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GenPMTO: Adaptation and feasibility study

Evaluation protocol

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About

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Project title	GenPMTO Evaluation - Feasibility and adaptation study		
Developer (Institution)	Implementation Sciences International Inc. (ISII)		
Delivery partner (Institution)	Barnardo's		
Evaluator (Institution)	Ending Youth Violence Lab (part of the Behavioural Insights Team)		
Principal investigator(s)	Tom McBride		
Evaluation plan author(s)	Neeraj Rahal, Lilli Wagstaff, Niall Daly, Emma Leith, Martin Wessel, Jack Martin, Tom McBride		
Evaluation setting	3 boroughs in London (Barking & Dagenham, Brent, and Tower Hamlets)		
Target group	Caregivers of young people aged 8-14, who have been identified as being at risk of committing violent acts and/or entering into the criminal justice system.		
Planned number of participants	 Approximately: 36-90 caregivers (quantitative sample) 9-12 caregivers (qualitative sample, subset of caregivers in quantitative sample) 12 GenPMTO trained practitioners (qualitative sample) 2 Barnardo's programme managers (qualitative sample) 6 staff from referring agencies (qualitative sample) 		
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About the Ending Youth Violence Lab

The Ending Youth Violence Lab ('the Lab') was founded in Summer 2022, bringing together expertise in intervention, evaluation and youth violence. It is funded by Stuart Roden and the Youth Endowment Fund (YEF) and is being incubated at the Behavioural Insights Team (BIT).

The Lab's mission is to catalyse a step change in understanding and tackling youth violence. To do this, we do 3 things: Firstly, we identify promising interventions which seek to address youth violence. Secondly, we fund the development and delivery of these interventions. Thirdly, we conduct research to assess the delivery of interventions, identify ways to improve them, and explore the potential for further evaluation (with a focus on early-stage testing, to support the work of YEF).

We prioritise three strands of activity:

- Supporting the importation, adaptation, and testing of well-evidenced interventions from overseas - we identify approaches with strong evidence of improving youth violence outcomes or related upstream factors in other countries, adapt these to the UK context, and deliver early-stage testing.
- Working with UK organisations to develop strong ideas into evaluable interventions we work with the youth violence prevention sector to find interventions that have strong theoretical underpinnings, are committed to rigorous evaluation, and oversee the development and early-stage testing needed to get them trial-ready.
- Working with developers, researchers, practitioners, and service users to co-design new and innovative approaches - we build partnerships and fund the development of novel approaches to tackling youth violence, with a focus on addressing underserved populations and unmet needs.

The project described in this protocol forms part of strand 1 of the Lab's approach.

Project overview

About the intervention

This project is a multi-stage evaluation of GenPMTO (Generation Parent Management Training – Oregon Model). GenPMTO is a parenting programme which involves trained practitioners using active teaching approaches (such as group problem-solving, role-play, and video modelling) to support caregivers in using positive parenting strategies at home. The programme is designed to improve parenting practices, as well as a range of outcomes for young people, including improving academic performance, reducing school exclusions, and reducing offending and criminal behaviour.

The programme was originally developed in the USA, though now operates internationally, including in Denmark, Iceland, Mexico, Chile, Canada, the Netherlands and Norway, where it has been delivered and successfully evaluated. However, GenPMTO has never been delivered in the UK.

Evidence registries in the USA¹ and UK² classify the programme's effectiveness as being strongly supported by research evidence. Importantly, and rarely for programmes of this type, GenPMTO has long-term evidence of reducing arrests^{3 4}.

About the evaluation

This project represents the first attempt to deliver and evaluate GenPMTO in the UK. To do so, the Lab is conducting a multi-stage evaluation, involving delivering the intervention across three London boroughs, with a focus on caregivers of 8-14-year-old children and young people (CYPs), who are identified to have risk factors associated with involvement in violence. The stages of the project include:

- Stage 1 & 2 Adaptation, training and feasibility study in its initial two stages, this project will be testing the extent to which it is feasible to deliver and evaluate in the UK. By adaptation, we mean making a series of changes to the programme to attempt to maximise its acceptability and feasibility in a UK context. Note that while adaptation (and training of practitioners) will start in advance of the feasibility study, the success of the programme's adaptation and practitioner training will continue to be monitored and tested in parallel with the feasibility study. Further adaptations may be made in advance of the next stage. If the results of these stages are positive and suggest that delivery and evaluation are feasible, the project will move to the third stage.
- Stage 3 Pilot trial the Lab will further test the extent to which it is feasible to robustly
 evaluate this programme, and gather preliminary evidence on the programme's impact during
 a pilot trial. If these results are positive, we will progress to the fourth stage.
- Stage 4 Efficacy trial the Lab will conduct an efficacy trial, to robustly determine if the
 programme can have a positive impact on outcomes for families and young people in the UK.

To design this project, the Lab has collaborated with two partners. The first is ISII (Implementation Sciences International, Inc.), a research-based, non-profit organisation based in the USA, which implements the GenPMTO programme, in partnership with the programme developers. ISII also trains

¹ <u>https://www.cebc4cw.org/program/the-oregon-model-parent-management-training-pmto-2/</u>

² <u>https://guidebook.eif.org.uk/programme/generation-pmto-group</u>

³ Forgatch, M. S., Patterson, G. R., Degarmo, D. S., & Beldavs, Z. G. (2009). Testing the Oregon delinquency model with 9-year follow-up of the Oregon Divorce Study. *Development and psychopathology*, *21*(2), 637-660.

⁴ YEF's toolkit of existing research on parenting programmes highlights a lack of evidence about the direct impact of parenting programmes on crime and violence.

community practitioners in its use across the world. The second partner is Barnardo's, the UK's largest children's charity, and the delivery partner for the project. Barnardo's bring significant expertise and experience in delivering similar services and working with vulnerable families.

About the rationale for this evaluation

Whilst there is evidence of GenPMTO's impact on a range of outcomes, this is based on studies conducted outside the UK. There is a known issue with programmes being transported into new countries and not demonstrating effectiveness when trialled in their new setting and there are several examples in the UK of failed replication of programmes^{5 6 7}. One often cited explanation for the high volume of null result trials in the UK, in the context of transporting programmes from overseas, is that these programmes haven't undergone the necessary formative work of ensuring they are appropriate, deliverable, and evaluable within the UK context⁸. These are necessary pre-steps to a full-scale impact evaluation and mitigate the risk of expending resources on an extensive trial before the programme has been adapted to the domestic context, which would ultimately yield uninformative results.

By undertaking a staged evaluation approach to GenPMTO, this enables gathering preliminary data on the programmes' feasibility of delivery and evaluability. This facilitates being able to refine the programme and approach to evaluation, to apply learnings from early stages to design a more robust full-scale efficacy trial. Provided feasibility, acceptability and evaluability are established, there is a strong case to conduct a full-scale efficacy trial on GenPMTO in the UK, given the strength of its existing evidence, cultural similarity with the European countries where evidence has already been gathered in, and its potential impact on reducing arrests post-delivery.

About this protocol

This document is the evaluation protocol for Stage 1 - Adaptation and training, and Stage 2 - Feasibility study. For ease of reference, we refer to this document as the 'feasibility study protocol'.

Should the evaluation progress to Stage 3 and Stage 4, we will publish a second protocol covering the pilot and efficacy trials, prior to their delivery. Our rationale for publishing separate protocols is that the design of the latter stages will be influenced by what we learn in the feasibility study. For example, there may be changes to the delivery of the programme, if we encounter issues with recruitment and retention in these first stages. We may also alter the set of outcomes we plan to measure if we find outcome surveys to be too lengthy, burdensome, or difficult for participants to understand.

⁵ Robling, M., Bekkers, M-J., Bell, K., Butler, C. C., Cannings-John, R., Channon, S. et al. (2016). Effectiveness of a nurse-led intensive home-visitation programme for first-time teenage mothers (Building Blocks): a pragmatic randomised controlled trial. *Lancet, 387*, 146-155.

⁶ Humayun, S., Herlitz, L. Chesnokov, M., Doolan, M., Landau, S. and Scott, S. (2017). Randomized controlled trial of Functional Family Therapy for offending and antisocial behavior in UK youth. *Journal of Child Psychology and Psychiatry* 58(9), 1023-1032.

⁷ Fonagy, P., Butler, S., Cottrell, D., Scott, S., Pilling, S., Eisler, I. et al. (2018) Multisystemic therapy versus management as usual in the treatment of adolescent antisocial behaviour (START): a pragmatic, randomised controlled, superiority trial. *The Lancet Psychiatry*, *5*(2), 119-133.

⁸ Lendrum, A., & Humphrey, N. (2012). The importance of studying the implementation of interventions in school settings. *Oxford Review of Education*, *38*(5), 635-652.

2. Intervention

Intervention overview

Background

GenPMTO is a targeted parenting programme for families with children and young people aged 3 -18, at risk of behaviour problems. It is based on the theoretical work of Gerald Patterson and colleagues at the Oregon Social Learning Center.⁹ GenPMTO aims to improve school functioning, social relationships, and prevent involvement in criminal justice and substance use.

Based on robust evaluations, the programme has a strong track record of improving a range of important outcomes for parents and young people, such as reducing child externalising and internalising problems. The Early Intervention Foundation (EIF) awarded GenPMTO an evidence rating of 4¹⁰. Level 4 is the highest rating on the EIF strength of evidence scale, identifying programmes with evidence of a long-term impact and multiple rigorous evaluations. The programme has been found to positively impact both on child mental health and wellbeing (through improved child adjustment, social competence, emotional regulation, and a reduction in internalised behaviour problems), and on crime, violence and antisocial behaviour (through reduced police arrests, child conduct problems, externalising behaviour problems, antisocial-aggressive behaviour, delinquency and criminal behaviour, and improved social/prosocial behaviour). In terms of magnitude and longevity of impact, EIF calculated GenPMTO is associated with an 'improvement index' ranging from 11-22, with positive impacts identified as long as 8.5 years after programme completion¹¹.

The programme has also demonstrated successful results when adapted to be delivered to culturally specific populations. For example: In the USA, the programme has been adapted for Latino/a families, and in Norway, the programme has been adapted for Somali and Pakistani mothers. Since the first international implementation in Norway in 1999, GenPMTO has been delivered to more than 50,000 families from a diversity of circumstances, socioeconomic backgrounds and cultures.

Delivery of GenPMTO

GenPMTO can be delivered to caregivers¹² on an individual family basis, or to groups of caregivers - however the focus of this project is the group-based version¹³. GenPMTO can also be delivered on-line, or in-person. More than one caregiver of a child or young person is able to be involved in the programme.

⁹ Fisher, P. A., & Gilliam, K. S. (2012). Research into theory into practice: an overview of family based interventions for child antisocial behavior developed at the Oregon Social Learning Center. *Clin Salud*, *23*(3), 247-259.

¹⁰ https://guidebook.eif.org.uk/public/files/pdfs/programmes-generation-pmto-group.pdf

¹¹ An index of 22 means one would expect the median participant in the comparison group who did not receive the intervention (i.e., someone for whom 50% of their peers have better outcomes and 50% have worse outcomes), to improve to the point where they would have better outcomes than 72% and worse outcomes than 28% of their peers, if they had received the intervention.

¹² We use the term 'caregivers' to refer to those individuals who are primarily and most consistently responsible for the care of a child. This is a broad term which includes parents, but also includes other individuals, such as grandparents, aunts, uncles, foster parents, etc. GenPMTO is designed to be delivered to a range of different types of caregivers and is not limited strictly to biological parents.

¹³ Training of practitioners for group-based delivery of the programme can be more easily adapted for individual-based delivery than vice-versa, and so group-based delivery was agreed with delivery partners and programme as a starting point.

The programme delivery model is to train a first 'generation' of practitioners in a given context to full certification by ISII. A select set of these certified practitioners are trained to train subsequent cohorts of practitioners, if the programme is to be continued and/or scaled in that context.

Practitioners attend a number of workshops both before and during the delivery of the programme, with ISII staff supporting and providing feedback to practitioners throughout. ISII staff review practitioner delivery of the programme in order to grant full certification to practitioners who have met the required standards of delivery.

Practitioners are trained to deliver the programme to groups of 12-15 caregivers over either 10, 12, or 14 weekly sessions (depending on the delivery context). These sessions are approximately 90 - 120 minutes in length and delivered by 2-3 practitioners.

During the feasibility study stage of this project, practitioners are being trained only in delivering the 14-week programme. While we will aim to have groups of 12-15 caregivers, groups may be as small as 6, depending on recruitment.

Programme topics and skills

Delivered across 14 weekly sessions, the programme covers 14 essential topics, with sessions being agenda-driven, responsive, and focusing on skill building to promote effective parenting during times of transition. Practitioners use active teaching approaches (such as group problem-solving, role-play, and video modelling) to support caregivers in using positive parenting strategies at home. The topics on which caregivers receive training are as follows:

- 1. Working through change
- 2. Encouraging cooperation
- 3. Teaching positive behaviour
- 4. Observing emotions
- 5. Regulating emotions
- 6. Active communication
- 7. Setting limits
- 8. Following through
- 9. Communicating with children
- 10. Problem solving
- 11. Encouraging cooperation: incentive charts
- 12. Monitoring children's activities
- 13. Promoting school success
- 14. Putting it all together

The programme seeks to develop the following core skills with caregivers:

- Encouraging positive behaviour
- Limit setting with mild consequences
- Family problem-solving
- Positive involvement
- Supervision/monitoring
- Identifying/regulating emotions
- Promoting active communication
- Promoting success at school

An overview of GenPMTO using the TIDieR framework can be found in Annex A.

Figure 1 below details a high-level Theory of Change for the intervention.

Intervention theory of change

Figure 1 - GenPMTO theory of change

	I WHY		 WHO)	Ном	J	(wi	HAT	I will the intervention a	achie	ve?
Evidence-based assumption		Evidence-based assumption	Evidence-based assumption		INTERVENTION		Evidence-based short-term outcomes		Evidence-based medium-term outcomes		Evidence-based long-term outcomes
Evidence-based observation		Evidence-based need Some parents need support and guidance in order to develop a set of behaviours and skills which will improve family interactions and create a stable and nurturing environment for their children Coercive parenting disrupts positive parenting.	Target population Parents of children between 3 and 18 at risk of developing or displaying early signs of behavioural challenges and externalising problems Target population for our trial: 8-14, showing signs of behavioural challenges and externalising problems		Intervention activities that will address the need Active teaching to engage parents in learning and how to apply the techniques effectively at home, covering: - Encouraging Positive Behavior - Family Problem Solving - Positive Involvement -Limit Setting -Monitoring		Immediate outcomes For parents: -Improved parenting strategies, increased positive parenting - More effective parenting - Decreased use of harsh discipline		Intermediary outcomes For children: - Reduced internalising behaviour - Reduced externalising behaviour - Increased prosocial behaviour		Primary outcomes For children: - Fewer school exclusions - Better academic performance - Lower levels of offending behaviour

How the intervention compares with other services and services-as-usual

Parenting programmes such as GenPMTO focus on enhancing parenting practices and behaviour. These can involve: developing and practising positive discipline techniques, learning age-appropriate child development skills and milestones, promoting positive interaction between parents and children, and locating and accessing community services and supports.

Well-known examples of parenting programmes in the UK include Triple P, Incredible Years, and Strengthening Families. These programmes typically involve educational elements relating to child development, as well as training elements which support parents to develop specific skills. An initial survey of the three London boroughs (Brent, Tower Hamlets, and Barking & Dagenham) in which GenPMTO is anticipated to be delivered suggests that other such parenting programmes are currently being delivered in these areas.

To the best of our knowledge, while there is strong evidence that other parenting programmes can be effective at reducing behavioural difficulties (which are associated with later involvement in violence), there are limited examples of parenting programmes with robust evidence of reducing crime and violence itself¹⁴. GenPMTO is a rare example of a parenting programme that has measured these outcomes and robustly demonstrated improvements.

While some other interventions share these characteristics, GenPMTO can be distinguished from many other parenting programmes on the basis that a) it is more intensive, and is delivered over a longer period of time, b) has a stronger international evidence-base, and c) has evidence of reducing arrests.

¹⁴ Gaffney, H., Farringdon, D.P. & White, H. (2021). Parenting Programmes: Toolkit technical report. Youth Endowment Fund: London. Retrieved from:

https://youthendowmentfund.org.uk/wp-content/uploads/2021/06/Parenting-programmes-Technical-Report.pdf

3. Research Objectives

As outlined above, this protocol focuses on Stages 1 & 2 of the evaluation. We've categorised our research questions for these Stages into four key aims:

- 1. Establish whether GenPMTO is able to be suitably adapted for delivery in the UK context.
- 2. Establishing whether GenPMTO is feasible to deliver in the UK context.
- 3. Establishing whether GenPMTO is acceptable in the UK context.
- 4. Establishing whether it would be possible to **evaluate** the impact of GenPMTO using a randomised controlled trial (RCT) in the future.

Stage 1 - Adaptation and training

- The purpose of this Stage is to prepare for initial delivery and the feasibility testing of delivery, by making any adaptations that may be necessary for the UK context and beginning practitioner training.
- The research objectives of this Stage firstly focus on identifying whether the programme may require adaptations to fit into the UK context and identifying and justifying appropriate adaptations. Secondly, we want to identify whether sufficient numbers of practitioners can be recruited and trained within the budget of the project, and to identify the optimal approach to recruitment and training of future practitioner cohorts to allow delivery at a larger scale.

Stage 2 - Feasibility study

- The purpose of this Stage is to understand the feasibility of delivering GenPMTO to the caregivers of children who have been identified as being at risk of violence, through testing recruitment, retention, fidelity, etc. We will also conduct further adaptation to the programme as necessary, responding to what we learn from practitioners and caregivers who have experienced the programme for the first time.
- The specific research objectives here focus on:
 - **Feasibility** Can Barnardo's recruit and retain caregivers of children who meet inclusion criteria and are at risk of youth violence, and deliver the programme with fidelity?
 - Acceptability Is the GenPMTO programme seen as acceptable and valuable by caregivers and practitioners in a UK context?
 - Evaluability Firstly, is there sufficient demand and capacity to deliver GenPMTO at a scale required for a randomised control trial? Secondly, is it feasible to collect outcome data from participants, which would support robust outcome data collection procedures during a pilot and/or efficacy trial?

It is worth noting that evaluability is generally not considered a research objective for a feasibility study (as the Lab and EIF's 10 steps framework defines a feasibility study¹⁵), and the testing of evaluation procedures is usually part of a pilot trial. However, given that in our case the pilot trial (Stage 3) is intended to be an internal pilot, with its sample forming part of the efficacy trial (Stage 4), we decided that there were important

¹⁵ Asmussen, K., Brims, L., & McBride, T. (2019). *10 steps for evaluation success*. London: Early Intervention Foundation.

research objectives regarding the collection of data that should be addressed during the feasibility study, to minimise risks to the pilot study¹⁶.

Table 1 below outlines the specific research questions we seek to answer in Stages 1 and 2, to address the above research objectives. These research questions were developed by the Lab in consultation with both Barnardo's and ISII.

¹⁶ Note that we will not be trialling or testing randomisation of participants during Stage 2 - Feasibility study.

Project Stage	Research objective(s)	Description of objectives	Research questions
Stage 1 - Adaptation and training	Establishing the feasibility of adapting GenPMTO for the UK context Establishing feasibility of recruitment and training of practitioners	 Should GenPMTO be adapted to appropriately fit the social, cultural and institutional context in the UK? Can Barnardo's recruit and train sufficient numbers of practitioners to enable initial delivery and evaluation? 	 Adaptation What changes do practitioners think should be made to the programme before delivery, to accommodate cultural sensitivities or factors specific to the UK that should be considered? Training Can enough of the appropriately qualified personnel be recruited and trained?
Stage 2 - Feasibility study	Establishing feasibility of delivery	Can Barnardo's recruit and retain parents of children at risk of youth violence to GenPMTO and deliver the programme with fidelity?	 Recruitment Can Barnardo's recruit a sufficient number of boroughs to participate in the programme? What factors affect the recruitment of boroughs? What factors affect the referral process? Which agencies and settings are referring families? How many families are being referred by each of these agencies/settings in terms of what proportion of participants are meeting inclusion criteria? Are there differences between referring agencies/settings in terms of what proportion of participants are taking part in the programme and completing the programme? Can the boroughs and Barnardo's recruit and retain a sufficient number of caregivers with children at risk of youth violence, given other parenting programmes available? Are the inclusion and exclusion criteria appropriate for identifying and recruiting sufficient numbers of caregivers with children at risk of youth violence? What factors affect recruitment and retention of caregivers?

Table 1: Research objectives and questions addressed during Stages 1 & 2

•	Does recruitment and retention of caregivers vary by ethnicity, gender or
	other baseline characteristics?

Fidelity

- Can GenPMTO be delivered with fidelity to the original programme design?
- What factors affect delivering GenPMTO with fidelity?
- What variations in delivery are appropriate for effective implementation?

Adaptation

- What further adaptations, if any, need to be made?
- What are core characteristics of the programme that should not be adapted, and what are surface characteristics that can be?
- How could the programme be adapted to improve recruitment and retention?
- Are the intervention materials appropriately defined, developed and suitable for the UK context (both those that are practitioner facing and those that are parent facing (i.e. training and role specific materials)?
- Are there any cultural sensitivities or factors specific to the UK that should be considered, which have not been considered in the previous stage?

Establishing acceptability of GenPMTO	Is the GenPMTO programme seen as acceptable and valuable by caregivers and practitioners in a UK context?	 Is the GenPMTO programme acceptable to caregivers? Is the programme acceptable to practitioners? What factors affect acceptability by practitioners and caregivers? Do caregivers and practitioners' views vary depending on whether GenPMTO is delivered virtually, or in-person?
Establishing evaluability of GenPMTO	• Do we have enough confidence in the feasibility of a randomised controlled trial, particularly in terms of recruitment, randomisation and outcome data collection, to justify a continuation of the trial to the internal	 Is outcome data collection possible and sufficient? What factors affect ease of outcome data collection? What factors affect the completeness and quality of outcome data collected?

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pilot?	 How could the approach to outcome data collection be improved to increase the ease of data collection, and the completeness and quality of data collected? Is there sufficient demand for the intervention to reach the scale required for a well-powered RCT?
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4. Monitoring and success criteria

We will use monitoring criteria throughout Stages 1 & 2 for two purposes:

- To monitor if the project is proceeding as expected, allowing for us to make adjustments or pause the work if needed.
- At the end of the feasibility study, to make recommendations to the Youth Endowment Fund as to whether progression to Stage 3 (pilot trial) should be pursued. At the end of the Stage 3, to make recommendations as to whether Stage 4 (efficacy trial) should be pursued.

We will use RAG (Red, Amber, Green) ratings to rate the progress of target criteria, on a monthly basis. Criteria meeting red or amber cut-off scores will prompt the following changes to our approach:

- Criteria with Amber ratings will indicate reviewing or adjusting delivery.
- Criteria with Red ratings will indicate pausing delivery for a period of time to carefully assess what changes would be required to justify resuming delivery.

Management information will be obtained on a regular basis to inform oversight of these criteria. As there are limited opportunities to make substantive changes to the content and delivery of GenPMTO between the pilot and efficacy trials, these monitoring criteria in the earlier stages of the study are particularly important.

The quantitative monitoring criteria used to monitor feasibility-related objectives are described in Table 2 below. While the criteria below offer guidance for the progression of the evaluation on the basis of quantitative assessments, these will also be complemented by qualitative measures, such as ongoing practitioner feedback and interviews with practitioners and caregivers.

The below monitoring criteria were developed iteratively in consultation with both Barnardo's and ISII, and help to ensure that the study does not progress from one phase to the next without sufficient evidence of overall acceptability and feasibility.

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Project stage	Criterion	Description	Target criteria	RAG scores
Stage 1 - Adaptation and training (Criteria for	Recruitment	Proportion of required practitioners recruited within c. 3-5 months of Stage 1 beginning	12 practitioners recruited	Red: <8 recruited Amber: 8 - 11 recruited Green: 12 recruited
progression to next Stage)	Training I	Number of practitioners enrolled in training in GenPMTO methodology within c.3-5 months of recruitment formally launching	12 practitioners enrolled	Red: <8 enrolled Amber: 8 - 11 enrolled Green: 12 enrolled
	Acceptability	Proportion of practitioners and caregivers who broadly indicate that GenPMTO will be acceptable to both practitioners and caregivers in a UK context	>60% practitioners and >60% caregivers	Red: <60% of target Amber: 60-79% of target Green: 80-100% of target
Stage 2 - Feasibility study (Criteria for progression to next Stage)	Referral volume	The volume of referrals to the programme received by Barnardo's on a monthly basis	> 5 referrals per month (average across referral months, considered for each borough involved in delivering GenPMTO during the feasibility study)	Red: Less than 3 Amber: 3-4 Green: 5 or more
	Referral suitability	The proportion of families referred to the programme who have a child in the eligible age range and who meets all other eligibility criteria	As per RAG score	Red: <40% of caregivers Amber: 50-69% of caregivers Green: 70-100% of caregivers

Table 2: Feasibility-related monitoring criteria listed by project stage

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	Caregiver ake-up	The percentage of families who are eligible, and offered inclusion in the delivery of GenPMTO in the feasibility study, who take up the service	As per RAG score	Red: <20% of eligible families Amber: 20-50% of eligible families Green: 50 - 100% of eligible families
т	Fraining II	Number of practitioners who complete the programme of training offered during the feasibility study stage ¹⁷	12 practitioners complete all training requirements during the feasibility study stage	Red: <7 Amber: 7-9 Green: 10-12
F	Fidelity	The ISII programme experts assess practitioner sessions according to the FIMP (Fidelity of Implementation Rating System) measure developed by ISII. ¹⁸	At the end of the feasibility study, practitioners have received an aggregate mean FIMP score of at least 4 ¹⁹	Red: <60% of practitioners Amber: 60-79% of practitioners Green: 80-100% of practitioners
	Dutcome data collection	Proportion of caregivers and their child/ren completing outcome measures during the feasibility study	As per RAG score	Red: <40% of caregivers Amber: 40-75% of caregivers Green: 75-100% of caregivers

 ¹⁷ Practitioner training involves participating in workshops and coaching sessions, as part of the accreditation process. However, accreditation is contingent on practitioners practising delivering GenPMTO to multiple cohorts of caregivers, which may not be possible during the length of the feasibility study. Therefore this monitoring criteria is focused on completion of training elements which take place during the feasibility study, and does not refer to practitioners' accreditation status.
 ¹⁸ ISII will monitor the delivery of GenPMTO during the feasibility trial, and assess the fidelity with which practitioners deliver each session of the GenPMTO programme. These fidelity ratings are captured in ISII's bespoke FIMP system and will be shared (in a de-identified format) with the Lab.

¹⁹ A FIMP score of 4 is considered to be the lowest score for what is considered acceptable implementation fidelity

5. Design and methodology

Stage 1 - Adaptation and training

Overview

'Adaptation' here refers to a process of thoughtful and deliberate alteration of the design or delivery of the intervention to improve its fit or effectiveness in this context. In particular, training materials for practitioners and teaching materials for caregivers may need to be adapted to ensure that they are relevant to both a UK audience generally, and to the target population specifically.

Given the limited opportunity to make adaptations after the feasibility stage, ensuring the content and approach of GenPMTO is appropriately adapted to meet the needs of UK caregivers, prior to Stage 3 (pilot trial) is important.

Design

The adaptation process will be split into two phases;

- Initial adaptation occurring prior to delivery of GenPMTO.
- **Further adaptation** occurring through a series of workshops with practitioners and caregivers during and after the feasibility study (as described in the Further adaptation section).

Whilst we had initially intended to conduct one larger adaptation exercise prior to delivery, we decided to split adaptation activity over time. This was informed by feedback from the programme developers that adaptation would benefit from practitioners' having completed formal training in GenPMTO and having learned the model on a deeper level by delivering the curriculum.

Any adaptations to the delivery or content of GenPMTO, and their rationale, will be recorded by the Lab. This process of adaptation will be undertaken as a collaboration between ISII (as the ultimate owners of the GenPMTO model), Barnardo's, and the Lab.

Initial adaptation

The purpose of this phase was to prepare for delivery of GenPMTO by making an initial round of 'light touch' adaptations to the programme prior to delivery and practitioner training. Given that GenPMTO has a rich evidence base across several countries, significant adaptations to the programme were considered unlikely. However, this phase was used to ensure that it was as suitable as possible for delivery in a UK context.

For the initial light touch adaptations, the ISII team and a team of practitioners from Barnardo's reviewed the existing GenPMTO practitioner manual and caregiver materials and made changes to those materials²⁰. These sorts of light touch adaptations focused on:

 Changes to language: modifying spelling from American to UK English (e.g. "behaviour" instead of "behavior")

²⁰ This phase of adaptation occurred prior to the publication of this protocol.

- Changes to cultural references: for example changing '\$10 role play' to '£10 role play'.
- Changes to images in materials to be more culturally relevant.

Reviewers were prompted to read through the GenPMTO programme materials and leave comments on these documents with any feedback or thoughts. If changes were suggested, practitioners were asked to provide a brief rationale about why the change would potentially improve the programme's chances of being effective and acceptable in the UK.

The specific prompts we shared with reviewers are described below in Table 3.

Table 3: Areas of adaptation and prompts for practitioners

Adaptation areas	Specific prompts
Language	 Is the language of the materials appropriate for parents and children here in the UK? Are there more suitable phrases to communicate ideas and build rapport with caregivers
Culture and norms	 Are examples in programme materials up-to-date and culturally appropriate (e.g. referencing family leisure activities which are more common to families in London, or statistics such as prevalence of knife crime, rather than gun violence)? Do these help participants to personalise the information? Does the programme's content reflect US cultural norms and values (especially those regarding child development, child-rearing and disciplining practices, socially desirable behaviours etc.) rather than UK ones, which might require some changes? Are there differences in social norms which might change the way caregivers respond to different elements of the programme? One example of where social norms may differ and where adaptation may be required relates to GenPMTO requiring lots of active participation, and activities like roleplay that might require confidence and being comfortable with 'putting yourself out there'. This might come more naturally to families from the US rather than UK families - would UK families need additional support or encouragement to engage in these activities?
Participant needs	 Does the current programme meet the needs of caregivers who may be referred to GenPMTO here in the UK? For example: English language fluency Literacy levels Accessibility needs
Contextual factors	• How might delivery of GenPMTO be affected or influenced by external adverse events which may be likely in the UK (e.g. teacher's strikes, train strikes)?

Training

The initial training of 7-12 practitioners will begin in August 2023, with training delivered by ISII personnel. After a 5-day training workshop facilitated by ISII, practitioners will begin working with families, as they implement what they have learned (e.g. session content, active teaching and co-facilitation strategies, process skills to promote engagement and cohesion). Practitioners will receive observation-based coaching on their group sessions. This activity provides opportunities for practitioners to reflect on their work, seek and receive feedback, practice session content, and prepare for upcoming sessions.

GenPMTO practitioner training stipulates that generally after 4-6 weeks of delivering sessions to caregivers, practitioners attend a second 5-day training workshop. Following this second workshop, practitioners will continue to develop by implementing what they have learned in the training sessions and receive observation-based coaching, with ISII staff reviewing their sessions with caregivers on a regular basis²¹.

Lab staff will monitor both practitioner attendance at these training workshops, and self-reported practitioner satisfaction with the content and delivery of GenPMTO. This is of relevance for evaluating the feasibility of delivering GenPMTO as it relates to both the 'Recruitment' and 'Training I' monitoring criteria outlined in Table 2. If the recruitment and/or training of practitioners in the initial stages of the study proves to be more challenging than anticipated, it may be a sign that one or more elements of programme delivery are either not feasible in a UK context, or need to change in order for the study to proceed to the next stage.

²¹ After a sufficient number of groups and sessions that have been positively reviewed by ISII fidelity raters, ISII will award GenPMTO 'certification' to a practitioner.

Stage 2 - Feasibility study

Design

As detailed in Methods and data collection section below, the feasibility study is designed to obtain an in-depth understanding of the experiences of a range of participants, stakeholders and delivery partners involved with delivering GenPMTO. The emphasis of the feasibility study is on understanding the nature of delivering GenPMTO in a UK context. It is essential that the feasibility study identifies as many issues with recruitment, retention, fidelity, and acceptability as possible, as there will be less scope for adjustment between the Stage 3 - Pilot trial and Stage 4 - Efficacy trial.

We will conduct rigorous in-depth qualitative research to answer our research questions about how feasible and acceptable delivery of GenPMTO is in the UK context. To supplement this rich qualitative data, we will also gather and analyse administrative data about referral rates, retention, and fidelity, to assess feasibility of delivery on an ongoing basis. The feasibility study will also investigate practitioners and caregivers' views on the programme when delivered in different modes (online and in-person), to inform decision-making about how to deliver in future stages of this evaluation. Whilst there are differing session lengths of GenPMTO, these all cover the same content, in varying levels of detail.

We will also invite caregivers receiving GenPMTO, and their children, to complete separate outcome surveys. All caregivers receiving GenPMTO will be invited to complete outcome surveys during programme delivery (both at baseline and post-intervention). We will also invite caregivers' children to complete a separate outcome survey, at the end of the programme delivery (i.e. post-intervention). These surveys will be used to measure the impact of the programme in Stages 3 & 4 (should the evaluation progress to the pilot and efficacy trial stages).

The outcome measures for caregivers are:

- Parenting Practices Interview (self-reported measure)
- Parental Locus of Control-Short Form Revised (self-report)

The outcome measures for CYPs include:

- Strengths and Difficulties Questionnaire (parent report of child)
- Eyberg Child Behaviour Inventory (parent report of child)
- Self-reported delinquency scale (child self-report measure)
- Victimisation sub-scale of the Problem Behaviour Frequency Scale (child self-report measure)

However, for the purposes of the feasibility study, we are administering these surveys primarily to obtain information about response and completion rates, ahead of the next stage of the evaluation. We will not be performing any impact analyses on the outcome measures of interest in the feasibility study. Ethical considerations of our approach are outlined in the Ethics and data protection section of this protocol.

Delivery of GenPMTO during the feasibility study

Upon completion of the first 5-day training workshop for practitioners, and assuming the recruitment of a sufficient number of eligible families, the delivery of GenPMTO during the feasibility study will begin in Autumn 2023, lasting for approximately 3-6 months.

This will involve 2-3 newly-trained practitioners delivering GenPMTO, to 1-2 cohorts of caregivers. . GenPMTO will be delivered across three London boroughs (Barking & Dagenham, Brent, and Tower Hamlets). Practitioners will aim to deliver GenPMTO to one cohort of caregivers online, alongside an in-person mode of delivery to another cohort of caregivers.

Participants

Overview

We are involving a range of people involved in the delivery of GenPMTO during the feasibility study. The details of participants are outlined in the Table 4 below.

Table 4: Sample size for participants involved in qualitative research

Participant group	Sample size	Number of participants
Caregivers receiving GenPMTO	• 3-4 caregivers ²² per delivery site who have been referred to GenPMTO ²³	9-12
Barnardo's practitioners delivering GenPMTO	 4 full-time practitioners 8 part-time practitioners²⁴ 	12
Barnardo's managers leading on delivery	• 2 managers responsible for delivery across the three sites	2
Referrers from statutory and non-statutory organisations	 1 staff member from a referring agency/setting, who has been involved in referring caregivers to Barnardo's for GenPMTO across each delivery site (feasibility study expected to involve two referring agencies) 	6
	Total participants	29-32

Inclusion and exclusion criteria for caregivers

²² We may also seek to oversample the number of caregivers we will interview (by one or two additional caregivers), in order to mitigate against caregivers withdrawing from interviews, or not being able to attend. In the event that all caregivers attend interviews, we will proceed to interview all these caregivers, and provide them with reimbursement.

²³ Caregivers are referred to GenPMTO by schools or services such as Pupil Referral Units (PRUs), Youth offending teams, Violence Reduction Units, third sector organisations, and possible social care services due to their child having behavioural challenges and/or involvement in violence.

²⁴ Barnardo's have recruited 12 practitioners to deliver GenPMTO as part of the feasibility study (4 full-time staff, and 8 part-time staff). We intend to interview all practitioners involved in delivering GenPMTO.

We have carefully considered the inclusion and exclusion criteria for caregivers participating in the feasibility study (including receiving GenPMTO). Our aim in developing this criteria are to:

- 1. Include caregivers who stand to benefit most from GenPMTO
- 2. Exclude any caregivers for whom the programme may not be best suited, or may be at an increased risk of harm if they were to participate

One of our objectives for the feasibility study is to test these criteria and make a judgement about whether they need to be adjusted for subsequent stages of the study. We may find that they are too inclusive - and we therefore aren't receiving a sufficiently vulnerable sample. Conversely, these may be too exclusive and cause difficulties in recruiting sufficient numbers to make the evaluation viable. Below, we have outlined the inclusion and exclusion criteria which we will test in the feasibility study.

Inclusion criteria

Caregivers are eligible to participate in the feasibility study (including receiving GenPMTO) if they:

- Have a CYP between the ages of 8-14.
- Are the primary caregiver (i.e. spend the most time with the CYP and are available to care for them).
- Live within one of the boroughs in which GenPMTO is being delivered (during the feasibility study).

And, if one of or more of the following is present:

- CYPs have engaged in criminal behaviour, such as breaking the law or "offending behaviour" for both non-violent and violent crimes.
- CYPs have engaged in violent and challenging behaviour (including within the home, e.g. against parents and/or siblings).
- CYPs have been reported as bullying other individual(s) in or outside of school settings.
- CYPs have low attendance at school (<50% within the last academic year).
- CYPs have been excluded from school within the last academic year.
- CYPs are engaged in substance abuse/misuse (e.g. drugs, alcohol)
- CYPs are at risk of involvement by gangs.
- CYPs are at risk of exploitation, or negative influence, by criminal peers.
- CYPs have a sibling(s) that has entered into the criminal justice system.

Exclusion criteria

Caregivers will be excluded from the feasibility study it at least any of the following are present:

• Caregiver(s) have received a parenting programme in the last two months, or are currently receiving one.

- Caregiver(s) and CYP does not have working proficiency in English, such that participation in GenPMTO and research activities would be unfeasible.
- Family has plans to move out of the borough within the 10-14 week delivery timeline, and thus may not be available for full delivery of GenPMTO during the feasibility study phase.
- Severe developmental delay for caregiver or CYP which may prevent caregiver from attending GenPMTO delivery sessions, implementing GenPMTO parenting strategies, or participating in evaluation.
- Caregiver(s) and/or CYPs are actively homicidal, suicidal or psychotic.²⁵
- Problem sexual behaviour is the central behavioural concern for child/young person.²⁶
- Significant child protection concern (i.e. basic needs of children are not being met by caregivers.²⁷

Referral pathway for caregivers

Referral services within local areas (such as Youth Offending Teams, or Pupil Referral Units) will refer caregivers/families to Barnardo's as the implementation partner. Referring agencies will have been provided with information regarding GenPMTO, including the inclusion and exclusion criteria for GenPMTO, and will initially screen for suitable caregivers to be referred to Barnardo's.

Upon receiving referrals, Barnardo's will check whether families/caregivers referred to GenPMTO, are suitable to receive the programme. If they are not, Barnardo's will not include them in this study and they will not receive GenPMTO. However they will be signposted or referred to pre-existing 'service-as-usual' (SAU) support provisions.

If a family is eligible to receive GenPMTO, and the caregiver(s) consent to participating in the feasibility study, they will receive GenPMTO. Those receiving GenPMTO will still be able to access services as usual if they wish. Barnardo's has been in discussion with the relevant contacts in local authorities to ensure that GenPMTO would be appropriately signposted both to appropriate local authority staff, and to suitable caregivers.

Figure 2 below outlines the proposed flow for caregivers participating in the feasibility study.

²⁵ This exclusion is considered to indicate requiring escalation/referral to appropriate services (rather than enrollment in GenPMTO).

²⁶ As above.

²⁷ As above.





Methods and data collection

We have devised a mixed-methods approach to answer our research objectives for the feasibility study. We will conduct both qualitative and quantitative research activities to evaluate the feasibility, acceptability and evaluability of GenPMTO in the UK context. The following section describes these activities in detail. Table 7 and Table 8, at the end of this section, provide a summary of the qualitative and quantitative research activities we will conduct, as well as the data that will be collected during the feasibility study.

Qualitative research activities

As outlined above in the Design section for Stage 2 - Feasibility Study, we will be conducting semi-structured **in-depth interviews** with a range of people involved in the delivery of the GenPMTO programme, including:

- 1. Caregivers receiving GenPMTO²⁸
- 2. Barnardo's practitioners delivering GenPMTO²⁹
- 3. Barnardo's managers leading on delivery of GenPMTO

²⁸ Caregivers will be provided with a choice whether to have an in-person interview (at the venue at which they are receiving GenPMTO), or to have a remote online remote interview (i.e. over the phone, or online via a video-call platform of their choice (Google Meet, Zoom, or MS Teams).

²⁹ Practitioners will be provided with a choice whether to have an interview over the phone or via an online-video platform of their choice (Google Meet, Zoom, or MS Teams). If remote interviews are not possible, we will accommodate in-person interviews (at a local Barnardo's office).

4. Referrers from statutory and non-statutory organisations

In these interviews, we will gather as much information as we can about perceptions of the content and delivery of GenPMTO and the context it was delivered in. The rich qualitative data we generate from these interviews will inform the feasibility study by:

- Providing a detailed understanding of the complexity and nuances of programme delivery across the different phases.
- Identifying contextual factors that may influence the implementation and hence the effectiveness of GPMTO in UK contexts.
- Generating information that can be used to inform programme implementation and aid decision-making.

Experienced qualitative researchers from BIT will conduct the qualitative research activities. A summary of types of interviews and data collected from different participant groups are outlined below in Table 5.

Participant group	Interview type and length	Data collected
1. Caregivers	Interview (60 minutes)	• Caregivers' perception of the quality of the content and programme delivery, barriers to engagement and areas for improvement
2. Barnardo's practitioners	Paired interview (60 minutes)	 Practitioners' perception of the content (including any adaptations), delivery and factors that impacted on implementing, GenPMTO Practitioners' perceptions of acceptability, quality of content, and quality of delivery for GenPMTO Practitioners' perception of the fidelity process / consultation with model developers Practitioners' perceptions of programme feasibility to be delivered with fidelity at scale
3. Barnardo's managers	Interview (45 minutes)	 Managers' perception of the programme, impact on practitioners, fit with other priorities and factors that impacted on implementation
4. Referrers from statutory and non-statutory organisations	Interview (45 minutes)	 Referrers' views about the programme and fit with their organisation's priorities / strategic aims and how it intersects with other services in the area Feedback on the effectiveness of the referral process

Table 5: Overview of interviews with participants groups

Caregiver interviews

Due to the nature of the programme, caregivers (and by association, children) might be at different stages of change / progress. Interviews would offer caregivers the opportunity to use a confidential

space to discuss their views on the content of GenPMTO and its delivery without caregivers feeling pressure to conform to group norms that might occur in focus groups, e.g. expressing opinions that are perceived as favourable or acceptable, or avoid expressing views that may be perceived as unpopular or controversial. Interviews are also generally easier to schedule and offer participants more flexibility of timings to fit around their responsibilities. Interviews will:

- Gain insight into caregivers' experiences with the intervention, including their level of engagement and satisfaction with the activities and how it was delivered.
- Explore parents' perceptions of how it has impacted on them and their parenting.
- Explore any barriers or facilitators to participation in the intervention.
- Gather suggestions for improving the intervention in the future.

We will conduct interviews with **3-4 caregivers per delivery site** and will be conducted within 20 working days after programme delivery has ended.

We will purposively sample across key characteristics, in order to determine the acceptability and feasibility of GenPMTO across a range of caregiver characteristics (as much as possible, within our sample size). These characteristics will be discussed in collaboration with ISII and Barnardo's, but are anticipated to include the following characteristics outlined in Table 6. We will aim to achieve the quotas specified below, but what is achievable will depend on the participants who are referred into the programme.

Characteristic	Quota / monitoring criteria
Age of caregiver	At least 2 below 35 At least 2 above 35
Gender of caregiver	At least 1 male caregiver At least 1 female caregiver
Age of CYP	At least two caregiver with a CYP under 10 At least two caregiver with a CYP between 10 - 12 At least two caregiver with a CYP between 12 - 14
Type of caregiver (e.g. single parent, extended biological family, non-biological family etc.)	At least 2 single parents across sample Monitor for other types of caregivers
Ethnicity	At least 3 caregivers from BAME groups
Educational attainment	Monitor for highest level of attainment
Experiences with previous intervention programmes	Monitor for those that have had experience of at least one other intervention

Table 6: Sampling and monitoring criteria for caregiver interviews

Reason for referral

Monitor for referral reason

Barnardo's practitioner interviews (paired)

We will conduct paired interviews with **all practitioners**³⁰ who have been involved in delivering GenPMTO during the feasibility study. Interviews will be conducted within 10 working days after programme delivery has ended.

Paired interviews are efficient and can illuminate different perspectives and insights as each person may have a unique viewpoint or experience related to the delivery of GenPMTO. The format will also provide an opportunity for clarification, where one practitioner can provide additional context or information that the other may have missed or overlooked. The interviews will explore:

- Practitioners' perception of the content (and any adaptations) and appropriateness for UK context (acceptability).
- The delivery method and its appropriateness for UK context (acceptability).
- Perceived barriers and facilitators to caregivers engaging well with GenPMTO (acceptability).
- Feedback on any recruitment and retention challenges (feasibility).
- Factors that impacted on implementation (e.g. allocation of resources, logistics) i.e. was the programme implemented as intended? (feasibility).
- Practitioners' perception of the fidelity process / consultation with model developers. (acceptability and feasibility).

Barnardo's manager interviews

We will conduct up to **2 interviews with Barnardo's managers** responsible for delivery across the three sites.³¹ They will be interviewed within 10 working days of programme delivery. The aim of these interviews is to understand how programme delivery impacts practitioners and teams, specifically:

- The resource allocation needed to successfully deliver GenPMTO, e.g. financial, logistical, and if these were planned in advance.
- Barriers and facilitators for successful delivery.
- Impact on staff (e.g. emotional demands).
- Acceptability of the programme.
- Considerations of what would make a sustainable programme in the longer term.

³⁰ Barnardo's have recruited 12 practitioners to deliver GenPMTO as part of the feasibility study (4 full-time staff, and 8 part-time staff). We intend to interview all practitioners involved in delivering GenPMTO. We note that some part-time staff may not have had the opportunity to deliver all 14 sessions of the GenPMTO programme, but will have experience in delivering some GenPMTO sessions.

³¹ We understand that Barnardo's will only recruit 2 managers to deliver GenPMTO during the feasibility study.

Referrer interviews

At each delivery site, we will conduct interviews with **1 staff member from 2 referring agencies** within each borough³² who have been referring caregivers to Barnardo's to participate in the feasibility study. We expect a total of 6 interviews to be conducted with staff from referring agencies in the feasibility study (from statutory and non-statutory organisations). These interviews will explore referrers' perceptions of the programme and the referral process. Specifically, we will explore:

- Factors involved in making a referral decision.
- Ease of referral, including speaking to caregivers and referrer's role in supporting engagement,
- The process of making a referral, and whether any adaptations should be made.
- The perception of GenPMTO, feedback from caregivers, the fit with the local cultural and social context, and the alignment with existing policies and practices (i.e. GenPMTO goals and referrers' organisational needs).

Qualitative feedback on outcome survey

As noted in the Design section, we will be administering outcome surveys to participants. However, our primary aim in administering these outcome surveys is to identify how feasible it is to administer these surveys, the ease of completing these surveys for participants, the completeness and quality of data collection.

To help understand participant's experience of completing outcome measures, we will also provide a free-text feedback box, at the end of the outcome survey. This will allow participants to provide us with qualitative feedback on how easy it was to complete the survey, or if they experienced any other issues or difficulties in completing the outcome survey.

Quantitative research activities

Outcome survey

All caregivers receiving GenPMTO will be invited to complete an outcome survey during programme delivery. As noted above, while this survey will be used to measure the impact of the programme in Stages 3 & 4, in the feasibility study we are administering outcome surveys to obtain information about response and completion rates. Additional detail on how we will calculate response and completion rates are noted in the Quantitative analysis section below.

These quantitative metrics will help us to identify whether particular measures, or aspects of the survey have lower rates of engagement of completion than others, and/or whether caregivers with certain demographic characteristics engage less with any aspect of the survey. This in turn, will allow us to adapt the outcome survey in advance of the pilot and efficacy trials, and/or make more of an effort to explain the purpose and content of the survey to caregivers if necessary.

Administrative data analysis

We will analyse administrative data from the following sources:

³² For the feasibility study, we expect two referring agencies to be involved. In subsequent stages, this number will likely increase.

- 1. GenPMTO referral forms
- 2. Barnardo's programme administration data³³ (including a brief survey measure administered to caregivers by Barnardo's to assess satisfaction with the programme)
- 3. ISII fidelity monitoring data³⁴

Based on this administrative date we will generate descriptive statistics on the following variables:

- Proportion of practitioners recruited to deliver GenPMTO
- Proportion of practitioners enrolled in training to deliver GenPMTO
- Number of referrals received by Barnardo's for caregivers to receive GenPMTO
- Proportion of referred caregivers deemed eligible for GenPMTO
- The proportion of eligible caregivers who are offered GenPMTO who accept this offer (take-up of services)
- Retention / drop-out rates of caregivers receiving GenPMTO
- Retention / drop-out rates of practitioners delivering GenPMTO
- Attendance data from GenPMTO delivery
- Caregivers' perception of the quality of the content and delivery
- Programme dosage data³⁵
- Ratings of practitioner fidelity

Incentives

We will be compensating caregivers for their time spent participating in the feasibility study research activities. We are proposing providing caregivers with shopping vouchers for each of the following research activities:³⁶

- £10 voucher for time taken to complete the outcome survey (estimated to take 25-30 minutes).
- £20 voucher to participate in a 60-minute interview.

If a caregiver consents to take part and attends the interview, but then changes their mind and withdraws either during or afterwards, they will still receive the incentive.

In addition to providing incentives to caregivers, we will attempt to minimise the impact of attrition by:

 ³³ Barnardo's systematically collects key delivery information throughout programme recruitment and delivery.
 ³⁴ ISII will systematically capture information regarding the delivery of GenPMTO during the feasibility study, to

assess the fidelity with which it is being delivered by Barnardo's. This information is provided to ISII by Barnardo's and includes video recordings of practitioners delivering GenPMTO.

³⁵ ISII capture the level of content covered by practitioners in each session, by asking practitioners to input this information at the end of each session, into their FIMP system.

³⁶We have proposed providing vouchers to participants rather than cash amounts, as providing cash risks impacting on caregivers' eligibility for other services and benefits.

- 1. Ensuring that evaluation activities are designed to be low-impact in terms of burden and time
- 2. Where needed, utilising the relationships that Barnardo's has built with local authorities to facilitate access and cooperation with staff and referring agencies

We will not be providing incentives to other participant groups (i.e. Barnardo's staff and referrers). Barnardo's staff are being funded to deliver and help facilitate the evaluation of GenPMTO. Nor do we expect their participation in the evaluation to add significant burden beyond what is already required in their role that supports the delivery of GenPMTO. Additionally, given the Lab is also acting as the funding body for this evaluation, providing compensation to these stakeholders risks being perceived as providing an incentive to (intentionally or otherwise) bias GenPMTO stakeholders' responses. GenPMTO is being provided to local authorities at no additional cost, therefore participating in research activities is considered an in-kind contribution to the cost of the evaluation.

Data analysis

Qualitative analysis

To analyse the depth interviews, we will employ a version of the framework approach which is widely used in applied social research and draws on the approach set out by Ritchie et al (2014). This approach is similar to other widely used thematic analysis approaches and aims to derive meaningful themes and patterns from the qualitative data. However, rather than focusing on coding the data, this approach involves summarising, or 'charting' the data into a thematic framework. The strength of the framework approach is that it enables systematic and comprehensive analysis of the complete data set in a manageable way.

Transcription

All interview recordings will be transcribed verbatim to ensure accuracy and facilitate subsequent analysis. Transcripts will be anonymised by assigning unique identifiers to each participant, replacing their names or any identifying information.

Familiarisation with the data

The research team will thoroughly read and familiarise themselves with key interview transcripts and observation notes - what is known as deep hanging out in the data. This step ensures that whatever headings are selected for the thematic framework are grounded in the data.

Data management

The first stage of data management will be for the research team to convene and discuss the possible themes that are emerging from the data, under which the data will be sorted. These themes will be both deductive (guided by the research questions and topic guides) and inductive (those that emerge from the data). Once the research team has agreed the key themes and sub-themes, these will be used to set up an initial thematic framework. For ease, this will be done in Excel/Google docs. The framework will be set up so that each individual sheet represents a theme and the columns within it represent the sub-themes. The rows represent individual participants. Each participant group will have their own thematic framework, so one for caregivers, another for practitioners etc. In some cases, the framework approach requires indexing and sorting of the data where the themes in the framework are used to annotate and label the data in the transcripts. However, since there will be a clear structure to the depth interviews, it is anticipated that the data will already be well ordered and this step will therefore not be needed.

Once the frameworks are set up, the data from each transcript will be 'charted' or summarised into them. The summaries will be written in the third person and aim to capture the key views of the participant under each of the themes represented by columns. The researchers doing the charting will remain as close as possible to the language used by the research participants. As the data is charted, researchers will identify key verbatim quotes from the transcripts and add these to the framework in italics to be used in the report if needed. Charting will be done by several researchers who will all read and quality assure each other's charting to ensure a consistent and comprehensive approach.

Throughout the data management stage, researchers will be mindful of revisiting the thematic framework and adjusting it where needed. For example, adding new sub-themes that were previously not discussed or collapsing themes together where necessary.

Analysis and interpretation

The first stage of analysis is descriptive. This will involve looking at each theme in turn and exploring the range of views held under that theme with a view to developing categories. This will be done by grouping the views into clusters and exploring the properties of each of these clusters until clear categories can be developed. Given the nature of the feasibility study and the size and likely diversity of the sample, it is highly likely that the majority of the analysis will be descriptive and aim to clearly map out the range and diversity of views that exist within each participant population on the key areas relevant to the research questions. However, where possible the researchers will proceed to a higher level of analysis and aim to look for patterns and linkages in the data. This stage will be facilitated by the framework approach as it easily allows the researcher to look both within and across cases to see how different parts of the data set are connected. The sorts of patterns and linkages that might be explored include links between particular experiences of the intervention and how those link to views or outcomes, or the research team may explore links between particular characteristics of the participants and their views and experiences. Where possible, the research team will then go on to look for explanations for the categories and linkages that have been found.

Throughout the analysis process, the research team will remain in contact with each other, sharing and testing emerging findings and ensuring that the analysis process remains rooted in the data.

Quantitative analysis

Outcome survey

We will calculate the following metrics based on data collected from outcome surveys administered to caregivers, and their children:

- Response rates this will involve calculating as a percentage the number of participants who started the survey, compared to the total number of participants who were invited to complete the survey.
- Completion rates this will involve calculating as a percentage the number of participants who finished the survey, compared to the total number of participants who started the survey.

We will report overall survey response and completion rates, as well as completion rates for each specific outcome measure. We will also calculate the response and completion rates, and the time taken to complete the survey (online only) for participants groups with specific demographic characteristics, including (but not limited to); age, gender, ethnicity, socio-economic status.

Administrative data analysis

As noted in the our Quantitative research activities section, this will include the descriptive statistics on key variables including:

- Proportion of practitioners recruited to deliver GenPMTO this will involve calculating, as a percentage, the number of recruited practitioners, compared to the total number of practitioners identified in Training criterion within the Monitoring and success criteria.
- **Proportion of practitioners enrolled in training to deliver GenPMTO** this will involve calculating, as a percentage, the number of practitioners enrolled in training, compared to the total number of recruited practitioners.
- Number of referrals received by Barnardo's for caregivers to receive GenPMTO this will involve identifying the total count of referrals received during the feasibility study, as well the mean and standard deviation of monthly referral totals across the feasibility study.
- **Proportion of referred caregivers deemed eligible for GenPMTO** this will involve calculating, as a percentage, the number of caregivers deemed eligible for GenPMTO, compared to to the total number of referred caregivers.
- Proportion of eligible caregivers who are offered GenPMTO who accept this offer (take-up of services) this will involve calculating, as a percentage, the number of caregivers who consent to take part in the feasibility study, compared to to the total number of caregivers who are considered eligible to receive and are offered the programme.
- Retention / drop-out rates of caregivers receiving GenPMTO this will involve calculating, as a percentage, the number of caregivers who complete a program, compared to the total number of caregivers who consent to receiving GenPMTO.³⁷
- Retention / drop-out rates of practitioners delivering GenPMTO this will involve calculating, as a percentage, the number of practitioners who have completed relevant training and are able to deliver GenPMTO, compared to the total number of practitioners who were enrolled in training.
- Attendance rate at GenPMTO sessions this will involve calculating, as a percentage, the number of caregivers who attended each GenPMTO session, compared to the number of caregivers who were expected (i.e. based on caregiver take-up/enrollment) to attend these sessions, as well the mean and standard deviation across the feasibility study.
- **Caregivers' perception of the quality of the content and delivery -** this will involve calculating the mean and standard deviation of scores, based on a short feedback survey administered by Barnardo's.
- **Programme dosage data** this will involve calculating the mean percentage of actual content delivered in GenPMTO sessions to a cohort of caregivers, compared to the amount of planned content to be delivered, as captured and recorded by ISII in their FIMP system.
- **Ratings of practitioner fidelity -** this will involve calculating the mean of practitioners' fidelity scores whilst delivering a full GenPMTO programme, as captured by ISII in their FIMP system.

In addition, we will conduct analysis of administrative data to test whether any of these metrics vary by key participant characteristics available in the data (e.g. borough, caregiver gender, child gender, caregiver ethnicity, child ethnicity, family socioeconomic status, child's age, whether the survey was completed online or in-person, etc.).

³⁷ We will consider that 'completing' the programme involves attending at least 75% of the programme sessions, (including the last session).

Further adaptation

As noted above, while we will conduct initial adaptations prior to training and first delivery, the bulk of this work will take place via a series of workshops during and after first delivery and the feasibility study. The benefit of conducting additional adaptation work at this time is that it can incorporate feedback from caregivers/families who have participated in GenPMTO, as well as practitioners who have gained experience in delivering the programme.

These workshops would be designed to elicit the views of practitioners with experience of delivering similar programmes, of practitioners in training for the delivery of GenPMTO, and of representative caregivers. Based on the views expressed in these workshops, the Lab and Barnardo's may agree to make adjustments to the content of the training materials for practitioners and/or the delivery/programme materials for caregivers. It is planned that as the implementation partner, Barnardo's would run these workshops, including overseeing the recruitment of workshop participants.

A range of frameworks for conducting intervention adaptation exist, many of which broadly recommend the same steps³⁸ (an example framework is detailed in Card et al., 2009³⁹). As part of this phase we will consider which approach and combination of steps towards adaptation would be most appropriate and proportionate for this project. A key step in many adaptation frameworks involves identifying a programme's core components and best-practice characteristics (in order to decide which characteristics should not be modified or disrupted). To do this we will work with the programme developer (ISII), consider existing research studies investigating this programme, and draw on broader evidence on best practice in youth violence prevention.

³⁸ Movsisyan, A., Arnold, L., Evans, R., Hallingberg, B., Moore, G., O'Cathain, A., ... & Rehfuess, E. (2019). Adapting evidence-informed complex population health interventions for new contexts: a systematic review of guidance. *Implementation Science*, *14*(1), 1-20.

³⁹ Card, J. J., Solomon, J., & Cunningham, S. D. (2011). How to adapt effective programs for use in new contexts. *Health promotion practice*, *12*(1), 25-35.

Table 7: Stage 1 - Adaptation and training methods and data collection

Participant group	Method	Data collected	Measure	Data analysis method	
	Acceptability of programme content and delivery				
Barnardo's practitioners	Paired interview (60 minutes)	 Practitioners' perceptions of the content (and any adaptations) of GenPMTO in a UK context 	Acceptability of adaptation	Framework analysis	
Barnardo's managers	Interview (45 minutes)	 Managers' perceptions of the content (and any adaptations) of GenPMTO in a UK context 	Acceptability of adaptation	Framework analysis	
	Feasibility of programme delivery				
Barnardo's practitioners	Analysis of programme administrative data	 Proportion of required practitioners recruited within [3-5 months] of the adaptation phase beginning, relative to agreed targets 	Recruitment (practitioners)	Descriptive statistics	
N/A	Analysis of programme administrative data	 Number of practitioners enrolled in training in GenPMTO methodology within [6 months] of recruitment formally launching 	Training	Descriptive statistics	

Pink = qualitative data; *Blue* = quantitative data

Table 8: Stage 2 - Feasibility study methods and data collection

Participant group	Method	Data collected	Measure	Data analysis method
		Acceptability of programme content and delivery		
Caregivers	Interview (60 minutes)	• Caregivers' perception of the quality of the content and programme delivery.	Acceptability of programme	Framework analysis

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Barnardo's practitioners	Paired interview (60 minutes)	 Practitioners' perception of the content (including any adaptations), delivery and factors that impacted on implementing, GenPMTO Practitioners' perceptions of acceptability, quality of content, and quality of delivery for GenPMTO 	Acceptability of programme	Framework analysis
Barnardo's managers	Interview (45 minutes)	 Managers' perception of the programme, impact on practitioners, fit with other priorities and factors that impacted on implementation 	Acceptability of programme	Framework analysis
Referrers from statutory and non-statutor y organisation s	Interview (45 minutes)	 Referrers' views about the programme and fit with their organisation's priorities / strategic aims Feedback on the effectiveness of the referral process 	Acceptability of programme	Framework analysis
N/A	Analysis of referral form data	 Number of referrals by LAs and other bodies Eligibility of referred families for programme 	Acceptability of programme	Descriptive statistics
Feasibility of programme delivery				
Caregivers	Outcome survey	• Understand how feasible the outcome survey is for caregivers to complete (i.e. time taken to complete, difficulty of questions etc.)	Feasibility of delivering outcome survey	Descriptive statistics
	Analysis of programme administrative data	 Proportion of caregivers agreeing to intervention and evaluation Proportion of caregivers completing the programme 	Recruitment and retention	Descriptive statistics
Barnardo's practitioners	Paired interview (60 minutes)	 Practitioners' perception of the fidelity process / consultation with model developers Practitioners' perceptions of programme feasibility to be delivered 	Feasibility of programme delivery	Framework analysis

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		with fidelity at scale		
N/A	ISII assessment	• The ISII programme experts assess practitioner sessions according to the FIMPsystem developed by ISII.	Fidelity	Descriptive statistics
Evaluability of the programme				

Pink = qualitative data; *Blue* = quantitative data

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7. Planned outputs

The outputs of this overall package of work and their timings are dependent on the outcomes of each of the 4 stages.

Regardless of the outcome of the feasibility study, **the Lab will provide a short report to the YEF outlining the key findings and observations of the feasibility study.** This will make a formal conclusion as to whether GenPMTO can be feasibly delivered in the UK, and recommend whether the evaluation should progress to Stage 3 (pilot stage).

If the feasibility study **concludes that GenPMTO** is **sufficiently feasible in the UK** and ready to progress to a pilot trial, we will not publish these findings externally at the completion of the feasibility study. We will instead report the findings of the feasibility study at whatever future point the project terminates (e.g. after the pilot stage (if the conditions for progression to efficacy are not met), or at the end of the efficacy stage). This report will contain findings and/or recommendations from the feasibility study, pilot trial and/or full-scale efficacy trial of GenPMTO. The Lab will share the findings more broadly where appropriate (and with the express permission from Barnardo's and YEF), such as in presentations, blogs and the Behavioural Insight Team's (BIT) annual report. The primary audience of YEF's website is practitioners and researchers interested in reducing young people's involvement in violence.

If the feasibility study **concludes that GenPMTO is not sufficiently feasible in the UK** and not ready to progress to a pilot trial, then these findings will be published externally at the completion of the feasibility study in the form of a short report, which will include the key findings of the feasibility study including any lessons learned during the trial.

8. Ethics and data protection

Ethics

Overview

This trial was self-assessed as being high risk due to the inclusion of high-risk participants in the form of vulnerable young people. As a result we sought ethical approval from an independent panel of external experts with experience of working with vulnerable children and experience with safeguarding and child protection.

The independent ethics review committee (ERC) reviewed the following information:

- Ethical review form
- Consent forms and information sheets for young people and parents/caregivers of young people
- Topic guides
- Safeguarding and distress protocol

The ERC discussed any issues raised by the research with The Lab with the aim of finding solutions that meet ethical requirements. The reviewers and the project manager agreed solutions to any outstanding issues, and the resulting changes to the way the project is being implemented have been included on the ethics form. The ERC was happy to approve the project with the inclusion of these amendments.

If there are substantial changes while the research or evaluation is being implemented, the ethics form will be revised and the revisions agreed with the ERC.

Informed Consent

All participants will be asked to provide written consent to participate in the feasibility study for ethical purposes, before data collection or interviews take place. Participants will be provided with an information sheet to inform them of what to expect from their involvement in the feasibility study. Caregivers taking part in the feasibility study will also be informed that their participation in GenPMTO, is contingent on participation in the evaluation - hence, opting out of data collection prior to intervention delivery would involve withdrawing from the programme.

We will invite all caregivers to complete outcome surveys, as well as asking for written parental consent from all caregivers to invite their children to complete outcome surveys. We will provide a verbal explanation of the purpose and process of the feasibility study, as well as a written information sheet to CYPs and seek their verbal assent to complete outcome surveys, prior to collecting any such data.

All participants will be informed of their right to withdraw their consent at any point during interviews and/or data collection sessions. We will make it clear to participants that we will use their information to inform the findings of our evaluation, which will be incorporated into a report, or other publicly publishable materials. However, no identifying information will be disclosed in any such materials.

We will also inform participants that they may be able to withdraw their data from the feasibility study, up until approximately 6 months after the end of the study (anticipated to be October 2026). At this point their data will be deleted from our systems, and anonymised information will have already been incorporated into reporting, or other publicly publishable materials.

Safeguarding

Safeguarding means protecting the health, wellbeing and human rights of children and at-risk adults, enabling them to live safely, free from abuse, violence and neglect. During the feasibility study, we protect children and adults-at-risk by following a strict safeguarding and distress protocol. Before any interviewing or surveying with vulnerable groups, any researcher will:

- Undergo, and obtain, an enhanced DBS check.
- Complete the NSPCC's Introduction to safeguarding and child protection training.
- Review the Nesta Group Safeguarding Policy and the GenPMTO Child safeguarding issues and Risk Assessment.
- Review the GenPMTO Safeguarding and distress protocol.

If, during any research activity, a participant discloses anything that leads a researcher to believe that they themselves, or someone else, might be at risk of harm, they will follow these steps:

- Step 1: Is there an immediate risk of harm to the interviewee or others?
 - If yes: they will call the police or other emergency services as soon as possible and follow up with an emergency report to the Nesta Group Chief People Officer (The Lab's Designated Safeguarding Lead) and the project's qualitative lead.
 - \circ $\,$ If no: proceed to step 2.
- Step 2: Establish an understanding of what has happened
 - They will keep questions to the minimum necessary to ensure a clear and accurate understanding of what has been disclosed. The researcher will only ask questions to help establish whether the participant is at risk of harm. They will not make allegations or lead them to make allegations.
 - The researcher will ask the young person or at-risk adult whether anyone is aware of what they have disclosed e.g. are the parents/caregivers aware of it. If the concern is about a pre-existing mental health condition that is known to the caregivers or medical professionals (e.g. the adults GP), for example, this would not represent a safeguarding concern that would need to be reported.
 - If you notice something concerning, which hasn't been disclosed: they will ask open questions to establish if there is an explanation e.g. "that looks like a big bruise. Can you tell me what happened?"

• Step 3: Make a written record

- The researcher will note down what has been said, any physical evidence that is available including injuries or the personal state of the participant.
- Step 4: Inform the participant
 - If the researcher considers that there is a risk, they will inform the participant that they
 need to tell the Lab's designated safeguarding lead. They will explain that a
 safeguarding lead is the person in an organisation that's responsible for dealing with
 concerns to people's safety.
- Step 5: Report the concerns

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- Nesta Group Chief People Officer (the Lab's Designated Safeguarding Lead) and the project's qualitative lead.
- The researcher will be available to the designated safeguarding leads to assist with further assessments, including whether cases need to be escalated to other parties such as the child protection services.

Data protection

We will follow appropriate data protection processes in accordance with BIT processes, including completing a Data Protection and Security Checklist and Data Protection Impact Assessment, which have both been reviewed and approved by BIT's legal team.

The Lab will store and handle all data securely and confidentially in line with requirements of the UK GDPR, and Data Protection Act (2018), including that Personal Data shall be processed lawfully, fairly and in a transparent manner that ensures the security of the Personal Data. It is initially proposed that only the Lab research team will have access to data collected as part of the evaluation. However, it is expected that in order to review the fidelity of the implementation of GenPMTO, and to coach and certify practitioners, ISII will require access to data from the sessions in which the practitioners deliver the programme to caregivers. Given that most ISII training staff are based in the USA, Barnardo's will likely need to establish a Data Sharing Agreement with ISII, with the Lab overseeing this process.

For the duration of the evaluation, the Lab will be the data controller who also processes data. This means that the Lab is responsible for deciding the purpose and legal basis for processing data. The legal basis is "legitimate interest". Article 6(1)(f) of UK GDPR states that "processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child."

The Lab has determined there is a genuine purpose to process this data. This data will inform the necessary evidence around what works to improve caregivers' skills and strategies, which in turn, improves positive behaviours, relationships and life outcomes of young people, particularly those at risk of, or who have engaged in, violent behaviours. Data processing is necessary to complete a robust evaluation. The Lab does not consider that collecting and gathering data for this trial will interfere with individuals' interests, rights or freedoms. The data subjects will include; at-risk youth, caregivers of at-risk youth, the developer team at ISII and the delivery team at Barnardo's.

During this trial, data will be stored on secure, password-protected and encrypted network drives (hosted by BIT). Access to the data will be restricted to the relevant members of the project team involved in this evaluation.

All data shared with BIT will be processed in line with its data protection policy. A summary of this policy can be found in Annex C. In the analysis, BIT will promote data quality and security through the following measures.

- All variables will be clearly named, coded and labelled before analysis
- Checks on the data received will be carried out for valid values, range, and consistency against already held data
- Any modifications to datasets will be recorded in the analysis code, which will be well-annotated
- Original raw datasets will never be amended

- Access to the project data will be restricted to project personnel
- All data stored by BIT will be backed up

In case a Personal Data Breach occurs despite the mitigations in place, project team staff will deal with the security incident without undue delays. All Personal Data Breaches (or suspected Personal Data Breaches) will be reported to BIT's Data Protection Officer as soon as a project team member becomes aware of one (including if this is outside of office hours) by contacting the Data Protection Officer directly and by completing a Data Incident Notification Form. Staff will not attempt to investigate a Personal Data Breach themselves but will take steps to contain the Personal Data Breach as quickly as possible. Such steps might be taken prior to reporting the incident to the Data Protection Officer where this is reasonable and necessary to protect Data Subjects and mitigate the potential impact of the Personal Data Breach.

Data management

All quantitative and qualitative data will be stored in a secure Google Folder where access is restricted to only researchers conducting the analysis. Data will be deleted upon completion of the project in October 2026.

Quantitative data

Survey data

We will use SmartSurvey to collect the survey data. SmartSurvey produces a spreadsheet where one row is a survey response. This will be used to code the survey outcomes using the methods outlined in the outcome measures table.

Surveys will ask participants to record their name. This enables us to link survey responses with demographic data and other outcome measures. Once survey responses have been linked, participants' names will be removed.

Programme administrative data

Barnardo's is responsible for providing us with the programme administrative data. All data shared with the lab by Barnardo's will be received via a secure transfer link (Virtru or Quatrix).

Programme administrative data includes the *referral data* and the *programme delivery data* (e.g. attendance sheets, fidelity checklists). *Referral data* will be collected via an online form (located on FormAssembly) completed by borough staff. Barnardo's will download the data in a spreadsheet and share the relevant data with the lab. *Programme delivery data* will be collected via Barnardo's , and shared with the lab.

Qualitative data

Interview transcripts

Interview recordings will be uploaded to McGowan for transcription. All interview recordings will be transcribed verbatim to ensure accuracy and facilitate subsequent analysis. Transcripts will be

anonymised by assigning unique identifiers to each participant, replacing their names or any identifying information. Transcripts, observation notes, and any additional relevant documents will be securely stored in a password-protected file area. Access to the data will be restricted to only project team members involved in the analysis. Recordings will be deleted upon completion of the project in October 2026.

9. Racial diversity and inclusion

The Lab is committed to conducting research in which equality, diversity and inclusion principles are firmly embedded across all stages of evaluation, from the design, recruitment, data collection, and analysis. Within the Adaptation and Training phase of the project in particular, we will strive to ensure that both the content and the delivery of the GenPMTO programme is suitably adapted to a UK context, and is informed by cultural, racial, and other relevant demographic sensitivities.

Groups included in the programme and evaluation

The Lab will work with Barnardo's to monitor for inequalities within the referral and recruitment processes to ensure that no demographic group is unduly excluded from access to the GenPMTO programme. At all stages, but during the Feasibility study stage in particular, we will monitor whether certain demographic groups are under- or over-represented in referrals to the programme by referral agencies. This may occur due to unconscious bias within referral agencies, and/or because the GenPMTO programme is viewed by referral agencies as unsuitable for families with certain demographic characteristics. In either case, the Lab and Barnardo's would seek to investigate this further in consultation with referral agencies.

Similarly, at all stages but during the Feasibility Study in particular, the Lab will work with Barnardo's to monitor whether the rate of acceptance to the trial (i.e. families accepting the offer to partake in either the non-randomised Feasibility Study or the randomised Pilot or Efficacy trials) varies across certain demographic groups. If this is the case, the Lab and Barnardo's will seek to investigate why this is the case, and whether the programme content and/or delivery needs to be adapted to ensure equality of acceptability and access.

Inclusivity during recruitment and programme delivery

The Lab will work with Barnardo's as programme delivery partner to ensure that inclusive practices are central to the *recruitment process* and that participant wellbeing is promoted by:

- 1. Being considerate of the sensitivity of the topic area during recruitment
- Providing caregivers with welcoming information documentation (during either the feasibility study, pilot trial, or efficacy trial stages), which provides all necessary information about data security, anonymity and the reasons for undertaking research, in plain English
- 3. Offering a flexible and varied range of times for introductory (and other) sessions, and the option of attending sessions remotely via video-link, allowing different groups and individuals the opportunity to participate.

Inclusivity during data collection

As outlined in Table 8, the collection of data directly from caregivers will occur via caregiver surveys and caregiver interviews. To ensure that the principle of inclusivity is adhered to during this process, the Lab will work with Barnardo's to:

1. Use inclusive and accessible language in all survey and interview questions and guidance;

- Ensure that sufficient numbers of either Lab and/or Barnardo's staff will be present at in-person sessions where caregiver surveys are being administered, to provide assistance or instruction as required;
- 3. Strive for equality of access by enabling online (remote) participation in caregiver surveys and interviews. Access issues could include a lack of time during the day to attend sessions, or distance from an in-person session.
- 4. Training for researchers: Prior to conducting interviews, researchers will complete the NSPCC's Introduction to safeguarding and child protection training and complete a pre-interview workshop on interviewing best-practice with NJ Research Ltd.

Wellbeing and safety during surveys and interviews

The Lab is conscious that families who engage in the evaluation could be vulnerable to negative and stressful impacts of the research process. The Lab will work to ensure the wellbeing and psychological safety of individuals during data collection by:

- 1. Designing interview questions to minimise harm and maximise comfort: The Lab will maximise wellbeing and minimise harm during surveys and interviews by (i) structuring questions to build in complexity and difficulty to increase comfort as rapport to develop, (ii) depersonalising questions to elicit comfort and stronger answers (e.g. instead of 'what do you hate about X', ask 'If you had a magic wand, what 3 things would you change about X?''), (iii) being aware of tension discomfort or distress during the interview, repeating that the interview can be stopped may help participants and repeatedly ask if they want to continue, (iv) ensuring that researchers are aware of places to signpost participants and offer this information, and (v) auditing the questions for their sensitivity within the context before the interview.
- Allowing the participants to choose their environment for participating: Where possible the Lab will allow the interviewees to make decisions about the survey and interview setting(s)
 at their home, a public place or over the phone, enabled by the online conference format.
- 3. **Reminding participants of anonymity and data security**: The Lab will seek to minimise anxiety for caregivers by reminding them that the process is fully anonymous and that all identifiable information will be removed from the transcripts and report.

10. Risks

We have identified the following risks and mitigations in Stages 1 & 2 of the project:

Table 9: Risks and mitigations for feasibility study

Risk	Impact	Likelihood	Mitigation
Number of trained practitioners is not sufficient to deliver GenPMTO to the number of caregivers recruited.	High	Medium	Barnado's and ISII will coordinate to establish a feasible timeline to recruit and train practitioners to be able to deliver GenPMTO throughout the feasibility study period.
Referral partners such as Local Authorities are not supportive of the GenPMTO programme.	High	Medium	Barnardo's continues to develop strong relationships with a range of boroughs across the feasibility study region. If there are challenges with certain boroughs getting on board, alternative boroughs could be contacted. Additionally, Barnardo's can reach out to Youth Offending Teams and Directors of Children's Services within boroughs directly to increase local authorities' engagement with the programme.
Recruitment of participants is below target	High	Medium	Barnardo's will provide additional marketing resources and support to local boroughs to socialise the programme. Barnardo's will deliver a launch event with boroughs and referring practitioners. Monitor engagement within boroughs to identify successful strategies used to receive referrals.
Low participation in research activities by caregivers (e.g. interviews)	Medium	Medium	Provision of incentives for participants. providing caregivers with shopping vouchers for each of the following research activities: £10 voucher for time taken to complete the outcome survey (estimated to take 25-30 minutes); £20 voucher to participate in a 60-minute interview. We will not be providing incentives to other participant groups (i.e. Barnardo's staff and referrers)as we do not expect their participation in the evaluation to add significant burden beyond what is already required in their role that supports the delivery of GenPMTO.
Content not suitable for UK context	Medium	Medium	Barnado's and ISII will work to adapt the design of the intervention to meet the needs of a UK population, including revising delivery content to better reflect delivering within the UK cultural context (where appropriate).
Disruptions to delivery of GenPMTO due to <i>force majeure</i> (e.g. Covid-19 pandemic)	Medium	Low	GenPMTO has the capability to be delivered online, which means delivery should be feasible if there were restrictions on in-person attendance at intervention sessions. Outcome measures may also be obtained from participants online, or through other digital methods of communication

11. Timeline

The study as a whole (feasibility and adaptation through to efficacy) is expected to last three years from April 2023 to May 2026. However, the overall timeline is dependent on the number of referrals received and any necessary pausing periods between stages. Below is a timeline of Stages 1 & 2 of the study, as described in this protocol:

Phase	Activity	Description of activity	Led by	Target dates
Project set-up	-	Protocol published and detailed internal plans and project management tools development	the Lab	June 2023
		Development of surveys, interview guides and other data collection tools	the Lab	June 2023
Adaptation and training	Adaptation Adaptation	Initial adaptation activities	Barnardo's / ISII / the Lab	July 2023
		Adaptation workshops delivered	the Lab	November 2-23 - January 2024
		Necessary adaptations recorded and made	Barnardo's / ISII / the Lab	July 2023 - February 2024
	Training	Practitioner training workshop 1	Barnardo's / ISII	September 2023
		Practitioner training workshop 2	Barnardo's / ISII	October 2023
Feasibility study	Borough recruitment	Recruitment of suitable boroughs	Barnardo's	July 2023 - September 2023
	Caregiver recruitment Initial delivery	1-2 cohorts of eligible caregivers referred to GenPMTO	Barnardo's	September 2023
		Deliver programme to 1-2 cohorts of parents/guardians of medium-risk children	Barnardo's	September 2023
	Data collection	Qualitative and quantitative data collection	Barnardo's / ISII	October 2023 - February 2024

Table 10: Timeline of key activities for Stages 1 and 2 of the GenPMTO evaluation project

Annexes

Annex A: Summary of GenPMTO programme using the TIDieR framework

Name: Provide a name or phrase that describes the intervention.	GenPMTO
Why: Describe any rationale, theory, or goal of the elements essential to the intervention.	 Positive parenting practices promote positive child/youth outcomes, and coercive parenting practices disrupt them. As children become adolescents, peers also become mediators of youth outcomes. The core positive parenting practices are: skill encouragement, limit setting, monitoring/supervision, family problem solving, and positive involvement. The programme aims to teach parents effective parenting strategies, increase effective parenting, and reduce deviant peer association, which then mediate programme effects on positive child/youth outcomes. In the short term, the programme aims to reduce children and young people's internalising and externalising behaviour problems. In the longer term, the programme aims to reduce police arrests, increase school functioning, improve social relationships, and reduce substance use. Parents show improved marital relationships, a rise out of poverty, and increased socio-economic status.
What - 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.	 Training materials and implementation guides for practitioners. Materials for parents/caregivers. Materials are purchasable from ISII.
What - Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	 Initial training and technical assistance - (ISII) provides extensive training and coaching to local practitioners, some of whom are eventually certified as leaders, mentors, trainers, coaches, or fidelity raters for the following generations of PMTO clinicians. Ongoing fidelity monitoring - Practitioners videotape programme sessions for review and coaching by ISII.

	 Practitioners upload written materials and video recordings to ISII's online platform, and receive feedback. 10- to 14-session parenting programme - Practitioners use active teaching approaches (such as group problem-solving, role-play, and video modelling) to support caregivers in using positive parenting strategies at home.
Who: For each category of intervention provider (such as psychologist, nursing assistant), describe their expertise, background, and any specific training given.	Qualifications required for practitioners depend on the agencies that employ them. Practitioners may have Bachelor's, Master's, or Doctorate level degrees. Practitioners serve in a wide variety of delivery systems including child welfare, youth justice, and child mental health.
How: Describe the modes of delivery (such as 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.	The intervention will be provided in group-format, either face-to-face or online. More broadly, the intervention can be delivered on an individual basis, but this mode of delivery will not be used as part of this project.
Where: Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	The programme can be delivered in out-patient health settings, the home, and community centres/settings. In this project, the programme will be delivered in community centres and settings.
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.	The programme can be delivered over different modes (i.e. in-person or online). Sessions are between 90 and 120 minutes each.
Tailoring: If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when and how.	Programme to be adapted using procedures articulated in this protocol.
Modification: If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	To be assessed as part of the feasibility study and future stages.

How well (planned): If adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Programme developer experts assess practitioner sessions using the FIMP (Fidelity of Implementation Rating System) measure, developed by ISII.
How well (actual): If actual adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	To be assessed as part of the feasibility study and future stages.

Annex B: Evaluation team experience

- Tom McBride is the Director of the Ending Youth Violence Lab and has over 15 years of experience in research and evaluation roles. He is the former Director of Evidence at the Early Intervention Foundation and Head of Strategic Analysis at the Department for Education. Tom will have overall responsibility for the delivery and quality of this work
- Jack Martin is an Assistant Director within the Ending Youth Violence Lab and has over 8 years of experience working at the Early Intervention Foundation and sits on the Government's Trials Advice Panel. Jack will oversee the delivery of the work and support, supervise and quality assure the work of the project team.
- **Patrick Taylor** is a Principal Research Advisor and leads BIT's education and youth evaluation work, supporting the design, improvement and evaluation of complex interventions in these fields. Patrick will provide support and quality assurance for the pilot evaluation.
- **Naomi Jones** is a highly experienced social research consultant who specialises in helping organisations to design, commission, deliver and use research better, with over 18 years applied research experience. Naomi was formerly head of social attitudes at NatCen, where she led a mixed-method research team and oversaw the British Social Attitudes Survey. Naomi will lead the qualitative evaluation.
- **Neeraj Rahal** is a Policy Advisor in the Home Affairs and Security team at BIT, focusing on projects involving crime and criminal justice. Neeraj will project manage and coordinate the project.
- Lilli Wagstaff is a quantitative research advisor in the Home Affairs and Security team at BIT and leads the evaluation and day-to-day delivery of a number of projects focusing on policy areas including reducing violence and recidivism. Lilli will lead the quantitative evaluation.
- **Niall Daly** is a Research Advisor in the Health and Wellbeing team at BIT, specialising in trial design, implementation, and quantitative data analysis across a range of projects within the health space. He will support the quantitative evaluation.
- **Emma Leith** is a Policy Advisor at BIT. Prior to joining BIT, Emma worked in social and market research with a particular focus on qualitative interviewing and questionnaire design. Her work to date with BIT has been primarily focused on mental health and work health and safety. Emma will support the qualitative evaluation.
- **Martin Wessel** Martin is an Associate Advisor in BIT's Home Affairs and Security team. He works on policy areas spanning crime, justice and social capital and mobility. Martin will support the qualitative evaluation
- **Dr Sajid Humayun** is a senior lecturer in psychology at the University of Greenwich. Sajid is an expert in youth justice and in evaluating interventions for youth crime. Sajid worked on the first RCT for a County Lines intervention and ran the first British evaluation of Functional Family Therapy. Sajid will be providing expert advice and challenge on the design and delivery of the evaluation on a consultancy basis.

Annex C: BIT data protection policy summary

The General Data Protection Regulation (GDPR) imposes certain obligations upon Behavioural Insights Limited (BIT), and other companies within the group, as Controllers and / or Processors in relation to processing Personal Data.

BIT takes these obligations seriously. BIT is committed to respecting the rights of all individuals whose personal data it processes:

- 1. <u>In relation to data security</u>, BIT has implemented appropriate measures to ensure the secure storage and handling of Personal Data, including obtaining a Cyber Essentials Plus certification and developing a comprehensive Data Handling Protocol.
- In relation to data protection and privacy rights, our data processing activities are conducted according to the principles relating to the processing of Personal Data set out in the GDPR, including that Personal Data shall be processed lawfully, fairly and in a transparent manner, and in a manner that ensures the security of the Personal Data. BIT has policies and procedures in place to ensure compliance with these principles.

More information on how we handle Personal Data in relation to projects we are working on is detailed below.

BIT is registered with the UK ICO under the terms of the Data Protection Act 2018. BIT's registration number is ZA038649.

Privacy by design

BIT conducts all trials and research projects with a privacy by design approach to protect and maintain the privacy and security of research participants' and research subjects' data. We work closely with clients, government departments and research partners when designing interventions to ensure that a privacy by design approach is implemented and respected.

Our data protection and data security policies and procedures reflect necessary legislative requirements and set out the standard to which BIT staff should work when dealing with Personal Data, including:

- Attendance at mandatory data protection training for all employees;
- Identifying data requirements from the outset of each project;
- Minimising use of Personal Data where possible and ensuring we have the right to handle any Personal Data where successful project delivery is reliant on using it;
- Putting in place data processing agreements with all clients and suppliers to clarify data handling arrangements ahead of any data being transferred;
- Complying with all relevant data residency requirements and implementing appropriate technical and organisational measures, to protect data and avoid unauthorised access, internally and externally;
- A clear internal reporting process in the event of a data breach, to consider the nature of the breach and identify any necessary action, including whether the breach should be reported to

the relevant authorities, i.e. the Information Commissioner's Office in the UK or the Office of the Australian Information Commissioner;

- Clear procedures on retention and destruction of Personal Data to avoid keeping hold of Personal Data longer than necessary for the purposes of each project; and
- Implementing robust investigation and reporting procedures in relation to any data breach or security issues that arise both within our own systems and those of our clients, partners and suppliers.

Data Protection Officer

The BIT group of companies has appointed a Data Protection Officer (DPO) who is the first point of contact for any issue regarding data protection and data security. The DPO can be contacted via email at dpo@bi.team or by writing to us at:

Data Protection Officer, Behavioural Insights Limited, 58 Victoria Embankment, London, EC4Y 0DS, United Kingdom.