FEASIBILITY PILOT RANDOMISED TRIAL

# Functional Family Therapy – Gangs

**University of Greenwich** 

Principal investigator: Dr Sajid Humayun



# Feasibility Pilot Randomised Trial of Functional Family Therapy – Gangs

**Evaluating institution: University of Greenwich** 

Principal investigator(s): Dr Sajid Humayun

Project title	Feasibility Randomised Trial of Functional Family Therapy – Gangs Study title: Pilot Randomised Controlled Trial of the Families Are Forever Service (PoRTal)		
Developer (Institution)	FFT LLC (developer), Family Psychology Mutual (Grantee)		
Evaluator (Institution)	University of Greenwich		
Principal investigator(s)	Sajid Humayun		
Evaluation plan author(s)	Sajid Humayun		
Evaluation setting	Children's social care and associated agencies		
Target group	10-17 year-olds at risk of criminal exploitation and gang involvement		
Number of participants	30-70		

# **Protocol version history**

Version	Date	Reason for revision
1.2 [latest]	11 <sup>th</sup> March 2022	Final version
1.0 [original]		

#### Intervention

Evidence-based interventions demonstrating efficacy for gang-involved young people (YP) are limited, while interventions for YP involved in County Lines Drug Networks (CLDNs) are very rare and are largely framed through a safeguarding lens (Child Safeguarding Practice Review Panel, 2020). There is also limited evidence for long-term effectiveness for interventions targeting problematic behaviour in adolescence and therefore there is a need for more evaluations of interventions in this age group (Maughan & Gardner, 2018).

Functional Family Therapy (FFT; Alexander et al., 2000) is a promising evidence-based intervention that possesses evidence of delivering positive outcome and engaging and retaining hard to reach YP and their families (Hartnett, Carr, & Sexton, 2016), 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 three stage model with the engagement and motivation phase 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 relevant family members in all the sessions to maintain a balanced alliance and a relational focus of any problem behaviour. Once engagement is secured then the behaviour change phase can begin, where new skills are learned and practiced in the session and in between sessions via homework. These new skills will 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, these learned skills are practiced in other contexts such as school, community or in relationships with other professionals. In this phase a relapse prevention and sustainability plan is developed to secure lasting positive outcomes. 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 early stages contact will be several times a week with home visits lasting 60-90 minutes and requiring all family members to be present, reducing to weekly contact through the second and third phases. Typical intervention length is 3-5 months. Post intervention the family may receive additional support visits as required. The FFT-G therapist will receive

training in the model and will receive weekly supervision with the FFT-G consultant remotely in the first year but then by the local FFT-G supervisor in the second year. Oversight remains by FFT-LLC as described below.

The initial goal of the first stage of FFT implementation is to impact the service delivery context so that the local FFT program builds a lasting infrastructure that supports clinicians to take maximum advantage of FFT training/consultation. By the end of Phase I, FFT's objective is for local clinicians 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, 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, FFT personnel provide the site feedback to identify progress toward Phase I implementation goals. By the eighth month of implementation, FFT will begin discussions identify steps toward starting Phase 2 of the Site Certification process.

The goal of the second phase of FFT implementation is to assist the site in creating greater self-sufficiency in FFT, while also maintain and enhancing site adherence/competence in the FFT model. Primary in this phase is developing competent on-site FFT supervision. During Phase II, FFT trains a site's extern (one of the FFT therapists) to become the on-site supervisor. This person attends two 2-day supervisor trainings, and then is supported by FFT through monthly phone consultation. FFT provides one 1-day on- site training or regional training during Phase II. In addition, FFT provides any on-going consultation as necessary and reviews the site's 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 implementation is to move into a partnering relationship to assure on-going model fidelity, as well as impacting issues of staff development, interagency linking, and program expansion. FFT reviews the CSS database for site/therapist adherence, service delivery trends, and client outcomes and provides a one-day on-site training for continuing education in FFT.

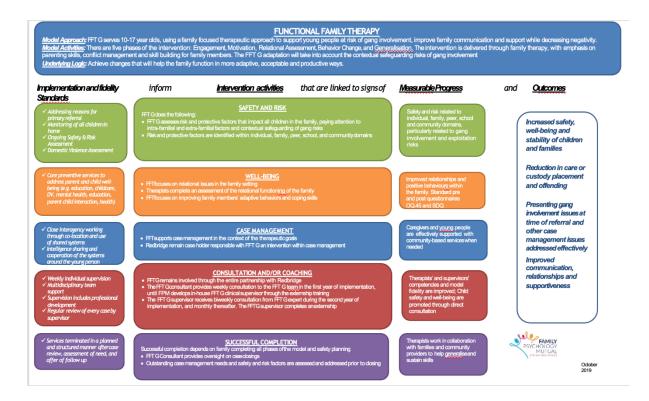


Fig.1 FFT-G logic model

The risk analysis process that takes place in FFT-G provides greater focus on certain individual, family and peer factors that increase contextual risk. This includes – at an individual risk level – impulsivity/risk taking behaviours, "neutralisation" (viz. justifying/excusing behaviour or externalising), anti-social tendencies and substance misuse. At a peer level, therapists consider negative peer influences (associations with friends that condone illegal activity or the referred young person minimising prosocial peers) and peer delinquency (association with friends involved in illegal activity). At a family level, consideration is given to parental supervision and significant life and family events (e.g. loss of friendship groups, family moves, death of family members, etc.). 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.

FFT-G has demonstrated effectiveness with gang members in the USA, but has not been evaluated in the UK and this work, and the body of work around FFT, highlights challenges that a new UK evaluation may face (Humayun et al., 2017). These include: (1) continued recruitment (i.e., case flow) of gang/CCE YP, which poses a threat to the statistical power of any evaluation, (2) acceptance of FFT-G and an evaluation of it (by both referring practitioners and families/YP), and, (3) understanding the counterfactual (i.e., what is FFT-G being

compared to?). Clearly more high-quality and robust evaluations of FFT and FFT-G are needed.

# Research questions and/or objectives

The primary aim of the study is to assess the feasibility of a future efficacy RCT and to determine the parameters and research methods required for that RCT. In order to do so, we aim to answer the following questions:

- 1) How many potentially eligible YP/families can be identified in one Local Authority (LA) i) per month, ii) over the whole study?
- 2) What proportion of 1) will meet study inclusion criteria after further investigation?
- 3) Of 2), how many will progress to each stage of recruitment (see fig. 2). What are the key barriers to recruitment of participants? How long does progress to each stage take? Is this associated with study attrition or treatment outcomes? Does progression through stages of recruitment differ by family characteristics?
- 4) How many YP/families can be randomised i) per month, ii) over the whole study?
- 5) What are the rates of missing data at baseline?
- 6) What are the attrition rates and rates of missing data at 6 months post-randomisation?
- 7) Do 5) and 6) vary by treatment group and family characteristics?
- 8) What are the means, standard deviations (SDs), effect sizes and confidence intervals (CIs) for the primary outcome?
- 9) Given 3), 4), 5), 6) and 8), what time period would be required to recruit a sample for an adequately powered randomised efficacy trial using a single LA? Would recruiting from multiple LAs be more feasible?
- 10) What are the means, SDs and effect sizes for secondary outcomes? How viable are the use of these secondary outcome measures in this population?
- 11) What are the pre-post change scores for the primary outcome and secondary outcomes for the FFT-G group? What are the pre-post changes of the proportion of participants in the clinical range in the Services As Usual (SAU) and FFT-G groups?
- 12) For the FFT-G group, what were the number of sessions/hours attended, number of phases completed, how many received a critical dose (8 sessions), what were the mean scores for therapeutic alliance and fidelity ratings?
- 13) How do variables in 12) compare to other FFT teams at a similar level of maturity?

- 14) What are the experiences of families, therapists and referring practitioners/managers of FFT in this setting?
- 15) What services as usual were received by the control group? What kinds of support were provided and how much support was received?

Please note that we have selected family functioning as a surrogate outcome (consort 2010 p.3) because the feasibility RCT is not set up to assess efficacy, primarily due to the lack of a follow-up post-treatment assessment other than one immediately after treatment is complete. As changes to family functioning are a key mediator of change (see logic model) in this intervention, we would determine likely estimates of treatment effects based on changes to family functioning (as measured by the SCORE-15) and calculate parameters for a future efficacy RCT based on effect sizes and confidence intervals of the family functioning measure (further details see below). However, we will also attempt to determine parameters on the basis of the SDQ conduct problems score also. We will also report on other outcomes, including SDQ impact scores and self-reported delinquency, but these will be descriptive statistics.

## Success criteria and/or targets

It is important to note that the study is a feasibility RCT, not a pilot RCT. I.e. we are not trialling a fixed proposed design for a future efficacy RCT but rather identifying problems and adapting our methods (within a limited framework) in setting up a RCT as the result of our learning. The final workable RCT design can then be scaled up to the larger RCT study. It is also important to note that we have aimed to start the feasibility RCT once the clinical team reached their second year of implementation, reaching adherence to the model, and with the introduction of a qualified FFT supervisor to lead the team. This has followed the developers' implementation guidance.

#### Success/stop-go criteria

Stop-go criteria are based on recommendations by (Avery et al., 2017) and (Lewis et al., 2021) and are assessed using a traffic light system of red, amber and green zones. Criteria in the red zone indicate that the trial should stop without progression to a full efficacy RCT because of probably intractable problems that are very unlikely to be remedied. Criteria in the amber zone indicate the need for changes to methodology before progressing to a full efficacy RCT because problems might be remedied. Criteria in the green zone indicate that the evaluation should progress to a full efficacy RCT immediately. Each criterion is linked to research questions (RQ) above.

Stop-go zones for 1 and 3 are based on similar RCTs in UK child social work and take previous success rates as minimum requirements for a progression recommendation. For example, (Dixon et al., 2014) report a recruitment rate of 15% of eligible YP into a RCT of Multidimensional Treatment Foster Care in UK child social care. We believe that additional lessons have been learnt since the publication of that paper and therefore we have set the upper boundary of our red zone for recruitment at 30%. Similarly, our previous study of FFT in UK youth offending (Humayun et al., 2017) had an attrition rate of 19% at 6 month follow-up but we have adjusted the upper boundary of our red zone for completion of post-treatment assessments to better reflect attrition rates in RCTs in UK child social care (e.g. 45% attrition as reported by Humphreys et al., 2015).

Stop-go zones for treatment outcome(s) are based on rates from similar new FFT teams provided by FPM and the programme developers.

- 1. Recruitment 1 (RQ: 3, 4, 5): proportion of families deemed eligible after FPM consultation who consent to the study, complete baseline assessment and are randomised
  - a. RED: below 40
  - b. AMBER: 40-65
  - c. GREEN: 65+
- 2. Recruitment 2: (RQ: 3, 4, 5): number of families deemed eligible after FPM consultation who consent to the study, complete baseline assessment and are randomised
  - a. RED: 0-30%
  - b. AMBER: 31-50%
  - c. GREEN: 51-100%
- 3. Critical dose of FFT-G (RQ: 12, 13): proportion of families randomised to FFT-G arm who receive at least the critical dose of intervention defined as 8 sessions by the programme developers
  - a. RED: 0-40%
  - b. AMBER: 41-60%
  - c. GREEN: 61-100%
- 4. Fidelity of FFT-G: proportion of families receiving FFT rated at a fidelity rating of adequate (3 or more)
  - a. RED: 0-25%
  - b. AMBER: 26-50%
  - c. GREEN: 51-100%

- 5. Study attrition (RQ: 6): proportion of families who complete post-treatment assessment
  - a. RED: 0-50%
  - b. AMBER: 51-70%
  - c. GREEN: 71-100%

#### Methods

#### Pilot trial design

A parallel, two-armed, feasibility 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) and gang involvement in the London Borough of Redbridge (LBR). 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 FPM. The study outcomes will assess the acceptability of the methodology, the intervention and outcomes related to YPs' engagement with CLDNs. Target YP and their family will be the unit of randomisation.

#### Randomisation

Randomisation will be undertaken after informed consent/assent is given and baseline assessment is complete using block randomisation with randomly varying block sizes (of 4 or 2) with equal allocation ratio in order to ensure the research team are blind to the randomization outcome. After baseline assessment is complete, the trial's researcher emails an independent statistician at the Tavistock Institute with a unique research ID and the YP's protocol ID taken from LBR systems. The statistician will email back the result of the randomisation within 24 hours. The researcher then informs the referring practitioner and the FFT-G team manager 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 are YP aged 10-17 being seen by child social work, youth offending and early intervention services and their primary caregiver. Inclusion criteria are:

#### **Inclusion Criteria YP and families**

Index child/ young person aged between 10-17 years (changed from 10-14 at the start of the trial)

#### AND

#### ONE OR MORE OF:

- Index child/ young person aged between 10-17 years (changed from 10-14 at the start of the trial)
- Known to Redbridge Children Services due to concerns around:
  - child sexual exploitation (CSE)
  - o child criminal exploitation (CCE)
  - o missing (from home or care) episodes
  - potential/actual gang, or CLDN affiliation as identified by police or other statutory service
  - o repeated school exclusion or absence

#### OR TWO OR MORE OF:

- Involvement as a perpetrator or victim of youth violence or criminality
- Family conflict or inadequate supervision
- Associating with antisocial peers
- Concerns about alcohol or drug use

#### AND EITHER

Index child/ young person 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 (to be discussed on a case by case basis)

#### AND

Parent(s) and index child or young person 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/cognitive conditions that may prevent family members making use of talking therapy
- Key family members refusing 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
   5 months

See appendix A for participant flow diagram. Eligible participants are identified by three means:

#### Screening for eligibility

- i) Referring practitioners refer YP on the basis of eligibility criteria to the Family Intervention Team (FIT) panel, a group of primarily service managers within LBR child social care who assign YP with contextual safeguarding risk to specialist services. The FFT team leader also attends this panel. The FIT panel undertake an initial assessment for eligibility on the basis of limited information available at the point of referral. If the case is deemed potentially eligible, an alternative intervention is identified on the basis of need and the case progresses to consultation.
- ii) The FFT team manager examines all new referrals to LBR child social care for cases that meet eligibility criteria on the basis of information held on Protocol, the LBR child social work case management system. If a case is identified as potentially eligible, it proceeds to consultation.
- iii) The FFT team manager attends internal meetings (with Junior FIT, CAF coordinators and YOS) to discuss cases and proceed to consultation (if potentially eligible).

Please note, ii) and iii) were introduced after the start of the feasibility RCT due to low recruitment numbers from i). This has resulted in much larger numbers of YP being referred.

#### Consultation

The FFT team manager has a meeting or call with the practitioner who holds the case and determines eligibility after further discussion with the practitioner. If the case is deemed eligible, a SAU service is identified (if it has not already been by FIT panel) should the case be

randomised to SAU. Towards the end of the call, the study RF is invited to join the call and i) explain the study to the practitioner in more detail, ii) provide their contact details and iii) ask the practitioner to request consent from the family for their contact details to be shared with the research team and iv) to set up a first call with the family.

#### **Consent and Assessment**

The RF meets the YP and primary caregiver via a Microsoft Teams video call, on the telephone or in a face-to-face meeting (in the family home or neutral venue), explains the study to the family and obtains consent (typically over a number of calls/meetings). The RF then conducts the assessment with the YP and their primary caregiver separately, usually in the form of an interview. If the participants wish to complete the measures online on their own, then the link to a Qualtrics survey is provided. Translated study materials and/or interpreters are used when required.

The intervention is typically delivered in the family home.

#### Sample size

As this is a feasibility study, a formal power calculation is not appropriate. Indeed, as recruitment rate is an outcome, it is not appropriate to provide an estimate of the final sample size. However, N=60-70 will provide a sufficiently precise estimate of key feasibility parameters to within 10 percentage points and produce stable estimates of population variances (Lewis et al., 2021). N=40-60 will provide an adequate estimate of parameters but with considerably less precision. N<40 will only allow for descriptive analyses.

#### Methods and data collection

#### **Methods overview**

Research methods	Data collection methods	Participants/ data sources (type, number)	Data analysis methods	Research questions addressed
Primary Outcome: family functioning	SCORE-15 questionnaire (Fay et al., 2013)	YP report; parent report. Collected by researcher prior to randomisation and then 6 months	Calculation of effect sizes and confidence intervals; estimate of future efficacy	5-9, 11

		post- randomisation	RCT sample size; initial analyses of efficacy (linear mixed methods regression)	
Demographic data	Self-report: gender, age, household composition, school attendance, type of school	YP report; parent report. Collected by researcher prior to randomisation (school attendance also collected from YP 6 months postrandomisation);	Descriptive	
Youth delinquency and violence	Self-report Delinquency questionnaire (Smith & McVie, 2003)	YP report. Collected by researcher prior to randomisation and then 6 months post- randomisation	Calculation of effect sizes and confidence intervals	10, 11
Gang involvement	Self-report questionnaire based on Eurogang definition (Weerman et al., 2009)	YP report. Collected by researcher prior to randomisation and then 6 months post- randomisation	Calculation of effect sizes and confidence intervals	10, 11
Peer delinquency	Self-report Behaviour of Friends (Goodnight et al., 2006) questionnaire	YP report. Collected by researcher prior to randomisation and then 6 months post- randomisation	Calculation of effect sizes and confidence intervals	10, 11
YP mental health, callous-	Self-report Strengths and Difficulties	YP and parent report. Collected by researcher prior	Calculation of effect sizes and	10, 11

unemotional traits, irritability	Questionnaire (including impact scores; (Goodman, 2001), CU traits items (Dadds et al., 2005), ODD subtype items (Stringaris & Goodman, 2009)	to randomisation and then 6 months post- randomisation	confidence intervals	
YP mental health	CORE-10 (Twigg et al., 2009)	Intervention group only: YP report. Collected at start and end of therapy. Data provided by FPM.	Calculation of effect sizes and confidence intervals	10, 11
YP attachment representation	Self-report Adolescent Attachment Questionnaire (Bodfield et al., 2020; West et al., 1998)	YP report. Collected by researcher prior to randomisation and then 6 months post- randomisation	Calculation of effect sizes and confidence intervals	10, 11
Parenting behaviour	Self-report Alabama Parenting Questionnaire-15 (Scott et al., 2010; Shelton et al., 1996)	YP and parent report. Collected by researcher prior to randomisation and then 6 months post-randomisation	Calculation of effect sizes and confidence intervals	10, 11
Parental self- efficacy	Self-report Brief Parental Self- Efficacy Scale	Parent report. Collected by researcher prior to randomisation and then 6 months post- randomisation	Calculation of effect sizes and confidence intervals	10, 11

Parental mental health	Depression Anxiety and Stress Scale 21 (DASS-21) (Henry & Crawford, 2005)	Parent report. Collected by researcher prior to randomisation and then 6 months post- randomisation	Calculation of effect sizes and confidence intervals	10, 11
Parental mental health	OQ45 (Kim et al., 2010)	Intervention group only: parent report. Collected at start and end of therapy. Data provided by FPM.	Calculation of effect sizes and confidence intervals	10, 11
Therapeutic alliance, matching and resistance	Family Self Report (FSR; FFT measure); Therapist Self Report (TSR; FFT measure)	Intervention group only: YP and parent report; therapist report. Collected by FFT therapist 6 times during therapy and given at the end of the first two sessions of each therapy phase (see 'Intervention' above). Data provided by FPM.	Descriptive	12, 13
Family perspectives of family functioning and behaviour change	Client Outcome Measure (COM-P, COM-Y; FFT measure)	Intervention group only: YP and parent report. Collected by FFT therapist at end of intervention. Data provided by FPM.	Descriptive	12, 13
Therapist perspectives of family functioning	Therapist Outcome Measure (TOM; FFT measure)	Intervention group only: Therapist report. Completed by FFT therapist at	Descriptive	12, 13

and behaviour change		end of intervention. Completed for all cases that were seen at least once. Data provided by FPM.		
FFT-G sessions attended	FPM/FFT monitoring data	Total number of sessions (and hours) attended and by whom; number of families completing: i) first session, ii) each phase of therapy, iii) all phases of therapy, iv) receiving 'critical' dose (8 sessions).	Descriptive	12, 13
FFT-G fidelity	FPM/FFT monitoring data	Rating scale of 1-6 used by FFT consultant and supervisor to rate individual sessions, aggregate scores for the therapy team will be reported	Descriptive	12, 13
SAU data	LBR monitoring data	Nature of SAU intervention, no of sessions attended	Descriptive	3
Recruitment data	Greenwich monitoring data	No of families moving to each stage of recruitment and time between each stage, attrition rates at each stage,	Descriptive	1-4,6

		reasons given for dropout		
Experience of FFT- G/feasibility trial	Qualitative interviews	Interviews with select number of YP/families, FFT therapists, caseworkers and managers	Thematic analysis	14

### **Data analysis**

We will conduct tests for baseline equivalence of key demographic variables relevant to study outcomes and on the primary outcome measure. We will test the effect of FFT-G on primary and secondary outcomes on an intention-to-treat basis using linear mixed modelling, with post-treatment and baseline outcomes, trial arm and trial arm by time interaction term as explanatory variables. 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 utilise descriptive statistics to identify differences in treatment outcomes in subgroups (e.g. by gender, age, baseline severity of delinquency and gang involvement).

Whilst we will conduct a formal test of the intervention effects, it is important to recognise the limitations of these analyses due to the specified sample size and subsequent power. To detect a minimal clinically important effect size of d=0.6 (a 5 point reduction on the Self-Report Delinquency Scale, similar to other successful trials of FFT (Hartnett, Carr, Hamilton, et al., 2016)), based on 80% power and p < 0.05, G\*Power software (Erdfelder et al., 1996) returned 90 participants, increased to 106 to allow for 15% loss at follow up. Therefore, inferential tests, whilst informative, will be treated with caution. Descriptive statistics will be equally important. The emphasis will therefore be on confidence intervals of effect size estimations, rather than hypothesis testing. This will allow us to explore the imprecision around effect sizes. We will calculate standardised effect sizes by dividing differences by the common baseline standard deviation of the measure. Estimates of population variances for future power calculations will use the upper 80th percentile of confidence intervals around the estimates. These calculations will allow us to determine the parameters required for a full efficacy trial of FFT-G.

Qualitative analysis: Thematic analysis using Braun & Clarke's (Braun & Clarke, 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 inductive. Qualitative interviews will investigate acceptability and feasibility from the perspectives of participating YP and primary caregivers, recruiting agency caseworkers and FFT therapists and supervisors. Commonalities and variations within and between these subgroups will be explored. Analysis will be conducted using a collaborative approach supervised by the lead qualitative researcher (Cleaver) and Research Fellow (RF). We will also ask how the following may or may not have changed over the course of the study: child violence, school attendance, police call outs.

#### **Outputs**

The final study report will provide data and analyses on all research questions and make a recommendation as to whether evaluation of the intervention should proceed to an efficacy RCT. Study results will also be presented. The first publication will be the YEF evaluation report, published on the YEF website. The authors may pursue academic publication of a peer reviewed journal article thereafter.

#### **Ethics and registration**

Please refer to attached approved ethics application. The trial has not been registered because the study is not a pilot RCT but rather a feasibility RCT with trial protocol being adapted as a result of ongoing learning.

#### **Data protection**

Please refer to attached Information Sharing Agreement.

#### Personnel

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# **Delivery Team**

3 full time FFT workers (FPM)

1 full time FFT supervisor (FPM)

1 part time Programme Manager (FPM)

1 part time Business Support Officer (FPM)

Evaluation team (all University of Greenwich)

1 project lead part time

2 senior co-investigators part-time

1 post-doctoral research fellow part-time

### **Timeline**

Dates	Activity	Staff responsible/ leading
3/21-11/21	Recruitment to study	GRE RF/FPM team manager
3/21-11/21	Baseline assessment	GRE RF
4/21-3/22	Delivery of intervention	FPM therapists
9/21-3/22	Post-treatment assessment	GRE RF

3/22-7/22 Analysis and write-up GRE team	3/22-7/22
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