PILOT TRIAL PROTOCOL

Your Choice: Randomised Controlled Trial of a CBT Informed Violence Reduction Programme

Institute for Fiscal Studies and Anna Freud Centre

Principal investigator: Professor Imran Rasul

YOUTH ENDOWMENT FUND

Pilot trial protocol: Your Choice: Randomised Controlled Trial of a CBT Informed Violence Reduction Programme

Evaluating institution: Institute for Fiscal Studies and Anna Freud Centre

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Project title[1]	Your Choice: Randomised Controlled Trial of a CBT Informed Violence Reduction Programme
Developer (Institution)	London Violence Reduction Unit (VRU)
Evaluator (Institution)	Institute for Fiscal Studies and Anna Freud Centre
Principal investigator(s)	Professor Imran Rasul
Evaluation plan author(s)	Imran Rasul, Julian Edbrooke-Childs, Laura van der Erve, Sarah Cattan
Evaluation setting	32 Local authorities in London
Target group	11–17-year-olds living in London at medium or high risk of serious violence
Number of participants	32 London boroughs, 200-400 young people

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

Protocol version history

Version	Date	Reason for revision
1.0 [*original*]	27/06/2022	
1.1	14/7/2022	More specificity added to the success/ progression criteria and success/ progression criteria shared with the project team (consistent with original version and no change to design).
1.2	26/9/2022	1) More detail added to progression criteria C 'Data can be accessed by evaluators'. They now include: • IG infrastructure for LAs sharing data with evaluators is created and sent to LAs for review and to be signed • Data sharing agreement approved by IGFL and signed copies received from LAs 2) YEF principles for consideration when deciding whether to progress to an efficacy study were added (see p.5)
1.3	27/12/2022	More details to the endline data collection procedure, which was not fully fleshed out in previous version given limitations of our knowledge on context.

Any changes to the design need to be discussed with the YEF Evaluation Manager (EM) and the developer team prior to any change(s) being finalised. Describe in the table above any agreed changes made to the evaluation design, research questions and approach, and the rational for these.

Intervention

This project is piloting the roll out of Your Choice, a large-scale project from London VRU and the Association of London Directors of Children's Services, developed in partnership with the Children and Adolescent Mental Health Service (CAMHS), which is proposing to train clinical practitioners in the Your Choice programme. Using a train-the-trainer model to support local roll out of the training, they will train youth workers (e.g. social workers, youth justice workers, teachers) in a range of CBT tools and techniques and will work intensively with young people aged 11-17, across London boroughs. Young people aged between 11-17, at medium to high risk of harm, who are discussed at multi agency panels will be eligible for the programme, with the aim of reaching children at risk of serious violence who typically are less likely to access CAMHS in clinical settings (e.g. young people from black and minoritized ethnic groups). Once assessed they will work intensively (three contacts per week with their Your Choice coach), towards goals that hold meaning and value to them to support positive behavioural activation. During sessions, which are likely to be held within community settings, whilst working towards their goals young people will be introduced to CBT tools and techniques through experiential learning to support skills development. The project will provide qualitative and quantitative evaluations of the intervention, where the latter will use a randomized control trial methodology. Although YEF only requires data collection on intervention costs, the evidence gathered by this evaluation will identify the costs and benefits (in terms of increases in school engagement, reductions in delinquency and reductions in emotional and behavioural difficulties) of delivering a CBT informed approach to young people at risk of violence. This will provide evidence to determine whether this project should be continued and rolled out in the rest of the country.

The logic model is attached.

Research questions and/or objectives

Objectives of the pilot trial:

1. To examine how the Your Choice intervention is implemented, fidelity of delivery, and what helps and hinders implementation;
2. To assess the adherence of Local Authorities and youth practitioners to randomisation.
3. To pilot study outcomes and evaluation methods, assess the parameters for conducting an efficacy evaluation and to assess whether operational progression

criteria have been met and if so to develop a full protocol for an appropriately powered efficacy study.

Success criteria and/or targets

The pilot is designed to establish whether Local Authorities have sufficient demand for Your Choice across youth service teams for a full-scale efficacy trial to be conducted. The pilot will also serve as a testing ground to understand whether Local Authorities can adhere to the randomization protocol, as we gradually expand the roll out of Your Choice during the pilot across teams. The pilot also serves as a test of whether primary data can be collected on young people (and from youth practitioners) who receive Your Choice, as well as those that receive business as usual (the control group). The pilot phase is also being used to explore how we can practically link these data to secondary administrative data sources collected by Local Authorities on young persons' pathways through Youth Services. If sufficient samples are generated in the pilot and randomization protocols are adhered to, then we hope to use the primary data collection to provide preliminary evidence on the short run efficacy of Your Choice on some outcome measures. If the pilot remains underpowered, it will still provide invaluable evidence on the ability of LAs and project team to engage in an RCT design, and the evidence generated can help inform updated power calculations for the efficacy trial. Establishing that LAs can adhere to the randomization protocols, and that the research design is valid are fundamental to the purpose of the pilot (even if underpowered to detect short run impacts).

In detail, the success criteria are:

A - Delivery is taking place as expected

- Teams assigned to receiving Your Choice are getting trained
- Teams not assigned to receiving Your Choice are not getting trained
- No other teams except treated and HO teams are delivering Your Choice
- Young people are being recruited and eligibility criteria are respected when recruiting young people in the study
- Delivery of work with young people is taking place

B - Data is being logged as it should

- Questionnaires are completed by young people and practitioners, when they are supposed to be completed
- Information about sessions is being shared through session forms
- LAs are filling out their Study Workbook in line with instructions

C - Data can be accessed by evaluators

- IG infrastructure for LAs sharing data with evaluators is created and sent to LAs for review and to be signed
- Data sharing agreement approved by IGFL and signed copies received from LAs
- LAs are complying with the requirement to share updated versions of their spreadsheet with evaluator every month

D - Verification of the design through data analysis

- Do young people in the treated and control teams have similar characteristics on average? Does this hold within services within LAs, as initially intended, or more broadly?
- Are young people in the control teams are actually receiving BAU and not Your Choice?
- Are young people in Your Choice actually receiving Your Choice?
- Are untrained practitioners using Your Choice practices?

If this set of criteria for success are not met during the pilot, then we would recommend stopping the study and not moving to a full efficacy trial.

The following principles are also considered by YEF when deciding whether to progress to an efficacy study:

- Project Implementation: Can the project be implemented as intended
- Evaluation recruitment: can enough numbers of young people been recruited (intervention & control)?
- Grantee, YEF, evaluator relationship: has the working relationship developed that could support moving to a larger and more complex study?
- Measurement & Findings: Can we collect data & information in the way that we need to?
- Change - Do we believe that this is likely to lead to change?
- Supplementary funding - Do we believe that we can bring in supplementary funding?

Methods

Pilot trial design

Randomisation

The randomization relates to the assignment of teams of youth practitioners to be trained to deliver Your Choice. Local Authorities have provided us with a list of all their services which may come into contact with our study participants, and the team structure within these services. They will be asked to provide a list of all the teams that they are happy to receive Your Choice training. The evaluators will then randomise which teams get trained in the first round of training (rather than later on in the trial) out of those teams put forward for training.

LAs participating in the pilot will be required to sign a Memorandum of Understanding specifying the requirements attached to their participation, including their willingness for their teams to partake in the randomisation, their readiness to share data about participants' background information and compliance with the study, their willingness to facilitate survey data collection, and the readiness to administer Your Choice during the duration of the pilot. Initial discussions between VRU, LIIA and LAs indicate that the number of LAs meeting those requirements could be lower than 32. LAs that are willing to be part of the randomisation but not ready to implement the randomisation, nor to collect data on the children receiving Your Choice, could not join the efficacy trial – because they will not be able to demonstrate being able to adhere to the randomization protocols or data collection requirements. LAs that are seeking the training but not willing to be part of the randomisation would not be part of the efficacy trial. They would also not be included in the IPE evaluation (see below).

Under the assumption that the assignment of young people to services and teams within services continues to be made independently of the fact that some teams have been trained in Your Choice, then this design randomises individuals into treatment and control groups. Children are assigned to teams within services based on which team has availability at the time the child is referred to the service. If this team is Your Choice trained, the young person will be in the treatment group, and when this is a team that is not (yet) trained, the young person will be in the control group.

While our understanding from the co-design period is that the assignment of children to teams within each service is largely done according to which team has availability at the point of referral, we have not been able to acquire more information about the assignment of children to teams during the co-design period to verify that this is absolutely the case. This will be an important point to verify during the pilot through further conversations with the project team and individual LAs. During the pilot, we will acquire detailed information about

the assignment process, the children's characteristics upon which allocation decisions are taken, as well as the characteristics of teams. We will compare children assigned to different teams based on the background characteristics collected and their responses to the SDQ and crime and violence questionnaires at baseline. Specifically, we will check balance on the following characteristics in the pilot trial:

- Using the data collected from the LA: age, gender, ethnicity, disability, in Education/Training/Employment, length of involvement with LA, most relevant primary need for involvement in teams involved in trial, nature of involvement in other council service,
- Using the baseline young person questionnaire: SDQ, crime and violence measure
- Using the baseline practitioner questionnaire (about the young person): practitioner's assessment of young person's involvement in crime.

In assessing whether imbalances are problematic for the validity of the design, we will pay particular attention to imbalances on characteristics that are most predictive of the outcomes the program intends to shift (based on the literature and correlations between background characteristics and baseline SDQ and crime and violence measure).

If there are small deviations from random assignment of children and young people into treated and control, we will consider using two strategies to correct for them: (i) explicitly control for pre-assignment characteristics of children (and maybe those of teams), and (ii) across LA variation in treated teams.

Importantly, our design also leaves open the possibility of excluding all children whose assignment was based on considerations of how much they would benefit from interactions with a specific team – hence effectively focusing only on those children who are randomly assigned. Through the qualitative work and the quantitative analysis of imbalances on baseline variables specified above, we will aim to get an understanding of the reasons where and why non-random allocation is most likely to take place in order to make an informed decision about children to be excluded from the sample, if any.

Note that these children will be excluded from the evaluation, but not the data collection. Having information on non-randomly selected children can also help later place the evaluation results in context – and if sample sizes permit, we can aim to see whether the evaluation results support the idea that these children – based on observables – are likely to gain more from the intervention than others.

Participants

Participants will be young people aged 11-17 referred to children's services and at high or medium risk of serious violence. All participants (and their parents if aged 11-15) will be asked to consent to be part of the evaluation before receiving the Your Choice programme.

Sample size

In the pilot study we will randomise one team to be trained in each of the local authorities who put forward at least two teams for training during the pilot. We will additionally include the local authorities who already randomised the training of teams during the Home Office funding training. This likely gives us 31 treatment teams (and a slightly larger number of control teams). Based on the results of the survey, we expect treated teams to enrol at least 4 new children in Your Choice each month. During the pilot we will enrol new participants for two months, which will mean a recruitment of over 200 children in the treatment group (and at least as many in the control group). From the information provided to us so far on the flow of young people through children's services, this should be feasible in the time frame of the pilot, and will allow for exploration of key parameters needed to confirm sample size calculation for the efficacy study.

Methods and data collection

Outcomes

We will have the following two primary outcomes:

- *Emotional and behavioural difficulties and pro-sociality* assessed using the Strengths and Difficulties Questionnaires (SDQ);
- *Offending, as measured in the Policy National Computer (PNC),* teams.

We will have several secondary outcomes:

- *Engagement and exposure to crime and violence,* as measured by a scale co-produced by the evaluation and project teams administered to both the young person and their lead practitioner
- *Social connectedness*, measured by a subscale of the the Student Resilience Survey
- *Mental Well-Being*, measured by The Short Warwick–Edinburgh Mental Well-being Scale (SWEMWBS)
- *Self-efficacy*, measured by the New General Self-Efficacy Scale

- *Self-regulation,* measured by the Trait Emotional Intelligence Questionnaire – Adolescent Short Form (teique-asf) – self-regulation subscale

As we have multiple primary and secondary outcomes, we will adjust inference for multiple hypothesis testing.

Our choice of outcomes is based on the Theory of Change. Both primary outcomes are supported by the theory of change and there is a clear rationale for including both in the pilot research. This is due to the importance of detecting impact on offending (including violence) if possible, as it is the ultimate aim of Your Choice. However, given that PNC only measures crime that have led to an arrest, impacts may be harder to detect. Power calculations indicate that we would need a much bigger sample to pick up relatively small impacts on offending (at least based on the literature, as shown in the annexed power calculations), even in the efficacy study. This makes only relying on a PNC-based measure of offending as primary outcome too risky. Therefore, another intermediate outcome has been selected, based on the theory of change. If needed, the choice of primary outcome will be refined during the pilot based on the qualitative and quantitative data that is being collected and the learning about the theory of change.

Data sources

1) Surveys of young people and surveys of practitioners about the young people

With the exception of the PNC-based offending measure, we will collect data on all outcomes using baseline and endline surveys completed by each young person and their practitioner in the evaluation sample.

The baseline surveys will be administered after a young person has consented to participate and prior to their practitioner delivering support to them. The young person baseline survey will include the SDQ, the self-reported measure of crime and violence developed by the project and evaluation teams, as well as the measure of social connectedness. The practitioner baseline survey about the young person will include an assessment of the youth's likelihood to engage in crime and violence based on the same questions asked to the young person.

The young people and practitioner endline surveys will take place 14-20 weeks later (so within 2 weeks of finishing Your Choice for those assigned to treatment, given that Your Choice should not take longer than 18 weeks to complete). The young people endline will include the SDQ (with follow up questions), the self-report measure of crime and violence, the social connectedness, mental wellbeing, self-efficacy, and self-regulation scales. The endline survey

will also ask a question about the young person's main activity (education, employment, training), and it will also include questions about the young person's experiences working with the practitioner over the past 3-4 months. Specifically, we will ask young people to report the extent to which their practitioners used different CBT techniques during their work with the youth. The endline survey will also include free text questions to examine intended and unintended outcomes, not captured through the standardised tests.

The endline practitioner survey will also ask the practitioner to report the extent to which they have used CBT techniques with the youth. The point of asking both the practitioner and the young people about the use of CBT techniques during their work together is to capture the extent to which a) treated practitioners actually make use of the training they receive and b) control practitioners also use these techniques (hence measuring cross-contamination).

The baseline practitioner surveys will be sent to practitioners via email. Practitioners trained in Your Choice will deliver Your Choice to all eligible young people assigned to them. They will therefore not be blind to the treatment status of the young person. The baseline young people survey will be completed in the session when the young person consents to participate, on a tablet provided by the practitioner. The practitioner will pass the tablet to the young person, who will fill in the survey. They will be on hand in case the young person has any questions, but will not see the questions and answers, which will be sent directly to the evaluation team. Where the young person is old enough and so desires, the practitioner can be asked to leave the room while the young person fills in the survey.

To administer the endline young people survey, we will recruit peer researchers to meet with the young people and support them with the completion of the questionnaire. These meetings will be either in person (in a Local Authority building) or online and will be arranged with the practitioner. The practitioner will be asked to be present at the beginning of the meeting in order to introduce the peer researcher to the young person and ensure that the young person feels more comfortable. This approach will minimize the burden of survey data collection on youth practitioners while minimizing any bias the presence of the youth practitioner may have on the young person's answers.

In the rare cases the youth practitioner advises against such a meeting (either because it would be unsafe for the peer researcher or because it would not be in the interest of the young person's wellbeing), we will ask the practitioner to have another practitioner support the young person to complete the questionnaire and, when this is not possible, to support the young person themselves (as in the case of the baseline questionnaire).

Finally, if the young person drops out of the intervention (but not out of the study) before it

is time to complete the endline questionnaire, we will contact them using their phone number or email address to organise a meeting with a peer researcher, either in-person or online, in order for them to complete the questionnaire. Should they not want to complete it during such a meeting, we will send them the questionnaire online for them to complete it on their own time.

While our preferred option will be for young people to complete their online questionnaire during meetings with peer researchers (and organized by their youth practitioner), our revisions to the initial approach are aimed to offer more flexibility than initially planned in order to minimize attrition, in addition to enabling us to collect endline data even on individuals who drop out of the programme. . During the pilot stage, we also prefer allowing different ways to collect data in order to learn whether flexibility should be allowed during the efficacy trial or not. A note will be made as to how each questionnaire is filled out (and which peer researcher supports the young person), in order to explore the extent to which there may be systematic differences in responses driven by the procedure employed to complete the questionnaire.

2) Data from Local Authorities

With the project team, we have created a spreadsheet for LAs to complete that will provide the following information:

- Background information on all young people participating in the study, held and easily accessible by the LAs: name, date of birth, gender, ethnicity, UPN/ULN where available, details about involvement with the LA
- Log of all practitioners who have under gone the Your Choice training
- Log of all clinical supervision sessions taking place during the study
- Log of all sessions scheduled between youth practitioners and young people participating in the study, including date, length, engagement of young people and content covered. We are considering developing an online form for practitioners to fill out this information themselves, on the go everytime they finish a session with the young person., as this will increase the quality of information collected.

3) Data from government data sources

Using name, date of birth and UPN/ULM when available, we will apply for PNC and NPD data (ILR and LEO data later on) to match individuals and measure their offending and school engagement and attainment both before and after the treatment.

Approach to implementation and process evaluation data

There are four components of the implementation and process evaluation data:

1. Endline quantitative survey data on therapeutic alliance as a core intervention process and follow up free text questions (described above)
2. Implementation monitoring data (described above)
3. Implementation survey (described below)
4. Interview and focus group data (described below)

An implementation survey will be collected from professionals working in sites implementing Your Choice, depending on the capacity of site alongside other evaluation activities during the pilot. The implementation survey will examine:

- Readiness for change
- Views and experiences on the journey of implementation
- Implementation plans
- Progress toward (and deviation from) implementation plans
- Acceptability of Your Choice (including recruitment rate and subsequent engagement)

The priority for the pilot phase is to examine the acceptability of Your Choice and the evaluation and to understand the processes of early implementation. Interviews will be co-facilitated with our appointed peer researcher. This will involve semi-structured interviews with 3-5 young people receiving Your Choice and 3-5 young people receiving usual practice. We will conduct interviews/ focus groups with professionals involved in the delivery of Your Choice, recruiting up to 5-7 youth workers, 3-5 implementers/trainers, and 3-5 referrers. Interview schedules for each group will be co-produced with the core implementation team and peer researcher, and our initial topic guides outlined below have been designed to capture YEF recommendations about important types of information from feasibility studies, relevant to Your Choice. We will also examine any available implementation data routinely collected by Local Authorities (e.g., to examine recruitment and retention rates).

During the pilot phase, we will work with our appointed peer researcher to conduct specific activities with the Research Young Person's Advisory Group (YPAG) to build knowledge of Your Choice, which may include joining meetings with the implementation team and shadowing implementation activities (such as training) where appropriate. Adverts to join the

YPAG will be disseminate to a range of networks (e.g., Anna Freud Centre, VRU YPAG) in addition to any local LA expert by experience groups. Any groups we feel do not have a voice in the YPAG will be identified in the early meetings and we will conduct ongoing recruitment to represent these voices. These activities are essential to enable the YPAG to meaningfully work alongside the research team in interpreting the findings from the pilot and using this learning to inform the ongoing planning for the full trial. It will also enable us to understand the views of young people on the early stages of implementation and programme, including their views on the encouragement design (what would and would not work), the intensity of the treatment, the best ways of collecting data in questionnaires, and their attitudes towards consenting their various data to be linked.

Interview and consultation topics guides will include:

- Views and experience of Your Choice
    - To what extent does the programme fit with and add to the landscape of existing practice?
    - Do youth practitioners view Your Choice as needed and why?
- How the programme is implemented
    - To what extent does this fit, or not fit, the theory of change and TIDieR?
    - How, if at all, could the programme be tailored to meet the context and population needs?
        - Interviews and focus groups with professionals will ask about equity for marginalised groups, including Black and minoritized ethnic groups, LGBTQ+ groups, neuro-diverse groups, and special educational needs.
        - Interviews with young people will ask about the extent to which Your Choice or usual practice met their individual needs and was personalised to and inclusive of them. We find this a more suitable way into such questions; for example, an intervention may not meet an individual's needs but they might not connect it to a particularly part of their identity.
        - In the quantitative analysis, if sample sizes allow, we will try to explore the differential returns to the intervention from targeting different racial groups or other minority groups such as SEN children.
    - How well are the different components being delivered?
- Barriers and facilitators to implementation
    - What helps and hinders recruiting young people to the programme and then engaging them?
    - Which components of the intervention are more, and less, readily delivered?
    - What would be needed to make components of the intervention more readily delivered?

- Impact of Your Choice have on young people
    - Is there evidence to support anticipated outcomes in the logic model?
- Acceptability of the research
    - An overview of the full trial, drawing on the infographic; for example, for the Research Advisory Group we say:
        - Half of the young people will get Your Choice. The other half will get existing help – this means the youth workers will work with them in the same way as they do at the moment. This will look different in different areas, as the project is across London.
        - Young people will get Your Choice or existing help randomly (by chance or the toss of the coin). This is important so that we can tell if Your Choice works.
        - Let's say young people feel better after Your Choice. We wouldn't know if they would have felt better anyway, even if they didn't get Your Choice, without having a group to compare to.
        - We do this at random so we can make sure young people getting Your Choice or existing help are as similar as possible. If we don't do this, young people who get Your Choice and existing help could be very different, for example young people with higher levels of difficulties are given Your Choice. If we find young people feel better after Your Choice, we wouldn't know if this was because of Your Choice or because young people had higher levels of difficulties to begin with.
        -
    - How would you feel if you received Your Choice or not by chance or the toss of a coin?
    - What do trainers, youth workers, and young people think about the information sheet, consent form, and measures? How could these be improved and/or made easier to complete?
    - What would help in recruiting young people to the full trial and retaining them?

Methods overview

Research methods	Data collection methods	Participants/ data sources (type, number)	Data analysis methods	Research questions addressed
IPE	Survey	1 per borough for all LAs which take part in the randomisation (likely to be 31)	Descriptive statistics	#3
IPE	Interview	3-5 young people (intervention), 3-5 young people (control)	Thematic analysis	#3
IPE	Interview/ focus group	5-7 youth workers (intervention), 3-5 implementers/trainers, and 3-5 referrers	Thematic analysis	#3

Note. IPE = implementation and process evaluation.

Data analysis

Our quantitative analysis will focus on two parameters: the Intention to Treat (ITT) which measures the impact of being offered treatment, and the Treatment on the Treated (TOT) which measures the impact of receiving the treatment. These parameters can differ due to non-compliance. For example, we may expect some young people to not participate in the Your Choice program, despite being referred to youth services and allocated to a Your Choice trained team of case workers. Moreover, dosage may also differ among those who get some treatment, as youth may drop out or disengage with youth practitioner teams during the delivery of Your Choice.

Assuming the pilot is sufficiently powered, our main measure of effectiveness will be based on the ITT, which we will estimate by regressing the outcomes on an indicator whether the youth is in the treatment group (i.e. was assigned to a team trained in Your Choice) and LA fixed effects. To increase power and adjust for regression to the mean we will, where possible,

control for pre-intervention outcomes such as the assessment score from the referral panel and prior referrals.

We will recover the TOT using instrumental variables, using the randomisation as an instrument for participation in the programme, and controlling for the same pre-intervention outcomes as for the ITT. We will also examine whether certain correlates of attrition (such as the timing of treatment – term-time vs school holidays) can be used as additional instrumental variation.

Qualitative data (i.e., transcripts, free-text responses) will be analysed using the NVivo qualitative data analysis software. We will use the framework analysis approach to manage the data, categorising transcripts according to which component of the logic model they address. We will then use thematic analysis to analyse the data organised in the framework to explore themes across participants' experiences and perspectives. At least two members of staff (including the peer researcher) will be involved and there will be regular coding review meetings throughout the stages of the analysis. Such approaches are commonly used in applied policy evaluations. Different reliability processes are available for qualitative data than quantitative data, and the research team will adhere to quality standards for establishing the trustworthiness of the data (i.e., credibility, transferability, dependability, and confirmability).

We are also using the pilot phase to explore obtaining access to secondary administrative data sources that follow a young person's pathway through engagement with Youth Services. We are still establishing whether this will be feasible, and how any matching to primary data collection can be reliably conducted, in accordance with ethics guidelines and with ethics approval.

Outputs

The outputs of the pilot trial will be:

1. A full report on the design, conduct, analysis and interpretation of progression to an efficacy trial.
2. If an efficacy trial is warranted a revised protocol for the design of that trial.

Cost data reporting and collecting

We will report cost of implementation in the final report following YEF guidance. That is:

- We will use a bottom-up approach and break costs down into: prerequisites, set-up costs, and recurring costs.
- We will report average cost for a typical single cohort receiving the intervention for one round of delivery and average costs per participant for one round of delivery, assuming full compliance. The exact definition of a typical single cohort remains to be determined, based on LA's experience in the pilot trial. We will engage with the project team and with the LAs to ensure we pick the most meaningful definition of a typical single cohort.

Initial discussions with the project team indicates that there may be a non-negligible amount of heterogeneity in the cost of implementation across LAs, depending on their size, internal organisation and efficiency. To report cost at the end of the pilot, we will build a template for LAs to report costs of items and to ask a sample of LAs to fill out such template. We will pick 3-4 LAs to be in this sample. We will build this template in collaboration with the project team, so as to ensure that all costs involved are appropriately itemised.

We expect most costs to fall within the following two categories:

- Staff cost: cost of practitioners, supervisors, and managers involved in the implementation of Your Choice
- Engagement initiatives: as part of Your Choice, practitioners can support young people by, say, paying for additional forms of support (e.g. tutoring costs, music lesson, training, etc) that would allow the young person to achieve their goals.

Ethics and registration

- We have submitted a high-risk ethics application to the UCL Research Ethics Committee, and expect to hear back by early May.

Data protection

Data storage

Data will be stored on the network of the Institute for Fiscal Studies (IFS) in a secure folder with access restricted to named researchers.

The IFS information security management system is ISO27001 compliant and the IFS has an Information Classification and Handling Policy which sets out a comprehensive set of guidelines for handling all types of data and information (including highly confidential information). AFC have similar Information Governance policies, and all information will be held on the secure AFC servers, with only approved researchers having access. All project team members will follow strict procedures in this policy and adhere to the IFS/AFC Information Security Policy when using or collecting data. All project team members will have received appropriate GDPR training.

Data deletion

We will keep the data for a minimum period of 10 years after the delivery of the final report, in line with UCL guidelines. This period of data retention is required for us to deliver a full analysis of the long-term effects of the interventions studied in this project and to go through the publication process of this work in peer-reviewed journals. Data in fully anonymised form will be made available on journal websites once the papers that result from this study have been accepted for publication.

We will only store digital records of the data, which will be held securely on the network as outlined above.

Data sharing

As part of the consent process, we will ask potential participants permission to link their survey answers to their National Pupil Database (NPD) records, their Police National Computer (PNC) records, their earnings records (HMRC) and benefits records (DWP). To operate such linkage, we will need to share the data with the Department for Education, MoJ, HMRC, and DWP. Specifically, we will do the following:

- Send these departments the names and DOB of study participants, alongside the survey questions we want them to match to linked data (e.g. treatment condition, background variables)

- The departments will match these individuals in the relevant datasets using names and DOB and prepare datasets with the outcomes of interest for our sample

- They will provide these datasets on the SRS or other Safe data platforms, after having removed the names and DOB of the individuals

- This (de-identified) data will only ever be used within the secure environment at the ONS SRS by approved researchers (for DfE and MoJ data) or equivalents (for HMRC/DWP) data.

Legal basis for processing

The lawful basis for processing is: Legitimate Interests (Article 6(1)(f)). A legitimate interest Assessment has been carried out.

Personnel

Our project is a partnership between the Institute for Fiscal Studies (IFS) and Anna Freud Centre (AFC). Professor Rasul will act as PI, taking overall responsibility for the project. The IFS team will lead the quantitative evaluation. The AFC team will lead the qualitative process evaluation.

Rasul will lead engagements with YEF and be responsible for ensuring the close integration of quantitative and qualitative work streams. Cattan and the project manager will lead in liaising with the delivery partner. All members will be engaged in the design of the evaluation and survey instruments. Costa-Dias will lead on methodological aspects and trial design. Cattan will lead on data collection and administrative data acquisition. Under supervision from all other team members, the Research Economist will clean and analyse data and provide frequent updates to the team. Rasul will take the lead on the write up and dissemination of results, with input from all team members.

Edbrooke-Childs will act as Process Evaluation Lead. He will lead engagement with YEF alongside Rasul. Edbrooke-Childs and Stapley will lead on the methodological design. Jacob will work closely with the project manager on operational oversight, planning, and risk/issue log monitoring. Jacob will supervise the Researcher and Peer Researcher who will lead on data collection, with specialist input from Stapley throughout. All team members will analyse the data, with Edbrooke-Childs, Stapley, and Jacob leading the reporting and dissemination. Deighton will provide ongoing critical appraisal with a view of the overall process evaluation.

The team will be supported by a 0.8 FTE project manager who will liaise across sites and evaluation teams to ensure all aspects of the project run smoothly. He/she will manage the day-to-day working relationship with partner, especially as they relate to research design and data collection operations; monitor implementation of intervention; supervise data collection, manage team of surveyors, and ensure quality control of research.

Relevant experience of team members

Prof. Rasul (Professor of Economics, UCL; Research Director, IFS) has two decades of research experience in designing and implementing multi-site randomized control trials to evaluate policy interventions, including projects combining quantitative and qualitative research streams. His has studied the causes and consequences of engagement in criminal activity, utilizing administrative records (e.g. PNC), conducted cost benefit analysis based on impact evaluations, and is a member of the Academic Advisory Group, Ministry of Justice Data First project.

Prof. Costa-Dias (Professor, University of Bristol; Deputy Research Director, IFS) is an expert in micro-econometrics evaluation methods. She has developed empirical methods for policy evaluation (e.g anticipation effects, spillover effects), studied impacts of multiple reforms on those treated and their families (e.g. New Deal for Young People, Housing Benefit), conducted evaluation feasibility studies (e.g. Universal Credit), is currently studying the long-shadow of mental health problems during adolescence using Danish data.

Dr. Cattan (Associate Director and Head of Education and Skills sector, IFS) has worked on several experimental and quasi-experimental evaluations of interventions to promote children's cognitive and emotional development (e.g. Sure Start, Head Start). She has extensive experience working with English administrative data and psychometric analysis, and disseminating her findings to policy-makers.

Laura van der Erve (Senior Research Economist, IFS) has extensive experience working with English administrative data and disseminating her findings to policy-makers. She has worked on a range of projects commissioned by the Department for Education and the Social Mobility Commission which have utilised linked administrative data.

Prof. Edbrooke-Childs (Professor of Evidence-Based Child and Adolescent Mental Health, UCL; Head of Evaluation, AFC; Deputy Director, Evidence Based Practice Unit, AFC and UCL) research focuses on empowering young people to actively manage their mental health and mental health care. He has extensive experience of leading qualitative research; e.g., PI of Evaluation, Health and Justice Specialised Commissioning Workstream (NHS England & NHS Improvement); lead qualitative researcher and Co-I, Mental Health Policy Research Unit funded by the Department of Health and Social Care.

Dr Stapley (Senior Qualitative Research Fellow, AFC and UCL) has led large-scale qualitative research studies nested in high-profile national research programmes, was the qualitative lead for the HeadStart programme involving extensive qualitative longitudinal study of over 80 adolescents' experiences for five years.

Dr Jacob (Research Lead Child Outcomes Research Consortium, AFC) has managed large-scale qualitative research (e.g. Community F:CAMHS, SECURE STAIRS), was Co-PI on a project involving interviews and focus groups with young people and professionals across eight countries, worked on the project "Child- and Parent-reported Outcomes and Experience from Child and Young People's Mental Health Services 2011–2015", which informed the rollout of Children and Young People's Improving Access to Psychological Therapies.

Prof. Deighton (Professor, UCL; Director of EBPU) is an expert in mental health and wellbeing in

childhood and adolescence. She has led various programmes of research (e.g. 7-year evaluation of HeadStart, DfE Mental Health Research Programme), has extensive experience of working with policy makers, and is the Co-I for the NIHR Children and Families Policy Research Unit.

Collaboration between IFS and AFC

The teams will work closely to maximise complementarities in expertise, expanding on the successful collaboration between Cattan and Deighton on the evaluation of HeadStart and the NIHR Children and Families Policy Research Unit. Regular meetings will keep the teams co-engaged in developing the research design, data collection strategy, interpreting and contextualising the evaluation results, and drawing policy lessons.

IFS has experience working on the causes and consequences of vulnerabilities among children and youth, especially in the context of education systems and labour markets; AFC brings expertise on the needs and trajectories of youth at risk or with prior involvement in crime and the youth justice system. On methods, IFS has designed and evaluated complex, multi-site randomised controlled trials; AFC has conducted mixed methods studies that included collection and analysis of qualitative data for process and implementation evaluations. IFS brings expertise in psychometric analysis and econometric analysis of survey and administrative data; AFC brings knowledge of measurement tools of antisocial and mental health problems. IFS has experience performing economic policy evaluation. AFC has institutional knowledge of CAMHS and services accessed by the target population.

Both organisations are unique in their focus on generating high-quality academic research to improve policy-making. They will use their experience speaking to policy-makers about research and activate their wide networks to enhance the impact of the study.

Risks

We have identified the following risks:

1) **Violations of the randomization of youth practitioner teams into Your Choice training (MEDIUM)**. We will need to ensure the randomized initial and later staggered timing of teams of youth practitioner being trained in Your Choice is adhered to. This requires that at the start of the pilot, LA's provide a list of at least two teams they would like to be trained and that, following our randomization, they will ensure that the selected team is trained and is kept together as far as possible (except in the obvious circumstance of members of the team permanently leaving youth services).
2) **Matching of young people to teams within service sections. (LOW)**. Our understanding is that referral panels designate the services young people should

receive but not the specific teams within each service section that should deliver the service. We require the assignment of teams to young people to be entirely independent of the Your Choice training status of the team – so that effectively the assignment of young people to teams within service sections follows the same procedures as those in place before Your Choice. Any targeting of young people to teams based on whether they have been trained in Your Choice would undo the randomization protocol and violate the requirements of the trial. Our understanding is that referral panels do not always know the Your Choice treatment status of teams. We have always made it very clear to local authorities in their Grant Agreements that any assignment of young people to teams should ignore the treatment status of teams.

3) **Insufficient data provision**. **(MEDIUM)**. Right at the start of the programme, we will require that Directors of Children's Services (or their teams) draw up the lists of youth services and teams delivering them, and indicate which they would like to be trained in Your Choice. We will also require real time data on each referral panel, the cases they assess and their recommendations. Referral panels meet at least once monthly in each LA, and there can be more than one panel per LA. From each sitting panel, we will need information on the panel composition, the young people being considered, their assessment scores (and other information utilized by the panel), and the decisions over services to be received by each young person. That information defines which young people enter our evaluation sample. The grant agreement clearly lines out for each local authority the data they need to collect, and emphasizes this is a condition for the receipt of YEF funding for this intervention.
4) **Not all LA's engaging with the evaluation exercise. (LOW)**. We hope to be able to mitigate these concerns by continuing to build a close working partnership with the VRU and LA's and by transmitting to them the importance of adhering to the randomization protocols (many of which require them to continue operating in the exact same way as they did prior to Your Choice) and to the consistent delivery of the programme within the diversity of the populations that LA's work with. We hope these risks are being mitigated by the close working relationship between the evaluation team, the VRU and the LAs. In the communication between the VRU and LAs, the requirements of the evaluation have been clearly spelled out, the required randomization protocols have also been explained, and a key deliverable indicated by the VRU is that LAs engage with the evaluation.
5) **Low recruitment (LOW).** The projected numbers provided by the VRU of 100 young people being identified as medium/high risk across London boroughs each month suggests the trial will be of the scale required by the power calculations. There is a risk that even when young people are identified, they might not consent to being involved

in the evaluation – further reducing sample size. To mitigate these concerns, we are making the information sheet and consent form as clear and approachable as possible for the participants, including creating a video explaining the study. There is an additional risk of lack of engagement of young people with the high-intensity schedule of meetings proposed under Your Choice. This is a risk the encouragement-to-all aspect of the design specifically addresses and we will closely monitor its effectiveness.

6) **Cross contamination between treated and control participants**. **(MEDIUM)**. This applies to both treated teams of case workers interacting with non-treated teams, and treated young people interacting with controls. With such spillovers, the benefits of the treatment could spillover onto controls, confounding measuring the impact of the intervention. We have discussed this concern throughout with the project team. We will ask both the control and treatment young people and practitioners about the techniques used during the sessions to measure the extent of cross-contamination.
7) **Contamination is between the Your Choice intervention and the NHS intervention London Vanguard (LOW).** The two programmes will overlap in time and will target similar populations, although London Vanguard has a wider reach by not being restricted to young people, and is planned to operate across multiple sites which may or not include LA premises. Given the dimension of the two programmes in terms of number of participants, and their concurrent focus on the population at risk of violent crime, there is a risk that some young people will be assigned to both programmes, or that some young people in the control group for Your Choice will participate in London Vanguard, and perhaps receive similar treatment to that delivered by Your Choice through London Vanguard. However, it is at this stage clear that not all young people assigned Your Choice will participate in London Vanguard. That is both due to capacity constraints and to the fact that London Vanguard will operate only in 3 out of the 5 Integrated Care Systems in London. While we cannot impede young people from participating in London Vanguard, we can control for it. We will require that information on treatment status by London Vanguard is provided to us, so that we know who is having the opportunity to receive the set of services provided by that programme. This will allow us to gauge the frequency of overlapping treatments. If in practice London Vanguard treats a significant proportion of the Your Choice population, we will be able to use information on participation in that programme to assess the additional impact of participating in Your Choice. In this case, and to better understand our results, we will aim to further our understanding of the services provided by London Vanguard. In particular, we will aim to keep a close contact with those designing the London Vanguard evaluation, including with Professor Peter Fonagy, to continue exchanging information on the scope of both programmes.

Timeline

Phase		Description of activities during phase	Target date
• Study and project mobilisation/set up. • Stage 1 of pilot (Home office pilot) (1st January 2022 – 31st March 2022)			
		• Evaluator completes theory of change/logic model, in partnership with project team • Evaluator finalises intervention description, in partnership with project team	28th February 2022
		Evaluator completes DRAFT information sheets and privacy notices for whole evaluation, including archive, for YEF review	11th March
		• Evaluator completes final information sheets and privacy notices for whole evaluation, including archive, incorporating YEF review feedback	25th March 2022
		Evaluator completes DRAFT pilot trial protocol for peer review	4th April
		Evaluator obtains ethical approval and provides confirmation to YEF	4th May 2022
		• Evaluator incorporates feedback from peer review and submits final pilot trial protocol	18th May
• Project delivery & stage 2 of pilot (YEF pilot): 1st April 2022 – 31st August 2022		Data collection begins	15th June 2022
	5	Completion of baseline data collection as specified in pilot trial protocol (rolling recruitment ends)	15th July 2022

	6	Completion of all data collection as specified in pilot trial protocol (includes both quantitative pilot trial data and implementation and process data)	15th December 2022
• Data analysis and report write up	7	Evaluator completes DRAFT interim evaluation report (basis of decision to progress to efficacy study) and submits for review	15th February 2022
	8	Evaluator incorporates feedback and completes final, peer reviewed interim evaluation report	15th March 2023
	9	Evaluator completes support for YEF publication process	15th April 2023

Your Choice:

Intervention Description

Item	*Description*
1. BRIEF NAME	Your Choice
2. WHY	Young people who get involved in violence (those most at risk) are those in most of need of therapeutic support, but most unlikely to receive it. We need to shift how we offer support to young people, by shifting the offer, so they can access it within their community, within a broader context of support and behavioural change. This can be delivered best through a holistic, community model delivered through all relevant partners.
3. a) WHAT (Your Choice)	Upskilling practitioners • 5 days of training for youth workers (delivered in a cascading model) • Monthly clinical supervision • Regular peer supervision • Handbook and resources to support delivering sessions Upskilling children and young people • 3 x weekly meeting with youth practitioner for 12 weeks • Build authentic and trusting relationship – safe space where young people can grow • Accessible clinical intervention, including emotional literacy, emotion regulation, understanding cognitive processes, and strategies for managing intense feelings (Brain Gym) • Solution focused • Goal setting (using Goal Based Outcome Tool) and practical support with activities to achieve these goals • Understanding and formulating young people's needs • Coach to guide self-understanding
3. b) WHAT (usual care)	Young people with medium or high risk. Description to be developed from evidence and learning from the pilot.
4. WHO PROVIDED	Youth practitioners: youth workers, social workers, youth justice

	worker, gang workers, etc
5. HOW	Individual or work with the family (e.g., psychoeducation for parents/carers
Item	***Description***
6. WHERE	Range of locations, accessible to the young person, so they are engaged in the places they want to be engaged; mainly community settings such as youth centre, cafes, gyms, etc
7. WHEN and HOW MUCH	3 x a week for 12 weeks (calls, meetings, going to the gym, working with parent/carer for psychoeducation); 45-60 mins (poss. longer)
8.TAILORING	To facilitate sustainability and meet local needs, it is important that Local Authorities own Your Choice; it will build on existing services and delivery for this cohort of young people, which will vary between different Local Authorities
9. MODIFICATIONS	To be determined based on the pilot
11. HOW WELL	To test fidelity monitoring during the pilot

Hoffmann T C, Glasziou P P, Boutron I, Milne R, Perera R, Moher D et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide BMJ 2014; 348 :g1687 doi:10.1136/bmj.g1687

Annex A – Power calculations (pilot)

The table below shows the number of teams required in each arm to detect various effect sizes for different combinations of baseline prevalence and ICC. This is based on a cluster size (number of CYP per team) of 8, based on 4 children per team per month, and a 2 months pilot. The cells highlighted in green show the effect sizes we can detect with 31 treated teams (the likely number of treated teams we can use in the pilot).

Table 1. Outcome: Probability of externalising disorder (based on SDQ)

ICC	Prevalence of externalizing problems in both arms at baseline	*MDE Size*				
		20%	30%	40%	50%	60%
0.05	50%	66	29	16	10	7
0.05	60%	46	20	11	7	5
0.1	50%	83	36	20	13	8
0.1	60%	58	26	14	9	6

Table 2. Outcome: Probability of committing at least one offence

ICC	Percentage of young people in the control arm who commit at least one offence	*MDE Size*				
		10%	20%	30%	40%	50%
0.05	20%	1019	244	104	56	34
0.05	30%	600	145	62	34	21
0.05	40%	390	95	41	23	14
0.1	20%	1283	308	131	70	43
0.1	30%	755	183	78	42	26
0.1	40%	491	120	52	28	18

Annex B – Power calculations (efficacy trial)

The table below shows the number of teams required in each arm to detect various effect sizes for different combinations of baseline prevalence and ICC. This is based on a cluster size (number of CYP per team) of 45, based on 3 children per team per month, and a 15 months efficacy. The cells highlighted in green show the effect sizes we can detect with 62 treated teams. The assumption of 62 treated teams relies on 31 treated teams in the pilot, all LAs going ahead to the efficacy, and all LAs having the capacity and resources to have an additional team trained and delivering Your Choice during the efficacy trial. It will need to be determined during the pilot whether this number of treated teams and number of children enrolled each month is indeed feasible.

Table 1. Outcome: Probability of externalising disorder (based on SDQ)

ICC	Prevalence of externalizing problems in both arms at baseline	*MDE Size*				
		20%	30%	40%	50%	60%
0.05	50%	28	12	7	4	3
0.05	60%	19	9	5	3	2
0.1	50%	47	20	11	7	5
0.1	60%	32	15	8	5	4

Table 2. Outcome: Probability of committing at least one offence

ICC	Percentage of young people in the control arm who commit at least one offence	*MDE Size*				
		10%	20%	30%	40%	50%
0.05	20%	429	103	44	23	14
0.05	30%	253	61	26	14	9
0.05	40%	164	40	17	9	6
0.1	20%	725	174	74	40	24
0.1	30%	427	103	44	24	15
0.1	40%	277	68	29	16	10

Table 3. Outcome: School engagement index

ICC	School engagement of control arm - Mean = 0, SD = 1	MDE Size (in SD of the control group)					
		0.03	0.05	0.07	0.1	0.15	0.2
0.05	N teams in each arm	1240	447	228	112	50	28
0.05	N kids per arm	55800	20115	10260	5040	2250	1260
0.1	N teams in each arm	2093	754	384	188	84	47
0.1	N kids per arm	94185	33930	17280	8460	3780	2115

YOUTH ENDOWMENT FUND

Impetus

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The Youth Endowment Fund Charitable Trust

Registered Charity Number: 1185413