PILOT STUDY PLAN

RISE Mutual Child to Parent Violence Programme

The University of Hertfordshire

Principal investigator: Professor Joanna Adler

YOUTH ENDOWMENT FUND

Pilot study plan template

The University of Hertfordshire

RISE Mutual Child to Parent Violence Programme

Project title	**Using a nonviolent resistance (NVR) and whole community approach to reduce violence and bring families together**
Developer (Institution)	RISE Mutual
Evaluator (Institution)	*University of Hertfordshire (UH)*
Principal investigator(s)	*Professor Joanna Adler.*
Evaluation plan author(s)	*Professor Brian Littlechild, Dr David Wellsted, Natalie Hall, Amanda Busby.*
Evaluation setting	*Family homes.* *The intervention planned to work with families referred by Local Authority staff, providing up to 20 sessions, working with the parents and the children separately; to engage with members of the community/other family members to support the parents and child; and to train referrers in the non-violent resistance (NVR) approach. RISE Mutual adopted the NVR approach with particular reference to young people's violence towards their parents.*
Target group	*The project was targeted at families where children and young people aged 10-14 were showing violence towards their parents within the family home.*
Number of participants	During the feasibility phase, the project worked with 90 families up until end of July 2021, with 90 being the maximum

	aimed for over the whole project. As numbers were reached prior to the pilot, the continuation of the evaluation will include more interviews with parents, referrers and RISE staff, and assessment outcomes re engagement and continuation with the families, as well as in the progress of the work from this REDcap data, including measurement of 'distance travelled' as demonstrated in the Strength and Difficulties Questionnaire (SDQ).

Study plan version history

Version	Date	Reason for revision
1.2 [*latest*]		
1.1	24.2.22	Responding to feedback from the YEF
1.0 [*original*]		*[leave blank for the original version]*

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.

Background and rationale

The Child to Parent Violence Programme seeks to change behaviours of 10- to 14-year-olds showing violence towards their parents. Behaviour manifests as poor engagement in school with subsequent poor attainment and increased risk of criminal activities. The programme engages parents and children in their homes through a programme of up to 20 sessions. Sessions with parents utilise and teach Non-Violent Resistance (NVR) techniques, including reconciliation methods. Sessions with young people are skills-based, trauma-informed and teach cognitive behavioural therapy (CBT) techniques to break negative cycles. Activities address needs, leading to outcomes through NVR techniques to best address CPV, as traditional engagement approaches with young people can be ineffective. NVR is seen as potentially having a greater chance of success because it does not rely on young people's engagement but provides parents with the skills and knowledge to deal with behaviour in a non-violent way, avoiding punishments and relying on natural consequences.

Rise Mutual CIC is therefore a little different from the other three family-based projects within this programme of work. Firstly, it starts with the parents and only moves onto young people if/when they are ready to engage. Then, there is a more limited empirical basis for the work. Nonviolent Resistance and/or the New Authority are techniques developed by Omer (e.g. 2004, 2011). The techniques have gained some popularity in practice and several relatively small-scale studies have been conducted, including within families where the children present significant behavioural/management challenges (e.g. Weinblatt and Omer, 2008; van Holen et al. 2016). Findings have been somewhat positive but were often with limited sample sizes or relatively uncomplicated family settings. This pilot evaluation will primarily evaluate outcomes for the RISE Mutual Child to Parent Violence Programme, which works with families presenting with more complex needs than those in some of the studies mentioned above It is also important to note that when working with young people, CBT is utilised.

CBT has been shown to produce some of the largest effects on reducing reoffending in young people up to age 25 (Lipsey 2009, Koehler et al. 2012). When considering young people just up to age 18, reoffending outcomes have been more mixed (e.g. Ford and Hawke 2012, Martsch 2005). The most promise may be where other modes of support are implemented alongside CBT (Burraston et al. 2010). The use of CBT within young people alongside changes in parenting style via NVR, can be seen as one such multi-modal approach.

Referral process

Referrals are received from the London Boroughs of Croydon and Bromley. The programme set out to receive referrals from Local Authority social workers, schools, family intervention workers and early help teams, alongside the Child and Mental Health Services (CAMHS).

Screening

All referrals are screened for suitability by RISE staff, following discussions regarding the suitability of each family.

Site contact

Site: Johanna Rowlatt, Business Development & Research Officer, RISE Mutual CIC

UH: Professor Brian Littlechild

Participant Inclusion criteria

Families living in Croydon and Bromley with children and young people aged 10-14 who are showing violence towards their parents within the family home, and meeting one of the YEF inclusion criteria

Exclusion criteria

Not meeting inclusion/referral criteria outlined above.

Sample size

During the feasibility phase, the project worked with 90 families up until end of July 2021, with 90 being the maximum aimed for over the whole project. As numbers were reached prior to the pilot, the evaluation will expand to include additional interviews with parents, referrers and RISE staff, and assessment outcomes related to engagement and continuation of families, as well as tracking their progress using REDcap data.

Recruitment and follow up

Following recruitment into the programme, the clients[1] will be followed up at one (t1), three (t2) and six months (t3). This cohort of clients may have data for follow-up to 9 (t4) and 12 (t5) months.

Adherence to Intervention

[1] We refer to all study participants (young people and parents) as clients for simplicity. Where necessary the subject will be specified more exactly.

Adherence to the intervention will be assessed by recording attendance at therapeutic interventions and follow ups assessments.

Service user experience:

Qualitative interviews with families (e.g. parents, carers, guardians and children) to investigate their experience of participating in the intervention will be completed

Analysis – additional measures

The RISE Mutual Child to Parent Violence Programme uses individual goal identification and attainment, and a modified behavioural measure which will be assessed alongside the core YEF measures of outcome.

Objectives

The Child to Parent Violence Programme (CPV Programme) has already been through the feasibility phase of the evaluation process and has progressed to a pilot study. The pilot study has a cohort design (N=90) and will assess change over time in main outcomes, and continued success of delivery. The programme had recruited 90 by the end of feasibility. A further aim is to determine whether it is possible to deliver a large-scale evaluation of the intervention.

Overall aims

The overall aim for the pilot evaluation is to investigate the CPV Programme's potential to improve young peoples' and families' outcomes. The outcomes listed below cover problem behaviour, emotions, trauma, family functioning, and engagement in criminal behaviour.

Objectives

- The main objective is to assess the improvement in emotion, problem behaviour, and family functioning, distress related to trauma, and reduction in engagement in criminal behaviour by the children involved in the programme.
- Progress to achieving Goals set as part of the CPV Programme will also be evaluated.
- To assess the potential effect size of the programme intervention.
- To evaluate the methods for recruiting clients from the intervention's target population and retaining clients in the programme once enrolled.
- To evaluate the readiness to deliver a larger scale randomised trial.

Core measures

YEF specifies a standard set of measures to be used and compared across a range of commissioned interventions and evaluations. This is referred to as the core measures dataset and are specified below. Additional optional measures have been agreed with individual grantees. For the RISE CPV programme agreement was made to collect a limited range of outcomes, in particular:

Primary outcomes

Psychological well-being:

- Strength and difficulties Questionnaire (SDQ)

Adherence to Intervention

- Adherence to the intervention will be assessed by estimating the number of missed appointments and missed follow-up assessments.

Service user experience

- Qualitative interviews will be completed with families (parents, carers and children) to investigate their experiences of participating in the intervention.

RISE specific outcomes

- The Child Violence Programme uses Goal setting as a therapeutic method, and progress on the Goals will form an additional outcome for this programme. In addition, RISE has modified the SDQ to capture a wider range of outcomes relating the child and family experience specific to the CPV programme intervention.

Long-term outcomes aim to reduce offending, improve school attainment, and improve community response to reducing violence.

Intermediate outcomes for children and young people aim to reduce violence, improve engagement with key individuals, improve emotional self-management, and improve behaviour.

Intermediate outcomes for parents/ family aim to improve de-escalation skills, reduce feelings of helplessness, improve confidence, strengthen community support networks, reduce social isolation and improve wellbeing.

Theory of change

Treatment is highly individualised. The RISE therapist works with parents on developing strategies and setting boundaries to achieve change in the young person's behaviour. Parental skills develop gradually with intense support, moving from training to role modelling, enacting with therapist support, to independent practice. Parental barriers to managing their child's behaviour are addressed. As parents succeed in the home environment, efforts are made to address contributory factors such as deviant peers, and investigating the possibility of reintegration into mainstream education.

The Child to Parent Violence Programme spans up to 20 sessions. Work was to be carried out with parents grounded in Non-Violent Resistance (NVR). Work with the children adopts a flexible skills-based, trauma informed approach with CBT techniques. The programme seeks to change behaviours of 10- to 14-year-olds showing violence towards their parents. Behaviours manifests as poor engagement in school with subsequent poor attainment and increased risk of criminal activities.

NVR does not rely on young people's engagement but provides parents with skills and knowledge to deal with behaviour in a non-violent way, avoiding punishments and relying on consequences. It is seen as being different to current provision where parenting courses are based on a punishment/ reward approach, encouraging parents to 'take control'. The project focuses on improving connective parenting, consistency and acceptance, taking the approach that problems within the family can only be resolved through a consistent whole family approach, working with parents, young people and siblings. CBT and mindfulness techniques are taught to young people, helping deal with anxiety and anger in a more productive manner.

Research objectives

The RISE Mutual Child to Parent Violence Programme has already been subject to the feasibility testing phase of the evaluation process and is progressing to a pilot evaluation. As the target of 90 families target has been achieved prior to the pilot phase, the evaluation will expand to include additional interviews with parents, referrers and RISE staff. Assessment outcomes regarding family engagement and continuation will be employed, as well as monitoring progress via REDcap data.

Aim 1: To evaluate improvement in core outcomes over time.

Research questions:

Describe the client sample at baseline.

Describe the magnitude and direction of the change in behaviour (SDQ) over time (before-after) at 1, 3 and 6, and where possible at 9 and 12 months in comparison to baseline and describe progress towards achieving Goals at 6 months for clients engaged in the programme.

Where possible, describe and evaluate the effect of baseline status on change over time

Aim 2: Evaluate the effect size of the Programme.

Research questions:

To estimate the likely effect size of the CPV Programme on behaviour (SDQ)

Aim 3: To describe the referral and screening process

Research questions:

To describe the flow of young people from referral, through evaluation, to engagement on the programme, including reasons for not progressing on the programme (Flow Chart)

To evaluate potential bias in selection, by considering sample characteristics at different points in the referral process and where possible, comparison across subgroups (eg referral sources)

Aim 4: Client retention and data completion

Research Questions

Do more than 75% of clients complete the intervention, and for clients who complete the intervention are more than 80% of the outcome measures completed.

Aim 5: To evaluate the readiness to deliver a larger scale randomised trial.

See success criteria

Aim 6: To assess implementation process

Research Questions:

Has the intervention been implemented with fidelity?

Have service users felt engaged?

How responsive has the intervention been to service users and referrers?

Success criteria

The main success criteria for the pilot will be to assess the readiness for a definitive trial, through the potential to scale up the intervention to meet a large sample size (typically N > 300). The estimated sample size for a trial to evaluate effectiveness of the intervention will be estimated from evaluation of the potential effect size. Key criteria to assess evidence of promise will be:

- Referral process: If bias in the referral process is identified, can this bias be addressed?
- Retention of at least 75% of young people in the intervention once the intervention was started, or evidence that retention can be addressed.
- Completion of at least 80% of outcome measures at baseline, 3, 6 and 12 months, or evidence that completion can be improved in a larger scale trial
- Given the likely required sample size for a larger scale trial:
    a. What population size is required to achieve that sample size, and
    b. Can likely delivery centres with a sufficient population be identified?
-

Additional potential success criteria for RISE, to be assessed within qualitative interviews:

Strong social networks and consistency are seen to reinforce and celebrate good behaviour. The project set out to work with schools, sports/youth clubs and other agencies to deliver a single approach within the community support network, reducing violence, including from gangs.

The programme also set out to train Bromley and Croydon social workers in NVR, to enable support for, and follow through from, the intervention.

Methods

Data collection

The CPV Programme evaluation draws upon different data sources and methods. These include the use of routine monitoring data collected by the projects, core measures specified by YEF relating to project participants, and qualitative data from interviews and focus groups with project participants and professional stakeholders.

Data collection methods

The majority of quantitative data collected will involve either data routinely collected within the Child to Parent Violence Programme, or the specified YEF core dataset.

As far as possible all identified data for each grantee programme will be by direct online entry to the REDCap system, stored securely on servers at UH, by members of the grantee team. Staff will receive training on data collection and use of the online system.

Data collection, data entry and queries raised by a member of the grantee team will be conducted in line with the Data Management processes as agreed between the grantees and the evaluation team.

Data will be routinely collected during the referral and screening process (as agreed with each grantee). Once clients are accepted onto the grantee programme the agreed core data will be collected (t0), and follow-ups with the clients will be arranged at 1 (t1), 3 (t2) and 6 (t3) months. Where possible data for this programme will also be collected to 9 (t4) and 12 (t5) months

Evaluation data

Routine monitoring data

The evaluation will undertake analysis of aggregated and anonymised data collected by the four family focused grantees relating to information about referrals into the service, the screening and assessment processes, and any formalised reviews. These data will also enable the profile of the source population to be characterised. By monitoring referrals, the evaluation team can assess whether appropriate referrals are being made (as measured against each project's referral criteria), and the extent to which selection bias occurs in accepting clients into the programme.

Key Demographic Data

Each programme will capture key client specific and demographic data, including age, ethnic heritage, gender, relationship to other grantee clients and index of deprivation[2].

Core measures

YEF specifies a standard set of measures to compare across the range of commissioned interventions and evaluations. This is referred to as the core measures dataset. Any additional optional measures have been agreed with individual grantees. For the Child to Parent Violence programme agreement was made to collect a limited range of outcome.

Strengths and Difficulties Questionnaire, SDQ [Family Member, Teacher[3] and Young Person completed]

https://www.sdqinfo.com/

This is a widely used and well validated measure which has several versions including one for 11 to 17-year-olds, for parents and for teachers. It is used to evaluate antisocial or other behaviour problems.

RISE have modified the SDQ to include a set of questions addressed by the child and parent relating to behaviour, life satisfaction, and engagement in violence.

Table 1 provides a summary of the data collection schedule.

TABLE 1: SCHEDULE OF PLANNED DATA COLLECTION AND ASSESSMENTS

	Referral	Screening	Baseline (t0)	1 month follow-up (t1)	3 month follow-up (t2)	6 month follow-up t3)
Demographics	X					
Programme Specific process	X	X				
SDQ			X	X	X	X
Goal setting and attainment			x			x
End of intervention, or engagement form			To be completed if a client withdraws, or when they complete the intervention.			

[2] The particular index of deprivation to be used, and the implications for data processing, are still being discussed at the time of writing.

Notes:

- SDQ – Strengths and Difficulties Questionnaire as agreed as part of initial contracting and are outlined in section 3.
- It may not be possible for clients to be followed up to 12 months for all grantees. Further, it is noted that decisions about whether to move from initial feasibility to pilot will be made before 12 months has elapsed. The expectation is thus that where 12 months data are possible to collate, they will feed into assessment of the pilot phase, not initial feasibility.

DATA SOURCES:

To simplify description of the data we use 'clients' to encompass the young people and/or families being considered for intervention, as appropriate. Data is captured separately for young people and their parents or carers separately. Please note that each client sub-set will be recorded in both aggregated and dis-aggregated ways to allow the evaluation to capture the different referral routes and their different potential experiences of the grantees' interventions.

The following objectives have been defined as core objectives that will be measured across all four Family Intervention Programmes.

- **Aim 1:** To evaluate the direction and magnitude of change in core outcomes over time, and for CPV Programme to assess progress towards achieving Goals.

The key data source will be the data collected on the REDCap database.

For RISE the SDQ has been modified to capture a range of outcomes, that are child and family completed, that are specific to the CPV programme. These measures capture a wider range of behavioural problems, satisfaction with life, and engagement.

The source data for Goal setting and attainment will be the client notes held by RISE. Transcription and transfer of anonymised Goal related data for clients from RISE to the evaluation team will be an ongoing process on a data format separately specified.

- **Aim 2:** To evaluate effect size.

The effect size will be estimated from the core dataset specified in aim 1.

- **Aim 3:** To describe the referral and screening process for the Child to Parent Violence programm**e.**

Data relating to screening and referral has been identified for each grantee programme, and where possible this has been incorporated into the REDCap database. Where the relevant

data cannot be captured in this way, the source data are the records held by the grantee, and transfer of anonymised data will be an ongoing process on a data format separately specified.

- **Aim 4:** Client retention and data completion

Attendance at therapeutic sessions, and the client completion record will allow evaluation of engagement in the CPV programme, and the database record will provide data on data completion.

- **Aim 5:** To evaluate the readiness to delivering a larger scale randomised trial.

Evaluation of this aim will utilise all the data collected in a summary process after all other aims have been evaluated.

Qualitative Interviews: Aim 6

The key focus of our pilot qualitative work will be to better understand: the factors that support or interfere with the intervention's delivery; the ongoing Implementation processes of the intervention's recruitment, retention and reach; alongside service users' experiences and views of the intervention. The interviews will help us to further assess acceptability of and engagement with RISE by the young people and their families. Interviews with practitioners/referrers will also help us to assess whether and potentially how successfully, processes can be managed and upscaled.

We anticipate inviting up to five children and their parents, carers, or legal guardians from each project to participate in an interview to inform the pilot evaluation. Professional stakeholders (up to five per project), including managers and delivery staff, will be sampled purposively. Across the full programme of four grantees, we therefore propose to conduct up to a total of 60 qualitative interviews – individually and in focus groups for the pilot study programme of work (up to 15 for RISE).

Interviews with the children and their carers may be individual, or as a joint interview depending on the particular context. This is subject to the normal procedure of the staff on the project discussing this with the parents and young people, as to whether they are willing to be approached or not by the evaluation team. As during the previous phase of the evaluation, given the very particular nature of the antipathy of young people towards their parents' wishes, and their attitudes towards authority, it is very unlikely that the young people will be prepared to be involved.

It has been agreed that to gain some form of feedback, the staff working with the families will actively seek the views of young people where possible to gain their views on the benefits

and the problems of the intervention from their perspective, which will be fed back to the evaluator.

Interview data will be transcribed sufficiently for deductive thematic analysis. In some cases the clients may refuse to be recorded for the interview, in such circumstances, a contemporaneous account of the interview will be taken and used for the analysis.

Referral process

Referrals are received from the London Boroughs of Croydon and Bromley (South London). The programme set out to receive referrals from Local Authority social workers, schools, family intervention workers and early help teams, alongside the Child and Mental Health Services (CAMHS).

Inclusion criteria

Participants will be considered eligible for enrolment in this pilot evaluation if they fulfil at least one of the criteria defined below.

- Parent or carer has agreed to an initial assessment

Behaviours to be addressed include at least one of the following:

- school refusal,
- regular absconding,
- violence,
- substance misuse,
- offending,
- defiant or severe oppositional behaviour or harmful sexual behaviour

Exclusion criteria

Not meeting any of the inclusion, or referral criteria outlined above.

Screening

All referrals are screened for suitability by RISE Centre staff using a set of bespoke tools developed for this task, including their own CBCL. A range of demographic information relating to current home status along with goal setting is recorded.

Sample size

The Child to Parent Violence Programme has planned to recruit 90 young people and their families which will be followed up during the pilot phase, giving a pragmatically determined sample size. Assuming a sample of this magnitude and a two-sided paired test, with 20% drop out (n-72), α=0.05 and 1-β=0.8, the minimum detectable difference is equivalent to d=0.33 which is a moderate to small effect.

Recruitment and follow up

Once clients have been accepted onto the Child to Parent Violence Programme baseline assessments (t0) will be collected along with other routine data agreed with the grantee programme and provisioned on the database. The clients will be followed up at one (t1), three (t2) and six months (t3). Where possible follow-up data will be collected at 9 (t4) and 12 (t5) months.

Data analysis

Methods overview

Research methods	Data collection methods	Participants/ data sources (type, number)	Data analysis methods	Research questions addressed
Secondary analysis.	Routine monitoring data collected by RISE (including core measures).	Those referred, screened, accepted, discharged, AND completing RISE programme. Includes progress against outcomes, as measured using YEF's core measures.	Descriptive and where appropriate inferential statistics.	Aims 1 through 4.
Primary data collection.	Qualitative interviews.	Purposive sampling of professional stakeholders (N=5) and opportunistic sampling of parents/carers (N=5) and children	Thematic analysis.	Aims 1 through 5

		(N=5) accessing RISE programme.		

The analysis plan provides a framework that is applicable to all 4 grantees. Each of the particular referral and screening processes are outlined above. Whilst several measures outlined by the YEF were planned to be collected and analysed for all projects, it was agreed that because of the very particular nature of this intervention compared to the three others, that there would be additions relating to the particular aims and outcomes of the intervention added into the SDQ – Strengths and Difficulties Questionnaire

Additional measures

Individual goal identification and attainment

The overall aim for the pilot evaluation is to investigate Child to Parent Violence Programme and the potential to improve the outcomes of young people referred into the programme. In addition, the data will be used to assess the potential for this programme to be evaluated in a larger randomised trial designed to evaluate either the efficacy or effectiveness of the intervention.

Objectives

Aim 1 and 2: To assess the direction and magnitude of change in the main outcome for the clients in the programme. To assess the potential effect size of the intervention.

The analysis will consider the modified SDQ, including the additional RISE specific outcomes, and progress against the Goals set within the Child to Parent Violence programme for each client. The initial analysis will be considered through descriptive statistics for the sample, as a whole, across all time points including all demographic and other factors. The analysis will describe change over time as a mean change from baseline, and estimated effect size (with confidence intervals) at 1 (t1), 3 (t2), and 6 (t3) months, and where possible at 9 (t4) and 12 (t5) months.

Sensitivity analysis will consider the influence of baseline characteristics, and missing data. As the dataset is small, any models will have to constrain the number of variables included. The analysis will seek to demonstrate gross effects of baseline variability, and missing data (by replacement of missing values) and interpret any influence on the observed change over time.

Goal attainment will be characterised as the graded progress against goals for each client. Where there is more than one goal for a client, identification of the main goal will be used. Progress against the goals will be characterised on the scale in a contingency table and summarised as a median with interquartile range.

Aim 3: Describe the referral and screening process

Analysis of the referral and screening process will be descriptive. A flow chart will be used to show the flow of client from referral through screening to completion of the intervention. Focus will be placed on why clients are not selected for the intervention at each stage. Descriptive analysis will seek to evaluate thought tabulation the extent to which selection of clients is subject to bias, excluding particular groups of clients. Numbers of clients will be small, but where possible analysis will use χ^2 to aid interpretation of the data.

Aim 4: Evaluate recruitment from the target population and client retention and data completion in the programme.

For clients starting the programme, retention to the end of the programme is important. Retention is defined as completing at least 66% of treatment sessions. This can be through missing sessions regularly through the treatment period, or by withdrawing from the program early.

The number of clients failing to attend scheduled appointments will be estimated, with the number and proportion of missed appointments and assessment sessions at each time point described. Overall adherence to the intervention (appointments) will be estimated as an overall proportion of appointments missed for each young person, and the proportion of young people attending at least 66% of treatment sessions. Characteristics of young people who do, and do not complete the programme will be tabulated and differences highlighted.

Data completion will be tabulated for each outcome.

Aim 5: To evaluate success criteria

Readiness to progress to a larger scale efficacy or effectiveness trial will be evaluated. It is likely that a sample size of 300 clients or more will be required but estimated more precisely in Aim 2. The progression criteria will consider the potential to deliver a trial of this magnitude.

Progression to a larger scale efficacy or effectiveness trail will consider four main criteria.

1. Bias in the referral process and whether bias can be addressed

Bias will be evaluated by highlighting any differences between groups of young people who start therapy, compared to those who are referred but are not accepted on to the treatment programme. The reasons for not progressing will be listed.

2. Retention of clients in the intervention.

Retention is an important secondary indicator of bias. Retention will initially be evaluated by determining whether Grantees are successful in retaining at least 75% of young people who start the programme. Secondary analysis will consider any apparent differences between young people and families who do and do not complete the programme.

3. Sufficiently robust and unbiased data completion.

Data completion for each of the outcomes will be tabulated. Data will be defined as complete for scales where sufficient data for each outcome has been completed to evaluate a scale score.

4. Whether a trial of sufficient magnitude could be delivered

Analysis will proceed by tabulating the assessed outcomes from analysis of each of the first 3 aims and any mitigation identified in the qualitative analysis. This will provide a summary statement of the success criteria, any bias in selection, and any adjustments that can be made in future studies. The potential number of recruiting centres will be estimated by considering how many young people and families could be recruited from treating centre per year, and the total number of treating centres required to achieve the required sample size.

Data management

Data relating to YEF's core measures collected by the Child to Parent Violence programme will be entered on to REDCap and securely stored on servers based at UH. The database will be username and password protected and only accessible to members of the YEF evaluation team, members of the grantee team and external regulators if requested.

Access to the evaluation database is controlled and administered by UH Data Management, and access is via end-to-end encryption. The servers are protected by UH firewalls and anti-virus products and are patched and maintained (including back-ups) according to best practice.

The database software (RedCap) provides a number of features to help maintain data quality, including; maintaining an audit trail, allowing custom validations on all data, allowing users to raise data query requests, and search facilities to identify validation failure, and missing

data. Rigorous testing has been carried out on the database, prior to use by grantees, in line with UH SOP's.

After completion of the evaluation the database and associated design documentation will be routinely archived for a period of five years.

Outputs

The UH evaluation team will provide YEF with pilot reports for each of the four grantees for peer review and publication (at YEF's discretion). In consultation with YEF, findings from the research may also be submitted for publication in academic journals and other outlets (e.g. conference presentations).

Ethics and registration and approvals

These studies were not pre-registered. They are a continuation of feasibility evaluations that will not be moving to RCT. The grantees began their interventions before data sharing protocols that are now normative for the YEF were in place and before the evaluators were appointed. As such, referral processes to the interventions and the potential for post evaluation data unmasking, and data linkage will not be possible.

The University's ethics and integrity policies and processes can be seen at: https://www.herts.ac.uk/research/research-management/ethics-and-research-integrity. In accordance with this process, the four pilot studies have full approval from the UH Health, Science, Engineering and Technology Ethics Committee (protocol number: LMS/SF/UH/04697). This approval grants the ability to collate data until 31.03.22

The team are bound by the codes of conducts of our relevant professional and statutory bodies--the British Psychological Society (professional body), Health and Care Professions Council, British Society of Criminology and, or Social Work England. We are all used to working to the DPA, 2018 and GDPR and within trauma informed ethical frameworks where we prioritise participant vulnerability, risks and legislative requirements.

Most of the administrative data being collated for this evaluation is being shared, stored and processed under the principles of legitimate interest. Additionally, there are interviews being undertaken (with service users, stakeholders and service providers) that will proceed on the basis of consent. When providing information and gaining consent from young people, will also ensure that parents/primary caregivers/legal guardians are informed and provide consent where possible. We are mindful that in some circumstances, parental

interests will conflict with young people's rights. In such circumstances, we will prioritise the children's interests. Wherever possible, we will also seek to avoid unnecessary criminalising of children and young people following principles embedded in CPS and policing guidance.

Safeguarding

In line with the process adopted at the feasibility evaluation, within the pilot studies, interview participants will be made aware that there may be situations, under the safeguarding framework, where there is a statutory obligation for members of the evaluation team to break confidentiality and provide information back to the organisation providing the intervention, or other statutory bodies. As outlined above, the research team would not process identifiable data, but participants need to be clear that for safeguarding reasons, anonymisation is not complete.

The team are used to conducting evaluation and practice with young people and adults who may be vulnerable by the situation in which they find themselves (Care Act, 2014; SVGA, 2006; Sexual Offences Act, 2003). Anyone conducting fieldwork and/or data analysis will be DBS cleared as appropriate and versed in the safeguarding protocol for that evaluation. The initial intention was that we would be following the safeguarding protocols provided by each grantee, working in close liaison with project managers from the grantee. Given the developments and dramatic changes to policy and process, we have now developed our own overarching practice which works in continued consultation with project managers. If a safeguarding concern is raised or identified, then we will enact the following process using common key principles including: if an immediate risk is identified, other work ceases until the police and/or social services are called; once identified, information is passed to the relevant duty safeguarding officer or project manager. Although information is protected by default, all research participants and grantees are aware that data will be shared appropriately to the circumstances of any particular safeguarding risk that may be identified. We will also use a precautionary principle in pre-identified situations of low/medium risk so that children are neither put at further risk, nor unnecessarily criminalised.

Consent

Most of the administrative data being collated for this evaluation is being shared, stored and processed under the principles of legitimate interest. Additionally, there are interviews being undertaken (with service users, stakeholders and service providers) that will proceed on the basis of consent. When providing information and gaining consent from young people, will also ensure that parents/primary caregivers/legal guardians are informed and

provide consent where possible. We are mindful that in some circumstances, parental interests will conflict with young people's rights. In such circumstances, we will prioritise the children's interests. Wherever possible, we will also seek to avoid unnecessary criminalising of children and young people following principles embedded in CPS and policing guidance.

When being invited to participate in interviews specifically for the evaluation, all prospective participants will be provided with an Information Sheet (PIS) and given time to read it fully, before any interview may proceed. Any questions will be satisfactorily answered and if the participant is willing to participate, written informed consent will be obtained. During the consent process it will be made completely and unambiguously clear that the participant is free to refuse to participate in all or any aspect of the pilot evaluation, at any time and for any reason, without incurring any penalty or affecting their continued involvement in the intervention. We will ensure that: information is provided in accessible, age and cognitively appropriate ways; consent is treated as an ongoing process; that consent and participation can be withdrawn without penalty; that findings and data will be anonymous where possible, confidential throughout and, where appropriate, depersonalised or anonymised as soon as possible according to principles both of the GDPR and UK anonymisation network.

Data protection

Given the sensitive nature of the data, its protection and security are of the utmost importance. UH has well-established procedures relating to confidentiality of information. We are registered and fully compliant with the requirements of the General Data Protection Regulations (GDPR) (Regulation (EU) 2016/679) and the Data Protection Act 2018. UH is certified through Cyber Essentials (the UH Cyber Essentials Certificate number is IASME-A-09513).

For these grantee evaluations data will be transferred to the University of Hertfordshire in pseudonymised form and analyses as specified in the Statistical Analysis Plan. As specified in the DIPA the data will be stored on secure servers and only available to personnel directly involved in the evaluation, or as required by statutory authorities. The data will be electronically archived, and destroyed 5 years after completion of the final evaluation reports.

Access to Data

Access to the evaluation database is controlled and administered by UH Data Management, and access is via end-to-end encryption. The servers are protected by UH firewalls and anti-

virus products and are patched and maintained (including back-ups) according to best practice.

Archiving

The pseudonymised evaluation data will be electronically archived on secure servers at the University of Hertfordshire for 5 years after the final evaluation reports have been completed. Access to the data will be managed, and only made available to members of the evaluation team, to YEF personnel, or where necessary for statutory regulatory processes.

Confidentiality

An important principle is to maintain the separation of anonymised client data collected for the pilot evaluation and the client's personal details. This will be achieved by ensuring that all data captured via REDCap is anonymous to the evaluation team. Pseudo anonymity will be achieved by providing each client with a randomly generated study id, used in the dataset that is unrelated to their personal details. All reporting will only provide summary data which avoids the potential to identify individual clients. Where quotes are included from qualitative interviews any identifying material will be removed or modified as appropriate.

By using a random id to protect the identity of the beneficiaries and service users, the projects can provide the data required for the evaluation while maintaining a level of protection against disclosing the clients' identities. We are adopting a relatively routine way to do this, which is for the organisations to retain a key which would allow identification of the clients from the random code. If subsequent data linkage had been possible then this key would also allow longer term follow-up from public and institutional databases. As it has now been agreed that these studies will not be moving beyond RCT (confirmed by the YEF Evaluation Manager via email, 14.09.21), there will be no need to unmask the data as no grantee in these evaluations will be required to collect and share identifiable data for depositing in YEF's data archive.

Central Monitoring

UH staff will review Case Report Form (CRF) data[3] for errors and missing key data points. The pilot evaluation database will also be programmed to generate reports on errors and error rates. Essential study issues, events and outputs, including defined key data points, will monitored and documented.

Direct access to participant records

Participating investigators must agree to allow pilot evaluation related monitoring, including audits and research ethics committee (REC) review, by providing access to source data and other pilot evaluation related documentation as required. Participant consent for this must be obtained as part of the informed consent process for the pilot evaluation.

Personnel

Johanna Rowlatt, Business Development & Research Officer, RISE Mutual CIC.

Professor Joanna Adler (University of Hertfordshire), Programme leadership including YEF liaison and report oversight.

Professor Brian Littlechild (University of Hertfordshire), Project management, grantee liaison. "Hands on" in all stages of the evaluation including interviews and focus groups. Oversee and conduct ethics, fieldwork, analysis and write up.

Dr Tim McSweeney (University of Hertfordshire), Programme leadership.

Dr David Wellsted (University of Hertfordshire), Programme leadership including YEF liaison and report oversight. Oversight of analysis and evaluation.

[3] The data collection process is organised around Case Report Forms, which is a generic description for the data collection forms that are provided at each time point, or to capture other important events (like withdrawal, or the end of evaluation case report forms).

Natalie Hall (University of Hertfordshire), Set up of REDCap and training (external and internal). Data Monitoring. Fieldwork (both interviews and focus groups), initial analysis, write up contribution.

Amanda Busby (University of Hertfordshire), Statistical support

Declaration of Interests

The investigators named on the protocol have no financial or other competing interests that impact on their responsibilities towards the scientific value or potential publishing activities associated with the pilot evaluation.

The investigators are not aware of any conflicts of interest. None of the co-applicants have raised any issues in relation to any conflicts or potential conflicts of interest, including any facts that, should they come to light at a future date, could lead to a perception of bias. This includes any relevant personal, nonpersonal and commercial interest that could be perceived as a conflict of interest. There is no commercial sector involvement with the application or the study.

Risks

Risk Assessment

Area	Risks	Likelihood	Impact	Mitigation
Robustness of evaluation	1. Incomplete/inaccurate Data Upload	Medium	Medium	1. Close liaison with grantee data entry personnel. Data Audits and Data Quality Monitoring.
	2. Unreliability of interview data	Low	Medium	2. Checking for internal and ecological validity within interviews. Ensuring participants are secure during interviews.
	3. Idiosyncratic interview analyses	Low	High	3. Inter-rater reliability checks and comparisons within and between projects.
	4. Data breach	Low	Med	4. All administrative data are pseudo-anonymous and there will not be data linkage made. Interview data will be

				transcribed, redacted and deindividuated. All reports will be based on aggregate or depersonalised data
Safeguarding	1. Immediate participant safeguarding.	Low	High	1. Depending on the risk identified and imminence of threat, interview stopped, police or social services called and grantee protocol invoked.
	2. Retrospective participant safeguarding	Low	High	2. Close reading of comments fields in RedCap and of Interview transcripts to monitor and take prompt, appropriate action, again invoking grantee safeguarding protocols as necessary.
	3. Safeguarding risk to others identified	Low	Low	3. As per 1 above, adopting general safeguarding principles if the identified vulnerable person is not part of a grantee intervention.
Timely Delivery	1. Further lockdowns or other Covid mitigations	Med	Med	1. Most of the pilot evaluation is virtually implemented however, some of the grantee activity is still face to face. We have already extended deadlines to allow for ongoing delays and are hopeful that will be sufficient to keep to the timelines in this document.
	2. Staff sickness	Med	Low	2. We have already dealt with team ill health and if needed, could do so again. Assist have also coped with ill health as needed. Again, we think that the timelines allow sufficient space, assuming that the pandemic does not significantly deteriorate further.
Reputation	1. Mismatch of expectations between the YEF, grantees and/or evaluators	Med	Med	1. Continue to encourage project management and project evaluation teams to liaise more closely with grantees.
	2. Use of findings in unintended ways	Med	Low	2. Reach agreement with the YEF as to how findings may be shared with grantees and with

				grantees as to how they can be shared more broadly.
3.	Publication management not completed in a timely manner	Med	Med	3. Close ongoing liaison and consultation with the YEF to ensure that findings are open access ideally, and certainly in the public domain.

The Quality Assurance (QA) and Quality Control (QC) considerations for the YEF Project evaluation are based on the formal Risk Assessment performed, that acknowledges the risks associated with the conduct of the evaluation and proposals of how to mitigate them through appropriate QA and QC processes. Risks are defined in terms of their impact on: the rights and safety of participants; project concept including pilot design, reliability of results and institutional risk; project management; and other considerations.

QA is defined as all the planned and systematic actions established to ensure the pilot evaluation is performed and data generated, documented and/or recorded and reported in compliance with the principles of GCP and applicable regulatory requirements. QC is defined as the operational techniques and activities performed within the QA system to verify that the requirements for quality of the pilot evaluation related activities are fulfilled.

Timeline

Dates	Activity	Staff responsible/ leading
28.02.22	Completion of all qualitative fieldwork	Littlechild
30.04.22	REDCap data , download and cleaning	Wellsted
30.09.22	Submission of draft final report for Child to Parent Violence programme	Littlechild
30.11.22	Peer review response and production of final report	Littlechild

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