

EVALUATION REPORT

Functional Family Therapy-Gangs for young people at risk of child criminal exploitation and County Lines involvement

Feasibility and pilot study

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About the Youth Endowment Fund

The Youth Endowment Fund (YEF) is a charity with a mission that matters. We exist to prevent children and young people becoming involved in violence. We do this by finding out what works and building a movement to put this knowledge into practice.

Children and young people at risk of becoming involved in violence deserve services that give them the best chance of a positive future. To make sure that happens, we'll fund promising projects and then use the very best evaluation to find out what works. Just as we benefit from robust trials in medicine, young people deserve support grounded in the evidence. We'll build that knowledge through our various grant rounds and funding activity.

Just as important is understanding children and young people's lives. Through our Youth Advisory Board and national network of peer researchers, we'll ensure they influence our work and we understand and are addressing their needs. But none of this will make a difference if all we do is produce reports that stay on a shelf.

Together, we need to look at the evidence, agree what works and then build a movement to make sure that young people get the very best support possible. Our strategy sets out how we'll do this. At its heart, it says that we will fund good work, find what works and work for change. You can read it [here](#).

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About the Evaluator

The evaluation team are based at the University of Greenwich, primarily in the Institute for Lifecourse Development (ILD). The ILD is a key anchor resource where professionals from many different fields work closely together with researchers and stakeholders from public, charitable and voluntary organisations. Together, we are developing effective and economically sustainable lifecourse solutions and tackling some of the most significant challenges facing society. Working with our extensive network of external healthcare and education partners and business and public sector organisations, we focus on using interdisciplinary expertise to promote the lifelong wellbeing of vulnerable and marginalised people in the community.

The Principal Investigator is based at the Centre for Vulnerable Children and Families within the ILD. The Centre is comprised of over 20 members working at the University of Greenwich in the Faculty of Education, Health and Human Sciences. The team's expertise represents a broad number of disciplines, such as psychology, social work and counselling, education, teacher education, early years education, health sciences, midwifery, youth and community work, children's nursing, and wellbeing studies.

Our work includes adults preparing for parenthood, prenatal development, childhood and adolescence. We focus on varied experiences of children and young people, including the impact of a parent being imprisoned, the effects of homelessness, factors influencing behaviour such as bullying, cyberbullying and antisocial behaviour, disabilities and neurodevelopmental disorders, and historical aspects of childhood. We have a strong interest in practice and work within nursing contexts, early education settings and schools, young offenders' institutes and pupil referral units. We have strong networks with researchers and practitioners nationally and internationally, working in countries including Spain, Chile, Uganda and Malaysia.

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Executive Summary



The project

Functional Family Therapy Gangs (FFT-G) is an intensive, home-based, family therapy programme for the families of young people with severe behavioural challenges. It aims to improve the safety, wellbeing and stability of children and families and reduce offending. Developed by FFT LLC, the programme in this project was delivered by Family Psychology Mutual (FPM) and targeted at 10–17 year olds at risk of involvement in County Lines Drug Networks or child criminal exploitation. Trained family therapists provided a bespoke number of therapy sessions to families over three to five months, beginning with an Engagement and Motivation phase to secure participation. This was followed by a Behaviour Change phase to teach new skills designed to interrupt problematic relational patterns, before a Generalisation phase asked families to practise the skills they had learned in other contexts (such as in school, in the community or in relationships with other professionals). Which family members were involved depended on who was regarded as important to the problem being addressed. In the early stages, contact was provided to families several times a week, with home visits lasting 60–90 minutes; in later stages of the intervention, contact was reduced to weekly.

The YEF funded a feasibility and pilot study of FFT-G. The feasibility study aimed to ascertain how feasible a randomised controlled trial (RCT) of the programme would be, exploring whether caseworkers would refer young people to an RCT, analysing what the most productive referral pathways were and evaluating whether enough referrals would be received to ensure adequate therapist caseloads. These questions were explored using 19 interviews with key professionals, organisational data gathering and a document review, and the intervention was delivered to 48 families in the London Borough of Redbridge (LBR). The Family Intervention Team (FIT), part of specialist services for vulnerable children within social care, referred young people to the programme. The feasibility study was delivered between October 2019 and March 2021. The pilot study then aimed to explore how many families were eligible for FFT-G; analyse the barriers to and implementation of trial recruitment; and examine a range of questions relating to the design of a potential future large-scale RCT (such as how many families can be randomised and how often, the rates of missing data at baseline testing, attrition rates and the effect sizes associated with the intervention). These questions were explored via the delivery of a pilot RCT, again delivered in LBR. Twenty-three young people's families received the intervention, while 22 received services as usual (SAU). Nine interviews were also conducted with families. The pilot took place between March 2021 and July 2021. Both the feasibility and pilot studies were impacted by the COVID-19 pandemic, requiring both the delivery and evaluation teams to adapt to challenging circumstances.

Key conclusions

Interviews with caseworkers in the feasibility study suggested that they would, albeit reluctantly, refer young people and their families to the programme to participate in an RCT. The most common reason given was to ensure the continuation of the service. A waitlist control was preferred by some caseworkers, but the evaluator adjudged a parallel RCT to be preferable.

In the feasibility study, FFT-G received a reasonable number of referrals (100 over 13 months), although this was lower than anticipated by therapists. The evaluator deemed completion rates to be adequate; where treatment data were collected, 61% of families enrolled completed the treatment.

The pilot study found that 95 families were identified over nine months in LBR to receive the programme – 73% (69) of them were eligible for the programme after full screening, out of which 66% (45) progressed through recruitment to be randomised into the pilot RCT.

Missing data rates in the pilot RCT were low at baseline. The RCT then measured parent-reported family functioning and young person-reported conduct problems. There was a 20% attrition rate. The evaluator deemed that in a small efficacy RCT, recruitment would be possible using only one local authority (LA). Given sample size calculations, they predicted that a sample between 51 and 248 would be required and advised aiming for the higher end of this range.

In the pilot study, 74% of families received eight or more sessions, and 83% completed the programme. In terms of what the families in the service as usual group were receiving, approximately one third received an alternative parenting programme; 27% do not appear to have received any services.

Interpretation

Social workers who were interviewed in the feasibility study felt that FFT-G complemented their services well. They would, albeit reluctantly, refer young people to the programme to participate in an RCT. Those most familiar with the intervention were more likely to refer, while the most common reason given for accepting an RCT was the continuation of the service. Most social workers had only a basic understanding of RCTs, and some had concerns about carrying out an RCT with vulnerable young people. They worried about causing frustration among those not receiving FFT-G, while FFT-G therapists were also wary of the disappointment experienced by social workers if the families they had taken time to recruit and refer were not part of the intervention group. After the evaluator explained the design of a waitlist control trial (where the control group would also receive the programme later), social workers were open to this possibility, recognising the need to evidence impact to secure funding. However, the evaluator concluded that a parallel RCT (where all receive some service as usual, and the intervention group also receive FFT-G) is preferable; concerns were noted that families' waiting to receive FFT-G in a waitlist design could alter their engagement with other usual services, while the wait for any support could be too long for such vulnerable young people.

In the feasibility study, FFT-G received a reasonable number of referrals (100 over 13 months). This was lower than expected by FFT-G therapists due to a number of reasons, including a lack of awareness by social workers around FFT-G, the cases not fitting the inclusion criteria and the length of time it takes to refer. The evaluator deemed completion rates to be adequate; where treatment data were collected, 67% received over eight sessions, and 61% of families completed treatment. The average number of sessions completed by families was 10.7.

The pilot study found that 95 families were identified over nine months in LBR to receive the programme. These were referred either by a Family Intervention Team panel, identified in meetings with service teams, or identified via screening of the borough's case management system. Seventy-three per cent (69) of them were eligible for the programme after full screening, out of which 66% (45) progressed through recruitment to be randomised into the pilot RCT. Recruitment to the RCT began slowly; after simplifying the communication to potential families, expanding the age eligibility range (from 10-14 to 10-17) and conducting a screen of the case management system, recruitment improved. Missing data rates in the pilot RCT were low at baseline (0% for 16 out of 21 measures and between 2% and 16% for the remaining five). The RCT then measured parent-reported family functioning and young person-reported conduct problems. These measures were deemed to be broadly suitable, but the evaluator encourages caution when drawing firm conclusions on the future suitability of these measures given the small sample size. There was a 20% attrition rate (with eight families in the SAU arm and one in the FFT-G arm of the trial not completing assessments after six months). The evaluator deems that in a small efficacy RCT, recruitment would be possible using only one LA. Given sample size calculations, they predict that a sample between 51 and 248 would be required and advise aiming for the higher end of this range.

The dominant view expressed in interviews with families was that the randomisation process was acceptable, and getting additional attention and support for their child was a recurring motivation for many participating in the study. Some families also expressed a desire to participate in giving feedback on services with a view to them improving in future. Of those who received support during the study, the common view was that the support was useful, although some young people were unable to say what was helpful to them. Of those who received service as usual, most perceived the support on offer to be helpful. However, some families who received usual service expressed negative experiences with professionals and the wider system.

In the pilot study, 74% of families received eight or more sessions, and 83% completed the programme. The average number of FFT-G sessions per family was 11.4. Approximately one third of families in the SAU group received an alternative parenting programme; 27% do not appear to have received any services.

The study met the requirements for a full efficacy RCT by meeting four out of five 'stop-go criteria'. The YEF has, therefore, opted to fund a further evaluation of FFT-G and will be setting up an efficacy RCT.

Introduction

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 also to be the activity of organised crime groups¹ (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, young people (YP) and adults are exploited in order to transport and/or store drugs (ibid.).

CLDNs are subsumed under the broader definition of child criminal exploitation (CCE), as defined by the Home Office (2022):

‘Child criminal exploitation is common in county lines and 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. Child criminal exploitation does not always involve physical contact; it can also occur through the use of technology.’

While some argue that involved YP exert agency when engaging in CLDNs (Moyle, 2019), this is best understood in the context of the limited set of choices available to them within their social fields (Firmin, 2020), and evidence of clear coercion and control are common, e.g. threats of violence against YP and their families and actual use of violence. There is some evidence to suggest that violence is more commonly involved in CLDNs than traditional drug markets and is likely to reflect the rapid rise in the rate of young homicide victims involved in the UK drug market (Black, 2020) and serious harm incurred by YP suffering CCE (Child Safeguarding Practice Review Panel, 2020). 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 gifts (e.g. expensive trainers), the use of debt bondage is common to maintain control. This can involve encouraging YP to take drugs (Coliandris, 2015) or a staged robbery, where the line manager will recruit a YP as a runner and then arrange for them to be robbed (Harding, 2020), thereby indebting the YP to the line manager. YP involved in CLDNs are at high risk of criminal conviction (Sturrock and Holmes, 2015), thereby increasing their vulnerability to subsequent exploitation.

¹ See <https://www.local.gov.uk/sites/default/files/documents/tackling-serious-and-orga-44a.pdf>

Vulnerability of YP, defined broadly, is seen as a risk factor for CLDN involvement (Harding, 2020), but some specific risk factors have been identified. Specifically, 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 CLDN exploitation (Child Safeguarding Practice Review Panel, 2020; EPCAT & Missing People, 2016; NCA, 2019; OFSTED, 2018). However, these known risk factors are not always reliable predictors of exploitation (Child Safeguarding Practice Review Panel, 2020), perhaps partly because of the ability of OCGs to adapt their recruitment strategy and target new groups of YP (NCA, 2019).

As a result, many exploited YP are known to child social care services. Unfortunately, effective practice for tackling involvement in CLDNs 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.

However, broader problems with the ability of services to tackle CLDN involvement have been identified. First, when involvement is identified, it is quite common for no further action to be taken (Lloyd and Firmin, 2019) and for YP to be rerouted to Youth Offending Services, with a risk of criminalisation for drug offences. Second, another common response is moving the YP out of borough which, while potentially effective in the short term, is not a viable long-term strategy (Child Safeguarding Practice Review Panel, 2020).

Third, these problems are likely situated in the broader problem of services not being configured to deal with risk outside of the family home. In part, this is due to a lack of effective multi-agency working (Home Affairs Committee, 2019) and early identification of at-risk YP (Maxwell et al., 2019). However, Firmin (2020) argues that these are part of a broader problem with UK child social work, specifically that the culture, policy frameworks, risk assessment and intervention approaches are all designed to deal with familial rather than extra-familial harm. Instead, contextual safeguarding approaches are being proposed to better deal with exploitation when the main risks originate from outside the family home. That is not to say that family factors and work with the YP's family are not important; rather, it is a recognition of the interconnected conditions leading to exploitation that require better understanding in order to keep YP safe (Beckett, Holmes and Walker, 2017).

Crucially, an understanding of the social fields in which YP make choices about their safety, and the limited nature of those choices, is necessary to intervene and help them make safer choices and reduce the risk of exploitation (Firmin, 2020). From this perspective, a key mechanism is likely to be the family's ability to support the YP to make those safe choices, with family breakdown a likely risk factor (Child Safeguarding Practice Review Panel, 2020). 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 that target extra-familial risks may be more effective. Interventions designed to improve family protective factors 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 Development.² 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. FFT-G 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).

While FFT-G has demonstrated effectiveness with gang members in the USA, there are a number of reasons not to move directly to an effectiveness, or even efficacy, trial. First, FFT has not been shown to be more effective in the UK than SAU. The one UK RCT of FFT found no differences across a range of outcomes between FFT and SAU (Humayun et al., 2017). This finding is in line with other failures to replicate USA-developed evidence-based interventions for youth crime in the UK recently (e.g. MST; Fonagy et al., 2018; 2020; Maughan and Gardner, 2018).

Second, FFT has not been formally evaluated in a UK child social work setting. RCTs in UK child social care are rare (Thyer, 2015), with few successful trials. For example, in a trial of Multidimensional Treatment Foster Care, a Blueprints Model programme, it was only possible to recruit 34 children across six local authorities (LAs), with a further 12 LAs refusing randomisation (Dixon et al., 2014; Green et al., 2014). A number of studies have identified challenges to RCTs in UK social care contexts, such as referral and treatment pathways

² <https://www.blueprintsprograms.org/>

(Alderson et al., 2020) and ethical and legal difficulties (Baginsky et al., 2017). The most common barrier identified to successful implementation of RCTs in UK child social care appears to be gatekeeping by social workers and other caseworkers (Alderson et al., 2020, Dixon et al., 2014b; Mezey et al., 2015a), with some studies finding anxiety and a lack of understanding of randomisation as the main reasons for failing to refer (Moody et al., 2021). The one UK RCT of FFT reported similar difficulties (Humayun et al., 2017).

Third, any RCT of an intervention is only informative in the context of the counterfactual. It is not clear what services YP at risk of CLDN receive, and therefore it is unknown what FFT-G would be compared to. For example, if SAU typically consist of no further action taken (Lloyd and Firmin, 2019), an RCT may not be viable due to the lack of an active control group intervention. This is because better outcomes in an FFT-G group compared to a control group may simply be due to more hours of support provided rather than anything specific to FFT-G. As a result, it would not be possible to determine if similar effects would have been found if the intervention being tested was more generic social work involvement.

Fourth, there has only been one evaluation of FFT-G, which was in the US and with a different primary outcome (Thornberry et al., 2018). Furthermore, not only was the target population different (not CCE/CLDN involved), but the methods of recruitment and referral are likely to be different in the UK (Gottfredson et al., 2018).

Thus, any RCT of FFT-G for CLDN involvement in the UK is likely to face a number of significant challenges. These include: (1) identifying referral pathways to facilitate adequate recruitment of suitable YP and families; (2) acceptance of FFT-G and a randomised evaluation of it by both referring practitioners and families/YP; (3) loss to follow-up assessment; (4) inadequate SAU; (5) suitability of assessment methods and rates of missing data; (6) engagement of families in FFT-G and completion of treatment; and (7) delivery of FFT-G to an adequate level of fidelity.

The aim of this project was i) to conduct a feasibility study to assess whether a randomised evaluation of FFT-G in child social care for CLDN involvement was viable and, if so, ii) to conduct a pilot RCT to establish parameters for a future efficacy or effectiveness trial.

Intervention

FFT is an intensive home-based family programme for adolescents with severe behavioural problems and their families. It is delivered by trained therapists in the home. The FFT approach includes five distinct clinical phases. The first phase, Engagement, is focused on establishing credibility with relevant family members to ensure their participation in sessions. The second phase, Motivation, is focused on creating a context in sessions where family members are willing to try something new. This context is achieved through interventions that are contingently and systematically implemented to reduce negativity and blame, increase hope and a focus on family relationships, and facilitate balanced therapeutic alliances with the family. In the Relational Assessment phase, the therapist identifies key

patterns of family interaction. These patterns are critical for implementing interventions in a manner that accommodates the family. In the Behaviour Change phase, new skills are learned and practised in the session and between sessions via homework. Skills are implemented at multiple levels, including family interactions and individual skills building (in conjoint sessions). In the Generalisation phase, these learned skills are practised in other contexts, such as school, community or in relationships with other professionals. In this phase, relapse prevention and sustainability plans are 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 skills training with the family is 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 Motivation phase, contact and sessions are matched to the intensity of risk factors. As such, there may be multiple sessions (60–90 minutes) in the first 10 days of the service episode. In later phases, sessions typically occur weekly. Typical intervention length is three to five months, with eight sessions being a critical dose (Robbins et al., 2003). Post-intervention, the family may receive additional support visits as required. The FFT-G therapist receives training in the model and weekly supervision with the FFT-G consultant remotely in the first year and 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 programme builds a lasting infrastructure that supports clinicians to take maximum advantage of FFT training/consultation. By the end of Phase One, 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 will be completed in one year and not last longer than 18 months. Periodically during Phase One, FFT personnel provide the site feedback to identify progress towards Phase One implementation goals. By the eighth month of implementation, FFT will begin discussions to identify steps towards starting Phase Two of the Site Certification process.

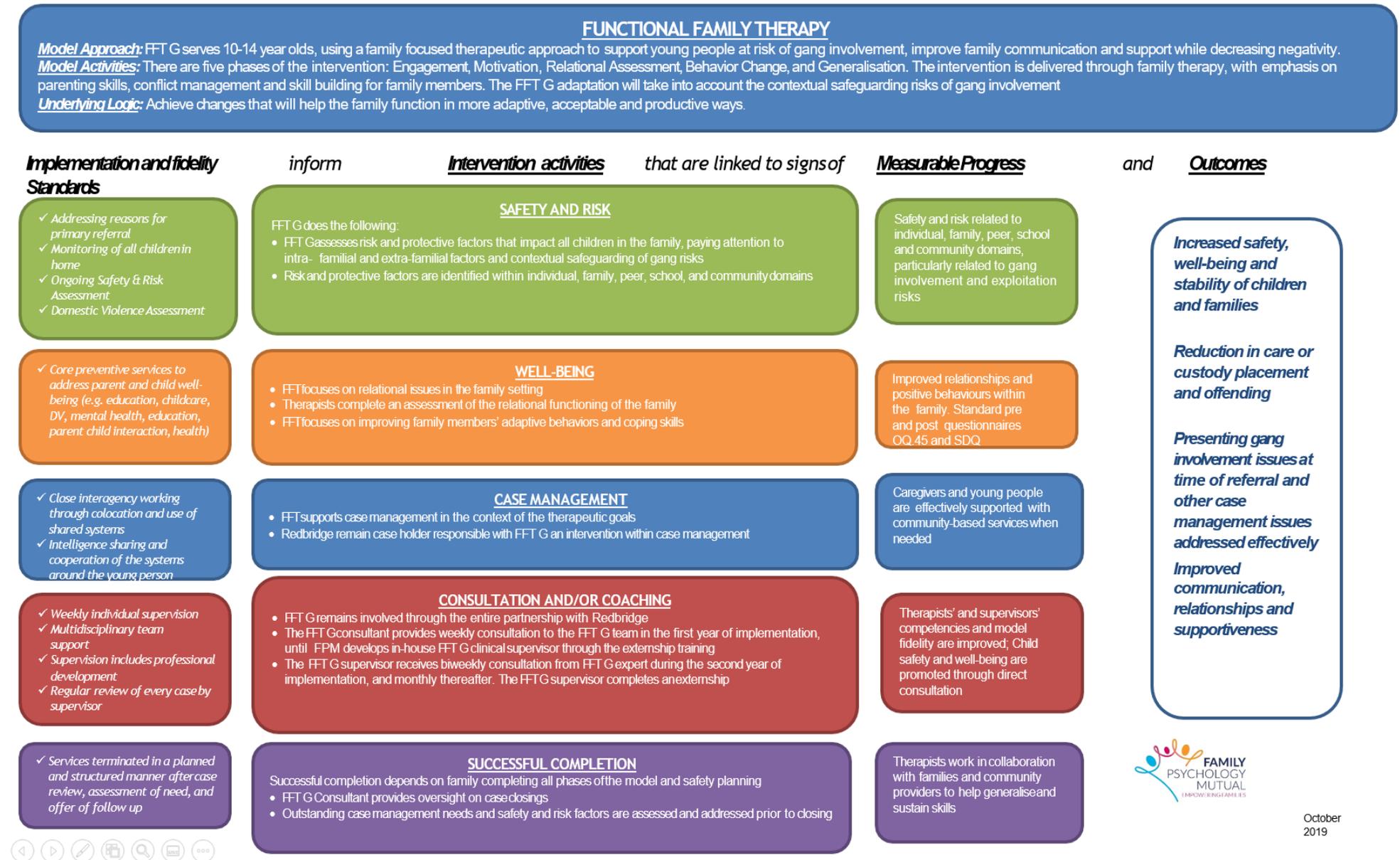
The goal of the second phase of FFT implementation is to assist the site in creating greater self-sufficiency in FFT, while also maintain and enhancing site adherence/competence in the FFT model. Primary in this phase is developing competent on-site FFT supervision. During Phase Two, FFT trains a site extern (one of the FFT therapists) to become the on-site supervisor. This person attends two two-day supervisor training sessions and is then supported by FFT through monthly phone consultations. FFT provides one one-day on-site

training or regional training session during Phase Two. In addition, FFT provides any ongoing consultations as necessary and reviews the site's FFT CSS database to measure site/therapist adherence, service delivery trends and outcomes. Phase Two is a year-long process.

The goal of the third phase of FFT implementation is to move into a partnering relationship to assure ongoing model fidelity and impact 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.³

³ Additional information on the implementation of FFT can be found at the developer's website: <https://www.fftllc.com/>

Figure 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), antisocial 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 and death of family members). 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. 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 its evaluation (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.

Ethical review

Please see Appendix A and B for full ethical review application, participant information sheets and consent/assent forms.

Feasibility study

Reference number: 19.2.5.5. Approved 26 January 2020. Chair's action to request amendments to enable interviews to take place remotely due to COVID-19 received 7 July 2020.

Recruitment: Some staff were already involved in study setup and were approached directly by the research team. Other staff were identified by their service managers and then approached by the research team. Eligibility criteria were either i) social workers or other practitioners with a caseholder role employed by Redbridge child social care or other children's services who could refer to the FFT-G team, ii) team managers of these

practitioners or senior managers in Redbridge, iii) FFT-G therapists or iv) FPM managers. See Feasibility Study>Findings>Participants>Staff interviews for more details.

Pilot RCT

Reference number: 20.3.5.8. Approved 14 March 2021. Chair's action to request amendments to enable assessments in the family home post-COVID-19 received 27 October 2021. Chair's action to request amendments to enable collection of written consent for participants who only provided verbal consent received 7 July 2022.

Recruitment: see the 'Participant recruitment' section of the pilot study for full details on recruitment.

If families were deemed eligible, the referring practitioner outlined the study using a prepared script (see appendices for full documentation) and obtained agreement from the YP and their family for the research team to contact them. They also provided them with the study participant information sheet and consent form. A research fellow (RF) and the practitioner then made a joint call (telephone/video call), and the RF explained the study to the YP and their family, worked through participant information sheets and obtained verbal assent (YP) and consent (parent or person with parental responsibility). Where possible, written consent was subsequently obtained. However, where this was not possible, participants were sent an email with a link to a Qualtrics page asking them to confirm their verbal consent. The email stated that if we did not hear from them, or if they did not complete the Qualtrics form, we would take that as confirmation of their verbal consent. The page also contained a link to the participant information sheet to ensure that participants still had access to a copy.

If YP and their family consented to take part, they were assigned an ID number, and the RF helped the family to complete all of the baseline assessments. The RF then accessed requested randomisation from a statistician independent of the research team.

The trial has not been registered because the trial protocol was adapted as a result of ongoing learning. All the changes from the original protocol have been recorded.

Data protection

Feasibility study

The feasibility study only involved interviewing staff, and no data for YEF archiving were collected. All data from Redbridge records were summary data (e.g. total number of YP with certain risk factors), and no individual-level data on families were collected.

After participants agreed to participate, they were allotted an identification number. Data and contact information were securely stored, in accordance with GDPR, using the identification number, with access limited to the research team only. Participants were informed that all information about them would be stored in this way. Data obtained from participants through questionnaires and interviews were kept separate from identifying information. All identifying information was stored in a secure place 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 had access to it. Published reports will not identify the research participant at any time. All data were encrypted and stored securely in password-protected files on password-protected computers, and only members of the research team had access.

Pilot RCT

Data were shared by the London Borough of Redbridge (LBR) under an Information Sharing Agreement (ISA) to allow access to social care records.

After participants agreed to participate, they were allotted an identification number (and pseudonyms would be used for interviews). Data and contact information were securely stored, in accordance with GDPR, using the identification number, with access limited to the research team only (except for the purposes of data archive; see Appendix A). Participants were informed that all information about them was stored in this way. Data obtained from participants through questionnaires and interviews were kept separate from identifying information. All identifying information was 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 have had access to it (other than for archiving; see Appendix A). Published reports will not identify the research participant at any time. All data were 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 had access.

Confidentiality: Confidentiality with regard to information shared has been maintained within the constraints of the Children's Act of 1989. Participants were informed of the limits of confidentiality in the information/consent form.

All information has been kept securely, and only the research team have had access to it other than for the purposes of data archiving (see Appendix A) or where information is already kept on LBR or FPM systems and then shared with the research team.

Personal data, as defined by the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, collected during the research were as follows:

- Names, addresses and contact details – stored separately from completed surveys
- Demographic information including age, gender and race
- Answers to questions in interviews and questionnaires
- Information collected from RCS and FPM systems

See Appendix B for information provided to participants.

Project team/stakeholders

The project was funded in its entirety by the YEF, except for bridging funding provided by the University of Greenwich to pay for cover for staff absence.

The intervention developer (FFT LLC) was not involved in the design conduct, analysis or reporting of the study. They were involved in the delivery of the intervention by way of staff training, consultation, fidelity checks and ongoing quality assurance. The project PI had a number of meetings with them to ensure elements of the intervention delivery were fully understood.

Family Psychology Mutual delivered the intervention.

The research project team consisted of

- Dr Sajid Humayun: Principal Investigator (UoG)
- Professor Darrick Jolliffe: Co-Investigator (UoG)
- Professor Karen Cleaver: Co-Investigator (UoG)
- Dr Cindy Morrison: Project Research Fellow (RF) (UoG)
- Dr Anna Cook: Researcher (UoG)
- Ms Tahlia Corrodus: Researcher (UoG)
- Dr Marianne Markowski: Researcher (UoG)
- Dr Aurelie Lange: Researcher (UoG/FPM)
- Ms Amanda Francis: Researcher (UoG)
- Ms Bhavika Sahiri: Researcher (UoG)
- Dr Vanessa Fortune: Researcher (UoG)
- Ms Chantel Smith: Researcher (UoG)

Please note that the time period between notification of funding and the start of the project (approximately one month) did not allow for the recruitment of a research fellow (RF).

Therefore, an existing UoG Institute of Lifecourse Development RF was seconded to the project. That RF left in February 2020, just before the start of COVID-19 pandemic and first lockdown. After discussion with YEF, we suspended any direct data collection and therefore did not hire an RF during that period. However, in the latter part of 2020, we needed to conduct staff interviews as part of the feasibility study, so we seconded another UoG RF to conduct that work.

The large number of researchers on the study was the result of required cover for staff who were absent or on reduced hours for the majority of the pilot RCT. Conduct of the study was adversely affected by these staffing issues.

Feasibility Study

Overview

Objectives

The objectives of this study were:

- To critically evaluate the perceptions of therapists, therapist managers and social workers and managers on the implementation of an RCT to evaluate FFT-G
- To examine the experiences of social workers who referred YP to FFT-G, as well as those who did not refer children to FFT-G, on their views of the referral process and intervention
- To assess likely referral flows and determine whether these will support a pilot RCT
- To assess the acceptability of measures for a pilot RCT
- To measure the actual number of referrals to the FFT team and basic implementation outcomes in the form of number of referrals, number of families completing therapy and fidelity ratings achieved
- To inform the design of a potential feasibility RCT of FFT-G

Research questions

1. Will caseworkers refer to a randomised trial of FFT-G, or will an alternative trial design, such as a waitlist control RCT or a QED, be more feasible?
2. What are likely to be the most productive referral pathways and processes to ensure adequate recruitment to a pilot RCT? Will referral from one LA be adequate for an evaluation?
3. Will an FFT-G team in UK child social care receive enough referrals to generate adequate therapist caseloads and demonstrate good therapeutic outcomes, specifically adequate fidelity and treatment completion by the end of the feasibility phase?

The feasibility study utilised a sequential mixed-method approach (Creswell and Creswell, 2018) starting with semi-structured interviews with key professionals to elicit the potential barriers and enablers for an RCT, followed by organisational data gathering to establish the feasibility for conducting an RCT and develop the RCT's pilot design. We also conducted a series of meetings and informal interviews throughout the feasibility study with LBR managers and FPM staff.

We undertook semi-structured interviews with staff and conducted thematic analyses to determine acceptability of an RCT to staff. We also used interviews and a document review of LBR systems to identify referral pathways and processes and reviewed the number of referrals and therapeutic implementation outcomes to assess the feasibility of the intervention.

Success criteria and/or targets

The feasibility study did not employ formal stop-go criteria. Instead, we aimed to use the information collected to ascertain whether an evaluation study of FFT-G in this setting was feasible and, if so, what form it should take. Specifically, we wished to determine whether social workers and other referring practitioners would refer to a parallel randomised evaluation to FFT-G or usual services or whether a waitlist control design would be more feasible. We also aimed to influence the design of a potential pilot RCT by determining likely eligibility criteria and referral pathways.

Ethics

See ethical review section above.

Participant selection

Setting

The London Borough of Redbridge (LBR), which has significant issues with organised crime and youth experiencing contextual safeguarding issues in the area, collaborated in the study. The LA is regarded as having excellent children's social care services and was deemed outstanding in an Ofsted report in 2019, with services dealing with exploitation and gang involvement commended. The FFT-G clinical team was embedded in the LBR child social work team, specifically in the Family Intervention Team (FIT), part of specialist services for vulnerable children within child social care. The FIT panel meets weekly to review referrals made to FIT by a number of other SW teams and practitioners, in particular i) from with FIT; ii) the Multi-Agency Safeguarding Hub (MASH); iii) the Child Protection and Assessment Team

(CPAT); and iv) broader Community Social Work (CSW) teams. Individual cases are then referred to specific specialist services. FFT-G was an addition to this range of specialist services.

The referral path to access FFT-G comprised several steps, starting with a form detailing inclusion and exclusion criteria for the case, which social workers used to refer to the FIT panel:

Families Are Forever is the new Functional Family Therapy (FFT) service in Redbridge.

FFT is a licensed, evidence-based programme with a strong track record.

We will work with families in which there is a child or young person 10–14 years old at risk of care entry primarily due to **contextual safeguarding concerns (CCE, CSE, gang affiliation, county lines or missing episodes)**.

Referrals can be made via the FIT panel. All referrals will require an allocated social worker.

See flowchart slide in this presentation for more detail on process.

Eligibility criteria

- 10–14 years old (up to 20% referrals can be for 15–16 year olds)
- Lives with family in borough at least 50% of the time
- Contextual safeguarding risks are a central concern
- Family conflict or dynamics suggest they would benefit from (and be open to engaging with) a voluntary whole-family intervention.
- NB: we have capacity to work with some reunifying families where the child has been out of the family home a maximum of six months.

Exclusory criteria

We cannot work with families in which:

- The child/young person is actively suicidal or psychotic.
- There are organic conditions (e.g. moderate/severe LD or ASD) preventing the young person and/or key parent from engaging in talking therapy.
- Problem sexual behaviour is the main concern.

Note: This service is part of evaluation research led by [Removed for anonymity]. We are currently in a 'feasibility' period (to end July 2020) with potential to progress to a full trial. Should the service progress, eligibility criteria may alter.

Given the limited information available on CLDN involvement and CCE, we chose to use relatively broad eligibility criteria to ensure as many potentially eligible cases were referred as possible. If the case was assessed as potentially eligible at the FIT panel, there was a consultation between the referring practitioner and FFT-G manager, which allowed the manager to further ascertain the suitability of the intervention for the case. The case was then discussed at an FFT-G team meeting and, in some cases, additional screening occurred. If the case was still deemed eligible, then it was allocated to a therapist, and the intervention began. In addition, some cases referred to the FIT panel that had not been referred for FFT-G were identified as potentially eligible and moved to consultation.

Nineteen staff were interviewed. FFT and SW managers were approached directly; SWs and FFT therapists were approached by their managers and asked if their contact details could be provided to the research team.

Theory of change/logic model development

FFT has a clear logic model, established over some decades of intervention development and research (Alexander et al., 2000). While FFT-G is an adaptation of the original intervention, its theory of change does not differ in any substantive way from the original intervention. Therefore, the development of a theory of change was not necessary in this study.

Data collection

Staff Interviews

Data collection took place between July 2020 and November 2020. The 19 semi-structured interviews were held remotely over MS Teams, video recorded and subsequently transcribed. Three researchers (KC, TC and MM) carried out the individual 30–60-minute-long interviews. The interview guide covered questions around the service professionals' role and experiences in working with young people, especially those who were at risk of contextual safeguarding and potentially involved in organised gang crime and CLDNs. As warm-up questions, the guide included prompts around their experience working in the 'lockdown' conditions of the pandemic. The guide further covered the interviewees' knowledge or attitudes towards FFT-G and its referral criteria, benefits and beneficiaries, as well as knowledge or attitudes towards RCTs, including issues around consent and randomisation. It used open questions such as: 'Can you share with us your understanding of what FFT is and its value for young people who are, for example, involved in "county lines"?' or 'What barriers do you think we might encounter when it comes to recruiting and selecting young people for involvement in the study?'. The guide varied slightly in the number of the questions depending on the interviewee group: social worker (SW), social work manager (SWM), FFT-G therapist (T) and FFT-G therapist manager (TM). For example, the interviewer did not ask FFT-G therapists and managers about their understanding of FFT-G.

Quantitative data

We were provided limited anonymised data on numbers of referrals with different risk factors by LBR. FPM provided us with data on sessions attended, fidelity ratings and other implementation outcomes.

Table 1: Feasibility study methods overview

Research methods	Data collection methods	Participants/data sources	Data analysis method	Research questions addressed	Implementation/logic model relevance
Interviews	Semi-structured interviews	LBR social workers and social work managers; FPM staff	Thematic analysis	1, 2	Assessing whether adequate referral pathways can be established in an RCT; assessing feasibility of measures
Document review	Review of documentation	Anonymous data on cases in LBR	Descriptive	1, 2	Assessing whether adequate referral pathways and eligibility criteria can be established in an RCT
FFT-G implementation data	Analysis of implementation data	Data provided by FFT LLC and FPM on cases seen	Descriptive	3	Assessing whether adequate referrals made to FFT-G team, adequate numbers completing therapy and adequate fidelity achieved

Analysis

Qualitative Analyses

We used semi-structured interviews and conducted thematic analyses to explore potential barriers to a pilot RCT because little is known about the causes of gatekeeping in RCTs in child social work; therefore, the use of quantitative data collection would not have been appropriate. We also explored attitudes to a waitlist control design as an alternative to a parallel RCT. We mainly used a deductive approach as our aim was to better understand barriers to referral to better inform the design of the pilot trial of FFT-G.

The corpus of data was deductively and inductively analysed using thematic analysis (Braun and Clarke, 2006a; Labra et al., 2020). The first phase was data familiarisation, where the three researchers who conducted the interviews (KC, TC and MM) read the transcripts of each other's interviews. The second phase was generating the codes where two researchers (TC and MM) initially looked for barriers and enablers to summarise and exchange initial findings with the wider research team. Phases Three and Four were concerned with developing overarching themes by iteratively reviewing themes and subthemes (codes). Phase Five was

concerned with ‘Defining and naming themes’, after which the final phase commenced for which the authors (MM, KC and SH), once more negotiated on selecting the key quotes to illustrate the themes in the results.

Document review, informal interviews and intervention implementation data

We conducted a document review of relevant LBR documentation and informal interviews with LBR managers to develop a clearer understanding of the potential referral pathways within CSW teams and identify the most productive systems of referral for the pilot RCT.

We were limited in our review by not having an ISA in place and so were not able to access Protocol, the LBR case management system, directly ourselves. Therefore, our document review consisted of a review of publicly available documentation and additional documentation we were provided with by LBR. This included some summary Protocol reports indicating numbers of YP with different risk factors.

We were provided with data on implementation of FFT-G by FPM. Descriptive analyses are provided for key implementation variables.

Much of our learning came from meetings and unstructured discussions undertaken as part of the study setup, particularly with staff at LBR. There were 82 of these meetings over the 18 month period of the feasibility study, 20 with LBR staff and a further 62 meetings with both LBR/FPM staff, FPM staff and FFT LLC. Only meetings where the PI attended are listed here; there were additional meetings between study researchers and LBR and FPM staff.

Timeline

Table 2: Timeline

Date	Activity
October 2019 – January 2020	Establish clinical team, initial eligibility criteria and referral pathways (FPM/UoG/LBR)
January 2020	Launch of FFT-G service and stakeholder event (FPM/FFT/UoG/LBR) Feasibility study ethics application approved (UoG)
February 2020	Referrals to FFT-G start (FPM/UoG/LBR)
23 March 2020	First UK lockdown starts
April–November 2020	Document review, meetings and informal interviews (UoG)
May/June 2020	Start of easing of lockdown restrictions

July–November 2020	Interviews conducted with staff (UoG)
October 2020	Second UK lockdown
October–November 2020	Negotiations with YEF on extension to project to mitigate effects of COVID-19 (UoG/FPM)
2 December 2020	Second lockdown ends
2 January 2021	Third UK lockdown starts
January 2021	Submission of pilot RCT ethics application (UoG)
8 March 2021	Start of easing of lockdown restrictions
March 2021	Pilot RCT ethics application approval received (UoG)
21 March 2021	End of feasibility study

Findings

Participants

Staff interviews

Purposeful sampling was conducted. In total, 19 participants were interviewed. Of those, five were from the FFT-G delivery organisation, namely the three therapists (T) and two therapist managers (TM). Fourteen participants were from the council's children services. Five of those were in a managerial position (SWM) and thus had no direct contact with families, but they were overseeing social workers' caseloads. The remaining nine participants comprised six social workers, one family intervention worker, one family support worker and one senior family support worker. Although there were some differences in the remit of their roles, they all had the opportunity to refer to FFT-G; therefore, and for the purpose of reporting, we refer to this group collectively to as 'social workers' (SW). Five of the social workers had referred one or more of their cases to FFT-G, while four of them had not yet done so.

Document review, informal interviews and intervention implementation data

See 'Intervention feasibility' below.

Intervention feasibility

Staff interviews

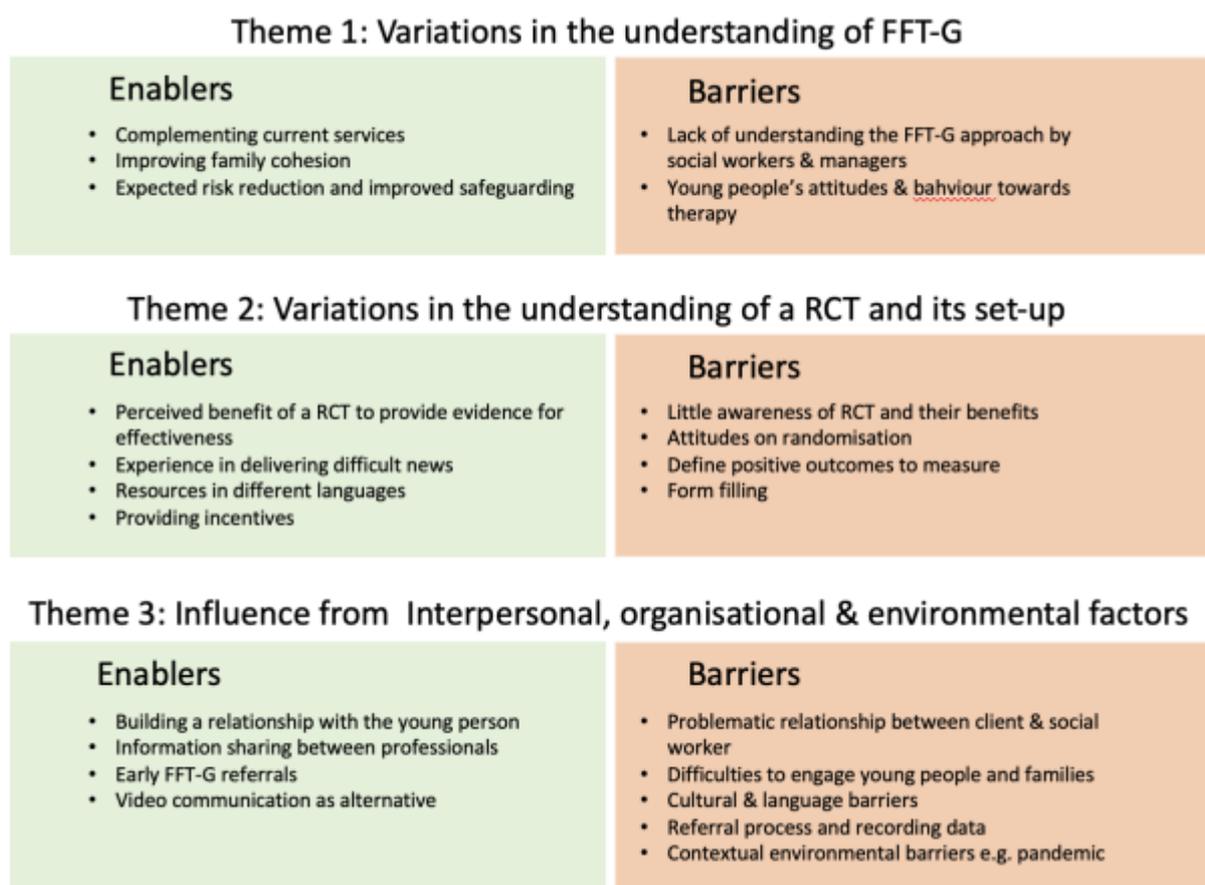
The analysis resulted in three themes extracted from the corpus of data:

1. Variations in the understanding of FFT-G
2. Variations in the understanding of an RCT and its setup
3. Influence from interpersonal, organisational and environmental factors

Each of the themes contains the perceived barriers and enablers to the implementation of an RCT. Figure 2 provides an overview of subthemes (codes) that act as barriers and enablers to the themes.

Note: participants' professional roles are denoted in bold: SW: social worker; SWM: social work manager; T: FFT-G therapist; TM: FFT-G manager.

Figure 2: Theme 1



Theme 1: Variations in the understanding of FFT-G

Those social workers and social worker managers who were familiar with the process of referring a case to FFT-G had a good understanding of FFT-G and were able to explain the essence of the FFT-G approach in their own words. However, social workers were not always sure how it differed from other therapies or why it included the word 'functional'.

PASW: *'Regarding Functional Family Therapy, I can't tell you exactly why that word functional is in there, for example, why it differs from a different kind of therapy, but I know what it's trying to address. It's trying to address the relationships between the family, relate that in some way to contextual concerns, and through everyone getting together and talking about what's going on within the dynamics in the family, it can bring about some positive change; that's my very basic understanding.'*

At the same time, some FFT-G professionals expressed concerns that social workers might perceive FFT-G as just another service complementing the social workers' toolkit for referable interventions and courses, rather than fully appreciating the difference of the FFT-G approach to other forms of non-systemic therapies. They felt that the key difference is related to the mindset of systemic thinking, which informs how one approaches thinking about a situation, which is demonstrated in the following quote:

PLTM: *'Sometimes, they [social workers] would refer for individual [interventions], but I'm thinking about the family interventions. So promoting systemic thinking and systemic formulations about this problem is quite important. [...] It's the way you look at problems. A problem is never individual; it's always systemic. So if you, and there's a lot of literature about offending behaviour and antisocial peers' involvement, it's often to do with not enough connecting at home or at school. There are systemic factors, and if you don't look at these and work with these, then you're less likely to make a change in the individual behaviour.'*

Knowing about FFT-G's approach and the change it can bring was an enabler for social workers to refer their cases. Those social workers who had referred learned even more about FFT-G in the intake session (the first therapeutic meeting with the family), in which they took part to introduce the FFT-G therapist to the family.

PPSW: *'What I saw [at the intake meeting] was that the family had these issues, they had been holding it in, and were obviously not talking about it, and that's where I think the Family Functional Therapy was brilliant because they were able to have all the family members there in one place and get them to open up in front of each other.'*

Social workers, even those who had not referred to FFT-G yet, described that FFT-G complemented their services well and 'plugged a hole'. They could see and anticipated improvements within families after receiving FFT-G around effective communication, improved family relationships and therefore improved safeguarding.

PGSW: *'It's a fantastic service to get the parents to understand what's going on for these children, rather than rejecting them and dismissing them, working with that child to look at making improvements in all their lives.'*

All interviewees communicated that there was a perceived barrier by the young person, and at times their families, towards the notion of 'therapy'. Young people and families appeared to hold a negative attitude towards 'therapy', and the word 'therapy' itself seemed to carry stigma, such as of one being severely mentally ill:

PCSW: *'I don't think professionals are barriers; I think it's the family themselves, and that's probably around the stigma around therapy. As soon as you say "therapy", kids are like, "I don't need therapy," so it's the stigma around the word, isn't it?'*

One social worker explained that he always used the words 'family support' instead of 'therapy' to gain greater buy-in.

Participants familiar with FFT-G fully understood the value of FFT-G for the family. They were able to explain to the family how the intervention improved communication and relationships and therefore made the home a 'safe space' again.

PKSW: *'It's about effective communication; it's about understanding family behaviour and it's unpicking and understanding interpretations of behaviour. For example, if a child storms out, a parent might interpret that behaviour as rejecting or disagreeing with what they're saying, when really the child may be feeling angry and doesn't want to show that anger because he doesn't want to upset his parents.'*

Social workers and managers expected that after a family had been exposed to FFT-G, the engagement of the family with other services was more likely to occur.

Theme 2: Variations in the understanding of an RCT and its setup

Most social workers and social workers' managers had only a basic understanding of RCTs, with some admitting that they were completely unfamiliar with them.

PGSW: *'I guess you are checking that FFT are doing what is expected of them. So a bit like Ofsted [a UK regulator] would come and inspect us and check that we're doing our job properly, because FFT is a new service, just checking that it's actually working and benefitting the young people that we're referring to them and kind of that it's actually, you know, doing what it says it should do.'*

Although FFT-G therapists and managers were more familiar with generating robust evidence in research, some of them still had concerns about carrying out an RCT with this type of population. In particular, randomisation was perceived as a problem:

PET: *'I feel that the young people that we work with [already] are marginalised and don't have options and opportunities like lots of other people do, so the fact that we have this intervention available but we're not going to offer it to them in a timely manner doesn't quite sit right with me personally and also professionally.'*

A potential waitlist control design of an RCT was explained to the interviewees as the scenario of two groups being compared after being randomly allocated to the groups. The first group would receive FFT-G immediately, and the second group would receive FFT-G with a six-month delay. After this explanation, interviewees were open to the possibility of a waitlist design because of the possibility of the study generating evidence for the effectiveness of FFT-G, which might lead to continued funding.

PFT: *'I think it's valuable for a study. For me, it makes sense to evaluate whether the intervention makes enough of a difference or not. I like that the families that don't have access to it now might have access to it later, so they're not completely neglected.'*

Social workers and therapists expected the families that would be randomly selected for the control group to experience disappointment, upset and frustration. Some social workers were concerned that the randomisation news might affect their families' interest in engagement with FFT-G since families did not like to think of themselves as 'pet rats' or did not want to be involved in 'experiments':

PCSW: *'I think a lot of young people would be like, "I'm not an experiment," so to speak; I know it sounds harsh. Because a lot of young people find social work intervention intrusive, and one thing, as I've learned, is being quite straight up to them going, "You know, I appreciate you don't want me here; however, this is why I am, and the only way I'm going is if that changes," and to say, "Oh, you're part of a trial," they'd be like, "Well, I don't want to be part of a trial.'"*

Other social workers expressed how engagement by young people or families completely depended on the case and the context and how this was highly variable.

PGSW: *'It all comes down to individual cases, you know, like I said if they're already involved in stuff and don't want to make changes, they're not going to want to engage with support services regardless of how it comes around – they're just not going to want to. I think it has to be on a case-by-case basis as to whether they're going to actually engage.'*

Interviewees perceived social workers as being best placed to deliver the randomisation news since they were highly skilled in delivering uncomfortable news to their clients. All interviewees pointed out that the appropriate choice of words was key.

PFT: *'Reactions might differ, depending on whether they know they've been randomly assigned or not, or if they've just been told, "You can't access this now, but you can possibly access it in six months because there's a waiting list," for example, rather than, "You've not been chosen." So I think it's the language, the way it's delivered, and also being careful about what we promise them.'*

There were further concerns about referral routes and the different characteristics of YP who might be recruited. Social work managers, who had an overview of the service, raised concerns about the validity of any results due to distinct groups of young people potentially receiving FFT-G with different levels of risk.

PISWM: *'The biggest blockage is going to be where you get those names from, how you work that out and how you get clear two groups; that's fair, because if you've got a young person who's 10 and has just said, "Oh, I'd really" ... seems quite excited about the idea of a gang and thingy, the work that you'll do there in the trial would be very different to someone that's been*

stabbed, three, four times, you know, county lines and how do you merge those and have a clear correct [result], because it's very easy to make the stats what we want them to be, which will show that FFT worked, but how do you do it fairly and correctly.'

Perceived potential benefits of an evaluation of FFT-G varied. Most social worker managers were interested in clearly measurable outcomes, such as reduced missing episodes, a reduction in certain behaviours, lowering the number of young people going into care and lowering the numbers of young people being caught up in the criminal justice system. Social workers, who were familiar with FFT-G, and therapists felt that positive change was less straightforward to define and therefore to measure:

PFT: *'Positive change, that's a good question. You'll get so many different answers for that question, depending on who you ask [laughs]. The reason I say that is because a success for me might just be a young person engaging in three sessions in 10 days, and for me, that's positive change. Because they actually stayed at home, they've not gone out, they're respectful to Mum on the call, and they're there.'*

Another perceived barrier regarding randomisation was raised by FFT-G therapists, who were worried about the reactions of social workers, who would have been through the thorough referral process for FFT-G, which is time-consuming, only to find out that their family has been randomly selected to be in the control group. In their view, social workers would feel disappointed and 'be cross' about the time they had invested.

One social work manager was particularly concerned about protecting her team and service from any lawsuit in case there were serious consequences when a family had been allocated to the control group, thus not receiving FFT-G at this point.

Social workers and therapists expressed concerns about filling in more forms. In particular, they worried about families' understanding of the trial and getting them to fill in the consent form:

PDT: *'For example, with this intake, you can see I've got quite a lot of paperwork that I need to complete already, so I suppose the problem might be if I've got another form that I have to get them to complete, so that might be another barrier.'*

Many social workers emphasised transparent communication regarding the trial with the families to be vital. One social worker suggested designing and handing out leaflets in the families' languages to ensure they understand the remit of the trial and what they are consenting to:

PPSW: *'Whatever the languages that are common in the borough now, and again that would help to ease those barriers because all of a sudden you've got something so simple that explains what it's all about, in one leaflet, so you can give to the family in their own language.'*

Providing a clear explanation of the research and how the families could benefit the greater good with their participation was seen an enabler for setting up an RCT.

PDT: *'I think that might be quite empowering for the family because they can understand that other families are in their situation, and they're not the only people that's in that situation.'*

Some participants, mainly social workers, suggested incentives such as shopping vouchers for taking part. On the other hand, this was also considered as a potential problem for engagement in the actual intervention since families might only take part to receive the incentives.

Theme 3: Influence from interpersonal, organisational and environmental factors

One enabler was the relationship between the YP and the social worker or youth worker and the fact that it is central to building trust and engagement. However, the development of a trusting relationship was not always a given:

PDT: *'The barrier would be the social worker and whether the young person and the family has a good relationship with the social worker because it can be quite a conflicting relationship, particularly if it's got to the stage of child protection.'*

The total number of service professionals (e.g. key workers, family support workers and therapists) can be a barrier to building the trusting relationship between the social worker and the young person. Good communication between the professionals and sharing of information and activities enables each professional to take on different aspects of case involvement.

PCSW: *'I'm quite cautious of too much involvement. So, on a standardised case of county lines, you should have a social worker, a gangs worker and FFT-G therapist. You could potentially have the youth offending team as well. That's too much. For example, I've done it on a case previously with YOT... the youth offending worker had a really good relationship with the young person. Do you know what? I'm not ruining that; I will take charge in something else, so I think social workers need to be more accountable in a sense of: here's the care plan, who's doing what? And don't duplicate.'*

All participants emphasised the importance of considering the timing of providing FFT-G and therefore not competing with other services that may be offered at the same time, which may affect engagement.

Social workers explained that the key to building the relationships is consistency, knowing the YP's background well and showing interest in their interests. Social workers and therapists described that it is typically harder to engage young people from the age of 13 onwards:

PHSW: *'Know their background and their history. There's no right or wrong answer. And their age does play a big part because their demeanour will change from a 12 year old to a 13 year old – it's insane.'*

The attitude of young people towards engagement with children's social services is frequently a barrier. Social workers described how non-engagement or lip service to questions could be more frequent than engagement.

PGSW: *'Even when we try and do a "return home interview", they're just like, "Yeah, I'm busy" or "I don't care," you know. So I think it's just a matter of if you can get one that wants to talk to you, fantastic, but don't be surprised if they don't want to talk to you. And I think as well that sometimes they just say what we want to hear, and they're not actually honest with us, so that could kind of be a barrier.'*

Considering the circumstances of the pandemic, social workers had to hold their meetings over video calls, although they preferred to meet in person with the YP as soon as they safely could. One social worker manager provided an example of a behaviour change in a young person due to the use of video meetings instead direct in-person meetings. In one instance, the young person displayed harmful sexual behaviours by 'forgetting' and mistaking the social worker as an 'unfaced screen person'.

The young people who were referred to the children services in this LA were from culturally diverse backgrounds, with Asian, African and African-Caribbean being the largest groups. Although social workers or youth workers were carefully matched considering culture and language of the families, there were still situations where cultural differences and language levels played a barrier to engagement:

PPSW: *'Even me, I speak Bengali, and a lot of my cases are Bengali families, but then I have lots of Pakistani and Indian families and Sri Lankan families, so again, even me, I need to call upon interpreters all the time because the parent that we're trying to get hold of or speak to doesn't speak English fluently, and it's quite difficult to obviously get them involved in all these services where they don't speak the language.'*

Overall, the volume of referrals to FFT-G was not as high as anticipated by therapists and therapist managers, which was due to a number of reasons, including a lack of awareness by social workers around FFT-G, the cases not fitting the inclusion and exclusion criteria and the length of time it takes to refer. The low number of referrals was perceived as a barrier by the social work managers and therapist managers to setting up an RCT. Furthermore, it was perceived as ideal if suitable cases could be referred to FFT-G as soon as the initial assessment

by the social worker had taken place. Interviewees expressed the view that FFT-G had a greater chance of being effective when initiated early and when the family was not at the point of an immediate crisis.

Another barrier was the considerations for capturing data and how to share them between the professionals. The council had to follow specific rules on data recording, for example, around the young person's potential criminal involvement, and the software did not allow for the flexible use of data easily.

PISWM: *'As a council, what we've realised is that we're not able to record clearly who is involved [in county lines], and that the police have a very clear pro forma as to what makes you involved, and we have to be careful if we call them [young people involved in] county lines or not, but we would say yes they are so.'*

Social workers and therapists shared their experiences of working during the first lockdown and noted the possibility that further lockdowns could not be ruled out. Using video meetings was the next best option to face-to-face meetings, but these were not ideal for building relationships or conducting FFT-G sessions:

PCSW: *'COVID was a big one because it ruined that face to face, and that did impact on our cases.'*

PFT: *'Very, very different [FFT-G sessions]. In some ways, it works quite well, to be able to be slightly more directive. And in some ways it didn't where, you know, the young person or family member can just get up and walk away, and you can't really do anything to get them back because it's on a screen. Or it's quite difficult to contain argument or blaming, which is bound to happen in family sessions. It's been challenging, but it's been quite revealing to see how we can actually work though, using videos... it's not impossible. For the families that I work with, it's been better this way than with nothing at all.'*

Discussion

First of all, it was notable in this study that there seemed to be an association between positive experiences and attitudes towards FFT-G and social workers' openness towards an evaluation of the intervention. Attitudes may have been different if FFT-G had not already been implemented in the LA. Nevertheless, not all social workers were fully familiar with FFT-G nor systemic thinking, which was a concern raised by FFT-G managers, but it was felt that this could be alleviated with further dissemination.

Overall, the results demonstrate that most social workers (whether they had referred to FFT-G or not) were sceptical but would support an RCT since it provides the needed evidence for the intervention and thus for continued funding. Social workers who had referred more to FFT-G were more accepting, suggesting that greater familiarity with the intervention facilitated acceptance of a randomised evaluation of it. Both groups (FFT-G professionals and

social work professionals) did not differ greatly when they expressed concerns around the setup of the RCT, ensuring the families' understanding, gaining consent and the issue of randomisation. At the same time, these barriers were felt to be surmountable by applying careful planning and using an appropriate choice of words (and in different languages). In addition, there was some appetite for a waitlist RCT (which was probably the preferred option) because families would still receive the intervention, but at a later point in time.

The role of involving social workers in the recruitment process, both in terms of introducing the study to the family and informing them about the results of randomisation, was described as important by a number of participants. However, understanding of RCT methodology was very limited in social workers, which may limit their ability to adequately explain or introduce the study to families.

Document review, informal interviews and intervention implementation data

Our document review and informal interviews aimed to assess the total number of cases seen in LBR child social care, how many were likely to be eligible and the feasibility of using LBR data for eligibility screening and outcome data.

The first source of data is the result of initial assessments conducted by the MASH (essentially, the front door of the service) when cases are referred to child social care and reasons for the contact are noted at this point. There was no flag for CLDN involvement, nor was there an overarching flag for contextual risk. There were flags for missing from home, gang involvement, CCE and CSE. In the financial year ending 2020, there were 245 cases flagged missing, 298 flagged gang-involved, 165 flagged CSE and 308 flagged CCE.

However, it is important to note a number of limitations of these data. First, contacts are unlikely to represent individual cases as additional referrals of the same individual may have different flags attached, i.e. an individual may be referred a number of times in a year with different flags each time and be counted as a separate contact in these data. Second, only one of these flags – called sub-categories of need – can be attached at a time. The most pressing concern is chosen, so flags may hide other risks. For example, CCE may be identified as a concern, but if the child is being sexually abused, then that is likely to be the flag attached to the case. Third, MASH assessments are conducted with very limited information, so additional assessments are likely to reveal further information that may well change the understanding of the risks for that individual YP.

The second source of data comes from the CPAT team who conduct more detailed Child & Family (C&F) assessment for those cases identified by MASH as likely to be at elevated levels of risk. Lower risk cases are often referred 'down' to Early Help services, other services or closed and would not have a C&F assessment undertaken. Therefore, the numbers in this data

source are smaller. These data show the number of risk factors identified in all C&F assessments that took place. C&F data we received included three risk factors: missing, CSE and gangs. We also received data on CCE but subsequently and from a slightly later time period (September 2019–October 2020), which we include here. There were 76 cases with missing, 82 with CSE, 140 with gangs and 198 with CCE.

In addition, early interventions services estimated that they had seen 198 cases that had gang or CCE concerns over the same period. On the basis of these data sources, we drew the tentative conclusion that there were likely to be adequate numbers of eligible YP seen in LBR to generate the required rate of referrals for a pilot RCT.

Our review of these data and informal interviews with LBR staff did indicate that relying on these sources of risk were unlikely, on their own, to identify whether YP would be eligible for a pilot RCT and additional screening would be required. Furthermore, our review of the data indicated likely problems with using it as outcome data, e.g. to assess whether FFT-G reduced CCE or CLDN involvement. However, without direct access to case files, we were unable to come to any firm conclusions on this issue and aimed instead to assess the use of LBR data as outcome data as part of the pilot RCT.

Meetings and informal interviews with social work managers also assessed the feasibility of a randomised pilot and of the measures used. Managers expressed considerable unease with a randomised design, partly due to the ethical implication of denying high-risk families a potential source of help. However, the reluctance of social workers to refer was cited as the main barrier, and the results of interviews with social workers helped to allay these concerns. While social workers expressed some reluctance to an RCT design, they also expressed grudging acceptance of the need for an RCT. This is in contrast to other studies that have found outright hostility to RCTs among social workers (e.g. Dixon et al., 2014). In addition, we emphasised that avoiding a randomised evaluation during this project would most likely mean simply delaying it to a future study as it would be required to demonstrate effectiveness.

While there was more acceptance of a waitlist RCT design, it was felt that this would in turn have created additional problems. First, given the level of need of many families who were likely to be recruited to an RCT, LBR and FPM staff felt that promising an intervention but delaying it for six months might have a negative effect on engagement with other services. Second, the circumstances of the family might have changed so much in that period that FFT-G might no longer have been suitable.

The aim of the feasibility study was not to assess the efficacy of FFT-G but rather to assess whether the intervention could be implemented in this setting. Therefore, we do not report clinical outcome data collected by FPM here but rather data on the number of referrals, the number of sessions attended by families (including how many received a critical dose), the number reaching each phase of therapy, the proportion completing therapy and mean fidelity ratings.

There were 100 referrals to FFT-G during the feasibility study that proceeded to the consultation phase because they were assessed to be probably eligible. This included both cases referred by social workers to the FIT panel for FFT-G and those referred for other services but who were identified as potentially eligible at the FIT panel. Fifty-two were deemed ineligible at consultation. Reasons for ineligibility varied considerably, but the two most common reasons were lack of contextual safeguarding risks and family refusing the service. Of the remainder, treatment data were available on 36 cases (all 10–14 years of age).

The mean number of sessions per family was 10.7 (SD = 6.61). Twenty-four families (67%) received the critical dose of eight or more sessions. Twenty-two families (61%) completed treatment, and the mean number of sessions in this group was 15 sessions (SD = 4.40), with a range of 8–30 sessions received. All completed cases received at least eight sessions.

Of the non-completers, two did not start the Engagement and Motivation phase, seven dropped out during this phase, and five dropped out during the Behaviour Change phase. For the majority, the reason for dropout appears to be the family withdrawing. However, one case ended because the YP ran away from home, four cases were referred to other services and there was no reason provided for one case. The mean number of sessions among non-completers was 3.9 (SD = 2.73), with a range of 0–8 sessions.

Fidelity data were available for 26 cases. Fidelity ratings were made by the FFT consultant on a seven-point scale using the Therapist Adherence Measure, and the mean fidelity was 3.3 (SD = 0.95). This is above the target level of 3, deemed adequate by FFT LLC (Robbins et al., 2011).

Conclusion: Feasibility Study

Table 3: Summary of feasibility study findings

Research question	Finding
1. Will caseworkers refer to a randomised trial of FFT-G, or will an alternative trial design, such as a waitlist control RCT or a QED, be more feasible?	Interviews suggested that caseworkers would refer, albeit reluctantly, to an RCT. A waitlist control was preferred, but given the practical and ethical implications, our tentative conclusion was that a parallel RCT was feasible.
2. What are likely to be the most productive referral pathways and processes to ensure adequate recruitment to a pilot RCT? Will referral from one LA be adequate for an evaluation?	Review of LBR documentation suggested that there would be an adequate number of eligible cases for a pilot RCT from one LA. However, given the uncertainty around the use of these data to determine eligibility criteria, we concluded that additional screening would be required.
3. Will an FFT-G team in UK child social care receive enough referrals to generate adequate therapist caseloads and demonstrate good therapeutic outcomes, specifically adequate fidelity and treatment completion by the end of the feasibility phase?	FFT-G received a reasonable number of referrals during the feasibility study, given that they were a new service in the LA. Approximately half of referrals were ineligible, suggesting that further scrutiny of cases for eligibility is required. Caseloads were low, but outcomes were acceptable. Two thirds of families completed treatment, and fidelity was adequate.

Evaluator judgement of intervention feasibility

We believe that the intervention is feasible. Overall, caseloads were low, but the service was new and setup was during the pandemic. The proportion of families completing therapy was relatively high, and the majority received a critical dose and with an adequate level of fidelity. The intervention was well received by both referring caseworkers and social work managers. We did not aim to assess whether the intervention should be adapted or changed.

Interpretation and Implications for pilot

The results of the feasibility study suggested that the intervention and a randomised pilot evaluation of the intervention were feasible. FFT-G was delivered to an adequate level of fidelity, and treatment implementation data indicated that it would be possible to implement it in UK child social care. Given the lack of effective interventions for this population and the urgent need to develop approaches to tackle CLDN involvement and CCE (Child Safeguarding

Review Panel, 2020), our results suggest that FFT-G could be embedded in this setting to target contextual risk, and an RCT is a potentially viable evaluation design.

One of the major challenges to RCTs in this area appears to be the effect of gatekeeping on recruitment by referring caseworkers (Alderson et al., 2020). Despite some concerns being expressed by staff about an RCT of FFT-G, there was general (albeit reluctant) acceptance of the need for a randomised evaluation design, in contrast with outright hostility found in some other studies (e.g. Dixon et al., 2014). Our results did suggest that a waitlist control RCT was preferred by caseworkers and managers. However, as noted above, there were concerns about the potential effect this could have on high-risk families' engagement with usual services during the time they were waiting to receive FFT-G. Also, it would have been extremely difficult to incorporate that design into the project funding. Therefore, we considered that a parallel RCT would be the most feasible design.

There were a number of questions we were unable to answer with an adequate level of confidence, leading to a number of risks for an RCT being identified, partly as a result of the COVID-19 pandemic. As a result, our plans for a pilot RCT included a number of plans to mitigate against those risks:

1. Although our results suggested that a parallel RCT was feasible, this was based mainly on the results of interviews with staff. We therefore planned to review whether recruitment was adequate in the early stages of the RCT and switch to a non-randomised design if necessary. One possibility that we were not able to explore was a matched controlled QED. We planned to further explore this possibility once an ISA was signed with LBR, allowing us to conduct a more thorough review of agency data.
2. We had anticipated collecting data on families seen by FFT-G during the feasibility phase. However, we agreed with YEF not to do so because of the impact of COVID-19. As a result, we were not able to assess the feasibility of measures adequately. In particular, there were serious concerns raised about the SRD instrument, which we shared, so we decided not to use this as a primary outcome. Furthermore, given the lack of a longer-term follow-up assessment in the pilot RCT (due to funding/time constraints), we concluded that a measure of externalising behaviour problems was unlikely to provide reliable data on parameters for a future trial because we would not expect much change as soon as the therapy had ended. We therefore decided to use Family Functioning (FF) as a proxy primary outcome measure. However, we would note that there is little data available on mediators of FFT, including FF. Therefore, we planned to interpret results using this measure with some caution.
3. Data held on potentially eligible YP were unlikely to provide enough information to determine eligibility, and therefore our conclusions about an adequate number of eligible YP were tentative. We therefore planned to explore potential expansion of the study to neighbouring LAs if necessary. We also considered that it was important for

eligibility criteria to continue to be assessed by the FFT team leader rather than assessing criteria based on LBR data on each case.

4. It was clear from the results of our interviews that it was important to involve referring social workers in the recruitment process but that their limited understanding of RCTs might restrict their ability to introduce the study to families. We therefore decided to:
 - a. Have a researcher join the end-of-consultation meetings with referring social workers if the case was deemed eligible in order to explain the study to the social worker
 - b. Write a script for social workers to introduce the study and provide the information sheets and consent forms, but to ensure they left it to the researcher to work through the consent process in a subsequent meeting
 - c. Determine what SAU would be for a family prior to randomisation so that the help they would receive would be clearer
 - d. Have the referring social worker explain the results of randomisation to the family
 - e. Establish mechanisms to allow for close collaboration between ourselves, FPM and referring social workers. To that end, FPM designed a live recruitment tracker with pseudonymised data that was shared with us.
5. We were concerned with the ethical and safeguarding risks involved in directly assessing YP for CLDN involvement and CCE (see 'Data collection/outcomes' in the pilot study for more details). We had anticipated determining if we could use LBR systems to that end but were unable to do so. We therefore planned to answer that question as part of the pilot RCT.

Pilot Trial

Overview

Research questions

The primary aim of the study was to assess the feasibility of a future efficacy RCT of FFT-G for YP at risk of CCE and gang and CLDN involvement and to determine the parameters and research methods required for that RCT. In order to do so, we aimed to answer the following questions:

- 1) How many potentially eligible YP/families can be identified in one local authority (LA) i) per month and 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 Figure 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 and 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 six 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 is 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 and number of phases completed, how many received a critical dose (eight sessions) and 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 SAU were received by the control group? What kinds of support were provided, and how much support was received?

Success criteria and/or targets

Stop-go criteria were based on recommendations by Avery et al. (2017) and Lewis et al. (2021) and were 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. 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 the research questions (RQs) 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 an RCT of Multidimensional Treatment Foster Care in UK child social care. We believe that additional lessons have been learned 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 six-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 (RQs 3, 4 and 5): proportion 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%
2. Recruitment 2: (RQs 3, 4 and 5): number 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+
3. Critical dose of FFT-G (RQs 12 and 13): proportion of families randomised to FFT-G arm who receive at least the critical dose of intervention, defined as eight sessions by the programme developers
 - a. RED: 0–40%

- b. AMBER: 41–60%
 - c. GREEN: 61–100%
4. Fidelity of FFT-G (RQs 12 and 13): proportion of families receiving FFT rated at a fidelity rating of adequate (three 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%

Method

Trial design

The pilot method was a parallel, two-armed, feasibility randomised controlled trial of FFT-G compared to SAU interventions in child social work, youth offending and early intervention services for YP at risk of CCE, CLDN and gang involvement in LBR. All study participants had an allocated caseworker and received statutory or other services provided or organised by child social care and other agencies (e.g. early help, Youth Offending Services). In addition, the intervention arm received FFT-G, and the SAU arm received 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 were designed to assess the acceptability of the methodology, the intervention and outcomes related to therapeutic outcomes, and YPs' engagement with CLDNs and antisocial behaviour. Target YP and their family were the unit of randomisation (see 'Randomisation' below for more details).

There were two changes to the trial design after inception: i) the age range was expanded from 10–14 to 10–17 (after changes to the YEF remit and due to the need to increase recruitment rates), and ii) additional methods for screening eligible participants were introduced (see 'Participant selection' below).

Participant selection

Inclusion criteria – YP and families

Please note: the key family member assessed is referred to as the 'primary caregiver' (PCG). This was usually, but not always, the parent (see Table 8).

The difficulty in identifying and recruiting eligible YP was one of the findings of the feasibility study. Therefore, in collaboration with FPM, we used broader criteria identified by the Child Safeguarding Practice Review Panel (2020) with a view to further screening undertaken subsequently:

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

AND

ONE OR MORE OF:

- Known to Redbridge Children Services due to concerns around:
 - Child sexual exploitation (CSE)
 - Child criminal exploitation (CCE)
 - Missing (from home or care) episodes

- Potential/actual gang or CLDN affiliation as identified by police or other statutory service
- 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 was living at home 50% or more each week.

OR

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

AND

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

Exclusion criteria – YP and families:

- Index child/young person was actively homicidal, suicidal or psychotic.
- Problem sexual behaviour was the central concern.
- Presence of organic/cognitive conditions that may have prevented family members making use of talking therapy.
- Key family members refused family-based therapy.
- Significant child protection concerns: basic needs of children were not being met.
- Family had plans to move out of borough, thereby making therapy unfeasible within five months.

See Figure 3 for the participant flow diagram. Eligible participants were identified by three means:

Screening for eligibility

- i) Referring practitioners referred 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-G team leader also attended this panel. The FIT panel undertook

an initial assessment for eligibility on the basis of limited information available at the point of referral. If the case was deemed potentially eligible, an alternative intervention was identified on the basis of need in case the family didn't receive FFT-G, and the case progressed to consultation.

- ii) The FFT-G team manager examined all new referrals to LBR child social care for cases that met eligibility criteria on the basis of reports produced from Protocol, the LBR child social work case management system. These reports included all cases with the following categories of need: missing episodes, gang activity, criminal activity and sexual exploitation. If a case was identified as potentially eligible, it proceeded to consultation.
- iii) The FFT team manager attended internal meetings (with junior FIT, CAF coordinators and YOS) to discuss cases and proceed 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 was primarily to identify if contextual risk was present.

Please note, ii) and iii) were introduced from 17 August 2021 (approximately five months after the start of the trial) due to low recruitment numbers from i). This was possible as an experienced FFT supervisor and team manager joined the team in July 2021 on a full-time basis. Before this time, there was a part-time programme manager who was not acting as a supervisor. Assessment of the effect of this change is reported below in findings>participants>recruitment.

Consultation

If a case was deemed potentially eligible, the FFT-G team manager had a meeting or call with the practitioner who held the case and determined eligibility after further discussion with the practitioner. If the case was deemed eligible, an SAU service was identified (if it had not already been by FIT panel), should the case be randomised to SAU. Towards the end of the call, the study RF was 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 RF met 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), explained the study to the

family and obtained consent⁴ (typically over a number of calls/meetings). The RF then conducted the assessment with the YP and their primary caregiver separately, in the form of an interview for the vast majority of cases. If the participants wished to complete the measures online on their own, then the link to a Qualtrics survey was provided. Translated study materials and/or interpreters were used when required to enable informed consent.

Sample size

As this is a feasibility study, a formal power calculation was not appropriate. However, n = 60–70 is typically regarded as providing 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 provides an adequate estimate of parameters but with considerably less precision. N < 40 only allows for descriptive analyses.

For the qualitative analysis, a smaller subset of participants from the larger feasibility study was required. Following Braun and Clark’s (2013, p. 50) guidelines for small studies, sample sizes for thematic analysis should be 6–10 participants.

Data collection/outcomes

Table 4: Pilot trial methods overview

Research methods	Data collection methods	Participants/data sources (type and 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 six months post-randomisation	Calculation of effect sizes and confidence intervals; estimate of future efficacy RCT sample size; initial analyses of efficacy (linear mixed methods regression)	5–9, 11
Demographic data	Self-report: gender, age, household	YP report; parent report; from LBR records. Collected	Descriptive	3

⁴ When it was only possible to obtain verbal consent, participants were subsequently contacted to attempt to obtain written consent.

	composition, school attendance and type of school	by researcher prior to randomisation (school attendance also collected from YP six months post-randomisation);		
Youth delinquency and violence	Self-Report Delinquency Questionnaire (Smith and McVie, 2003)	YP report. Collected by researcher prior to randomisation and then six months post-randomisation	Calculation of effect sizes	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 six months post-randomisation	Calculation of effect sizes	10, 11
Peer delinquency	Self-report Behaviour of Friends (Goodnight et al., 2006) questionnaire	YP report. Collected by researcher prior to randomisation and then six months post-randomisation	Calculation of effect sizes	10, 11
YP mental health, callous-unemotional traits and irritability	Self-report Strengths and Difficulties Questionnaire, including impact scores (Goodman, 2001), CU traits items (Dadds et al., 2005) and ODD subtype items (Stringaris and Goodman, 2009)	YP and parent report. Collected by researcher prior to randomisation and then six months post-randomisation	Calculation of effect sizes	10, 11

YP mental health	CORE-10 (Twigg et al., 2009)	Intervention group only: YP report. Collected at start and end of therapy. Data collected by FPM.	Descriptive	10, 11
YP attachment representation	Self-report Adolescent Attachment Questionnaire (West et al., 1998; Bodfield et al., 2020)	YP report. Collected by researcher prior to randomisation and then six months post-randomisation	Calculation of effect sizes	10, 11
Parenting behaviour	Self-report Alabama Parenting Questionnaire-15 (Shelton, Frick and Wootton, 1996; Scott, Briskman and Dadds, 2010)	YP and parent report. Collected by researcher prior to randomisation and then six months post-randomisation	Calculation of effect sizes	10, 11
Parental self-efficacy	Self-report Brief Parental Self-Efficacy Scale	Parent report. Collected by researcher prior to randomisation and then six months post-randomisation	Calculation of effect sizes	10, 11
Parental mental health	Depression Anxiety and Stress Scale 21 (DASS-21; Henry and Crawford, 2005)	Parent report. Collected by researcher prior to randomisation and then six months post-randomisation	Calculation of effect sizes	10, 11
Parental mental health	OQ45 (Kim, Beretvas and Sherry, 2010)	Intervention group only: parent report. Collected at start and end of	Calculation of effect sizes	10, 11

		therapy. Data collected by FPM.		
Therapeutic alliance, matching and resistance	Family Self Report (FSR; FFT measure) and Therapist Self Report (TSR; FFT measure)	Intervention group only: YP and parent report; therapist report. Collected by FFT therapist six times during therapy and given at the end of the first two sessions of each therapy phase (see 'Intervention' above). Data collected by FPM/FFT.	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/FFT.	Descriptive	12, 13
Therapist perspectives of family functioning and behaviour change	Therapist Outcome Measure (TOM; FFT measure)	Intervention group only: Therapist report. Completed by FFT therapist at end of intervention. Completed for all cases that were seen at least once. Data collected by FPM/FFT.	Descriptive	12, 13
FFT-G sessions attended	FPM/FFT monitoring data	Intervention group only: Total number of sessions (and hours) attended and by whom; number of families	Descriptive	12, 13

		completing: i) first session, ii) each phase of therapy, iii) all phases of therapy and iv) receiving 'critical' dose (eight sessions). Data collected by FPM/FFT		
FFT-G fidelity	FPM/FFT monitoring data	Intervention group only: Rating scale of 1–6 used by FFT consultant and supervisor to rate individual sessions, aggregate scores for the therapy team reported. Data collected by FFT	Descriptive	12, 13
SAU data	LBR monitoring data	Nature of SAU intervention and no. of sessions attended	Descriptive	15
Recruitment data	Greenwich monitoring data	No. of families moving to each stage of recruitment and time between each stage; attrition rates at each stage; and reasons given for dropout	Descriptive	1-4,6
Experience of FFT-G/feasibility trial	Qualitative interviews	Interviews with select number of YP/families, FFT therapists, caseworkers and managers	Thematic analysis	14

Unless stated otherwise above, all data were collected by a Greenwich researcher. Demographic data were collected from the PCG. Where any of these variables were missing, they were collected from the YP. In three cases, it was necessary to collect these data from Protocol.

For six-month follow-up assessments, participating families were contacted approximately five months after randomisation, and assessments were conducted between five to seven months after randomisation. If we struggled to arrange a six-month assessment with the family, we asked the currently allocated caseworker to help.

A note on collection of CCE/CLDN data: To assess the feasibility of a future fully powered RCT, we needed to determine parameters around primary outcome measures (effect sizes, confidence intervals and therefore likely future sample sizes). The results of the analyses of these variables will go some way to determining the design and the viability of the first efficacy/effectiveness trial of FFT-G in this country. The most effective way of doing this is by assessing CLDN involvement and CCE.

Our view was that asking YP about this behaviour may i) result in emotional distress due to fear of the consequences of revealing this information, such as potential reprisal by OCGs, and ii) might represent a genuine safeguarding risk to the YP. We concluded that this risk outweighed the potential benefits of the study. Furthermore, we were doubtful as to whether we would receive reliable data on these outcomes because of the reluctance of YP and their families to answer and because there is no validated measure (self-report or otherwise) of CLDN involvement.

Therefore, as outlined in the feasibility study report, we aimed to collect this information from LBR systems where possible, where CCE risks are already measured as part of routine assessments, although not regularly. We also decided to use a proximal measure of intervention effect—family functioning and relationship quality—as our primary outcome measure (e.g. SCORE-15). We did include a YP questionnaire on self-reported delinquency, which includes questions on criminality, drug use and self-identification as a gang member. However, we did not include any questions about being coerced into engaging in criminal behaviour or other forms of CCE.

We were also asked by the YEF to include an additional primary outcome relevant to youth delinquency. Therefore, our two primary outcome measures were:

1. Family Functioning PCG report (SCORE-15)
2. Conduct Problems YP report (SDQ CP scale)

Qualitative interviews: design and recruitment

Six months or more after families had been randomly allocated to receive SAU or FFT-G, qualitative data were collected using semi-structured interviews. Participants were asked if

they were interested in completing a follow-up interview for the study when they completed the six-months follow-up survey. Those who were interested were then contacted. Initially, five families who had SAU and five families who had FFT-G were invited to participate in the interviews. Out of this initial group, four families were willing to participate. A further four families were then contacted and, from this group, one family agreed to take part in the interview. Therefore, four young people and five parents (from five families – four SAU and one FFT-G) completed the interviews.

Interviews were conducted online between 30 May 2022 and 9 June 2022 and were recorded using Microsoft Teams. The length of the interviews varied from four minutes to 25 minutes. The interview schedule included questions about the services received by families and the experience of randomisation, e.g. 'As part of the study, you and your family were randomly allocated to one of two groups. How did you feel about this process? Did it have an effect on your willingness to take part in the study?'. The interview schedule can be found in Appendix C. After completion of the interviews, participants received a voucher to compensate them for their time. We were unable to interview referring social workers or FFT therapists.

Randomisation

Randomisation was undertaken after informed consent/assent was given and baseline assessment was complete. Block randomisation with randomly varying block sizes (of four or two) with equal allocation ratio was used to ensure that the research team and service provider were blind to the randomisation outcome in advance. Fixed block sizes can result in some randomisation outcomes to be predicted in advance (e.g. the last randomisation in a block of AABB can be determined after AAB randomisations have been completed). The randomisation ratio was developed by an independent statistician at the Tavistock Institute and known only to them. After baseline assessment was completed, the trial's researcher emailed the statistician with a unique research ID. The statistician emailed back the result of the randomisation within 24 hours. The researcher then informed the referring practitioner and the FFT-G team manager of the outcome. Families were then notified about the outcome of randomisation by the referring practitioner and informed in more detail about the relevant intervention. Therefore, the researcher was blind to treatment allocation during the baseline assessment but not to allocation during the six-month follow-up assessment. Families were not blind to treatment allocation.

Analysis

Quantitative analyses

We tested for associations between the following demographic characteristics and the six-

month values of the two primary outcome measures: YP age, PCG age, YP gender, PCG gender, PCG relationship to YP, number of adults in the house, number of children/YP in the house, whether the YP was attending school, which service referred the YP and the number of days from first contact between a caseworker and the FFT team manager to randomisation. While there were no statistically significant associations, YP gender was weakly associated with YP-reported SDQ CP at six months ($F(1,34) = 2.85, p = 0.073$; males higher) and was therefore included as a covariate in analyses. There were no associations with parent-report FF.

We tested whether demographic characteristics predicted missing values of the primary outcomes at six months and included any in analyses (see Findings>Participants for details).

We calculated effect sizes and confidence intervals for all primary and secondary outcomes where those outcomes included data collected from both treatment groups using the University of Cambridge Centre for Evaluation and Monitoring effect size calculator.⁵ For all other variables, descriptive data are provided.

We tested the effect of FFT-G on primary outcomes on an intention-to-treat basis using repeated measures ANCOVA, controlling for demographic characteristics associated with missing outcomes at six-months follow-up. We had aimed to use linear mixed modelling, but the small achieved sample size meant that this was not feasible. We did not conduct any tests of differences by family characteristics as we had originally planned because of the small sample size.

While we conducted 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 an effect size of $d = 0.6$ (a five-point reduction on the Self-Report Delinquency Scale, similar to other successful trials of FFT [Hartnett et al., 2016]), based on 80% power and $p < 0.05$, G*Power software (Erdfeider, Faul and Buchner, 1996) returned 90 participants, increased to 106 to allow for 15% loss at follow-up. Therefore, inferential tests, while possibly informative, should be treated with extreme caution. Descriptive statistics can be arguably more informative. The emphasis of our analyses of primary outcomes is therefore on confidence intervals of effect size estimations rather than hypothesis testing. This allows us to explore the imprecision around effect sizes and conduct power calculations. These calculations allow us to determine the parameters required for a full efficacy trial of FFT-G.

⁵ <https://www.cem.org/effect-size-calculator>

Qualitative analysis

The primary aim of the interviews was to capture participants' experience of both interventions received and participating in the trial, especially the experience of randomisation. We therefore also explored attitudes to a waitlist control design as an alternative. We used a deductive approach as our aim was to better understand barriers to recruitment and predictors of attrition, as well as experiences of interventions received, in order to better inform the design of a future effectiveness trial of FFT-G.

All interviews were auto transcribed verbatim using a transcription software. These were then formatted and cleaned by CM and CS, with the researchers cross-referencing the interview recordings while editing the transcripts.

Interviews were analysed by CS using thematic analysis (TA). Guidelines for the stages of TA outlined by Braun and Clarke (2006) acted as a framework for the analysis. The researcher familiarised themselves with the data by printing the transcripts and then reading and re-reading through them to immerse themselves in the data. During this phase, the researcher highlighted potentially interesting and useful data points. Transcripts were then coded using NVivo. Codes were created systematically by highlighting extracts of interest and assigning meaningful labels to them. Once the initial codes had been finalised, SH read the transcripts and checked all the codes. CS then had separate discussions with SH and CM (the latter of whom conducted the interviews). These discussions acted as a quality assurance to ensure codes drawn from the data reflected the reality in which other researchers working on the study also understood the narrative given by the interviewees. After codes had been confirmed, they were grouped into candidate themes and subthemes. These themes were discussed, refined and agreed upon by CS, SH and CM.

Using this same method, the researcher explored if different narratives on experiences during the study occurred based on two key factors: the type of participant (PCG vs YP) and allocation to group (SAU vs FFT-G). Examining the data based on these groupings allowed the researcher to analyse if experiences during the study were markedly different depending on what services were received and by whom. It should be noted that those who received FFT-G were interviewed disproportionately less than those who received SAU (two vs seven, respectively) and only one family interviewed received FFT-G. Therefore, the scope of the analysis based on group allocation is considered extremely limited.

Research team and reflexivity

As outlined by Braun and Clarke (2021), reflexivity is considered an important process in qualitative analysis. Thus, the researchers involved in this analysis considered how their background may have impacted upon their conduct of the interviews and subsequent

analysis. The researcher who conducted the TA is a current master's student in the field of child and adolescent psychology. The RA who conducted the interviews is educated to doctorate level. As such, the lens through which the analysis was conducted is a psychological and social science one.

Timeline

Table 5: Timeline

Date	Activity
22 March 2021	Start recruitment (UoG/FPM)
17 August 2021	Change eligibility screening (UoG/FPM)
October 2021	Start six-month assessments (UoG)
December 2021	Complete recruitment (UoG/FPM)
June 2021	Complete six-month assessments and interviews (UoG)
July 2021	Analysis and write-up (UoG)

Findings

Participants

Recruitment

Three participants were either referred or identified at screening more than once. For these, only the last instance is included in this analysis. One family wrote to the study team and asked to be formally withdrawn from the study. This family is included in analyses of recruitment, missing data and attrition but is not included in analysis of characteristics of families or any subsequent analyses.

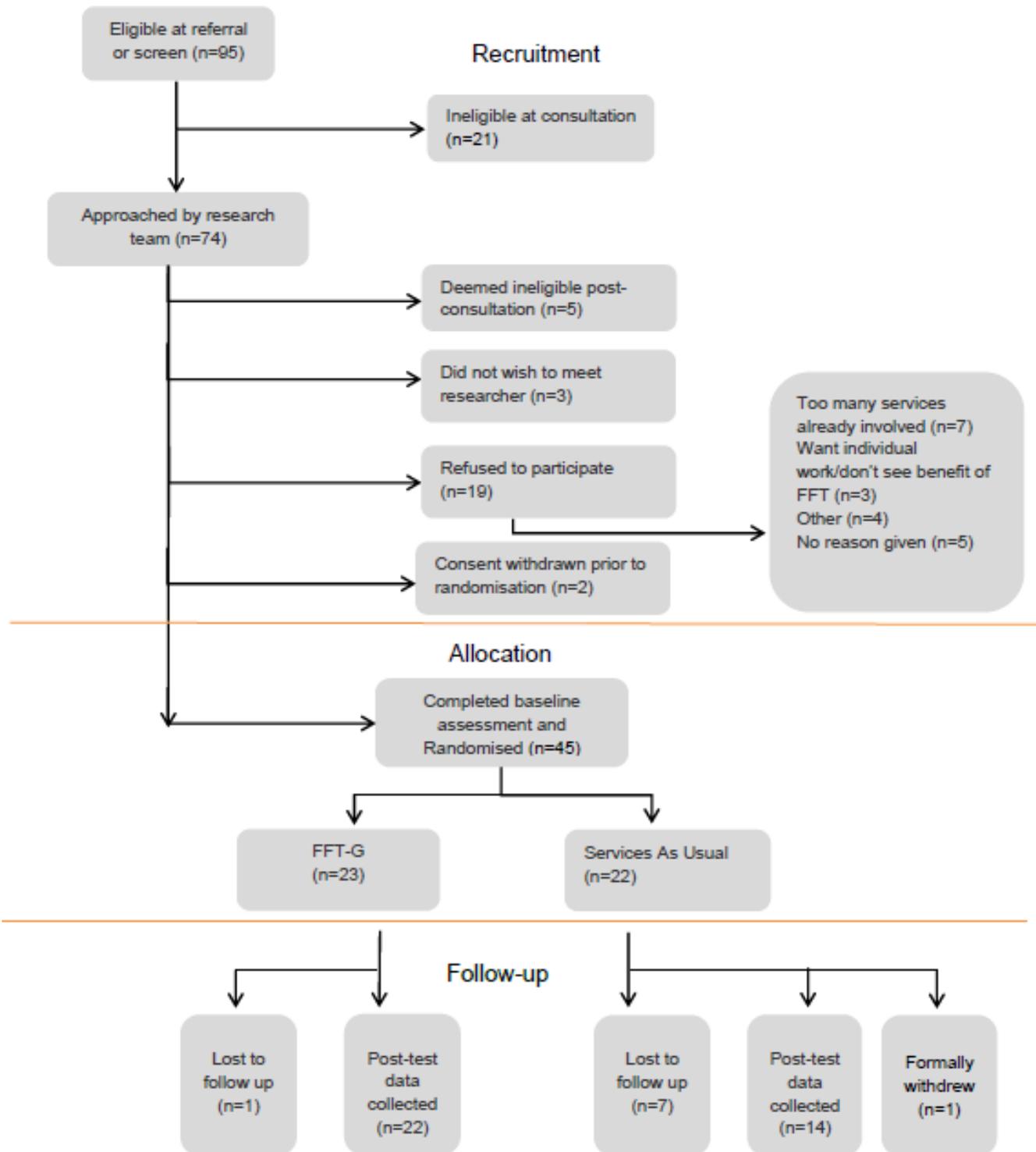
Figure 3 provides details of participant flow through the recruitment process. There were a total of 95 cases (10.7 a month; **Q1**) either referred via the FIT panel, identified in meetings with service teams or identified via screening of Protocol during the recruitment period of 22 March–14 December 2021. Of these, 26 (27%) were deemed ineligible either at consultation (21) or after consultation but before randomisation (5; **Q2**). Sixty-six out of the remaining 69 families (96%) agreed to meet a researcher. Of these, 19 refused to give consent, with the most common reason given being the involvement of too many services at that point. Two families gave consent but subsequently withdrew consent prior to randomisation. Forty-five families in total were randomised – 65% of all eligible families.

Recruitment was very slow in the first two months of the RCT, with only four randomisations in the first seven weeks. This suggested that the results of the feasibility interviews with professionals had been misleading and that the introduction of randomisation might significantly reduce the number of referrals. Therefore, we considered changing to a non-randomised design. However, after further investigation, it transpired that referrals to the FIT panel, which referred to a range of specialist services and not just FFT-G, had dropped dramatically in February, March and April. In fact, the panel, which meets weekly, was cancelled a number of times because of the low rate of cases referred.

Referrals and randomisations did increase over the subsequent three months, and the increase in randomisations may be in part due to some changes in the recruitment process and eligibility criteria. We identified two problems with our initial approach. First, referring caseworkers were attempting to provide more information on the study to participants than they were comfortable doing, most likely due to their lack of understanding of RCT methodology. Therefore, we further simplified the script they were using to ensure that they were introducing the study briefly and leaving the researcher to provide a full explanation to the family. Second, the researcher was attempting to provide too much information about potential services the family would receive (especially SAU) than they were qualified to provide. Therefore, we ensured that more detailed conversations were left to the referring caseworker after randomisation. In addition, on 20 May 2021, we changed the age range of

YP eligible to the study from 10–14 to 10–17 years of age.

Figure 3: Participant flow diagram



Furthermore, in August 2021, we reviewed the overall recruitment strategy of relying on referrals to the FIT panel for study cases because the number of randomisations per month were still below our targets. We came to an agreement with FPM and LBR to allow the FFT-G team manager, an experienced FFT supervisor who joined the team full time in July, to review Protocol reports for cases with sub-categories of need most relevant to eligibility criteria and then proactively approach caseworkers to discuss a referral to the study.

As there is no catch-all contextual risk flag on Protocol, the following four sub-categories were used to identify potentially eligible cases: missing, gang activity, criminal activity and sexual exploitation. Each case was then reviewed for the presence of contextual risk, and if that was present, then the caseworker was contacted for a consultation. The FFT-G team leader also started attending team meetings with professionals referring to Early Help, as these cases are not recorded on Protocol with sub-categories of need.

We therefore provide a limited analysis of recruitment rates prior to this change to recruitment and after, summarised in Table 6.

Table 6: Recruitment rates by study time period

Recruitment period and method	Potential cases identified per month	Randomisations per month	Days to randomisation
22 March–16 August: individual referrals to FIT panel	12.0	3.9	45.0
17 August–14 December: identification of cases on Protocol and at Early Help team meetings	11.5	6.5	22.9

There were 49 cases referred from the start of the study in 22 March 2021 to 16 August 2021 from individual caseworkers referring to the FIT panel. This was at a rate of 12 per month, and of these, 19 were randomised at a rate of 3.9 per month. From 17 August to 14 December, 46 cases were identified at a rate of 11.5 a month. Twenty-six of these were randomised, at a rate of 6.5 a month (**Q4**).

Contrary to expectations, changes to the recruitment process did not increase the number of potentially eligible cases considered. However, it did increase the proportion of cases that were deemed eligible after consultation (from 38.8% to 56.5%) and coincide with the monthly rate of randomisation increasing by more than 50%.

It is possible that a range of other factors may have led to an improved rate of randomisation during this period other than these changes to the recruitment process. For example, the researcher covering for the study RF was more familiar with the recruitment process and had more experience recruiting families. Coordination with FPM on recruitment was also

improved. It is also possible that the inclusion of alternative referral routes, in particular Early Help, increased the proportion of eligible cases that were randomised.

Table 7: Sources of referrals and randomisation

Recruitment period and method	Total cases referred (% of total referrals)	Randomisations	% Randomised
Child Protection and Assessment Team	40 (42.1)	21	52.5
Family Intervention Team	15 (15.8)	7	47.7
Early Help Teams	11 (11.6)	8	73.7
Broader Child Social Work	18 (18.9)	4	22.2
Youth Offending Service	10 (10.5)	3	30.0
Looked After Children Team	1 (1.0)	1	100.0

However, it is also possible that the increase was due to the FFT-G team manager identifying families where there were increased levels of contextual risk, thereby increasing the proportion of families likely to accept the study. Prior to August, we were relying on individual caseworkers to decide which families should be referred, albeit by following a set of eligibility criteria. It is possible that the families recruited from August may have been more positive about the possibility of additional specialist services, like FFT-G or some of the SAU provision being offered, such as Groundworks. If so, increased rates of randomisation may have been partially mediated by faster recruitment, as the time taken from identification of the case to randomisation more than halved in the second period (Q3). The increased availability of a full-time experienced team manager/supervisor secured good oversight of the through-put of cases. There were weekly meetings between FPM and the research team using a shared database, purposely designed by FPM, to identify and review any barriers in the recruitment process and problem-solve them.

Characteristics of randomised families

Table 8 provides a summary of the characteristics of randomised families by treatment group.

Table 8: Characteristics of families, n (%) or mean (SD)

Measure	Randomised sample	SAU	FFT-G
YP gender (%)			
Male	24 (54.5)	10 (47.6)	14 (60.9)
Female	17 (36.6)	9 (42.9)	8 (34.8)
Other	3 (6.8)	2 (9.5)	1 (4.3)
YP age	14.3 (1.81)	13.9 (1.80)	14.6 (1.8)
YP attending school	30 (68.2)	16 (76.2)	14 (60.9)
PCG gender (%)			

	Male	5 (11.4)	1 (20)	4 (17.4)
	Female	39 (88.6)	20 (95.2)	19 (82.6)
	Other	0 (0)	0 (0)	0 (0)
PCG age		43.8 (8.52)	42.2 (8.1)	45.2 (8.8)
PCG relationship to YP				
	Mother	37 (84.1)	19 (90.5)	18 (78.3)
	Father	4 (9.1)	1 (4.8)	3 (13)
	Grandparent	1 (2.3)	1 (4.8)	0 (0)
	Other	2 (4.5)	0 (0)	2 (8.7)
Adults in the household		2.1 (1.35)	2.1 (1.70)	2.1 (0.90)
Children/YP in the household		2.1 (1.04)	1.95 (0.97)	2.17 (1.11)
Referring service:				
	Child Protection and Assessment Team	21 (47)	13 (61.9)	8 (34.8)
	Family Intervention Team	7 (15.9)	4 (19.0)	3 (13.0)
	Early Help/Junior FIT/CAF coordinator	8 (18.2)	1 (4.8)	7 (30.4)
	Broader Child Social Work	4 (9.1)	1 (4.8)	3 (13.0)
	Youth Offending Service	3 (6.8)	1 (4.8)	2 (8.7)
	Looked After Children Team	1 (2.3)	1 (4.8)	0 (0)
Time from first enquiry to randomisation		32.6 (25.44)	40.3 (32.86)	25.5 (13.21)
SDQ impact score (PCG-reported – mean [SD])		13.2 (3.75)	14.5 (3.35)	11.9 (3.75)
High or very high SDQ (PCG-reported):				
	Total difficulties	25 (67.6)	15 (83.4)	10 (52.6)
	Conduct problems	27 (61.4)	16 (76.2)	11 (47.8)
	Emotional problems	20 (46.5)	10 (47.6)	10 (45.5)
	Hyperactivity	15 (34.1)	9 (41.8)	6 (26.1)
	Peer problems	22 (50)	12 (57.1)	10 (43.4)
	Prosocial behaviour ¹	21 (47.7)	11 (52.4)	10 (43.5)

¹ High scores indicate high levels of prosociality

The randomised sample was predominantly male and typically aged between 12 and 16. The PCG was female and were the YP's mother in the vast majority of cases. Approximately, 30% of YP were not attending school at the point of randomisation and presented with significant mental health problems. Two thirds had high or very high scores on the SDQ total difficulties scale, with only 16% scoring close to average. Conduct problems were particularly elevated, with 61% scoring in the high to very high range. Because of the small sample size, we were not able to assess whether characteristics of families were associated with recruitment.

Differences between treatment groups are described below, but it is worth noting that a greater proportion of the SAU group were in the high or very high range for total difficulties and conduct problems than the FFT-G group. The SAU group were more likely to be referred by CPAT and less likely to be referred by Early Help, and the period between screening/referral and randomisation was considerably longer than in the FFT-G group.

Loss to follow-up

We were unable to complete six-month assessments with nine families (20% total attrition rate; **Q6**), eight in the SAU arm and one in the FFT-G arm of the trial (**Q7**). Thus, missing data rates were significantly different for the two groups (36% for SAU, 4% for FFT-G; $X^2(1,45) = 6.2, p = 0.013$). Of the nine families, we were unable to contact four; three refused, citing poor SAU as the reason; and two refused because they or their SW said that they were in crisis and

overwhelmed. For the remainder of randomised cases, all six-month assessments were completed with both family members, and all measures were completed. Therefore, rates of six-month missing data are the same for YP and PCG reported measures.

We tested for associations between the following demographic characteristics and missing values of the two primary outcome measures at six months using chi square and binary logistic regression: YP age, PCG age, YP gender, PCG gender, PCG relationship to YP, number of adults in the house, number of children/YP in the house, whether the YP was attending school, which service referred the YP and the number of days from first contact between a caseworker and the FFT team manager to randomisation. Whether the YP was attending school was associated with missing values of PCG-reported FF and YP-reported SDQ CP at six months ($X^2(1,42) = 4.2, p = 0.044$; **Q7**).⁶ We therefore included these variables as covariates in analyses of primary outcomes. There was no association between the time taken to recruit participants and missing data at six months (**Q3**).

Evaluation feasibility

Rates of missing data and suitability of measures

Rates of missing data at baseline are reported in Table 9 (**Q5**). There was insufficient data to compute the SDQ impact score for four cases when reported by PCG and seven cases when reported by YP. One parent provided incomplete responses on the APQ and DASS, and there were two cases where there were incomplete responses on the BPSES. Rates of missing data at baseline were too low to enable any analysis of the effect of family characteristics on levels of missing data (**Q7**).

Table 9: Measures used, means, SDs and missing data rates at baseline

Measure	Cronbach's alpha	N (%) missing	Mean (SD) or N (%) SAU group	Mean (SD) or N (%) FFT-G group
SCORE-15 Family Functioning (PCG report) ¹	.88	0 (0)	37.6 (12.21)	31.9 (10.34)
SCORE-15 Family Functioning (YP report) ¹	.92	0(0)	42.1 (12.61)	39.2 (14.73)
SDQ Conduct Problems Scale (PCG report)	.75	0(0)	5.7 (2.80)	3.6 (2.10)
SDQ Conduct Problems Scale (YP report)	.43	0(0)	4.6 (1.99)	3.8 (1.89)

⁶ Analysis excludes withdrawn family.

SDQ total difficulties (PCG report)	.81	0(0)	22.4 (7.54)	17.9 (7.06)
SDQ total difficulties (YP report)	.87	0(0)	20.2 (8.29)	17.2 (8.07)
SDQ impact score (PCG report)	.75	4 (9.1%)	14.5 (3.35)	11.85 (3.75)
SDQ impact score (YP report)	.72	7 (15.9%)	12.2 (4.13)	11.4 (3.40)
Self-reported delinquency total	.76	0(0)	8.7 (7.31)	6.0 (6.24)
Gang involvement ²	N/A	0(0)	4 (9.1%)	1 (2.3%)
Peer delinquency (BFQ)	.88	0(0)	27.0 (9.67)	21.0 (7.37)
Parenting behaviour (PCG report)	.76	1 (2.3%)	54.3 (5.15)	59.1 (8.90)
Parenting behaviour (YP report)	.80	0(0)	54.6 (8.85)	55.4 (9.66)
YP attachment representation-AAQ	.84	0(0)	31.9 (6.19)	35.5 (7.27)
Parental self-efficacy	.85	2 (4.6%)	17.3 (5.04)	19.2 (4.32)
Parental internalising problems-DASS	.94	1 (2.3%)	42.8 (11.46)	36.8 (17.17)

Notes: 1. SCORE-15 (Fay et al, 2013). Note: high score indicates poor functioning; 2. Using Eurogang definition, dichotomous measure.

Internal reliability of measures in Table 10 was acceptable to excellent with one exception: the YP-reported conduct problems subscale of the SDQ, which was unacceptable. This is in contrast to the PCG-reported CP scale and, in fact, other PCG-reported SDQ subscales, which were all in the acceptable range, with the exception of peer problems ($\alpha = .45$). Item statistics for the YP-reported CP scale suggest that the problem was not driven by one or two questions. Furthermore, the other YP-reported SDQ subscales did not perform as well as PCG reported ones, with only emotional problems and hyperactivity demonstrating acceptable internal reliability. However, this measure did correlate with other measures of externalising behaviour problems (SRD $r = .51^{**}$; peer delinquency $r = .50^{**}$; PCG SDQ CP scale $r = .36^*$) and with attachment representation and parental efficacy in the expected direction (see Table 10). However, it was not associated with the PCG-reported FF or parenting behaviour. This is problematic given that the YP-reported CP was one of the two primary outcomes.

The other primary outcome, PCG-reported FF (SCORE-15) performed better. It demonstrated good internal consistency and was associated with most measures of externalising behaviour problems, YP-reported FF and both PCG- and YP-reported parenting.

The SRD measure was highly skewed; therefore, we recoded all items so that responses of three times or more in the last six months were recoded as '3'. However, additional problems remain with the measure as 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).

Our limited examination of Protocol case files suggests that these responses were not honest. Furthermore, parent-reported SDQ CP items suggest elevated rates of externalising

behaviour problems in this sample (see Table 8) and, in fact, YP's own responses on the SDQ indicate that 61.4% had high or very high CP scores (although see above for problems with these CP items).

To summarise, most measures included in the study performed well, with a small number of exceptions. However, caution should be exercised when drawing firm conclusions on the future suitability of these measures, given the small sample size.

Table 10: Correlations between main study variables (n = 44)

	Family Functioning (PCG) ¹	SDQ CP (YP)	SRD (YP)	Peer Delinquency (YP)	SDQ Total (PCG)	SDQ Impact (PCG)	APQ Total Positive Parenting (PCG)
SDQ CP (YP)	.18	-					
SRD (YP)	.25	.51**	-				
Peer Delinquency (YP)	.30*	.50**	.70***	-			
SDQ Total (PCG)	.34*	.27	.11	.29	-		
SDQ Impact (PCG)	.49**	.16	.15	.26	.53**	-	
APQ Total Positive Parenting (PCG)	-.49**	-.12	-.26	-.25	-.23	-.32*	-
Attachment (AAQ; YP)	-.28	-.63**	-.38*	-.39**	-.32*	-.40*	.23

Notes: 1. High scores indicate poor FF

* $p < .05$; ** $p < .01$; *** $p < .001$

Availability and suitability of administrative data

One of our original aims had been to compare the total number of potentially eligible active cases in LBR CSW teams and the number that were considered to be eligible after screening/referral. The aim was to use these data to estimate how many sites a future RCT would require to achieve an adequate sample size. We were also interested in exploring whether data held on Protocol could be used as outcome data, given the challenges in directly assessing CCE and CLDN involvement.

We noted some likely limitations to the use of Protocol data in the feasibility phase of the study but noted that limited access to the system meant that we were not able to fully assess the viability of using these data. We did, however, gain full access to Protocol towards the end of the pilot study. We conducted a review of data held on a subsample of cases to determine whether i) relevant risk factors were recorded in a systematic enough way to use the data to determine eligible cases in a future RCT, ii) whether these risk factors could be used as outcome variables and iii) whether data on SAU were held in order to identify the nature and quantity of SAU. We also had informal discussions with SW team managers and senior managers to answer these questions.

Our findings suggest that the answers to i) and ii) are no. Protocol is a case management system and, like other similar systems, is not designed with systematic recording of outcome variables in mind. Most notably, the variables that are most likely to act as outcome variables and markers of risk are sub-categories of need. As noted in the feasibility study, while there is no CLDN or contextual risk sub-category, there are flags for missing episodes, gang involvement, CCE and CSE. However, only one sub-category can be recorded against a YP at any time. Therefore, the absence of a relevant risk factor does not mean that it has not been detected. For example, CCE might be detected, but if there is a more pressing concern, such as CSE, then CSE will be recorded and CCE will not. An interview with the FFT team manager confirmed these limitations, as he stated that a number of the YP identified on Protocol reports as potentially eligible would be found ineligible after a more detailed review of the case.

Therefore, we were not able to clearly ascertain how many eligible cases were known to LBR CSW teams during the RCT recruitment period. We did receive data on categories of need assigned to cases during the RCT period. Specifically, there were 94 cases with CSE, 108 with CCE and 66 with gangs sub-categories of need. It was not possible to retrieve data on how many cases had a category of need of 'missing from home' during this period. However, for the reasons stated above, it is unclear whether these figures capture the total number of probably eligible YP during this period.

Differences between groups at baseline

We did not conduct formal tests for baseline equivalence on measures. However, we note that there appear to be large differences on some measures between the FFT-G and SAU groups at baseline. Both PCG- and YP-reported measures suggest that the SAU group scored higher on measures relating to externalising behaviour than the FFT-G group, and on the whole, caregivers reported more parenting difficulties and worse FF.

Randomisation procedures were robust and independent, so we can only assume that this likely imbalance between groups occurred by chance. The fact that the majority of Early Help cases were randomised to the FFT-G arm may be part of the reason. Irrespective of any differences in outcomes at six months, assessments should be interpreted with caution as they may be due to differences at baseline.

Interviews with PCGs and YPs

We conducted interviews with family members to capture their experience of participating in the RCT. Our aim was to capture information that might contribute to the design of a future effectiveness RCT. So, while we were interested in family members' experience of FFT, our focus was more on experiences of recruitment and randomisation and experiences of SAU and the extent to which this affected willingness to both participate and to complete six-month assessments. We also wanted to explore whether a waitlist design would have been preferred by participants.

Based on the interviews with parents and young people, three major themes were generated. The first theme, 'Participant perceptions of the study', illustrates the variations in how acceptable the process of randomisation was in the study and how participants in the SAU condition would view having to wait six months for therapy. The second theme, 'Variations in motivation for participating', explores the reasons why participants agreed to take part in the study. In the third theme, 'Differences in family experiences with professionals' are discussed, as it was apparent, even when using a small sample, that some families had positive experiences with professionals during the study while others were unhappy with their interaction with some professionals. These themes are captured in more detail below, illustrated with extracts from the interviews. These extracts are followed by participant group allocations (SAU = services as usual; FFT-G = Functional Family Therapy-Gangs) and type of participant (YP = Young person, PCG = Parent).

Participant perceptions of the study

Acceptability of the study: In order to understand the extent to which participants felt the study was acceptable, the interviewer asked participants about their initial perceptions of the study. All participants who were asked if they had any concerns about the study indicated

they did not have any concerns with participating. Importantly, the dominant view was that the randomisation process of the trial was acceptable. However, some expressed uncertainty about the study. Specifically, some parents appeared concerned about the type of service they would be provided with:

'I remember when you called me first time, and I was like, "Okay, maybe." But this will be the same like Redbridge for someone who will work with me.' (PCG, SAU).

'Obviously, the family intervention team was a little bit of an unknown for us.' (PCG, SAU).

Perception of six-month wait: All participants who received SAU were asked if they would prefer to wait six months and receive FFT-G in comparison to the random allocation they received during the study. Views were mixed, and some who said they would have waited said that receiving the necessary support was their only option.

'And we don't have choice. We will wait six months, eight months, one year. We don't have choice, to be honest.' (PCG, SAU).

Variations in motivation for participating

To receive support: For many of the participants, getting the attention and support for their child and family was a recurring motivation for participating in the study. There was concordance in parents' and young people's desire to get this help and to see an improvement in the young person:

'Just basically... just to see if it would help my daughter. You know, as I say, anything that would help, I just would take. And then talking about it after and listening to her views and stuff.' (PCG, SAU).

'I wanna help. I know if I have help that I will... I'll be a better person.' (YP, SAU).

For some parents, the urgency to receive this help and support for their child was apparent:

'We just needed to get on somebody's radar. It was, you know, almost as if they'd said, "Okay, there[s] a road of hot coals, walk down it [to receive support]" – I would have done it. To make sure that we and, [YP] specifically, was getting the help she needed.' (PCG, SAU).

To voice their opinion of the services: Another recurring motivation for participation was to use the study as a means to give their feedback on services. In particular, both young people and parents expressed a desire to give feedback to help improve services for future users:

'It raises awareness as to what needs to be done going forward. And that's the reason why. And that's something in society if we don't all contribute to this, then it would just be all of us being selfish. I want to help the next person down the line, you know?' (PCG, SAU).

To obtain monetary incentive: A final motivation was based on the monetary incentive to participate, as all participants were given vouchers for their participation. This was not a motivation for the vast majority of participants.

Differences in family experiences with professionals

During the interviews, participants expressed a variety of complex and mixed experiences of interactions with professionals. These professionals included social workers at Redbridge, CAMHS service providers and some non-profit organisations such as Violence Against Women and Children (VAWG). As such, the following theme will be discussed in two sections, starting with positive experiences expressed and then negative experiences.

Positive family experiences with professionals

Fostering positive relationships: Of those who received some form of support during the study, including those who received FFT-G, there was an underlying sense that the relationship they had with professionals influenced their experience during the study. Of note, being able to connect and build a trusting relationship with the professional was important to participants:

‘And I know she’s connected really, really well with [YP]. It was one of the things that the social services assessment worker was really keen to pass on ‘cause it was needed to be somebody who could connect with [YP]. She has, she’s just, she’s been an absolute rock. And that’s been amazing.’ (SAU, PCG).

Furthermore, participants expressed that the qualities the professionals they encountered held, such as upholding confidentiality and not being judgemental, were seen as an important aspect in building trust and rapport between participant and professionals:

‘[I don’t have any concerns about the study] because I was told that, you know, our identification wasn’t shown and stuff. So, because of that, I just felt a bit more comfortable. You know that I won’t get anyone just calling us and stuff.’ (PCG, SAU).

‘[The best bits of the support were] the confidentiality. I’ve never had that before. So the privacy has been a lot better.’ (YP, SAU).

‘[The VAWG worker] was just there to listen and not judge [YP]. You know, [YP] was able to talk to her, and she was able to listen and give her advice... And [YP] felt like she trusted her because [YP] used to have a lot of trust issues, and she really does trust them.’ (PCG, SAU).

Effective practical support: Of those who had received support during the study, the common view was that the support was useful, although some young people were unable to say what

was helpful to them. Following on from this, participants were asked about what specifically was useful for them during the study.

One dominant aspect of support that was seen as helpful, regardless of services given, was simply having someone to talk to who would listen to them and their families:

'[I found it helpful that] she was listening to her, what she was doing, how things were in that week.' (PCG, FFT-G)

'[The best bit was] he understands, my therapist understands my situation, and we can talk things through.' (YP, SAU).

Similarly, some participants expressed that having a professional as a reliable source of contact for navigating through their problems during the study was helpful in having a successful outcome for the family:

'I think what I hadn't realised up until the point that [Social Worker Name] came on the scene was how much of a juggling act everything was and how... how actually having her as like a single point of contact, "I'm going to take this forward for you, you don't need to worry about calling these people, I'll do that," and all of that kind of thing. Like I don't, I don't mean to say like sound flippant, but it's like having a social secretary, a really, really good social secretary.' (PCG, SAU).

'... just little things like her having to get to school, and she wasn't sure what bus route to take and [VAWG worker] would always be like, "Well, that's not a problem; I'll come with you; we'll do it one day before you have to go, and we'll find a route. I'll jump on the bus." You know, she's very there beside her supporting her. And if she's ever feeling down, she just has to text them and [VAWG worker] will speak back to her.' (PCG, SAU).

Negative family experiences with professionals

Unprofessional experiences: During the study, some participants who received SAU reported that they believed the experience they had with services was unprofessional to some degree. Some of these experiences were with social workers within RBS. Some believe the quality of their experience was due to a perceived lack of training of the social workers:

'[Social worker] is an amazing young lady. I like her, but she's not professional. For me, this one we know from Redbridge from the support team, they're not for this job. Maybe they have a fake education, I don't know.' (PCG, SAU).

Ineffective support: As part of some of these negative experiences, some participants felt that the support they had received from professionals was ineffective, and some did not receive support due to their refusal of services as a result of previous negative experiences with social workers and other mental health services. When this issue was explored further, participants indicated that such issues negatively impacted their perception of these services:

'We've talked about this before... working with professionals who are not good at their job. It's not my place to judge if they're doing their job properly, but at the same time, it is because it's the service for me. And if they're not helping me, there's no point of wasting time on it.' (YP, SAU).

Issues with case management: During the study period, some participants explained that they had received minimal contact or had a lack progression of their cases from their social worker/professional services. This impacted their ability to receive the support that they required:

'There is initial contact, but then they just fizzle out...' (PCG, SAU)

One participant indicated that frustration over the organisation of the system had prevented implementation of support:

'They would re-refer us back; it'd be like we're going round in circles kind of thing. So initially, one department will refer us to say from A to B, then B would refer us back to A, and so we just going around in circles.' (PCG, SAU).

Negative experiences with professionals in CAMHS: Several participants who received SAU had also been using CAMHS services alongside the support they received from their social worker. However, these experiences with CAMHS were often described as negative. For example, participants felt that the help they received from CAMHS was unhelpful:

'CAMHS... they gave me medication to try and balance out my moods. But I had to stop that shortly after I started it... The support from CAMHS was not helpful, not really.' (YP, SAU).

'So when I was working with [CAMHS therapist], that's when my mental health was the worst it's ever been like I was. He knew this, and he would do this thing where I would come inside the room, and he would just not say anything. We would just sit quiet for a solid 10 minutes. You know, he wouldn't speak to me – he would wait for me, and he would make comments sometimes. Really patronising in general.' (YP, SAU)

Furthermore, participants felt that CAMHS workers disregarded their poor mental health:

'Anytime I mention the fact that I'm depressed, they say low mood. And I say that I'm anxious, and they say you're a teenager... All of the professionals I worked with from CAMHS do this every time. They just tell me you're a teenager. You have hormones. You're not depressed, stuff like that.' (YP, SAU).

Discussion

We found that acceptance of randomisation was the widespread and dominant view. This is in contrast to the view of many social workers interviewed during the feasibility study, who indicated that randomisation would not be acceptable to families. This would suggest that

randomisation should not necessarily act as a barrier to participation in an RCT for families being seen by UK child social care services.

We were also interested in exploring participants' views of a six-month waitlist design in comparison to the parallel RCT they took part in. When participants who were allocated to SAU were asked if they would have preferred waiting six months to guarantee they would receive FFT-G, in comparison to the randomisation to SAU, there was a mixed response, with some participants saying they would wait and others saying they would not. However, it should be noted that it appeared that some participants misunderstood what was meant by this question, believing that it implied they were being asked if they would wait six months for any help, not for FFT-G specifically. Due to this misunderstanding, it is harder to assess the extent to which participant responses reflected their actual opinion on this question and if a waitlist control design would facilitate more successful recruitment.

Participants expressed a number of motivations for taking part in the trial. For many, it was a chance to receive the support that either they or their family needed; it appeared that some expressed a near desperation to receive the help they needed. For others, it was a chance to give feedback on the services they had received, with the desire to improve services for future users. Further, it is noteworthy that financial compensation was rarely a motivation. This suggests that participation in the study was intrinsically motivated, and their primary drive to participate did not derive from monetary incentives.

In terms of experiences during the study, the interviews suggest that participants had mixed experiences of the services that were provided. Of those who received SAU, it appeared that the dominant view was that the support they received was helpful and that this was facilitated by building a positive relationship with professionals alongside the practical support they received. In particular, young people expressed that the professional qualities of those working alongside them, specifically qualities such as not being judgmental and valuing the confidentiality of their patients, were important in fostering this rapport with families.

However, some participants who received SAU expressed negative experiences with professionals and the wider system, which acted as a barrier to receiving the support they needed. Specifically, the perception that some support providers both within the Redbridge system and notably CAMHS were inexperienced or acted unprofessionally appeared to negatively influence participants engagement with system, with some participants refusing to engage due to these experiences. Further, system issues, such as a lack of progression with cases, meant support was unable to be implemented when it was required. There appeared to be a variety of experiences, with some participants indicating that in long-term work with social workers, quality relationships are less frequent, and some social workers were hostile if services were used involuntarily. However, other service users reported more positive experiences with social workers (Ferguson et al., 2020; 2021). These findings suggest that the interviews with participants highlight and reflect the reality of inconsistent service provision

within the social work system. The range of experiences of SAU in particular may well be associated with the chance of attrition during the trial and therefore rates of missing data at six-month assessments.

Limitations

Despite the useful information provided by the interviews, there are some limitations to the interviews that should be highlighted. First, the majority of participants interviewed received SAU. During the recruitment stage for the interviews, it appeared that those who received SAU indicated that they would like to be interviewed more often than those who received FFT-G. Therefore, it is difficult to interpret the differences of experiences between the groups, especially since the FFT-G interviews were from the perspective of only one family.

Furthermore, the quality of the interviews varied significantly. In terms of length, many interviews were under 10 minutes, suggesting that some participants may not have detailed all their experiences during the study. In particular, interviews with young people were lacking in detail, with many young people answering questions in short sentences and with little insight or simply answering yes/no to questions. Because of this, it should be noted that the discourse of the interviews, and therefore subsequent analysis, is based more on parents' perceptions and experiences of the trial than young people's. Finally, we were only able to interview families who agreed to take part in the study and who completed six-month assessments. We were unable to recruit other families for interviews, which limits the generalisability of our findings.

Evidence of promise

Clinical monitoring data

SAU

We had aimed to provide a detailed description of SAU received. However, initial information on this from LBR was received too late for us to undertake the more detailed review of case files that we had planned. Instead, the limited data that we do have are reported in Table 11.

Table 11: Interventions received by SAU group

SAU provision	Number of YP/parent using this service during RCT/ (%)
Parenting Programme	7 (31.82)
FIT team	4 (18.18)
Family Group Conference	2 (9.1)
Mentoring	2 (9.1)
Direct work with SW	2 (9.1)
Family support worker	1(4.5)
Bereavement counselling	1(4.5)
Groundwork*	2 (9.1)
Box-Up Crime*	1(4.5)
Child sexual exploitation provision	2 (9.1)
Tiger Light*	1 (4.5)
Follow CIN plan	1(4.5)
Phoenix Programme*	1(4.5)
ADD UP*	1(4.5)
Spark 2 Life*	1 (4.5)
Fusion*	1 (4.55)

No record	6 (27.27)
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*Definitions of provisions provided below where possible:

Groundwork is a London based community action group that helps transform communities and those in poverty, with a particular focus on gang-involved youth. Box-Up Crime is a social youth organisation that works with young people who have been affected by crime and includes boxing training alongside self-motivation strategies.

Tiger Light is a service provided by Barnardo's to support children who have experienced sexual abuse.

Spark 2 Life is a community initiative to help reduce and prevent the risk of young people offending through therapeutic mentoring.

Note: some families will have received more than one service

FFT-G

The mean number of FFT-G sessions per family was 11.4 (SD = 5.70). Seventeen families (74%) received the critical dose of eight or more sessions (Robbins et al., 2003). Nineteen families (83%) completed treatment, and the mean number of sessions in this group was 13.6 sessions (SD = 3.34), with a range of 6–17 sessions received. Seventeen (89%) completed cases received at least eight sessions.

Of the non-completers, two were never seen and did not start the Engagement and Motivation phase, and two dropped out during this phase. The reason for dropout appears to be the family withdrawing or declining services for all cases. Only one of these families completed more than one session.

Fidelity data were available for 19 cases, and the mean fidelity was 3.4 (SD = 0.96). This is above the target level of 3, deemed adequate by FFT LLC. Fifteen families (79%) had a fidelity rating of 3 or above.

Differences between groups in six-month outcomes

Effect sizes and differences in groups in outcomes at six months are reported in Table 12. Please note that due to the small sample size, we have not presented analysis by family characteristics.

Table 12: Means, SDs, pre-post change scores by treatment group and effect sizes for secondary outcomes (Q10)

Measure	Mean (SD) or % (N) SAU at 6m	Mean (SD) or % (N) FFT-G at 6m	Change score SAU	Change score FFT-G	Effect size (Hedges' g) and CIs
Family Functioning (PCG report) ¹	38.83 (12.64)	34.64 (10.13)	1.24	2.77	.37 [-0.31,1.04]
Family Functioning (YP report) ¹	39.07 (12.76)	33.45(11.58)	-3.03	-5.72	.46 [-0.22,1.13]

SDQ Conduct Problems Scale (PCG report)	5.0 (2.77)	3.64(2.52)	-0.7	0.03	.51 [-0.17,1.19]
SDQ Conduct Problems Scale (YP report)	5.29 (2.73)	3.0(2.12)	.72	-.78	.94 [0.24,1.65]
SDQ Total Difficulties (PCG report)	21.64 (7.26)	16.43(7.44)	-.76	-1.47	.69 [0.00,1.38]
SDQ Total Difficulties (YP report)	20.85 (9.28)	15.71(7.83)	.61	-1.53	.60 [-0.09,1.28]
SDQ Impact Score (PCG report)	14.21 (4.06)	12.1(4.5)	-.24	0.25	.48 [-0.02,1.15]
SDQ Impact Score (YP report)	11.57(5.26)	10.09(4.99)	-.64	-1.3	.31 [-0.37,0.98]
Self-Reported Delinquency Total	5.2(6.23)	5.28(5.5)	-3.53	-.72	-.01 [-0.69,0.66]
Gang involvement	N in a gang= 0	N in a gang= 0	-4	-1	
Peer delinquency (BFQ)	26.57(7.63)	20.36(5.35)	-.43	-.67	.94 [0.23,1.64]
Parenting behaviour (PCG report)	53.5 (8.7)	58.33 (7.33)	-.83	-.76	-.60 [-1.28,0.09]
Parenting behaviour (YP report)	55.36(8.15)	59.45(7.06)	.93	4.01	-.53 [-1.21,0.15]
YP Attachment representation- AAQ	32(7.98)	37.05(6.6)	.10	1.55	-.69 [-1.38,0.00]
Parental Self-Efficacy	19.64(4.81)	20.95(2.87)	2.34	1.77	-.34 [-1.02,0.33]
Parental Internalising Problems- DASS	41.86(15.05)	36.82(13.64)	-.89	-.01	-.34 [-0.33,1.02]

Tests of treatment group on main outcomes (Q8)

Repeated measures ANCOVA was used to test for the effect of treatment group on PCG-reported Family Functioning covarying for school attendance. We found no statistically significant difference between groups ($F(1,33) = 1.802$, $p = 0.189$; $g = .478$). Scores increased slightly over the six months, indicating worse FF in both groups (see Table 13 for estimated marginal means). FF was lower in the FFT-G group at six months but also lower at baseline (see Figure 4).

Table 13: Results of ANCOVA for effect of treatment group on main outcomes

Outcome	6m estimated marginal mean SAU (SE)	6m estimated marginal mean FFT-G (SE)	Effect size (hedges g)	CIs of effect size	P value
Family Functioning (PCG report) ¹	38.78 (3.02)	34.67 (2.41)	0.36	-0.32,1.03	0.189

SDQ Conduct Problems Scale (YP report)	5.08 (0.60)	3.13 (0.48)	1.15	0.13,1.52	0.025
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Notes: 1. SCORE-15 (Fay et al, 2013). A high score indicates poor family functioning.

Repeated measures ANCOVA was used to test for the effect of treatment allocation on YP-reported SDQ Conduct Problems covarying for school attendance and YP gender. There was a statistically significant difference between groups, with lower scores in the FFT group at six months ($F(1,32) = 5.542, p = 0.025; g = 1.15$). Scores were higher for the SAU group at baseline and increased between baseline and six months, whereas they decreased in the FFT-G group (see Figure 5).

Figure 4: EM means and SE of PCG-report Family Functioning by group and time

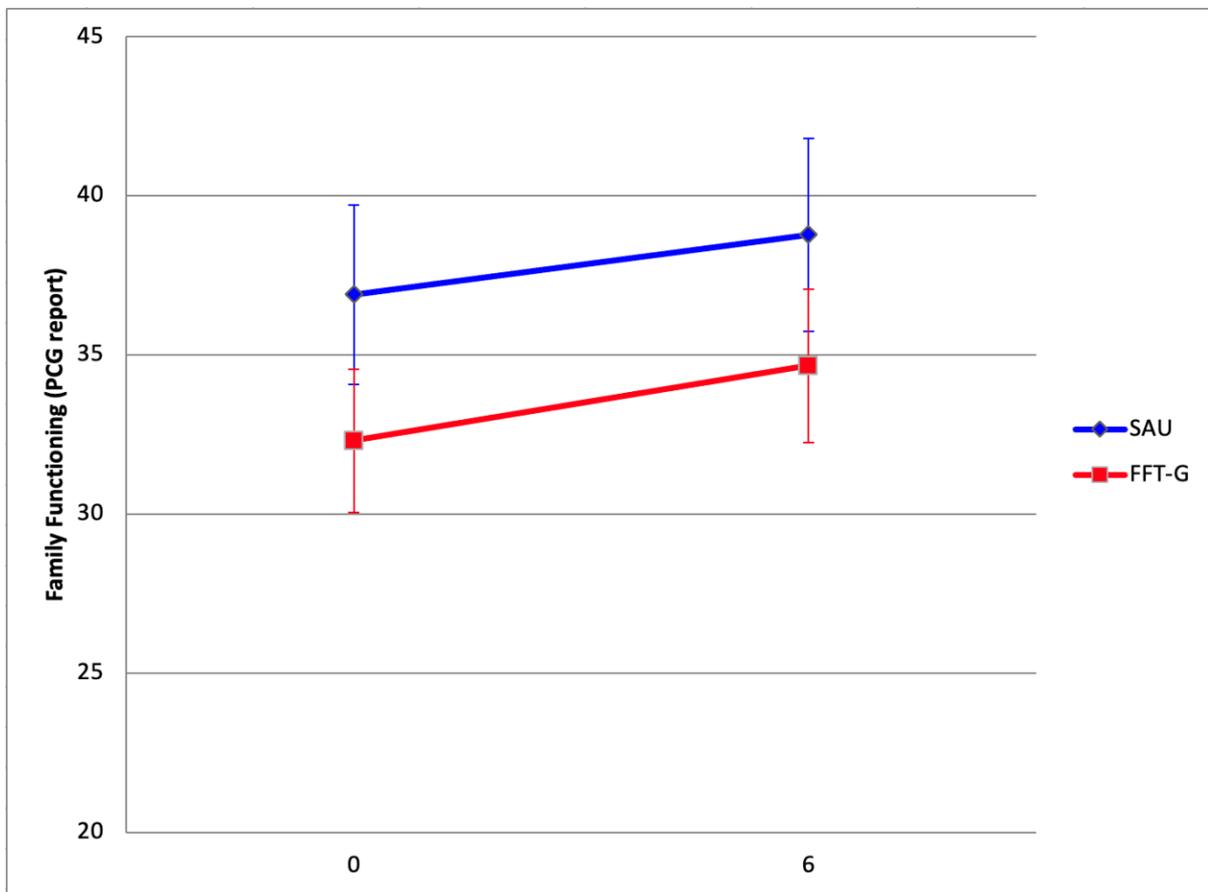
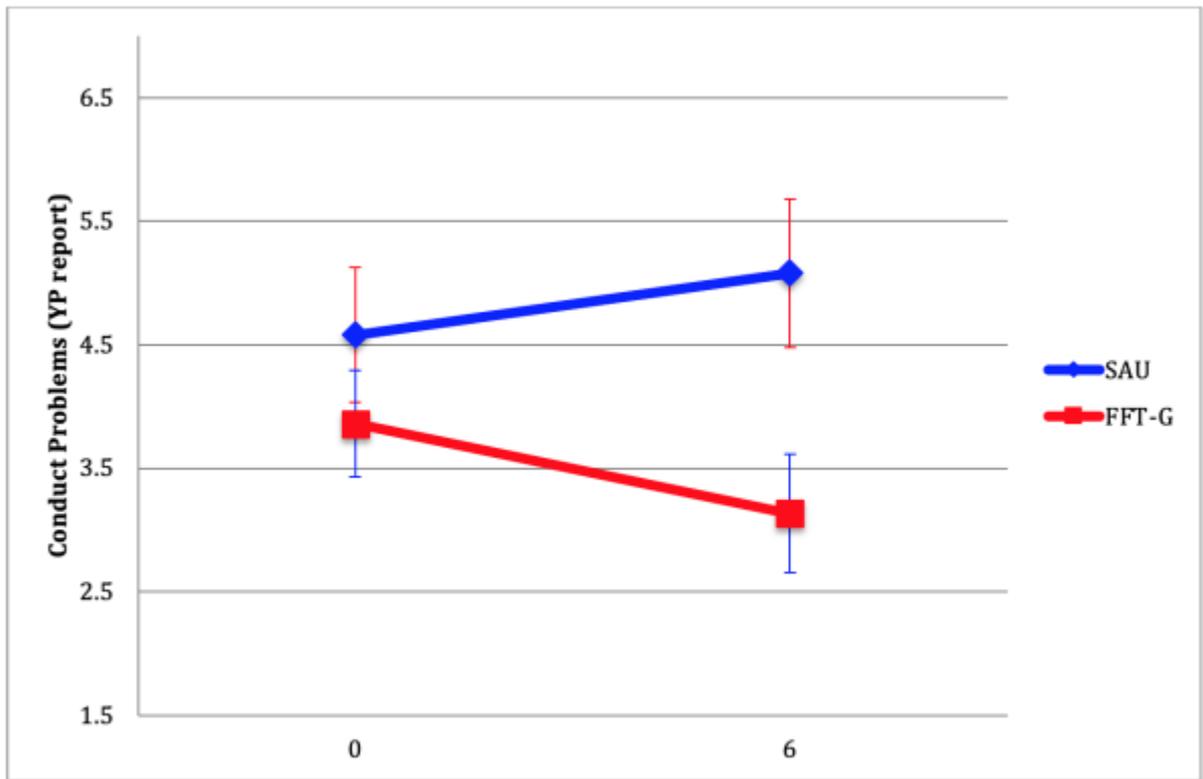


Figure 5: EM means and SE of YP-report SDQ Conduct Problems by group and time



Sample size calculations for effectiveness RCT

Sample size estimates for a full effectiveness 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.

For the PCG-reported Family Functioning outcome, clincalc.com returned 238 participants, increased to 286 to account for 20% loss to follow-up. For YP-reported CP, clincalc.com returned 42 participants, increased to 51 to account for 20% loss to follow-up.

Readiness for trial

Stop-go criteria are listed below with zones reached in the pilot RCT.

1. Recruitment 1 (RQs 3, 4 and 5): proportion 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%: 65% of eligible families were randomised

2. Recruitment 2: (RQs 3, 4 and 5): number 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: 45 families were randomised**
 - c. GREEN: 65+
3. Critical dose of FFT-G (RQs 12 and 13): proportion of families randomised to FFT-G arm who receive at least the critical dose of intervention, defined as eight sessions by the programme developers
 - a. RED: 0–40%
 - b. AMBER: 41–60%
 - c. **GREEN: 61–100%: 74% of FFT-G families received eight sessions or more**
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%: 79% of all FFT-G families had a fidelity rating of 3 or more**
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%: 80% of families completed six-month assessment**

The trial outcomes were in the green zone for four out of five stop-go criteria and in the amber zone for the remaining outcome. This suggests that the intervention is ready to be evaluated at a larger scale using an efficacy RCT. The intervention was delivered with fidelity and was taken up by the majority of families. Loss to follow-up was low, especially given the high-risk population. The majority of eligible families agreed to take part, and had we continued to recruit for another three months, it is very likely that we would have met our original recruitment targets. By halfway through the pilot, referral pathways and recruitment protocols were clearly delineated and functioning well. However, it is likely that more than one site would be required in order to recruit a large enough sample for an efficacy RCT.

Conclusion: Pilot Study

Table 14: Summary of pilot findings

Research question	Finding
How many potentially eligible YP/families can be identified in one local authority (LA) i) per month and ii) over the whole study?	Between 10 and 11 per month; 95 over the course of the study
What proportion of 1) will meet study inclusion criteria after further investigation?	Sixty-three per cent were eligible.
Of the eligible families, how many will progress to each stage of recruitment? 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?	Sixty-six eligible families (96%) agreed to meet a researcher. Of these, 45 (65%) were randomised. The most common reason for not giving consent was that there were already too many services involved with the family.
How many YP/families can be randomised i) per month and ii) over the whole study?	Between 3.9 and 6.5 per month, with 45 randomised over the course of the study.
What are the rates of missing data at baseline?	The rates were 0% for 16 out of 21 measures and between 2% and 16% for the remaining five.
What are the attrition rates and rates of missing data at six-months post-randomisation?	Twenty per cent attrition rates; no additional missing data
Do missing data and attrition rates vary by treatment group and family characteristics?	The sample size was too small to test associations between all family variables and these outcomes. Attrition was associated with poor school attendance.
What are the means, standard deviations (SDs), effect sizes and confidence intervals (CIs) for the primary outcome?	See Table 13.
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?	This is dependent on which power calculation is used. See below.

What are the means, SDs and effect sizes for secondary outcomes? How viable is the use of these secondary outcome measures in this population?	See Table 12. The FFT-G group had better outcomes on most measures compared to the SAU group.
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?	See Table 12. There were small increases in poor family functioning in both groups. There were large increases in conduct problems in the SAU group and large decreases in the FFT-G group. The sample size was too small to test for subgroup differences.
For the FFT-G group, what were the number of sessions/hours attended and number of phases completed, how many received a critical dose (eight sessions) and what were the mean scores for therapeutic alliance and fidelity ratings?	The mean number of sessions was 11.4, with 74% of families receiving a critical dose or more. Eighty-three per cent completed all phases and completed treatment. The mean fidelity score was 3.4, and 79% of cases had a fidelity score of adequate or above. We were not able to compute therapeutic alliance scores.
How do variables in (12) compare to other FFT teams at a similar level of maturity?	We were not able to test this.
What are the experiences of families, therapists and referring practitioners/managers of FFT in this setting?	We were unable to interview practitioners and therapists about FFT due to time limitations. We did interview families, but the majority were SAU families.
What SAU were received by the control group? What kinds of support were provided, and how much support was received?	We had limited data to answer this question, but most appear to have been referred to a specialist service.

Evaluator judgement of evaluation feasibility and interpretation

Our view is that the intervention is ready for an efficacy RCT and that the methods we trialled in this pilot are suitable for use in that trial. Four out of five stop-go criteria were in the green zone, and the only criterion that was amber should be interpreted in light of the length of the pilot. Given the lack of effective interventions for this population and the urgent need to develop approaches to tackle CLDN involvement and CCE (Child Safeguarding Review Panel, 2020), our results suggest that FFT-G is a promising intervention in this setting to target contextual risk, and an RCT is a viable evaluation design using the recruitment and referral mechanisms that we trialled in the second half of the RCT.

It is important to note that we only recruited for nine months due to the impact of COVID-19 and UK lockdowns on the project. For the second half of the pilot RCT, the research team

were at full capacity recruiting participants, and we would have reached our target of randomising 60–70 families if we had continued recruiting for another three months. Therefore, we would expect an efficacy RCT to at least match the rates of recruitment we achieved in the second part of the pilot RCT. It is worth noting that the rate of recruitment was much higher than in the first UK RCT of FFT (Humayun et al., 2017).

The vast majority (96%) of eligible families agreed to meet a researcher, and two thirds were randomised (65%). This would suggest that, after some tweaking, our recruitment approach was effective. However, recruitment and randomisation rates were quite different in the first and second halves of the study. Having the FFT-G team leader identify potentially eligible cases and approach caseworkers appears to have been key to improving recruitment, and this approach should be replicated in an efficacy study, as should close collaboration between an evaluator and intervention delivery organisation.

Missing data rates at baseline were low, and the majority of measures performed reasonably well. We would advise keeping the majority of these in an efficacy trial as those that are not viable secondary outcomes are likely to be potential moderators and mediators of treatment effects. We would advise not using the Edinburgh self-report delinquency measure. There are more recent and up-to-date measures that are likely to perform better. We would also be sceptical about the use of the gang membership measure we used, given the very small number of YP who admitted to being gang members.

Intervention outcomes were positive, the intervention was well received by referring caseworkers and the view of managers and caseworkers was that it was a good fit for the broader child social care ecosystem. Recruited YP did appear to be individuals with high levels of conduct problems and a broader range of difficulties. However, it is difficult to assess how many were involved in CLDNs on the basis of LBR data. Furthermore, we were unable to interview an adequate number of families who received FFT-G and therefore were not able to capture their experience of receiving the intervention.

We would suggest the development and careful piloting of a self-report CLDN involvement measure for a future efficacy study. There are considerable risks involved in using such a measure, but direct assessment of the primary outcome is critical for an efficacy study.

Most measures indicated better outcomes in the FFT-G group than the SAU group. However, randomisation does not appear to have been entirely successful, so these differences should be interpreted with caution as they may well be due to differences at baseline.

This caution should also apply to interpretation of the primary outcomes. The effect size for PCG-reported family functioning was small but not negligible and favoured the FFT-G group. However, this may be due to differences at baseline. The effect size for the YP-reported conduct problems scale was very large, and the changes from baseline to six-month assessment suggest sizeable reductions in the FFT-G group and increases in the SAU group.

However, the groups may have not been equivalent at baseline on this measure, and internal reliability of the measure was poor.

These findings are surprising and the opposite of what we had expected. We had expected to see clearer differences in family functioning and little difference in measures of externalising, given that the six-month assessment was directly after intervention had ended, allowing little time for the effects of FFT-G to bed in.

Given that sample size calculations are based on the effect sizes of these two measures, they should also be interpreted cautiously. The estimated sample size for an efficacy RCT differs enormously, from 51 to 248 (including accounting for 20% attrition). We would certainly advise a conservative approach and aiming for the higher end of this range of sample sizes. The wide range of confidence intervals around these estimates suggests that aiming for a sample size of less than 200 for an efficacy RCT would be risky.

If 200 participants is the likely target, then recruiting from one LA may take longer than is feasible. We were randomising 6.5 families per month in the second half of the study. This was likely limited by staffing issues (the study RF was working at 0.6FTE, even when at full capacity), so a full-time researcher might manage a randomisation rate of seven to eight families per month, at most. To recruit a sample size of 200, this would take more than two years of recruitment.

In addition, we would advise at least six months of an FFT-G team seeing cases prior to randomisation starting in order to build up caseloads, become familiar with the model and establish relationships with referring caseworkers. We strongly believe that the long feasibility period of this study resulted in better recruitment and clinical outcomes during the RCT pilot. Setup, staff recruitment and ethics applications would require another three to six months. A further six months would be required for six-month post-treatment assessments, and we would strongly advise a further follow-up assessment at least six months later. This is when any persisting benefits of the intervention are likely to be detected. At least three further months would be required for analysis and write-up.

Therefore, an efficacy RCT at one site would, at a minimum, take three-and-a-half to four years to complete. We would therefore aim to recruit from two or three sites to reduce the recruitment period to one year or less. Ideally, these should be neighbouring sites and with some existing partnership arrangements in place in the areas of youth justice, policing or social care.

Final Summary

We believe the intervention should now be evaluated with a fully powered efficacy RCT with a sample size of at least 200 families, replicating the design of the pilot RCT. We advise

identifying potentially eligible YP from agency records rather than waiting for referrals. We would advise replicating the pilot RCT design in this project but with some changes to measures used, in particular by including a measure of CLDN involvement and CCE.

We anticipate two likely publications from the current project: one describing the feasibility study and one describing the pilot RCT.

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Appendix A: Approved Research Ethics Application

University Research Ethics Committee Application Form

APPLICATION REFERENCE:

for office use only

NOTE: PROCEDURES FOR THE ETHICAL APPROVAL OF RESEARCH HAVE CHANGED FOR 2019/20. APPLICATIONS FROM POSTGRADUATE RESEARCH STUDENTS SHOULD NOW NORMALLY BE REFERRED TO FACULTY RESEARCH ETHICS COMMITTEES FOR APPROVAL RATHER THAN TO THE UNIVERSITY RESEARCH ETHICS COMMITTEE. SEE [GUIDANCE ON ETHICAL APPROVAL FOR RESEARCH FOR FURTHER DETAILS.](#)

Checklist

Name of applicant: Sajid Humayun	
Faculty/Directorate: FEHHS	
Title of research: The PoRTal study <u>Pilot Randomised Controlled Trial</u> of the Families Are Forever Service	
These papers must be attached to this application form (please tick):	
• Participant information sheet	✓
• Participant consent form	✓
These papers may be required (tick if included):	
• Letters (to participants, parents/guardians, participating institutions etc)	✓
• Questionnaire(s) or indicative questions for interviews	✓
• Advertisement /flyer/copy of message inviting participation	✓
• Annex I - Drugs and medical devices	N/A
• Annex II - Research involving the storage of human tissue	N/A
• Annex III - Ionising radiation	N/A

Has the form been signed?

YES

Have any annexes been signed where necessary?

N/A

SECTION 1: APPLICANT DETAILS

1.1 Surname	Humayun	Forename	Sajid	Title	Dr
Faculty/Directorate FEHHS					
University address, including Faculty Department Faculty of Education, Health & Human Sciences University of Greenwich, Dreadnought Building, Room 101, Old Royal Naval College, Park Row, London, SE10 9LS, United Kingdom					
University telephone	020 8331 9564	E-mail	s.humayun@gre.ac.uk		
1.2 Are you: A member of staff					
Programme of study (if applicable to this application) MPhil / PhD / EdD / Masters by Research / other (please specify) N/A					
If you are a postgraduate research degree student, has your research project been approved by your Faculty Research Degrees Committee? Indicate YES or NO. N/A					
If YES, when?		What is the FRDC reference number?			
If NO, why not?					
1.3 What is the primary purpose of the research? (Please indicate YES or NO)					
<ul style="list-style-type: none"> • Educational qualification • Internally funded research • Externally funded research (please provide details of funding) YES <p>Pilot Randomised Controlled Trial (RCT) to assess the feasibility of a full RCT of Functional Family Therapy-Gangs for Young People (YP) at risk of County Lines involvement and gang and criminal exploitation. The study is funded by the Youth Endowment Fund (see appendix M for contract).</p> <ul style="list-style-type: none"> • Other (please specify)..... 					
1.4 Project supervision (students only) – give the name of the research supervisor(s) and their contact information					

N/A

1.5 Details of any co-researchers within the university

Prof Darrick Jolliffe
Greenwich Maritime Campus
Old Royal Naval College
Park Row
London SE10 9LS

Prof Karen Cleaver
Avery Hill Campus
Southwood Site
London
SE9 2UG

Research Fellow (tbc)

1.6 Details of any co-researchers external to the university

N/A

1.7 Membership of professional bodies - are you or any co-researcher(s) a member of any professional, or other, bodies which set (i.e. require compliance with) ethical standards of behaviour or practice such as the British Psychological Society, Nursing and Midwifery Council, medical Royal Colleges etc.? If so, please specify.

Prof Cleaver. NMC Registrant, Member of Royal College of Nursing.

SECTION 2: PROJECT DETAILS

2.1 What are the principal research questions in this research? Describe briefly, in lay terms, the proposed research project including step by step methodology, and its potential outcomes and benefits (no more than 250 words).

Background/objectives:

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 largely framed through a safeguarding lens (Ford 2018). There is limited evidence for long-term effectiveness for interventions targeting problematic behaviour in adolescence. Functional Family Therapy - Gangs (FFT-G) is an adaptation of an established intervention; current evidence suggests this therapeutic approach delivers positive outcomes, engaging and retaining hard-to-reach YP and their families (Gottfredson et al., 2018), with tentative evidence for gang-affiliated youth (Thornberry et al., 2018). The Youth Endowment Fund have commissioned The University of Greenwich to establish the feasibility of using RCT

methodology to evaluate the implementation of FFT-G by Family Psychology Mutual (FPM) in the London Borough of Redbridge Children's Services (RCS).

Methods:

A pilot randomised controlled trial of FFT-G compared to Business as Usual (BAU) interventions in child social work, youth offending and early intervention services for YP at risk of Child Criminal Exploitation (CCE). The study outcomes will assess the acceptability of the methodology, the intervention and outcomes related to YPs engagement with CLDNs. See appendices B to E for a full list of measures. Assessments will be conducted prior to intervention (baseline) and then six months later (post-intervention). Outcomes for a third group of YP identified using Propensity Score Matching (PSM) will also be used in the form of secondary anonymised data provided by RCS.

Potential outcomes/benefits:

The study will be the second randomised evaluation of FFT-G and the first to be conducted in the UK. It will provide critical information on the feasibility of assessing the effectiveness of intervention approaches for a very high-risk group for whom no effective intervention currently exists, enable assessment of long-term outcomes and help to identify markers of risk for CCE.

2.2 Are any of the following involved? (Please indicate YES or NO)

- Intrusive procedure e.g. questionnaire, interview, focus group, diary, video or voice recording (attach a copy of your questionnaire or indicative questions) **YES**
- Invasive procedure e.g. venepuncture, tissue sampling **NO**
- Physical contact **NO**
- Covert observation or covert filming / recording (video or voice) **NO**
- Children / young people (under 18) – please include age of participants **YES age 10-16**
- Vulnerable people (elderly, physically or mentally ill, people with learning difficulties, in care, bereaved, prisoners, other) **YES**
- Research involving animals (refer to 1.2.2 of the [University of Greenwich Research Ethics Policy](#) for more information) **NO**
- Research involving harmful or criminal, or sensitive or extremist subject matters or research protocols (refer to 1.2.3 of the [University of Greenwich Research Ethics Policy](#) for more information) **YES**
- Research where the source of funding of the research raises concerns that it may be inconsistent with the University's values (1.2.4 of the [University of Greenwich Research Ethics Policy](#)). Particular scrutiny should be given to funding from organisations which the University's [Ethical Investment Policy](#) indicates it will not invest in. **NO**
- Drugs, medicinal products or medical devices (if YES, complete [Annex I](#)) **NO**
- Storing human tissue (if YES, complete [Annex II](#)) **NO**

- Working with sources of ionising radiation (if YES, complete [Annex III](#)) **NO**

2.3 Has there been a pilot study (refer to 2.2 of the [University of Greenwich Research Ethics Policy](#) for a definition) for this research? (If YES, please give details)

Yes. A feasibility study (UREC/19.2.5.5) has been completed, with analysis ongoing. This has taken the form of a process evaluation in the form of a case study of the intervention provider's delivery of FFT-G (called Families Are Forever) and referral flows. It has included a document review of both the intervention providers and local authority children services and interviews with 18 participants: 9 social workers or other social work practitioners, 4 social work managers, 3 FFT therapists, and 2 FFT managers. Data on referral flows indicate adequate numbers for a randomised study. Interviews (including with social workers who have not referred to FFT) demonstrate much more acceptance of randomisation than expected and has contributed to the decision to move to a randomised evaluation study.

2.4 What is the proposed start date (i) of the project and (ii) of the fieldwork (if different)?
i) March 2021

The end date of the project is 15th October 2022 and the end date of the fieldwork is 15th September 2022

SECTION 3: PARTICIPATION AND CONSENT

3.1 What are the selection criteria for the proposed participants in the study?

Inclusion Criteria Young People for entry to RCT.

ONE OR MORE OF:

- Index child/ young person aged between 10-14 years (if older, to be discussed on a case by case (20% of overall sample can be 15-16))
- Known to RCS due to concerns around:
 - child sexual exploitation (CSE)
 - child criminal exploitation (CCE)
 - missing [from home or care] episodes
 - potential/actual gang, or CLDN affiliation as identified by police or other statutory service
 - 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:

- 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 during the next 6-12 months

Propensity Score Matched Control Group

There is a risk that randomisation may not be feasible due to the effect on social worker gatekeeping and participant recruitment. We aim to carefully monitor referral and recruitment rates and interview a small number of social workers in the first few months of the study to assess the acceptability and effect of randomisation and will retain the option to change the study design to an evaluation study without a randomised design at any point during the study lifetime. Under this alternative study design, all YP and their families will be offered FFT-G. To mitigate the effect of this potential change of design on the methodological rigour of the study, we aim to identify a matched control group from RCS records on the basis of a PSM approach based on variables identified in the intervention group. All secondary data provided by RCS will be anonymised.

Selection of practitioners for follow-up/ interview to assess acceptability

- Employed by RCS as a social worker or other practitioner who has or could refer to the study
- Manager of RCS services with staff who could refer to the study
- FFT-G therapist or manager

3.2 How many participants are to take part?

1. We anticipate interviewing a maximum of 15 staff
2. 92 YP and their primary caregivers

3.3 How will prospective participants be recruited / contacted and informed about their role in the project? (Give details and attach your participant information sheet, advertisement, email etc.)

Staff

The feasibility study has involved interviewing a number of staff already involved in study setup and these staff will be approached for further interview directly by the research team. Other staff will be identified by their managers as having referred to the service and will be initially approached by managers and then contacted by the research team. New FFT therapists will be initially approached by their manager and then contacted by the research team.

YP and families

YP and families will be recruited following initial checks for eligibility. This process involves the following steps (see appendix F for flow chart):

1. Social workers and other practitioners from Redbridge child social work, Youth Offending, schools or Early Intervention/Early Help services refer YP to the Family Intervention Team (FIT) weekly referral panel. The panel determines the most appropriate intervention for YP in this service. Practitioners refer by using a consultation form with the eligibility criteria listed in section 3.1.
2. The FIT panel will determine the potential for eligibility based on the criteria in 3.1 and on the basis of the limited information provided as part of the referral process. If the YP is deemed potentially eligible, the panel will decide which business as usual interventions (BAU) would be suitable in the event that the YP is randomised to the control group. The case is then referred to the Families Are Forever (FAF) team (the name of the FFT-G service in Redbridge).
3. The FAF team conduct further screening, including discussions with the referring SW/practitioner to further assess eligibility on the basis of the criteria specified in 3.1. If, at this point, YP are determined ineligible, they will be assigned to the BAU service determined in step 2 above and excluded from the study.
4. If eligible, the referring practitioner will outline the study using a prepared script (see appendix G) and obtain agreement from the YP and their family for the research team to contact them. They will also provide them with the study Participant Information Sheet and consent form. A research fellow (RF) and the practitioner will make a joint call (telephone/video call) and the RF will explain the study to the YP and the family, work through participant information sheets and obtain verbal assent (YP) and consent (parent or person with parental responsibility). Where possible, written consent will be obtained subsequently. However, where this is not possible, participants will be sent an email with a link to a Qualtrics page asking them to confirm their verbal consent (see appendix O). The email will state that if we do not hear from them, or if they do not complete the Qualtrics form, we will take that as confirmation of their verbal consent. The page will also contain a link to the Participant Information Sheet to ensure that participants still have access to a copy.
5. If YP and their family consent to take part, they will be assigned an ID number and the RF will help the family to complete all of the baseline assessment except the Strengths and Difficulties Questionnaire (see appendices B and C). The RF will then access a predetermined block randomisation schedule that will have been produced by a statistician independent of the research team. If the family are randomised to the control group, the

researcher will help both the primary caregiver and the YP complete the Strengths and Difficulties Questionnaire. If they are randomised to the intervention arm, the FAF therapist will do so at the first intervention session.

6. The researcher will inform the SW, FIT panel and the FAF team of the result of randomisation. The YP and family will be informed of which group they have been randomised to subsequently by either the FAF therapist (if to the intervention arm) or the practitioner leading the BAU intervention (if to the control group).

Following this, the relevant intervention will begin. If the family have been randomised to the treatment group, then this will be FAF. If they have been randomised to the control group, this will be business as usual and will draw on the usual range of interventions according to assessed (by FIT panel) need and the specific services identified by the FIT panel as appropriate (see 2. above; see appendix G for representative services).

All participants will be given a verbal explanation of the study and what it will involve by the researcher. They will also be given a participant information sheet and consent form by their referring social worker and the researcher will clarify any issues that are not clear and read out the information sheet if required. Participants will then read and sign the consent form (if a physical meeting takes place, otherwise see 4. above) and the researcher will read out the consent form if required.

Participants will be informed of their right to withdraw from the study for any reason whatsoever and without the need to provide a reason during the lifetime of the study up until March 2022 when data analysis will begin. They will also be informed that they can request for their data to be destroyed and excluding from archiving at any time up until June 2022. They will be told that they do not have to answer any questions they do not wish to and do not have to provide any reason for not answering any questions.

Staff will be informed that participation in the study will not affect their employment with RCS or FPM. Young people and families will be informed that withdrawal from the study will not affect the services they receive from RCS and that if they are in the intervention arm, withdrawal from the study will not affect receipt of FFT once the intervention has begun. Furthermore, they can choose to stop receiving FFT and still remain in the study if they choose.

All participants will be informed that any information they provide to the research team will be not be shared with anyone else, including FPM, RCS or any other agencies, with the exception of data archiving (for YP and families; see 4.2) to the Office for National Statistics (ONS) Secure Research Service (SRS) and in the case of there being a risk of ongoing harm. The data archiving process and long-term storage of their data with the SRS will be explained carefully and a privacy notice will be included in the participant information sheets.

Data collected from participants will be stored on University of Greenwich secure systems protected by, at a minimum, two factor authentication on OneDrive or Microsoft Teams (this has been determined following advice from the University of Greenwich Information Security and Compliance Manager). YP and families will be informed that information about

them collected by RCS and FPM will be shared with the research team and will be stored in the same way.

3.4 Where will the interaction with participants take place? E.g. online, classroom, public facility, laboratory, office, home etc.

Research assessments

Interviews with staff will be conducted either i) at the offices of Redbridge Children and Family Services or ii) online using Microsoft Teams.

Assessments with YP and families conducted by a researcher will be conducted either i) at the offices of Redbridge Children and Family Services, ii) other safe neutral locations convenient to young people and their families (e.g. their school), iii) in the family home, iv) online using Microsoft Teams, v) or on a telephone call. Many families seeing Redbridge services live very busy lives and also may not feel comfortable talking about the services they have received in Redbridge Services offices. We will therefore offer to conduct assessments in alternative locations if they prefer. Locations of any assessments will be determined by ongoing risk assessments, assessments of COVID-19 related risk and following University and government guidance. Should face-to-face assessments be conducted, we will ensure that a COVID-19 risk assessment will be conducted and signed-off in advance. Questionnaires will also be hosted on the Qualtrics survey platform, so some participants may choose to complete these without the help of the RF, although we anticipate the majority will be conducted with the involvement of the RF.

There are a number of reasons we will sometimes conduct assessments in the family home. First, the families we will recruit are very often difficult to engage, having sometimes had negative experiences of services and are often reluctant to take part in research relating to services. It is therefore important that we demonstrate that we will do everything in our power to accommodate their needs and circumstances. They expect social workers to visit them in their home and FFT therapists deliver almost all sessions in the family home, so our refusal to do so suggests a lack of effort on our part and is detrimental to engagement and recruitment.

Second, most families do not have time to go to a neutral venue in order for us to conduct assessments. Therefore, without home visits, we have to conduct assessments online. During lockdown, there has been some understanding from families as to why online assessments have been necessary. That no longer applies when other professionals regularly visit the family home. This is not conducive to engagement because it gives the families the impression that we are not willing to make the effort to visit them, even though other professionals are.

Third, online assessments typically involve asking the family to set up Teams on their devices. This presents a serious barrier to engaging families, many of whom do not have the digital literacy skills to do this themselves. Furthermore, for online assessments to be successful, the family home needs to have a strong enough internet connection, which is often not the case. Therefore, by insisting on assessments taking place in a neutral venue or by using MS Teams, we are effectively making it more difficult for families with less access to IT and poorer digital literacy skills to take part in this study and potentially receive an intervention that may reduce the risk of their child being criminally exploited by drug dealers or hurt. Financial and digital poverty are clearly correlated with BAME status in the population we work with, so not visiting family homes effectively leads to a discriminatory approach to study recruitment.

We use a detailed safety protocol in order to keep researchers safe on assessment visits, with a series of phone calls and texts used to ensure safety and safety apps and personal alarms provided. Full details of these can be found in Appendix O: Safety Protocol section from study manual. Most of this protocol has been used in a previous evaluation study of FFT funded by the DfE and run at King's College London, led by the applicant. In that 5 year study, almost all assessments of 111 YP, being seen by Youth Offending Teams and their families, at three assessment timepoints, were conducted in family homes and there were no significant safeguarding incidents (KCL Research Ethics ref: **CREC/07/08-141**). The protocol has been adapted after consultation with the FEHHS Health and Safety Manager, James Francis and includes risk assessment for COVID-19.

The Strengths and Difficulties Questionnaire is collected as part of routine practice by FAF therapists employed by FPM at the start of the intervention. Rather than asking participants in the intervention group to complete these twice, the data from these questionnaires will be provided to the study team by the FAF team when participants are randomised to the intervention group and complete their first session. Participants will be informed that FPM will share the results of these questionnaires in the privacy notice they provide to participants. For participants in the control group, the SDQ will be conducted by a researcher instead or by participants on Qualtrics.

In addition, some additional questionnaires on therapy outcomes are collected as part of routine practice by FAF therapists through the course of the intervention (see appendix H). FPM will also share this data with the study team.

Additional research data will be collected directly from RCS case management systems and will not involve interaction with participants (an Information Sharing Agreement and Data Protection Impact Assessment are currently being drawn up).

Interventions

The location of delivery of intervention services varies widely depending on the individual service being provided and family needs. We cannot provide specific details of the location of the range of Redbridge services (see appendix G) that participants may receive, but we anticipate that the majority will be delivered at local authority or charity owned premises or online.

FAF therapists adopt an active outreach approach to service delivery and will work with the family on the basis of the family's needs. Under normal circumstances, this is usually the family home, but therapy is also provided in Redbridge offices. More recently, therapy has been delivered online using video calls.

3.5 Are any external bodies' premises or resources to be used? Please indicate YES or NO and give details of permission sought.

YES – Redbridge Children and Family Services, who have agreed to work with FPM on this project. Other neutral venues may be used for YP and family assessments. See appendix L for a letter of support from Redbridge.

3.6 What is the expected total duration of participation in the study for each participant? E.g. 20 minutes to complete a questionnaire, an hour for an interview, etc.

Staff

Interviews with staff at the end of the study will be approximately one hour in length. We will also conduct a short survey taking 5-10 minutes in the first few months of the study in order to determine acceptability of randomisation. Therefore, some staff may be participate twice.

YP and families

We anticipate YP questionnaires will take 40 minutes to complete and caregiver questionnaires 20 minutes to complete.

We plan to interview a small subset of families from both the intervention and control groups at the end of the study and anticipate these to be approximately one hour in length.

The length of BAU intervention services will vary widely, so we cannot estimate how much of participants' time these will take. FFT-G is typically delivered in ten to twelve one-hour sessions over a five-month period, although this can vary considerably depending on individual family needs.

3.7 Is consent to be obtained using the UREC consent template? (Please indicate YES or NO and attach your [consent form](#)). If NO please indicate how consent is to be obtained, and attach a copy.

YES

3.8 If children or young people (under 18) are involved, please say how consent will be sought, from both the children / young people and their parents, guardians or those acting *in loco parentis* (e.g. school).

Consent for participation of staff will be requested by a researcher from staff. Consent for participation of YP and caregivers will be requested by a researcher from caregivers. Assent for participation will be requested by a researcher from YP. Information and consent forms will be given to caregivers outlining the nature of the study and they will be asked to provide consent if they wish their YP and themselves to take part in the study. Information and assent forms will be given to YP and participation for YP will be requested by a researcher. All forms will be read out by the researcher if required, will be translated if required and a London Borough of Redbridge translator will be used during assessment visits if required.

Participants will be informed of their right to withdraw from the study at any point up until the end of the study without giving a reason and will be assured of no adverse consequences. They will be informed that withdrawal from the study will have no effect on the intervention services they receive, e.g. they will continue to receive FAF if they decided that they do not wish to take part in the study. Participants will be informed that they may withdraw consent at any time and, in addition, ask for any of the information collected from them to be destroyed at any time up until data analysis and write up (1st March 2022). If caregivers withdraw consent to participate but do not withdraw consent for their YP to participate, and the YP has provided assent, the YP will remain part of the study. We will inform all participants that there will no penalties for not taking part, that they can choose not to answer any questions they do not wish to. The information sheet will emphasise that if they do not wish to take part, YP will receive BAU services. Taking part in the trial is in no way related to the assessment of their progress undertaken by participating agencies.

3.9 Will any payment, incentive or reimbursement of expenses be made? (Please indicate YES or NO and give details, including amount)

YES – Caregivers and YP will each be provided with £30 to compensate them for their time in the form of shopping vouchers after each of the two assessments. Participants will still receive their incentive if they withdraw after the assessment has taken place. YP and families will be reimbursed travel expenses if required.

Staff will not receive incentives.

SECTION 4: ETHICAL CONSIDERATIONS

4.1 What do you consider are the main ethical issues and risks that may arise in this research? (Refer to the [Guidance on Ethical Approval for Research](#)). What steps will be taken to address each issue?

Protection of participants: The targeted nature of FFT-G as an intervention means that study participants are potentially highly vulnerable YP at risk of involvement in criminal activity and violence and at risk of criminal exploitation. Our guiding principle in designing this study is to ensure we do not put our participants at increased risk due to their involvement. In doing so, we have to balance the need to effectively assess the feasibility of a future RCT of FFT-G, with potential risks to participants. There are three areas where this issue applies:

1) Collection of outcome data: To assess the feasibility of a future fully powered RCT, we need to determine parameters around primary outcome measures (effect sizes, confidence intervals and therefore likely future sample sizes). The results of the analyses of these variables will go some way to determining future funding for FFT-G in this country. As this intervention is one of very few that has demonstrated any potential for this client group, there is an onus on us to do this in the most effective way possible. The most effective way of doing this is by asking YP about criminal behaviour associated with gang membership and CLDN involvement.

However, our view is that asking YP about this behaviour may result in emotional distress due to fear of the consequences of revealing this information, such as potential reprisal and that this risk outweighs the potential benefits of the study. Therefore, we aim to collect this information from RCS systems where possible, where CCE risks are already measured as part of routine assessments, although not regularly. As a result, there is a risk that we will not be able to collect enough data to assess parameters for a future RCT. We will attempt to mitigate that risk by i) exploring the possibility of accessing and coding social worker free text case record logs which appear to contain more information on CCE (informal agreement has been provided by the Redbridge Director of Children’s Services and this will be included in an Information Sharing Agreement), ii) using a proximal measure of intervention effect, family functioning and relationship quality, as our primary outcome measure (e.g. SCORE-15; see appendices B and C). Our funder does require us to include a YP questionnaire on self-reported delinquency, which includes questions on criminality, drug use and self-identification as a gang member. However, we have not included any questions about being coerced into engaging in criminal behaviour or other forms of CCE.

2) **Randomisation:** When participants are told about a new form of support that is being evaluated, they can sometimes assume that it is more helpful than existing sources of support. There is often concern amongst practitioners that if they are subsequently randomised to a control group, this may lead to disillusionment with and disengagement from other services, with potentially adverse consequences for the YP and family (e.g. see Losel, 2012). Whilst this is possible, we do not believe this is a likely outcome because, first, we did not find disengagement from BAU services in our previous RCT of FFT in Brighton and Hove and West Sussex and, second, our interviews with Redbridge social workers as part of the feasibility study (see 2.3) indicate broad acceptance of randomisation. The interviews have provided valuable information about how to approach and talk to families about the intervention and the study and we have used that information to design our materials for families. Furthermore, we have adapted study methodology on the basis of advice from RCS practitioners and managers so that it will be practitioners who inform the family of the result of randomisation. This will reduce the risk of disappointment and allow practitioners to explain the benefits of the particular service that the YP and family will receive.

3) **Safeguarding:** Assessments include questions about topics that may be sensitive or upsetting. We will ensure researchers have received training in how to support participants who may become upset and direct them to further sources of support. Researchers will attend relevant university training but will also receive training from the senior research team, who all have extensive experience of conducting studies with vulnerable participants.

We will inform participants that if they tell us anything that indicates that they or someone they know are at risk of ongoing harm, we will be obliged to breach confidentiality and inform relevant services. We anticipate that if this does happen, it will typically be the relevant social worker who will be informed.

Protection of researcher:

Whilst we anticipate that the majority of assessments will be conducted online, it is possible that some assessments will be conducted in person. These will be subject to risk assessments and we will also ensure extensive safety protocols are in place. All face-to-face assessments will be conducted in a safe venue. Venues will be public places and monitored. All researchers will a) have attended a basic and follow up personal safety day including personal defence training; b) have personal safety alarms on their person at all times. In addition, researchers will make use of a 'buddy' safety system if conducting in-person assessments outside of Redbridge offices. This is an involved procedure which includes a series of actions to ensure a) that the project lead plus one other is always aware of where the researchers are, b) that researchers call in to confirm safety (or are called if they have not), use code words to indicate their personal safety, and remove themselves immediately from problematic situations and c) that the police are called immediately when a researcher does not respond when expected.

Through these procedures (personal safety/defence training, alarms, buddy system), due diligence will be applied to ensure that the researcher is protected from physical threat or abuse. In addition, there may be a risk of psychological trauma, as a result of threatened violence or the nature of what is disclosed during the interview. Where this is the case, the researcher will be provided with debriefing opportunities, particularly when an interview has been upsetting, without breaching confidentiality.

Informed consent: Informed consent will be obtained from the concerned parents and adolescents and agency staff. Participants will be informed of their right to withdraw from the study at any point without giving a reason and will be assured of no adverse consequences. Further details can be found in 3.3 and 3.8.

Coercion: Some staff (i.e. therapeutic staff) will be identified for interview by service managers. In order to avoid coercion in the recruitment process, staff will fully informed about the study and given adequate time to consider the information before making a decision to participate. These staff will be reassured that they are not obliged to participate and refusal will not compromise their employment with FPM/Redbridge Children's Services.

Data protection: After participants have agreed to participate, they will be allotted an identification number (and pseudonyms will be used for interviews). Data and contact information will be securely stored, in accordance with GDPR, using the identification number, with access limited to the research team only (except for the purposes of data archive; see 4.2). 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. 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; see 4.2). 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 in July 2022, all study data as well as limited identifiable information on YP and families will be provided to the YEF to facilitate data archiving and assessment of long-term effectiveness of the intervention (see 4.2).

Adverse events: No adverse events have reported in the literature on evaluations of this intervention and we did not encounter any in our previous trial of FFT. In that study, there were three instances (out of 111 YP) of breach of confidentiality due to safeguarding concerns. All three participants were directed to additional sources of support.

Confidentiality: Confidentiality with regard to information shared will be maintained within the constraints of the Children's Act of 1989. Participants will be informed of the limits of confidentiality in the information/consent form.

All information will be kept securely and only the research team will have access to it other than for the purposes of data archiving (see 4.2) or where information is already kept on RCS or FPM systems and then shared with the research team.

4.2 Will personal data, as defined by the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, be collected during the research (Refer to the [Guidance on Ethical Approval for Research](#))? Indicate YES or NO. If YES, please specify the nature of the personal data to be collected, and give details of how you will deal with that data to ensure compliance with legal requirements.

YES

- Names, addresses and contact details will be provided, but these will be stored separately from completed surveys.
- Demographic information including age, gender and race.
- Answers to questions within interviews and questionnaires.
- Information collected from RCS and FPM systems.

During the study

Data will be held in a secure location (password protected files on password protected computers using University OneDrive and Microsoft Teams storage and using a minimum of two factor authentication) and electronic data in encrypted files on password-protected computers. Data will only be shared with co-researchers and with TypingWorks, a university approved supplier who will transcribe interviews. Interviews will be shared by secure Microsoft Teams transfer. Published reports will not identify the research participant at any time. All data will be anonymised.

We will collect information about study participants directly from RCS case management systems (see appendix J). Information will include social worker assessment of criminal and sexual exploitation, gang and County Lines Drug Network involvement and other potential antisocial behaviour and criminality. Participants will be informed that we will collect data on them from these systems. We are currently in the process of negotiating an Information Sharing Agreement and Data Protection Impact Assessment with FPM and the London Borough of Redbridge. The university's general counsel is taking a lead on these discussions.

The study will end on 31st July 2022. All data held by the study team will be destroyed five years after the end of the study (July 2027).

Data Archiving

The process of archiving

At the end of the study, all data that we collect as well as identifiable information will be transferred to the Youth Endowment Fund for archiving and future analyses. At that point, the YEF will become the data controller of said data. The archiving process will involve the following steps:

1. The YEF will send the data we provide to the Department for Education (DfE)
2. The DfE will use the identifiable data in the datasets we provide to identify the target YP on the National Pupil Database (NPD)
3. The DfE will replace all identifiable data with YP's unique Pupil Matching Reference (PMR) number from the NPD. I.e., at this point, all identifiable data will be destroyed and the

- YP's data and that of their family will become pseudonymised. From this point onwards, the DfE will be the only organisation that has the effective 'key' to re-identify individuals
4. The DfE will pass the trial data to the ONS Secure Research Service (SRS)
 5. The archive data may be linked to other government datasets using the PMR (including the Police National Computer) to assess the long-term effectiveness of FFT-G
 6. The data will be held in the SRS indefinitely
 7. The YEF will use Public Task as the legal basis for processing
 8. Therefore, whilst participants are able to make a request for their data to be removed from the archive, and the YEF will consider all such requests on an individual basis, there is not an automatic right for data to be withdrawn from the archive.
 9. As Controller of the archived data, the YEF would never permit the recombining of the data in the YEF Archive with DfE data that would enable reidentification of individual data subjects. Furthermore, neither would the DfE or the ONS facilitate access to the NPD for this purpose. From the perspective of anyone accessing YEF Archive data, it will effectively be anonymised

Accessing the archive

The YEF will only allow information in the archive to be accessed and used for research in accordance with the [ONS's 'Five Safes' framework](#) and via the ONS-SRS.

Understandably, there may be issues of concern about how personal data in the YEF Archive may be used in the future, in particular because the YEF is funded by the Home Office (e.g. potential concerns that Participant data being used for immigration enforcement purposes or other punitive action). However, there are practical barriers, ethical checks and legal provisions that prevent this from occurring:

- The degree of anonymization (see above) means there is no way for future researchers to identify individual data subjects using data in the archive alone.
- All applications to use data in the YEF Archive must also be supported by a recognised ethics panel and will be assessed by the ONS's independent Research Accreditation Panel. Furthermore, as Controller, the YEF will also sign-off all applications to use data in the archive. These steps would preclude authorising research projects intended to take actions against or target individuals.
- Limits imposed by data protection legislation when processing data for archiving and research purposes, prevent using this data to identify individuals for the purpose of taking actions against them. Section 19 of the Data Protection Act 2018 states, "(3) Such processing does not satisfy that requirement if the processing is carried out for the purposes of measures or decisions with respect to a particular data subject, unless the purposes for which the processing is necessary include the purposes of approved medical research." This means, the YEF could not be legally compelled to share data in the archive for this purpose.
- Participants can withdraw from the study up until March 2022 and therefore from the archiving of the data without any impact on their right to receive the interventions.

Rationale for the archive

The current lack of evidence on what works is not ethically justifiable

There is limited UK and international research on the sustained impact of activities to reduce offending. Particularly, there is limited evidence of the impact of interventions targeted at children against offending outcomes recorded in the criminal justice system.

Any process for tracking outcomes through administrative records, to overcome this evidence gap, will require the processing and archiving of sensitive personal data. It is arguably unethical that activity continues to be delivered to vulnerable young children without knowing whether it improves outcomes or potentially causes serious harm. Therefore, it is the YEF's view that, whilst proposals to gather highly sensitive data require considerable ethical scrutiny, this does need to be balanced with large volumes of taxpayers' money being used to deliver services to highly vulnerable children without any evidence if they are effective over the long-term. The data archiving of the data from this project aims to contribute to what works in the long-term.

Legal basis and precedent

Guidance produced by the National Archive ([here](#)) clearly sets out the grounds under which sensitive personal data can legally be archived indefinitely for the purpose of conducting research in the public interest. Limits on the rights to erasure extend where erasure would impair the intended aims of the archiving project. The YEF will consider all requests for erasure on ethical grounds, on a case-by-case basis. However, the high degree of anonymisation achieved in the YEF Archive, coupled with practical and legal barriers prevent the YEF, researchers or others (e.g. government officials) from identifying individuals once the data has been archived. The right to erasure must be balanced with the ethics of delivering on the wider public benefits of conducting this long-term research. Archiving of the National Pupil Database (NPD) and the Police National Computer (PNC) already occurs. The work conducted by the DfE and the Ministry of Justice (MoJ) to link together the NPD and the PNC is an ongoing commitment between government departments. This dataset exists and will be made available via the ONS-SRS, for approved researchers. There is a commitment to refresh this on a regular basis. It is this dataset that YEF trial data will be linked to in the future. The linked NPD-PNC dataset is a very powerful research tool. It effectively allows for the anonymous analysis of data on all children in English State schools and any proven offences committed by these young people.

It is the view of our funder that its archiving activity does not increase the risks of disclosure. The archived data effectively becomes an additional set of variables that is added to the NPD-PNC dataset, in order to identify which children attended a YEF funded programme. Having this additional information, and the other outcomes data collected as part of the trials, is unlikely to increase the risks that children will be identifiable or the potential for actors (e.g. Government departments) to use this information to take actions against them. The Education Endowment Foundation (EEF) has been conducting evaluations in schools since 2011. All data on project participants collected and analysed as part of these evaluations is archived using a very similar approach to that developed by the YEF. That is, child level data is pseudonymised at the end of EEF evaluations in such a way that allows for future matching against education records (see [here](#) and [here](#) for details).

Data collected as part of EEF evaluations is held indefinitely and the EEF relies on Public Task as the legal basis for processing. There is no known precedent for projects linking data directly to official offending records. However, data stored as part of EEF trials could be linked to the Police National Computer (PNC) using the same framework the YEF has developed.

The work conducted by the EEF demonstrates the enduring value of archiving trial data. For example, the recent report published by the What Works for Children’s Social Care (WWCSC) reanalysed data from 63 EEF trials to estimate programme impacts on the numbers of children that experience social care ([here](#)). This type of valuable research could only have been conducted because data was held in a pseudonymised form for a long period of time and was processed on the basis of Public Task.

We will provide all participants with additional information on archiving provided by the YEF (see appendix L). Please see the YEF DPIA (appendix K) for further information on the legal basis for archiving. Please note that the requirement for archiving is consistent with our contract with the YEF (see appendix M; please note that the contract has now been extended to July 2022, awaiting final sign-off) and the University general counsel and Information Compliance Officer have confirmed that there is a legal basis for us sharing the data for archiving. The University general counsel, the YEF and FPM have all approved the participant information sheet and privacy notices. We are awaiting on approval from the London Borough of Redbridge legal and data compliance teams as part of negotiations led by the University general counsel to draw up an Information Sharing Agreement and Data Protection Impact Statement.

SECTION 5: FINANCIAL INTERESTS

5.1 Indicate by “YES” or by ticking one of the statements below:

- I declare there is no financial or other direct interest to me or my Faculty or Directorate arising from this study **YES**
- I declare there is a financial or other direct interest to me or my Faculty or Directorate arising from this study (supply details)

Signatures

I undertake to carry out research in accordance with the University’s [Research Ethics Policy](#). In the case of a postgraduate research degree, I confirm that approval has been given by the Faculty Research Degrees Committee.

Signature of applicant

Date 31st January, 2021

Print name Sajid Humayun

I have discussed the project with the applicant, I confirm that all participants are suitably qualified to undertake this research and I approve it.

Signature of supervisor (to be signed if applicant is a student) Print name	Date
I have reviewed the project with the applicant, or applicant's supervisor, and I confirm that all participants are suitably qualified to undertake this research and I approve it.	
Signature of UREC representative Print name	Date 5/2/21
PLEASE INSERT ELECTRONIC SIGNATURES OR SCAN THE FINAL SIGNED FORM. SIGNED FORMS AND APPENDICES SHOULD BE SENT BY EMAIL TO RESEARCHETHICS@GRE.AC.UK BEFORE THE UREC APPLICATION DEADLINE . YOU DO NOT NEED TO SUBMIT THE FORM IN HARD COPY.	



Faculty of Education, Health & Human Sciences | University of Greenwich| Dreadnought Building | Old Royal Naval College | Park Row | London | SE10 9LS

Project Lead: Dr. Sajid Humayun | T: 020 8331 9564 | E: s.humayun@greenwich.ac.uk

The PoRTal Study: An Evaluation of the Families Are Forever service

UREC Protocol Number: xxxxxx

INFORMATION AND CONSENT FORM FOR YOUNG PEOPLE

The University of Greenwich are doing research on the Families Are Forever Service, in order to find out how this service might help young people and families. The project is funded by the Youth Endowment Fund. We would like to invite you and your family to take part in this study.

What does the research involve?

- Your family will be offered the services normally provided by Redbridge Children's Services.
- On top of that, they will be provided with either the Families Are Forever service or another service.
- We will compare how families experience the Families Are Forever service compared to other services.

If you agree to take part in this study, the decision about which additional service you will receive will be made fairly, by a 'flip of a coin' (at random). If you do not receive Families are Forever, this does not mean that you are missing out. It is important to note that children's services in Redbridge have been rated as 'outstanding' by Ofsted, so whatever support you receive will be of a high standard.

If you decide to take part, we would ask you to:

- Complete some questionnaires about your wellbeing and behaviour, your friends' behaviour, and your relationship with your family.
- Possibly agree to be interviewed about your experience of receiving services.
- Provide permission for us to have access to information stored on London Borough of Redbridge IT systems about you and your family, about i) how quickly you were referred and seen, ii) how you and your family used services, iii) what outcomes you experienced using services.

We will not ask you if you have been asked to do anything illegal by someone else.

You will be asked to complete questionnaires at the start of the study (now) and then six months later. We would prefer to help you fill these in, but you can do these online yourself instead. We can do this either on a video call, or in the offices of Redbridge children services or another place that suits you and your child (subject to COVID-19 restrictions and risk assessments).

We understand that by taking part in the study you will be giving up valuable time so we will pay any expenses you incur and you will receive a £30 amazon gift voucher, both at the start and end of the study.

Do I have to take part?

No, it's up to you. If you don't want to take part, you don't have to. You can stop taking part at any time and that will not affect any services you receive. You can ask us to destroy any information we collect up until March 2022. You do not have to give a reason.

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 possibly 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
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ICO website: <https://www.ico.org.uk>

Thank you

YOUNG PERSON ASSENT FORM

To be completed by the young person.

- I have read the information sheet about this study
- I have had an opportunity to ask questions and discuss this study
- I have received satisfactory answers to all my questions
- I have received enough information about this study
- I understand that I am free to withdraw from this study:
 - At any time (until such date as this will no longer be possible, which I have been told)
 - Without giving a reason for withdrawing
 - (If I intend to become a student at the University of Greenwich) without affecting my future with the University
- I understand that all personal data relating to research participants is held and processed in the strictest confidence, and in accordance with General Data Protection Regulation (GDPR) the Data Protection Act (2018).
- I agree to take part in this study

Signed (participant)	Date
Name in block letters	
Signature of researcher	Date
Researcher's contact details (including telephone number and e-mail address):	
[RF name] Tel: [RF no] Email: [RF email]	



Faculty of Education, Health & Human Sciences | University of Greenwich| Dreadnought Building | Old Royal Naval College | Park Row | London | SE10 9LS

Project Lead: Dr. Sajid Humayun | T: 020 8331 9564 | E: s.humayun@greenwich.ac.uk

The PoRTal Study: An Evaluation of the Families Are Forever service

UREC Protocol Number: xxxxxx

DEBRIEF FORM FOR YOUNG PEOPLE

Thank you for taking the time to be involved in this study. The aim of the study is to find out how the Families Are Forever service might help young people and families. We are doing this by comparing the experiences of families who received it to those who received other services. This will give us some idea of whether the Families Are Forever service is more helpful and will help to design a bigger study in the future.

If you want to withdraw your information from the study, you can do so at any time up until by 1st March 2022 and you don't have to give any reason for doing so. Please get in touch with us using the contact details at the bottom of this sheet. On 30th July 2022, information will be sent to the Youth Endowment Fund for archiving and we will no longer be able to destroy it.

If you would like a copy of the overall findings of this study, please contact me on the email below and I will be happy to send them to you.

Many thanks for your help in this research.

RF Name:

RF tel:

RF email:



Faculty of Education, Health & Human Sciences | University of Greenwich | Dreadnought Building | Old Royal Naval College | Park Row | London | SE10 9LS

Project Lead: Dr. Sajid Humayun | T: 020 8331 9564 | E: s.humayun@greenwich.ac.uk

The PoRTal Study: An Evaluation of the Families Are Forever service

UREC Protocol Number: xxxxxx

INFORMATION AND CONSENT FORM FOR PARENTS/CAREGIVERS

Dear Parent/Carer,

The University of Greenwich are doing research on the Families Are Forever Service, in order to find out how this service might help young people and families. The project is funded by the Youth Endowment Fund. We would like to invite you and your child to take part in this study.

You can choose to take part in this study or not. Please take time to read the following information carefully. Please ask us if there is anything that is not clear or if you would like more information.

What does the research involve?

In this study we are aiming to find out more about the best ways to help young people and their families when young people are at risk of getting into trouble or being exploited by gangs. To do this, we want to compare the Families Are Forever service to other services provided in Redbridge. All of the families in the study will be offered the services normally provided by Redbridge Children's Services. In addition, they will be provided with either the Families Are Forever service or another service.

If you agree to take part in this study, the decision about which additional service you will receive will be made fairly, by a 'flip of a coin' (at random). You will then be offered either the Families are Forever service or another service provided by Redbridge. The reason that we are doing this study is because we don't know if Families are Forever helps young people and families more than other services in Redbridge. So, if you do not receive Families are Forever this does not mean that you are missing out. It is important to note that children's services in Redbridge have been rated as 'outstanding' by Ofsted, so whatever support you receive will be of a high standard.

If you decide to take part, we would ask you to:

- Complete some questionnaires about your wellbeing, your child's wellbeing, and your relationship with your child and your family.
- Consent for your child completing some questionnaires about their wellbeing, their behaviour, their friends, and their relationship with you.
- Possibly agree to be interviewed about your experience of receiving services.
- Provide permission for us to have access to information stored on London Borough of Redbridge IT systems about your child and their family, about i) how quickly you were referred and seen, ii) how you and your family used services, iii) what outcomes you experienced using services.

You will be asked to complete questionnaires at the start of the study (now, or as soon as possible) and then six months later. You can do these online yourself, or we can work through them with you. We can do this either on a video call, or in the offices of Redbridge children services or another place that suits you and your child (subject to COVID-19 restrictions and risk assessments).

We understand that by taking part in the study you will be giving up valuable time. In recognition of this, and the important contribution you are making in helping us, we will pay any expenses you incur. You and your child will also receive £30 amazon gift vouchers, both at the start and end of the study.

What will happen to the information collected?

We will not share any of the personal information you give us with other organisations, except for archiving (see below). The London Borough of Redbridge, and the "Families are Forever" service, will already have access to any information we have collected from them. The only exception we would make is if we believed there were an imminent risk to your safety, or the safety of another person. In that case we might have to inform another organisation that could provide immediate help, such as the emergency services.

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.).

We will use the information we analyse to write a report of the research findings to the Youth Endowment Fund and possibly articles in academic journals. The reports and articles will not include any names or any other identifiable details.

After this research has finished, all the questionnaire/interview answers and information about who took part will be stored for future research. The data may also be linked to government datasets, including education, criminal justice and other administrative data to research the long-term outcomes of the CRC Project. This data will be used for research purposes only and it is illegal for it to be used for it to identify your child. The data will be stored in the Office for National Statistics secure research archive indefinitely. The Youth Endowment Fund have provided additional information that [you can access here](#).

If you decide not to take part in the study, you and your child will be offered services in the normal way. If you do decide to take part, you are still free to withdraw from the study at any time and you do not need to give a reason. If you withdraw from the study, this will not affect the services you and your child are receiving.

In addition, you can, at any time up until data analysis begins (1st March, 2022), ask the researchers to destroy all the information they have collected from you. You do not need to give a reason for your decision.

How long will data be kept?

In July 2022, all the information collected as part of the study and information on who took part will be passed to the Department for Education and will then be stored for future research in the Office for National Statistics secure research service. The data may also be linked to government data sets, including education, criminal justice and other administrative data to research the long-term outcomes of the FAF service. This data will be used for research purposes only and be stored indefinitely. Only approved researchers will be able to access this data and the identities of children will not be known by anyone accessing this data in the future.

The University of Greenwich will destroy all study data that we keep five years after the study is complete (July 2027).

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. Alternatively, you can contact my supervisor, Sajid Humayun, using the contact details at the top of this form.

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	

Thank you

PARENT/CAREGIVER CONSENT FORM

To be completed by the parent/caregiver.

- I have read the information sheet about this study
- I have had an opportunity to ask questions and discuss this study
- I have received satisfactory answers to all my questions
- I have received enough information about this study
- I understand that I am free to withdraw from this study:
 - At any time (until such date as this will no longer be possible, which I have been told)
 - Without giving a reason for withdrawing
 - (If I, or my child, intends to become a student at the University of Greenwich) without affecting my / my child's future with the University
- I understand that all personal data relating to research participants is held and processed in the strictest confidence, and in accordance with General Data Protection Regulation (GDPR) the Data Protection Act (2018).
- I agree to take part in this study

Signed (participant)	Date
Name in block letters	
Signature of researcher	Date
Researcher's contact details (including telephone number and e-mail address):	
[RF name] Tel: [RF no] Email: [RF email]	



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Project Lead: Dr. Sajid Humayun | T: 020 8331 9564 | E: s.humayun@greenwich.ac.uk

The PoRTal Study: An Evaluation of the Families Are Forever service

UREC Protocol Number: xxxxxx

DEBRIEF FORM FOR PARENTS

Thank you for taking the time to be involved in this study. The aim of the study is to find out how the Families Are Forever service might help young people and families. We are doing this by comparing the experiences of families who received it to those who received other services. This will give us some idea of whether the Families Are Forever service is more helpful and will help to design a bigger study in the future.

If you want to withdraw your information from the study, you can do so at any time up until by 1st March 2022 and you don't have to give any reason for doing so. Please get in touch with us using the contact details at the bottom of this sheet. On 30th July 2022, information will be sent to the Youth Endowment Fund for archiving and we will no longer be able to destroy it.

If you would like a copy of the overall findings of this study, please contact me on the email below and I will be happy to send them to you.

Many thanks for your help in this research.

RF Name:

RF tel:

RF email:



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Project Lead: Dr. Sajid Humayun | T: 020 8331 9564 | E: s.humayun@greenwich.ac.uk

The PoRTal Study: An Evaluation of the Families Are Forever service

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INFORMATION AND CONSENT FORM FOR PRACTITIONERS

The University of Greenwich are doing research on the Families Are Forever Service, in order to find out how this service might help young people at risk of criminal exploitation and their families. The project is funded by the Youth Endowment Fund. We would like to invite you to take part in this study.

You can choose to take part in this study or not. Please take time to read the following information carefully. Please ask us if there is anything that is not clear or if you would like more information.

What does the research involve?

This pilot study aims to assess the feasibility of undertaking a randomised controlled trial (RCT) of the Families Are Forever service. We will do this in a number of ways, primarily by conducting assessments with families and young people. However, we are also interested in the views of practitioners in order to understand how well the service fits in Redbridge and how it benefits families. We are also interested in your views about the RCT, including the process of referring families to the study, your experience and families' experience of randomisation and families' experience of assessments, how appropriate you thought the eligibility criteria were and what barriers you think exist for a future, larger study.

If you decide to take part, we would invite you to be interviewed about the areas outlined above. Interviews will take approximately one hour and will take place at your office premises (subject to risk assessments) or on Microsoft Teams. With your permission, the interview will be recorded so that it can be listened to at a later date.

By taking part in the evaluation, you will help us to assess the feasibility of a future RCT. You will be making an important contribution to helping us to gain knowledge that will guide the next steps of the evaluation.

What will happen to the information collected?

The information we collect will be used for research purposes only and only people on the research team will have access to it. The information we collect from you will be stored securely in accordance with General Data Protection Regulation (GDPR) the Data Protection Act of 2018. This means that that the information you give us will be stored under an identification code number only (which we will give you) – it will be kept completely separate from any identifying information (names, addresses etc.). Information collected from you will be anonymised. You will be given a pseudonym so that you will not be identifiable from your transcript in any evaluation report.

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.).

We will use the information we analyse to write a report of the research findings to the Youth Endowment Fund and possibly articles in academic journals. The reports and articles will not include any names or any other identifiable details. We will destroy all study data that we keep five years after the study is complete (in July 2027).

If you do decide to take part, you are still free to withdraw from the project at any time and you do not need to give a reason. In addition, you can at any time up until data analysis starts (1st March 2022), ask the researchers to destroy all the information they have collected from you. You do not need to give a reason for your decision.

If you have any questions, would like to know more, you can call me, [RF name] on [RF number] or email me [RF number] for further advice and information. Alternatively, you can contact my supervisor, Sajid Humayun, using the contact details at the top of this form.

Thank you

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Under data protection law, you have rights including:

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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.

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Wilmslow		
Cheshire		
SK9		5AF
Helpline	number:	0303 123 1113
ICO website:	https://www.ico.org.uk	

Thank you



CHILDREN'S SERVICES/FPM STAFF CONSENT FORM

PLEASE TAKE A NOTE OF YOUR ID NUMBER WHICH WE HAVE PROVIDED

<ul style="list-style-type: none"> • I have read the information sheet about this study • I have had an opportunity to ask questions and discuss this study • I have received satisfactory answers to all my questions • I have received enough information about this study • I understand that I am / the participant is free to withdraw from this study: <ul style="list-style-type: none"> ○ At any time (until such date as this will no longer be possible, which I have been told) ○ Without giving a reason for withdrawing ○ (If I am / the participant is, or intends to become, a student at the University of Greenwich) without affecting my / the participant's future with the University • I agree to take part in this study • I agree to the interview being recorded and understand that all personal data relating to research participants is held and processed in the strictest confidence, and in accordance with General Data Protection Regulation (GDPR) the Data Protection Act (2018). • We may wish to use your research data for a further project in anonymous form. If you agree to this, please tick here <input type="checkbox"/> 	
Signed (participant)	Date
Name in block letters	
Signature of researcher	Date
Researcher's contact details (including telephone number and e-mail address):	
RF name RF Tel: RF Email:	



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The PoRTal Study: An Evaluation of the Families Are Forever service

UREC Protocol Number: xxxxxx

DEBRIEF FORM FOR PRACTITIONERS

Thank you for taking the time to be involved in this study. The aim of the study is to find out whether it is possible to conduct a future randomised trial of the Families Are Forever service in the UK. We are doing this by comparing the outcomes of families who received it to those who received other services as well as investigating the implementation of the service and the pilot RCT.

If you want to withdraw your information from the study, you can do so at any time up until the beginning of analyses on 1st March 2022 and you don't have to give any reason for doing so. Please get in touch with us using the contact details at the bottom of this sheet and by providing your ID number.

If you would like a copy of the overall findings of this study, please contact me on the email below and I will be happy to send them to you.

Many thanks for your help in this research.

RF Name:

RF tel:

RF email:

Appendix C: Pilot Interview Schedule

The purpose of this interview is to help us get a better understanding of the support that you may have received from Families are Forever or other Redbridge services. This will help us understand how the Families Are Forever service or other services in Redbridge were received and this will also help us planning for the future

As part of the study, you and your family were randomly allocated to one of two groups. How did you feel about this process? Did it have an effect on your willingness to take part in the study?

[For SAU group]: Would you have been more willing to take part if you would have definitely received the intervention but might have had to wait for six months first?

[If not already answered:] What was the main reason you agreed to take part in the study?
[i.e. why did they say yes even if they had concerns?]

Current help received [adapt dependent on SAU vs FFT-G group]:

How have things been for you since the study started? (prompts – ‘did you receive any support? What were the best bits of this support? Was there any part of the support that you didn’t like?)

What help have you received since the study started (capture usual services for both groups)?

Have you found this support helpful? Which bits in particular?

If not, why hasn’t this been helpful?



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