STATISTICAL ANALYSIS PLAN

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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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
SAP 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, children's services, youth development, and early help.

Target group	10-18 years (extended to 10-21 years in youth development services) who are referred to the participating 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.

SAP version history

Version	Date	Changes made and reason for revision
1.0 [*original*]		

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Introduction

The efficacy trial design is a mixed method, two level, individually randomised controlled trial of a trauma informed intervention, Trauma Recovery Model Relationship Building Together (RBT), versus business as usual (BAU) for adolescents and young adults served by Bridgend Youth Services (youth justice, edge of care, youth development and early help). There are two levels to the study randomisation. Level one involves selecting staff to be trained in RBT. 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. 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, children's services, youth development, and early help) and speciality (specialised staff versus generic staff). 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 stratified by service (youth justice, edge of care, children's services, youth development and early help), 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.

It is not possible to blind staff to their allocated group but young people are unlikely to be aware of the group they have been allocated to. Follow-up at months 6 and 12 will be conducted by researcher staff 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.

Staff are considered eligible to participate in the study, and are allocated to RBT or BAU, 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. 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.

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.

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.

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.

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. 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.

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. 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.

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 Justice 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 and Children's Services are social work focussed aiming to avoid a young person going into care or to manage 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.

Design overview

Trial design, including number of arms		Two-level, two-arm prospective, individually randomised controlled trial
Unit of randomisation		Level 1: Practitioner Level 2: participant
Stratification variables (if applicable)		Level 1: Service and speciality (specialist versus generic) Level 2: Service *(*youth justice/edge of care/ children's services/ 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,

[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.

		prosocial behaviour, externalising behaviours, 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.

Sample size calculations overview

		Protocol
Minimum Detectable Effect Size (MDES)		0.25
Pre-test/ post-test correlations	level 1 (participant)	n/a
	level 2 (cluster)	n/a
Intracluster correlations (ICCs)	level 1 (participant)	n/a
	level 3 (cluster)	n/a
Alpha		0.05
Power		0.8
One-sided or two-sided?		Two-sided
Average cluster size		n/a
Number of clusters	intervention	n/a
	control	n/a
	total	n/a
Number of participants	intervention	253
	control	253
	total	506 (562 allowing for 10% attrition at month 6)

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 506 young people to be followed-up at our primary endpoint, 6-months post-randomisation, 253 in each group. There is no reliable literature on pre- and post-test correlations for the SRDS, so we have erred on the side of caution and not accounted for this in the sample size calculation as an incorrect assumption increases the risk of an under-powered trial. 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 562. We have 73 potential interventionists, 35 randomised to control and 36 randomised to be trained in the intervention delivery. 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 56 of these interventionists participating throughout the trial, 28 in each arm, thus allowing for a potential loss of interventionists of 17, 23% 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 702 young people, over the recruitment period. Allowing for a slower start of 20/ per month recruited over the first three months, means 36 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.

Analysis

All analysis is conducted using STATA 16 SE. Analysis will be conducted and presented in accordance with the CONSORT guidelines. The validity of randomisation will be explored by presenting baseline measures of central tendency and estimates of precision for continuous variables, and proportions for categorical variables broken down by allocated arm and stratification factors for both staff and participant samples.

Primary outcome analysis

The primary outcome relates to the participant and is the quantity of self-reported delinquent acts in the six months after randomisation assessed using the SRDS. The quantity of delinquent acts is calculated as the sum of positive endorsements for each of the nineteen questions in the SRDS. Two datasets will be created for statistical analysis, the primary analysis will be based on the intention to treat (ITT) dataset. The secondary analyses will examine intervention effects under different scenarios for compliance with allocation (see compliance section below): complier average causal effects (CACE); and per protocol (PP).

The ITT dataset contains all available data for participants who were randomised, regardless of whether they complied with allocation. This dataset will include participants who were withdrawn/withdrew from the trial post-randomisation. These analyses are a lower bound estimate of intervention effects as they represent the effect of offering an intervention, rather than the effect of receiving the intervention.

The primary outcome is the quantity of offences at 6-months post-randomisation. We expect the primary outcome will take the form of a linear distribution. Prior to analysis we will conduct a series of diagnostic tests and assess the underlying assumptions prior to choosing an appropriate and statistically rigorous regression approach. The analysis will take the form of an analysis of covariance using a linear regression. Models will be adjusted by baseline values, quantity of offences in the six months prior to randomisation and stratification factors, service, age group and sex, as covariates. The regression model specification is as follows (eq.1):

$$SRDS6_{i,j} = \alpha + \beta_1(allocation)_{i,j} + \beta_2(SRDS0)_{i,j} + \beta_3(sex)_{i,j} + \beta_4(age)_{i,j} + \beta_5(service)_j + \varepsilon_i$$

Where for participant i within service j; $SRDS6$ is the 6-month SRDS score, $allocation$ is the allocated group, $SRDS0$ is the baseline SRDS score, sex is the participant sex, age the age group, $service$ the service level dummy variables to adjust for fixed effects and ε_i the individual level error.

An estimate of difference will be generated as a mean difference between the groups and the associated 95% confidence interval.

Secondary outcome analysis

For participants the quantity of offences reported at 12-months will be analysed using similar methods as 6-months (eq. 2).

$$SRDS12_{i,j} = \alpha + \beta_1(allocation)_{i,j} + \beta_2(SRDS0)_{i,j} + \beta_3(sex)_{i,j} + \beta_4(age)_{i,j} + \beta_5(service)_j + \varepsilon_i$$

Where for participant i within service j; $SRDS12$ is the 12-month SRDS score, $allocation$ is the allocated group, $SRDS0$ is the baseline SRDS score, sex is the participant sex, age the age group, $service$ the service level dummy variables to adjust for fixed effects and ε_i the individual level error.

Other secondary outcome analysis at months 6 and 12, will be based on the ITT dataset. All secondary outcomes are continuous in nature, and after the examination of diagnostic plots to establish that the underlying assumptions for a linear analysis of covariance are met, they will be using an approach similar to that used in the primary outcome analysis (eq.3).

$$OUT_{i,j} = \alpha + \beta_1(allocation)_{i,j} + \beta_2(OUT0)_{i,j} + \beta_3(sex)_{i,j} + \beta_4(age)_{i,j} + \beta_5(service)_j + \varepsilon_i$$

Where for participant i within service j; OUT is the 6 or 12-month outcome, $allocation$ is the allocated group, $OUT0$ is the baseline outcome value, sex is the participant sex, age the age group, $service$ the service level dummy variables to adjust for fixed effects and ε_i the individual level error.

Staff outcomes (ARTIC score, wellbeing and rates of absence) will be analysed using an analysis of covariance adjusted for baseline values and stratification factors: service and specialist versus generic.

Outcomes will be presented for each allocated group as means and the associated estimates of precision, 95% confidence intervals.

Subgroup analyses

To maintain power in the analysis we will avoid analysing sub-groups and instead use the whole sample for latent class analysis to explore for the emergence of clusters of participants who may have a differential response to the RBT intervention. Latent class approaches allow for clusters to emerge from the data rather than being pre-specified. In addition to the baseline variables being collected we will also include measures of ethnicity, material deprivation and therapeutic alliance assessed at month 6 using the short revised therapeutic alliance scale for children (TASC-r; (Shirk and Saiz, 1992)).

Further analyses

To explore the proposed mechanism of change we will conduct a prognostic linear regression analysis to model the relationship between pre-randomisation factors; age, gender, ethnicity, IMD, SRDS, SDQ, BFRS, GHQ and observed outcomes at 6- and 12- months respectively on the primary outcome at either 6- or 12-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. This analysis will be augmented by an additional

analysis including participants in the RBT arm only using the same pre-randomisation factors but also including process measures of compliance, therapeutic alliance, and interventionist attitude to trauma informed practice.

Interim analyses and stopping rules

No interim analyses are planned. The trial will only be stopped if evidence emerges of a serious adverse event associated with participation in the trial. As the intervention has already been implemented in practice with youth offending populations there is no evidence at the outset that a serious adverse event is likely to occur.

Longitudinal follow-up analyses

Assessments are conducted at baseline, prior to randomisation and then again at months 6 and 12, with 6-months being considered the primary endpoint. Table 2 provides an overview of what measures are being conducted at each time-point.

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		✓	✓

Imbalance at baseline

Rather than just assume the randomisation has worked, we will assess observed balance by comparing the means and distributions of the groups created by randomisation for both participants and staff. If they are systematically different across those variables we observe – e.g. always larger / smaller in one group - then that would suggest the randomisation has not been successfully implemented. Baseline equivalence following randomisation will be

assessed by first looking at allocation by the three stratifying variables, service, sex and age group for participants and service and specialism for staff.

Baseline characteristics will be summarised by allocated group. Summary measures for the baseline characteristics of each group will be presented as mean and standard deviation for continuous (approximate) normally distributed variables, medians and interquartile ranges for non-normally distributed variables, and frequencies and percentages for categorical variables. Following CONSORT when comparing intervention and control groups we will not employ statistical testing.

If there is a large imbalance between groups on a specific variable, then that variable will be included in the analysis model. If there are systematic differences across multiple variables that are indicative of failed randomisation then it would be necessary to explore alternative analysis methods to estimate intervention effects, such as instrumental variable models, using allocation as the IV.

Missing data

The proportion of missing data and patterns of missingness will be examined for the primary outcome only, quantity of offences at 6-month post-randomisation. Levels of missing data will be reported along with any systematic occurrences of missing data observed in the dataset.

In trials some participants are inevitably lost to follow-up. Sample size estimation assumed 10% of patients would not provide an evaluable 6-month follow-up assessment. We will explore the mechanism of missing data to establish whether the data can be considered missing completely at random or missing at random. For each arm we will present baseline data for those followed-up at 6 months and those lost to follow-up and logistic regression analysis to explore for any systematic differences between the allocated group. If no predictor variables emerge from the regression model then the missing data can be classed as missing at random.

To avoid loss of efficiency missing outcome values will be imputed using multiple imputation, if the proportion of missing data is greater than 5% and less than 40%. Where there is less than 5% missing data, the proportion of missing data is considered negligible and missing observations will be excluded. Multiple imputation methods perform less well when the amount of missing data is substantial, if more than 40% of the primary outcome data are missing for the primary analysis the assumptions are less plausible. The interpretative limitations of the trial data will be discussed in the results section, where this is the case.

An initial variable reduction analysis will explore the relationship between all potentially prognostic baseline covariates and whether a follow-up data point is missing. Only variables where there is an association, p-value > 0.10, will be included in the imputation model. The

association between the number of imputations will be dependent on the amount of missing data. As a minimum the number of imputations will be derived to ensure at least 96% statistical efficiency *(RE)* according to the formula below, where λ is the fraction of missing values and M is the number of repetitions (eq. 4).

$$RE = \left(1 + \frac{\lambda}{M}\right)^{-1}$$

The statistical model and assumptions made in the analysis of the primary outcome will also be implemented in the multiple imputation procedures. If it is suspected data is missing not at random or the pattern of missing data is associated with trial allocation, sensitivity analysis will be performed using a pattern mixture approach with mixed modelling and multiple imputation to compare the sensitivity of conclusions to varying assumptions about the missing value mechanism.

Intra-cluster correlations (ICCs)

The trial is individually randomised with stratification at the level of service, no ICC's will be calculated.

Compliance

To explore the role of compliance on outcomes we will conduct a Complier Average Causal Effects analysis (CACE). The definition of compliance with allocation for this trial is as follows (see Table 1 below): (i) those who receive trauma screening (TS) and 80% of RBT interventions offered will be considered 'compliers' in the intervention group (cell A); (ii) those in the control group who did not receive any RBT intervention (cell D). In the intervention group, those attending no trauma screening and/ or less than 80% of interventions offered will be considered 'non-compliers', (cell B). All non-compliers in the intervention group are regarded as being 'contaminated' because they received the control condition (no RBT interventions). For the control group, there is no option for control participants to access the intervention, so there cannot be non-compliance hence this is n/a (cell C).

To further explore the role of compliance on outcomes we will create several thresholds for intervention compliance;

1. TS versus no TS.
2. TS and/ or < 20% of RBT interventions versus TS and >= 20% RBT.
3. TS and/ or < 40% of RBT interventions versus TS and >= 40% RBT.
4. TS and/ or < 60% of RBT interventions versus TS and >= 60% RBT.
5. TS and/ or < 80% of RBT interventions versus TS and >= 80% RBT.

CACE analysis will be undertaken for each threshold and presented as a sensitivity analysis to allow a comparison of outcomes, (RBT group vs BAU) at different thresholds of compliance.

Table 1: Compliance/non-compliance according to group allocation versus intervention received.

	Actually received…	
Allocated to… ↓	**Intervention**	**Control**
Intervention	*A. Intervention complier* Meeting the stated threshold	*B. Intervention non-complier* Not meeting the stated threshold
Control	*C. Control non-complier* n/a	*D. Control complier* Control group participant

We will assess intervention effects in the presence of non-compliance, with compliance measured at the individual level and including all those allocated as part of the trial. Our approach for assessing intervention effects under non-compliance will be via the instrumental variable framework (IV). The benefit of using an IV approach is that randomisation is maintained in the analysis, which is crucial for estimating unbiased intervention effects. In summary, with a binary measure of compliance CACE weights the analysis by treatment allocated (ITT) intervention effect by the proportion of compliers (eq. 5):

$$CACE = ITT / proportion\ compliant$$

If the proportion compliant is 1.0 (i.e. perfect compliance) then the CACE estimate is the same as the ITT estimate, but otherwise the impact of this approach is to increase the magnitude of the intervention effect.

CACE uses a two-stage least squares (2SLS). The first stage model uses intervention received (T) as the outcome, with random allocation (Z) as the independent variable (eq. 6):

$$T = \alpha + Z$$

Based on the stage 1 model, we then calculate predicted values of intervention received ($\hat{T}$) for use in stage 2. The second stage model predicts the substantive outcome (*Y* e.g. quantity of offences) using the predicted values of intervention received ($\hat{T}$) based on the stage 1 model (Eq.7):

$$Y = \alpha + \hat{T} + \varepsilon$$

An additional sensitivity analysis will employ a per protocol approach (PP), containing all data for participants who complete the trial as planned – in intervention and control groups - without any major protocol violations or exclusions. PP analysis essentially drop those individuals who have not strictly complied with their allocation – both those who only partially complied with their allocated intervention and those who did not receive their allocated intervention. This means that PP represents a likely 'best case scenario' for intervention effect estimation. The PP dataset will be analysed in a similar manner to the ITT dataset.

Presentation of outcomes

As the sample is large, effect size differences will be calculated using Cohen's d, specified in the following equation (eq. 8):

$$\delta = (Y_i - Y_c)/S$$

Where Y_i and Y_c are the regression adjusted means, derived from eq. 1, for the intervention and control groups respectively and S is the pooled standard deviation.

Effect sizes will be reported with 95% confidence intervals and p-values to reflect statistical uncertainty.

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The Youth Endowment Fund Charitable Trust

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