EVALUATION PROTOCOL

Solutions Trial: Solution Focused Brief Therapy (SFBT) in 10–17-year-olds presenting at police custody - A Randomised Controlled Trial with internal pilot

The University of Warwick and Cardiff University

Principal investigators: Samantha Flynn and Peter Langdon

YOUTH ENDOWMENT FUND

Project Title: Solutions Trial: Solution Focused Brief Therapy (SFBT) in 10–17-year-olds presenting at police custody: A Randomised Controlled Trial with internal pilot.

Evaluation protocol

Evaluating institution: The University of Warwick and Cardiff University

Chief investigator(s): Samantha Flynn and Peter Langdon

v2.0 07 Sep 2023

Sponsor:	Lancashire and South Cumbria NHS Foundation Trust
Sponsor ref:	n/a
Funder:	Youth Endowment Fund
Funder ref (invoice code):	LGR1-EVAL-112110
REC ref:	22/YH/0198
IRAS number:	316435
ISRCTN ref:	ISRCTN14195235
Q-Pulse Document Template Number:	TPL/003/2

Project title	Solution Focus Brief Therapy (SFBT) in 10-17-year-olds presenting at policy custody: A Randomised Controlled Trial with internal pilot
Short title	Solutions Trial
Developer (Institution)	Lancashire and South Cumbria NHS Foundation Trust
Evaluator (Institution)	University of Warwick; Centre for Trials Research, Cardiff University
Principal investigator(s)	Dr Samantha Flynn, Professor Peter Langdon
Co-applicants	Samantha Flynn, Peter Langdon, Richard Hastings, Kylie Gray, Paul Thompson, Elinor Coulman, Rebecca Playle, Jeremy Segrott, Fiona Lugg-Widger and Gwenllian Moody.
Trial design	Randomised controlled trial with internal pilot
Trial type	Efficacy
Evaluation setting	Community based settings
Target group	Children and young people (CYP) (aged 10-17 years) presenting at a custody suite in Lancashire and South Cumbria NHS Trust region who are referred to the Liaison and Diversion (L&D) team.
Number of participants	282 CYP
Primary outcome and data source	Self-Report Delinquency Measure (SRDM)
Secondary outcome and data source	1. Criminal offence data-arrest, caution, reprimands, warnings, and conviction data for participants (data held in the Police National Computer). 2. CYP well-being: the parent/guardian and self-report versions of the Strengths and Difficulties

	Questionnaire (SDQ) (including internalising, externalising, and prosocial behaviours). 3. Gang Affiliation: The Gang Affiliation Risk Measure
Potential moderators	1. Callous and Unemotional Traits: 24-item Inventory of Callous and Unemotional Traits – Parent/guardian Report and Youth Self-Report Versions. 2. Learning disabilities (LD): Estimated verbal reasoning skills based on two subtests of the Wechsler Abbreviated Scale of Intelligence and a closed question about learning disability.
Planned number of sites	One site (Lancashire and South Cumbria), with up to 12 custody suites at site.
Inclusion criteria	• Aged between 10 to 17 years. • Referred to the Liaison and Diversion Team having been through a custody suite
Exclusion criteria	• A clinician has judged that the child or young person is presenting with a mental illness of a nature and degree warranting immediate intervention from specialist services, including assessment for detention under the Mental Health Act. • The young person is to be remanded into custody. • A child or young person aged 16 years or older judged to lack mental capacity to decide about participating in this trial by staff responsible for gaining informed consent. • The child or young person is living outside the area served by Lancashire and South Cumbria NHS Foundation Trust. • The child or young person is unable to converse in English.

	• Parents/guardians are unable to converse in English (at least one must be able to converse in English to complete parent/guardian measures) • Parents/guardians of under 16s judged to lack mental capacity to decide about participating in this trial by staff responsible for gaining informed consent.
Treatment duration	6 bi-weekly sessions over 12 weeks
Follow-up duration	6 months and 12 months post-randomisation
Planned trial period	36 months
Primary objective	To determine whether there is a benefit of support as usual (SAU) plus Solution Focused Brief Therapy (SFBT) over SAU alone in reducing offending behaviours in 10–17-year-olds presenting at a police custody suite.
Secondary objectives	1. Complete an Internal Pilot in the first seven months to examine whether moving to a definitive trial is warranted and feasible. 2. Generate evidence to consider whether SFBT + SAU reduces externalising and internalising behaviours. 3. Examine whether there is a relationship between changes in externalising and internalising behaviours and changes in offending behaviours. 4. Carry out exploratory sub-group analyses of outcomes by evidence of a learning disability, and callous- unemotional traits 5. Monitor and report and adverse events related to SFBT. 6. Complete a process evaluation using key indicators drawn from the logic model, including an evaluation of acceptability and the experiences of children,

	young people, families and guardians, and other key stakeholders (e.g., practitioners, delivery team) and fidelity of delivery of SFBT. 7. Explore availability of routine data sources. 8. Explore how any reduction in offending behaviour relates to critical moments of school exclusion.
Intervention	Solution Focused Brief Therapy (SFBT). Six 1-hour sessions will be delivered over 3 months. The sessions will be delivered by a registered counsellor and management/ clinical/ safeguarding supervision will be provided by the LSCFT safeguarding team in partnership with the L&D Service Manager.

Protocol version history

Version	Date	Reason for revision
2.0	tbc	• Addition of six months to the pilot phase. • Change to sample size and power calculation as research team received information about pre post-test correlation for primary outcome. • Remove reference to requesting the trial risk assessment. • Addition of social media recruitment strategy to increase recruitment. • Included increasing the number of sites (NHS Trusts) in the future which may be planned.
1.6	12.06.2023	• increasing the monetary incentives each by £5 for each participant (child/young person) at each data collection timepoint (at baseline they will receive

		£20, at 6 month follow-up £25 and at 12 month follow-up £30). • introduction of a 'participant journey' document to be provided to participants • The protocol also has been amended to show that qualitative recordings can be conducted by Cardiff or Warwick research staff and transcripts shared with each University. • Removing mention of a specific number of custody suites we are recruiting from and adding that we will recruit from up to 12 custody suites (all from LSCFT site). • Some changes to statistics section to be in line with SAP • Remove mention of number of practitioners delivering therapy. • Research assistant/practitioner delivering SFBT/CYP practitioner can all take consent and collect quantitative data
1.5	23.03.2023	• Added details about interviews with site staff (already included details on interviews with practitioners delivering intervention but wanted to include interviews with other site staff who are stakeholders). • Added that as well as the Wechsler scale being used to as a measure of learning disability that a question asking if the child has a learning disability has been added to the CRF. • Remove that Research Assistant is a University of Warwick employee, research assistant can also be site employee. • Trial information to be provided via leaflet and poster as well as video and audio file. • Amount of shopping vouchers amended for parents/guardians and CYP to encourage CYP recruitment • A brief one page version of the PIS has been created to provide trial information (as an aid, not a replacement to the full PIS). • The main trial PISs (parent/guardian, young person under 16, and young person 16 and over) have been amended to reflect the new shopping voucher amounts offered as incentives, and also wording

		relating to weather anonymised data will be sent from the PNC as we are unsure if this will contain names when sent to Warwick.
1.4	13.12.2022	• Amended to clarify that site staff, not trial staff would inform participants of randomisation outcome
1.3	25.10.2022	• Eligibility criteria wording amended
1.2	10.10.2022	• Updated the study email address. • We need to re-consent at age 16 if a young person entered the trial before they were 16 but turns 16 during the course of the trial. • We removed the secondary objective relating to collecting A&E data as this was included in error (this was not included in IRAS, just the protocol) • Added in the possibility of maintaining contact with participants via WhatsApp as well as via post, email, text • Added a study website URL. • Clarified that potential participants can also get in touch with the trial team directly if they have been screened and are interested in taking part (rather than waiting for the trial team to contact them). • Clarified that WASI can be completed face-to-face as well as via telephone or teleconferencing. • Added other trial team members to the list that can perform randomisation when Trial Manager is unavailable (and do not have to be kept blind). • Renamed BSFT to SFBT (the therapy can be known by ether name but is more widely known as SFBT)
1.1	18.08.2022	Added detail of how informed consent will be obtained for qualitative interviews
1.0 [*original*]		*[leave blank for the original version]*

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

Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the relevant trial regulations, GCP guidelines, and CTR's SOPs.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies from the trial as planned in this protocol will be explained.

Trial Sponsor:		
Name	**Position**	**Date**

Director:		
Name	**Signature**	**Date**

Joint Chief Investigators:		
Name	**Signature**	**Date**
Dr Samantha Flynn		
Name	**Signature**	**Date**
Prof Peter Langdon		

General Information This protocol describes the Solutions clinical trial and provides information about the procedures for entering participants into the trial. The protocol should not be used as a guide, or as an aide-memoire for the treatment of other participants. Every care has been taken in drafting this protocol; however, corrections or amendments may be necessary. These will be circulated to the known Investigators in the trial. Problems relating to the trial should be referred, in the first instance, to CTR.

Contact details – Chief Investigators & Co-Investigators

CHIEF INVESTIGATORS

Title and name: Dr Samantha Flynn

Position: Assistant Professor

Add1: Centre for Educational Development, Appraisal and Research

Add2: University of Warwick, Warwick, Coventry.

Postcode: CV4 7AL

Tel : 07823362152

E-mail : s.flynn.1@warwick.ac.uk

Title and name: Professor Peter Langdon

Position: Professor

Add1: Centre for Educational Development, Appraisal and Research

Add2: University of Warwick, Warwick, Coventry.

Postcode: CV4 7AL

Tel : 02476522912

E-mail : Peter.Langdon@warwick.ac.uk

CO-APPLICANTS

Title and name: Prof Richard Hastings

Position: Professor and Cerebra Chair of Family Research CEDAR

E-mail : R.Hastings@warwick.ac.uk

Title and name: Prof Kylie Gray

Position: Professor

E-mail : K.Gray.1@warwick.ac.uk

Title and name: Dr Paul Thompson

Title and name: Dr Elinor Coulman

Position: Research Fellow in Applied Statistics

E-mail : Paul.Thompson.2@warwick.ac.uk

Position: Research Associate

E-mail : johne1@cardiff.ac.uk

Title and name: Dr Rebecca Playle

Position: Reader and Deputy Director of Statistics

E-mail : playlera@cardiff.ac.uk

Title and name: Dr Jeremy Segrott

Position: Senior Lecturer

E-mail : segrottj@cardiff.ac.uk

Title and name: Dr Fiona Lugg-Widger

Position: Research Fellow

E-mail : luggfv@cardiff.ac.uk

Title and name: Dr Gwenllian Moody

Position: Research Associate

E-mail : moodyg@cardiff.ac.uk

SPONSOR contact details:

Name: Andrew Pennington

Position: Associate director R&D

Institution: Lancashire and South Cumbria NHS

Foundation Trust

E-mail: Andrew.pennington@lscft.nhs.uk

Trial Co-ordination

The Solutions trial is being coordinated by the Centre for Trials Research (CTR), Cardiff University, a Clinical Research Collaboration (UKCRC) registered trials unit.

This protocol has been developed by the Solutions Trial Management Group (TMG).

For **all queries** please contact the Solutions Trial team through the main trial email address. Any clinical queries will be directed through the Trial Manager to either the Chief Investigator or a Co-Investigators.

Main Trial Email:	solutionstrial@cardiff.ac.uk/solutions@warwick.ac.uk	
Trial Administrator:	Charlotte Scoble	Tel: 02920687929
Trial Manager:	Gwenllian Moody/Eleri Owen-Jones	Email:moodyg@cardiff.ac.uk/owen-jonesce@cardiff.ac.uk
Data Manager:	Andrea Longman	
Trial Statistician:	Paul Thompson	
Director:	Prof Mike Robling	

Randomisations

Randomisation
Stratified permuted block randomisation, ensuring balance on prognostic factors (Verbal Comprehension Index) and stratifying by custody suite EMAIL CONTACT DETAILS FOR RANDOMISATION solutionstrial@cardiff.ac.uk

Serious Adverse Events

SAE reporting
Where the adverse event meets one of the serious categories, an SAE form should be completed and submitted to the trial team (solutions@warwick.ac.uk) within 24 hours of becoming aware of the event (See section 16 for more details). **Contact details:** solutions@warwick.ac.uk

Table of Contents

Glossary of abbreviations

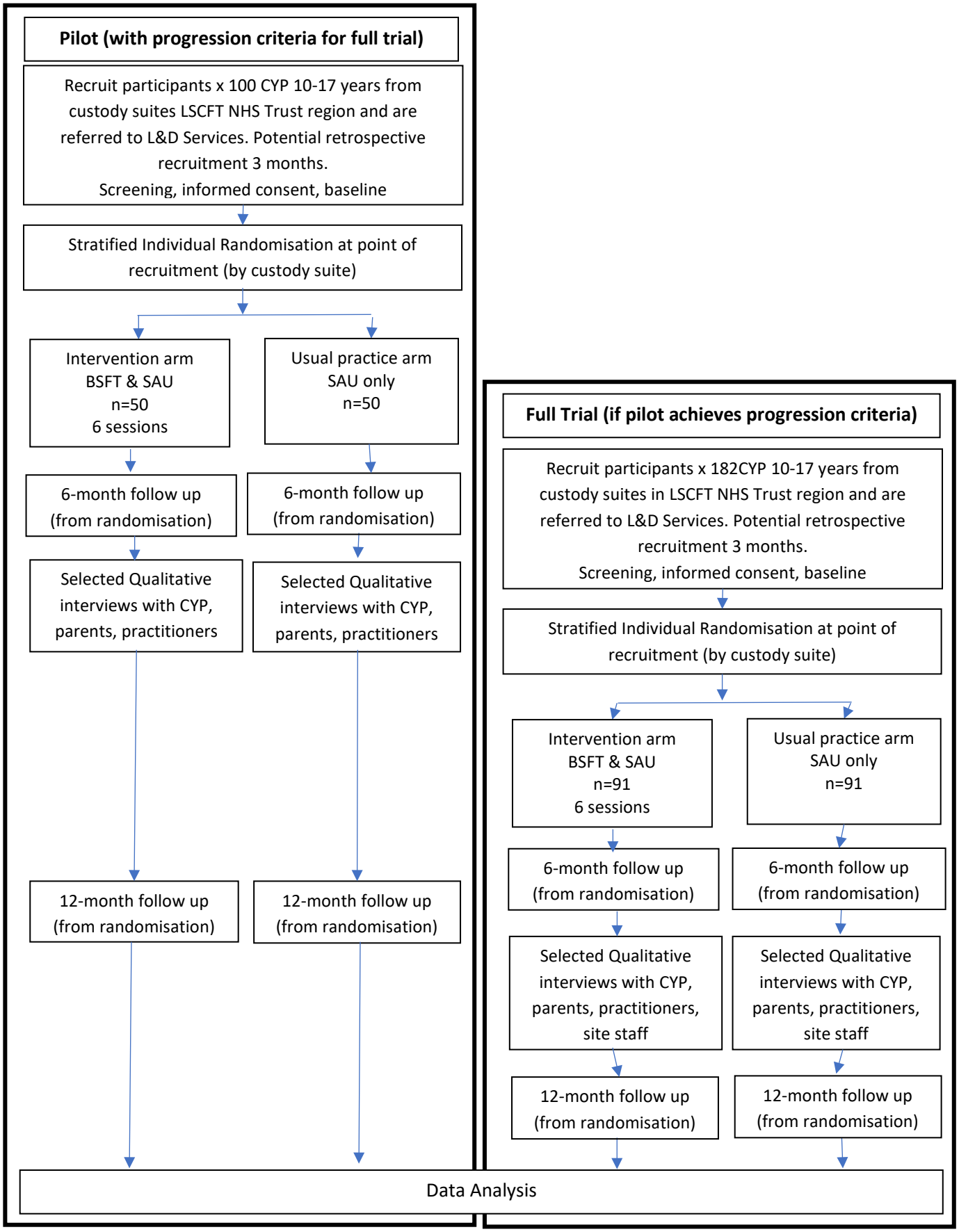
AE	Adverse Event
CF	Consent Form
CI	Chief Investigator
CRF	Case Report Form
CTR	Centre for Trials Research
CTU	Clinical Trials Unit
CU	Cardiff University
CYP	Children and Young People
GCP	Good Clinical Practice
GP	General Practitioner
HB	Health Board
HE	Health Economics
IC	Informed consent
IDMC	Independent Data Monitoring Committee
IEC	Independent Ethics Committee
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trial Number
L&D	Liaison and Diversion
LD	Learning Disability
NHS	National Health Service
PI	Principal Investigator
PIAG	Participant Information Advisory Group
PID	Participant Identification Number
PIS	Participant Information Sheet
QA	Quality Assurance
QALY	Quality-adjusted Life Years
QC	Quality control
QL (QoL)	Quality of Life
R&D	Research and Development

RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

1. Trial summary & schema

1.1 Participant flow diagram

Figure 1. Participant flow diagram


Pilot (with progression criteria for full trial)
Recruit participants x 100 CYP 10-17 years from custody suites LSCFT NHS Trust region and are referred to L&D Services. Potential retrospective recruitment 3 months.
Screening, informed consent, baseline
Stratified Individual Randomisation at point of recruitment (by custody suite)
Intervention arm
BSFT & SAU
n=50
6 sessions
Usual practice arm
SAU only
n=50
6-month follow up (from randomisation)
6-month follow up (from randomisation)
Selected Qualitative interviews with CYP, parents, practitioners
Selected Qualitative interviews with CYP, parents, practitioners
12-month follow up (from randomisation)
12-month follow up (from randomisation)
Full Trial (if pilot achieves progression criteria)
Recruit participants x 182CYP 10-17 years from custody suites in LSCFT NHS Trust region and are referred to L&D Services. Potential retrospective recruitment 3 months.
Screening, informed consent, baseline
Stratified Individual Randomisation at point of recruitment (by custody suite)
Intervention arm
BSFT & SAU
n=91
6 sessions
Usual practice arm
SAU only
n=91
6-month follow up (from randomisation)
6-month follow up (from randomisation)
Selected Qualitative interviews with CYP, parents, practitioners, site staff
Selected Qualitative interviews with CYP, parents, practitioners, site staff
12-month follow up (from randomisation)
12-month follow up (from randomisation)
Data Analysis

1.2 Trial lay summary

Children and young people who come into contact with the police often need help. This trial aims to test out whether offering these children and young people a psychological treatment called Brief Solution Focused Therapy is helpful. Brief Solution Focused Therapy is a short-term therapy that helps people to change by focusing on building solutions rather than getting stuck thinking about problems. We want to find whether this treatment works by running a clinical trial. We will give some children and young people Brief Solution Focused Therapy plus the routine treatment that they would normally get. Other children and young people will only get the routine treatment that is currently offered when they come into contact with the police. We will decide who gets which treatment at random, which is like flipping a coin.

In order to work out whether Brief Solution Focused Therapy is helpful, our trial has two parts. In the first part, we will run what is called a 'pilot'. This is a test version of the trial which tests whether the trial can be run. If we find that this is the case, we will then move to do the second part, which is continuing with the main trial by inviting more children and young people to take part.

All of the children and young people who take part will be asked to complete some measures of things that may change because of taking part in Brief Solution Focused Therapy. We are particularly interested in whether they are involved in any antisocial behaviours over the course of the trial. We will also ask about their background, their general well-being, any criminal activity they have been involved with in the past and any gang connections. We will also interview some of the children and young people receiving SFBT, their parents/guardians, and the professionals that deliver the SFBT therapy. We will ask them about their experiences of taking part in the trial.

2. Background

Liaison and Diversion (L&D) away from criminal justice for those with mental illness was recommended over 30 years ago by the Home Office (1990). Two years later, one of the key recommendations of the Reed Report (1992) was the development and implementation of a national multiagency L&D service for those with mental health problems who are arrested and appear in court. Lord Bradley (2009) outlined the marked complexity of services for children and young people (CYP), those with mental health problems, and those with learning disabilities (LD) who encounter criminal justice. They often require additional interventions to help reduce risk and improve health to prevent further contact with criminal justice. Lord Bradley, in his report, argued that a multi-agency and multi-professional approach was needed as the level of need is high. This led to the further development and implementation of L&D services around the country, and Lord Bradley specifically recommended earlier intervention and diversion for CYP who are at risk of offending, including more mental health staff to work with this group.

The current NHS Long Term Plan has a focus upon CYP, including those with mental health problems, and those who encounter criminal justice. One of the important aims is to further develop services to help CYP access treatment faster. This includes expanding services to deliver them when and where CYP need them, which could include schools and colleges, as well as when they encounter the police. The objectives set for the NHS for 2020/2021 included an expansion of L&D services such that 100% of those who need this service receive this service (NHS England, 2016). As part of this, a significant expansion of high-quality mental health care for CYP was planned, meaning that an additional 70,000 CYP should be able to access psychological therapies when and where needed by 2021 (NHS England, 2016). Under the long-term plan, services for CYP were set to expand within community-based settings with an increased focus upon timely and appropriate crisis support and intervention. The current project fits with this policy landscape and overall goals as set by NHS England and the government. At the same time, the current project fits with the vision set by the Youth Endowment Fund (YEF) to prevent CYP from becoming

involved in violence through the expansion of L&D services by offering psychological therapies to CYP when and where needed (YEF website, 2022).

Child Criminal Exploitation (CCE) forms part of the contextual safeguarding agenda and has been identified as a strategic priority by the Children's Safeguarding and Assurance Partnership (CSAP) in Lancashire. Such activity is associated with high levels of serious youth violence and poses significant risk of harm to our adolescent population of children. In March 2020, the child safeguarding practice review panel for England and Wales published a report in relation to criminal exploitation across England and Wales (UK Government, 2020). The review identified three 'critical moments' in children's lives that could provide a 'window of opportunity' for professionals to intervene and make a difference to their long-term outcomes. The three critical moments being:

1. The point at which a child is excluded from school
2. The point at which a child is physically injured and
3. The point at which a child is arrested and comes into contact with custody.

When children are arrested, they come into contact with custody and are referred to the liaison and diversion service. The liaison and diversion service is provided by LSCFT in 12 custody suites across Lancashire and Cumbria. There has been little research undertaken because child criminal exploitation is a relatively new and emerging area of safeguarding practice. The children that are assessed by Liaison and Diversion are not always the same children that are supported by statutory services such as children's social care or child youth justice. The current trail provides an opportunity to test the effectiveness of SFBT as a psychological intervention, aimed to divert children from serious youth violence and safeguard them from criminal exploitation in the community. The focus is on early intervention, often with children who are not already supported by statutory services. Liaison and Diversion have not traditionally offered any intervention as they are an assessment and signposting service. There is no research yet to show the effectiveness of SFBT as delivered by Liaison and Diversion teams as psychological interventions are not traditionally offered by these teams. The testing of SFBT within these teams makes this trial unique.

2.1 Rationale for current trial/Justification of Treatment Options

A systematic review of 38 best evidence studies (Woods et al., 2011) reported that Solution Focused Brief Therapy (SFBT) led to reductions in internalising and externalising behaviour problems in children and young people. In the proposed research, we will conduct a randomised controlled trial with process evaluation and internal pilot (to assess trial feasibility) where CYP presenting at a police custody suite will be randomly allocated to receive Solution Focused Brief Therapy (SFBT) plus Support as Usual (SAU) or SAU alone to evaluate reduction in offending behaviours.

3. Trial objectives/endpoints and outcome measures

3.1 Primary objectives

The primary objective of this trial is to determine whether there is a benefit of SAU plus SFBT over SAU alone in reducing offending behaviours in 10–17-year-olds presenting at a police custody suite.

3.2 Secondary objectives

The secondary objectives (SO) are to:

- Complete an internal pilot in the first seven months to examine whether moving to a definitive trial is warranted and feasible.
- Generate evidence to consider whether SFBT + SAU reduces externalising and internalising behaviours.
- Examine whether there is a relationship between changes in externalising and internalising behaviours and changes in offending behaviours.
- Carry out exploratory sub-group analyses of outcomes by Learning Disability (LD) status, and callous- unemotional traits.

- Monitor and report any adverse events related to SFBT.
- Complete a process evaluation using key indicators drawn from the logic model, including an evaluation of acceptability and the experiences of children, young people, parents/guardians, and other key stakeholders (e.g., practitioners, delivery team) and fidelity of delivery of SFBT.
- Explore availability of routine data sources.
- Explore how any reduction in offending behaviour relates to critical moments of school exclusion.

3.3 Primary outcome measure

The proposed primary outcome measure for this trial is the Self Report Delinquency Measure at 12-months post-randomisation (SRDM; Smith & McVie, 2003) which is a short measure comprising 15-items pertaining to antisocial behaviours (e.g., burglary, violence). It requires CYP to respond with yes or no with reference to a time-period (6 months). They then report the estimated frequency of the behaviour, and whether they have ever been caught. There is evidence that asking respondents to indicate whether they have engaged in these behaviours is accurate (Nock et al., 2003; 2007). We will collect these data from CYP.

3.4 Secondary outcome measures

Secondary outcome measures include:

- Criminal offence data: with consent from parents/guardians and CYP we will work with referrers and the police to gain access to arrest, caution, reprimands, warnings, and conviction data for participants (data held in the Police National Computer). We aim to initially collect crime data over the 6-month period prior to the commencement of treatment, and at the 12-month follow-up.
- Emotional and behavioural difficulties: the parent/guardian and self-report versions of the Strengths and Difficulties Questionnaire (SDQ) will be used to assess CYP well-being (including internalising, externalising, and prosocial behaviours). The SDQ is a

robust and well-validated measure of behavioural and emotional problems (Deighton et al., 2014); measured over the preceding 6 months

- Gang Affiliation: The Gang Affiliation Risk Measure (Raby & Jones, 2016; Raby, Jones, Hulbert, & Stout, 2017) is a 26-item measure of gang affiliation that was developed with teenagers.
- Parent/guardian-report other therapies received (including pharmacological)

3.5 Potential moderators

In addition to the primary and secondary outcomes, we have considered that the following outcomes may moderate the outcomes of this trial.

- Callous and Unemotional Traits: This will be measured, at baseline and 12-month follow-up, using the 24-item Inventory of Callous and Unemotional Traits – Parent/guardian Report and Youth Self-Report Versions (Essau et al., 2006) which are robust and well validated instruments (Ciucci et al., 2013)
- Learning disabilities (LD): Children and young people will be invited to complete two subtests of the Wechsler Abbreviated Scale of Intelligence-II (WASI-II; Wechsler, 2011) to index their Verbal Comprehension Index at baseline only. This scale is to be administered with a researcher (face-to-face, telephone, videoconferencing). The two subsets are to be included are Vocabulary and Similarities. We are also including a closed question asking if the child has a learning disability (parents and children will be asked this) taken from the Millennium Cohort Study. These measures are essential to randomisation.

4. Trial design and setting

The trial is a two-arm individually randomised RCT of SFBT plus SAU versus SAU alone, involving CYP (age 10-17 years old) who have presented at police custody suites in the Lancashire and South Cumbria NHS Trust region. Additional sites (NHS Trusts) may be added in the future. The trial involves an internal pilot to be completed at month 12 of the

trial, the set-up phase will last five months, and the pilot phase will last eleven months (see section 12 for more details). Approximately 282 CYP participants will be recruited. Participants will be randomised on a 1:1 basis to either intervention or control arm using stratified permuted block randomisation, balancing on prognostic factors (Verbal Comprehension Index), and stratifying by custody suite.

Table 1. Trial Design

Trial design, including number of arms		Two-arm randomised control trial
Unit of randomisation		Individual participant
Stratification variables (if applicable)		Custody suite
Primary outcome	Variable	Self-reported delinquency
	measure (instrument, scale, source)	Self Report Delinquency Measure at 12-months post-randomisation (SRDM; Smith & McVie, 2003) which is a short measure comprising 15-items pertaining to antisocial behaviours (e.g., burglary, violence). It requires CYP to respond with yes or no with reference to a time-period (6 months). They then report the estimated frequency of the behaviour, and whether they have ever been caught.
Secondary outcome(s)	variable(s)	1. Criminal offences data 2. Self-reported and parent-reported emotional and behavioural difficulties 3. Self-reported gang affiliation
	measure(s) (instrument, scale, source)	1. Criminal offence data-arrest, caution, reprimands, warnings, and conviction data for participants (data held in the Police National Computer).

		2. CYP emotional and behavioural difficulties: the parent/guardian and self-report versions of the Strengths and Difficulties Questionnaire (SDQ) (including internalising, externalising, and prosocial behaviours). 3. Gang Affiliation: The Gang Affiliation Risk Measure
Baseline for primary outcome	Variable	Self Report Delinquency Measure (SRDM)
	measure (instrument, scale, source)	Self Report Delinquency Measure at Baseline (SRDM; Smith & McVie, 2003) which is a short measure comprising 15-items pertaining to antisocial behaviours (e.g., burglary, violence). It requires CYP to respond with yes or no with reference to a time-period (6 months). They then report the estimated frequency of the behaviour, and whether they have ever been caught.
Baseline for secondary outcome	Variable	• Criminal offence data • Self-reported and parent-reported emotional and behavioural difficulties • Self-reported gang affiliation
	measure (instrument, scale, source)	• Criminal offence data-arrest, caution, reprimands, warnings, and conviction data for participants (data held in the Police National Computer). • CYP emotional and behavioural difficulties: the parent/guardian and self-report versions of the Strengths and Difficulties Questionnaire (SDQ)

		(including internalising, externalising, and prosocial behaviours). • Gang Affiliation: The Gang Affiliation Risk Measure

The trial will take place within community-based settings. A clinician within L&D Services will identify potential CYP participants who come into custody suites in Lancashire and South Cumbria NHS Trust region. We may add additional sites in the future. Schools, colleges, Pupil Referral Units, etc. may also be able to direct a young person who has been through custody suite and received study information but may not have engaged at the time back to L&D. We will also use a bespoke and targeted social media campaign (e.g., Facebook, Instagram, Twitter, Reddit, etc.) to share information about the trial with children, young people and parents who may be eligible developed and managed by Health Research (https://www.healthresearch.study). YPs and parents/guardians (for CYP under 16 years of age) will be provided with trial information at this point, screened to check initial eligibility and invited to take part in the trial if deemed likely to be eligible. All participants who agree to participate and for whom consent has been given (parental/guardian consent + CYP assent for CYP under 16 years-of-age, and consent from young people 16+ years-of-age) will be screened to ensure they meet the eligibility criteria.

The baseline questionnaire assessments (see section 9) will be completed with a research assistant (with a choice given (see section 9) to participants how they wish to complete these, but the Wechsler scale must be completed with a researcher), with participants prior to randomisation (which will be embedded in the trial database, built by CTR). Participants randomised to the intervention arm will receive SFBT as well as L&D services (SAU), and those randomised to the control arm will receive SAU alone. The research assistant completing baseline measures will contact CTR when a participant is recruited and provide details needed for randomisation (this is done via the database) and unique participant identification number (PID) only (no identifiable data). The research assistant will also send

the delivery team the PID and identifiers (e.g., name). CTR will randomise the participant and inform the delivery team/site staff of allocation who will in turn inform participants. All contacts between the research assistants, CTR, and delivery team will be done securely via fast file. The delivery team/site staff will therefore hold the 'key' between PID, randomisation allocation, and identifiers. There will be monitoring built into this procedure.

All participants (in both trial arms) will complete assessments at baseline, 6- and 12-months post-randomisation and will be given a choice of how these are completed. These assessments can be completed in a number of ways, face-to-face, online on a website, via telephone, via videoconferencing, or on paper via the post. Participants, parents/guardians, and key stakeholders will be invited to participate in semi-structured interviews to ascertain acceptability and their experience of the treatment.

Due to the nature of the trial, participants and practitioners will not be blind to allocation arm. In addition, the Trial Manager, Data Manager, Senior Trial Manager and researchers completing qualitative interviews will not be blind to allocation. All other researchers, including the Trial Statistician responsible for analysing the data will be blind to allocation arm. If inadvertent unblinding occurs during contact with a participant, this will be recorded and reported to the Trial Manager.

4.1 Risk assessment

A trial risk assessment has been completed to identify the potential hazards associated with the trial and to assess the likelihood of those hazards occurring and resulting in harm. This risk assessment includes:

- The known and potential risks and benefits to human subjects
- How high the risk is compared to normal standard practice
- How the risk will be minimised/managed

This trial has been categorised as a low-risk trial, where the level of risk is comparable to the risk of standard care. The trial risk assessment is used to determine the intensity and focus of monitoring activity.

5. Site and Investigator selection

This trial will be carried out at 1 participating site within the UK: custody suites in the Lancashire and South Cumbria NHS Trust region. Additional sites may be added in the future. All suites who are interested in participating in the trial will be required to complete a registration form to confirm that they have adequate resources and experience to conduct the trial.

Before the site can begin recruitment a Principal Investigator at the site must be identified. The following documents must be in place and copies sent to the Trial email account (see contact details):

- Local governance/ R&D approvals (confirmation of capacity and capability)
- Favourable opinion from the relevant Research Ethics Committee
- A signed Trial Agreement
- Current Curriculum Vitae and GCP training certificate of the Principal Investigator (PI)
- Completed Site Delegation Log and Roles and Responsibilities document
- Full contact details for all personnel involved, indicating preferred contact
- A copy of the most recent approved version of the Participant Information Sheet(s) and Consent Form(s) on site organisation headed paper
- A copy of the GP letter. GPs will be informed of trial participation, where participants have provided us contact details for their GP

Upon receipt of all the above documents, the Trial Manager will send written confirmation to the Principal Investigator detailing that the site is now ready to recruit participants into the trial. This letter/email must be filed in each site's Site File.

Occasionally during the trial, amendments may be made to the trial documentation listed above. CTR will issue the site with the latest version of the documents as soon as they

become available. It is the responsibility of the CTR to ensure that they obtain local approvals for the new documents.

Site initiation/ training will be by teleconference.

6. Participant selection

Participants are eligible for the trial if they meet all of the following inclusion criteria and none of the exclusion criteria apply. All queries about participant eligibility should be directed to the Trial Manager before randomisation/recruitment.

6.1 Inclusion criteria

- 10-17 years of age
- Referred to the Liaison and Diversion Team having been through a custody suite

6.2 Exclusion criteria

- A clinician has judged that the child or young person is presenting with a mental illness of a nature and degree warranting immediate intervention from specialist services, including assessment for detention under the Mental Health Act.
- The young person is to be remanded into custody.
- A child or young person aged 16 years or older judged to lack mental capacity to decide about participating in this trial by staff responsible for gaining informed consent.
- The child or young person is living outside the area served by the NHS Trust who are a participating site.
- The child or young person is unable to converse in English.
- Parents/guardians are unable to converse in English (at least one must be able to converse in English to complete parent/guardian measures).
- Parents/guardians of under 16s judged to lack mental capacity to decide about participating in this trial by staff responsible for gaining informed consent.

7. Recruitment, Screening and registration

7.1 Participant identification

There will be two pathways for recruiting participants within L&D services in the site;

1) Practitioners in L&D services will identify potential CYP participants who come into custody suites within a participating site.
2) Potential CYP participants or their parent/carer will fill out an online expression of interest form from a bespoke targeted digital media campaign on the following website:

For both pathways, potential CYP participants and parents/guardians (for CYP under 16 years of age) will then be provided with trial information (either physically or by post/email) including an information sheet, copy of the consent/assent forms and contact information for the site staff. The screening and eligibility log will be completed by site staff. The screening log will also contain details of how a participant would prefer to complete the questionnaire (mode of completion). If the CYP (and parent/guardian if appropriate) are interested in taking part, an appointment will be arranged with a research assistant (via telephone or teleconference) and the following will be carried out:

- The trial will be explained in detail, including the randomisation and consent process. Research assistants and others taking consent (Practitioners delivering SFBT, CYP Practitioners) will ensure that the participant has had sufficient time to consider the information in the information pack.
- Eligibility will be confirmed.
- Consent to participate will be obtained from either:
    - CYP parent/guardian alongside assent from CYP if CYP is under 16 years-of-age
    - CYP consent from young people 16+ years-of-age

The appointment with the research assistant/practitioner delivering SFBT/CYP practitioner can be made in two ways, the research assistant/practitioner delivering SFBT/CYP practitioner can contact the participant/parent or guardian to arrange the appointment

(using contact details from the screening log), or the participants/parent or guardian can get in touch directly with the reach assistant to request the appointment. If the participant is eligible and has been recruited to take part in the trial, their consent and contact details will be securely transferred to the trial team. In practice, if a potential participant is under 16 then their parent/guardian needs to approve that they are willing to take part before the young person can agree. This means that on occasion, where a young person under 16 attends custody suite without a parent/guardian, then the young person can be sent home with information about the trial to give to the parent/guardian and the L&D team will follow-up with the parent/guardian via telephone to ask if they are happy for the child to take part.

7.2 Screening logs

A screening log of all ineligible and eligible but not consented/not approached will be held in a secure online database that can be accessed by the trial team and the research department so that any biases from differential recruitment will be detected. When at site, identifiable information should only be entered on these for those CYP who say that they want to take part, for those who do not want to take part only no-identifiable information (e.g. ID) will be held on the screening log. Screening log data will be monitored and a TMG/TSC report will be produced for each meeting containing summaries of screened, recruited, refusal of participants. Plots of the actual vs predicted recruitment will also feature in each report.

7.3 Recruitment rates

A total of 282 participants will be recruited across custody suites. One hundred participants will be recruited in the pilot phase, and 182 in the main study phase.

7.4 Informed consent

The CYP participant and parent/guardian will have been sent or handed a Participant Information Sheet and copy of the consent/assent form prior to the first appointment taking place and given sufficient time to read the information. There will be two versions of the Participant Information Sheet for CYP who take part in the main trial, one for 10 to 13-year-olds, and one for 14-year-olds and up. Trial information will be appropriately adapted for use by younger CYP. We will provide trial information in alternative formats (e.g., audio file, video, leaflet, poster, brief one page PIS, participant journey document) and make these available to all participants. Research assistants/practitioner delivering SFBT/CYP practitioner, who have been fully trained in trial procedures, will explain the trial in detail, including randomisation and consent for long-term follow-up using routinely collected data and appropriate data linkage. If happy to take part, informed consent will be obtained from CYP 16+ years of age and parental/guardian consent and CYP assent obtained from CYPs under 16 years of age. Verbal consent will be obtained (either via telephone, video conferencing or face-to-face meeting). Research assistants/practitioner delivering SFBT/CYP practitioner will 'sign' an online consent form on behalf of the participant is they choose to join the trial, evidence of this will be sent to the participant in the form of a PDF document showing the online form on screen. If participants choose to complete the baseline assessment on the website or via post, they will still have to complete the WASI-II, which can be completed via video conferencing, on the telephone, or face-to-face when the verbal consent can take place. If a participant turns 16 during the course of the trial, they will be re-consented (i.e. asked to complete a consent form for age 16+), before the next data collection/follow-up stage.

A contacts form will be completed for participants including multiple methods of contact (address, telephone, email address) to minimise loss to follow-up. Preferences for follow-up data collection (face-to-face, telephone, online, videoconferencing, or postal) will be obtained to ensure that participants are being contacted in the way that suits them best. They can change their mind at any stage.

Consent will be sought for data (including personal data and special category including criminal offence data) to be archived at the end of the trial via the ONS Secure Research Service. This is a condition of taking part in the trial and a requirement of the funder. We have drawn on the YEF template wording for this. Furthermore, data sharing plans will be explicitly included in the participant information sheets.

The right of the participant to refuse to participate in the trial without giving reasons must be respected and participants will remain free to withdraw at any time from the trial without giving reasons and without prejudicing their further treatment. Additionally, parents/guardians will have the right to withdraw their child from the trial at any point if the child is under 16.

Contact details will be securely transferred from the site to the research assistant/practitioner delivering SFBT/CYP practitioner, who will conduct baseline data collection and randomisation. Only when informed consent has been obtained from the participant AND they have been randomised/enrolled into the trial will they be considered a trial participant.

Informed consent will be taken by research assistants prior to the qualitative interviews. The CYP participant, parent/guardian, and practitioner will have been sent a Participant Information Sheet and copy of the consent/assent form prior to the interview taking place and given sufficient time to read the information. There will be two versions of the Participant Information Sheet for CYP who take part in the qualitative interviews, one for 10 to 13-year-olds, and one for 14-year-olds and up. Trial information will be appropriately adapted for use by younger CYP. Research assistants, who have been fully trained in trial procedures, will explain the qualitative component in detail. If happy to take part, informed consent will be obtained from CYP 16+ years of age and parental/guardian consent and CYP assent obtained from CYPs under 16 years of age. Informed consent will also be obtained from parents/guardians and practitioners who choose to take part. Verbal consent will be obtained (either via telephone, video conferencing or face-to-face meeting). Research assistants will ‘sign’ a consent form on behalf of the participant if they choose to take part.

7.5 Baseline and follow-up data collection

Participants will be screened at site or online or via the telephone and eligibility will be assessed. Potential participant details will be passed from the trial site to the Research Assistant/practitioner delivering SFBT/CYP practitioner. The Research Assistant/practitioner delivering SFBT/CYP practitioner will contact the participant as per their preferred choice of data collection to take consent and complete the baseline data:

- Baseline demographic CRF including:
  - DOB (month and year only)
  - Sex/gender
  - Who they live with and any changes in living arrangements between baseline and follow-up, and if they are being looked after
  - Whether they are in school
  - Type of school
  - School year
  - Ethnicity
  - If English is their first language
  - GP contact details
- Baseline outcome measures completed (WASI-II is to be completed with researcher assistance [telephone, teleconferencing, or face-to-face])
- The trial team will also collect contact details including name, address including postcode, telephone number and email address for the purposed of completing follow-up. These will be kept separate from trial data. The trial team will make use of text messages, email, post, and WhatsApp messages, to maintain contact with participants and remind them of upcoming appointments. Full DOB will also be collected as the trial team will send participants a birthday card during the course of the trial.

After completion of the baseline measures, participant details will be passed from the Research Assistant/practitioner delivering SFBT/CYP practitioner to the CTR and the participant will be randomised.

Participants will be followed-up, as described above, at 6 months post-randomisation and 12 months post-randomisation.

7.6 Assessments

We will also work with the provider team to ascertain what routinely collected data are available that can be used to inform our evaluation further (e.g., specific risk assessment measures). We will explore whether the Ministry of Justice data linked to Department for Education (DfE) would be available for this trial (i.e., it would need to be available real-time), which is available via the Data First collaboration with ADRUK. Behavioural problems (absence, exclusion) can be identified via the National Pupil Database and trial participants linked to these datasets. The availability of data will fall outside the timelines for the evaluation but consent to link for this purpose will be explored. The DfE will pseudonymise identifiers sent to them by the study team, and these will be replaced with a unique Pupil Matching Reference Number. The DfE will then submit this to the Office for National Statistics (PNS) for storage in the YEF Data Archive.

Please see Table 2 for the schedule of assessments in the trial

Table 2. Schedule of enrolment, interventions and assessments

Procedures	**Data collection timepoints**				
	Screening	**Baseline**	**Treatment Phase**	**6 month follow-up**	**12 month follow-up**
Screening logs	X				
Eligibility	X				
Informed consent and assent	X				

Contacts form	X				
Demographics		X			
Randomisation		X			
Delivery of intervention			X		
Compliance			X		
Outcome measures:					
CYP current case management		X			
Self Report Delinquency Measure		X		X	X
CYP wellbeing self-report: self-report version of the Strengths and Difficulties Questionnaire		X		X	X
CYP wellbeing parent/guardian-report: parent-report version of the Strengths and Difficulties Questionnaire		X		X	X
Gang Affiliation Risk Measure		X			X
Self-report Callous and Unemotional Traits		X			X
Parent/guardian-report Callous and Unemotional Traits		X			X
LD: Wechsler Abbreviated Scale of Intelligence – II (Vocabulary and Similarities Subtests). Question		X			

about if child has learning disability.					
Parent/guardian-report other therapies received (including pharmacological)		X			X
Criminal offence data: arrest, caution, reprimands, warnings and conviction data (referrers and the police)		X			X
Fidelity measures: Attendance/ engagement logs Session summary forms				X X	
Qualitative interviews (post 6 month follow-up): • CYP • Parents/guardians • Practitioners • Site staff				X X X X	X X X X
Withdrawal forms		X	X	X	X

7.7 Registration and Randomisation

Registration

Contact details will be securely transferred from the site to the trial team, who will conduct baseline data collection (Warwick) and randomisation (CTR).

Randomisation

CYP will be randomised on a 1:1 basis to either the intervention (SFBT and SAU) or control arm (SAU only) using stratified permuted block randomisation, ensuring balance on prognostic factors (i.e., Verbal Comprehension Index), and stratifying by custody suite. The randomisation system will be embedded within the trial database, and outcome assessors, trial statisticians responsible for analysing the data, and the research team excluding the trial manager, Data Manager, Senior Trial Manager and those undertaking the process evaluation will remain blind to allocation. The online system also ensures allocation concealment is blinded for researcher recruiting participants.

8. Withdrawal & participant retention

8.1 Withdrawal

Participants have the right to withdraw consent for participation in any aspect of the trial at any time. The participants care will not be affected at any time by declining to participate or withdrawing from the trial because they will still receive services as usual. If a participant initially consents but subsequently withdraws from the trial, clear distinction will be made as to what aspect of the trial the participant is withdrawing from. These aspects will be:

- Withdrawal from intervention (SFBT only)
- Partial withdrawal from future follow-up data collection (e.g., some questionnaires, interviews)
- Withdrawal from previously collected data, prior to data analysis

Participants cannot withdraw from the trial but still receive the intervention, if they withdraw from the trial then they will receive usual services only. Participants who consent and subsequently withdraw should complete the trial withdrawal form or the withdrawal form should be completed on the participant's behalf by the site staff/ trial team based on information provided by the participant. This withdrawal form should be sent to the Trial email address. Any queries relating to potential withdrawal of a participant should be forwarded to the Trial Manager.

8.2 Participant retention

Participants who do not complete the 12-month follow-up data collection will be considered lost to follow-up. The trial team will monitor retention throughout the trial. In order to minimise loss to follow-up participants (both CYP and parent/guardian) will be (i) offered shopping vouchers for taking part in this trial, contingent upon questionnaire completion at each time-point, which for CYP will be stepped to encourage completion at the follow-up timepoints (CYP: baseline=£20, 6-months=£25, 12-months=£30, parent/guardian: baseline=£10, 6-months=£10, 12-months=£10). CYP and parent/guardian will also be offered £20 shopping vouchers for participating in an interview, and (ii) sending CYP and their families thank-you cards following each contact. In addition, some participants may have difficulties with reading and writing. We will make materials (including trial materials such as PIS where possible) available in alternative formats (e.g., audio file, video) and provide a choice of data completion methods (see earlier). The materials will be written in easy to read, lay language. Further, we have adapted the trial materials for CYP to ensure that they are developmentally appropriate. Participants will be given the choice of how to complete the follow-up questionnaires (with a Research Assistant/practitioner delivering SFBT/CYP practitioner face-to face, over the telephone, or via videoconferencing, or directly in the secure bespoke online database). Participant will be sent email or text message reminders that their next assessment is due, and a reminder if the assessment has not been completed in a certain number of days. A plan will be followed, and a fixed number of reminders will be sent as not to burden participants with reminders. Considering that nature of the difficulties that many of these CYP face, multiple reminders may be required.

9. Trial Intervention

9.1 Brief Solution Focused Therapy

Brief Solution Focused Therapy (SFBT) is a six-session manualised intervention, delivered face-to-face bi-weekly over 12 weeks, on a one-to-one basis, that helps people to change by focus on building solutions rather than getting stuck thinking about problems. Through a

programme of SFBT, it is hoped that children and young people can be diverted away from the criminal justice system, reducing their risk of serious youth violence. The six sessions are detailed below.

Session 1: Negotiating the contract.

Introductions are made between the therapist and CYP, with a focus on establishing a therapeutic relationship. There is a focus on engaging the CYP in problem free talk, giving an opportunity to connect on more positive aspects of the CYP's life, rather than the problems that have led to the referral to L&D. The session then moves on to establish the CYP's hopes for the session, asking them what they are hoping to achieve. Boundaries are defined, and a confidentiality agreement is agreed upon.

Session 2: A preferred future

The session begins with problem free talk, including the CYP's highlights of the week, or since the last session. This session focusses on the miracle question and the CYP's preferred future.

The miracle question opens the door to the CYP's possibilities for therapy. It does this by simply asking them to consider what an alternate reality might look like – one in which things are different, better, and problems are resolved (Strong & Pyle, 2009). Questions are asked about this preferred future, including: in the preferred future, one where a miracle has happened, what things would the CYP notice? What would be different? The aim is to keep descriptions ordinary, mundane, and small scale so not beyond the CYP's abilities. The history of their preferred future follows this to identify what aspects of the preferred future are already happening. For example, identifying small positives from their everyday lives that may have been overlooked, including exception to what has been frames as normal problem behaviour for the CYP (e.g., tell me about a time where you have felt angry but haven't exploded?). The aim of this is to find the exceptions to sow the seed of hope for an alternative, and positive, future.

Sessions 3-5: Using scales

Each session begins with problem free talk and a chance for young person to reflect on the time between sessions, including any highlights. The therapist and CYP will discuss the preferred future from session 2 and identify any aspects of the preferred future that have been present since the last session.

The therapist will then introduce the use of scales that will form the basis of sessions 3-5 (0-10, with 10 being the most preferred outcome and 0 being the least, the CYP will rate themselves). The focus of the discussions will be the CYP's position from a positive perspective. So, if the CYP scores themselves a 3/10 - why are they a 3 and not a 2? Any topic can be included here for example, behaviour at school, relationship with parents/guardians, young person's mood or self-esteem.

Scales can be presented verbally but can also be drawn and used as a worksheet (e.g., ladders, mountains, stairs), or could be built with toys (e.g., Lego or building blocks). The focus will be on hopes, past achievements, and current strengths.

Session 6: Ending session

The focus of the final session is to end the therapeutic relationship safely. The therapist will ask about what is better for the CYP now, compared with in session 1. They will reflect on CYP's improvements, using the scales as evidence, and ask the CYP what they did to achieve that improvement. They will go on to consider what difference the improvements have made on other areas of the CYP's life. For example, behaviour in school and the impact that has had on exclusions, relationships with peers, parents/guardians, experience of violence, contact with police, mood, and self-esteem.

The therapist will ask the CYP how they will know that things are continuing to improve after the sessions have ended, and work with them to identify short-term goals post-intervention, as well as who their support team is (e.g., a trusted 5 on a worksheet) to be their continued support.

The intervention will be delivered from month six to 19 of the trial. The therapists have been recruited from the existing Liaison and Diversion workforce within LSCFT. Practitioners are from a health and social care skill mix and are in band 5 / 6 clinical roles as per Agenda for Change. All practitioners recruited to support the trial already have experience in supporting children through custody. For the trial, they have then undertaken 36 hours of SFBT training, facilitated by the same training provider at the same time.

Children will be offered a choice of where to participate in the sessions, but choice will be limited to home, school, LSCFT clinical site, community clinic e.g. youth centre. Six sessions

will be included and will last no less than 15 minutes and no more than one hour each. The six sessions will be facilitated over a 12-week period. Sessions will be no more frequent than once a week and no less frequent that bi-weekly- this should allow for sickness / absence and inconsistent engagement. Existing fidelity measures are to be adapted.

10.Internal pilot

The design incorporates an internal pilot in the first year with progression criteria (Avery *et al.*, 2017) to examine whether moving on to a definitive trial is warranted and feasible. The proposed progression criteria will be approved by the trial steering committee and funder and reviewed by the trial steering committee following the internal pilot. The proposed criteria are:

Recruitment

(i) n = 100 CYP recruited within the internal pilot (11 months) l (green=≥80% accrual amber=<80 to 69% ; red=<69% accural);

Randomisation

(i) Number of CYP randomised (of CYP consented green=≥90%; amber=50-89%; red=<49%).

Retention

(i) Number of CYP (of randomised) not explicitly withdrawn from the trial (at 11 months: green=≥80%; amber=50-79%; red=<50%);

(ii) Are the approaches to maximise retention acceptable to participants in this trial? (assessed qualitatively through interviews with a small sample of CYP and parents/guardians).

Fidelity and adherence

(i) Fidelity assessed according to a fidelity checklist (developed in collaboration with the delivery team, prior to the internal pilot – see later in Process Evaluation) (green=≥80 of sessions meet criteria; amber=50-79%; red=<50%);

(ii) Adherence: session attendance (green=≥ 66.6% of scheduled sessions attended; amber= 50-66.6%; red=<50%) (an average of the number of sessions)

Outcomes

(i) Willingness of CYP to participate in trial processes (data completeness for 6-month Self Report Delinquency Measure: green=≥75%; amber=50-74%; red=<50%).

How does SFBT differ from SAU?

(i) SAU data from intervention and control groups in the internal pilot will be examined for any overlap with the content of the SFBT intervention (assessed by SAU questions in baseline questionnaire, and qualitatively through interviews with a small sample of CYP and parents/guardians), and to;

(ii) examine whether SAU is similar in the intervention and control groups, with the data collated from services received (assessed by SAU questions in questionnaires, and qualitatively through interviews with CYP, parents/guardians, and practitioners).

All progression criteria and assessments will inform the design of the trial if continued.

11.Process evaluation

The process evaluation will aid interpretation of trial outcomes by examining four key aspects of intervention implementation: 1) recruitment and reach; 2) intervention delivery, including adherence and fidelity; 3) factors influencing intervention implementation, 4) intervention mechanisms. We will use MRC guidance as a framework for the process evaluation.

Recruitment and reach

Demographic and baseline data will be used to describe the numbers of CYP approached to participate in the trial, and the proportion who agree to do so.

Screening logs and withdrawal data will be used to record how many CYP were approached, recruited, retained at all stages, and reasons for attrition (if given).

Ethnicity age, sex, Verbal Comprehension Index will be entered into our interview sampling framework.

RAs will collect the data.

A framework will be used, including session attendance and therapist. The Research Assistants collecting this data are separate to the delivery team. Data collection and analysis supervised by the CIs and Co-app supporting, using existing tested methods.

Implementation fidelity/adherence and dosage

SFBT attendance/engagement data will be recorded in logs by practitioners, including: start date of CYP engagement with the intervention; number of sessions offered and completed. The number of sessions delivered will be recorded by practitioners in Session Summary forms and any implementation challenges recorded. To measure fidelity, each practitioner will be required to complete a fidelity checklist at the end of each session completed. We have worked with the Project Advisory Group (made up of CYP in LSCFT) to ascertain the most acceptable way of independently measuring fidelity. Audio-/video-recording of the practitioner delivering the session, or a researcher/practitioner observing the session were considered by the research team. However, our Project Advisory Group, comprised of young people, advised that any recording, via video or audio would be unacceptable, as would the inclusion of an observer. The fidelity rating scale is being developed in collaboration with the delivery team by the trial team. Quantitative data on adherence and fidelity will be used for analysis of key trial outcomes, to investigate relationships between intervention outcomes and intervention receipt, adherence, and fidelity.

Factors influencing intervention implementation

Interviews with 30-40 CYP in the intervention group will establish their experiences of the trial (e.g., randomisation, questionnaire completion), of SFBT, and factors impacting adherence. Interviews with up to 15 CYP in the control group will establish their experiences of being in the trial, this will be balanced across custody suites where possible. All interviews will explore retention to the trial, and factors affecting this. We will sample CYP with a range of ages, and from different custody suites (if additional custody suites are added). Semi-structured telephone/online interviews with up to 20 parents/guardians across both arms of the trial with the majority from the intervention arm from across the three custody suites will gather in-depth data about: their experiences of the trial, attitudes/perceptions of SFBT, and factors impacting adherence (if their CYP was in the intervention arm). Interviews with

up to 15 practitioners will explore their experience of delivering SFBT, and the potential systems and structures which would be needed for future implementation of SFBT. Interviews with up to 10 site staff who are not practitioners will also be conducted to explore their experiences and views of the trial and the intervention. We propose asking CYP in the baseline questionnaire about what case management and other therapies including pharmacological) they are currently receiving. We will quantitatively describe these data. Interviews with CYP, parents/guardians and practitioners will explore the provision of existing services (usual practice) and how SFBT is distinct from this provision.

Intervention mechanisms

Interviews with up to 15 practitioners in the intervention arm will also explore factors impacting adherence and fidelity, which will help us to understand the mechanisms that might contribute to/explain the outcomes of the trial. Qualitative interviews with CYP and parents/guardians will explore perceived benefits and mechanisms of the interventions. Qualitative interviews with practitioners will explore unintended effects and key components of SFBT. These data will enable us to explore the extent to which key intervention mechanisms appear to be working as intended, variation across context (e.g., by practitioner, custody suite, family context), and any unintended mechanisms or barriers to participation. Together with quantitative data on hypothesised short, medium, and long-term impacts, this data will be used to refine the intervention's logic model and to examine ways in which SFBT adds to and/or strengthens potential impacts of SAU.

12.Safety reporting

Expected adverse events will be assessed by the Trial Steering Committee and reported to the Research Ethics Committee for consideration as required.

The Principal Investigator is responsible for ensuring that all site staff involved in this trial are familiar with the content of this section.

All SAEs must be reported immediately (and within 24 hours of knowledge of the event) by the PI at the participating site to the Trial team unless the SAE is specified as not requiring

immediate reporting. The Trust safeguarding SOP will be followed and all SAEs/AEs will be reviewed by the PI at site who is medically trained.

12.1 Definitions

This trial will collect GCP SAEs and trial-specific SAEs and AEs.

Table 3. SAE definitions

Term	Definition
Serious Adverse Event (SAE) (GCP)	Any adverse event that - • Results in death • Is life-threatening* • Required hospitalisation or prolongation of existing hospitalisation** • Other medically important condition***

***Note:** The term 'life-threatening' in the definition of serious refers to an event in which the trial participant was at risk of death at the time of the event or it is suspected that used or continued used of the product would result in the subjects death; it does not refer to an event which hypothetically might have caused death if it were more severe.

** **Note:** Hospitalisation is defined as an inpatient admission, regardless of the length of stay, even if the hospitalisation is a precautionary measure for continued observation. Pre-planned hospitalisation e.g., for pre-existing conditions which have not worsened, or elective procedures, does not constitute an SAE.

*** **Note:** other events that may not result in death, are not life-threatening, or do not require hospitalisation, may be considered as an SAE when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

12.2 Trial Specific SAE Reporting requirements

In addition to the SAE reporting requirements above, for the purposes of this trial the following events will also be considered SAEs and must be captured on the SAE form and reported to the CTR with 24 hours of knowledge of the event:

- Detention within hospital using the Mental Health Act.
- Increasing suicidal ideation and/or plans or actual attempts to harm oneself with associated suicidal intent.

The following will be considered AEs:

Deliberate self-harm which is not life-threatening nor associated with suicidality as judged by the treating clinician.

A deterioration in mental state defined as increased anxiety, low mood, aggression, or new evidence of thought disorder and/or perceptual disturbances as judged by the treating clinician.

Disclosure of a history of physical and/or sexual abuse and/or criminal exploitation.

Imprisonment.

Removal from the family home.

Safeguarding risk to the young person has increased during their participation in the trial to such an extent that the LA have had to initiate care proceedings.

12.3 Causality

Causal relationship will be assessed for the SFBT intervention. The Principal Investigator (or another delegated qualified person from the trial team) will assess each SAE to determine the causal relationship and the Chief Investigator (or another appropriately qualified member of the Trial Management Group) can also provide this assessment where necessary:

Table 4. Causality in SAEs

Relationship	Description	Reasonable possibility that the SAE may have been caused by the intervention?
Unrelated	There is no evidence of any causal relationship with the intervention	No
Unlikely	There is little evidence to suggest there is a causal relationship with the intervention. There is another reasonable explanation for the event.	No
Possible	There is some evidence to suggest a causal relationship with the intervention. However, the influence of other factors may have contributed to the event.	Yes
Probable	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.	Yes
Definite	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.	Yes

The causality assessment given by the Principal Investigator (or delegate) cannot be downgraded by the Chief Investigator (or delegate), and in the case of disagreement both opinions will be provided.

12.4 Expectedness

The Chief Investigator (or another delegated appropriately qualified individual) will assess each SAE to perform the assessment of expectedness.

Expected events (AE) will be listed here:

Increased expression of emotion (e.g., crying) during sessions with a therapist.

This event does not need to be reported as an AE.

12.5 Reporting procedures

Participating Site Responsibilities

The PI should sign and date the SAE CRF to acknowledge that he/she has performed the seriousness and causality assessments. Investigators should also locally report SAEs in accordance with local practice. A completed SAE form for all events requiring immediate reporting should be submitted via email to the CTR within 24 hours of knowledge of the event. A separate form must be used to report each event, irrespective of whether or not the events had the same date of onset.

The participant will be identified only by Participant identification number, partial date of birth (mm/yy) and initials. The participant's name should not be used on any correspondence.

It is also required that sites respond to and clarify any queries raised on any reported SAEs and report any additional information as and when it becomes available through to the resolution of the event. Additionally, the CTR may request additional information relating to any SAEs and the site should provide as much information as is available to them in order to resolve these queries.

Serious Adverse Event (SAE) email address:

solutions@warwick.ac.uk

Serious adverse events should be reported throughout the treatment period up to 28 days after the participant receives the intervention.

An SAE form is not considered as complete unless the following details are provided:

- Full participant trial number
- An Adverse Event

- A completed assessment of the seriousness, and causality as performed by the PI (or another appropriately qualified person registered on the delegation log).

If any of these details are missing, the site will be contacted and the information must be provided by the site to the CTR within 24 hours.

All other AEs should be reported on the CRF.

The CTR responsibilities

Following the initial report, all SAEs should be followed up to resolution wherever possible, and further information may be requested by the CTR. Follow up information must be provided on a new SAE form. The CTR should continue reporting SAEs until 28 days after the participant receives the last part of the intervention. Once an SAE is received at the CTR, it will be evaluated by staff at the CTR and sent to the Chief Investigator (or their delegate) for an assessment of expectedness.

Related and unexpected Serious Adverse Events (SAEs) will be submitted to the REC. These should be sent within 15 days of the CI becoming aware of the event.

12.6 Urgent Safety Measures (USMs)

An urgent safety measure is an action that the Sponsor, Chief Investigator or Principal Investigator may carry out in order to protect the subjects of a trial against any immediate hazard to their health or safety. Any urgent safety measure relating to this trial must be notified to the Research Ethics Committee immediately by telephone, and in any event within 3 days in writing, that such a measure has been taken. USMs reported to the CTR will be handled according to CTR processes.

13.Statistical considerations

13.1 Randomisation

CYP will be randomised on a 1:1 basis to either the intervention or comparator arm using stratified permuted block randomisation, ensuring balance on prognostic factors (Verbal

Comprehension Index) and stratifying by custody suite. The randomisation system will be embedded within the online trial database, i.e. it will be computer-generated.
The Trial Manager will be responsible for allocation and informing intervention practitioners/site staff of a participants' allocation by secure file transfer using Fastfile. Delivery team/site staff will be responsible for informing participants of their allocation.

13.2 Blinding

Due to the nature of the trial, participants and practitioners will not be blind to allocation arm. In addition, the Trial Manager, Data Manager, Senior Trial Manager, and researchers completing qualitative interviews will not be blind to allocation. All other researchers, including the Trial Statistician responsible for analysing the data and researchers carrying out follow-up data collection, will be blind to allocation arm. If inadvertent unblinding occurs during contact with a participant, this will be recorded and reported to the Trial Manager. We do not foresee any circumstance where unblinding will be necessary.

13.3 Sample size

282 CYP participants will be recruited allowing for up to 20% dropout from the trial (N=225). Recruiting this number of CYP, and on the basis of detecting a minimal clinically important difference (MCID) 0.325 (mean difference of 4 points with SD=12.32), assuming a correlation between baseline and follow-up of 0.5 (Fonagy et al., 2020;) and using a two-sided alpha of 0.05, the trial would then be 80% powered (Borm, Fransen & Lemmens, 2007). Our assumptions about the minimally detected effect size (MDES) are informed by previous research by the developers of the SRDM measure (Smith, Shute, Flint, McVie, Woodward and McAra, 2001). They report mean and SD in the development samples and based on expertise in our target population have made a conservative adjustment to use a smaller MDES to reflect some level of uncertainty. We have also included the pre-post

correlation based on values obtained from the START trial using the same outcome measure and in a similar population of adolescents (Fonagy et al., 2020).

Initial sample size estimates were calculated at n= 448 assuming 90% power and a more conservative correlation between baseline and follow up, r=0.334. Adjustments made in the revised power calculations included reducing power from 89% to 80% and adjusting the pre-post correlation from r= 0.334 to r= 0.500, using what is thought to be a new reliable estimate of the pre-post correlation from existing research. This provided an indicative sample size of 282.

The sample size has been designed to address the primary analysis only. Following completion of the internal pilot phase, the pre-post correlation for the primary outcome will be calculated on the available follow-up sample and the assumption made in the existing sample size calculation will be reviewed.

Table 5. Sample size

		PARAMETER
Minimum Detectable Effect Size (MDES)		0.33
Pre-test/ post-test correlations		0.50
		-
		-
		-
Alpha		0.05

Power		0.80
One-sided or two-sided?		Two-sided
Number of participants	Intervention	141
	Control	141
	Total	282

13.4 Missing, unused & spurious data

A final Statistical Analysis Plan will be produced prior to any analysis being undertaken and will provide detail of handling missing data. We will explore the impact of missing data on trial outcomes by investigating likely missing data mechanisms and re-fitting the primary outcome within a multiple imputation framework (including exploring MAR and MNAR mechanisms via delta-based controlled multiple imputation).

13.5 Procedures for reporting deviation(s) from the original SAP

Any deviations from the original SAP will be submitted as substantial amendments where applicable and recorded in subsequent versions of the protocol and SAP.

13.6 Termination of the trial

Beyond the internal pilot, there will be no formal 'stopping rules' or 'discontinuation criteria' for individual participants, parts of trial and entire trial. Any concerns with participant well-being will cross reference this section with those for the TSC as this group is likely to be involved with this decision-making process.

Continuation of the trial from internal pilot to main trial will be decided by the Trial Steering Committee and funder at month 12 (see Internal Pilot Section).

13.7 Inclusion in analysis

All randomised participants' data will be included in analysis, if consent has been obtained to use their data and have not withdrawn from the trial, and they have not withdrawn consent to use their data.

14.Analysis

A final Statistical Analysis Plan will be produced prior to any analysis being undertaken.

14.1 Internal Pilot analysis

Statistical analysis for internal pilot feasibility outcomes will be primarily descriptive. Feasibility outcomes will be estimated as frequencies and percentages, means and standard deviations, or medians and interquartile ranges as appropriate. Feasibility outcomes will be assessed against the pre-specified progression criteria. Percentage of missing data will also be reported descriptively.

14.2 Primary and Secondary analysis at 12 month follow up

Our primary analysis will include all randomised participants who provide outcome data (i.e., an intention to treat analysis set) and compare mean scores between arms on the SRDM at 12-months post-randomisation using linear regression, adjusting for baseline SRDM score, Verbal Comprehension Index, and custody suite. We will report effect sizes as Hedges' g (adjusted mean difference; Hedges, 1981) and, in addition, all estimates will be reported with their associated 95% confidence intervals.

Secondary outcomes will be analysed following a similar framework. The parent/guardian and self-report versions of the Strengths and Difficulties Questionnaire (SDQ) will be analysed following the same model as our primary outcome, but given that our secondary outcomes, number of Criminal offences and the Gang Affiliation Risk Measure, are counts and range-restricted variables respectively, we will use Generalized linear models accordingly. For the count variable, we will a Poisson regression checking for zero inflation and overdispersion. For the range restricted variable, we will use a Tobit regression (Tobin, 1958).

We will explore the extent to which there were differential intervention effects by custody suite by extending our primary analysis model to include sub-group by trial arm interaction terms. Similarly, potential moderators, learning disability status and callous-unemotional traits, will be explored by inclusion of an interaction of moderator and treatment allocation variables into the primary analysis model. In addition to interpreting the magnitude and statistical significance of interactions, plots of the interactions will also be examined. These analyses will be hypothesis generating in nature only (i.e., will not be confirmatory and only indicate whether further research targeting the intervention may be warranted). As a further secondary step in the analyses, we will also explore whether age and sex covariates influence outcomes (adjust estimates) by inclusion as covariates in the linear regression model.

We will additionally consider the role of therapist as a source of clustering. As counsellors will deliver the intervention to individuals allocated to the intervention arm only, this will be a form of partial nesting and may lead to an underestimation of standard errors (and thus inflated Type-I error) if not appropriately accounted for. We will also report intra-cluster correlation coefficients, the number of clusters, and cluster sizes. To account for any clustering, we will fit a heteroscedastic partially nested mixed-effects model structure. The model will have a two-level structure, level 1 (individual) and level 2 (counsellor). Verbal Comprehension Index and intervention variables will be included at level 1 and custody

suite at level 2. Given that age and sex are also potentially related to outcome, we will also present adjusted estimates following their inclusion into the model.

We will also fit linear mixed models, accounting for repeated post-randomisation measures (six- and 12-months post-randomisation) within participants, adjusting for baseline measures, custody suite and practitioners to investigate the overall effect of the intervention on post-randomisation measures.

All analyses will be checked subject to satisfying required assumptions. These checks include:

1. Linearity – plotting residuals vs predictor(s). If a structure is present, then transformation or an alternate model specification is required (i.e. GLM).
2. Homogeniety of variance – variance of the residuals across groups is the same. There is scope to fit models allowing for heterogeneous groups, but the setup is different (Generalized linear mixed model - GLMM).
3. Residuals are approximately normally distributed – plotting QQ plot

If distributional assumptions are not satisfied, as appropriate, a generalized linear model with alternate link function will be used. Alternatively, data transformation could be used but use of the GLM is preferable.

We will conduct two sensitivity analyses:

• Exploring the impact of missing data on trial outcomes by investigating likely missing data mechanisms and re-fitting the primary outcome within a multiple imputation framework (including exploring MAR and MNAR mechanisms via delta-based controlled multiple imputation);

• Exploring the impact of different levels of intervention receipt on outcomes. We will use either two-stage least squares instrumental variables regression or inverse probability of

treatment weighting methods to examine the effect of the intervention in those who receive varying levels of it.

We will describe process evaluation measures and fit regression models whereby we explore their association with outcomes. As these will only be measured in those allocated to the intervention, these will be associational in nature.

Exploratory mediation analyses may also be carried out to examine variables at 6 months that may mediate intervention effects between baseline and 12-month follow-up. Any such analyses will be specified once a final Logic Model is confirmed.

14.3 Sub-group & interim analysis

LD status and callous-unemotional traits will be explored by inclusion of an interaction of moderator and treatment allocation variables into the primary analysis model.

14.4 Qualitative analysis

Framework Thematic Analysis will be used to analyse qualitative interview data, with the framework informed by a combination of the MRC Process Evaluation guidance and the logic model. Quantitative data on recruitment, adherence and fidelity will be analysed descriptively. Triangulation will be conducted, combining the qualitative and quantitative data on recruitment, adherence, fidelity and intervention mechanisms. Qualitative data will be used to interpret patterning in recruitment, adherence and fidelity data, with analysis of quantitative data in turn highlighting areas which should be further explored in qualitative interviews and analysis.

14.5 Cost effectiveness analysis

A full economic analysis has not been included, but we will collect data to enable us to estimate the delivery costs SFBT, as follows:

1) Personnel for the implementation of the programme. Collected by the delivery team, including the number of SFBT sessions delivered per CYP and the number of person days per CYP.

2) Programme costs. Collected by the delivery team including costs of travel per CYP.

3) Facilities, equipment and materials. Collected by the delivery team, including costs to L&D services of reproducing support materials when needed for the intervention.

4) Other programme inputs. Practitioners and L&D services will keep note of any other costs arising as a result of intervention delivery. These data will be used to estimate the intervention costs, which will be reported with appropriate confidence limits.

15.Data Management

Source data will be paper or online versions of the CRFs/questionnaires. If CRFs/questionnaires are completed by the Research Assistant face-to face, over the telephone, or via videoconferencing the research assistant will complete the questionnaire on a tablet directly onto a secure bespoke online database. The research assistant will also be able to complete a paper copy of the CRF as a 'backup' in case of technical difficulties. If CRFs/questionnaires are posted to the participants, they will be returned in free-post envelopes to the University premises where the data can be inputted by trial team staff. CRFs/questionnaires will only contain a unique identifier (PID) per participant, initials and

date of birth (partial so not identifiable – month and year only). No other identifiable information will be recorded on the CRFs/questionnaires. Participants will also be able to complete the CRF/questionnaire directly in the secure bespoke online database.

The trial team at Cardiff University will enter paper CRF/questionnaire data on to the secure bespoke online database. Access to the database will be via username and password and restricted to appropriately-trained personnel only. The database will be housed on local servers managed by Cardiff University staff in accordance with all appropriate legislation.

Identifiable data will be encrypted and stored separately from non-identifiable data.

Wherever possible data will be validated at point of entry, thereby reducing the opportunity for missing or unexpected data. All changes made to the data will be recorded and visible via an audit log within the database.

The planning, development, testing and maintenance of the database will be performed in line with CTR SOPs, as will the data management function. Copies of CRFs/questionnaires will be returned to the CTR/ Trial Manager by courier or scanned and sent via FastFile. Qualitative interview recordings will be recorded on encrypted audio-recorders/video-recorders and stored on password protected computers at Warwick or Cardiff. All files will be encrypted. Any transcripts will be fully pseudonymised and shared with the researchers at Warwick or Cardiff.

A data management plan will be developed to outline the details of how data will be collected, transferred stored and accessed by the team.

The following source data will be collected:

Trial data	Source Data											
	Screening logs	Eligibility forms	Consent form	Contacts form	CRF	Questionnaire	SAE form	Withdrawal form	Fidelity Checklist	Attendance logs	Session forms	Resource forms
Recruitment and retention data	X							X				
Eligibility		X										
Consent			X									
Contacts info				X								
Demographics					X							
Outcome measures						X						
Fidelity of session content									X			
Attendance data										X		
Qualitative data									X			
HE data												X

15.1 Data collection

Data will be collected through multiple methods, including online, by post, in person, using videoconferencing, and over the telephone. In previous trials completed by our team, using a choice of methods for data collection has ensured that participants are able to participate in a way that best suits them (Flynn et al., 2020). Offering choice also helps to address inequalities affecting participants. For example, participants who are concerned about their reading ability can opt to complete measures by telephone with a researcher, without having to explain that this is because they cannot read.

15.2 Completion of CRFs

Paper CRFs

The hard-copies of CRFs/questionnaires will be completed by the Research Assistant/practitioner delivering SFBT/CYP practitioner and returned to the CTR for data checking/ querying within approximately four weeks of completion. CRF pages and data received by the CTR will be checked for missing, illegible or unusual values (range checks) and consistency over time. If missing or questionable data are identified, a data query will be raised on a data clarification form. The data clarification form will be sent to the researcher collecting the data and shall be requested to respond to the data query on the data clarification form. The original CRF pages should not be altered.

All answered data queries and corrections should be signed off and dated by a delegated member of staff. The completed data clarification form should be returned to the CTR and a copy retained with the Research Assistant. The CTR will send reminders for any overdue data. It is the Research Assistant's responsibility to submit complete and accurate data in a timely manner.

Electronic CRFs

Participants will be given the option of completing CRF and questionnaire data using an online system. The system will be developed by the CTR and tested prior to going live. Participants will be provided with a unique Participant Identification (PID) number and will access the online CRF using this number, initials and DOB.

Database

It is intended to develop data recording for this trial as a web-based system. This is a secure encrypted system accessed by an institutional password, and complies with the General Data Protection Regulation 2016. The system can be accessed on:

A user password will be supplied to investigators upon completion of all processes required prior to opening. All data on the online database will be subject to data check for data quality, as per the data management plan. Due to the low-risk of this trial and based on participant numbers, this QC check is set as 10%. A full Data Management plan will be written.

15.3 Routine Data

The list of previous reprimands, arrests, cautions and convictions will be collected from the Police National Computer (PNC) system will be collected over the 6-month period prior to the commencement of treatment, and at the 12-month follow-up.

16.Protocol/GCP non-compliance

All trial team staff, including the Principal Investigator at site, should report any non-compliance to the trial protocol or the conditions and principles of Good Clinical Practice to the CTR in writing as soon as they become aware of it.

17.End of Trial definition

The end of the trial is defined as the date of final data capture to meet the trial endpoints. In this case end of trial is defined as the date of the last follow-up data collection.

The sponsor must notify the Ethics Committee of the end of a clinical trial within 90 days of its completion or within 15 days if the trial is terminated early.

Sponsor must notify the main REC of the end of a clinical trial within 90 days of its completion or within 15 days if the trial is terminated early.

18.Archiving

The Trial Master File (TMF) containing essential documents will be archived at an approved external storage facility for a minimum of 15 years. The CTR will archive the SMF on behalf of the Sponsor. The Principal Investigator at each site is responsible for archival of the Site file on approval from the Sponsor. Essential documents pertaining to the trial shall not be destroyed without permission from the Sponsor.

19.Regulatory Considerations

19.1 Ethical and governance approval

This protocol has approval from an NHS Research Ethics Committee (REC) that is legally "recognised" by the United Kingdom Ethics Committee Authority for review and approval.

This trial protocol will be submitted through the relevant permission system for global governance review by HRA for the lead site Lancashire and South Cumbria NHS Trust.

Approval will be obtained from sites who will consider local governance requirements and site feasibility. The Research Governance approval from sites must be obtained before recruitment of participants within that host care organisation.

We will attempt to have this trial adopted onto the NIHR Clinical Research Network (CRN) Portfolio of studies which would bring some additional support from the CRN in England (e.g., additional support for gaining participant consent).

The trial will be registered on the International Standard Randomised Controlled Trial Number (ISRCTN) website.

19.2 Data Protection

The CTR will act to preserve participant confidentiality and will not disclose or reproduce any information by which participants could be identified, except where specific consent is obtained. Data will be stored in a secure manner and will be registered in accordance with the General Data Protection Regulation 2016. We must ensure that it is in the public interest when we use personally identifiable information (such as date of birth) from people who have agreed to take part in research and that we are using it properly in accordance with the General Data Protection Regulations (GDPR). Data will be collected from data providers such as the police (on the Police National Computer (PNC), and data will be shared with Department for Education and Office for National Statistics.

Participants will always be identified using a unique Participant identification number (PID) and additional identifiers. All other identifiable information will not be stored with collected data.

19.3 Indemnity

- In the case of negligent harm, health care professionals undertaking clinical trials or studies on volunteers, whether healthy or patients, in the course of their NHS employment are covered by NHS Indemnity. Similarly, for a trial not involving medicines, the NHS body would take financial responsibility unless the trial were covered by such other indemnity as may have been agreed between the NHS body and those responsible for the trial. In any case, NHS bodies should ensure that they are informed of clinical trials in which their staff are taking part in their NHS employment and that these trials have the required Research Ethics Committee approval.
- Non-negligent harm: This trial is an academic, investigator-led and designed trial, coordinated by the CTR. The Chief Investigator, local Investigators and coordinating centre do not hold insurance against claims for compensation for injury caused by participation in a trial and they cannot offer any indemnity. The Association of the British Pharmaceutical Industry (ABPI) guidelines will not apply.

19.4 Trial sponsorship

Lancashire and South Cumbria NHS Trust will act as Sponsor for trial. The Trust shall be responsible for ensuring that the trial is performed in accordance with the following:

- Conditions and principles of Good Clinical Practice.
- Declaration of Helsinki (1996)
- UK Policy Framework for Health and Social Care Research.
- The General Data Protection Regulation (2016)
- Other regulatory requirements as appropriate.

The Sponsor will be delegating certain responsibilities to Cardiff University (CTR), the Chief Investigators, Principal Investigators and sites as appropriate in accordance with the relevant agreement.

19.5 Funding

The trial is funded by the Youth Endowment Fund (YEF). Sites will meet the costs of programme delivery through funding from YEF.

20.Trial management

20.1 TMG (Trial Management Group)

The TMG will normally meet bimonthly during the trial. TMG members will consist of all Co-investigators, collaborators and the trial team and will oversee all aspects of the trial. The role of the TMG will be to help set up the trial by providing specialist advice, input to and comment on trial procedures and documents (information sheets, Protocol, etc.). They will also advise on the promotion and running of the trial and deal with any issues that arise. TMG members will be required to sign up to the remit and conditions as set out in the TMG Charter.

20.2 TSC (Trial Steering Committee)

A Trial Steering Committee (TSC), consisting of an independent chair with relevant expertise, and at least two other independent members including a lay representative and Statistician, will meet at least annually and will oversee all aspects of the trial. Non-independent members will include the joint CI. The joint CI, statistician, Trial Manager and other members of the trial management team may attend in an observer capacity at the request of the Chair.

The first meeting will be as soon as possible, to review the Protocol and arrange the timelines for the subsequent meetings. If necessary, additional/more frequent meetings may occur. The TSC will provide overall supervision for the trial and provide advice through its independent chair. The ultimate decision for the continuation of the trial lies with the

TSC and funder. TSC members will be required to sign up to the remit and conditions as set out in the TSC Charter which will be filed in the TMF.

20.3 DMC (Data Monitoring Committee)

The Trial Steering Committee will be responsible for determining if a DMC is required for this trial. If a DMC is deemed necessary, DMC members will be required to sign up to the remit and conditions as set out in the DMC Charter. It was agreed with the funder that no DMC would be necessary due to the low-risk nature of the trial. The TSC will take DMC responsibilities.

20.4 PAG

The Participant Advisory Group will be responsible for providing advice on all trial aspects from the perspective of young people in similar circumstances. The Lancashire and South Cumbria NHS Foundation Trust will assist in finding appropriate members for this group.

21.Quality Control and Assurance

21.1 Monitoring

The clinical trial risk assessment has been used to determine the intensity and focus of central and on-site monitoring activity in the trial. Low monitoring levels will be employed and are fully documented in the trial monitoring plan.

Investigators should agree to allow trial related monitoring, including audits and regulatory inspections, by providing direct access to source data/documents as required. Participant consent for this will be obtained.

Findings generated from on-site and central monitoring will be shared with the Sponsor, CI, PI & local R&D.

21.2 Audits & inspections

The trial is participant to inspection by regulatory bodies. The trial may also be participant to inspection and audit by Lancashire and South Cumbria under their remit as Sponsor.

22.Publication policy

Outputs from the trial will include open access peer reviewed journal articles in international academic journals, at national and international academic conferences and at University public engagement events. A publications plan and policy will be written for the trial and approved by the TMG. All publications and presentations relating to the trial will be authorised by the TMG. The first report published about the imapct of the intervention will be the evaluation report to the funder.

23.Timelines

Dates	Activity	Staff responsible/ leading
April-Aug 2022	Finalise study documentation Apply for an ethical opinion	CI(s)/Trial Manager
June 2022	Finalise protocol	CI(s)/Trial Manager
July-Aug 2022	Site initiation visit	Trial Manager

Sept 2022-April 2024	Internal pilot	Trial Manager
April 2024	Decision about whether to proceed to main study (definitive trial)	TSC/Funder
May 2024-December 2026	Main study (definitive trial)	Trial Manager
Feb 2024 to Dec 2026	Process evaluation interviews	Process evaluation/qualitative Trial Staff
Jan to Feb 2026	Analysis	Statistician
Mar 2026	Report writing and dissemination	CI(s)/Trial Manager

24.References

Austin P.C., Escobar M., Kopec J.A. (2000). The use of the Tobit model for analyzing measures of health status. *Qual Life Res*, 9(8):901-10. doi: 10.1023/a:1008938326604. PMID: 11284209.

Borm G.F., Fransen J., Lemmens W.A. (2007). A simple sample size formula for analysis of covariance in randomized clinical trials. *J Clin Epidemiol*, 60(12):1234-8. doi: 10.1016/j.jclinepi.2007.02.006.

Ciucci E., Baroncelli A., Franchi M., Golmaryami F.N., Frick P.J. (2013). The Association between Callous-Unemotional Traits and Behavioral and Academic Adjustment in Children: Further Validation of the Inventory of Callous-Unemotional Traits. *Journal of Psychopathology and Behavioral Assessment*, 36(2):189-200.

Deighton, J., Croudace, T., Fonagy, P., Brown, J., Patalay, P., & Wolpert, M. (2014). Measuring mental health and wellbeing outcomes for children and adolescents to inform practice and policy: a review of child self-report measures. *Child and adolescent psychiatry and mental health*, 8(1), 14.

Department of Health and Home Office, 1992, Review of health and social services for mentally disordered offenders and others requiring similar services (The Reed Report).

Essau C.A., Sasagawa S., Frick P.J. (2006). Callous-unemotional traits in a community sample of adolescents. *Assessment*, 13(4):454-69.

Flynn, S., Hastings, R. P., Burke, C., Howes, S., Lunsky, Y., Weiss, J. A., & Bailey, T. (2020). Online Mindfulness Stress Intervention for Family Carers of Children and Adults with Intellectual Disabilities: Feasibility Randomized Controlled Trial. *Mindfulness*, *11*(9), 2161-2175. doi: 10.1007/s12671-020-01436-0.

Home Office, 1990, Provision for mentally disordered offenders. Home Office Circular 66/90

Lord, B. (2009). The Bradley Report. London: Department of Health.

NHS England (2016). Implementing the Five Year Forward View for Mental Health. NHS England.

NHS. The NHS long term plan. 2019. https://www.longtermplan.nhs.uk/

Nock, M.K., Kazdin, A.E., Hiripi, E., & Kessler, R.C. (2006). Prevalence, subtypes, and correlates of DSM-IV conduct disorder in the National Comorbidity Survey Replication. *Psychol Med*, 36(5), 699-710. doi:10.1017/S0033291706007082

Nock, M.K., Kazdin, A.E., Hiripi, E., & Kessler, R.C. (2007). Lifetime prevalence, correlates, and persistence of oppositional defiant disorder: results from the National Comorbidity Survey Replication. *J Child Psychol Psychiatry*, 48(7), 703-713. doi:10.1111/j.1469-7610.2007.01733.x

Raby, C., & Jones, F. (2016). Identifying risks for male street gang affiliation: a systematic review and narrative synthesis. *The Journal of Forensic Psychiatry & Psychology,* 27(5), 601-644. doi:10.1080/14789949.2016.1195005

Raby, C., Jones, F.W., Hulbert S., & Stout, J. (2017). Design, development and validity testing of the gang affiliation risk measure (GARM), *The Journal of Forensic Psychiatry & Psychology*, 28:6, 753-776, DOI: 10.1080/14789949.2017.1324578

Smith, D.J., & McVie, S. (2003). Theory and method in the Edinburgh study of youth transitions and crime. *British Journal of Criminology,* 43(1), 169-195.

Tobin, J. (1958). Estimation of relationships for limited dependent variables, *Econometrics*, 26, 24-3

Twisk, J., Rijmen, F. (2009). Longitudinal tobit regression: A new approach to analyze outcome variables with floor or ceiling effects, *Journal of Clinical Epidemiology*, 62(9), 953-958, https://doi.org/10.1016/j.jclinepi.2008.10.003.

Wechsler D. Wechsler Abbreviated Scale of Intelligence - Second Edition. Bloomington, United States: Pearson; 2011.

Youth Endowment Fund. Our vision and mission - Youth Endowment Fund. https://youthendowmentfund.org.uk/about-us/our-mission/#:~:text=Our%20mission%3A,put%20this%20knowledge%20into%20practice. Accessed 27.06.2022.

It was hard to escape. Safeguarding children at risk from criminal exploitation. The Child Safeguarding Practice Review Panel, UK Government, 2020. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/870035/Safeguarding_children_at_risk_from_criminal_exploitation_review.pdf.

Hedges, L. (1981). Distribution Theory for Glass's Estimator of Effect Size and Related Estimators. Journal of Educational Statistics. Vol. 6, No. 2 (Summer, 1981), pp. 107-128.

YOUTH ENDOWMENT FUND

Impetus

Home Office

youthendowmentfund.org.uk

hello@youthendowmentfund.org.uk

@YouthEndowFund

The Youth Endowment Fund Charitable Trust

Registered Charity Number: 1185413