EVALUATION PROTOCOL

Mixed method, two level, individually randomised controlled trial of a trauma informed intervention, Trauma Recovery Model Relationship Building Together, versus business as usual for adolescents and young adults served by Bridgend Youth Services

University of Kent

Principal investigator: Professor Simon Coulton

YOUTH ENDOWMENT FUND

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Evaluation protocol

Evaluating institution: University of Kent

Principal investigator(s): Professor Simon Coulton

YEF trial protocol for efficacy and effectiveness studies

Project title	Mixed method, two level, individually randomised controlled trial of a trauma informed intervention, Trauma Recovery Model Relationship Building Together, versus business as usual for adolescents and young adults served by Bridgend Youth Services.
Developer (Institution)	Bridgend County Borough Council
Evaluator (Institution)	University of Kent
Principal investigator(s)	Professor Simon Coulton
Protocol author(s)	Professor Simon Coulton, Nadine Hendrie, Professor Dorothy Newbury-Birch, Dr Judith Eberhardt
Trial design	Two level, two arm individually randomised controlled trial with concurrent qualitative evaluation.
Trial type	Efficacy
Evaluation setting	Youth services including youth justice, edge of care, youth development, early help.

Target group	10-18 years (extended to 10-21 years in youth development services).
Number of participants	80 staff and 562 young people.
Primary outcome and data source	Number of delinquent offences in the past 6 months derived from the Self-Report Delinquency Scale (SRDS) at month 6.
Secondary outcome and data source	**Young Person:** Number of delinquent offences in the past 12 months derived from the SRDS at months 6 and 12. Self-report behaviour and personality attributes (overall emotional and behavioural difficulties, emotional symptoms, conduct problems, hyperactivity, peer relationships, prosocial behaviour, externalising behaviours, internalising behaviours) derived from the Strengths and Difficulties Questionnaire (SDQ) at month 6 and 12. Self-report non-psychotic mental health derived from the General Health Questionnaire (GHQ12) at months 6 and 12. Self-report wellbeing derived from the Short Warwick Edinburgh Mental Wellbeing Scale (SWEMWBS) at month 6 and 12. Self-report family cohesion, expressiveness and conflict derived from the Brief Family Relationship Scale (BFRS) at month 6 and 12. Self-report Client Service Receipt Inventory (CSRI) to assess police involvement at month 6 and 12 (arrests, cautions, charges, court attendance), educational outcomes (suspensions, exclusions, managed moves) and employment status. **Staff** Self-report Attitudes Related to Trauma Informed Care

	(ARTIC) measured before training, and at month 6 and 12 after training. Self-report Short Warwick Edinburgh Mental Wellbeing Scale (SWEMWBS) before training and at month 6 and 12 after training. Staff turnover throughout the trial and staff absence throughout the study period.

Protocol version history

Version	Date	Reason for revision
1.3	17/02/25	Incorporate pre- post-test correlation in sample size calculation
1.2	16/04/24	Removal of Children's Services as an additional service
1.1	05/02/24	Inclusion of Children's Services as additional service
1.0 [*original*]	23/1/24	

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Study rationale and background

Exposure to Adverse Childhood Experiences (ACE) in childhood has been found to have a strong association with a range of health behaviours and outcomes, including: early onset of alcohol use (Dube et al., 2006), binge-drinking (Bellis et al., 2014a, Bellis et al., 2014b, Bellis et al., 2014c), illicit drug use (Dube et al., 2003), depression (Anda et al., 2002, Chapman et al., 2004, Fang et al., 2016, Schilling et al., 2007); low life satisfaction (Bellis et al., 2014c) unintended teenage pregnancy (Bellis et al., 2014a, Bellis et al., 2014b), HIV risk behaviours (Fang et al., 2016), as well as a range of non-communicable diseases (Brown et al., 2010, Dong et al., 2004) and premature death (Brown et al., 2009). There is also evidence of a relationship between ACE and future violent behaviour, both as a victim and perpetrator; in Wales those who have experienced four of more ACE were found to be 15 times more likely to have been the perpetrator of a violent incident (Bellis et al., 2015). A study of almost 12,000 young offenders (Fox et al., 2015) found that, on average, exposure to each additional ACE increased the risk of becoming a serious, violent, or chronic young offender by 35%.

Trauma informed practice aims to address the consequences of adverse childhood experiences by changing the relationship between practitioners and participants and addressing stigma to create a safe environment for young people to express their emotions and understand the relationship between their emotions and behaviour (Skuse and Matthews, 2015). This safe environment allows those who experienced trauma to see adults in a more positive light and aims to disrupt the transition from poor emotional regulation to dysfunctional behaviour.

The Youth Justice System in England and Wales works to prevent offending and re-offending by those under the age of 18 years. The latest available data indicates that there were 19,000 arrests of young people in 2019, which is an 82% drop from 2009 (Youth Justice Board, 2020). Reasons for this decrease include a police focus on more serious offences, usually committed by adults, and a more child-centric approach to policing, including the use of community resolution outcomes and diversion from criminal justice (Sutherland et al., 2017). Of these, boys made up 83% and the average age was 15.3 years. Over the same period there were 11,000 first time entrants, first reprimand or warning of community conviction, to the Youth Justice System which is a reduction of 84% since 2009 (Youth Justice Board, 2020). It is estimated that 38.5% of new offenders go on to re-offend after serving their initial sentence (Youth Justice Board, 2020). The Crime and Disorders Act 1998 is clear that the principle of youth justice is prevention; diverting young people away from youth justice and addressing their core needs through the provision of youth orientated services are a critical part of achieving this goal.

The Trauma Recovery Model (TRM; (Skuse and Matthews, 2015)) and Enhanced Case Management (ECM) are psychology-based, trauma-informed means of working with young

people with complex needs who are suspected of or known to have experienced trauma. Delinquent behaviour and offending are seen as responses to trauma and the model aims to build relationships with young people that are sensitive, empathetic, and non-punitive. The model involves the sequencing of interventions to meet the young person's needs.

Key elements of ECM, using the TRM, include case formulation with, and ongoing supervision by, an experienced psychologist, and sharing the case formulation across multiple agencies working with the young person. The key aim is to ensure that any professional interactions and interventions are designed to align with the young person's developmental and mental health needs. Creating positive experiences and strong trusting relationships between young people and professionals are key components in ensuring young people are capable and willing to engage in supportive intervention and to take advantage of prosocial opportunities to not only reduce delinquent behaviour but also improve across a spectrum of psychosocial domains. Several Youth Offending Teams (YOT) across England and Wales have started to implement TRM and ECM and all YOTs in Wales have had some training in the approach.

Previous research in youth justice services has found high levels of staff fidelity and stakeholder acceptability of the ECM approach, and changes in practitioner perspectives from viewing offending behaviour as being fixed and intentional to viewing it as adaptive and changeable (Cordis Bright., 2017). Improvements for young people across a variety of domains were also found: improved relationships with practitioners and families, greater confidence in accessing support, improved emotional regulation and greater positivity about the future (Cordis Bright., 2017, Glendinning et al., 2021). Yet these previous studies have used research designs that lack the scientific rigour to assign causality to the intervention. Previous research has tended to be simple before and after studies with no control comparator; hence, despite strong theoretical underpinnings the approach does not have strong evidence of effect. Further, previous evaluations have tended to focus on ECM alone in YOTs rather than the combination of TRM and ECM across multiple services meeting the needs of a broad range of young people.

What is needed is scientifically rigorous research that provides clear evidence of whether TRM and ECM works in adolescent and young adult populations, using a tiered approach across multiple services with TRM alone for the least complex cases and ECM for the most complex cases as in the Relationship Building Together (RBT) model. The proposed research aims to address these key questions. We propose a mixed method, two-level, individually randomised controlled trial of a trauma informed intervention, Relationship Building Together, versus business as usual (BAU) for adolescents and young adults served by Bridgend Youth Services.

Intervention

The intervention, RBT, involves a model of practice that aims to avoid stigmatising and criminalisation of young people through the identification and formulation of a sequence of

interventions that respond to the childhood trauma experienced by the young people. Greater detail on the theoretical framework and the intervention approach is available here: https://www.trmacademy.com/#theModel and the hypothesised theory of change is articulated in figure 1. The intervention builds on work already delivered in youth justice services in Bridgend over the past 18 months, to include a population of young people in other services: Edge of Care, Youth Development, and Early Help – who may be starting to display challenging behaviour as a response to their trauma.

Practitioners are randomly allocated to receive training or not using a secure on-line randomisation service employing a minimisation algorithm which means staff are allocated to ensure balance between service and specialisation. 50% are allocated to RBT training and 50% continuing with BAU. The initial training is delivered to 35-40 staff members over 3-days by specialist trainers from the Trauma Recovery Model Academy. Trainers are experienced practitioners; social workers, clinical psychologists and youth workers who have developed and delivered the RBT intervention for many years across several different services working with young people. Training aids practitioners to understand the impact of prior trauma on the young person's behaviour, the development of strategies to reduce the behavioural consequences of trauma, building relationships and communication, the principles of case management and how to employ evidence-based interventions to promote positive development, and ensuring trauma histories are embedded in the case management process.

Up to ten senior members of staff, consisting of managers for each service and those currently responsible for core assessment of need on referral, will receive an additional two-day training with the aim of becoming trauma leads and champions within their departments. These staff will receive monthly mentoring throughout the project and shadowing from other similar services in Wales. These trauma leads will take responsibility for the core assessment of need, case formulation meetings and embedding trauma informed practice within services.

Practitioners engage in trauma screening for any young person allocated to the intervention arm, and dependent on the young person's need the intensity of intervention is agreed. Tier 1, the lowest tier of need, includes young people who have evidence of past trauma, but it is not complex (it may be due to temporary family or financial difficulties for example), and they have experienced periods of recovery. Tier 2 involves young people who have more complex trauma with little evidence of periods of recovery, often a result of family breakdown or significant traumatic events; these young people require more intensive intervention involving an in-house multi-disciplinary team. Young people in tier 3 are the most complex, they will have a significant history of trauma, often as a result of neglect, breakdown, or involvement in criminal activity, with no evidence of any periods of recovery, and intervention needs to be both multi-disciplinary and led by a clinical psychologist. A brief comparison of BAU and different tiers of intervention is provided in table 2 and more detail provided below.

Tier 1 involves guidance and support from the trauma leads to the case manager and other relevant professionals involved in the case, on engaging with and supporting the young person in a trauma-informed manner. The trauma leads assist to ensure that assessments and reports are conducted with a trauma-informed perspective. This involves considering the young person's trauma history, understanding the potential triggers, and incorporating trauma-related information into the assessment process. This approach helps to gain a comprehensive understanding of the young person's needs and informs the development of an effective intervention plan. Trauma leads will review the progress of interventions mid-intervention against the Trauma Recovery Model (TRM) framework. This assessment helps identify any necessary adjustments or modifications in the intervention plan, ensuring that it remains responsive to the young person's evolving needs and progress.

In addition to trauma screening, tier 2 involves a relationship-based mapping exercise led by the trauma lead that plays a crucial role in understanding the young person's life experiences, trauma history, and developmental needs. The trauma lead organises a multi-agency meeting with professionals from various disciplines involved in the young person's care. This may include social workers, educators, medical professionals, and other relevant professionals who have been in the young person’s or family's life. The meeting serves as a platform for collaborative information sharing and decision-making.

During the meeting, the attendees collectively create a timeline that captures significant events in the young person's life, starting from pre-birth. This timeline includes not only the young person's experiences but also the mother's experiences prior to giving birth. The timeline helps identify potential sources of trauma, understand their impact, and establish patterns or triggers that may affect the young person's well-being. Professionals will also be asked to provide input on the young person's emotional, social, and cognitive age based on their observations and professional expertise. This information helps develop a comprehensive understanding of the young person's overall development and potential developmental gaps resulting from trauma.

To visualise and timeline trauma events, an interactive system is utilised. The system allows attendees to collaboratively add trauma events, notes, and observations onto a shared digital platform. This visual representation enhances the understanding of the young person's experiences and facilitates effective communication among the professionals involved. Developmental mapping is also conducted to assess the young person's current developmental stage and to identify any areas where trauma has impacted their development. This mapping process helps identify strengths, vulnerabilities, and areas requiring targeted interventions. Importantly, the developmental mapping can be updated and followed throughout the young person's journey into adulthood, providing a comprehensive framework for long-term support.

Based on the information gathered from the relationship-based mapping exercise, trauma leads generate a formulation report. This report provides an in-depth profile of the young person, including their trauma history, developmental strengths and challenges, and recommendations for intervention. The report highlights trauma-informed strategies and interventions that are tailored to the young person's specific needs and are developmentally appropriate. The recommendations outlined in the formulation report are implemented by all professionals involved in the young person's care. This ensures a consistent and coordinated approach to trauma recovery and intervention. Professionals collaborate closely, sharing information and working together to provide continuous support and appropriate interventions throughout the young person's journey.

All services involved commit to maintaining a continuity of trauma intervention. This means that the young person receives consistent support from various professionals over a universal designated period. Regular reviews are undertaken at specific intervals to assess the effectiveness of interventions, adjusted if necessary, and ensure that the young person's evolving needs are addressed appropriately.

Tier 3 is similar to Tier 2, but with the addition of a trauma specialist clinical psychologist who leads the mapping exercise. The psychologist will produce the formulation report based on the information discussed in the timelining exercise, providing further insights and recommendations for intervention.

Business as usual is usual practice, it involves no trauma screening or developmental assessment and focusses on the assessment and mitigation of risk. It differs across services, but it focusses on the young person and family, based on the referral with no multi-agency involvement in case formulation. Interventions can be relatively short term, for Edge of Care services, where crisis interventions might last 6-8 weeks or they can be longer term, 6-9 months, for Youth Offending Services. Interventions differ across services. In Early Help the approach is focussed on early intervention, providing practical advice and support for young people and their families, and acting as a liaison between different services. Youth Development Services are often delivered within youth centres and involve signposting and mentoring, addressing issues such as health and wellbeing, education, employment, and housing. Edge of Care Services are social work focussed aiming to avoid a young person going into care or managing child protection or child in need procedures, interventions encompass a range of approaches including family and young people’s support, Signs of Safety, placement support, social work assistant interventions, family therapy and the involvement of young people’s mental health services. Youth Justice Services deliver interventions for young people involved with the criminal justice service, with the aim of preventing re-offending. Multi-disciplinary interventions focus on wellbeing and resilience, restorative justice, and prosocial engagement.

Figure 1: RBT Theory of Change

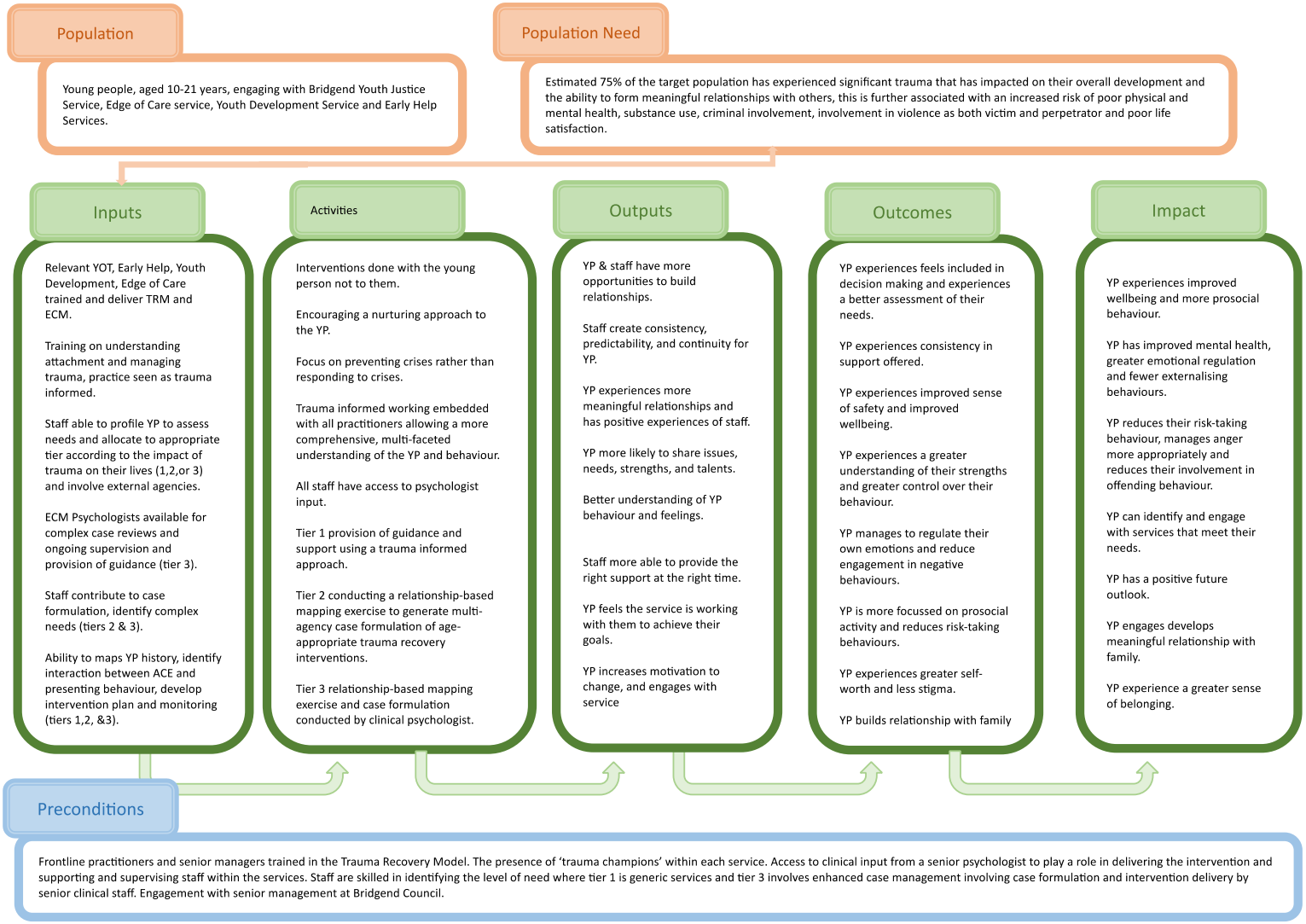

Table 2: RBT Tiers of intervention compared to BAU.

Business as usual	TRM Tier 1 Trauma Aware (TA)	TRM Tier 2 Relationship Building Practice (RBP)	TRM Tier 3 Enhanced Case Management (ECM)
☐ Assessment and Intervention without developmental mapping. ☐ Responding to risks and focus on how to manage risk. ☐ Different plans for different services. ☐ Child / family supported by practitioner with the usual training they have been offered. ☐ Formulates a plan of work based on the referral. No multi-agency meeting or developmental mapping. ☐ Undertakes direct work with the child.	☐ Trauma Recover Model (TRM) Training. ☐ Access to clinical psychology support – group supervision. ☐ Consistent plans and tool kit for practitioners across the services. ☐ Input, advice, and guidance available from trauma lead.	☐ Trauma Recover Model Training. ☐ Multi-agency case formulation meeting chaired by trauma lead. ☐ Developmental mapping and TRM assessment informing the planning to undertake direct work. ☐ Ongoing consultation/supervision with the trauma lead. ☐ Summary report of case formulation meeting. ☐ Ongoing multi-agency review meetings. ☐ Access to clinical psychology support.	☐ Trauma Recover Model Training. ☐ Clinical Psychologist led. ☐ Multi-agency case formulation meeting. ☐ Ongoing consultation and supervision with the clinical psychologist. ☐ Developmental mapping and TRM assessment informing the planning. ☐ Full clinical psychologist report. ☐ Ongoing multi-agency review meetings.

Impact evaluation

Study objectives

1. To conduct a prospective RCT to evaluate the efficacy of the Relationship Building Together (RBT) approach compared with business as usual (BAU) on offending behaviour, measured using the Self Report Delinquency Scale (SRDS), over 6- and 12-months post-randomisation, in a population of young people, aged 10-21 years inclusive, accessing services provided by Bridgend Youth Offending Team, Bridgend Youth Development Services, Bridgend Early Help Hubs, Bridgend Edge of Care Services.

2. To evaluate the efficacy of the RBT versus BAU in terms of emotional regulation, peer, prosocial, conduct, hyperactivity, internalising and externalising behaviours (SDQ), wellbeing (SWEMWBS), psychological health (GHQ12), family cohesion (BFRS), school, work, and criminal justice involvement (CSRI), in a population of young people, aged 10-21 years inclusive, accessing services provided by Bridgend Youth Offending Team, Bridgend Youth Development Services, Bridgend Early Help Hubs, Bridgend Edge of Care Services, at 6- and 12-months post randomisation.

3. To evaluate the impact of RBT versus BAU on staff perception of trauma informed care (ARTIC), staff wellbeing (SWEMWBS), staff turnover and staff absence in the 6 and 12 months after training across Bridgend Youth Offending Team, Bridgend Youth Development Services, Bridgend Early Help Hubs, Bridgend Edge of Care Services.

4. To conduct a micro-costing exercise to provide estimates of the cost of delivering the intervention from the perspective of the intervention delivery organisation.

5. To develop a prognostic model exploring the baseline demographics (age, sex, ethnicity, IMD), psychological (SDQ, GHQ12, ACES), therapeutic alliance (TASC-r) and family factors (BFRS) that may impact observed outcomes and using the results to elaborate mechanisms of change and where appropriate revise the intervention logic model.

6. To conduct a latent class analysis to explore potential interactions between population subgroups, intervention received, and outcomes observed.

7. To assess and report on any iatrogenic or adverse effects of the control and intervention. Adverse events include but are not limited to; concerns for the physical and emotional wellbeing of a child, self-harm, suicidal ideation, or death, physical,

mental, and emotional abuse as a victim or perpetrator, actual or intended violent offences as a victim or perpetrator. Ensuring that any serious events are brought to the attention of the funder in accordance with their safeguarding policy https://youthendowmentfund.org.uk/wp-content/uploads/2023/04/2304-YEF-Safeguarding-Policy.pdf.

Design

Table 1: Trial design

Trial design, including number of arms		Two-arm prospective, individually randomised controlled trial
Unit of randomisation		Individual participant and practitioner
Stratification variables (if applicable)		Service (youth justice/edge of care/ youth development/early help), Sex (male/ female), age group (<15 years, >= 15 years)
Primary outcome	variable	Quantity of self-reported delinquent acts at 6 months[1]
	measure (instrument, scale, source)	Self-Reported Delinquency Scale (SRDS)
Secondary outcome(s)	variable(s)	**Participant** Quantity of self-reported delinquent acts at 12 months Self-report behaviour and personality attributes (overall behaviour, emotional symptoms, conduct problems, hyperactivity, peer relationships, prosocial behaviour, externalising behaviours,

[1] The requirement of the funding means a report needs to be available by September 2025, this means the primary outcome is the 6-month version of the SRDS. As some interventions take longer than 6-months to deliver a second report using SRDS at month 12 will also be produced later.

		internalising behaviours), psychological health, wellbeing, family cohesion, police involvement, school exclusions, suspensions, managed moves and employment status. At 6 and 12 months. **Staff** Attitudes and perceptions towards trauma informed care, wellbeing, absence, turnover at 6 and 12 months
	measure(s) (instrument, scale, source)	**Participants** Self-Reported Delinquency Scale (SRDS), Strengths and Difficulties Questionnaire (SDQ), General Health Questionnaire (GHQ12), Short Warwick Edinburgh Mental Wellbeing Scale (SWEMWBS), Brief Family Relationship Scale (BFRS), Client Service Receipt Inventory (CSRI) **Staff** Attitudes related to Trauma Informed Care (ARTIC), Short Warwick Edinburgh Mental Wellbeing Scale (SWEMWBS), Staff records.
Baseline for primary outcome	variable	Quantity of self-reported delinquent acts in previous six months
	measure (instrument, scale, source)	Self-Reported Delinquency Scale (SRDS)
Baseline for secondary outcome	variable	**Participant** Number of offences in the 6-months prior to baseline. Self-report behaviour and personality attributes (overall behaviour, emotional symptoms, conduct problems, hyperactivity, peer relationships, prosocial behaviour, externalising behaviours, internalising behaviours) derived from the Strengths

		and Difficulties Questionnaire, psychological health, wellbeing, family relationships at baseline. Police involvement, school exclusions and suspensions, employment status over the past 6 months at baseline. **Staff** Attitudes and perceptions towards trauma informed care and wellbeing at baseline. Days' absence and turnover over the past 6 months at baseline.
	measure (instrument, scale, source)	**Participants** Self-Report delinquency Scale (SRDS), Strengths and Difficulties Questionnaire (SDQ), General Health Questionnaire (GHQ12), Short Warwick Edinburgh Mental Wellbeing Scale (SWEMWBS), Brief Family Relationship Scale (BFRS), Client Service Receipt Inventory (CSRI), Staff Attitudes related to Trauma Informed Care (ARTIC), Short Warwick Edinburgh Mental Wellbeing Scale (SWEMWBS), Staff records.

Randomisation

There are two levels to the study randomisation. Level one involves staff being allocated to be trained in RBT or remain delivering BAU. This allocation is done for all staff, after baseline staff data collection, and is conducted by an on-line independent secure randomisation service, Sealed Envelope Ltd. Staff in Youth Development Services will be youth workers and mentors who work directly with young people, in Early Help they will be staff who support young people and families, in Edge of Care Services staff will predominantly be social workers and social work assistants and in Youth Justice Services they will be professionals who work with young people to reduce reoffending. Staff already trained in RBT in the YOT will be ineligible. Consent will be sought from all eligible staff prior to randomisation. As allocations are done at the same time and because we want to maximise balance across the groups on

key parameters, we will employ minimisation for the allocation of staff. Our aim will be to maximise balance in terms of service (youth justice, edge of care, youth development, early help) and sex (male or female). Provision has been made to conduct a second wave of staff randomisation and TRM training if there is a high turnover of staff throughout the trial – a high turnover is one that exceeds 30%.

Level two allocation involves the randomisation of young people to RBT or BAU. This will be conducted by research staff, using a secure, on-line randomisation service (Sealed Envelope Ltd). after informed consent has been taken and the baseline assessment completed and before any trauma screening has been conducted. The allocation will involve an equal probability of receiving RBT or BAU and will employ random permuted blocks of variable size (4, 6 or 8) with a random block seeded throughout. Randomisation will be conducted by research staff using a secure, independent randomisation service, Sealed Envelope Ltd. Randomisation will be stratified by service (youth justice, edge of care, youth development, early he), sex (male, female), and age group (<15 years, 15 years or more). Stratification variables have been chosen to ensure allocation is balanced across services, sex, and age as some workers specialise in working with older or younger males and females. A full quality assurance AUDIT trail will be kept of all allocations and research staff will not be able to see future allocations. The allocated group will be relayed back to delivery staff in the services who will decide which staff member, matching their allocated intervention or control group, a young person should be assigned to.

It is not possible to blind young people or staff to their allocated group although follow-up at months 6 and 12 will be conducted by researchers' blind to allocation. Follow-up questionnaires are completed by participants and are the same for both groups, the questionnaires collect no details on what group the participant was allocated to.

Participants

Staff are considered eligible to participate in the study, and are allocated to training or business as usual, if they work with the target population within their service and volunteer and provide consent to randomisation. New staff will only be able to participate if a second wave of training is planned.

To maximise the generalisability of the study, inclusion and exclusion criteria have been minimised. All young people aged 10-21 years inclusive, referred for assessment and intervention, to one of the participating services (only the Bridgend Youth Development Service includes participants aged 18 to 21 years), who are able and willing to consent will be eligible for inclusion in the study. Participants who have previously been randomised in the study will be excluded from further randomisation but will be maintained as part of their previously allocated group. Young people and their carers will be provided with a

comprehensive information sheet prior to their initial appointment with the service. At the first appointment staff will answer any questions the parent or young person may have and if they are able and willing to consent, they will take signed consent. It is practice within all the services to request formal signed consent from family or caregivers for all young people aged 15 years or less, if parental/ caregiver consent is not forthcoming for those aged less than 15 years, staff are trained in assessing Gillick competence and making informed decisions regarding the young person's ability to consent. If a young person is considered Gillick competent consent will be sought from them directly.

After consent has been taken the staff member will collect demographic and contact data and the baseline outcomes. All young people will be identified using a unique identifier provided by the service, to ensure participants can be tracked across services and can only be randomised once. Once the baseline questionnaire is complete it will be sent using a secure, encrypted email service to research staff at the University of Kent who will use the information to conduct a randomisation using the secure randomisation service, and the outcome of the randomisation will be emailed back to the staff member on the same day. Allocation to specific staff in the control group for those in Youth Justice Services will take account of the fact that some existing staff are trained in RBT, so control group participants will only be allocated to untrained staff in this service.

After randomisation, staff will carry out the trauma screening assessment with those allocated to the intervention group and assign them to an appropriate tier of intervention support. A researcher will also contact the young person and/ or their caregiver in both control and intervention groups to explain who they are, check contact details for sending a £20 voucher redeemable at Amazon and give the young person and caregiver an opportunity to ask any questions or seek clarification about the trial. The researcher will contact the young person 3- and 9-months after randomisation to check contact details and 6- and 12- months after randomisation to conduct follow-up assessments, where they will also receive a £20 voucher. Young people will be supported in the completion of follow-up questionnaires with the researcher being concurrently available to address any issues.

Sample size calculations

Sample size calculations were derived using Stata 16 and are based on the Self-Report Delinquency Scale (Smith and McVie, 2003). This measure has 18 two-part questions that measure the number of different offences committed, and the volume of offences committed over a fixed period. We are interested in the latter outcome over a six-month period. The scale has good psychometric properties (Fonagy et al., 2018, Humayun et al., 2017) and correlates well with official police charges (R = 0.95; (McAra and McVie, 2007)).

We have used an effect size difference of 0.25 as an important difference; this equates to a difference in volume of offences of circa 12% over a 6-month period, similar effects as found

in other psychologically focussed interventions to reduce recidivism in adolescent populations (Hodgkinson et al., 2021). To detect this difference or greater, using a two-sided test, alpha of 0.05 and power at 80% requires young people to be followed-up at our primary endpoint, 6-months post-randomisation, 253 in each group. Similar RCT's in similar populations (Coulton S et al., 2023, Fonagy et al., 2018) suggest a pre- post-test correlation for the SRDS of 0.644 (95% CI 0.474 to 0.815), we have erred on the side of caution and included a correlation of 0.5 into the sample size calculation, and this reduces the required sample at the primary end-point to 380, 190 in each group. If we take a potential loss to follow-up of 10%, similar to attrition found in our other studies of young people (Coulton S et al., 2023), this inflates the required baseline sample to 422. We have 71 potential interventionists, 35 randomised to each arm. Each interventionist can manage a harmonic mean of 10 young people through the course of the study. To achieve our target, we would need to have at least 42 of these interventionists participating throughout the trial, 21 in each arm, thus allowing for a potential loss of interventionists of 29, 40% of those available.

Assuming only 80% of young people approached consent to take part, as found in similar studies (Coulton S et al., 2023), means we would need to approach 528 young people, over the recruitment period. Allowing for a slower start of 20/ per month recruited over the first three months, means 33 will need to be recruited in each month between January 2024 and February 2025, allowing for a six-month follow-up for the interim report submitted in September 2025.

Table 2: Sample size calculations

		PARAMETER
Minimum Detectable Effect Size (MDES)		0.25
Pre-test/ post-test correlations	level 1 (participant)	0.5
	level 2 (cluster)	n/a
Intracluster correlations (ICCs)	level 1 (participant)	n/a
	level 2 (cluster)	n/a

		PARAMETER
Alpha[2]		0.05
Power		0.8
One-sided or two-sided?		Two-sided
Average cluster size (if clustered)		n/a
Number of clusters[3]	Intervention	n/a
	Control	n/a
	Total	n/a
Number of participants	Intervention	190
	Control	190
	Total	380 (422 allowing loss at month 6 of 10%)

Outcome measures

To ensure outcomes are accessible to a wide range of potential participants we will make outcomes available in English and Welsh and provide translators for other languages. As we anticipate a higher level of intellectual disability than the general population, we will seek the advice of specialists in how outcomes can be presented to meet the needs of the target population; this will include using different fonts, colours, and the restriction on the amount of text presented on each page. All outcome tools will be agreed with our youth advisory panel prior to use.

[2] Please adjust as necessary for trials with multiple primary outcomes, 3-arm trials, etc., when a Bonferroni correction is used to account for family-wise errors.

[3] Please state how the data is clustered, if there is any clustering (e.g., by delivery practitioner or setting).

Baseline measures

Key demographic variables will be collected at baseline, these include age, sex, ethnicity, and index of material deprivation (IMD) derived from the participants postcode and converted to IMD using the IMD Wales lookup tool:

https://geoconvert.ukdataservice.ac.uk/help/faq.html.

Primary outcome

Self-reported delinquency will be assessed using the Self-Report Delinquency Scale (SRDS; (Smith and McVie, 2003)) over the previous six months. This 19-item questionnaire has established psychometric properties (Fonagy et al., 2018) in this population and has a strong correlation (R=0.95) with police charges (McAra and McVie, 2007). This outcome will be assessed at baseline, 6- and 12-months post randomisation. As the funder requires a final report by September 2025, the 6-month post-randomisation time-point will be the primary endpoint.

Secondary outcomes

Emotional symptoms and behavioural difficulties will be assessed using the self-completed Strength and Difficulties questionnaire (SDQ; (Goodman, 1997)). This assesses behaviour across several domains including, conduct, hyperactivity, emotional regulation, peer relationships and prosocial behaviour and allows for the generation of two multi-component outcomes: internalising and externalising behaviours with the latter highly associated with current or future offending behaviour. We will assess total score, domain scores and multi-component scores. The outcome is widely used and has demonstrated excellent validity and moderate reliability in adolescent populations (Goodman, 2001). The SDQ is suitable for completion by those aged 10-17 years and those with mild learning disabilities (Law and Wolpert, 2014)

Wellbeing will be assessed using the Short Warwick-Edinburgh Mental Well-being scale (SWEMWBS; (Clarke et al., 2011)). SWEMWBS is a 7-item, self-completed scale addressing different aspects of eudemonic and hedonic mental health wellbeing. The scale is validated for adolescents and demonstrates good internal consistency (Ng Fat et al., 2017), and discriminant, construct and convergent validity (McKay and Andretta, 2017, Ng Fat et al., 2017).

Non-psychotic psychological health will be assessed using the General Health Questionnaire (GHQ12; (Goldberg and Hillier, 1979)), using norms derived for adolescent populations. This 12-item instrument has established validity and reliability in adolescent populations (Baksheev et al., 2011).

To assess the potential impact on the family environment we will assess family cohesion using the Brief Family Relationship Scale (BFRS; (Fok et al., 2014)), this 16-item instrument assesses family relationships, cohesion, and conflict, and has established convergent and discriminant validity.

We will use questions derived from a Client Service Receipt Inventory (CSRI;(Coulton et al., 2022)) to assess the frequency of school attendance, exclusions and suspensions, work status and criminal justice involvement over the previous 6-months. Client Service Receipt Inventory methods are an established and valid form of assessing participant resource use in randomised controlled trials and can be adapted for the target population (Knapp and Beecham, 1990).

All these outcomes will be assessed at baseline and then again at 6- and 12-month post-randomisation.

The assessment battery takes 15 minutes to complete on average based on the use of a similar question battery with an adolescent population in other studies. Each young person will be supported during completion, at baseline by staff in the services and at 6- and 12-month by researchers who will be blind to participant allocation. Research staff will provide training in baseline data collection to staff in Bridgend across the four services through an interactive in-person training session and this will include a training manual and on-going support. At the end of each assessment point and at the end of any qualitative interview the young person will be provided with an opportunity to debrief and reflect on the impact of answering the questions. This debrief is designed to identify any negative impacts of reflecting on themselves and any potential re-traumatisation. If issues are identified, the potential adverse event standard operating procedure will be activated, and trauma leads in each service asked to conduct an assessment and provide any necessary intervention. All adverse events in both arms of the study will be recorded and reported.

In addition to key demographics (age, sex, ethnicity, and IMD) that will be assessed at baseline we will assess the exposure to adverse child experiences assessed on entry to the service using existing records.

Six months after randomisation, in both arms of the study, young people will be contacted by phone or email by researchers and asked to complete the short revised therapeutic alliance scale for children (TASC-r; (Shirk and Saiz, 1992)), this assesses the quality of the relationship between the young person and staff member. Therapeutic alliance is a strong predictor of outcome, and this will be used in the prognostic model (objective 5).

Staff will be asked to complete the Attitudes Related to Trauma Informed Care (ARTIC; (Baker et al., 2016)), a psychometrically robust instrument that assesses professional attitudes and perceptions of trauma informed care. The instrument has established internal consistency

(Cronbach α 0.91), test-retest reliability (0.84), criterion and construct validity (Baker et al., 2016). Staff wellbeing will be assessed using the Short Warwick-Edinburgh Mental Well-being scale (SWEMWBS; (Clarke et al., 2011)). They will complete these just prior to randomisation and again 6- and 12-months after randomisation to RBT or BAU. In addition to self-completed outcomes, staff turnover and percent days absent will be assessed over the intervention delivery period from Bridgend administration databases.

Compliance

As interventions are personalised to the young person's needs across both the RBT and BAU groups, compliance and dose will be assessed from two perspectives. From a staff perspective we will assess fidelity to the components of the allocated tier in the RBT arm (case formulation, multi-agency meetings, reviews). For participants, the dose will be assessed in both arms as the proportion of planned meetings attended. Interactions between young people and staff are recorded on the same system between the different participating services. Records include planned meetings, who leads the meeting, staff member, trauma lead or psychologist and attendance. Compliance will be categorised into 5 quintiles, 0-19%, 21-40%, 41-60%, 61-80% and 81-100%. These will be employed in a dose response analysis. In addition, we will use this data to augment the micro-costing of the intervention.

Analysis

The proposed analysis is covered in depth in the associated statistical analysis plan.
Objective 1: Participant flow through the study will be presented as a CONSORT diagram. We will present demographics and outcome variables for each group at each time-point. We will explore the validity of the randomisation procedure by presenting baseline outcomes and estimates of precision by allocated group.

Objective 2: The primary outcome is the mean difference between BAU and RBT in number of offences over the 6 months from baseline, assessed using the SRDS at 6-months. The analysis will be conducted using an analysis by intention to treat (ITT) and will include all available data with participants maintained as members of their allocated group, irrespective of whether they complied with the intervention or not. Data will be assessed for distributional assumptions and will probably take the form of a generalised linear regression model, adjusted for baseline stratification covariates and baseline SRDS score. Both the intervention and control vary by service, with a higher to lower hierarchy of complexity running from youth justice, edge of care, youth development to early help. What is delivered in both the intervention and control group is tailored to the young person's needs. While we can describe the variety of different sessions delivered in our results, we cannot completely account for it in the analysis, nor can we adjust for any potential contamination due to multi-agency working. Instead, we take a holistic approach, seeing what is delivered as a whole, rather than

the sum of its individual parts. Though as complexity is hierarchical across services, we will adjust the analysis for service. This provides the best estimate of effect of how the intervention is proposed to be implemented across diverse services and as a rigorously designed RCT any potential errors introduced will be equally distributed across both groups and mitigated in the analysis. We will apply a multi-level model allowing for participants to be nested within services as a fixed effect. Results will be presented as a mean difference and associated 95% confidence intervals. A secondary analysis will be conducted using a similar approach at month 12.

Secondary outcomes will be assessed in a similar way by establishing diagnostic plots to identify the most appropriate regression approach; logistic for dichotomous outcomes, ordinal for ordered categorical outcomes, linear for continuous outcomes and fractional for proportions. Stratification factors and baseline covariates will be included within the model.

If the missing data exceeds 5%, sensitivity analyses will be performed using a pattern mixture approach and multiple imputation to compare the sensitivity of conclusions to varying assumptions about the missing data, particularly whether data is missing at random (MAR) or missing not at random (MNAR). This allows for an assessment of both random and systemic bias. Results based on complete data analysis, MAR and MNAR will be presented to explore the influence of missing data on outcomes observed.

We will conduct a Complier Average Causal Effects (CACE) analysis using an instrumental variable framework to explore the impact of compliance on the primary outcomes at different levels of compliance, both fidelity to the steps involved in each tier and quintiles of compliance. CACE weights the analysis by the ITT treatment effect by the proportion of compliance, this allows the estimation of unbiased treatment effects and maintains the allocation in the analysis.

Objective 3: For staff we will explore the differences between the groups in terms of overall wellbeing, perceptions of working in a trauma informed manner and confidence in working with young people who have experienced adverse childhood experiences derived from the SWEMWBS and ARTIC questionnaire at months 6 and 12 using linear regression adjusted for baseline score and service. Staff turnover and proportion absence will be assessed in a similar manner using fractional regression.

Objective 5: Stepwise regression analysis will be performed to model the relationship between pre-randomisation factors and demographics, on observed outcomes at 6 months. Interaction terms with allocation arm will be included in the analysis, and a significance level of 0.1 will be used to determine which factors are to be included in the regression model. Pre-randomisation factors will include sex, age, ethnicity, IMD, family cohesion, adverse

childhood experiences assessed by the service, and process measures, staff perceptions, staff confidence, and therapeutic alliance. The allocated arm will be included in this analysis as an interaction term.

Objective 6: To maintain power in analysis we will avoid the analysis of sub-groups. We will use latent class analysis to explore the existence of subgroups within the sample who may have a differential response to the intervention.

Longitudinal follow-ups

Participant data will be collected at baseline (prior to randomisation) and again at 6- and 12-months post randomisation. Our primary endpoint will be the 6-month post-randomisation date, to meet the deadline for a report in September 2025. We will conduct a secondary analysis using 12-month outcomes to provide longer term effects using the strategies highlighted above. Core outcomes and the time of data collection are presented in table 3.

Table 3: Core outcomes and time of collection

Outcome	No of items	Baseline	Six months	Twelve months
Primary				
Self-reported delinquency (SRDS)[1]	36	✓	✓	✓
Secondary				
Strength and Difficulties (SDQ)[1]	25	✓	✓	✓
Wellbeing (SWEBWMS)	7	✓	✓	✓
Psychological Distress (GHQ12)	12	✓	✓	✓
Family environment (BFRQ)	16	✓	✓	✓
Receipt Inventory (CSRI)	8	✓	✓	✓
Staff attitudes to trauma informed care (ARTIC)	35	✓	✓	✓
Staff wellbeing (SWEBWMS)	7	✓	✓	✓
Staff turnover & absence	2	✓	✓	✓
Exploratory				
Adverse childhood experiences (ACE-Q)	10	✓		
Process				
Therapeutic relationship	12		✓	
Proportion of sessions planned & delivered	1		✓	✓

[1] SRDS and SDQ are YEF core outcomes.

Implementation and process evaluation

Research objectives

A synthesis of quantitative and qualitative analysis will be used to address key objectives addressing the implementation, process and equity associated with the intervention. The focus of this is to assess: the extent to which the intervention has been implemented as intended including factors that facilitate or hinder implementation; the acceptability of the intervention from the perspectives of participants, staff and key stakeholders; the impact of dosage, adherence and staff turnover on outcomes observed; the extent to which the findings are generalisable to the wider population, particularly in terms of ethnicity and equity; and to identify positive and negative experiences associated with the intervention and when they occur.

Research Questions

The IPE is framed in 7 research questions:

1. To what extent do staff within services adhere to the intended delivery model?

2. What factors facilitate or hinder intervention delivery?

3. How acceptable is the intervention from the perspective of participants, staff and key stakeholders?

4. How is the 'dose' of, and adherence to, the intervention associated to outcomes observed?

5. How generalisable are the findings to the wider population accessing the services?

6. What positive or negative experiences do participants and staff highlight and when do these occur?

7. Do changes in the behaviour change model occur as hypothesised?

Table 4: IPE methods overview

IPE Question	Data collection methods	Participants/ data sources (type, number)	Data analysis methods	Research questions addressed	Implementation/ logic model relevance
IPE.Q1	Process data regarding interventions planned and delivered.	Receipt of initial case formulation in accordance	Descriptive statistics.	To what extent do staff within services adhere	Adherence to the delivery model leads to better outcomes.

		with identified tier of need. Session data highlighting components of intervention planned versus components delivered.		to the intended delivery model?	
IPE.Q2	Semi-structured interviews addressing facilitators and hindrances associated with intervention delivery, and factors associated with non-compliance.	20 staff members, 10 participants and 10 parent/carers purposively sampled by service, age and ethnicity.	Inductive thematic analysis. Findings will be mapped onto NPT.	What factors facilitate or hinder intervention delivery?	Understanding what factors facilitate or hinder engagement with the intervention can identify modifications that can be made.
IPE.Q3	Semi-structured interviews addressing acceptability.	20 staff members, 20 participants and 10 parent/carers and 10 key stakeholders (clinical psychologists, inter-agency workers) purposively sampled by service, age and ethnicity.	Inductive thematic analysis. Findings will be mapped onto NPT.	How acceptable is the intervention from the perspective of participants, staff and key stakeholders?	Understanding acceptability can lead to modifications that increase engagement and have better outcomes.
IPE.Q4	Quantitative analytical model exploring the role of 'dose' on outcome observed, service staff turnover and staff wellbeing.	Session data, intervention participants survey data, staff turnover and wellbeing.	Stratified regression analysis to explore the relationship of 'dose' on outcomes controlling for potentially confounding	How is the 'dose' of, and adherence to, the intervention associated to outcomes observed?	Does the 'dose' of intervention stratified by tier have an impact on outcomes observed.

			factors, including allocated tier.		
IPE.Q5	Semi-structured interviews focussing on the appropriateness of referral process and explore whether some groups are unable to access the service.	20 semi-structured interviews with participants, 20 interviews with practitioners and 20 semi-structured interviews with key stakeholders, 10 of which will be parents/ carers. Purposively sampled to get variety by service, age, and ethnicity	Inductive thematic analysis Findings will be mapped onto NPT.	How generalisable are the findings to the wider population accessing the services?	The intervention has to be accessible by all potential participants.
IPE.Q6	Semi-structured interviews focussing on the positive and negative experiences of the intervention and when these occur.	20 semi-structured interviews with participants, 20 interviews with practitioners and 20 semi-structured interviews with key stakeholders, 10 of which will be parents/ carers. Purposively sampled to get variety by service, age, and ethnicity.	Inductive thematic analysis. Findings will be mapped onto NPT.	What positive or negative experiences do participants and staff highlight and when do these occur?	Identify potential modifications that can be made to maximise the impact of the intervention.
IPE Q7	Semi-structured interviews focussing on	20 semi-structured	Inductive thematic	Do changes in the behaviour	Is the ToC a valid representation of

	perceptions of what change has occurred.	interviews with participants, 20 interviews with practitioners and 10 semi-structured interviews with parents/ carers. Purposively sampled to get variety by service, age, and ethnicity.	analysis. Findings will be mapped onto NPT.	change model occur as hypothesised?	what changes actually occur.

Research Methods

The qualitative component of the study will be purposive and include semi-structured interviews with at least 20 young people, 20 intervention delivery staff and 20 key stakeholders to answer IPE Q2, Q3, Q5, Q6 and Q7. The key stakeholders would include 10 parents/carers, and 10 staff from key services involved, such as the psychology team linked to the All-Wales Forensic Adolescent Consultation and Treatment Service (FACTS) and staff from other services who become involved in formulation and trauma planning and who are invited to create the trauma intervention (e.g., relevant multi-agency partners such as education, children social care, and police). Participants will be chosen purposively to provide diversity in terms of service and age and ensure appropriate participation by sex and ethnicity to explore issues of equity and inclusion. Although a total sample of 60 interviews will be the aim, the sample size considerations of the qualitative component are driven by the need to achieve data saturation, and this needs to be judged in practice rather than stated in advance.

Semi-structured interviews will be conducted between month 7 and month 28, either online or face-to-face, as appropriate. A research associate will interview each participant once, and within that interview we will explore each of the relevant IPE research questions.

All interviews will be recorded, with consent, and transcribed verbatim. Inductive thematic analysis (Braun & Clarke, 2006) will be used to analyse the narrative accounts, with the understanding that saturation will guide the requisite sample size, which cannot be predetermined. If saturation is not achieved, an additional 5-10 stakeholders may be recruited. Efforts will be made to incorporate views from those who dropped out or were non-compliant with the intervention, though practical feasibility of this inclusion is a limitation.

The interviews aim to capture diverse perceptions of the intervention, utilising Normalisation Process Theory (NPT). This approach will facilitate mapping findings onto NPT's constructs: coherence (how the intervention is perceived and understood), cognitive participation (engagement and commitment of stakeholders), collective action (integration of the intervention into practice), and reflexive monitoring (ongoing assessment and adaptation of the intervention). Bracketing, reflexivity, and member checking will be integral to ensuring research trustworthiness and rigour.

Data will be analysed using NVivo software, employing an inductive approach without the constraint of existing theories, to allow for the natural emergence of findings. This analysis aims to identify critical elements of the intervention, explore implementation issues, and understand ethnicity and equity concerns. It will also focus on identifying perceived barriers or facilitators to implementation in usual practice. This inductive analysis, grounded in the data, will contribute valuable insights into the practicalities of the implementation process.

We propose to augment the qualitative analysis with the secondary quantitative analysis, detailed in the analysis section on page 19, to explore how content, compliance, and therapeutic alliance impact on the outcomes observed. A regression model will be conducted, with the primary outcome, number of offences in the previous 6-months, as dependent variable and adjusting for key covariates identified. This will allow for a quantification of what dimensions of the intervention are associated with outcomes and will enable an exploration of whether certain domains are more important than others and should be emphasised in the intervention delivery and, by extension, the training. Allied to this, we will assess the impact of staff turnover across the services, wellbeing of practitioners and the extent to which staff perceptions of working in a trauma informed manner, assessed using ARTIC 35, influences outcomes. In addition, the perception of therapeutic alliance will provide an insight into whether therapist communication style influences outcomes.

A secondary analysis, a Complier Average Causal Effects (CACE) model, will be conducted using an instrumental variable framework. CACE analysis allows us to avoid bias by weighting the ITT treatment effect by the dose of intervention or control treatment received, as a proportion of what was offered. This provides an unbiased estimate of the role of dosage in the outcomes observed. Compliance will address the extent to which those in the intervention group received the different elements of their allocated tier. By incorporating different quintile thresholds of dose, we can explore the nature of the relationship between compliance, dose, and outcomes observed.

In addition to this we would want to explore whether certain factors are associated with non-compliance to identify potential clusters of participants who do not comply. We will conduct a latent class analysis to identify clusters associated with non-compliance. This will enable an exploration of whether there are groups of participants who are harder to reach than others

and by augmenting this quantitative approach with targeted qualitative interviews with young people and interventionists, enable the wider research group to explore what adaptations may be necessary to increase accessibility and compliance.

An aspect of our qualitative work with key stakeholders involves examining participants' positive and negative experiences of the allocation to different tiers of the intervention, exploring how these perspectives concur with those who conduct the trauma screening and allocate the participant to a tier, to explore at what points negative and positive experiences are at their greatest and what steps could be taken to ameliorate these experiences to improve the delivery and acceptability of the intervention. This information will be elicited as part of the semi-structured interviews.

The mechanism of change will be explored using a mediation model approach. Exploring factors that impact on the mechanism of change will be assessed using regression analysis to model the relationship between pre-randomisation factors and observed outcomes at 6 months. Interaction terms with allocation arm will be included in the analysis, and a significance level of 0.1 will be used to determine which factors are included in the regression model. Pre-randomisation factors include sex, age, ethnicity, IMD decile, number of adverse child experiences and family cohesion.

In addition to quantitatively understanding the mechanism of action, the qualitative analysis will provide an opportunity to explore the perceptions of the intervention from the point of view of a variety of stakeholders. The analysis will allow us to explore what elements of the interventions are useful and what elements are unnecessary, issues around how the interventions are planned and implemented and the perceived barriers or facilitators of implementation in usual practice.

Through a detailed exploration of the key dimensions, we plan on stating our logic model at the start of the project and revise this again at the end of the efficacy stage. The logic model will incorporate the qualitative research exploring stakeholder perceptions of acceptability and usefulness, hindrances and facilitators associated with the process and intervention but will also combine quantitative analysis exploring adherence, dosage, fidelity, and mediators associated with behaviour change. This mixed methods synthesis will enable us to understand what works, how it works, when it works and for whom it works and provide a detailed elaboration of the mechanisms and processes through which it works.

Cost data reporting and collecting

Costs associated with delivering the intervention will be derived using a micro-costing approach accounting for the actual local costs and resources used in delivering the intervention and associated training. This will include salaries, resources, facilities, overheads, and management costs. The cost perspective will be that of the service. We will include any

costs associated with supervision and additional training and use the time horizon of the trial to estimate staff turnover. We aim to estimate the cost of delivering the intervention in real practice rather than the cost of delivering the intervention in the trial. The cost data will be provided as mean cost per participant with 95% confidence intervals and be adjusted to occur each year. Data will be collected using activity logs recorded on the administration system of each service, highlighting all activity associated with a single participating case. The main sources of uncertainty in the analysis of costs include within year variations in salary costs, assumptions regarding intervention time and costs associated with non-attendance and lack of clear estimates of staff costs. We will address each of these by using initial salary cost estimates on 1st January 2024, making standard assumptions of the time an intervention takes and assessing the time allocated to missed appointments. Where direct staff salaries are not available, we will establish costs using the median salary for similar staff within the service. Results will be presented as a table including key assumptions and how costs vary with these assumptions.

Diversity, equity, and inclusion

Participants in research should reflect the diversity of the society where any intervention will be delivered. All the research team will engage in unconscious bias training, training in delivering research to diverse populations, and conducting trauma informed research training and the study will undergo an Equality, Diversity, and Inclusion Audit (EDIA) prior to ethics submission.

The study has been designed to minimise sources of bias. This includes having enough participants to encompass a diverse population that is representative of the target population, minimising inclusion and exclusion criteria to reduce barriers to participation, ensuring randomisation is conducted independent of the research team, flexibility in conducting baseline and follow-up assessments to allow those with literacy difficulties to complete assessments verbally if required.

We will actively monitor recruitment on key ethnic, socio-cultural and inclusion parameters and where differences occur in the numbers eligible and the numbers consenting, we will explore the reasons why using qualitative interviews to provide an insight into the cultural and ethnic acceptability of the intervention.

We will conduct qualitative and quantitative analysis to explore the role inequality, ethnicity, and socio-economic disadvantage plays in the outcomes observed.

All materials will be available in both English and Welsh and for those who have difficulties in spoken English or Welsh we will provide a translation service. During our co-production phase we identified a high prevalence of potential participants with intellectual disabilities. We will

link with existing services to modify the presentation of measures to address the needs of the population. This will include using larger fonts, coloured transitions between outcomes, and where psychometrically acceptable, simplification in language used and presenting less text on each page of the outcome assessment. All materials will be considered by our young people advisory panel.

As a trauma informed study, we are aware of the potential for re-traumatisation of participants and staff through quantitative and qualitative data collection process. We will take steps to minimise any adverse events associated with the research. We will establish a Youth Advisory Board; young people recruited through local partners that reflect the target population in terms of age, sex, ethnicity, and lived experiences with trauma. This diversity will ensure that the materials developed are inclusive and relevant to a wide range of experiences, by gathering feedback on their clarity, relevance, and potential to trigger traumatic responses. We will use this feedback to make necessary adjustments and refinements.

We will ensure all research staff have completed the University of Kent trauma informed research training and will provide a safe environment for staff to seek support for any traumatic experiences. Staff will build trust and rapport: foster a safe and supportive environment by creating open communication channels, emphasising confidentiality, and ensuring everyone's opinions and experiences are respected. At each data collection point participants and staff will be asked to reflect on their responses and be debriefed to establish any negative impact of the outcomes. Trauma leads will be available in each site to provide appropriate intervention if required.

Ethics and registration

The study will be conducted in accordance with the principles of Good Clinical Practice, the Declaration of Helsinki and Caldicott principles. Participants will only be recruited to the study once independent full ethical approval has been granted by the University of Kent Social Research Ethics Committee and the trial will be registered in a recognised trial registry. Trial methods and data collection instruments will be assessed by our Youth Advisory Board and their recommendations for changes will be incorporated.

We will ensure participants do not feel coerced to participate in the study. Once a participant is referred to the service any consent or assent to participate in the trial is theirs solely to make. Not consenting to the research will not impact on the BAU they receive, and this will be explained verbally and in writing. If a participant does consent it will be made clear that they can withdraw consent at any time during data collection for the study. Participants will be able to withdraw from any interventions and still provide follow-up data; withdraw, and have data already completed included in the trial analysis but provide no further additional data; or withdraw completely and have data already collected removed from the analysis.

We will minimise the potential for participants and staff to experience any adverse or iatrogenic events. In our experience of conducting similar studies in similar populations the risk of adverse events is low, as is the risk of iatrogenic events. We will implement a standard operating procedure for the reporting of adverse events that involves an independent experienced third-party making recommendations on the severity of any event and whether they are associated with the trial. All staff involved in the study will have enhanced DBS accreditation and will be familiarised with safeguarding practice and procedures. Each service will have a named trauma lead in each site available for assessment and intervention if re-traumatisation is suspected.

Data protection

All systems and personnel are approved for the management of clinical and sensitive data and are ISO certified to ISO27001 standard. This includes all physical systems, systems to detect intrusion, encryption of data from point of collection to storage, quality assurance and audit trails associated with any data collected. All identifiable data collected will be done with explicit consent and limited to data to allow participants to be contacted for follow-up. Data linkage will employ a unique identifier where the link to identifiable information will be stored on an encrypted secure database. Researchers will be trained to General Clinical Practice (GCP) standard and will comply with all relevant data protection legislation. Once final follow-up is completed, personally identifiable information will be deleted from the dataset held by the university and where consent has been granted for the study encrypted data will be transferred to the Youth Endowment Fund data archive. Data collection and management will be governed by a trial specific Standard Operating Procedure agreed and approved by ethics.

The basis of processing data is the public task basis to use their personal information. Where the Party is a public body, entity or authority, the applicable lawful basis for the processing of Personal Data under this ISA is provided for in the UK General Data Protection Regulation ("UK GDPR"), article 6 (Lawfulness of Processing), specifically article 6.1 (a) and (e) as well as article 9 (Processing of Special Categories of Personal Data), specifically article 9.2 (a), (h), (i) and (j).

Article 6.1

(a) the data subject has given consent to the processing of his or her personal data for one or more specific purposes.

(e) processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller; […]

Article 9.2

(a) the data subject has given explicit consent to the processing of those personal data for one or more specified purposes, except where Union or Member State law provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject.

(h) Processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3.

(i) Processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy.

(j) Processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

We only use special category information (such as information about health, religion, race, or ethnic origin) if it is necessary for research purposes or statistical purposes which are in the public interest. Potential participants, their carers, and participating staff within services, will be provided with a trial specific privacy notice prior to providing consent. This privacy notice outlines what data will be collected, for what purposes and for how long. In addition to the trial specific privacy notice the evaluation team at the University of Kent and the intervention delivery team at Bridgend Borough Council will agree and sign an information sharing agreement highlighting what information will be shared, the reasons for sharing information and the means of sharing information. All communication between the intervention and evaluation team will use encrypted channels secured using a virtual private network.

As the study is being conducted solely in Wales only anonymised quantitative data will be transferred to the YEF data archive at the end of the study.

Stakeholders and interests

Developer and delivery team

Christa Bonham-Griffiths, Service Manager, Bridgend Youth Justice Service.

Alex Williams, Edge of Care Manager, Bridgend CBC.

Evaluation team

Simon Coulton, University of Kent, Principal Investigator.

Nadine Hendrie, University of Kent, Trial Management Oversight.

Rosa Vass, University of Kent, Trial Co-ordinator.

Tracy Pellat-Higgins, University of Kent, Statistical Analyst.

Dorothy Newbury-Birch, Teesside University, Qualitative Oversight.

Judith Eberhardt, Teesside University, Qualitative analyst.

TBC, Teesside University, Qualitative Researcher.

Risks

See the attached risk register.

Timeline

See the attached Gannt chart.

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