this population and to evaluate it. This efficacy study builds on the learning from this pilot trial and aims to assess the effect of FFT-G on levels of self-reported delinquency in YP at risk of CCE, CLDN involvement and other extra-familial harm.

Design overview

This is 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). 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 randomisation outcome. We will use small block sizes to ensure full caseloads for the clinical teams. 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 randomisation.

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)

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

Secondary outcome(s)	variable(s)	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(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 (this includes some demographic data). Service being seen; days from first caseworker contact to randomisation measured by administrative 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.
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Sample size calculations overview

Sample size calculations are not determined on the basis of a priori MDES but rather results from the pilot RCT.

		Protocol	Randomisation
Pilot study Effect Size		*g* = 0.36 [-0.32,1.03]	
Pre-test/ post-test correlations	level 1 (participant)	0.523	
Alpha[6]		0.05	
Power		0.8	
One-sided or two-sided?		One sided	

[6] 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.

		Protocol	Randomisation
Number of participants	Intervention	144	
	Control	144	
	Total	288	

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.

The primary outcome in the efficacy study is *Offending***:** Self-reported delinquency (SRD) - International Self-Report Delinquency Study 4 survey offending scale (ISRD4; Marshall et al., 2022). 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.

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: PCG reported family functioning (total scale score) and YP reported conduct problems (CP; subscore of the SDQ). As a result, power calculations for this efficacy trial did not make use of SRD data from the pilot study. Based on the effect size for PCG-reported Family Functioning outcome in the pilot study (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. The pre-test/post-test correlation also mirrors the results of the pilot trial (i.e., 0.523).

However, as subsequently 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.

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.

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 the 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 (which are listed as secondary outcomes above).

Based on evidence from the pilot trial it is possible that some outcome variables may be skewed, in particular the primary outcome. We will determine whether transformation or scaling is appropriate depending on the skew and distribution of the data.

The analytical approach has been determined a priori and will be conducted with R Studio and SPSS.

Primary outcome analysis

The primary outcome is the ISRD4 total score which is a continuous variable. All YP will complete this measure at baseline, 6 months after randomisation and 12 months after randomisation. The main test of treatment effect will be at 12 months after randomisation. The total score uses a sum of the total volume of delinquent acts using 14 questions. The response scale for each question can be from 0 to whatever the total number of acts reported is (although see above for transformation approach). A hierarchical linear mixed model will be used with site as a fixed effect.

Regression models will be adjusted by the baseline number of offences in the six months prior to randomisation and stratification factors; age group and site, as covariates. The regression model specification is detailed in eq. 1.

Eq. 1

$$OFF6_{i,j} = \alpha + \beta1\,(allocation)_{i,j} + \beta2\,(OFF0)_{i,j} + \beta3\,(age)_{i,j} + \beta4\,(site)_j + \beta4\,(study)_j \varepsilon$$

Secondary outcome analysis

The secondary outcomes are:

- YP Child Criminal Exploitation measured by items added to the Self-Report Delinquency Scale (YP report).
- YP Substance Misuse measured by ISRD3 substance misuse subscale (YP report).
- YP Conduct Problems measured by the conduct problems subscale of the SDQ (YP and parent report).
- YP mental health and adjustment measured by total score and impact score on the SDQ (YP and parent report; impact score parent report only).
- Parental mental health measured by the DASS-21 (parent report).

We will add three additional questions to the SRDS scale asking about missing from home episodes, storing or transporting drugs or weapons and engaging in sexual activity in exchange for money or goods. For each of these additional questions and for each of the 14 SRDS questions we will ask whether anyone has tried to involve the YP in these behaviours, who they were and how many times this happened. The CCE scale will be calculated from the total volume of how many times they were involved by others in these 17 behaviours and will range from 0 to the total number reported (although see above for transformation approach).

The ISRD3 substance misuse scale asks about the use of 5 substances, with response options varying depending on the substance. The scale can be from 0 to whatever the total number of times substances were used is (although see above for transformation approach). In addition, we will add questions on use of synthetic substances and on non-prescribed medications. We will calculate an additional total scale with these additional items and this will be analysed separately from the main ISRD3 substance misuse subscale.

SDQ subscales, including the conduct problems subscale, contain 5 items scored 0, 1 and 2, with scale values from 0 to 10. The SDQ total difficulties scale ranges does not include the prosocial scale and therefore ranges from 0 to 40. The impact score is computed by summing questions on distress and impairment and ranges from 0 to 10.

The DASS-21 contains 21 items, 8 for each of the anxiety, depression and stress subscales, with response values of 0, 1, 2 and 3. We will calculate the total score which ranges from 0 to 63.

All secondary outcome scores are treated as continuous, and a hierarchical linear mixed model will be used with site as a fixed effect. As noted above, we will determine whether transformation is appropriate depending on the data.

Subgroup analyses

Any subgroup analyses will be exploratory in nature. Sample size calculations for the trial have been conducted on the basis of the main primary outcome analysis, not for subgroup analyses. Therefore, it is possible that subgroup analyses may be underpowered. We will conduct post-hoc power analyses when all data has been collected and frame our reporting of these analyses accordingly. Analyses will be conducted using interaction terms.

The subgroup analyses proposed in the protocol were differences in gender, age, temperamental irritability, CU traits and presence of offending behaviour at baseline as identified by caseworker.

We aim to conduct the following analyses

- Race: we will explore whether FFT was equally effective with YP and parents from minoritised backgrounds as for those from White backgrounds. Specifically, we would expect to compare those of Black backgrounds to those of White backgrounds and compare those of South Asian backgrounds to those of White backgrounds. This is on the basis that those from minoritised backgrounds may face more structural challenges that may impede the impact of FFT-G.

- Age: we will explore whether age moderates the effect of FFT using a continuous measure of age. We may expect that FFT-G may work better for those who are younger and therefore at an earlier age of their criminal careers.

- Gender: we will explore whether FFT is as effective with YP who identify as female as much as with those who identify as male. We are unlikely to have an adequate sample size to include those who do not identify as male or female in these analyses so will use a dichotomous measure of gender. As FFT-G has been predominantly developed, delivered and evaluated with males we may expect less impact on females.

- Callous-Unemotional (CU) Traits: we will explore whether the presence of CU traits moderates the effect of treatment. Specifically, we would hypothesise that YP with elevated CU traits would be less responsive to treatment. CU traits will be measured with the CU Traits MAP, consisting of 4 items with a total scale of 0 to 12.

- Temperamental Irritability: we will explore whether the presence of temperamental irritability moderates the effect of treatment. Specifically, we would hypothesise that YP with elevated irritability would be more responsive to treatment. Temperamental irritability will be measured with 3 items from the SDQ and ODD subtyping items, with a total scale of 0 to 9.

- Offending at baseline: we will explore whether FFT reduces self-reported delinquency more in YP whose referring practitioner reported that they were offending at baseline compared to those who reported to not be offending at baseline. This will use a dichotomous score.

Further analyses

These analyses were planned after the protocol, but before the commencement of the trial. We will explore potential mediators of treatment using Structural Equation Modelling. These analyses will be exploratory in nature. Sample size calculations for the trial have been conducted on the basis of the main primary outcome analysis, not for mediation analyses. Therefore, it is possible that mediation analyses may be underpowered. We will conduct post-

hoc power analyses when all data has been collected and frame our reporting of these analyses accordingly.

We will test the following mediators:

- Parental supervision, knowledge and child disclosure, measured by ISRD3 subscales, 12 items, scale ranges from 0 to 48.
- Family functioning measured by SCORE-15, 15 items, scale ranges from 15 to 75.
- Attachment representation using the AAQ, 9 items, scale ranges from 0 to 36.
- Parental self-efficacy measured by the BPSES, 5 items, 5 to 15.
- YP self-efficacy using the NGSE, 8 items, scale ranges from 8 to 40.

We would anticipate conducting analyses comparing the explanatory power of individual YP vs. parent/family factors in predicting mediation of treatment effect, covarying for baseline values of outcomes.

Interim analyses and stopping rules

We do not plan to conduct interim analyses. We will monitor data completion and missing data rates and monitor and report adverse events. The trial will stop if the YEF, FPM and the University of Greenwich decide that the trial is unable to recruit a sufficient number of participants.

Longitudinal follow-up analyses

No longitudinal analyses other than those to test treatment effects will be conducted.

Imbalance at baseline

We will produce a table of baseline characteristics by trial arm, including age, ethnicity, gender, school attendance, CU traits, temperamental irritability, offending at baseline and outcomes. We will report means and standard deviations and counts and percentages with histograms of baseline data. We will not formally test for imbalance at baseline but will address any effects of potential imbalance using the missing data strategy specified below.

Missing data

We will report on rates of missing data of all measures by treatment group. We will use logistic regression models to identify predictors of missingness and include these as covariates in analyses of outcomes described above. If levels of missing data warrant it, we will consider

imputation techniques but the precise techniques used will depend on the pattern and extent of missingness. We will comply with the YEF Guidance on Missing Data.

Compliance

We use FFT LLC's own guidance of defining and measuring family compliance with the intervention. This stipulates that the total dose will depend on the needs of the family. However, we will report on the number of families who attended at least one session, and consider how many families moved through how many phases of treatment, how many received a critical dose of 8 sessions, mean number of sessions received and how many were deemed to have completed treatment. We will also report on therapist fidelity to the FFT model. This data will be provided by FFT LLC using the clinical monitoring system completed by FPM therapists. We will also explore whether time from referral to first FFT session is associated with compliance and improvement in outcomes. If power permits, we will explore whether compliance and fidelity are associated with improvements in the primary outcome and in CCE and SDQ conduct problems.

As advised by the YEF Statistical Guidance we will use an Instrumental Variable approach. This will use a Two Stage Least Square Analysis guidance (2SLS) approach with group allocation as the instrumental variable for the compliance indicator. Results for the first stage will be reported alongside with i) the correlation between the instrument and the endogenous variable; and, ii) a F test.

Intra-cluster correlations (ICCs)

This is not applicable to the current trial.

Presentation of outcomes

Effect sizes will be calculated using Hedges' g. Hedges' g is specified using the following formula:

Hedges' g = (x1 – x2) / √((n1-1)*s12 + (n2-1)*s22) / (n1+n2-2)
where:

x1, x2: The sample 1 mean and sample 2 mean, respectively

n1, n2: The sample 1 size and sample 2 size, respectively

s12, s22: The sample 1 variance and sample 2 variance, respectively

The confidence interval for the Hedge's g statistic is:

g±ϕ - 1 (1-(α/2))gse
where:

ϕ - 1 = the percent point function of the normal distribution

gse= the standard error of the g statistic

= √(n1+n2)/n1n2 + g²/2(n1+n2)

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We will add in to revised version.

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