

EVALUATION PROTOCOL

**Randomised Control Trial of the
Child and Adolescent to Parent
Violence and Abuse (CAPVA)
programme run by RISE Mutual CIC**

University of Hertfordshire

Principal investigator: Joanna R Adler

Randomised Control Trial of the Child and Adolescent to Parent Violence and Abuse (CAPVA) programme delivered by RISE Mutual CIC



Evaluation protocol

Evaluating institution: University of Hertfordshire

Principal investigator(s): Joanna R Adler

Table i. Frontispiece

Project title	Randomised Control Trial of the Child and Adolescent to Parent Violence and Abuse (CAPVA) programme run by RISE Mutual CIC.
Developer (Institution)	Haim Omer (Tel Aviv University) and Peter Jakob (Partnership Projects UK)
Evaluator (Institution)	Adler et al. (University of Hertfordshire)
Principal investigator(s)	Joanna R Adler
Protocol author(s)	Joanna R Adler, Caroline Cresswell, David Wellsted, Amanda Busby, Jane Fry, and Karen Irvine (UH) Shivani Sharma (Aston University); Kuljit Sandhu, Rachael Ward and Johanna Rowlatt (RISE) with additional support during co-design from Andrew Laughland, Brian Littlechild, Amanda Ludlow, Megan Smith (UH) and Gordon Ashley-Smith (RISE).
Trial design	Two-arm randomised controlled trial with random allocation to BAU/Intervention post referral and initial screening for suitability.
Trial type	Efficacy with implementation process evaluation (IPE).
Evaluation setting	Family home, community and family hubs.
Target group	Parents and carers (foster or kinship) of children aged 9-17 referred for child or adolescent to parent violence and abuse
Number of participants	376 families required to completion, based on MDES of 0.29.
Primary outcome and data source	Child/adolescent to parent/carer violence, measured using the parent report on the Abusive Behaviour by Children Indices (ABC-I; Simmons et al. 2019)

Secondary outcome and data source	Problematic internalising/externalising behaviours, measured using the parent reported SDQ (Goodman 1997).
	Family conflict, using routine measures from RISE CAPVA manual (RISE, 2024).
	Family relationships, measured with practitioner assessments, plus impact supplement from SDQ and considered further within the IPE.

Table ii: Protocol version history

Version	Date	Reason for revision
1.4 [latest]	11.6.24	Following YEF suggested amendments pre-publication
1.3	03.6.24	Post peer review response
1.2	26.4.24	Feedback from GEC0 ahead of peer review
1.1	23.2.24	Feedback from internal YEF review to shorten delivery duration, remove three month follow-up from outcome measurement and remove IPE survey.
1.0	23.1.24	

The evaluation team are grateful to an anonymous reviewer who flagged additional consideration that was made prior to finalising this protocol.

NB. Please see Appendix 1 for changes made since the feasibility to pilot evaluation.

Any changes to the design or methods need to be discussed with the YEF Evaluation Manager and the developer team prior to any change(s) being finalised. Describe in the table above any agreed changes made to the evaluation design. Please ensure that these changes are also reflected in the SAP (CONSORT 3b, 6b).

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Study rationale and background

A randomised control trial (RCT) is proposed to test the efficacy of the RISE Mutual CIC (RISE) Child and Adolescent to Parent Violence and Abuse (CAPVA) programme. In parallel, an implementation process evaluation (IPE) will be conducted, permitting concurrent triangulation of findings¹. Ibabe (2020) defines CAPVA as ‘Young people/children who consciously direct physical, psychological, emotional, financial, or sexual aggression toward one parent or caregiver, repeatedly over time’. An earlier, alternative definition is also useful: ‘Parent abuse is any harmful act by a teenage child intended to gain power and control over a parent. The abuse can be physical, psychological, or financial’ (Cottrell, 2003 p1). Both definitions focused on adolescents although the commissioned age range for this trial will be from nine to 17.

In attempting to assess prevalence of CAPVA, a particularly useful exercise was undertaken by Brennan et al. (2022). Their research has informed the dimensions on which statistical analyses will be planned for the current trial (see below). Brennan et al. (ibid) drew on Metropolitan Police Service (MPS) data that reflected the start of the COVID-19 pandemic within London and pooled data from 2012 to 2020 waves of the Crime Survey for England and Wales (CSEW). Data came from 322,990 respondents of whom, 5,246 reported violent incidents. Of all violence reported to the CSEW, 1.2% (133 incidents reported by 102 respondents) could be identified as CAPVA cases; using the relatively limited filters available in the dataset. It was noted that less than half (40%) of the CAPVA incidents recorded in the CSEW were reported to the police. Within the MPS dataset, prevalence fluctuated, and it was not clear what the final effects of lockdown would be at the time of publication. The lowest recorded number of CAPVA offences across London per year was 577 (2020) and the highest was 846 (2018).

A gendered dimension to CAPVA incidents was also found with 71% of incidents recorded in the CSEW and 81% recorded by the MPS, being acts of violence by males and 78% of reported victims in the CSEW being female (overwhelmingly, the mother). Families from the global majority (ethnically minoritised) were over-represented when compared to national and local prevalence, comprising 53% of reported CAPVA. The analysis conducted of deprivation showed no association between index of deprivation and incidence of CAPVA. However, this could only be run at the borough level and in London, there is likely to be more variation within boroughs than between them (data taken from chapter six and annex three, Brennan et al. 2022).

¹ This protocol has been mapped to the TIDieR (Template for Intervention Description and Replication) checklist, which can be seen in Appendix 2. As part of the subsequent stages, it will also be mapped against the Standards for Reporting Qualitative Research (O’Brien et al. 2014)

Harms from CAPVA 'can be physical, emotional and psychological, material and financial, and legal' (Baker and Bonnicksen, 2021 p12). Although ever-more recognised in policy and practice (Holt, 2022), much of the research around CAPVA has concentrated on how it feels to live with CAPVA within families (Holt and Lewis, 2021). It is also pertinent to note that under the Domestic Abuse Act 2021, once they reach 16, children and young people (CYP) could be liable to prosecution for CAPVA.

This trial will add to a relatively scarce literature concerning interventions to reduce and/or otherwise ameliorate CAPVA. Referred families may be experiencing sharp impacts of trauma, crime, health, poverty, disadvantage and further intersections with race, ethnicity, disability and gender. The RISE CAPVA intervention aims to change behaviours of CYP showing CAPVA by first engaging with their parents/caregivers, working with them before any direct intervention with CYP.

The current trial builds on a feasibility to pilot evaluation that found relatively large reductions in CAPVA and improvements in problematic behaviours (Adler et al. 2023). Changes made for this protocol, informed by the feasibility and pilot evaluation, include a decision to incorporate additional neurodiversity, trauma and inclusion expertise. Also, to employ an embedded researcher to ensure that the validity of the design is maintained, rather than relying entirely on intervention practitioners, lead professionals and/or families for data collection. Relatedly, this trial will use the database software (Research Electronic, Data Capture-REDCap) survey tool so that no-one other than evaluators will need direct access to the database. The surveys mean that data will be automatically captured to the database without any evaluation participants or practitioners needing to access it directly (this is a change from the previous evaluation where some areas of that database were set up to allow identifiable RISE practitioners to upload data directly).

Two key challenges that have been considered during co-design relate to business as usual (BAU) and the safe engagement of CYP in the evaluation. BAU varies in different boroughs and may also vary depending on the referred family's needs. For example, some families may be awaiting intervention from Child and Adolescent Mental Health Services (CAMHS) others, from educational liaison services. In some boroughs, competing models are being used to address CAPVA such as those that target the CYP rather than the parents/carers first (e.g. Respect n.d.). In others, there will be no specific CAPVA intervention. It is expected that all families referred for CAPVA will have been assigned a lead professional such as a social worker, early help practitioner and/or that a youth worker. The minimum BAU considered for the control intervention of this trial is therefore being taken as allocation to a lead

professional for support and provision of safety measures, routinely provided by RISE as part of the initial screening and assessment for suitability².

The safe engagement of CYP was considered within a participatory session run with representatives of the YEF youth advisory board. It is intended that the steps outlined here will be further reviewed, amended and potentially supplemented during the contracting, ethics and governance and mobilisation phases of the trial. Also, it is intended that participatory groups will form part of the quarterly trial monitoring. Safe engagement steps include:

1. Ensuring age appropriateness and readability of all materials, written, verbal and visual;
2. Drawing on and creating bespoke, accessible materials for adults and CYP to make clear who is conducting the evaluation, who will be delivering the intervention, what to expect from the trial and why it would be helpful to sign up, whether assigned to BAU or intervention arms of the trial;
3. Acknowledging the “adultification” (e.g. Davis, 2022) that referred CYP may have experienced and responding appropriately to neither patronise CYP with tone or content of materials, nor to worsen or reinforce responses to them that do not acknowledge that they are still children;
4. Checking with practitioners and lead professionals prior to inviting CYP to participate directly in IPE research;
5. Gaining informed consent in a process that starts with gatekeepers (as in 4), followed by parents/carers and then young people themselves. Where potential participants are 16 or 17, they will still be seen as vulnerable and although their parents/carers will not be approached prior to their invitation to research, the practitioners working with them will still be asked for a safeguarding-informed view;
6. Routine provision of safety measures to all families at screening/assessment for suitability;
7. Routine recording and reviewing of adverse events, including ways for families (adult and CYP) to self-report;
8. Monthly reviewing of the outcome measures will include a double check of potential safeguarding instances associated with the evaluation.

One published randomised trial compared non-violent resistance (NVR) against BAU within support provided to foster families (Van Holen et al., 2016), although the study was underpowered, and without statistically significant effects of behaviour. Despite lack of

² Initial screening processes will be modified to incorporate supplementary information on the evaluation to aid recruitment and provide clear, specific, information about what BAU to expect, should families be assigned to the control arm.

observable change between the control and intervention group, the authors noted improvements in behaviour over time within the NVR group. Nonetheless, due to the sampling problems, it is not possible to interpret those changes meaningfully. More recently, Fongaro et al. (2023) conducted an RCT comparing NVR against parental counselling with psychoeducation. That study did not assess frequency or severity of violent or abusive behaviours, but rather, focussed on parental stress. When compared to psychoeducation, NVR had similar outcomes on the Child Behavior Checklist (CBCL; Achenbach and Rescorla, 2001) and Strengths and Difficulties Questionnaire (SDQ; Goodman, 1997) parent-completed measures but was not as effective at reducing parent-reported stress by the end of the programme. The study's acknowledged limitations include that although the authors found improved outcomes over time for families with NVR, they did not make any between group comparison against treatment as usual, longitudinally. The current trial will be better powered than either of the two mentioned above and will specifically seek to test for reductions in CAPVA, concomitant impacts on families, the communities around them, CYP school attendance and attainment.

Intervention description

The CAPVA programme run by RISE seeks to change behaviours of young people (aged 9-17) showing violence towards their parents and carers. It does this first by seeking to change the ways in which parents and carers respond to the young people's behaviours. Behaviours of concern manifest as moderate through to severe violence, typically targeting parents, carers, siblings and other family members. Behaviours may be different when aimed at different family members hence experiences of mothers may not mirror those of fathers. RISE's CAPVA intervention applies a whole family approach in line with the understanding that long lasting change will be better facilitated if all members of the family understand NVR. Typically, poor engagement in school is also seen, with subsequent poor attainment and increased risk of criminal activities beyond the home.

As part of assessment for suitability for the CAPVA programme, a robust assessment and suitability process is conducted with all families to explore previous patterns of behaviour and violence including levels of coercive control. Some families referred to RISE may not appear to be in crisis due to physical violence being absent by the point of referral, or less frequent and/or intense. With such cases, screening frequently finds that families who have previously attempted to implement boundaries have seen increases in violence. As a result, they may have adopted complementary patterns of escalation (see [underpinning principles](#) below). These families are assessed as suitable to embark on the intervention, despite physical violence not being a key feature at the time of referral.

For the CAPVA programme, RISE routinely assess a number of vulnerabilities and risks in one or two sessions with parents/carers (see [intervention screening](#) process below), which include:

- Self-harm and/or suicidal ideation;
- Mental health difficulties and disabilities (un-diagnosed, or diagnosed);
- Substance misuse;
- Violence and harmful behaviours outside the home – what settings and to whom;
- Vulnerability factors – e.g. exploitation risk, absconding;
- Previous intimate violence or abuse (IPVA), or current concerns.

The identification of vulnerabilities and risks inform how the intervention can be tailored for individual families (for examples see [intervention delivery](#) below). Baseline assessment is also made of family functioning and how the CAPVA affects the family and systems around the family.

The CAPVA delivery team works with other practitioners assigned to the family to ensure they also understand the principles being adopted (e.g. the social worker and/or youth worker allocated) and the CAPVA intervention is delivered using a trauma informed approach (Asmussen et al., 2022) that is inclusive of cultural and diverse needs. RISE practitioners are rooted in cultural and trauma-informed approaches, recognising that families possess diverse worldviews shaped by their cultural backgrounds. For instance, families’ distinct norms may differ according to gender roles or belief systems, necessitating a personalised approach in delivery. The evaluators and project team expect that there will also be cultural factors that influence how appealing the CAPVA programme may be, which both teams will be aware of as part of a commitment to an inclusive intervention experience. For example, practices in managing difficult child behaviour are well established as being impacted by cultural norms (Fox, Dunlap and Powell, 2002). As NVR does not follow a sanctions/reward perspective, CAPVA practitioners will explore these beliefs in more depth with the families to help challenge any practice that incompatible with NVR principles.

Theory of change: CAPVA programme

The CAPVA programme delivery centres around the NVR approach and is consistent with the principles of the New Authority (Omer 2004, 2011). Four overarching ‘elements’ have been characterised within NVR interventions: *presence, self-control, social support, and structure*. (Shimshoni, Omer and Lebowitz, 2021). The underlying concepts and principles drawn on within NVR are summarised in table one below and have been derived from Omer and Lebowitz (2016).

The model has been further developed within the UK by Partnership Projects (Jakob, 2016), including making more formal acknowledgement of trauma. The NVR practices adopted by RISE’s CAPVA practitioners are intended to create a safe family environment for trauma management by facilitating change processes in the larger system around the family. This

includes, but is not limited to, helping parents to request support from others instead of delegating their authority to critical, potentially prescriptive or coercive other adults. Other elements are drawn from psychology clinical practice including that neuropsychological and physical responses to trauma become entwined and that ‘the body keeps the score’ (van der Kolk, 2015). Techniques are then used that include helping parents identify their own physiological responses to other adults as a measure of emotional safety in communication.

Other principles from Jakob (2016) include providing and preparing the ground for compassionate and appreciative witnessing to take place. An example of compassionate witnessing would be enabling and facilitating parent/carers to name the violence, share their own distress and share their understanding of harm caused to everyone in and around the family. A potential forum for this being within a supporters’ meeting. An example of appreciative witnessing would be exploring with the parent/carer, accounts of what NVR actions they have taken. RISE practitioners would facilitate and encourage parent/carers to give these accounts of parental agency to potential supporters. This may also have the benefit that if others around the family see an adult increase their parental agency, then they are subsequently more likely to become safe supporters (*ibid*).

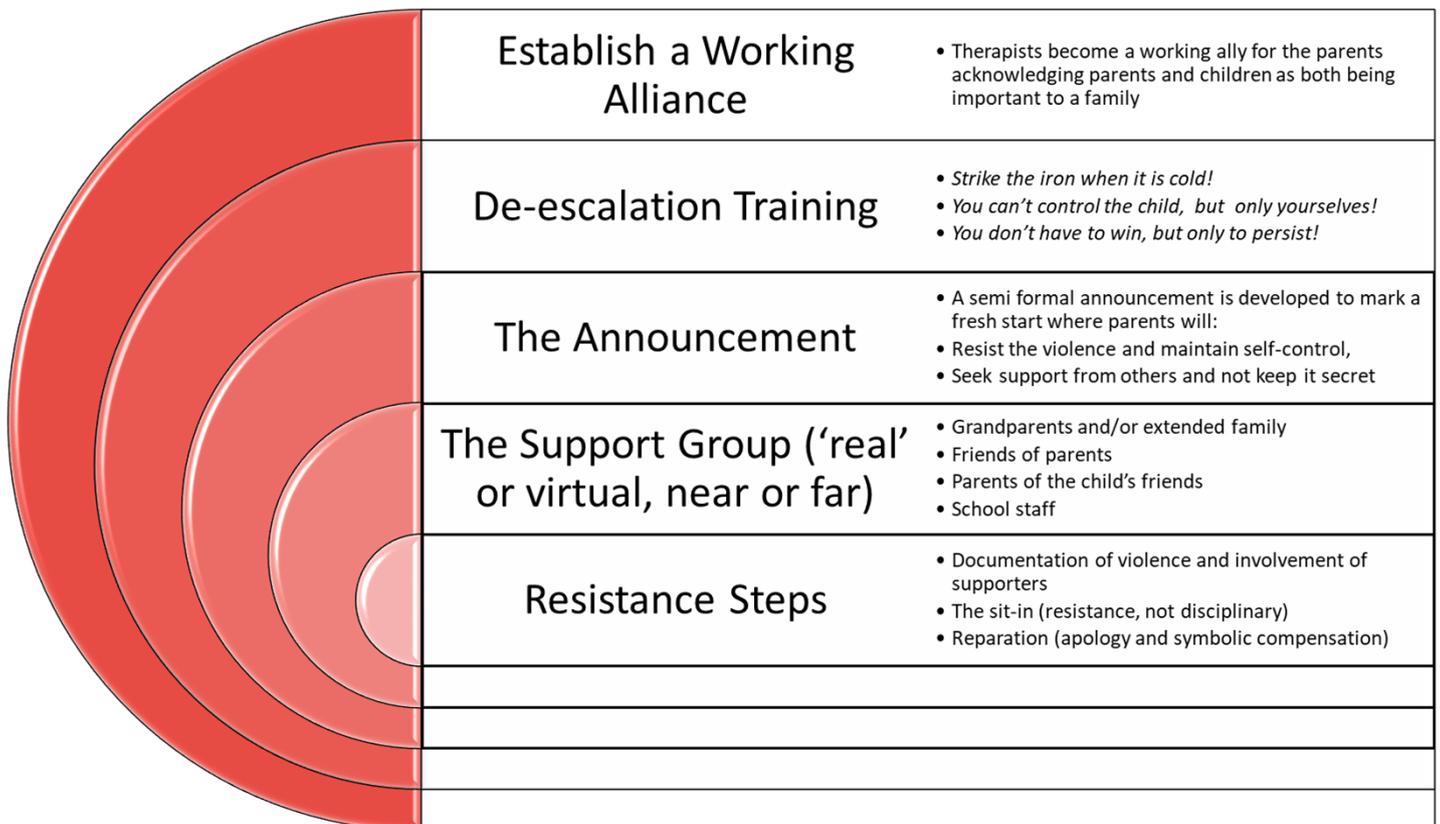
The UK adaptation of NVR also draws on the idea of ‘erasure’ (Dolberger et al, 2016, cited in Jakob, 2021) where people may become disconnected from their previous values, potentially losing some of their sense of self. Alongside this, families may lose touch with support networks and develop distorted images of how others perceive them. This kind of fracturing or disconnect is posited as being part of sustained psychological injury. Some trauma-focussed NVR methods include practitioners: helping parents to understand their traumatic responses and traumatic triggers, learning about parent/carers’ self-calming strategies, learning about parents/carers’ interpersonal calming resources and teaching grounding techniques. The key underlying concepts are summarised in Table 1.

Table 1: Underpinning concepts:- after Omer and Lebowitz 2016 p693-695

<p>Parental feelings of helplessness</p>	<p>Even if they are coercive or violent themselves, parents with children who are violent often feel helpless and may be tempted to vent their frustration in ways that can be inconsistent, and perpetuate the child’s aggression/domination</p>
<p>Escalation</p>	<p>Two forms of escalation are characterised within the model: <i>complementary escalation</i> is seen as when parental submission increases a child’s negative behaviours and <i>reciprocal escalation</i> is when “hostility begets hostility” (p693). De-escalation skills training is therefore a central part of intervention.</p>
<p>Reconceptualising power & control</p>	<p>Violence should be resisted in ways that are “rigorously nonviolent” (p693), with emphasis on resisting, rather than controlling children’s violence. This is designed to restore control through diminishing the sense of helplessness articulated above and reframing care where parents “don’t have to win, but only to resist” (p694)</p>
<p>Presence</p>	<p>Omer and Lebowitz provide the example of “choosing to be physically present in situations and locations where the child is at risk for destructive or high-risk behaviours” (p694) thereby maintaining authority while helping to reduce risk. Parents and carers learn to be present “while rejecting authoritarian practices based on fear or physical force.” This helps to establish authority without being authoritarian and minimises the likely negative reactions to fear and shame that the young person may be feeling. Improved, appropriate presence will also help the parent and carer themselves to be less fearful and less likely to retreat from the child.</p>
<p>Support, Openness & Transparency</p>	<p>Parents and carers are encouraged to draw on support from friends and family beyond the home. Being open is also designed to reinforce parents and carers’ own commitment to reducing their use of violence. The supporters act to reinforce parental approaches and can validate children’s feelings while still challenging the inappropriate behaviours, helping to make clear what is tolerable and what is unacceptable.</p>
<p>Respect & Reconciliation</p>	<p>Acts of respect and reconciliation acknowledge that the child is neither an opponent, nor is their behaviour unremittingly bad. I.e. this principle centres on the idea that there are things that can be celebrated about a young person’s life, even when they are sometimes being dangerous to others.</p> <p><i>The most common conciliatory steps are verbal or written messages of appreciation, small symbolic gifts, proposals of pleasurable joint activities, offers of small unrequested services, reminders of positive events from the past (without contrasting them to the more bleak present) (p695)</i></p>

Omer and Lebowitz (2016) also outline the typical treatment stages within NVR, these have been summarised in Figure 1 below. The materials drawn on by RISE are available on request but have not been appended to this published protocol due to commercial sensitivity.

Figure 1. The interlinked steps to NVR within CAPVA: after Omer and Lebowitz 2016 p695-6



The theory of change and associated approaches taken by CAPVA practitioners have been summarised into a logic model, which is slightly revised from that originally developed within the feasibility to pilot evaluation (Adler et al., 2023); it can be seen on the next page. In the logic model, the time allowed for completion of the intervention is taken to be between 9 and 11 months. In rare cases, families can complete the intervention in as few as six months, typically when they just engage in the minimum possible adult only 'dosage' of 12 sessions. Sometimes, the full 20 sessions can run for around a year; this includes the last one or two, optional sessions, which involve practitioner follow-up, after completion of the main intervention. In planning this evaluation, time has been allowed for a likely pause between assessment and delivery of the rest of the sessions to allow for engagement in the trial, completion of baseline outcome measures and allocation to BAU or intervention.

Table 2: Logic Model: RISE CAPVA programme

Problem statement	The programme seeks to change behaviours of 9-17 year-olds violence towards their parents. Behaviour manifests as violence and abuse within the family home, poor engagement in school, with subsequent poor attainment and increased risk of anti-social behaviours.		
Inputs	Deliverables and Short-term outcomes	Mid-term outcomes	Long-term outcomes
<ul style="list-style-type: none"> Up to 20 sessions with families (including up to two for initial screening and assessment and up to two for optional follow-up) Engage community and wider family to support the parent/carers and the child/young person; Brief lead professionals, community members and referrers in NVR. <p>Teaching NVR to parents might include: De-escalation skills to reduce risk; resistance and repair techniques; removing barriers (including punishments and rewards); building confidence; creating acceptance of the young person; helping build a relationship with the child before reinstating boundaries.</p> <p>Trauma informed CBT For children might include: Experiences of trauma, anger management and self-regulation techniques; decision-making processes; dealing with and recognising emotions; empathy; perspective taking & goal setting</p>	<p>Deliverables</p> <ul style="list-style-type: none"> Two family assessment sessions occur prior to programme delivery. Over somewhere around 9 to 10 months, parents/carers engage in at least 12 face-to-face CAPVA sessions, with 6 involving the CYP (if no engagement, parent/carers can receive sessions). Engagement in a minimum of 12 sessions (post screening/assessment) is posited to induce a reasonable therapeutic effect. Throughout the delivery phase, bi-monthly one-off online NVR training workshops are provided to key individuals supporting the family/young person (e.g. teachers, youth leaders and sport coaches). Briefing meetings held with a lead professional allocated to a family. <p>Short-term outcomes</p> <p>Short-term outcomes anticipated for the family and their network:</p> <ul style="list-style-type: none"> Whole family and community engagement with a consistent understanding of NVR principles within the network. 	<p>Intermediate outcomes for the child/young person include:</p> <ul style="list-style-type: none"> reduced violence; enhanced engagement with key individuals; improved emotional self-management; better behaviour. <p>Intermediate outcomes for parents, carers and/or the rest of the family are intended to include:</p> <ul style="list-style-type: none"> increased de-escalation skills; reduced feelings of helplessness; improved confidence; enhanced community support networks; reduced social isolation; improved wellbeing. 	<p>Longer-term outcomes related to the child are intended to include:</p> <ul style="list-style-type: none"> reduced offending; improved school attainment; improved community response to reducing violence and gang related activities. <p>It is also intended that key stakeholders – lead professionals, sports coaches and teachers – will be able to draw on acquired skills for other client work.</p>
Impact	Improved connective parenting, consistency and acceptance will be further supported by enhanced community and wider family ties to better enable the young person to manage anxieties, anger and frustrations, thereby reducing familial, child and community/social harms, including violence, abuse and anti-social behaviours.		

Intervention referral

Assuming that the trial goes ahead as planned, then intervention mobilisation will be for two months from September 2024. Referrals should start to come in by the end of October 2024 with delivery continuing until October, 2026. For this efficacy trial, the CAPVA programme will be compared against BAU. As described above, BAU varies in different boroughs and may also vary depending on the referred family's needs. Families are normally considered eligible for inclusion if they have a child or adolescent in the household aged 10-17 (or possibly aged nine) referred due to medium to high-risk situations where they have used verbal, financial, physical and/or emotional means to exert power and control over a parent/carer. The manualised exclusion criteria include: where a parent has a history of child abuse towards the child; where there is evidence of violence between the parents, such that they could not engage in joint parenting sessions; and if there is current domestic violence between the parents and the perpetrator is living at home (RISE, 2024). Project and evaluation teams will jointly deliver briefings on the intervention to referring boroughs, and prospective families to clarify information on suitability criteria for referrals and the reasons for the study. Information for referred families (potential evaluation participants) will be produced in accessible and creative ways (e.g. provision of a card with QR code/link to a recruitment video) and shared with referrers to support the recruitment process and ensure participants are fully informed. It is expected that 8-10 boroughs will make referrals, which are likely to be received from within children's social care and/or a borough's clinical services. Referrals will follow the usual RISE processes as far as possible where referrals are received by RISE and triaged, according to the inclusion and exclusion criteria, by the CAPVA programme team leader. An allocations meeting is held, and the team leader subsequently begins allocating families to practitioners for screening and suitability assessments (see next section). For the trial, an additional amendment will be that the RISE practitioner triaging referrals will contact eligible families to remind them of the purpose of referral, i.e. to potentially join a trial.

Intervention screening

To determine suitability for the intervention, and thus trial, RISE Practitioners will interpret the screening tool (RISE, 2024, excerpt in [Appendix 3](#)) alongside data received on the family through a referral report and other sources of information (such as multi-agency meeting minutes and/or reports from statutory services, including children's social care, the police, CAMHS). The data used to assess suitability alongside the screening tool includes frequency and severity of family violence. During assessment, this data is drawn on by the practitioner to assess which areas on the screening tool require further exploration with each family. Referral information does not always fully reflect the families' dynamics and complexities of their circumstances yet the practitioner needs to explore these areas and assess such information alongside the screening tool. So, additional information is sought as part of initial screening. The practitioner makes a reflective judgement, based on the referral data and the parental responses to the screening tool. The practitioner then sets out a therapeutic plan based on their clinical judgement; this plan maps out the focus of each session, who the practitioner will work with, in what ways they may need to individualise the work, and when they may begin work with the CYP. Judgements made from the point of screening to formulating a therapeutic plan are

discussed with the lead practitioner: Practitioners complete a post-assessment suitability and intervention planning report for the team leader to review and sign off. Under usual conditions, families are then contacted regarding their suitability and practitioners will begin arrangements for the sessions. Practitioners will also confirm the start date and intervention plan with referrers. For the trial, this step will be revised to allow families to receive further information about the trial (including what will happen to them in control or intervention arms), decide whether or not to join the trial, complete baseline outcome measures and then for random allocation to be made.

Intervention delivery

The intervention is delivered by CAPVA practitioners or for more complex cases, an advanced practitioner (AP). Practitioners are required to complete Foundation Level 1 training in NVR and APs complete advanced NVR training at levels 2 and 3. All training is provided by Partnership Projects.³ The intervention is delivered to families by CAPVA practitioners who are trained to lead NVR sessions and support families to develop the skills and knowledge necessary to apply NVR techniques. All CAPVA practitioners have experience in delivering trauma-informed work with families and/or in work on domestic abuse interventions or case work. Practitioners may hold qualifications in social work, advanced NVR, probation work or cognitive behavioural or family therapies. APs are similarly qualified to CAPVA practitioners but may hold additional qualifications in forensic and/or clinical psychology. An AP will have experience of delivering and quality assuring interventions to people with complex issues. The AP currently oversees a caseload of 70% of families; this oversight involves direct work with the family, acting as a mentor to the assigned CAPVA practitioners, and conducting specialist risk and practice reviews. All practitioners delivering the intervention are line managed by the team leader, ensuring practice standards are achieved and providing general oversight of the intervention.

The RISE Practitioner works with parents first, on developing strategies to raise parental presence and reduce the risk of violence using de-escalation and resistance techniques. Refusing demands and re-setting boundaries are focussed on during the later stages of the intervention. This combination of approaches is designed to facilitate change in the young person's behaviour. Parental skills are intended to develop gradually with intense support, moving from training and role modelling, enacted with therapist support, to independent practice. Parental barriers to managing the child's behaviour are addressed. As parents and carers succeed in supporting change within the home environment, efforts are made to address contributory factors such as deviant peers and investigating the possibility of reintegration into mainstream education.

CAPVA practitioners often see parents present with constraints to *how* they care for their children. One example being a negative internal representation or image of the child (Jakob, 2019). Using the NVR model, it is intended that CAPVA practitioners work with parents to see an improving child,

³Partnership Projects are an established training provider for professionals delivering NVR (for further information visit: www.partnershipprojects.uk.com).

focussing on the child 'as they are in the present' and coach parental resistance methods to potentially dismissive behaviour from the child, this is designed in turn, to protect parents from triggering negative interpretations in the child or young person.

Work with parent/carers is grounded in NVR. If they subsequently engage, then work with CYP adopts a flexible skills-based approach using trauma informed care alongside CBT techniques and mindfulness. Using CBT to support children displaying PTSD is within NICE guidelines (2018) and generally draws on the model developed by Meiser-Stedman (2002). 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 an alternative to provision where parenting courses are based on a punishment/reward approach, encouraging parents to 'take control'. The CAPVA intervention focuses on improving connective parenting, consistency and acceptance, taking the stance that problems within the family can only be resolved through a consistent whole family approach, working with parents, young people and siblings (Weinblatt and Omer, 2008).

The CAPVA programme can be delivered in the home, community or family hubs and practitioners can attend other locations as needed to support the family. One or more parent or carer can participate, and work can be individual, joint, whole family or a combination of these delivery modes. Delivery to any one family spans up to 20 sessions, which include two screening and assessment meetings preceding formal delivery and two optional follow-up sessions. At least 12 programme sessions are with parents/carers and up to 6 sessions are with the CYP, including a joint session. For a minimum treatment effect, at least 12 programme sessions should be completed at a frequency of every two weeks at most. CAPVA practitioners employ techniques to encourage CYP engagement; however, should a CYP not engage, remaining sessions can be used to continue to support the rest of the family (RISE, 2024).

Intervention tailoring

The intervention is highly individualised with sessions tailored for families according to the identification of any needs, risks, and vulnerabilities during screening. For example, work with some families may involve using different principles of the NVR model at different times depending on their needs. For example, one family may need to focus on self-care as a starting point to raise their own parental presence, whilst another family, whose patterns of escalation are symmetrical, may need to start with self-control and anchoring functions before they are able to de-escalate effectively (see [theory of change](#) for rationale behind approach).

For work with a parent who is a survivor of IPVA, the CAPVA practitioner assume a strengths-based approach to recognise the developed strengths and/or acts of resistance relating to times when the IPVA was prevalent. Accordingly, practitioners may identify that the parent worked hard to care for their child(ren)'s physical and emotional safety, their basic needs and to maintain as safe, stable, and nurturing an environment as possible during the abusive relationship. Helping survivors to recognise

these strengths involves helping them to identify the steps they took, even if the perpetrator thwarted their efforts or they had not previously acknowledged their own efforts.

When it has been assessed that substance misuse is present, but the parent may be able to function adequately to begin the intervention, practitioners explore the positive intentions of the parent and their use of drugs or alcohol as self-medication. Solution-focussed methods will be used to explore alternatives to substance misuse when a parent is coping with trauma that has been triggered by the child's violence. For example, practitioners will support parents to understand their own triggers and trauma responses to develop self-calming techniques early on, help reduce anxiety and develop self-efficacy.

Where CAPVA is present, CYP may sometimes use self-harm and suicidal ideation, as forms of coercive control that can result in an escalation or withdrawal from parents. Practitioners apply the same methods regardless of whether the child is seen as saying such things coercively, demonstratively, or genuinely. Practitioners support the parents to respond with increased vigilant care, while encouraging them to inform their child of the vigilant care actions they will be taking and why. Practitioners will also respond to identified risks outside the home for the young person, such as exploitation, by focussing on increasing support networks and vigilant care among parents.

Efficacy evaluation

Research questions or study objectives

Primary research question:

1. What is the efficacy of the RISE CAPVA programme in reducing child/adolescent to parent violence and abuse when compared to BAU?

Secondary research questions:

2. Does the RISE CAPVA programme lead to:
 - a. Reduced problematic internalising behaviours?
 - b. Reduced problematic externalising behaviours?
 - c. Reduced family conflict?
 - d. Improved family relationships?
3. Are there variations in outcomes (CAPVA and other behaviours) by intervention recipient type, specifically parent only delivery of the intervention compared with whole family engagement?
4. Are there variations in outcomes (CAPVA and other behaviours) by family ethnicity (broadly defined)?

The trial design is summarised in Table 3, below.

Table 3: Trial design

Trial design, including number of arms		Two-armed randomised controlled trial with allocation to BAU/intervention post consent and concurrent triangulation via the IPE
Unit of randomisation		Family
Stratification variables (if applicable)		Gender of referred child: male; female; non-binary Age of referred child: under 12; 12-17 Ethnicity: Asian, Black, Mixed, White, Other
Primary outcome	variable	Extent and severity of child to parent violence
	measure (instrument, scale, source)	ABC-I (Simmons et al. 2019)
Secondary outcome(s)	variable(s)	Problematic internalising and externalising behaviours
	measure(s) (instrument, scale, source)	Strengths and Difficulties Questionnaire (SDQ) (Goodman 1997) parental report; emotional, conduct, hyperactivity, peer problems and impact subscales.
Baseline for primary outcome	variable	Extent and severity of child to parent violence and abuse (implemented post-screening and consent)
	measure (instrument, scale, source)	Abusive Behaviour by Children Indices (ABC-I), parental report, full scale (Simmons et al. 2019)
Baseline for secondary outcome	variable	Perceived difficulties of the young person, assessed by parents (implemented post-screening and consent)
	measure (instrument, scale, source)	SDQ parental report.

Randomisation

Following referral from the relevant local authority, families (starting with parent/carers) will be screened for eligibility into the trial by RISE practitioners, over a maximum of two sessions, this will include provision of information about the trial. To determine inclusion into the trial, RISE practitioners use their clinical judgement in interpreting the screening tool (see intervention screening). For the evaluation, one parent will be the nominated respondent to complete outcome measures.

Families that have been assessed as suitable for the RISE CAPVA intervention, have consented to take part in the trial, and completed the baseline assessments will then be randomised with a 1:1 allocation ratio to either the RISE CAPVA intervention (the intervention arm) or business as usual (the BAU arm). Brennan et al. (2022) also provide data to inform why it will be important to consider potential effects of age, gender and ethnicity. Older, or grown-up children tended to be reported to police more than younger children; boys were more likely to be reported for incidents than girls; women more likely to be recorded as victims than men and families from minoritised communities were more likely to be recorded in the MPS dataset. These British findings are consistent with those from elsewhere, including in Canada where Cottrell (2003) highlighted the importance of puberty as being a potential phase when violence starts or becomes more problematic. Please also see [diversity, equity and inclusion](#).

Therefore, allocation will be by minimisation using Taves' method (Scott et al., 2002), using the child's age (under 12, 12-17), gender (male, female, non-binary), and ethnicity (Asian, Black, Mixed, White, Other) as factors. The randomisation process will be managed online via the evaluation database (REDCap). Once a family has consented to take part in the trial and completed baseline assessments, REDCap will trigger an alert to the evaluation team members with necessary access permissions. An allocation for that family will automatically be generated. The allocation code, along with the family study ID will be emailed to the agreed specified point of contact (within RISE and/or each borough) and the trial manager. The specified point of contact will inform the families of trial arm allocation by telephone.

Participants

Within this trial, there is the intention that at least 188 families will complete outcome measures from each arm (control-BAU provision; and intervention-RISE CAPVA programme). At this stage, it is not possible to be sure of the proportions of families based on demographic characteristics of the young people referred. However, within the YEF community portal, RISE have indicated likely proportions based on previous work in some of the proposed boroughs. The predicted rates of referral and timeline for enrolment into the trial (Appendix 5), have also been based on RISE staff's previous experience of delivering the programme in and around London. Please see [diversity, equity and inclusion strategy](#) for ways in which outreach and engagement to increase both representativeness and diversity of the participants will be promoted.

More information is provided in the sample size section below on the numbers of families to be screened (705) and sought for initial enrolment to allow for attrition to 188 in each arm (235 families initially recruited to each arm). If successful in recruiting 470 families to the trial, then theoretically, the maximum potential participant number in the efficacy evaluation and IPE would be 940, that is 470 parent/carers and 470 children/adolescents. The predicted final numbers are thought to be closer to 376 parent/carers for analysis of primary outcome measures and 25-50 children/young people participating in surveys within the IPE. The outcomes focus is on the comparisons of parent/carers' reports of the CYP behaviours over time and between arms of the study. CYP voices will be more

directly heard via surveys and interviews within the IPE (see [implementation and process evaluation](#) and [ethics and registration](#)).

Sample size calculations

In the feasibility to pilot evaluation, both the measure of violence⁴ and the SDQ showed considerable change with effect sizes greater than 1, using Cohen's d. However, there was no counterfactual in the feasibility to pilot evaluation so there is not an indication of the likely between group differences to expect. This may be further complicated by the reality of there being multiple types of BAU against which the RISE intervention will be compared. It is also assumed that the awareness of being observed and/or some element of novelty introduced by the evaluation, may have some influence on the families in the control group and the practitioners providing the BAU interventions, and that the group difference will be smaller than the observed change over time.

No published norms were found for what would be an expected, or typical, effect size observable in CAPVA interventions. In estimating the required sample size, a specific group difference has not been considered, due to uncertainty regarding differences in provision of BAU between boroughs and how much influence will be brought to bear by either novelty or the awareness of being observed.

The following concerns were considered when estimating the effect size: On the original CAPVA measure, if it is assumed that the correlation within participants is $r=0.7$, with a standard deviation of 13.8, this would give an effect size in excess of $d=5$ (Chow, Wang and Shao, 2008), which is unlikely when two independent groups are compared. Based on the same data, the minimal detectable change is 7.04, which is also in the same range (Kovacs et al., 2008). The total scale score for the new measure (the ABC-I) is 54, meaning that a group difference of between 4 and 5 points equates to between 7.4% and 9.3% of the scale range, which is generally recognised as a reasonable limit for meaningful change in a scale. This would equate to a group difference of 5.18 for an effect size $d=0.4$ and 3.89 for an effect size $d=0.3$.

These considerations initially led to the conclusion that a suitably conservative minimum detectable effect size (MDES) would be 0.3. Using the commissioner's preferred MDES of 0.2 would require a sample size close to twice that required for an MDES of 0.3. Given the evidence that the MDES is likely to be larger than 0.2 (N=788), exposing an additional 400 families to a randomised trial with an untested intervention would be unethical. The somewhat rigid interpretations of quality regarding MDES are also noted in the YEF rigour assessments and these led to a modified position that working with an MDES of 0.29 is essentially similar enough to 0.3 from the perspective of the calculations above, but would have the benefit of increasing the 'padlock rating' from three to four without a substantial increase in the required sample size, thereby posing less of an ethical dilemma. The agreed

⁴ Originally designed for the Responding to Child to Parent Violence project, funded under EU DAPHNE.

MDES from the co-design phase is now 0.29. All estimation was undertaken using STATA 15.1 (StataCorp LLC), see [Appendix 4](#).

Allowing for an effect size of 0.29, with power $1-\beta=0.8$, the required sample size is $n=188$ families per arm, and $n=235$ per arm allowing for 25% drop out, giving $N=470$ families in total. A 25% dropout has been taken as likely, given the response rates from feasibility to pilot and in acknowledgement of the severe circumstances faced by the referred families. Those circumstances also mean that it is seen as being unlikely that all referred families will agree to participate in a research trial. When that is considered alongside the routine considerations regarding whether or not a family is suitable for the intervention, it is estimated that it will be necessary to screen 705 referred families to gain the baseline sample of 470 families. See [Appendix 5](#) for the quarterly target and predicted rate of recruitment. For the stipulated power, the minimum intended sample size for outcomes assessment is 376 parents/carers. The sample size calculations required for primary outcome analyses are summarised in Table 4.

Table 4: Sample size calculations

		PARAMETER
Minimum Detectable Effect Size (MDES)		0.29
Pre-test/ post-test correlations	level 1 (participant)	0.7
	level 2 (cluster)	NA
Intracluster correlations (ICCs)	level 1 (participant)	NA
	level 2 (cluster)	NA
Alpha		0.05
Power		0.8
One-sided or two-sided?		Two
Average cluster size (if clustered)		NA
Number of clusters	Intervention	NA
	Control	NA
	Total	NA
Number of participants	Intervention	188 families (1 nominated parent/carers for each referred CYP)
	Control	188 families (1 nominated parent/carers for each referred CYP)
	Total	376 families

Outcome measures

All referred families will be screened for suitability by RISE practitioners (see intervention screening). The screening is conducted alongside initial assessment. Where families agree to join the trial, additional measures needed for the trial, that would not otherwise be used, will be provided for baseline measurement. This will need to be after consent but prior to randomisation and delivery of any (more) programmed sessions with families.

Baseline measures

At baseline for the trial, parents and carers will be asked to complete the ABC-I (Simmons et al., 2019) and SDQ (Goodman, 1997) see primary and secondary outcomes below.

Primary outcome

The primary outcome is child/adolescent to parent/carer violence and abuse, assessed pre- and post-intervention, measured with the ABC-I (parent report), for those in the intervention arm compared to those receiving BAU at completion of the intervention/BAU.

Secondary outcomes

Please note that for the secondary outcomes listed below, information will be collected via the parent-report versions of measures. Again, this will be pre- and post-intervention--comparing those in the intervention arm to those receiving BAU, at completion of the intervention/BAU.

- *Reducing problematic internal behaviours*: the internalising behaviour score of the SDQ (sum of the emotional and peer problems scales);
- *Reducing problematic external behaviours*: the externalising behaviour score of the SDQ (sum of the conduct and hyperactivity scales);
- *Reduced family conflict*: assessed using routine measures from the RISE CAPVA manual (RISE, 2024);
- *Improved family relationships/Family functioning*: Measured through the SDQ impact supplement.

Monitoring data and measures

Demographic and family status data

In line with YEF guidance on demographic data collection and requirements of the trial design, current age (years), sex, gender, looked after status and ethnicity (Asian, Black, Mixed, White, other) will be collected for all CYP in the participating families. Free school meals eligibility will be recorded as a proxy measure of socioeconomic status. Additional variables collated for both CYP and adults will include whether English is an additional language. For data archiving, the CYP name, address, and full birthdate will be required and held with restricted access (see also [data protection](#)).

Family status data is intended to incorporate demographic factors, e.g. family make-up, ages, ethnicities, income, and indices of deprivation (based on postcode). Family status will always be recorded in collaboration with the family and where necessary, supported by referrer data:

1. Family involvement with social services, youth offending services and other statutory and non-statutory services, including removal of children from a family during the evaluation;
2. Recorded incidents of abuse and/or neglect;
3. CYP school/alternative provision attendance;
4. New access to health services (physical or mental) requiring admission or extended outpatient engagement;
5. Eligibility for free school meals (a common proxy measure for socio-economic disadvantage);
6. Family adherence to intervention ('length-of-treatment'), captured through a log and evaluated as attendance at scheduled sessions;
7. Differences between intervention recipients (parent only or whole family engagement), captured through a log and evaluated as attendance at scheduled sessions;
8. Adverse events: A process for reporting, recording and responding to adverse events, for completion whenever occurring, while the family is actively participating in the efficacy trial:

The trial's tools will be designed to facilitate self-report of adverse events by participants. Family members will still be able to discuss adverse events with their assigned or referring practitioner, but those practitioners will be asked to direct the participants to complete the relevant REDCap self-report form. This will avoid potential duplication of adverse event reporting. Furthermore, information will thereby be provided directly from the person concerned avoiding potential skewing from practitioner interpretation. Although the form will be self-report, practitioners and the embedded RA will be available to support completion, if needed.

The information provided to participants will include a plain English definition of what should be recorded as an adverse event and how it differs from events routinely being observed, i.e., adverse events are not related to violence or abuse directly towards the parent or carer. A prompt for adverse events will be added to data collection requests as well as a (participant specific) ongoing log which participants can access. To further ease this process, specific examples will be provided and the prompt will be set up with a free text field.

Any recorded events will be set to prompt an automated email to the trial email address to say PIDXXXX has reported an adverse event for review. That email address will be monitored only by those members of the team who have governance and/or trial leadership roles. Then, the team member can go into the database, review the information, respond, and/or escalate

accordingly. An automated email will also be sent to the participant to acknowledge that this information has been sent to the trial team who will review the report and respond accordingly; this will include signposting links for external support.

Young people's characteristics

In the feasibility-pilot study, several challenging behaviours were noted without formal screening/diagnoses. To assess some of the most relevant behaviours associated with neuro atypical young people, the Extreme Demand Avoidance eight item measure (EDA-8) (O'Nions et al., 2021) and the Glasgow Sensory Questionnaire (Robertson and Simmons, 2012) parent report, short version (Smees et al., 2022) will be used. The intention is that these measures will be completed post-screening by the parent or carer; if possible, as part of baseline measurement after consent has been given. As these measures are only implemented once, they can be completed after randomisation if preferred. These measures will permit subsequent analysis of potential differential responses that could be attributable to relevant CYP characteristics.

Additional measures

Please see cost data reporting and collecting for information about practitioner logs of activity that will be designed. These logs of activity will also include the three items of the Clinical Global Impressions Scale (CGI; Busner and Targum, 2007) to capture practitioner insights into families' change over time. Lastly, for additional explanatory information regarding family functioning, it may be possible to draw on practitioner assessments that are routinely collected as part of the RISE CAPVA programme.

Selection of measures and links to logic model

It is recognised that young people may be particularly hard to recruit to the study and to engage in any intervention directly. It is also recognised that CYP may feel shame and stigma around the behaviours triggering referral. As such, it is felt that burdens on them should be minimised with as little as possible additional data collection being sought, beyond that required for intervention. Conversely, it is also felt important to hear from them about their experiences and to amplify the voices of those CYP who may want to participate in the evaluation, whether or not they engage directly with intervention. On balance, it has been agreed that no outcomes measures will be requested but there will be additional efforts made to incorporate CYP within the IPE (see [ethics and registration](#)).

For the feasibility to pilot study, RISE were using a measure of CAPVA designed under the EU DAPHNE strand of work-as part of the Responding to Child to Parent Violence project (RCPV). Although tested as part of RCPV, it has not yet met necessary validity tests for commissioner-approved continued use. When designing this trial, it was possible to draw on a slightly more developed literature base than was available in 2019. Of particular relevance was the Ibabe review of measures (2020), which identified three potentially suitable tools, as the best validated and most applicable to both research and practice. Each of these tools has a degree of overlap about how potentially violent, coercive or

otherwise abusive behaviours may manifest from adolescents but they are different in whether they seek to contextualise such behaviours and if so, how. All have versions for use with parent/carers.

It was initially proposed that The Child to Parent Violence Questionnaire (Contreras et al. 2019) be adopted as the most comprehensive of the three tools in assessing types of violence and encouraging respondents to report how far/whether the CAPVA can be seen as being in response to others' behaviours. During the co-design phase, it became clear that the wording of the tool and the additional complexity introduced by the measures of context made it feel unwieldy to practitioners and to members of the YEF youth advisory board. It was also noted by practitioners that none of the potential measures consider possible influences of social media within the contextual explanations.

Through the co-design process, it was settled instead that the Abusive Behaviour Checklist Indices (ABC-I) (Simmons et al. 2019) be adopted as the measure of violence, another of the three drawn from Ibabe, 2020. This tool does not provide any direct measure of context but does break down forms of violence further than the alternatives. It is also the only one of the three tools that has been explicitly published alongside a companion tool-the BACPAQ-designed to be used to reset scoring thresholds for cultural relevance (Simmons, McEwan and Purcell, 2019). It will be beyond the scope of this trial to establish norms within the differently racialised and/or minoritised groups in the trial. However, this could be a useful planned follow-on set of studies and the items from the BACPAQ can be drawn on to inform the IPE. It should be acknowledged that the ABC-I was the only one of the three measures recommended by Ibabe (2020) without directly published comparisons that would have made it suitable for inclusion in a more recent meta-analysis centred around internal consistency (Burgos-Benavides et al., 2023). It can still be seen as a well-validated measure and as Burgos-Benavides et al. acknowledge (2023), any measure used should be seen as suitable by, as well as for, the potential research participants, hence testing the measures' appeal with practitioners and the advisory board and the intention to further refine materials with participatory group involvement.

The first secondary outcome measure will help assess both the impact of NVR techniques adopted by the parents/carers and direct work undertaken with children and adolescents, particularly the CBT informed trauma support. The Strengths and Difficulties Questionnaire (SDQ) (Goodman, 1997) provides a total score to assess problem behaviours (the difficulties), alongside subscale scores. Of the five standard subscales, this trial will draw on the four needed for internalising (emotional and peer problems subscales) and externalising behaviours (conduct & hyperactivity scales). There is also a supplemental impact sub-scale which is appropriate.

The main addition to acknowledge diversity of neurotypes is the EDA-8 (O'Nions et al., 2021). This is a short test, used mainly for research purposes to help screen for oppositional defiance disorder (ODD) and pathological demand avoidance (PDA). PDA and ODD may present similarly disruptive challenges for parents but they should be managed differently and this is partly why additional attention is being paid to the relatively high proportions of neuro untypical children and young people likely to be referred to the CAPVA programme. The assessment of sensory difficulties is also relevant and will be measured using the shorter parent-report version of the Glasgow Sensory Questionnaire (Smees et al.; 2022).

The protocols for practitioner logs of activity will also include the three items of the CGI (Busner and Targum, 2007). These will be slightly modified to reflect that the intervention is a programme of activity, not a drug. These short questions are designed to capture practitioner insights into the severity of families' needs, whether there is any improvement and the extent to which they ascribe any change to the intervention.

The logic model acknowledges other forms of anti-social, potentially criminal behaviour, beyond the CAPVA in the home, but it is not recommended that the trial adopts the YEF-preferred self-report measure of delinquency (McVie, 2007). This was dropped, with YEF agreement, during the feasibility-pilot evaluation and is likely to feel intrusive and additionally shaming to young people. It is recommended instead that additional data on potential offending be gathered via practitioners working with the families as part of the "family status data" outlined above.

It is intended that all scales will be used in their validated forms, with no amendments apart from two slight amendments to the ABC-I. The ABC-I asks respondents to report what has happened in the previous 12 months. However, as support provided is likely to have lasted less than 12 months and to vary, it is proposed that at intervention completion, trial participants who are asked to complete the ABC-I will be asked to report on activity "over the past three months". Also, the word "check" will be changed to "tick".

Another adaptation that will be made relates to how measures are presented. This is not just about them being moved into REDCap surveys but is also intended to make them feel as accessible as possible. For instance, although the Likert scales will be kept with the same items and anchors as in validated measures, how they appear in an electronic survey can be altered to make them as appealing and accessible as possible. Similarly, the evaluation team will provide contextual guidance around each of the scales used, to give relevant examples of how they may be interpreted. This will be done to assist in self-completion and in ways designed to minimise potentially leading responses. The UH ethics procedures and participatory groups will assist in refining such adaptation.

Data collection

For baseline and follow-up outcome measures, parent/carer participants will be sent an email link, automated via the trial database software's survey tool. All measures will be completed online and responses captured on REDCap. Baseline surveys will be sent post-consent, pre-randomisation, with follow-up surveys automatically sent to participants either at completion of the intervention or 11 months following suitability assessment. It is estimated that completion of the CAPVA intervention (without optional follow-up) will typically be around 10 months, so this will be matched within the control arm. If people drop out of either arm, or complete early, they will still be sent the post-intervention measures at 10 months following suitability screening. This is intended to be 10 months plus or minus a month as requests for outcome measure completion will begin at nine months, post screening and be repeated weekly, with offers of assistance from the embedded research assistant for up to two months.

The decision on automation and timepoints will be reviewed and may be refined further as part of the statistical analysis plan and after routine monitoring of data has begun. Monitoring and additional data will also be collected on REDCap, using a combination of surveys designed for practitioner completion (e.g., demographic data) alongside information provided directly from families (e.g., family status information).

Participant information documents will provide families with contact details of the trial manager should any questions or difficulties arise on the measures. Both the embedded research assistant and trial manager will work closely with the delivery teams to support participants in completing measures. Depending on their preference, participants may complete the surveys independently, or be supported by CAPVA practitioners or a member of the evaluation team. This might involve helping to administer questionnaires directly, either during a visit to the family home or by telephone. RISE staff and key practitioners in the BAU arm, will receive training on data collection and the use of the online system.

Compliance/adherence

As described in the theory of change, parent/carers will receive at least 12 intervention sessions, post screening. CYP will be offered up to six sessions, which will be transferrable to parent/carers if the CYP do not wish to engage. Compliance can be defined as parent/carers completing at least 75% of the number of sessions intended for their completion, as recorded by the allocated caseworker. Non-compliance can be through missing sessions intermittently or regularly across the treatment period, or by withdrawing from the programme early. The number of families failing to attend scheduled appointments will be estimated, with the number and proportion of missed appointments and assessment sessions at each time point described.

In assessing adherence to the intervention, a little less conservative threshold will be used. Adherence will be defined as an overall proportion of appointments missed for each family and the proportion of families attending at least 66% of treatment sessions. Characteristics of families that do and do not complete the programme will be tabulated and differences highlighted.

A cut off of 66% will be taken to ensure that the analysis captures more of the families who do engage, but just miss the 75% cut off. This will also help to clarify the extent to which attendance does influence the potential efficacy of the intervention. The choice of limits to define adherence is a difficult challenge for evaluations, but most studies have limits between 66% and 75%. In general, limits can be defined by the intervention team, which makes a judgement about the minimum number of intervention sessions that should be attended to achieve a reasonable therapeutic effect. However, this is only informative where clients are required to attend a high proportion of available sessions to achieve the desired intervention outcome.

In practice, adherence determined in this way tends to have a biphasic distribution; that is, clients tend to attend therapeutic sessions or not, and attendance is either very low or greater than two-thirds. By using a 66% limit, the analysis allows for measurement error (Midgley et al. 2018). This also means

that if non-adherence is a significant issue, it can easily be detected and flagged (see also CACE analysis below).

Analysis

CONSORT flow chart and baseline assessment

Summary statistics (number, percentage, means and standard deviations or medians and interquartile ranges as appropriate) will be estimated. The flow of participants through the study will be presented in the CONSORT flow chart to evaluate the flow of families from referral, through screening and consent, to randomisation and implementation of intervention/BAU. The number of families/CYP referred to the programme, recruited, and the number who dropped out will be reported by age, sex and ethnicity, in line with YEF guidance.

Family characteristics and measures collected at baseline (ABC-I, SDQ, EDA-8 and the Glasgow Sensory Questionnaire) will be estimated by intervention group. No statistical tests will be performed to assess baseline balance, since any differences at baseline will be due to chance (Schulz et al., 2010). Baseline differences in participant/family characteristics between referral boroughs will be assessed using appropriate statistical methods (e.g. t-tests).

Evaluation of efficacy

All evaluations will report the relevant test statistic (e.g. t , r , χ^2) along with the observed probability (p). Where the threshold for a significant difference is not met ($\alpha=5\%$) the power of the test statistic ($1-\beta$) will also be reported to aid interpretation.

In line with YEF's analysis guidance, on an 'intention to treat' (ITT) basis, the efficacy of the intervention will be estimated by the difference in the primary outcome (CAPVA measured on the ABC-I) between the intervention and BAU trial arms at completion of the intervention (10 months plus/minus a month from suitability screening). The differences will be estimated along with the effect size (Cohen's d) and 95% confidence intervals. The secondary outcomes (internalising and externalising behaviours, family conflict, and improved family relationships) will also be evaluated for differences between the trial's arms. Regression models will be used to compare differences between the study arms in outcomes for families at the end of the intervention.

Subgroup/Exploratory Analyses

The study will not be powered for subgroup analyses. However, exploratory analyses will assess differences between subgroups, focussing first on those for which stratification was made: gender (male, female, non-binary), age (under 12 years, 12 years and over) and ethnicity (Asian, Black, Mixed, White, Other). Where possible, relevant IPE questions answered by CYP will also be used in sensitivity analyses to explore how family engagement affected parent/carer reported CAPVA outcomes.

Where additional information has been provided, additional exploratory analyses can be conducted, if appropriate. For example, looking in more granular detail at the ethnic or cultural heritages, or

socioeconomic status (using free school meals eligibility as a proxy measure) of families in the study or considering differences between delivery to parents only in comparison to whole family engagement. Where CBT techniques or mindfulness strategies are offered, differential effects will be explored if possible. The number of sessions attended will be considered, to differentiate between those who completed early due to successful intervention and those who dropped out of the intervention and/or evaluation. The reasoning behind considering these analyses includes the general literature that supports the clustering of disadvantages such as low household income, mental health and physical wellbeing that can all act to compromise intervention engagement and outcomes when not tailored sufficiently (see [diversity, equity and inclusion](#)). It also acknowledges the importance of exploring additional granularity and the need to avoid pitfalls such as ignoring differences between minoritised groups (e.g. The Centre For Social Justice, 2020).

Where possible, GLM and/or multilevel models will be used to account for the data structure in exploratory analyses. For GLM models, fixed effects will be used in line with the principle of estimating the efficacy of the intervention (and efficacy design). Adjustments will be made for baseline status and family characteristics (including socioeconomic status), as appropriate. Differences by referral source will also be considered, to reflect potential variation in BAU across boroughs, and where possible, the type of BAU offered. Group means (or medians) will be reported, and comparison between the study arms evaluated using regression models or more simple group comparisons (e.g., t-test). As the analysis is exploratory, and underpowered for these exploratory analyses, no adjustment will be made for multiple comparisons. Additionally, it is noted that while the sample size may be suitable to observing patterns, it will be important not to over interpret from potentially very small sub-group analyses. Thus these exploratory analyses will be further supplemented within the IPE, which will include qualitative, more participant-centred approaches, to elicit experiential data.

As further exploratory analysis, the complier average causal effect (CACE; Connell, 2009) will be estimated by comparing the primary CAPVA outcome (measured using the ABC-I) for those families who complied with the intervention against those in the control group (BAU) using analytic methods described above ('Evaluation of efficacy'). Compliance will be determined by participant completion of the minimum dosage of 12 parent/carer sessions ([Theory of change: CAPVA programme](#)), posited to induce a reasonable therapeutic effect. In addition, descriptive statistics will compare intervention 'compliers' with 'non-compliers' to identify any patterns.

Missing Data Strategy

Incentives will be offered to families for data completion, data collection will be monitored throughout the trial, and reminders sent to families. If needed, nudges will also be made to practitioners; for example, to remind them about missing characteristic information for collection during screening. Nonetheless, there may still be missing data, in which case YEF guidance for handling missing data will be followed.

Missing data patterns will be explored for outcome measures across both trial arms and to assess whether any systematic differences exist. The extent of missingness will be established, and the

number of complete cases reported. Missing data will be considered with potential mechanisms (missing completely at random [MCAR], missing at random [MAR]), missing not at random [MNAR]), which will be explored using logistic regression. Where appropriate, the variables predictive of non-response will be identified. If missing data is less than half but more than a trivial amount (5%) and the data are not MNAR, then multiple imputation using the Multivariate Imputation by Chained Equations (MICE) procedure will be performed, with the imputation model containing at least those variables in the analytic model. Further details will be included in the statistical analysis plan. Sensitivity analyses will compare results to those from complete case analyses.

Interim Analyses and Stopping Rules

Although recruitment and data completion will be monitored throughout, no interim analyses are planned, since the pilot study found no indication of significant harm coming to the families due to the intervention. Therefore, there will be no stopping protocol in place. See [project oversight](#) for more information on safety processes.

Longitudinal follow-ups

Outcome measures will be assessed at baseline and completion of the intervention. The decision was taken during co-design to drop interim measurement as completion and follow-up post-completion had been considered the most important by research and project teams who both wished to reduce burden on the families. Following review by the YEF, an additional decision was taken to drop follow-up, post-completion. The sole outcome measure of change is now at completion.

The evaluators will deploy several strategies to retain participants allocated to both study arms. Participant-facing material will endorse the value of involvement in the evaluation (not just the RISE CAPVA intervention) and there will be communication with participants at key points to facilitate and sustain engagement. For example, participant reminders will be sent to encourage completion of outcome measures (via scheduled phone calls/texts, as appropriate). Communication approaches and general engagement with families will be kept in line with the [EDI strategy](#). By also incentivising participants for completion of measures, it is hoped to reduce the likelihood of missing data. Love to shop vouchers will be offered, £10 for each parent/carer for providing outcome measures at the completion point. This will be one voucher per total set of measures submitted, whether or not they fully complete each measure within the set. Within the [IPE](#), where CYP will be invited to take part in a survey, they will also be offered £10 incentives. Again, this will be paid on submission of a response, whether or not they have completed all questions within it. Participants will also be invited to interviews within the IPE where the incentive will be entry into a random draw for a £50 voucher, whether adult or CYP (six draws to be made).

Implementation and process evaluation

The IPE design follows updated MRC guidance (Skivington et al., 2021) for studies involving complex interventions. IPE development also draws on the evaluation team's experience delivering the Reflective Fostering Study (RFS) (Midgley et al., 2021) and evaluations of criminal justice, mental health and wellbeing interventions. The key aims are to explore participant experiences of the support offered, implementation of the intervention, including fidelity to the delivery model and how contextual factors interact with the perceived benefits and the achievement of its intended outcomes. Questions that arise from the IPE will also inform an understanding of necessary adaptations to support future implementation and potential iatrogenic effects.

The IPE is designed to test mechanisms outlined in the logic model, providing an exploration of the effects of diversity on outcomes. The support received by families in the intervention arm and those in the BAU/control arm will differ. Therefore, the IPE will also seek to explore the intervention's perceived value relative to BAU and potential alternate sources of support that families in either study arm may access. The guiding research questions, target participant sample, and associated data collection strategies are offered below.

Research questions

To meet the stipulated objectives of the IPE, the research questions are structured according to implementation fidelity, engagement of families (i.e. parent/carers and CYP) and stakeholders with the intervention/study, intervention responsiveness for families, experiences of BAU/alternate support, and intervention responsivity in respect to its identified impacts and anticipated outcomes (see [logic model](#)). Alongside these questions, the data source will be listed:

- Monitoring/status: parent/carer reported data collected alongside outcome measures and from adverse events reporting (see [monitoring data and measures](#));
- Survey: CYP reported data, with protocols designed to be a mixture of drop down and free text (outlined below);
- Interview: CYP, stakeholder/professional and parent/carer reported data from interviews and focus group(s) (outlined below);
- Practitioner log: CAPVA practitioner log to record key information on each intervention session, family adherence to intervention and practitioner judgement on family progress (see below and [cost data reporting and collecting](#)).

Implementation fidelity

1. What were the facilitators and barriers to the implementation of the CAPVA intervention?
 - a. How did any identified factors support or interfere with fidelity of approach?
 - b. Consequently, are there any adaptations recommended to support future implementation of the intervention? (Interview)
2. To what extent was the intervention delivered as intended?
 - a. What was the intervention 'dose' and which factors led to any adaptations to this?

- b. Were the different components delivered as intended? (Practitioner log and interview)
- 3. What were the facilitators and barriers to delivery as intended, and what strategies or practices were used as supports or mitigations?
 - a. In what ways did these identified factors interfere with fidelity of approach?
 - b. Are any adaptations required to the CAPVA model to enhance fidelity, engagement and responsiveness? (Interview)

Intervention/evaluation engagement

- 4. What factors promoted the recruitment of families, engagement of CYP, and retention for the CAPVA intervention?
 - a. What changes during implementation and delivery of the intervention may be required to increase or facilitate recruitment, engagement and retention?
 - b. What factors promoted the recruitment of families and/or subsequent engagement in the study?
 - c. Where parent/carer/CYP engagement were harder to sustain, what adaptations/inputs were implemented to support engagement and retention in the intervention? (Survey and interview)
- 5. What factors promoted the engagement of stakeholders in the intervention/study? (Interview)
- 6. Were there any unintended consequences or adverse events in providing the intervention?
 - a. Were there differences in adverse outcomes between trial arms? (Monitoring/status)

Intervention/BAU responsiveness

- 7. Across the study period, what changes have families identified and experienced?
 - a. What were the families' experiences of the study (intervention and evaluation)?
 - b. What, if any, alternate support were families able to draw upon to facilitate potential change processes?
 - c. Did the intervention seem different from alternate provision? If so, in which ways and to what extent? (Survey and interview)
- 8. What were the identified barriers to accessing alternate support? (Survey, interview and monitoring/status)

Intervention Arm

- 9. What were parent/carer, practitioner and CYP views of the CAPVA intervention's components and its perceived benefits?
 - a. How was delivery of CAPVA experienced?
 - b. What, if any, programmatic adaptations may be required? (Survey and interview)
- 10. What facilitators and barriers to the engagement in/experience of the intervention were identified by practitioners/stakeholders, parents/carers and CYP?

- a. How did the experience and identified benefits of the intervention differ among diverse subgroups of families (e.g. ethnicity, neurodiversity, gender, children in care/who are care experienced)?
- b. Which contextual/systemic factors may negatively affect the experience of the intervention and its potential benefits? (Survey, interview and monitoring/status)

BAU/Control Arm

11. What facilitators and barriers to the engagement in/experience of alternate support were identified by practitioners/stakeholders and parent/carers?
 - a. What is the nature of alternate support sought and accessed?
 - b. How did the experience and identified benefits of alternate support differ among diverse subgroups of parent/carers (for example, ethnicity, neurodiversity, gender, children in care/who are care experienced)?
 - c. Which contextual/systemic factors may negatively affect the experience of alternate support and its potential benefits? (Interview and practitioner log)

Intervention responsiveness

12. To what extent did the intervention achieve its intended outcomes?
 - a. Were the core principles of CAPVA (such as de-escalation skills) understood by families and what, if any, were the perceived impacts?
 - b. What factors facilitated or inhibited the achievement of these intended outcomes?
 - c. How did CYP and parents/carers experience family relations during and beyond the intervention period?
 - d. Where change is identified, which programme component(s) were identified as beneficial? (Survey, interview and practitioner log)
13. What were the unexpected/unintended outcomes identified? (Survey, interview and monitoring/status)
14. Were there variations in outcomes (CAPVA and other behaviours) by subgroup (racialised communities, girls and young women, children in care and/or with experience of care, neuro-nontypical CYP, or other vulnerable groups)? (Monitoring/status)

Data collection

Surveys of CYP

To provide CYP the opportunity to reflect on their experiences and views of the intervention, a subset of CYP will be invited to complete an IPE survey (via a link to REDCap). It is intended to recruit CYP from within the intervention arm only (see [ethics](#) for rationale), whether or not they chose to engage directly with the CAPVA programme. This is to facilitate understanding of CYP experiences, where their

parents/carers have engaged in the intervention, irrespective of whether CYP have directly engaged. It is predicted that approximately 15-25% of CYP from the intervention arm will participate in the IPE, which would be in the region of 25-50 CYP.

Shortly after parents/carers have begun to engage in the intervention, consent will also be sought for CYP to be invited to take part in a survey. Collaboration with practitioners will occur during the recruitment of CYP even when they reach 16—the intention being to balance safeguarding and vulnerability with the potential for barriers imposed by gatekeepers with whom the CYP may not have previously engaged. The informed consent/assent of CYP will be gained on the survey tool, with an option for the CYP to be supported by their assigned practitioner or embedded researcher, should they have any difficulties in completing the survey.

Interviews of referred families

Interviews will also be conducted with a subgroup of parent/carers and CYP participants during the delivery of intervention. In the BAU arm of the trial, only parents/carers will be involved in the IPE (see [ethics and registration](#)). Interviews will explore families' views of intervention delivery and potential impact of intervention, along with study processes such as recruitment, retention and engagement. Twenty parent/carers from the intervention arm will be recruited to interviews through purposive or convenience sampling, with an aim to capture diverse backgrounds, histories and experiences. Ten parent/carers from the control group will be interviewed to explore their experiences of BAU (see below for more information on CYP recruitment).

To encourage wide participation from parent/carers, they will receive a REDCap link to indicate interest in an optional interview alongside requests to complete outcome measures. Additional consent for this element of the trial will subsequently be sought by the evaluation team. In the event that the invitations do not elicit enough responses, convenience/snowball sampling of parent/carer participants will be employed, and participation will be sought through direct contact by the evaluation team and supported by CAPVA practitioners or lead professionals where required (e.g. where a practitioner deems a parent/carer well-placed or possibly interested). It is anticipated that IPE interviews with families can be conducted in the weeks preceding the final completion of intervention sessions (approximately six months post-baseline). Undertaking IPE interviews at this stage will help keep families engaged in the efficacy study and parents/carers will be encouraged to complete the end point outcome measures during interview-related contacts.

Potential CYP interview participants (n=15-20) will be recruited via the survey and by using convenience/snowballing approaches to encourage potential participants who have not previously completed the survey. For CYP, the consent process will be supported by project gatekeepers and parent/carers (see [ethics](#)). Within the interviews, CYP participation will be facilitated through the use of creative, arts-based elicitation techniques to help them express difficult experiences and enhance accessibility beyond traditional interview formats.

Stakeholder reporting and interviews

As part of the costs analysis for the intervention arm, practitioners will be asked to complete log sheets after each intervention session, to summarise the inputs, including time spent. It is posited that a small additional amount of 'supplemental' information will be requested via the CGI and routine practitioner record on family progress, alongside a more general summary of activity. This would include space for practitioner insight on facilitating and hindering factors. This will again be set up as individual surveys via REDCap and can include information useful to both IPE and costs analyses. Within the BAU arm of the trial, no costs analyses will be undertaken. However, the 'supplemental', IPE related questions will be sent to BAU practitioners in parallel to the intervention arm.

Using purposive and convenience sampling (where required), practitioners delivering the intervention (n=7-11), the project management and intervention leads (n=3-5) and key stakeholders (e.g. coordinating practitioner or relevant service lead) from referral boroughs (n=5-8) will be invited to participate in the IPE. The intervention team (CAPVA practitioners) will be invited to participate in interviews or focus groups (as most appropriate) to explore their experiences of intervention delivery, and factors that may have helped and hindered intervention delivery and family outcomes. In addition, CAPVA practitioners will be expected to complete the log sheets to capture family adherence to the intervention, implementation fidelity (e.g. dose) and professional judgement on family progress. Following the above data collection and initial analyses, a focus group will be run involving the project management and support team and stakeholders from referral sites (two mixed focus groups will be run if the maximum number are recruited). This will focus on key themes derived from the IPE relating to intervention implementation and BAU and will consider arising questions around intermediate to long-term impacts and sustainability of approach.

This trial is focussed on outcomes measurement to determine efficacy. It is noted that the data will be archived and that subsequent analyses may be able to consider impacts of the evaluation more directly than will be possible here (Heneghan, Goldacre and Mahtani, 2017). Findings from the IPE interviews/focus groups may also be useful in informing how the outcome of the efficacy evaluation might be used to inform activity that may lead to impact, and in how to assess such impact (e.g. assessing social returns on investment).

Analysis

Table 5 summarises the approaches proposed for the IPE, across both arms. A descriptive summary of the support received by families in each arm will be produced. The descriptions will focus on the type, range and frequency of support received, compared between the study arms. Where less experiential findings are expected, for example in response to supplemental elements of the costing surveys, it is not intended to provide more than these descriptive summaries, derived from a content analysis where needed. Additional descriptive quantitative analyses will centre on monitoring and family status data to make consideration of potential differences between sub-groups in the implementation process. It may also be possible to draw on these data for additional sensitivity analyses of the parent and carer outcome data (the primary and secondary outcomes).

To assess the key elements of the IPE (fidelity, engagement, responsiveness and responsivity), deeper consideration of IPE findings will be made via Framework Analysis (Ritchie and Spencer, 1994). This will enable evaluators to prioritise people’s experiences of the support provided (whether in intervention or control arms) whilst doing so in a relatively efficient way, requiring some iteration, but less than alternative methods. It also has the appeal of comparing experiences and requires the research team to approach findings reflexively both inductively and deductively. Framework Analysis was designed to be of particular use in policy settings (Goldsmith, 2021). Lastly, as part of the production of the final report, synthesis will be made of the IPE with the outcome measures, based on concurrent triangulation.

Table 5: IPE methods overview

Research methods	Data collection methods	Participants/ data sources (type, number)	Data analysis methods	Research questions addressed	Implementation/ logic model relevance
Survey; closed and open-ended questions	Online delivery	CYP intervention arm (n=25-50)	Descriptive summaries from content analysis (of responses to closed questions). Framework analysis (inductive and deductive for open-ended questions, triangulate with descriptive summaries).	4, 7-10, 12-13;	To capture CYP views on the intervention benefits, and challenges including consideration of intermediate outcomes (potential reduced family conflict, behavioural change and potential improved emotional wellbeing).
Semi-structured interviews (parent/carers-intervention)	Telephone or online video conferencing. NB, no in-person interviews can be offered within the required staffing/budget	Parent/carers - intervention arm, n=20.	Framework analysis (inductive and deductive)	1-4, 7-10, 12-13	To capture parent/carer views on the intervention and its benefits, including consideration of potential intermediate outcomes (such as, improved de-escalation skills, increased wellbeing and reduced social isolation).

Semi-structured interviews (parent/carers-BAU)	Telephone or online video conferencing.	Parents - control arm, n=10.	Framework analysis (inductive and deductive)	7-8, 11, 13	To capture parents/carers views on business as usual for further contextual understanding of the intervention implementation/mechanisms and perceived benefits to families where CAPVA is present.
Semi-structured interview, supported through creative elicitation techniques	In-person; telephone or online video conferencing.	CYP intervention arm (n=15-20)	Framework analysis (inductive and deductive).	1-4, 7-10, 12-13	To capture CYP views on the intervention, its benefits and challenges, including assessment of potential intermediate outcomes (such as, reduced family conflict, behavioural change and improved emotional wellbeing).
Semi-structured interviews (focus groups, where required)	Telephone or online video conferencing.	Intervention team: CAPVA practitioners, n=7-11.	Framework analysis (inductive and deductive)	1-5, 7-10, 12-13	To capture barriers/facilitators to intervention implementation and engagement and a deeper understanding of fidelity (implementation and theoretical). To capture views on the intervention mechanisms and impact on its intended outcomes.
Focus group(s)	Online video conferencing or in-person UH meeting room	Stakeholders: RISE Management and intervention leads, (n=3-5) Key stakeholders from referring boroughs (n=5-8).	Framework analysis (inductive and deductive)	1-5, 8, 10-13	To consolidate and extend IPE learnings in respect to intervention implementation, BAU, impacts and sustainability of approach.
Practitioner log entries following each intervention session	Online delivery; numerical data and free-form text.	CAPVA practitioners working with up to 235 families.	Summary quantifiable and deductive qualitative descriptive analyses.	2, 12 (also monitoring data collated via logs will feed into questions 6, 8, 10 13-14)	To capture dimensions of intervention fidelity (and to support <u>cost analyses</u>). Additionally, to triangulate explanatory data from the CGI on family functioning and exploratory data on

					professional judgement of family progress through the intervention.
Practitioner log entries in BAU arm	Online delivery of just the “supplemental” elements of the intervention arm practitioner log.	BAU practitioners working with up to 235 families.	Summary quantifiable and deductive qualitative descriptive analyses.	11	To consider practitioner views of family progress through BAU.
Family status/monitoring data	Referrer data on family demographics/	Family status data of up to 470 families, recorded and shared by referrers (from 8-10 boroughs) with project team and gained in collaboration with parents/carers	Monthly reports will be generated from routine monitoring of data collected through REDCap. Descriptive quantitative analyses. Data may additionally be used for sensitivity analyses of parent/carer outcome data.	6, 8, 10, 13-14	To explore potential differences between sub-groups in the implementation of the intervention.
Adverse event reports	Parental report via online link to REDCap proforma (with practitioner/RA support if needed)	Parent/carers across both trial arms, up to 470 and CYP in the IPE.	Monthly reports will be generated from routine monitoring of data collected through REDCap. Descriptive analyses of adverse events. Content analysis of adverse events reports and descriptive reporting on number, frequency and type of adverse events.	6, 13	To examine potential unintended consequences of the intervention and adverse events during trial lifespan and analyse for differences in adverse outcomes between trial arms.

Cost data reporting and collecting

RISE is the main organisation involved in delivery within the cost data reporting. RISE employs NVR practitioners and advanced practitioners to screen families for suitability for the programme, assess risks, vulnerabilities and baseline indications of CAPVA then to deliver the CAPVA intervention (using hybrid delivery methods). There are additional costs incurred for training the RISE practitioner staff, initially and to maintain CPD and in the administration and support of delivery. RISE also provides training to referring agencies and other organisations working with referred families.

Costs information will be reported for all practitioners (the cohort) and as an average cost per family of delivery (essentially per participant) but with data collated from the perspective of RISE. Additional analysis will estimate separately costs of delivery to CYP in comparison to costs of delivering to parent/carers. Data will be collated via RISE practitioners, administrators and management and consider the organisation and delivery of the intervention. Currently, there are seven NVR practitioners employed and it is anticipated that a further four will be recruited and trained in NVR as part of this trial. Each practitioner is assigned a caseload that can vary both in terms of challenges faced by the families and the borough in which the family is located, or to which the practitioner is deployed. For this reason, the cost analysis will consider one delivery cohort to be all practitioners/participants involved in the intervention arm of the study.

All 11 practitioners will be asked to complete service delivery diaries for labour cost calculations. The extent and frequency of information sought within these diaries will be refined during the contracting and mobilisation phases of the trial as it is understood that RISE already maintain practitioner time logs and wherever possible, the evaluators will seek to avoid duplicating and/or adding unnecessary workload in support of the evaluation.

Current understanding of costs includes those mentioned above and outreach costs to enhance engagement e.g. community meetings, information sessions at temples and/or churches, work with any specialist organisations (including those supporting the Traveller community). For programme delivery: two sessions are conducted with most referred families for initial screening, assessment and provision of safety measures. If families are deemed suitable for the CAPVA intervention, consent to take part in the RCT, and if they complete the baseline outcome measures, then this will take them to randomisation where they will either be assigned to BAU—at which point no further costs data are collected relating to their experience of the trial—or to the intervention.

If assigned to the intervention, then the costs predicted to be incurred will be related to the work undertaken by the practitioner to which families are assigned and the support necessary for that practitioner. Expected work will be up to 18 further sessions provided to each referred family (up to 20 in all). Sessions are typically every two to three weeks and may involve practitioner travel to the family home and/or to third party locations where for example, practitioners may support families during a child protection or child at risk meeting. Each family will typically be offered at least 12 sessions with just the parent/carers (post screening/assessment for suitability). The remaining sessions may involve a combination of intervention to support CYP directly and/or additional work to

support parent/carers. There is variability in time taken for delivery and the exact number and type of sessions will vary, depending on need and the ways in which families respond to the intervention.

This means that for costs calculations:

1. it is proposed that the intention to treat is taken as 20 sessions (up to two for screening, baseline assessment, up to 16 for the core of the intervention, up to two optional, follow-up sessions, post completion);
2. actual numbers of sessions delivered and the type of sessions will be recorded;
3. costs will first be calculated on the basis of actual number of sessions and means of delivery;
4. if not all families receive 20 sessions, costs will then be extrapolated to what the costs would have been, had 20 sessions been delivered;
5. sensitivity analyses will be made to consider the impact of different modes of delivery, some different assumptions regarding frequency and duration of ongoing intervention sessions, service delivery diary non-completion or recall error and the impact of different scenarios for the extrapolation mentioned in (4);
6. all CAPVA delivery practitioners will be asked to maintain service delivery diaries, rather than a subset of practitioners as there is little way to know how much variance is likely between practitioners

During the co-design phase, the evaluation team raised several costs-related queries to the project. It is expected that these will be further refined as evaluators' understanding of delivery develops during the first two phases, post grant confirmation and that these will lead to refinement, ready for trial delivery. Additionally, understanding of costs will be monitored via quarterly governance meetings that UH propose to conduct jointly with RISE.

As there is no active control being proposed, the control arm costs will be those of BAU. Following the YEF costing guidance, the economic evaluation will therefore focus on the cost of delivery, solely evaluated for the intervention arm. During contracting and mobilisation, a standardised, straightforward, tool will be developed to capture inputs by the team supporting families. It is envisaged that this tool will be run via the REDCap survey functionality. As mentioned above, this will be designed to minimise additional burden to the project team, informed by the YEF cost reporting specifications. As the survey tool will be used within REDCap, limited additional training is seen as being needed for self-completion of costings surveys, however, the UH team will be available for clarification and support in the process.

Prerequisite and set up costs will be established via surveys and meetings with RISE management to establish wage costs and oncosts. Data for recurring costs will be routinely captured following families recruited into the intervention arm of the evaluation. This will be via a practitioner completed, service

delivery diary with reminders following each contact with families, and regular requests to complete a summary of inputs for service managers and administration staff.

The final areas of uncertainty are around screening and sensitivity relating to uptake: RISE screen all referred families, taking the first one or two sessions to establish suitability, gain understanding of baseline circumstances, provide safety measures that can be used irrespective of take-up and ensure that families understand the aims of the CAPVA intervention. This screening takes place routinely and is costed as part of the intervention. During the evaluation, screening is also where information about the trial will be provided and it is only if consent is then given and baseline measurement completed, that randomisation will occur.

For the cost data reporting, costs of screening families who are subsequently assigned to the control condition can be excluded. However, there is no way to estimate the effect of the trial itself in determining whether a family agrees to take part in the CAPVA intervention. As such, there is some uncertainty over whether the proportion of families screened--who are deemed suitable but then do not proceed to randomisation--will be reflective of the proportion of families who might otherwise be expected to opt out after assessment. Some sensitivity analysis may be possible in this regard, drawing on referral and screening pathways from the feasibility to pilot evaluation and information from RISE management.

Diversity, equity and inclusion

The boroughs that have agreed to be involved in the trial and those that are currently in negotiation with RISE, have diverse communities within them, ethnically, religiously and culturally. There will also be variation in levels of deprivation, with this more likely to cluster with certain ethnic groups according to ONS data (e.g. Ministry of housing, communities and local government, 2019). Referred families may be disproportionately drawn from groups minoritised within their local area and nationally and more likely living in socioeconomic disadvantage. Service users might have histories of being viewed through culturally insensitive lenses by practitioners and evaluators. Such factors are related to systemic disparity stemming from institutional racism, and a lack of representation within settings like children's social care (www.ethnicity-facts-figures.service.gov.uk, 2023). Being mindful of these issues will help guide both teams to stop inappropriate practices and continue to implement inclusive approaches, to which the project lead for EDI (SS) brings experience in both research and organizational leadership. In doing so, the team will continue to be informed by the evolving landscape of support intended to further inclusion in research such as that by the NIHR (CRN INCLUDE- Learning for Involvement, n.d. and Parekh, Andrews and Peckoo, 2019) and guidance and tools developed by members of the current project team (currently under consideration for publication).

A holistic lens will be critical to ensure that barriers in access to participation do not arise as a product of research design. Additionally, the evaluation and intervention teams will work to build trust in communities who may have valid reasons for being concerned about participation. For example, fear of how differing beliefs and practices on managing child behaviour may be viewed through alternative cultural perspectives.

The impact of prior learning across a range of research types will be maximised in approaching this trial. The proposed design adopts similar principles to those implemented in RFS, where a dedicated workstream (InCLUDE) continuously considered under-representation in the study, including intersecting factors, to increase equity of access and completion. InCLUDE was co-produced work that engaged widely with people from identified under-represented communities. Together, the group examined possible barriers and co-produced solutions to reduce them. Recruitment of under-represented groups (South Asian, kinship carers and male carers) was increased by adopting barrier reduction strategies – offering programmes to targeted groups, being with trusted community connectors, not relying on local authorities to recruit and specifically recruiting using targeted media (e.g. a Muslim radio station).

The EDI approach builds on similar methods that have broadened access to research in other fields (Sharma et al., 2023) where success has been evidenced throughout the research cycle from consent to retention and completion. Sharma et al 2023, was a health research study on a highly sensitive topic, yet the consent to completion rate amongst minoritised ethnic communities was over 95%. Similarly, retention in RFS was favourable. In both cases, this was helped by community connectors maintaining end to end support.

Drawing on past successes, a toolkit for inclusive research that was an output of the InCLUDE work will be available to support recruitment into the study. This will raise awareness of inclusion as a critical priority where attending to gender, ethnicity, disability, and deprivation alongside their intersections, are seen as clusters of disadvantage. All involved with the evaluation will have access to this toolkit and will build on it further, as an aid to training described below. It is also important to note that the team brings further insight to neurodiversity (ALu) and learning disabilities (SM), with experience in adapting study processes, participant-facing materials and participatory research (CC). The following approaches will be implemented, as far as possible by the end of the mobilisation phase, continuing through the trial where relevant:

- Study team members will have all undergone essentials of EDI training, developed specifically for this study and using the InCLUDE toolkit as an aid;
- An InCLUDE group will support decision making in research throughout the trial;
- Recruitment to the trial will be sensitive to disadvantage factors and harness tools and participatory involvement to address this as far as possible e.g. gender decoding, and culturally inclusive practices;
- The evaluation team will review the CAPVA intervention for inclusion and both the evaluation and project teams will work to avoid unconscious bias, cultural insensitivity and neurotypical bias that may creep in. Each team will retain awareness of different parenting practices, designing materials to include diverse examples and where relevant, seek to facilitate groups for equal power of voice;
- For evaluation and intervention, a safe space will be provided to share honestly and openly with cultural matching to communities as far as feasible.

Equity considerations will be included in analyses of differences between control and intervention arms, (e.g. who enrolls in the trial, stays/drops-out) as well as more detailed consideration of the heritages, neurodevelopment, cognitive capacities and intersectional experiences of participants beyond the high-level stratification deployed as part of randomisation. Lastly, as part of the reflexivity brought to the trial, evaluators will consider influences and experiences on decisions made and implementation of the trial.

Inclusion of children and young people in the research

Before moving onto the ethical considerations of this trial, it was felt important to consider the inclusion of CYP as a general principle within this research. The intervention is open to CYP but targets their parents/carers primarily. In the BAU arm of the trial there will be differential engagement and support available across referral sites. The minimum BAU acceptable for borough engagement in a trial will be based on having an assigned lead professional and receiving a safety sheet.

In consultation with the commissioners and in keeping with ethical principles articulated below, careful consideration was made of whether study participation should include referred CYP, in either trial arm. It was concluded that CYP will be invited to participate directly in the IPE from the intervention arm of trial but will not be invited to participate if allocated to the BAU arm. CYP in the intervention arm are offered opportunity to engage in tailored support. The main purpose of the IPE is to examine how the intervention works and to test the logic model. The main reason for excluding CYP from the BAU arm is that being invited to the research may have put them under additional risk of harm or distress beyond that which they are currently experiencing, without having the ways to mitigate the distress that are available to the CYP in the intervention arm. Within the intervention arm of the trial, the evaluation and project teams have considered ways to enhance CYP likely engagement with the support offered to them and with the evaluation's IPE. Bespoke recruitment strategies will be adopted e.g. films and accessible information about the providers and evaluators. The evaluators will also build relationships with CAPVA practitioners and youth workers supporting CYP in parallel to the intervention, to facilitate their roles as gatekeepers to CYP recruitment, engagement and retention in the IPE. Furthermore, the youth advisory board from the YEF will continue to be drawn on and the intention is to create a participatory group to advise on trial processes, including engagement and retention.

Participatory group

The participatory group will also help with the co-delivery and monitoring of the evaluation, providing additional focus on diversity and inclusion. This group will advise how to maximise the numbers joining the trial and the diversity of families engaged. The participatory group should comprise individuals from different minoritized ethnic groups, neurodiverse CYP, and those from (particularly) deprived areas. They will be encouraged to advise how the evaluation is conducted through its lifecycle to dissemination. The parent/carers of CYP are also included, given the intervention focus, although CYP should be supported to meet independently of parent/carers. Participatory group members will be remunerated for their time and contribution following the NIHR (2022) best practice principles

concerning public involvement payments. Facilitators of all participatory groups will be confident and experienced in managing these spaces sensitively, ensuring that inclusion is a lived reality within the research participation and co-production.

Ethics and registration

UH ethics and integrity policies and processes can be seen at: <https://www.herts.ac.uk/research/research-management/ethics-and-research-integrity> and safeguarding at: https://www.herts.ac.uk/data/assets/pdf_file/0017/333422/HS10-Safeguarding-policy-v02.0.pdf. The core team are bound by professional body and statutory codes of ethical conduct and are used to working to the DPA, 2018 and UK GDPR requirements, also within trauma informed ethical frameworks, incorporating participant vulnerability, risks and legislative requirements. All materials designed for use in the trial will be subject to scrutiny by the UH Health, Science, Engineering and Technology Ethics Committee and risk assessment will conform to the additional requirements of the School of Life and Medical Sciences. Within this section, focus is on ethical consents necessary for direct participation in the evaluation. In the following section, the data protection requirements are outlined. It should be noted that much of the routine data, including that necessary for archiving will be gathered on the basis of legitimate interest. Data protection impact assessments (DPIA) will be made and data privacy notices will be implemented so that families understand what data will be gathered and, where relevant, subsequently archived both for the intervention itself and for the evaluation. The rest of this section concentrates on ethical principles and practices that will be followed for activities associated with the evaluation that would not otherwise form part of the intervention.

Obtaining consent to participate in the IPE from CYP and on their behalf may be lengthy, especially if they are looked after by someone other than their parents. Parental/carer interests may conflict with young people's; in such circumstances, the interests of the child(ren) will be prioritised. Processes will be designed to avoid unnecessarily criminalising CYP, following prosecution and policing principles. Gaining CYP involvement is likely to be extremely difficult. Consideration and discussion of CYP behaviour, particularly CAPVA, has the potential to be triggering and even asking about CAPVA may be considered an intervention. The evaluation team will work in ways that are non-shaming and non-stigmatising, ensuring that the research does not bring additional distress and will continue to be informed by the YEF youth advisory board members and participatory group, about both engaging young people's interest and in supporting them appropriately.

The team are used to working with young people and adults who may be vulnerable by their situations (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 agreed safeguarding protocols. Key principles will include: 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, information should be protected by default but shared appropriately if a safeguarding risk is identified. A precautionary principle will be adopted in pre-identified situations of low/medium risk so that children are neither put at further risk, nor unnecessarily criminalised. Study participants will be made

aware that there may be situations, under the safeguarding framework, where there is an obligation for members of the evaluation team to break anonymity and provide information back to the organisation providing the intervention, or other statutory bodies.

Other ethical issues include that as CYP are not involved directly in outcome measurement, data will be collected about their behaviours, from other people's perspectives, without their direct consent/assent. Data will be generated about young people and archived for each referred CYP on the basis of parental consent and reporting. This leads to additional importance regarding the CYP potential right to be forgotten or to request to have data about them deleted from the data archive, once they reach 18, please see erasure requests within [data protection](#).

Those in the control arm of the study will not be offered any support beyond that already available in their area (at a minimum, the support of a lead professional). There may still be increased protection of CYP via the additionally close monitoring of them for the evaluation. Conversely, the evaluation may lead to additional risks of harm, for example via the increased risk of criminalisation through that closer monitoring. Given the variability of the support provided under BAU, it is important to note that as part of routine screening of all referred families, RISE will provide a set of safety measures that families may choose to enact. This will go to all families screened, whether or not they are subsequently found to be suitable for the trial and whether or not they consent to join the trial. See also [project oversight](#).

The potentially limited support for those in the BAU arm of the trial may also be seen as problematic to the RISE CAPVA practitioners and/or to psychologists or commissioners within the boroughs. This partly stems from the belief that the intervention "works". Further, RISE practitioners may be concerned that the CAPVA programme would be the better option for potential participants than BAU, particularly when that would be very limited support, or would be support derived from potentially contradictory theoretical stances to those underpinning NVR. Through the co-design process, the evaluation and project teams have considered these ideas, looking to the purposes of research and embedding the evaluation within principles of equipoise and the need for a rigorous evidence base about efficacy, over time and when compared to alternatives.

During trial inception, potential boroughs sought clarity on the ethical principles on which an RCT is based. These largely stemmed from concerns that treatment would ostensibly be withheld from families allocated to the BAU arm and that Ofsted, or other regulatory bodies may criticise them for making referrals to the trial. This section has therefore been expanded to consider such principles further, starting with equipoise (Freedman, 1987; Rosen et al., 2006). It is intended to show that in designing this research protocol, all parties have considered carefully the risks of research against the risks of untested intervention (see Chalmers (2017) for an accessible summary of such risks in education research).

As discussed in the introduction ([see study rationale](#)), there is little research about intervention into CAPVA, with most centring on families' experiences. Where interventions have been designed, there is ongoing professional and family debate about whether the children, the parents or both should be targeted by intervention, whether separately or together and whether or not to include wider family

members--all of which are elements of the NVR programme (see Theory of change: CAPVA programme). Although previous research has been conducted into NVR, CAPVA-relevant studies have been with small samples and/or did not directly consider CAPVA outcomes. The starting point undertaking an RCT is therefore met as equipoise can be assumed. Or, “there is disagreement in the professional community as to the preferred treatment” (Horn and Weijer, 2015, p1).

Moving onto the use of BAU as the control condition: there is no established effective intervention (Council for International Organizations of Medical Sciences (CIOMS), 2016) to offer as an active control to compare against the intervention. Therefore comparing the intervention against current processes in the trial (i.e. BAU) is as close as possible. It is noted nonetheless that some practitioners and commissioners are also concerned about ethical, statutory and/or reputational risks of apparently withholding treatment in the BAU arm of the trial.

Firstly, it should be noted that the trial is offering a service to families that they might not otherwise be offered. Thus, rather than none of them gaining the service, half of them will be able to access an intervention. This intervention is not something to which anyone is routinely entitled (Chalmers, 2017; The Abdul Latif Jameel Poverty Action Lab (J-PAL), 2016). Within the trial, additional care will also be taken to ensure that families typically disenfranchised from interventions will be included, again enhancing engagement for some.

Secondly, concern about withholding treatment is only relevant if one knows that the intervention is effective and that it causes no harm (Chalmers *ibid*, J-PAL *ibid*; Rosen et al., 2006). “We need evidence from impact evaluations to know if a program works. Without this evidence, providing the program to everyone may be wasting resources and people’s time. It is also possible that the program may even be harming participants.” (Hanson and Pergamit, 2022, p9). Given these principles, this study is designed in keeping with the idea that RCTs are therefore necessary in criminal justice (Weisburd, 2003) albeit that they still present ethical dilemmas which must be considered (see for example ‘Sample size calculations’ above).

Lastly, similar discussions have taken place regarding the importance of waiting to deliver the intervention sessions until after families have consented to take part in the trial, completed baseline measures and been given their allocation (to BAU or intervention). This has been acknowledged in the risk register and will be emphasised further as part of evaluation engagement with practitioners in the BAU arm of the trial. Such dialogue will be further supplemented within the training planned at the end of the mobilisation phase which is intended to be jointly run, to embed best practice in research and evaluation in general and equity, diversity and inclusion, in particular.

- *After peer review the evaluation team will ensure the trial is registered at www.controlled-trials.com and include the ISRCTN (International Standard Randomised Controlled Trial Number) in the protocol as soon as it becomes available. The team will also ensure the trial registry is updated with outcomes at the end of the project (CONSORT 23).*

Data protection

At baseline, data about approximately 470 young people will be collected from their families. By project completion, it is intended that 376 young people's families will still be involved. Also, that at least 25 CYP (of parents/carers in intervention arm) will have directly participated in the IPE. Data from all parents, carers and young people enrolled to completion will be prepared for archiving at the end of the trial.

It is noted that best principles from the information commissioner's office (ICO) for research include both gaining and maintaining ethical consent from participants and working within a suitable basis for processing data under UK GDPR and DPA 2018 (ICO, 2023a). As contracted evaluators, UH will require access to RISE and borough-held, sensitive client data, necessary for the intervention and longitudinal follow up. In line with YEF consent advice, and data privacy requirements, following referral to the intervention (hence potentially to the evaluation), families need to be given detailed information about the trial. If they chose to join the trial, they will need to provide additional consent showing that they are aware that routinely collected information and trial specific information will be used to enable evaluation and that this could include identifiable data to facilitate matching against governmental data, consequent to archive.

Robust evaluation of the intervention provided is in the public interest, and processing of the data for this purpose is justifiable under DPA, 2018 and UK GDPR under both legitimate interest and public task. Data flows will be considered as part of the trial governance and contracting phase when the DPIA will also be made. This will inform data sharing agreements that will be drafted in the same phase and will need to be in place with RISE and for each borough, prior to the trial itself beginning in any one area. They will need to consider, not just the data required for the trial, but also for lodging in the YEF archive.

For some elements of the evaluation, consent will be sought for ethical reasons. However, it is not the basis on which data will be collated, held and processed. It is further noted that although ethical requirements around consent for research will have different processes dependent on children's chronological age (where for example children under 16 will need parental/carer consent as well as their own) the UK GDPR basis for which data are being processed operates the same for children as for adults (ICO, 2023b). From a best practice perspective, accessible versions of the privacy notices will be developed, using the YEF templates as a starting point (YEF, 2023), but there are no additional UK GDPR requirements under the legitimate interests.

Data will be kept secure through following the UH ethics, data management and handling processes: Database access will be kept to a minimum and roles will be assigned within the database to limit further who has access to personal and special/sensitive data. Only high-level summary or aggregate data, which cannot be used to identify individuals, will be reported in a wider context. The limits of reporting and archiving will be specified in the evaluation contract, scrutinised by the ethics processes and implemented in line with ethical approvals, data management processes and project oversight.

Data will originate from referrers who are the initial data controllers, these data are then processed by both RISE and UH. However, as part of the trial, additional data will be gathered by both RISE and UH, including special category data and each organisation will thus be data controllers as well as processors. For example, within the trial, UH will need routes to contact every family in order to send out surveys, this will involve emails for data completion links and mobile phone numbers for reminders. In order to maximise data protection compliance, “permissions” will be applied to “roles” in REDCap. So that only those who need access to identifiable data (e.g. the trial manager) can see them but others (e.g. statisticians) cannot.

As an additional level of security, initial records with information on consent will be separated and all data will be masked using participant identification codes. Those who need access to the database for maintenance and analysis, would see only the identification codes, not identifiable data. There will be a ‘key’ to allow data linkage for archiving. This key will therefore facilitate longer term follow-up from public and institutional databases but is not needed for analyses within the evaluation.

After data archiving, identifiable data will only be held for an agreed period during which the archive managers will be able to raise any queries that might require identifiable data. Thereafter, all identifiable data will be destroyed and only depersonalised data held at UH. The depersonalised data will be held for five years to allow for secondary analysis, publication and queries that may arise through those processes. If a request for erasure is made by a person who was a child at the time that data were collected from or about them, then additional ICO guidance outlines how requests should be facilitated and considered ICO (2023c). The YEF’s data processing principles (YEF, 2023) conform to these principles and the evaluation team’s approach will align with both.

Project oversight

Project management will be ever present throughout the trial and appropriate resources will be allocated to ensure timely milestone delivery. The project management philosophy that will be adopted is to keep the YEF evaluation team fully and transparently informed of progress and to ensure there are ‘no surprises’. Dr Cresswell, the trial manager (TM), will act as the point of contact for all operational issues, service management correspondence and will liaise closely with Prof Adler as principal investigator (PI).

Additionally, the following core approaches will be adopted:

- Defined roles - each member of the team will have clearly defined roles with task/workload delivery managed by the TM;
- Communication/liaison with commissioner, project, boroughs and between the team members
 - Periodic review of the evaluation will be undertaken via a trial steering committee (TSC; see below) and with participatory groups;
 - The PI and TM will meet weekly, and the TM will have regular communications with other members of the research team, at least fortnightly;

- End of phase reviews will also be conducted to facilitate ongoing learning and potential modifications to practice; if necessary critical incident reviews will also be undertaken.
- Project design control – research methodology is based on accepted good practice, enhanced through previous similar, peer reviewed projects;
- Documentation and quality – draft and final reports will be monitored and verified by the TM and final authorisation will be via the PI (alongside peer, technical and YEF reviews);
 - Corrective actions – The PI will be responsible for monitoring, evaluation and enhancement of the quality of outputs at each milestone leading to successful project achievement.
- Team resources – the research team have been selected for relevance, experience and quality of similar research outputs;
- Research team wellbeing – UH has well-supported line management and employee assistance programmes including free, confidential, access to counselling and/or psychological therapies. Line managers run annual appraisals with half-year appraisal reviews and an occupational health service offers both wellbeing maintenance drop-in services and full OH support via self or line manager referral. Additionally, UH is a member of the Vitae researcher development framework (Vitae, n.d.) and the team will draw on supplementary materials developed under the RES-WELL project to support researchers working in emotionally or ethically challenging projects (Zschomler et al., 2023);
- Project team wellbeing - RISE ensures that practitioners delivering NVR and trauma informed techniques to parents, carers, children and young persons, receive comprehensive, multi-faceted support and supervision to maintain their wellbeing and professional development and to promote resilience. Group clinical supervision is held approximately every 6 weeks through the Partnership Project, offering practitioners the opportunity to reflect on practice collectively. To further enhance support structures, staff undergo annual appraisals with quarterly reviews, fostering continuous feedback and goal setting. Additionally, practitioners benefit from individual sessions with their line manager and the opportunity to meet with a counsellor. Moreover, practitioners undertake regular practice/team days, complementing team meetings and bi-monthly team briefings. These platforms facilitate discussions on cases, risk management reviews and the overall impact of their work on both families and themselves;
- The Clinical Trial Support Network (CTSN) will provide oversight and guidance around study governance and oversight including identification of and adherence to appropriate Standard Operating Procedures.

Independent oversight of the conduct of the trial will be provided by a Trial Steering Committee (TSC). The TSC will have an independent chair and it is intended that 2/3rds of the members will be independent. The formal constitution of the TSC will happen in the first phase of the trial and would typically include an independent statistician, independent trials expert, and an independent subject

expert. The TSC will provide oversight of the conduct of the trial and where necessary, will make recommendations to YEF for changes to the conduct of the trial, and or the trial protocol⁵.

The evaluation team will also conduct routine monitoring of adverse events reported by families. The TSC will monitor the risk of adverse events in the trial arms (from depersonalised data), and if the differences in reported adverse events seem concerning, a separate, unmasked analysis will be considered by a subgroup. Should safety become a significant concern, the trial steering committee may recommend stopping the trial.

Quality Assurance

The Quality Assurance approach is fundamentally grounded in 'getting it right first time'. That is, the systems practised stress *quality assurance* rather than *quality control*. The trial will be conducted according to the Quality Management System (QMS) provided by the CTSN⁶. The TM and all study related staff will have access to the CTSN QMS and the relevant parts of the QMS will be identified and applied to the conduct of the trial.

The management system adopted ensures all staff are valued and an integral part of the overall enterprise. All staff are aware that quality practice is fundamental but also that if a problem occurs, it should be identified, investigated and rectified with efficiency and speed. As such, the team are able to have a high degree of autonomy within the parameters of the agreed research plan. This is supported by employing high quality research and support staff and the wellbeing support outlined above. Additionally, mentoring from more experienced team members will be required, and a system of frequent informal 'catch ups' instituted to allow both positive feedback and any issues requiring attention to be raised.

The trial data will be monitored weekly via a semi-automated, focused process. Where missing data or data errors are identified, a data log will be completed. The appropriate person will be asked to complete the missing data (or request completion from a study participant if that is possible), or to provide a data correction on the relevant log. The log will be used to provide data correction in real time as the trial progresses. Deeper-level monthly reviews will be made of the range of data issues identified.

⁵ NB, it is assumed that people will offer services for free as part of academic facilitation. No budget has been allocated to the TSC.

⁶ <https://www.herts.ac.uk/research/research-management/ethics-and-research-integrity/the-clinical-trials-support-network/standard-operating-procedures-sops>

Stakeholders and interests

- Developers: Haim Omer, originator (Tel Aviv University) and Peter Jakob, UK lead developer (Partnership Projects UK)
- Delivery team: RISE Mutual CIC--Kuljit Sandhu (KS), CEO; Johanna Rowlett (JR), Business development and research officer; Rachael Ward (RW), Employee Director and Lead CAPVA practitioner; and Gordon Ashley-Smith (GA) CAPVA practitioner.
- Evaluation team: University of Hertfordshire--Joanna R Adler (JA), Principal investigator; Caroline Cresswell (CC), Trial manager; David Wellsted (DW), Methods Lead; Amanda Busby (AB), Statistics Lead; Jane Fry (JF), Cost data reporting; Karen Irvine (KI), Safeguarding lead and trial manager mentor; Andrew Laughland (ALa), Database design and implementation; Amanda Ludlow (ALu), Neurodiversity lead; Megan Smith (MS); Trial oversight; Silvana Mengoni (SM), IPE senior advisor and trial manager mentor (currently on parental leave, returning in August); Research Assistant to be appointed (RA) and Shivani Sharma (SS) (emerita UH, now at Aston University), REDI.
- UH has not fully costed this according to FEC, given the funder's constraints on overheads, and is thus providing a degree of support to the project through offices, library, administration, legal, technical and other post-award support not directly included within the budget.
- Match funding is received by RISE from Local Authorities like London Borough of Lambeth, the MOPAC VRU (Violent Reduction Unit), and London Borough of Barnet (where RISE first started delivery of CAPVA). No other interests.

Risks

Please see separately submitted risk register and [project oversight](#).

Timeline

The timeline in Table 6 has been mapped to the more detailed Gantt chart provided. In this draft, the overall time has been reduced by five months from that in the previous iteration. This is a more ambitious delivery frame but should still be achievable. The cuts include: a reduction of one month for time allowed for overall delivery of the intervention to all cohorts; removal of time allowed for the IPE survey—which was a proposed element not required by commissioners. Removal of the allocated time for follow-up of outcome measures was made for similar reasons. The main area that no longer conforms to YEF guidance on the time to allow, is the data archiving; this has been set at slightly shorter than the 90 days recommended and is over the university long vacation when staff are encouraged to use their leave. This is a potential risk that has been acknowledged in the risk register. Adjustments to the timeline reflect these modifications to the trial design and have been carried forward into a revised budget (submitted separately). Milestone payments are to be negotiated.

Table 6: Outline of Phases

Dates	Activity	Staff responsible/ leading
1/4/24-31/8/24	Contracting, inception and governance. Please be aware that this phase is mainly for the evaluation team. Work asked of the project team is largely in support of the evaluation.	Full UH team, minus RA, operational lead: CC; Strategic lead: JA RISE: RW and GAS operational responsibility with KS and JR in strategic lead.
02/09/24-25/10/24	Mobilisation. This has been taken as starting when the project team will be most active in finalising preparations for the delivery of the intervention. The distinction between the contracting phase and mobilisation phase acknowledges the different preparations necessary for evaluation and intervention. It also responds to guidance received on maximum duration of project delivery from point of mobilisation.	UH lead: CC RISE lead: JR
28/10/24-2/10/26	Fieldwork, referrals, screening, randomisation and delivery in intervention and control arms	UH lead: CC RISE lead: RW
02/10/26-25/01/27	Data analysis, and initial report drafting	Full UH team, apart from RA, operational lead: CC; Strategic lead: JA
25/01/27-04/06/27	Review and revision of report through to publication	UH lead: CC with oversight from JA
07/06/27-30/09/27	Data archiving	UH: ALa and AB with oversight from CC

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Appendix 1: Changes since the previous YEF evaluation

Appendix Table 1: Pilot to efficacy stage changes

Feature		Pilot to efficacy stage
Intervention	Intervention content	The content is broadly similar but the manual has been revised to better reflect routine practice. In particular, more is said on trauma informed care, cultural differences and the safety measures provided at screening.
	Delivery model	No substantive changes, as hybrid delivery was adopted during feasibility and works well so has been continued.
	Intervention duration	No changes but again codified a little more clearly: up to 18 sessions (after an additional two sessions for family based suitability assessment and including one to two sessions for follow-up post completion of the core intervention). Normally, at least 12 sessions are with parents/carers and the rest are a combination of young people (with or without the parent/carer), other agencies (with parent/carer). Typically delivered over nine-10 months, sometimes up to 12.
Evaluation	Eligibility criteria	YEF have agreed to commission places for a wider age range so a switch from 11-14 to 9-17.
	Level of randomisation	<i>Not applicable to pilots.</i>
	Outcomes and baseline	<i>Not applicable to pilots.</i>
	Control condition	<i>Not applicable to pilots.</i>

Appendix 2: Template for Intervention Description and Replication

Appendix table 2: TIDieR checklist

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
BRIEF NAME			
1.	Provide the name or a phrase that describes the intervention.	p1	_____
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	pp4-5, 8-11	_____
WHAT			
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	pp6-8	Handbook on request
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	pp13-16	_____
WHO PROVIDED			
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	p15	_____
HOW			
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	pp15-16	_____
WHERE			
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	p15	_____

8.	WHEN and HOW MUCH Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	p15	_____
9.	TAILORING If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	pp15-16	_____
10.†	MODIFICATIONS If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A	_____
11.	HOW WELL Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	pp22, 26-28	_____
12.†	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	N/A	_____



Appendix 3: Screening and assessment items from the CAPVA manual

RISE suitability Assessment Template CAPVA

Family Details	
Name of Young Person	
Race/Ethnicity/Religion	
Name of parent/Carer	
Race/Ethnicity/Religion	
Referrer	
Borough	
Dates of Assessment	

Reason for referral
<p>What led to the family being referred to the programme? – Include details from the referral and parents/carers views.</p>
<p>What behaviour (in the last 6 months) is your child displaying that is most worrying?</p>
<p>Tell me about a time when you have felt threatened by your child. What sort of things does he/she do or say?</p>
<p>How confident are you at dealing with this? What do you do if things turn physically or verbally aggressive? (What would be the consequences? How might boundaries be set?)</p>

Family Dynamics/Support Networks
<p>Your Family and Others Who is in your family? Family and significant others indicating, when relevant, the relationships between people.</p>
<p>Who is around to support you in your parenting? Who can you confide in, rely on for support? (friends, community groups).</p> <p>*Do you have extended family members, such as grandparents, aunts, uncles or other relatives, influence, or impact on your family dynamics? Are there specific roles or responsibilities that they take on? *(consider any cultural factors)</p>
<p>Cultural Considerations</p> <p>(When conducting an assessment on a family, it is crucial to consider cultural factors to ensure a comprehensive understanding of the family dynamics and to provide appropriate support. Here are some cultural considerations to keep in mind and questions to ask the family:</p> <p>Do you think your cultural background has an influence on our beliefs, values, and traditions?</p>

<p>What are some of the key practices related to raising children in your culture i.e. in relation to discipline, religion or teaching your children?</p> <p>Have you or your child experienced any instances of discrimination or unfair treatment based on factors such as race, ethnicity, religion, gender, or any other identity markers? How have these experiences influenced your family dynamics and your approach to parenting?</p>
<p>Are there any specific communication barriers that we should be aware of? Would an interpreter be required throughout the CAPVA intervention?</p>

<p>Risk and the Safety of Others</p>
<p>What happens after an argument or incident has occurred.</p>
<p>Has there been any violence towards others such as other pupils, professionals or family including siblings?</p>
<p>Who else in the family is affected by the behaviour and how?</p>
<p>Have you ever had to call the police?</p>
<p>Are there any other risk concerns e.g. self harm, absconding etc</p>
<p>Has the Local Authority given you any safety measures, if so what are they?</p>

<p>Domestic Violence Considerations (The following questions are about domestic abuse and need to be considered with caution if both parents/partners are attending – these may therefore need to be asked at a different time). Please note CPV cases are deemed unsuitable if there is ongoing/current DA taking place within the home.</p>
<p>Have you been threatened by anyone else in your family or in other relationships?</p>
<p>Has there been violence in any of your relationships – now or in the past? (If so, who with, what was the nature of this, who witnessed it, is this still on-going, does the parent require further support)</p>

<p>Parents wellbeing</p>
<p>Are you feeling low or finding your emotions hard to cope with? Do you have suicidal thoughts or ever self-harmed?</p>
<p>Do you see yourself as vulnerable in any way, or have you any special requirements in accessing support? (consider if there are any cultural barriers to accessing services)</p>
<p>Have you ever used drugs and/or alcohol to manage difficult situations or feelings? What is the nature of your use?</p>

Diagnosis
Previous support

Childs well being
<p>Has your child had problems in the now or in the past with any of the following leading to difficulties in daily functioning? If yes, please specify which and give relevant details if known.</p> <ul style="list-style-type: none"> • Drugs (prescription or other) • Alcohol • Mental health including depression, suicidal or isolated or have a specific mental health diagnosis?
<p>Does your child have any problems with addictive behaviours e.g., on-line gaming, viewing pornography, social media? What are the details of these?</p>
<p>Do you have any self-harm concerns?</p> <p>Does your child ever threaten self-harm or suicide to control what you do or how you respond?</p>
<p>Does your child have any additional neurodivergent needs (diagnosed or undiagnosed) that should be considered e.g Learning needs, ADHD, ASD, ODD etc</p>

Other Agencies
Are there or have there been other agencies involved with your family?

Hopes for parenting
What strategies have you tried in the past that have been helpful in resolving the problem?
When the problem behaviour isn't occurring, what is different in your relationship with your child?
What do you appreciate about your child? What would they say they appreciate about you?)

Conclusion/Outcome of assessment.
Assessment of suitability and motivation.
Current Risk – Who is at Risk, What is the Risk?
Obstacles for Successful completion

Treatment Goals for the Intervention

By developing strategies to manage risk, the Child to Parent Violence intervention uses a Non-Violent Resistance Approach. This is with the aim of parents/carers building up their authority and parental presence without getting involved in fruitless power struggles. In order to be suitable parents, need to commit to resisting violence and to avoiding violence when responding to their child, regardless of the provocation.

The Non-Violence Resistance approach is based on the following principles and formulates the treatment goals for the intervention:

- De-escalation skills – This helps parents the skills needed to resist violence and de-escalate aggressive behaviour and incidents. This allows a reduction in psycho/physiological arousal in the parents and child.
- Deferring the response – Parents are encouraged to avoid reacting during an incident and instead respond later (strike while the iron is cold). A carefully planned response will take place sometime after any incidents.
- Reconcile and Praise – Parents make unconditional gestures of love, concern and praise towards child, instead of rewards. This is in order to raise parental presence without punishments or consequences. The reconciliation gestures are not rewards for good behaviour, they are practised as a caring presence from parents to reassure the child of the consistency of the parent and child relationship.
- The Support Network: - Parents’ disclosure about the extent of the problem of violence with a number of significant people who they also invite to be part of a support network, such as grand-parents, aunts and/or uncles, or friends.
- Increased Parental Presence: This involves changing the ways in which parents are present in their child’s life and refocusing interactions away from persistent conflict.

Assessment completed by	
Role	
Date	

Appendix 4: YEF RISE Protocol development 2023/2024, Stata Code

Stata 15.1, StataCorp LLC

Power estimation, D Wellsted January 2024

Estimating Effect Size, before after studies

Following: Chow S-C, Shao J, Want H. Sample size calculations in clinical research. 2nd Ed
Boca Raton: Chapman and Hall, 2008.

Estimating standard deviation of change

```
di 13.8*(2*(1-0.7))^0.5 /* 10.69 */
```

Estimating the critical t value

```
di invt(31,0.975) /* 2.04 */
```

Estimating the non-centrality parameter

```
nctncp 2.04 0.2 31 /*2.89 */
```

Estimating the effect size for change

```
di 2.8927/sqrt(32)*10.69 /* 5.466 */
```

Minimal Detectable Change, after Kovacs et.al

$MCD = t_{\alpha} \cdot \sqrt{2} \cdot SEM$

```
di invt(31,0.975)*sqrt(2)*13.8/sqrt(32)
```

Summary code, sample size

Scoping sample size assuming $\alpha=0.05$, $1-\beta=0.80$, twosided test.

```
power twomeans 10 (12, 13, 14), sd(10)
```

```
power twomeans 10 12.9, sd(10)
```

Adjusting for 25% drop out

```
display 188*1.25
```

Appendix 5: Target and predicted referral and recruitment rates

Appendix Table 3: Quarterly referral and recruitment rates

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Total
Months (e.g. Oct-Dec 23):	Oct-Dec 24	Jan-March 25	April-June 25	July-Sept 25	Oct-Dec 25	Jan-March 26	April-June 26	July-Sept 26	
Target number of children and young people referred into the project	100	135	135	130	130	75	No referrals	No referrals	705
Target number of families recruited to the project and evaluation	20	90	90	90	90	80	10	0	470
Predicted number of families who withdraw/drop out/during trial	3	16	16	16	16	14	10	3	94



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