EVALUATION PROTOCOL

Evaluation of the Trauma Informed Schools UK Training and Implementation (TISUK): A cluster randomised controlled trial

Ipsos UK, The University of Kent, TONIC

Principal investigator: Facundo Herrera, Peter Sakis, Dr Jessica Ozan, Dr Amanda Carr, Prof. Simon Coulton

YOUTH ENDOWMENT FUND

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Project title[1]	Evaluation of the Trauma Informed Schools UK Training and Implementation (TISUK): A cluster randomised controlled trial
Developer (Institution)	TISUK
Evaluator (Institution)	Ipsos UK, The University of Kent, TONIC
Principal investigator(s)	Facundo Herrera, Peter Sakis, Dr Jessica Ozan, Dr Amanda Carr, Prof. Simon Coulton
Protocol author(s)	Facundo Herrera, Peter Sakis, Prof. Simon Coulton
Trial design	Two-armed cluster randomised controlled trial with random allocation at the school level
Trial type	Efficacy
Evaluation setting	School
Target group	Children and young people (CYP) in Year 8

[1] Please make sure the title matches that in the header and that it is identified as a randomised trial as per the CONSORT requirements (CONSORT 1a).

Number of participants	100 schools and 16,000 Year 8 pupils (with 1,100 receiving targeted support)
Primary outcome and data source	Externalising behaviour: SDQ – combined conduct and hyperactivity scores (Survey)
Secondary outcome and data source	(CYP) Internalising behaviour: SDQ – combined emotional regulation and peer problems (Survey) (CYP) Prosocial behaviour: SDQ – Prosocial behaviour (Survey) (CYP) Total difficulties: SDQ – combined emotional regulation, hyperactivity, conduct, and peer problems (Survey) (CYP) Non-psychotic psychological distress: General Health Questionnaire (GHQ12) (Survey) (CYP) Well-being: Short Warwick Edinburgh Mental Well-being Scale (Survey) (CYP) Sense of connectedness: School Connectedness Scale (Survey) (CYP) Percentage of exclusions & suspensions: administrative records (CYP) School attendance: administrative records (School staff) Attitudes related to TIC: Attitudes Related to Trauma Informed Care (ARTIC) (Survey) (School staff) Well-being: Short Warwick Edinburgh Mental Well-being Scale (Survey) (School) Staff retention: administrative records (School) Staff sickness: administrative records (School) Percentage of exclusions & suspensions of CYP: administrative records

	(School) Percentage of school attendance of CYP: administrative records

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Protocol version history

Version	Date	Reason for revision
1.2	July 2024	• Updated the sections on fidelity, engagement, and compliance (see section 5)
1.1 [*latest*]	February 2024	• Update to indicate that geographic location of school has been dropped from the stratification mechanism at randomisation stage (see section 3.3 for explanations) • Updated to explain the timing of randomisation in two batches to accommodate fieldwork of baseline testing in schools (see section 3.3) • Updated all the geographic region from where schools will be recruited (see section 2.6)
1.0 [*original*]	October 2024	

1. Study rationale, background and evidence for equipoise

Background of the problem

Numerous scientific studies have confirmed the severe impact of multiple adverse childhood experiences (ACEs) on children and young individuals. These distressing experiences increase the risk of developing mental health problems, behavioural issues, social difficulties, and learning disabilities, as well as contributing to poverty, long-term unemployment, self-harm, and engagement in violent and criminal activities (Baglivio, Wolff, DeLisi, & Jackowski, 2020; Felitti et al., 1998; Neil et al., 2022). This issue is particularly concerning in the UK, with over two million minors facing mental health difficulties, leading to more than 66,000 recorded referrals to Child and Adolescent Mental Health Services (CAMHS) in 2022. Shockingly, the End the Wait Campaign reported that 25% of these young individuals attempted suicide while

waiting for treatment, highlighting the dire state of waiting lists in many UK areas (Young Minds, 2023). ACEs have long-lasting effects and increase the risk of serious, violent, and chronic juvenile offending due to trauma-induced adverse changes in the brain and body, such as an overactive threat response system, abnormal hormonal axis functioning, impaired reward processing, and diminished executive functions in the frontal lobes (Blankenstein et al., 2022; McCrory et al., 2011; Van Voorhees & Scarpa, 2004).

In schools, traumatised children often display behavioural and relational issues, classified as conduct disorders or anti-social behaviour. Unfortunately, punitive measures and zero-tolerance policies used to address these behaviours worsen mental health problems instead of addressing their root causes. As stressed by (Le, Abdinasir, & Rainer, 2023) such approaches negatively affect traumatised children's well-being and fail to encourage positive behavioural changes. Consequently, these vulnerable children are often expelled from schools instead of receiving the necessary support to cope with their trauma, contributing to the school-to-prison pipeline phenomenon. For instance, research shows that a significant proportion of the 85,000 people in UK prisons were previously excluded from school during childhood (IPPR, 2017). The correlation between school disengagement, exclusion, and an increased risk of youth violence is emphasised by the Youth Safety Taskforce (Gill, Quilter-Pinner, & Swift, 2017). Hence, adopting alternative strategies to support this vulnerable student population is crucial for society.

TISUK's intervention

An alternative approach to dealing with children and young people (CYP) in a school setting who have suffered ACEs is a trauma-informed practice (TIP) framework. Previous research on TIP indicates that TIP training can immediately affect staff awareness and knowledge. Additionally, it appears to enhance positive interactions between young individuals and practitioners. However, initial findings propose that a comprehensive approach is necessary for substantial changes in practice – a pivotal factor in the TIP theory of change influencing child-level outcomes. This approach combines training with whole organisation strategies, involving senior leadership, training frontline practitioners, and creating a supportive environment that acknowledges and assists practitioners dealing with their own or vicarious trauma. Merely conducting training in isolation is unlikely to achieve the desired results (Molloy, 2022).

TISUK has developed a TIP framework with promising results. TISUK offers a comprehensive training package for schools, equipping all staff with insights into the neuroscience and psychology of psychological trauma and its impact on behaviour, learning, relationships, and mental health. They assist school leadership in fostering a mentally healthy culture by developing trauma-informed policies and practices.

Their approach is rooted in deep knowledge of emotionally healthy and unhealthy organisational environments (Høidal & Hanssen, 2022; Marmot & Brunner, 2005; McIntyre & Mazza, 2020; Sapolsky & Share, 2004) to address disaffection, feelings of undervaluation, isolation, anxiety, depression, and stress-related issues. TISUK also trains staff in creating supportive environments where individuals feel valued and seen, especially during times of stress, enhancing their ability to provide positive student experiences.

Preliminary evidence and rationale for equipoise

Over the last six years, TISUK has collaborated with over 5,000 educational professionals across the UK, including every school in Cornwall, through the HeadStart Kernow project funded by Big Lottery Fund. According to monitoring data collected by TISUK, the experience of schools implementing the TISUK approach suggests positive outcomes, including decreased fixed-term exclusions, suspensions, and incidents of physical restraint. Additionally, there has been an improvement in staff and student well-being, learner engagement, attainment, and attendance. Staff have reported that vulnerable CYP develop trusting relationships with emotionally available adults (EAAs), leading to transformative changes in their trauma recovery. Many school staff delegates have expressed that the training not only transformed their relationships with students at school but also improved their relationships with family members at home. This qualitative evidence suggests that schools could play a role in mitigating mental health disorders and behavioural issues among traumatised children and young individuals.

Furthermore, TISUK's comprehensive efforts align with the UK Government's Green Paper on Children and Young People's Mental Health. The Green Paper emphasizes the effectiveness of adequately trained and supported school staff, such as teachers, school nurses, counsellors, and teaching assistants (TAs), in dealing with mild to moderate mental health concerns. These concerns encompass issues like anxiety, conduct disorder, substance use disorders, and post-traumatic stress disorder (Department of Health and Social Care & Department for Education, 2018).

Despite the intervention showing promise and offering potential benefits, its effectiveness remains uncertain due to the limited availability of robust evidence supporting this approach. Consequently, this trial aims to address this gap and provide valuable insights.

2. Intervention

This section describes the intervention following the Template for Intervention Description and Replication (TIDieR)[2].

Brief name: Trauma Informed Schools UK Training and Implementation

2.1. Who (recipients of the intervention)

The intervention will be implemented across the whole school by improving school staff awareness of TIPs leading to changes in policies and practices that are consistent with TIP.

The whole-school intervention targets primarily school staff who are expected to implement institutional changes but also all CYP attending the school. The intervention encompasses headteachers/school leaders, staff directly working with vulnerable CYP, and the CYP themselves. The TISUK team is responsible for providing school staff with comprehensive training, including whole staff and senior leadership training, network consultancy, and reflective supervision training. Moreover, webinars for staff and students, along with specialized diploma practitioner training for selected teachers, will be facilitated by the TISUK team. A subgroup of more vulnerable CYP will receive extra and targeted support from these practitioner-trained school staff.

2.2. What (physical or information materials used in the intervention)

The intervention will make use of the following resources:

- 4 x Webinars with discussion guides and e-books
- Delegate Handbook (Diploma)
- 'Helping teenagers talk about their lives' cards
- Senior Lead Training e-book
- School wellbeing audit and staff wellbeing questionnaire
- Implementation checklist and RAG rating for network consultancy

2.3. What (procedures, activities and/or processes used in the intervention)

The intervention consists of six activities:

[2] Cochrane Collaboration and Training, C., 2022. Template for Intervention Description and Replication (TIDieR).

1. **Whole staff training**: The entire school staff, including support staff, administrators, and others, will participate in two 3-hour sessions. These sessions aim to provide staff with an overview of what constitutes trauma, its potential impact, ACEs, protective factors, the neuroscience of trauma, and relational approaches. The two sessions will be scheduled with a gap of 2-3 terms, strategically timed to address the decrease in momentum that typically occurs after the initial project launch. The sessions will be conducted virtually, potentially accommodating multiple schools in each training session. These sessions serve as the initial catalyst for staff members. They ignite interest and change attitudes to distressed and vulnerable CYP whilst outlining what is needed to implement a whole school approach. The whole school training lays the foundation for further development of staff understanding and skills as well as empowering each member of the school community to see that they have a role to play.

2. **Senior leadership training**: This training will involve approximately six members (5-7 depending on the size of the school) of the Senior Leadership Team (SLT) from each school. They will attend a 2-day training session focusing on the key elements of creating a trauma-informed and mentally healthy culture, through ethos, policy and practice. The training aims to increase understanding of the effects of trauma, develop skills and understanding to implement effective relational practice, procedure and interventions to break the cycle from ACEs to criminal behaviour and violence. Leadership will be equipped with the tools, materials and knowledge to evaluate and track TIP within their organisation. There is a focus on fostering psychologically safe and inclusive environments and delegates are asked to identify priorities for staff wellbeing and ensure access to EAAs for all. The training will be conducted in cohorts across the project schools, with SLT members from each school attending the training at different times, minimising the impact on the day-to-day running of the school.

3. **Network consultancy support**: Schools will be provided with three consultancy support meetings from an experienced educational consultant at TISUK with each one involving two to three schools. The purpose of this is to support school leaders to embed changes in culture, policy and practice; they will identify and overcome barriers to implementation within the unique context of their school, monitor the quality of provision and identify accurately priorities for improvement as well as opportunities for peer support and the sharing of best practice, ideas and resources.

4. **Diploma practitioner training**: Approximately six staff members (5-7 depending on size of school) will be chosen from each school to undergo a comprehensive 11-day Level 5 Diploma Practitioner Training. This training will be conducted over 5-6 months in 2-day blocks, with a final assessment to complete their accreditation. Delegates will be required to deliver a presentation on the implementation of their new knowledge and skills. TISUK recommend including at least one member from the SLT who has strategic

oversight and can oversee the organisation of resources and interventions and embed practice into policy. Other staff members are likely to be teachers, Special Educational Needs Co-ordinators (SENCOs), pastoral leads or TAs. The training aims to provide these individuals with a deeper understanding of trauma and its recovery process, equipping them with the skills, knowledge and understanding to respond effectively. It covers topics such as identifying protective factors and safety measures within the school culture, skill and knowledge development to provide targeted support to vulnerable children through individual or small group interventions, implementing strategies and approaches to support staff and fostering a trauma-informed school culture, as well as enhancing communication skills to promote and challenge the practices of others. Once trained, these practitioners assume the role of champions within the school; they provide support to students directly and enable them to reflect on painful life experiences. They also collaborate with the SLT to bring about cultural, policy, and practice changes within the school which includes updating and overseeing the school's referral process for vulnerable pupils and integrating TISUK measurement tools into this where appropriate. They receive mentoring throughout the process.

5. **Reflective supervision workshops**: Reflective Supervision is a supportive, respectful and purposeful process which is a vital component of a Trauma Informed School community. The aim of Reflective Supervision is for staff to feel supported enough to reflect with another and to gain further professional insight into work related interactions and patterns of behaviour or underlying emotional need. It is fundamentally concerned with how to best support practitioners, to best support the children with whom they work alongside. TISUK will offer Reflective Supervision training to two practitioners from each school who have completed the 11-day diploma training. These two practitioners will need to access external supervision themselves, but the training aims to equip them with the necessary skills to establish an effective, sustainable reflective supervision model for key staff across their setting.

6. **Webinar viewing for staff and CYP**: Schools will be given access to three webinars for staff and young people to view at a convenient time: 1) *The Neuroscience and Psychology of Relationships,* 2) *The Neuroscience and Psychology of Emotions* 3) *The Psychology of Gangs, Violence and County Lines from People Who Know.* Teachers will be asked to lead a discussion after each of these; guidance will be provided to staff on how to facilitate this. There will also be one webinar for all staff to view*: Conversations that Matter; from racial trauma and discrimination in schools and communities, to respecting and celebrating difference and diversity (policy & implementation).*

Based on TISUK's previous experience, the project is expected to yield the following outcomes within the first 5-6 months:

a. Staff: Increased knowledge, understanding and skills regarding the causes and impact of trauma and how relationship-based approaches can support when working with young people who have experienced past traumatic events. Staff respond to young people in ways that are stress reducing, promote connection and safety and enable CYP to make sense of their experiences.

b. Schools: Enhanced staff support structures, changes in school policies and procedures to create a mentally healthy culture and the creation of psychologically safe environments. This should lead to improved mental health and well-being amongst staff and students and as a result reduced absence and increased engagement.

c. Students: Heightened feelings of safety, improved relationships with EAAs, decreased exclusions, and enhanced attendance, engagement, and academic achievement. Furthermore, students are less likely to demonstrate behaviours that challenge and are at a reduced risk of involvement in crime and violence in the long term.

2.4. Who (intervention providers/implementers)

The intervention was developed by TISUK and will be implemented by quality assured TISUK trainers and consultants. All TISUK trainers and consultants undergo a rigorous interview, training and quality assurance process to become accredited by TISUK. All trainers have extensive experience in education and/or therapeutic work. TISUK's quality assurance process involves observing trainers and providing specific descriptive feedback and development points, support from the senior training team, access to reflective supervision sessions and annual trainer development reviews.

2.5. How (mode of delivery)

All trainings will take place remotely via Zoom, led by TISUK trainers and consultants. Schools will facilitate webinar viewings at a time convenient for them.

2.6. Where (location of the intervention)

The intervention will take place in secondary schools recruited from the below regional geographical areas[3]:

- Greater Manchester (Manchester, Tameside, Salford, Bolton)

[3] The areas of scope has broaden during the co-design phase to increase the achieved sample at school (cluster) level and ensure sufficient statistical power

- West Midlands (Birmingham, Staffordshire, Sandwell, Dudley, Solihull, Stoke-on-Trent, Wolverhampton)
- South West (Gloucestershire, Somerset, Bristol City, Bournemouth/Christchurch/Poole, Devon, Wiltshire)
- London (Harrow, Newham, Bromley, Lambeth, Hounslow)
- East of England (Bedford, Norfolk, Cambridgeshire, Essex, Hertfordshire)
- Yorkshire and the Humber (East Riding of Yorkshire, Leeds, Wakefield, North Yorkshire)
- East Midlands (Nottinghamshire, Lincolnshire, Leicestershire, Derby, Northamptonshire)
- North East (Northumberland, Hartlepool, Darlington, Sunderland, North Tyneside, South Tyneside)
- North West (Blackburn with Darwen, Cheshire West and Chester, Cheshire East)
- South East (Kent, Hampshire, Surrey, Brighton and Hove, Bracknell Forest)

2.7. When and how much (duration and dosage of the intervention)

The intervention encompasses various components, to include: 2x 3 hours of training for the entire staff, 11 hours of training for senior leaders, 7.5 hours of network consultancy, 20 hours of reflective supervision workshops, 6 hours of webinar input with discussion for staff and students, and 60.5 hours of training for diploma practitioners.

Recruitment of schools has taken place from June 2023 when information sheets were sent out. The Memorandum of Understandings (MoUs) should be returned by schools a month before baseline data collection which will be undertaken in the Autumn term 2023. The duration of the TISUK intervention will be four school terms from Jan 2024 - March 2025.

2.8. Theory of change

A **theory of change** is depicted in Appendix 1.

The theory of change begins with recognising two main issues. Firstly, CYP experience a range of challenges, including ACEs, which can lead to long-term physical and mental health issues, school exclusions, and various social problems such as crime, violence, addiction, and poverty. Secondly, the school staff lack adequate empowerment and training in TIPs. The proposed

intervention is whole-school strategy that aims to empower school staff in delivering changes in policies and practices following TIP.

The successful implementation of the intervention depends on critical resources: TISUK trainers, delegates chosen from schools, school personnel, senior school leaders, consultants, training materials, and quality assurance of TISUK trainers. Section 2 above has described the set of activities as part of the intervention.

The central hypothesis of this intervention is that training school staff and raising awareness through workshops and webinars (activities) will result in a change in policy and practices at the school level (outputs). Thus, the resulting outputs of such activities are:

- New policies and practices fostering psychological safety, emotional regulation, and mentalisation
- New systems to identify and address the needs of all CYP
- New reflective supervision for key staff
- Schools educate CYP about the neurochemistry of mental health
- Schools identify skilled EAAs for vulnerable children
- New targeted interventions for CYP with a trauma history

The short-term outcomes of such cultural changes and new practices at the whole school level would be:

- New restorative practices
- Enhanced staff awareness of childhood adversity
- Shift in staff attitudes towards distressed and vulnerable CYP
- Staff relation to CYP from a position of social engagement rather than social defence
- School staff can now effectively manage children who are experiencing dysregulation
- CYP gain a better understanding about the neurochemistry of mental health
- Reflective conversations with CYP about painful life experiences

The intervention pathways bring about several positive impacts:

- CYP externalising behaviour decrease
- School exclusions for CYP reduce

- CYP experience improved mental well-being
- CYP develop a stronger sense of belonging

Additionally, the intervention would impact school staff positively. Their attendance, engagement, retention, and well-being are expected to improve. Ultimately, the school community transforms into one with a mentally healthy culture where everyone feels valued and included. It becomes a welcoming and inclusive environment that promotes psychological safety.

The pathways rely on assumptions that will be tested through an implementation and process evaluation (IPE) – see section 5. The **main underlying assumptions** are:

1. Resources are in place for the delivery of activities
2. All relevant stakeholders (delivery team, school staff) are actively engaged with the intervention
3. Activities are delivered in frequency and dose as intended
4. Outreach is achieved in numbers and by category of stakeholder/participant as intended
5. Activities are delivered with high quality
6. Schools implement changes as a result of the intervention (intended outputs)
7. Schools staff change attitudes and awareness resulting from the new practices (outcomes)

3. Impact evaluation

This trial is designed to address primary and secondary research questions related to the respective primary and secondary outcomes at CYP and school staff levels. This section sets out the research questions for the efficacy trial, the research design, the randomisation approach, the participants and the sample size calculations.

3.1. Research questions (efficacy)

Primary research questions

The primary **research question at the CYP level** is:

- ERQ1: What is the mean difference in externalising behaviour, measured by the Strengths and Difficulties Questionnaire **(SDQ) subdomains of Conduct Problems and**

Hyperactivity, between CYP in intervention settings receiving TISUK training and CYP in control settings receiving business as usual at follow-up?

Secondary research questions

The secondary **research questions at CYP** level are:

- ERQ2: What is the mean difference in internalising behaviour, measure by the Strengths and Difficulties Questionnaire **(SDQ) subdomains of Emotional Problems and Peer Problems,** between CYP in intervention settings receiving TISUK training and CYP in control settings receiving business as usual at follow-up?

- ERQ3: What is the mean difference in prosocial behaviour, measured by the **SDQ subdomain of Prosocial behaviour,** between CYP in intervention settings receiving TISUK training and CYP in control settings receiving business-as-usual at follow-up?

- ERQ4: What is the mean difference in Total Difficulties, measured by the **SDQ subdomain of Conduct Problems, Hyperactivity, Emotional Problems and Peer Problems,** between CYP in intervention settings receiving TISUK training and CYP in control settings receiving business-as-usual at follow-up?

- ERQ5: What is the mean difference in non-psychotic psychological distress, measured by the **General Health Questionnaire (GHQ),** between CYP in intervention settings receiving TISUK training and CYP in control settings receiving business as usual at follow-up?

- ERQ6: What is the mean difference in well-being, measured by the **Short Warwick Edinburgh Well-being Scale** (**SWEMWBS**), between CYP in intervention settings receiving TISUK training and CYP in control settings receiving business as usual at follow-up?

- ERQ7: What is the mean difference in the sense of connectedness, measured by the **School Connectedness Scale**, between CYP in intervention settings receiving TISUK training and CYP in control settings receiving business as usual at follow-up?

- ERQ8: What is the mean difference in the percentage of exclusions[4] between CYP in intervention settings receiving TISUK training and CYP in control settings receiving business as usual at follow-up?

[4] ERQ8 to ERQ11 is based on administrative data

- ERQ9: What is the mean difference in the percentage of suspensions between CYP in intervention settings receiving TISUK training and CYP in control settings receiving business as usual at follow-up?

- ERQ10: What is the mean difference in the percentage of attendance between CYP in intervention settings receiving TISUK training and CYP in control settings receiving business as usual at follow-up?

- ERQ11: What is the mean difference in all primary and secondary CYP outcomes between CYP in intervention settings who received TISUK training and CYP in control settings who received business as usual, considering sub-group analysis by sex, ethnicity, and free school meal (FSM) eligibility?

The secondary **research questions at the school staff level** are:

- ERQ12: What is the difference in attitudes related to trauma-informed care (TIC) of school staff, measured by the **Attitudes Related to Trauma-Informed Care** (**ARTIC**) survey, between school staff in the intervention setting receiving TISUK training and school staff in control settings receiving business as usual at follow-up?

- ERQ13: What is the difference in well-being, measured by the **SWEMWBS,** between school staff in the intervention setting receiving TISUK training and school staff in control settings receiving business as usual at follow-up?

The secondary **research questions at the school level** are:

- ERQ14: What is the difference in the percentage of school staff retention[5] at the school level between schools in the intervention setting receiving TISUK training and schools in control settings receiving business as usual at follow-up?

- ERQ15: What is the difference in the percentage of school staff sickness at the school level between schools in the intervention setting receiving TISUK training and schools in control settings receiving business as usual at follow-up?

- ERQ16: What is the difference in the percentage of CYP suspensions at the school level between schools in the intervention setting receiving TISUK training and schools in control settings receiving business as usual at follow-up?

[5] ERQ14 to ERQ19 are based on administrative data

- ERQ17: What is the difference in the percentage of CYP exclusions at the school level between schools in the intervention setting receiving TISUK training and schools in control settings receiving business as usual at follow-up?

- ERQ18: What is the difference in the percentage of CYP school attendance in the targeted years at the school level between schools in the intervention setting receiving TISUK training and schools in control settings receiving business as usual at follow-up?

- ERQ19: What is the difference in the percentage of CYP school suspensions/exclusions/attendance in the targeted years at the school level between schools in the intervention setting receiving TISUK training and schools in control settings receiving business as usual at follow-up, considering sub-group analysis by sex, ethnicity, and free school meal (FSM) eligibility?

In addition to the above research questions, the evaluation team will monitor any unintended consequence of the intervention or serious negative effect.

3.2. Design

This efficacy trial will be a two-arm, cluster-randomised controlled trial (cRCT). A maximum of 100 schools will be recruited from across England. These schools will be randomly assigned to either the treatment group (TISUK) or the control group (business as usual). Every school that signs up to take part in the trial will have an equal probability (50%) of being assigned to the treatment or control groups.

Business-as-usual (BAU)

The **business-as-usual** will be captured at baseline by asking schools interested in joining the trial to explain their current and past approach to trauma and supporting vulnerable CYP. The mapping exercise will also capture staff ratios, specialist support available (e.g., counsellors, Speech and Language Therapist), and other programmes the school may be engaging with (e.g., National Education Nature Park).

In addition, we will conduct a short survey at **six and 12 months from the start of the intervention** targeting one key staff member within schools in the control arm, such as the Headteacher or Senior Mental Health Lead. This survey aims to gather essential information regarding mental health, wellbeing, and trauma-informed training available to school staff in the control group.

The survey will consist of the following questions:

- What mental health/well-being or trauma-informed training is available to staff?

- How many (or what proportion of) staff have completed the training in the past 6 months?
- Is the school currently involved in any specific interventions, trials or initiatives relating to pupil or staff mental health, well-being or behaviour?
- What is the school currently doing about:
    - Promoting positive behaviour
    - Reducing externalising behaviour
    - Addressing absenteeism / non-attendance
    - Promoting a sense of school connectedness among pupils and staff
    - Promoting staff wellbeing

Trial phases

The project is divided into three main phases: **pre-intervention, intervention, and post-intervention**.

The **pre-intervention phase (April 2023 - December 2023)** foresees four main activities:

- Research design & ethics
- Recruitment
- Baseline assessment
- Randomisation

Research design & ethics

The evaluation team will complete the necessary protocol and prepare important documents for school recruitment, such as the MoU and opt-out letters for staff to distribute to parents/carers. We will also develop data collection tools, semi-structured interview topic guides and observation protocols.

The MoU will set out the expectations for participating schools. By entering into this agreement, schools that join the intervention and receive the treatment are unable to opt-out of the evaluation. In other words, delivering the intervention automatically entails joining the evaluation as well. The MoU stresses that the school staff are expected to commit to completing the staff outcome surveys as a fundamental part of signing up for the trial.

All the documents related to the research design and data collection activities will be submitted for ethics approval to the University of Kent ethical committee.

Recruitment

During this phase, TISUK will collect expression of interest from potential schools within eligible areas and collect signed MoUs from schools who meet the inclusion/exclusion criteria. More detail on the recruitment process is given in sections 3.3.

Baseline assessment

Baseline assessment will be conducted on all schools that are recruited into the trial before each school is allocated to intervention or control arm. Section 4 below describes the baseline measures and timing of data collection.

Randomisation

Eligible schools for randomisation (recruited by the delivery team) will be randomly assigned one of two groups, and implementation will commence. More detail on the randomisation process is given in section 3.4 below.

In **the intervention phase (January 2023 – February 2025)**, schools in the intervention group will actively participate in the TISUK programme and implement the structural changes, while schools in the control group will continue BAU.

The evaluation team will monitor adherence to the intervention in schools within the intervention arm and BAU in the control group. More detail on compliance and monitoring adherence is provided in section **Error! Reference source not found.** and 5.

The post-intervention phase (March 2025 – September 2025) consists in three main activities:

- Outcome assessment
- Data analysis and reporting
- Data archiving

Outcome measurement

The evaluation team will conduct data collection for the primary and secondary outcomes once the intervention has finished, that is, by February 2025. This data collection will be conducted on all schools regardless of their arm. More detail on outcomes and sources are discussed in section 4.

Data analysis and reporting

During this phase, the evaluation team will prepare qualitative and quantitative data and undertake the analysis. The results of the data analysis will be incorporated into a draft evaluation report, expected in September 2025, delivering a final version in December 2025.

Incentives

We will introduce financial contributions for schools across both treatment and control groups in this project considering the following principles:

- **Bias**: equal incentives for both arms minimises any potential behavioural bias and self-selection
- **Fairness**: regardless of what they receive (treatment or not), both types of schools face the same data collection burden for the efficacy trial
- **Financial compensation**: considering the estimated amount is expected to cover only the costs, we do not foresee adding a distortion or bias per se but minimising the impact on the school budget. Hence, the financial contribution is an economic compensation for staff time rather than an incentive to participate in the trial for financial gain.
- **Easing recruitment:** a financial contribution may help mitigate the potential unwillingness of schools to take part due to foreseen impact on the school budget. Considering the contribution amount, we do not think this would introduce a distortive incentive but instead send a reassuring signal to potentially interested schools.

The estimation of the contribution and the disbursement timing are the following:

- £500 per school for all schools in the intervention and control group with a first payment of £250 at the completion of baseline data collection and a second payment of £250 at the end of the data collection process in the follow-up phase
- £500 per school for those schools recruited for case studies after the completion of data collection

Table 1 Trial design

Trial design	**Two-arm and cluster randomised at school level**
Unit of randomisation	**School**

Stratification variables (if applicable)		**Median of percentage of pupils eligible for Free School Meals (FSM)**
Primary outcome	variable	**(CYP) Externalising behaviour**
	measure (instrument, scale, source)	**SDQ – Combined conduct and hyperactivity scale scores (0-20) (Survey)**
Secondary outcome(s)	variable(s)	**(CYP) Internalising behaviour** **(CYP) Prosocial behaviour** **(CYP) Total difficulties** **(CYP) Non-psychotic psychological distress** **(CYP) Well-being** **(CYP) Sense of connectedness** **(CYP) Exclusions & suspensions** **(CYP) School attendance** **(School staff) Attitudes related to TIC** **(School staff) Well-being** **(School) Staff retention** **(School) Staff sickness** **(School) Exclusions & suspensions of CYP** **(School) School attendance of CYP**
	measure(s) (instrument, scale, source)	**(CYP) Internalising behaviour:** SDQ – Combination of emotional regulation and peer problems (0-20) (Survey) **(CYP) Prosocial behaviour:** SDQ – sub-dimension of prosocial behaviour (0-10) (Survey) **(CYP) Total difficulties:** SDQ – Combination of sub-dimensions of conduct, hyperactivity, emotional regulation, and peer problems (0-20) (Survey) **(CYP) Non-psychotic psychological distress**: General Health Questionnaire (GHQ12) (0-12) (Survey)

		(CYP) Well-being: Short Warwick Edinburgh Mental Well-being Scale (7-35) (Survey) **(CYP) Sense of connectedness:** School Connectedness Scale (Survey) **(CYP) Exclusions & suspensions:** administrative records **(CYP) School attendance:** administrative records **(School staff) Attitudes related to TIC:** Attitudes Related to Trauma Informed Care (ARTIC) (Survey) **(School staff) Well-being:** Short Warwick Edinburgh Mental Well-being Scale (7-35) (Survey) **(School) staff retention:** administrative records **(School) staff sickness:** administrative records **(School) Percentage of exclusions & suspensions of CYP:** administrative records **(School) Percentage of school attendance of CYP:** administrative records
Baseline for primary outcome	variable	**(CYP) Externalising behaviour**
	measure (instrument, scale, source)	**SDQ – Combined conduct and hyperactivity scale scores (Survey)**
Baseline for secondary outcome	variable	**(CYP) Internalising behaviour** **(CYP) Prosocial behaviour** **(CYP) Total difficulties** **(CYP) Non-psychotic psychological distress** **(CYP) Well-being (CYP) Sense of connectedness** **(CYP) Exclusions & suspensions** **(CYP) School attendance** **(School staff) Attitudes related to TIC** **(School staff) Well-being** **(School) Staff retention**

		(School) Staff sickness **(School) Percentage of exclusions & suspensions of CYP** **(School) Percentage of school attendance of CYP**
	measure (instrument, scale, source)	**(CYP) Internalising behaviour:** SDQ – Combination of emotional regulation and peer problems (0-20) (Survey) **(CYP) Prosocial behaviour:** SDQ – sub-dimension of prosocial behaviour (0-10) (Survey) **(CYP) Total difficulties:** SDQ – Combination of sub-dimensions of conduct, hyperactivity, emotional regulation, and peer problems (0-20) (Survey) **(CYP) Non-psychotic psychological distress**: General Health Questionnaire (GHQ12) (Survey) **(CYP) Well-being**: Short Warwick Edinburgh Mental Well-being Scale (Survey) **(CYP) Sense of connectedness:** School Connectedness Scale (Survey) **(CYP) Exclusions & suspensions:** administrative records **(CYP) School attendance:** administrative records **(School staff) Attitudes related to TIC:** Attitudes Related to Trauma Informed Care (ARTIC) (Survey) **(School staff) Well-being:** Short Warwick Edinburgh Mental Well-being Scale (Survey) **(School) staff retention:** administrative records **(School) staff sickness:** administrative records **(School) Number of exclusions & suspensions of CYP:** administrative records **(School) School attendance of CYP:** administrative records

3.3. Randomisation

A team from the University of Kent will conduct the randomisation, operating independently from the evaluation team at Ipsos UK. The University of Kent will be provided with a list of schools without school names but marked with ID codes, ensuring they cannot discern the

schools' identities, thus maintaining blindness during the randomisation procedure. As a cluster trial, schools will be randomly allocated to the treatment or control group after screening (see section 3.4 below for the inclusion/exclusion criteria).

Simple randomisation balances confounding factors and provides unbiased average estimates (Morgan & Rubin, 2012). However, within a specific experiment, an uneven distribution of covariates might persist – both observed and unobserved – even after randomisation. Disproportionate distribution of crucial covariates among treatment groups can impact the analysis and interpretation of outcomes. While adjusting for this *post hoc* is possible, this method is less efficient than achieving balanced groups from the outset. Furthermore, it is not feasible when all individuals with specific characteristics are assigned to a single treatment group (Bruhn & McKenzie, 2009).

One approach to address this imbalance is randomising through minimisation which conduct the randomisation stratifying on one or more variables. In its simplest form, minimisation involves creating groups based on sampling variables and other relevant measures related to student achievement. In the current study context, schools are randomly assigned based on whether they are above or below the median proportion (%) of pupils with FSM6 (Median and below, above Median). The FSM6 indicator captures the history of pupils' eligibility for free school meals[6].

Initially, the plan was to randomise using FSM6 in conjunction with school geographic locations. However, with the increasing number of eligible trial areas and strata included to ensure adequate recruitment, there was a significant decrease in the number of schools per stratum. As Roberts and Torgerson (1998) discussed, stratification is more efficient when the number of strata decreases. Consequently, the geographic area as a factor was dropped, relying only on FSM6 for randomisation, ensuring a more efficient approach.

The randomisation process underwent a minor amend, now conducted in two batches, to provide schools ample time to implement the survey, thus maximising response rates and statistical power. The initial batch took place in early December 2023, involving schools that completed baseline testing by that time, while the second batch occurred in early January 2024, encompassing the remaining schools that completed baseline testing throughout December and January.

[6] This refers to the situation when a student holds a historical FSM status. Following their FSM eligibility end date, they will retain the "Ever 6 FSM" classification for the subsequent six years. To illustrate, if a student was eligible for FSM from 1st September 2018 until 31st October 2020, their Ever 6 FSM status will continue until 31st October 2026, encompassing a 6-year duration beyond their FSM end date.

The randomisation process is blind to both the evaluation and the delivery team. The delivery team will be informed of the allocation to initiate the training.

3.4. Participants

Recruitment for the trial will be managed by the delivery team and done at the school level, according to the following recruitment activities:

- Contacting virtual heads and local authority mental health leads who have expressed an interest in trauma-informed training in areas where TISUK have not run courses.
- Attending virtual head meetings to give an outline of the project.
- Encouraging partners who express interest to create links/share with contacts in neighbouring regions to increase the recruitment scope.
- Distributing briefing notes/information sheets through partners in these areas asking for EOI from schools.
- Schools are invited to attend regular online information briefings to find out more about TISUK.

Three 1.5-hour project specific information briefings held in July 2023.

The delivery team will focus recruitment efforts on those schools that expressed interest in the trial.

Eligible schools to the trial must satisfy the following **inclusion criteria**:

- Located within the target area[7]

Schools will not be selected if they meet any of the below **exclusion criteria**:

- Schools should not have a staff member who has completed the TISUK 11-day diploma
- Schools should not have received TISUK whole staff training in the last three years.

[7] The target includes the following areas: Greater Manchester, Greater London, West Midlands, Gloucestershire, Somerset, Bristol, West Yorkshire, South Yorkshire, Merseyside, Tyne and Wear, East Sussex, Norfolk, Northumberland, Bedfordshire, Hertfordshire, Cambridgeshire, East Riding of Yorkshire, Darlington, Northamptonshire, Lincolnshire, Essex, Cheshire, Leicestershire, Bournemouth, Christchurch and Poole, Southampton, Kent, Shropshire, Devon, Bolton, Kingston upon Hull, Herefordshire, Wiltshire, Surrey, Hampshire, North Yorkshire, Derby, Swindon, Nottinghamshire

- If a member of staff has completed TISUK SLT or SMHL training, then they should not have made changes to policy or wider staff practice within the school (e.g., staff training around PACE).
- Schools should not have received intensive training around TIP and implementation from a different provider within the last three years.
- Be a fee-paying school
- Be alternative provision or special schools with 'SEMH' focus.

The delivery team will focus recruitment efforts in the above three locations although additional areas may be considered if the number of schools recruited does not reach the desired sample size.

There are two levels of participation for CYP in the intervention arm of the study. At a whole school level, the intervention targets school staff who will implement structural changes in policies and practices that ultimately impact all CYP in that school. Outcomes will be measured for a single-year group (Year 8).

At a targeted level, one aspect of the intervention involves training diploma practitioners who will target a sub-group of CYP across the school with a trauma history and provide tailored support. This sub-group of CYP is made up of children who already receive targeted support within the school and so will continue to do so but making use of new skills and knowledge provided by the intervention. Additionally, the measurement tools diploma delegates access through TISUK sessions (ACEs/resilience questionnaire/developmental deficit and gang affiliation checklists and school bonding survey) are integrated into this process.

As this population is only identified in intervention schools, a study within a trial (SWAT) will be undertaken focussing on those identified for this additional support who are in Year 8 (and so are already included in the outcomes measurements for the trial). As the control group cannot be randomised, a quasi-experimental design is appropriate creating a control group using a propensity score matching (PSM) approach. Section 4.1 and Appendix 2 discuss this in detail.

3.5. Sample size calculations

The sample sizes presented in Table 4 have been calculated using Stata 17© according to the following assumptions:

1. No pre-post correlations are assumed as there are no reliable sources of these for externalising behaviours and estimating them would add uncertainty to the final

sample size calculation. By omitting this parameter, we obtain a conservative estimate of sample size for an analysis of covariance.

2. The adolescent population SDQ (externalising scale) mean is 6.0 and the assumed pooled Standard Deviation (SD) is 1.74[8], using the UK self-report population norms for 11-15 year olds[9]. Thus, to detect an effect size of 0.2 or greater we need a SDQ externalising behaviours score difference of 6.0 (control) versus 5.66 (intervention). This difference requires 527 participants in each group, 1,054 for the whole sample.

3. Assuming 10% pupil-level attrition between baseline and follow-up requires a total sample size of 1,172.

4. Following Shackleton, Hale, Bonell, and Viner (2016) and Parker, Nunns, Xiao, Ford, and Ukoumunne (2021), with an ICC of 0.03 and a harmonic mean year group of 200 pupils, based on the average year group size in England of 197 (ONS, 2023) of whom 80%, 160, will consent to participate, the design effect is 5.8 (1+(0.03*160)), which inflates the sample to 6,798 (5.8*1,172).

5. Given assumptions 1 to 4 above, we need a minimum of at least 25 schools in each arm for an efficient cluster trial, that is 50 schools in total. Nevertheless, we propose double the sample size aiming to recruit 100 schools with 50 on each arm. The rationale for this is further discussed below. Table 2 provides an overview of the numbers available at the primary endpoint for a variety of school retention rates (100%, 90%, 80%, 70%, 60%) and pupil retention rates (100%, 90%, 80%, 70% and 60%) scenarios. In all scenarios the numbers recruited and followed up are sufficient to meet the sample size requirements when we account for the different design effects (i.e., as more pupils drop out, the design effect, which is a function of the cluster size, decreases, hence the overall sample size decreases).

Table 2 Impact of different pupil and school retention rates on sample size

		Proportion of pupils retained				
		100%	90%	80%	70%	60%
Number of schools retained	100	16,000	14,400	12,800	11,200	9,600

[8] The SD has been estimated as the standardised SD using the same raw data for both scales

[9] https://www.sdqinfo.org/norms/UKNorm1.pdf

	90	14,400	12,800	11,200	9,600	8,640
	80	12,800	11,200	9,600	8,640	7,680
	70	11,200	9,600	8,640	7,860	6,720
	60	9,600	8,640	7,860	6,720	5,760

Table 3 Impact of different pupil and school retention rates on MDES

		Proportion of pupils retained				
		100%	90%	80%	70%	60%
Number of schools retained	100	0.1064	0.1074	0.1086	0.1102	0.1122
	90	0.1122	0.1132	0.1145	0.1161	0.1183
	80	0.1190	0.1201	0.1214	0.1232	0.1255
	70	0.1272	0.1284	0.1298	0.1317	0.1341
	60	0.1374	0.1385	0.1402	0.1422	0.1449

Several considerations come into play to target 100 schools and 16,000 young people. First, a larger pool of schools increases the likelihood of recruiting a diverse population of school types (e.g., school-level of deprivation, FSM, different socioeconomic backgrounds) and student demographics, enabling robust subgroup analyses and generalizability of findings across various contexts. Second, a large overall sample size enhances statistical power to detect smaller but potentially meaningful intervention effects, minimising the risk of false negatives and providing reliable findings to inform future interventions. Third, the target sample size was selected to ensure sufficient power for the quasi-experimental design (QED) analysis focused on a targeted subgroup of students. Lastly, a larger sample size accommodates the cluster randomised trial design, accounting for potential clustering effects and maintaining adequate power for the primary analysis.

The sample size calculation has also considered **the trade-off between internal/external validity and ethical considerations**. Thus, outcomes will be measured on a specific cohort rather than the whole school population to minimise the burden on schools, school staff, and students while achieving efficient data collection. Through co-production workshops with teachers and a youth advisory board, the Year 8 cohort (2023/2024) was carefully selected as the appropriate group for measurement.

Table 4 Sample size calculations

		Scenario 1
Minimum Detectable Effect Size (MDES)		**0.1064**
Pre-test/ post-test correlations	level 1 (participant)	n/a
	level 2 (cluster)	n/a
Intracluster correlations (ICCs)	level 1 (participant)	n/a
	level 2 (cluster)	**0.03**
Alpha		**0.05**
Power		**0.8**
One-sided or two-sided?		**2**
Average cluster size (if clustered)		**160**[10]
Number of clusters	Intervention	**50**
	Control	**50**
	Total	**100**

[10] Average school size in England is 986, average year size is 200 and accounting for a potential 20% not consenting, hence, cluster size 160.

		Scenario 1
Number of participants	Intervention	**8,000**
	Control	**8,000**
	Total	**16,000**

4. Outcome measures

The impact of the intervention is measured through a primary outcome at the CYP level, the combined conduct and hyperactivity scale scores from the Strengths and Difficulties Questionnaire (SDQ) at CYP level, and a list of secondary outcomes at CYP, school staff and school level. Table 5 sets out the primary and secondary outcomes.

Table 5 Primary and secondary outcomes

Outcome	Primary / Secondary	Level	Scales of instrument	Description and source
Externalising behaviours	Primary	CYP	SDQ – combined conduct and hyperactivity scales (0-20)	The Strengths and Difficulties Questionnaire (SDQ) is a brief questionnaire designed to assess behavioural patterns in children and adolescents aged 3-16. It consists of 25 items covering various psychological attributes, including positive and negative aspects. YEF utilises the Strengths and Difficulties Questionnaire in all its projects (where appropriate) to ensure uniformity and facilitate comparisons across various evaluations. Further information about the SDQ is available here: https://www.sdqinfo.org/.

Outcome	Primary / Secondary	Level	Scales of instrument	Description and source
				Data will be collected electronically by the evaluation team (Ipsos) using Dimensions[11].
Internalising behaviour	Secondary	CYP	SDQ – combined emotional problems and peer problems scales (0-20)	SDQ Data will be collected electronically by the evaluation team (Ipsos) using Dimensions.
Prosocial behaviour	Secondary	CYP	SDQ – Prosocial behaviour scale (0-10)	SDQ Data will be collected electronically by the evaluation team (Ipsos) using Dimensions.
Total difficulties	Secondary	CYP	SDQ – Total score (sum of internalising and externalising behaviours scales (0-40)	SDQ Data will be collected electronically by the evaluation team (Ipsos) using Dimensions.
Non-psychotic psychological distress	Secondary	CYP	General Health Questionnaire (GHQ-12)[12] - total score, depression, anxiety and	The self-administered questionnaire serves to identify non-psychotic and minor psychiatric disorders. Clinicians widely employ it as an initial screening method for assessing individuals within the general population and in a community or non-psychiatric clinical settings such as primary care or general medical outpatient facilities. Suitable for

[11] Dimensions is a software developed by Ipsos to conduct surveys, similar to Qualtrics.

[12] Goldberg D, Williams P. A user's guide to the General Health Questionnaire. Windsor: NFER-Nelson; 1988

Outcome	Primary / Secondary	Level	Scales of instrument	Description and source
			confidence sub-scales	adolescents and adults, the questionnaire consists of 12 questions. Data will be collected electronically by the evaluation team (Ipsos) using Dimensions.
Children's well-being	Secondary	CYP	Short Warwick Edinburgh Mental Well-being Scale[13]	The SWEMWBS is a shortened version of the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) that was created to facilitate the monitoring of mental well-being within the general population. It is also used to assess the effectiveness of projects, programs, and policies to enhance mental well-being. The SWEMWBS comprises seven out of the 14 statements found in the WEMWBS, explicitly focusing on thoughts and feelings related to functioning rather than pure emotions. The seven statements in the SWEMWBS are phrased positively and offer five response options ranging from "none of the time" to "all of the time." Children and young individuals are requested to reflect on their experiences over the past two weeks. More info on SWEMWBS is available at https://www.corc.uk.net/outcome-experience-measures/short-warwick-edinburgh-mental-wellbeing-scale-swemws/ Data will be collected electronically by the evaluation team (Ipsos) using Dimensions.

[13] Clarke, A., Putz, R., Friede, T., Ashdown, J., Adi, Y., Martin, S., Flynn, P., Blake, A., Stewart-Brown, S. & Platt, S. (2010). Warwick-Edinburgh mental well-being scale (WEMWBS) acceptability and validation in English and Scottish secondary school students (The WAVES Project). NHS Health Scotland; http://www.healthscotland.scot/media/1720/16796-wavesfinalreport.pdf.

Outcome	Primary / Secondary	Level	Scales of instrument	Description and source
Sense of connectedness (ERQ5)	Secondary	CYP	School Connectedness Scale[14]	The scale consists of 10 items designed to evaluate the interpersonal connection individuals experience within their social environment. Participants rate their responses on a Likert scale, ranging from 1 (strongly disagree) to 6 (strongly agree). This tool will measure the sense of belonging at the school level. More information on this instrument is available here: https://doi.org/10.1007/s12187-020-09726-8 Data will be collected electronically by the evaluation team (Ipsos) using Dimensions.
Percentage of exclusions, suspensions and attendance	Secondary	CYP	% of each indicator at CYP level	This will be collected through the SIMS or a similar database recorded by schools.
Attitudes related to TIC	Secondary	School Staff	Attitudes Related to Trauma Informed Care (ARTIC-45)	The ARTIC is a psychometrically valid Trauma-Informed Care (TIC) measure documented in peer-reviewed literature. Its development emerged through a collaborative effort between the Traumatic Stress Institute of Klingberg Family Centers and Dr Courtney Baker from Tulane University. The primary objective of the ARTIC is to assess the positive or negative attitudes of service providers towards TIC. It operates on the foundational belief that staff attitudes significantly influence their behaviours, and the real-time behaviours of staff play

[14] Lee, R. M., Draper, M., & Lee, S. (2001). Social connectedness, dysfunctional interpersonal behaviors, and psychological distress: Testing a mediator model. Journal of Counseling Psychology, 48(3), 310.

Outcome	Primary / Secondary	Level	Scales of instrument	Description and source
				a pivotal role in the successful implementation of TIC. What sets ARTIC apart is its unique approach. While numerous self-assessment tools have been designed to evaluate organisational aspects of TIC implementation (such as screening, training, treatment models, and policies), the ARTIC focuses specifically on measuring staff attitudes. For more information on ARTIC see: https://www.traumaticstressinstitute.org/the-artic-scale/ Data will be collected electronically by the evaluation team (Ipsos) using Dimensions.
Staff well-being	Secondary	School staff	Short Warwick Edinburgh Mental Well-being Scale	See above on the same measure for CYP
Proportion of school staff retention	Secondary	School	Staff retention rate as a percentage of total staff	This will be collected through the SIMS or a similar database recorded by schools
Proportion of staff sickness	Secondary	School	Staff sickness rate as a percentage of total staff	This will be collected through the SIMS or a similar database recorded by schools
Number of exclusions	Secondary	School	CYP exclusion rate as a percentage of total CYP	This will be collected through the SIMS or a similar database recorded by schools

Outcome	Primary / Secondary	Level	Scales of instrument	Description and source
Number of suspensions	Secondary	School	CYP suspension rate as a percentage of total CYP	This will be collected through the SIMS or a similar database recorded by schools
Number of attendance	Secondary	School	CYP attendance rate as a percentage of total CYP	This will be collected through the SIMS or a similar database recorded by schools

We will measure primary and secondary outcomes at CYP, staff and school levels at baseline. The follow-up data collection of all primary and secondary outcomes will happen 15 months after baseline data collection to allow outcomes to become apparent, namely, in the post-intervention stage. This is expected to occur in March-April 2025.

Surveys will be administered to pupils via an online survey link using Ipsos's survey software (Dimensions) sent to schools during baseline and follow-up data collection periods. School staff will be supported in the administration of the survey via our **School liaison officer** who will provide detailed instructions on the administration procedure, respond to questions and provide technical support as required.

Schools will be asked to administer the survey to the target year group (Year 8) in whole class, or smaller, groups in ICT or computer rooms with one child allocated to each computer. A member of school staff will be present throughout and provide short instructions (script provided) before and after the surveys are complete. Paper copies will be provided on request for those who need them. The survey will take approximately 15 minutes to complete.

The survey link will include an introductory page highlighting confidentiality, right to withdraw and data protection procedures written in accessible and child-friendly language. Each pupil will be asked for their assent to take part by providing their name and class name before clicking through to the start of the survey. Name/class information, date of birth, ethnicity and sex will be used to match baseline and follow-up data and identify Unique Pupil Number.

Data on staff well-being and attitudes to trauma will be gathered though a survey. Staff will be asked for their consent to take part before starting the survey. The **administrative records** will be gathered from schools coordinated by our School liaison officer accessing SIMS or any other corresponding database managed by schools at baseline and at the end of the intervention, corresponding to two academic years.

4.1. Analysis

The analysis will be conducted using an analysis by intention to treat (ITT) and will include all available data maintaining participants as members of their allocated group. The primary analysis will likely take the form of a linear regression model, adjusted for baseline stratification covariates (above/below the median proportion of FSM6) and the baseline value of the outcome. As there is variation across sites, a multi-level model will be applied, considering pupils are nested within schools (random effect).

As discussed in section 3.3 the minimisation method incorporates %FSM6 as a stratifying factor, ensuring that schools with similar levels of FSM6 are evenly distributed across the control and intervention conditions. After baseline testing, the evaluation team will check balances across arms. If, by chance, randomisation had not achieved the desired balance on those key socio-demographic characteristics that may affect outcomes, we may consider a multilevel analysis of covariance (ML-ANCOVA) as an additional model to test the robustness of our results. Nevertheless, if the randomisation incorporates % of FSM, it is unlikely that there is an imbalance across arms on FSM.

Secondary outcomes will be assessed similarly by establishing diagnostic plots to identify the most appropriate regression approach, including stratification factors and baseline covariates within a multi-level model. Diagnostic plots are graphical tools used to assess the assumptions and fit of a statistical model. These may include residual plots (e.g., residuals vs. fitted values, normal Q-Q plots) to check for non-linear patterns, unequal variance, outliers, and normality assumptions. Partial regression plots can be used to examine the relationship between the outcome and specific predictors, while leverage plots help identify influential observations. Additionally, added variable plots can assess the linearity assumption between the outcome and predictors. Outcomes at individual level (CYP and school staff) will be approached through multi-level analysis, while outcomes at the school level will be done through linear regression.

Stepwise regression analysis will be performed to model the relationship between pre-randomisation factors and demographics on observed outcomes at 15 months. Interaction terms with the allocation arm will be included in the analysis, and a significance level of 0.1 will be used to determine which factors are to be included in the regression model. Pre-

randomisation factors will include pupil sex, FSM status and ethnicity. This analysis will be augmented by an additional analysis including participants in the intervention arm using the same pre-randomisation factors, process measures of intervention delivery, and staff changes in perceptions of trauma-informed care.

Table 6 sets out the statistical analysis for each outcome by level.

Table 6 Statistical analysis by outcome and level

Outcome	Level	Model	Covariates
<u>Primary outcome</u> Externalising behaviour <u>Secondary outcomes</u> Internalising behaviour Non-psychotic psychological distress Well-being Sense of connectedness Exclusions, suspensions and attendance at individual (CYP) level	CYP	Multi-level model	Pre-treatment scores of outcomes at CYP level Demographic factors (sex, FSM status) at CYP level
<u>Secondary outcomes</u> Attitudes related to TIC Well-being	School staff	Multi-level model	Pre-treatment scores of outcomes at staff level
<u>Secondary outcomes</u> Staff retention Staff sickness Exclusions & suspensions of CYP School attendance of CYP	School	Linear regression (OLS)	Pre-treatment scores of outcomes at school level

Sub-group analysis

The sub-group analysis will be twofold. First, we will conduct a latent class analysis (LCA) on the intervention group to explore whether there are emerging sub-groups with differential effects. LCA refers to the model whose underlying indicators are all categorical while for the continuous case, LCA is known as latent profile analysis (LPA) (Sinha, Calfee, & Delucchi, 2021). The LCA model will include the socio-demographic variables (sex, ethnicity, FSM) together with primary and secondary outcomes. This will allow us to observe 'latent' groups emerging from the data.

Second, we will conduct multilevel model by sub-groups considering a model with interaction may be more demanding in terms of power analysis. However, we will also consider for robustness check a multilevel model with interaction between treatment and sub-group dummy variable.

Missing data

We do not anticipate large amounts of missing data. If the missing data exceeds 5%, sensitivity analyses will be performed using a pattern mixture approach and multiple imputations will be conducted to compare the sensitivity of conclusions to varying assumptions about the missing data, notably whether data are missing at random (MAR) or missing not at random (MNAR) to allow for an assessment of both random and systemic bias. The variation of the primary outcome by different assumptions of missing data will be presented.

Compliance

We will conduct a Complier Average Causal Effects (CACE) analysis using an instrumental variable framework to explore the impact of compliance on the primary outcomes at different levels of compliance. CACE weighs the intention-to-treat (ITT) treatment effect by the proportion of compliance, this allows the estimation of unbiased treatment effects and maintains the allocation in the analysis. The CACE analysis will be implemented using a two-stage least squares (2SLS) approach clustering the standard errors, where the first stage models compliance as a function of the randomised treatment assignment, and the second stage models the outcome as a function of the predicted compliance from the first stage and other covariates.

Compliance will be measured at the school level through a binary variable, compliance (Yes/No). Compliance for those schools in the intervention arm will be assessed based on the level of engagement. Section 5 discusses an engagement tool in more detail. The engagement tool assesses level of schools engagement with the delivery of TISUK intervention across five key dimensions:

- Individual Training,
- Whole Staff Training,
- Consultancy,
- Reflective Supervision,
- Webinars.

Each dimension is scored based on specific criteria, such as the number of staff trained, attendance at meetings, and utilisation of resources. The tool uses a point-based system, with 100 points possible across all dimensions. The final score is calculated as a percentage, with clear thresholds for interpretation:

- up to 50% indicates poor engagement,
- 51-75% moderate engagement,
- 76-90% good engagement, and
- 90-100% excellent engagement.

The score will be used to measure compliance in the CACE analysis. CACE weighs the intention-to-treat (ITT) treatment effect by the proportion of compliance, allowing for the estimation of unbiased treatment effects while maintaining the original randomisation in the analysis. Therefore, a school in the intervention arm will be considered compliant with the trial if showing engagement of 76% or higher. As a robustness check in the analysis, we will explore how compliance is associated with the outcomes and if any threshold for minimum compliance emerges by setting compliance at 76%, 80% and 90% of the engagement tool. This finding could serve in the future of a trial to establish a minimum threshold that ensures a successful delivery.

Quasi-experimental design on targeted intervention

Appendix 2 provides more details on the QED research design and analysis, including research questions and sample size analysis. To explore the impact of the intervention on a targeted group of CYP who are receiving tailored support, we will undertake a study within a trial (SWAT).

A full statistical analysis plan would be developed during the project, and we are committed to working with the approaches set out within the YEF's analysis guidance.

5. Implementation and process evaluation (IPE)

Following the process evaluation guidelines recommended by the EEF (Humphrey et al., 2016), we aim to conduct a process evaluation that delves into the intricate aspects of TISUK. This intervention, designed to promote a trauma-informed approach by fostering changes in policies and practices across the entire school, requires testing moderators and assumptions that link the pathways from inputs and activities to outcomes at CYP, school staff and school levels.

The main focus of the process evaluation will be to accurately assess the extent to which the intervention is implemented as intended throughout the school, ensuring fidelity to the intervention's principles. In addition to fidelity, other dimensions to test are: dosage, responsiveness, quality, and reach.

5.1. Research questions (IPE)

The IPE is framed by nine broad research questions, as shown below.

- IPE1: To what extent do TISUK staff adhere to the intended delivery model?
- IPE2: To what extent has the intervention been delivered in the intended dosage?
- IPE3: To what extent do school staff and leadership engage with the intervention?
- IPE4: To what extent are the different components of the intervention delivered with high quality?
- IPE5: What is the participation rate by intended recipients (school staff and leadership)?
- IPE6: What is the perceived need for and benefit of the intervention among school staff and leadership?
- IPE7: What strategies and practices are used to support high-quality implementation?
- IPE8: How do structural factors (e.g., institutional racism, lack of diversity in the workforce) affect CYP from Black, Asian and ethnic minority backgrounds?
- IPE9: How do CYP from different sex and Black, Asian and ethnic minority backgrounds experience the intervention?

These questions will be answered through primary data collected with various research methods (interviews, case studies, observations) and administrative records. Section 5.3 shows how data will be analysed and triangulated.

5.2. Research methods

Table 7 gives an overview of the data collection methods to address the IPE research questions. The sampling approach for interviews and case studies will ensure that the sample is diverse regarding the location and fidelity of the intervention.

Table 7 IPE methods overview

Data collection and data/sources	Sample size and population	Data analysis methods	Research questions addressed	Implementation /TOC relevance	Timing
Semi-structured longitudinal interviews	20 school staff Sampled across 10 schools, 2 per school	Thematic analysis	IPE1, IPE3, IPE4, IPE5, IPE6, IPE9	Answer IPE questions and test TOC's assumptions	Intervention phase (May-June 2024)
Semi-structured interviews with TISUK trainers and consultants	10 TISUK consultants & trainers purposively sampled	Thematic analysis	IPE1, IPE3, IPE4, IPE5, IPE6, IPE9	Answer IPE questions and test TOC's assumptions	Intervention phase (Nov-Dec 2024)
Observations	2 observations of whole staff training (Session 1 & Session 2) 4 observations of network consultancy meetings 1 observation of Diploma Training (Day 11) 1 observation of Senior Leadership Training	Narrative analysis	IPE3, IPE4, IPE7	Answer IPE questions and test TOC's assumptions focused on the mechanisms for good quality delivery and engagement.	Intervention phase (Jan-Nov 2024)
Case studies	5 case studies from schools in the treated arm 3-5 interviews with schools' staff and 2 with TISUK trainers/consultants One focus group with 4-6 CYP (aged 11-18) per case	Thematic analysis	IPE3, IPE4, IPE6, IPE7, IPE8, IPE9	Answer IPE questions and test TOC's assumptions focused on the mechanisms that enable the changes from activities/outputs to impacts.	Post-intervention phase (Mar-May 2025)

Data collection and data/sources	Sample size and population	Data analysis methods	Research questions addressed	Implementation /TOC relevance	Timing
	2-3 one-to-one interviews with students *(Fieldwork per case involves about 3 in-site visit in school, to allow three interviews with staff face-to-face)*				
Monitoring data	Monitoring data collected by TISUK • Implementation checklists & attendance data (MI provided by TISUK) • School RAG rating • Schools staff well-being audit • School bonding questionnaire • List of CYP who received targeted support by diploma practitioners	Descriptive statistics, cross-tabulation	IPE1, IPE2, IPE3, IPE5, IPE9	Answer IPE questions with a focus on factual and quantitative data	Intervention phase (Jan-24 to Mar-25)

Longitudinal interviews with school staff

The aims of this data collection activity are:

- Explore school staff perceptions around the need for and benefit of the TISUK interventions.
- Understand how schools have experienced and engaged with the different elements of the intervention.

- Explore factors affecting the implementation of a whole school trauma-informed approach, including facilitators and barriers.
- Consider the different strategies and practices used by schools to support the high-quality implementation of TIP.
- Understand the mechanisms for change that support a cultural shift in schools.
- Explore whether any structural factors might affect the reach and impact of the intervention.
- Examine perceptions of changes to staff wellbeing and attitudes to TIP.
- Understand what lessons can be learned from this intervention to inform any future scale-up of the intervention.

This data collection activity foresees 40 interviews[15] (20 interviews at two time points) with 20 staff members across 10 schools (i.e., two per school). Each staff member will participate in two interviews. The first interview will be conducted whilst TISUK is delivering their intervention within the school. The second interview will take place during the last two months of the intervention phase. This would give staff members the time to reflect and allow the evaluation to capture how experiences and perceptions have changed over time, as well as explore how staff see the schools amend their approaches to working with CYP following the TISUK intervention.

The interviews will be semi-structured, combining structure with flexibility. Whilst key topics will be covered in each interview, the guide is written to ensure discussions are responsive and remain open to new areas and unexpected information.

The interviews will be between 45 minutes and 1 hour and take place online using TEAMS or Zoom. Interviews will include time to establish rapport, introduce the research, and ensure that informed consent has been given. The fieldwork will take place over two time periods as described above. The interviews will take place at a time convenient for the school staff taking part. Time slots in the early evening will be offered to accommodate those who cannot participate during the day.

The 10 schools will be sampled from the schools receiving TISUK interventions that are participating in trial. The sample would aim for an even split of schools across the locations.

[15] We will outreach 24 instead to allow some drop-off between first interview and follow-up.

The sample for the schools will also consider the following factors: size, Ofsted ratings, and catchment area demographics.

Ipsos will liaise with each of the 10 schools that agree to take part to identify the two members of staff best placed to take part in interviews (ideally those who have had the most engagement with the TISUK interventions). Across the 20 school staff recruited, there would ideally be good representation across a range of roles, including senior leaders, staff that have taken part in the Diploma Practitioner Training, SENCO leads and Pastoral leads.

Interviews with TISUK trainers and consultants

This activity aims to:

- Assess whether the TISUK programme across the three locations was delivered as intended.
- Explore what works well and less well about how interventions are delivered, and what can be improved.
- Understand how well schools adhere to the intended delivery model and explore what helps or hinders this.
- Explore factors affecting implementation and school engagement, including facilitators and barriers.
- Considering what strategies and practices schools use to support high-quality implementation of TIP.
- To explore TISUK staff perspectives on the need for and benefit of the intervention.
- Understand what lessons can be learned from this intervention, to inform any future scale-up of the intervention.
- Provide valuable implementation evidence around TIP training and support that the wider sector can use.

Ten interviews will be conducted with ten different trainers and consultants supporting the delivery of TISUK interventions in schools across the locations. These interviews will allow the evaluation to gather insights from professionals about the delivery of interventions across a range of different schools and to reflect on any variations that have been identified and what key facilitators and barriers to successful implementation have been in different settings.

Similarly to the longitudinal school staff interviews, the interviews will be semi-structured, combining structure with flexibility. Whilst key topics will be covered in each interview, the guide is written in such a way that ensures discussions are responsive and remain open to new areas and unexpected information. The interviews will be about an hour long and take place online using TEAMS or Zoom. Interviews will include time to establish rapport, introduce the research, and ensure that informed consent has been given. The interviews will take place at a time that is convenient for the TISUK trainers and consultants taking part.

Trainers and consultants helping deliver the interventions across schools participating in the trial will be invited to participate. An initial ten trainers and consultants will be invited to take part based on a sampling strategy, with a backup list of 10-15 to reach out too if any from the original sample decline to participate. The sample would aim to include trainers delivering all training courses offered by TISUK. Ipsos will liaise with TISUK to help identify a list of ten trainers and consultants and a backup list.

Observations

This activity's aims are:

- To understand how the training courses are delivered in practice.
- To understand how attendees respond and engage with the training, school staff taking part in the training engage and respond during the training sessions.
- To understand how TISUK are supporting schools to implement learnings captured through training sessions.

The research team will use observations to assess staff engagement with the TISUK programme, providing an opportunity to gain deeper insights into the implementation of TISUK. Observations will be conducted for:

Whole of staff training – 2 x 3 hour whole staff training sessions to observe the two components of the training (Session 1 and Session 2).

Network consultancy meetings – 4 x 2 hour network consultancy sessions to observe conversations between school delegates and TISUK trainers around implementation of learnings and process of troubleshooting issues/risks.

Diploma training – Full day observation on Day 11 of the Diploma Training course. On Day 11, delegates will present their understanding of training, and how they've implemented learning within their relevant school.

Senior leadership training – Full day observation of online Senior Leadership Training. Ipsos will liaise with TISUK trainers to determine which of the two-day training session it is most appropriate to attend.

For all observations, members of the evaluation team will initially introduce themselves to all attendees but then turn their cameras and microphones off not to impact delivery. A template to record observations across a number of thematic areas will be developed to ensure that reflections are collected consistently and systematically across all the observations.

Trainers and consultants that will be observed will also be offered a catch-up call with a member of the evaluation team to discuss what the observation will involve and offer them the chance to ask any questions. They will be reassured that the evaluation is not focusing on the performance of individual trainers but instead exploring the enablers and challenges of delivering these training sessions overall.

Reflective Supervision training and sessions will not be observed by the research team due to ethical constraints. Reflective Supervision sessions can involve private and sensitive conversations about students or other matters. Presence of Ipsos evaluator within these meeting is not considered viable.

Case studies

The key aims of this data collection activity are:

- Explore perceptions around the need for and benefits of the intervention.
- Explore how the programme has been delivered within a particular school, as well as what has worked well or less well about delivery.
- Understand how staff have experienced and engaged with the different elements of the intervention.
- Explore factors (e.g. quality of facilitation, school leadership, existing school policies and initiatives, school size and demographics, cultural responsiveness) affecting the implementation of a whole school trauma-informed approach.
- Consider the different strategies and practices used by schools to support the implementation of TIP.
- Understand the mechanisms for change that support a cultural shift in schools.
- Explore to what extent the school adhered to the intended delivery model and what factors influenced this.

- Understand the experiences of young people who received targeted support.
- Explore whether any structural factors might affect the reach and impact of the intervention.
- Understand what lessons can be learned from this intervention to inform any future scale-up of the intervention.

This data collection activity will include carrying out in-depth case studies across five schools in the geographic locations. **This means up to three on-site school visits per case to maximise flexibility and ease scheduling considering school/staff timelines**. For each of the five case studies, the following fieldwork will take place:

- An initial set-up meeting with each school to discuss the overall approach, discuss any sampling criteria and recruitment strategies, agree on a safeguarding protocol, and answer any questions.
- 3-5 interviews with staff members within the school involved in the TISUK interventions. The interviews would last up to an hour and can take place in person during a visit or online using TEAMS or Zoom.
- 2 interviews with TISUK network consultants that have worked directly with that school, helping them use the training they have received to implement a whole school trauma-informed approach to working with young people. The interviews would last up to an hour and most likely take place online using either TEAMS or Zoom.
- 1 focus group with 4-6 students. The focus group would last around 1.5 hours and take place in person during a school visit by the evaluation team. A private room on school premises will be secured for the focus groups.
- 2-3 one-to-one interviews with young people. The interviews would last around 45 minutes and take place in person during a school visit by the evaluation team. The evaluation team will work with the school to ensure a private and familiar room is used for theses interviews to make participants feel as comfortable as possible. Young people will be given the option of having another trusted adult in the room.

The interviews and focus groups will be semi-structured, combining structure with flexibility. Whilst key topics will be covered in each interview, the guides are written to ensure discussions are responsive and remain open to new areas and unexpected information. Interviews and focus groups will include time to establish rapport, introduce the research, and ensure that informed consent has been given.

A Youth Advisory Board for the evaluation has been established and includes diverse young people. All the research tools and questions will be co-produced with this group and will help

ensure that the materials developed are inclusive and relevant to a wide range of experiences. This is particularly the case for the guides used to run the focus groups and interviews with young people.

The five schools will be selected from the sample of schools taking part in the trial, within the intervention arm, and have not been selected for the longitudinal interviews. The sample will also consider the following factors: school size, how many elements of the TISUK training offer they have participated in, Ofsted ratings, and catchment area demographics. An initial 10 schools as potential candidate for case study will be identified based on this sampling strategy and invited to take part, only five out of ten will be retained based on first-come-first-served.

The 3-5 interviews with school staff would ideally include those that have been most involved with the TISUK interventions. This could be with the senior leaders, staff that have taken part in the Practitioner Training, SENCO leads, safeguarding leads, or a staff member in a pastoral position. Ideally, it would also include a member of staff providing 1:1 targeted support to young people within that school. The IPE team will liaise with the school to identify the staff best placed to take part in the interviews.

The focus group will be with young people in Year 9.[16] The 1:1 interview with young people would be with students from Year 9 who have received more intensive support from staff members. Students will not be able to participate in both focus groups and 1:1 interviews. The evaluation team will liaise with the school to help recruit the students for interviews and focus groups, however we will aim to sample students based on a mix of:

Demographic diversity (1:1 interview & focus groups): Ensure a diverse group of student that represent differing gender and ethnicity.

Duration of support (1:1 interview): Variation in the length of intensive support from staff members to students.

Prior support provision (1:1 interview): We aim to select a mix of students who either received relevant support for the first time after implementation of TISUK and those who were receiving pastoral support or other counsel prior.

Engagement

[16] Case studies will be undertaken in 2025. Students were in Year 8 at the start of the evaluation, and match the cohort (in age) of the efficacy trial.

The quantitative data from the delivery team will be used to populate an engagement tool that assigns a score at the school level. This tool employs a comprehensive scoring system to evaluate the extent of each school's engagement with the intervention and their level of compliance.

It consists of five key dimensions, each weighted differently to reflect their relative importance in the overall implementation:

1. Individual Training (45 points): This dimension assesses the number of staff who have completed specialised training courses, specifically the SLT (Specialist Leader of Teaching) and Diploma courses. The scoring ranges from 0 points (no staff trained) to 30 points (optimal ratio of trained staff to pupils), with intermediate scores based on the number and type of staff trained.
2. Whole Staff Training (25 points): This evaluates the extent of training the entire staff receives. Points are awarded based on the number of completed training hours, ranging from 0 points for no training to 25 points for the full 6 hours.
3. Consultancy (15 points): This dimension measures attendance at termly meetings and adherence to guidelines for staff involvement. It is divided into two sub-components: attendance at meetings (up to 10 points) and following staff involvement guidelines (up to 5 points).
4. Reflective Supervision (10 points): This assesses staff participation in reflective supervision training. Points are awarded based on the number of training days completed, from 0 points for no attendance to 10 points for completing all four training days.
5. Webinars (5 points): This dimension evaluates the utilisation of provided webinars by the school. Schools can receive 0 points for no webinar use, 3 points for viewing 1-3 webinars, or 5 points for viewing all four webinars.

The tool uses a 100-point scale, with each dimension contributing maximum points. Points are summed across all dimensions and converted to percentages to calculate the overall engagement score. This scoring system allows for a nuanced assessment of engagement, considering various aspects of the intervention, from staff training to resource utilisation. The weighted nature of the tool emphasizes the importance of individual and whole staff training in successfully implementing the programme.

The tool is displayed in tabular format as Appendix 3.

5.3. Analysis (IPE)

The main focus of the IPE is to test the theory of change to check whether the intervention is operating as hypothesised. The analysis approach will primarily be deductive but flexible

enough to capture any emerging or unforeseen themes arising from the data. All interviews will be recorded with consent and transcribed completely.

These transcripts will then be uploaded to Nvivo. An analysis framework will be created, incorporating the research questions and main elements of the Theory of Change (see Appendix 1). The framework will consist of appropriate nodes and sub-nodes, accompanied by detailed descriptions to ensure consistent coding by the research team. In the initial stages of analysis, the IPE team will code several transcripts using the framework as a guide. This will be followed by a team analysis meeting to evaluate the inter-rater reliability of coding decisions and address any inconsistencies.

A thematic analysis will be conducted, using coding themes derived from the research questions and theory of change. The analysis will employ a Framework Analysis approach outlined by Smith and Davies (2010). This approach involves obtaining an initial understanding of the data, constructing a preliminary framework based on the research questions, coding or charting the data in detail according to the themes within the framework, and ultimately interpreting the data within the established framework.

Data synthesis will aim to triangulate evidence from different sources and methods, namely, case studies, interviews, observations, and focus groups. This approach allows us to gather evidence from multiple perspectives, enhancing the validity and reliability of our findings. By triangulating evidence, we will cross-validate information obtained from different data sources to gain a comprehensive understanding of the implementation and process of the intervention. The case studies will provide in-depth insights into specific instances, while interviews will offer personal accounts and opinions. Observations will allow us to observe the intervention in action directly, and focus groups will provide a platform for participants to collectively discuss and reflect on their experiences. By integrating findings from these diverse sources, we can establish robust evidence and draw well-rounded conclusions about the assumptions in the theory of change, what worked well, and obstacles and enablers for change.

Once the data collection is achieved, **the analysis and triangulation process** will be structured on the following steps:

1. Data coding: once the data is collected, evidence from each source will be coded and categorised, identifying common themes, patterns, and categories within the data.

2. Data comparison: findings across different sources will be compared and contrasted, looking for convergence/divergence.

3. Data integration: findings from different sources will be integrated to form a coherent and holistic picture. This involves identifying common themes, trends, or critical

insights across various data sources and complementary or contradictory evidence that adds depth and richness to the analysis.

4. Triangulation matrix: a triangulation matrix will be created to visually represent the connections and relationships between the different data sources. This matrix can serve as a reference tool to guide the analysis and interpretation of the findings.

5. Interpretation and synthesis: the triangulated evidence will be analysed in light of the research questions.

6. Cost data reporting and collecting

The cost estimation will be done from the perspective of the school and the delivery team. We do not anticipate costs for the families, the CYP, or the government.

The main cost items for the estimation consist of the following:

- FTEs of the teams (school staff + TISUK) involved in the delivery of activities;
- FTEs of the school staff in charge of introducing changes to policies and practices;
- Value of salaries/wages of both school staff and TISUK team involved
- Material resources used in the activities;
- Any other financial/material resource used directly as input for activities.

The approach to costing is bottom-up according to the YEF guidelines on cost reporting[17]. We do not anticipate procurement costs, but these will also be incorporated into the final estimation if that is the case. Also, no cost of the evaluation will be added to the equation.

The time spent on activities and the category of staff involved will be collected through interviews with staff, and triangulated by the monitoring data collected by TISUK. Data on salaries will be collected through secondary sources.

7. Diversity, equity and inclusion

[17] https://youthendowmentfund.org.uk/wp-content/uploads/2022/01/21.-YEF-Cost-reporting-guidance.pdf

The evaluation and delivery team are firmly committed to upholding the principles of diversity, equity, and inclusion, ensuring that these principles are embedded within the research design and intervention delivery.

The measures to ensure these principles are met are:

- The proportion of pupils eligible for FSM at school is one of the stratification variables for the randomisation of schools.
- We will provide flexibility in conducting baseline and follow-up assessments by allowing individuals with literacy difficulties to complete assessments verbally if needed, facilitated through our School liaison officer and promoted through information sessions and recruitment materials.
- We will monitor the recruitment on key racial and inclusion parameters
- We will deploy a Youth Advisory Board, composed of people from diverse backgrounds, to inform evaluation design and ensure recruitment and data collection materials are accessible and appropriate.
- The outcomes will be analysed by sub-group analysis (ethnicity, sex and FSM).
- The analysis and triangulation of evidence from the IPE will look at lived experiences by sub-groups (ethnicity and sex).

The evaluation of this intervention, spanning from Phase 1 (co-design) to Phase 2 and Phase 3, brings diversity, equity, and inclusion to the core. A pivotal aspect in achieving these goals is adopting a co-production approach led by TONIC. This approach ensures that data collection tools and activities are developed through a participatory process involving a Youth and Teacher Advisory Board. By incorporating their feedback, the evaluation process becomes more inclusive and reflective of diverse perspectives, enhancing the overall quality and relevance of the findings. All members of the evaluation project team will have completed (1) unconscious bias training and (2) TISUK webinar – Conversations That Matter: From racial trauma and discrimination in schools and communities to respecting and celebrating difference and diversity.

8. Ethics and registration

The trial has been approved by the Ethics Board at Ipsos UK. Reference number: 23-019045-01. The trial will be registered with the ISRCTN on agreement of the protocol.

9. Data protection

This section outlines the measures and considerations undertaken to ensure compliance with data protection regulations for this trial. This statement has framed the Memorandum of Understanding, information sheets, and privacy notice provided to potential participants within schools.

Legal Basis for Processing Personal Data

The processing of personal data in the context of the trial is conducted under the legal basis of the UK General Data Protection Regulation (UK GDPR), specifically Article 6(1)(e). Article 6(1)(e) pertains to the processing of personal data necessary for performing a task in the public interest or exercising official authority vested in the controller.

Legal Basis for Processing Special Data

The processing of special category personal data within this trial is justified under the UK GDPR, specifically Article 9(2)(j). Article 9(2)(j) permits processing for archiving purposes in the public interest, scientific or historical research or statistical purposes.

The rationale for Selected Legal Bases

The selected legal bases for processing personal and special data align with the public task basis under the UK GDPR – 6(1)(e) and 9(2)(j). The Evaluation team (Ipsos UK, Tonic and the University of Kent) is committed to conducting the evaluation in the public interest and exercising official authority vested in the controller. The collection and processing of personal and special data are essential for this trial's research and statistical purposes. The overarching goal is to contribute to children's and young people's and school staff's well-being.

GDPR Compliance

To ensure compliance with the GDPR, the Evaluation team will implement the measures below:

1. Protecting Individual Data Subjects' Rights: Data subjects will be informed of their rights regarding their personal data, including the right to access, rectification, erasure, restriction of processing, and objection. Mechanisms for exercising these rights will be provided.

2. Purposes for Data Processing: The trial-specific privacy notice provided to potential participants (CYP, parents/guardians, and school staff) will clearly outline the purposes for which their data will be collected and processed.

3. Parties with Access to Data: Access to personal data will be limited to authorised personnel involved in the Ipsos team. Access will be granted on a need-to-know basis and in adherence to data protection principles. Data will be held securely on the UK servers at Ipsos UK and all personal/sensitive information is stored in secure folders, encrypted/password protected, and only accessible by the Ipsos team working on the trial.

4. Retention Periods: The retention of personal data will be limited to the duration necessary for the purposes outlined in the trial-specific privacy notice. Once the data is no longer required, it will be securely deleted from all locations by the evaluator and/or delivery team.

5. Information Sharing Agreement: The evaluation and intervention delivery teams will establish and sign an information sharing agreement that clearly outlines what information will be shared, the reasons for sharing, and the means of sharing. This agreement will ensure that data is shared securely and in compliance with data protection regulations. We use Ipsos Transfer for the secure transfer of files containing personal/sensitive information encrypted to a minimum standard of AES 256.

6. Secure Communication: All communication between the intervention and evaluation teams will occur through encrypted channels secured using a virtual private network (VPN). This approach will protect the confidentiality and integrity of the data during transmission.

Data Processing Roles

During the evaluation process of the trial, the roles of the data controller and any processors are as follows:

- Data Controller: Ipsos UK assumes the role of the data controller and holds the responsibility for determining the purposes and means of processing personal data within the scope of the RCT.

- Processors: The evaluation team, comprised of Ipsos UK, Tonic, and the University of Kent, as well as the intervention delivery team at TISUK, act as processors who process personal data under the instructions and on behalf of the data controller. Their involvement is essential for the evaluation tasks outlined in the RCT.

Consent collection

The privacy notice provided to potential participants will clearly outline the parties from whom consent will be obtained, ensuring transparency and informed decision-making.

For surveys with CYP and schools staff, all respondents (CYP and school staff) will be given the chance to opt-out from data collection activities though opt-out letters before baseline testing (for CYP this opt-out option will be offered to their parent/guardians given the age of the CYP). Assent from CYP and school staff will be obtained immediately before surveys start. This will be outlined within the privacy notice as well as within introductory text prior to respondents commencing survey questionnaires. Information sheets will specify the aims of the study, what the data is being used for (including a description of the Data Archive) as well as the legal basis for processing personal data.

For interviews and focus groups with students, obtaining consent will occur via two steps. Schools will be asked by the School liaison officers to provide consent forms to parents of identified students eligible to participate together with information sheets. Students will participate in the data collection after giving assent and once the school has received a signed consent from the student's parent/guardian. Privacy Notices as well as information and

consent/assent forms will have full details of the research as well as contact details of key evaluation research staff should parents or students require further information. All students participating in interviews and focus groups will be required to provide written assent prior to the activity taking place.

For all other qualitative data collection with TISUK trainers, network consultants and school staff, consent will be obtained either in writing or verbally prior to commencement of the interview. All participants will be sent an information sheet as well as a Privacy Notice in advance of any fieldwork activity.

Data Sharing Agreements (DSAs) and Data Protection Impact Assessments (DPIAs)

For schools collaborating with TISUK and the evaluation team, the following measures will be implemented:

Data Sharing Agreements (DSAs): A comprehensive data sharing agreement will be established between the schools and the relevant parties involved, including TISUK and the evaluation team. This agreement will outline the specific information to be shared, the purposes of sharing, and the means of sharing. It will ensure that all parties involved are aware of their responsibilities and obligations regarding data protection and confidentiality.

Data Protection Impact Assessments (DPIAs): A DPIA will be conducted for the schools involved in this trial. This assessment will identify and evaluate any potential risks and impacts on the privacy and rights of individuals whose data is processed within the school setting. The DPIA will assess the necessity and proportionality of the data processing activities, as well as the measures in place to mitigate any identified risks. The evaluation team, in collaboration with TISUK and relevant school authorities, will ensure that appropriate DPIAs are conducted in accordance with the requirements of the UK GDPR.

10. Stakeholders and interests

The evaluation team for this trial is as follow:

Facundo Herrera (Ipsos UK): project director, responsible for all aspects of the study and overall direction, lead on reporting and responsible for the statistical approach and analysis.

Peter Sakis (Ipsos UK): project manager, responsible for day-to-day management and communications with YEF, delivery partners and other stakeholders; key role in reporting.

Dr Jessica Ozan (Ipsos UK): Youth Board advisor, responsible for advising on the IPE, children's participation and ethics.

Dr Amanda Carr (TONIC): TIP director, advising on TIP.

Karl Ashworth (Ipsos UK): RCT design advisor responsible for advising on the statistical design of the trial.

Prof Simon Coulton (University of Kent): Trial Design Director, statistical lead and responsible for advising on efficacy research design and statistical analysis.

Lottie Hayes (Ipsos UK): School liaison officer responsible for engagement with schools.

The team will be supported by Ipsos Consultants and Research Executives who will be involved in data collection and analysis.

The delivery team is made of:

Rowan Jones (TISUK): Project Lead - Main point of contact for YEF trial and project schools. Responsible for school recruitment and reporting.

Rachel Toller (TISUK): Director of Operations and training - Overseeing project management, staffing, HR and the coordination of training as well as director consultancy support across all internal TISUK teams

Julie Harmieson (TISUK): Director of Education and National Strategy - Director consultancy support across all internal TISUK teams including training and consultancy.

Dr Margot Sunderland (TISUK): Director of Innovation and Research - Director consultancy support across all internal TISUK teams including training and consultancy.

Carly Bateman (TISUK): Training Officer - Processing training applications, tracking attendance, assisting delegates to make up missed days, sending out handouts and feedback form. technical and administrative support for training,

Lisa Aire (TISUK): Training and Admissions Co-ordinator - Coordinating training, technical and administrative support for training, ensuring school engagement.

Helen Turner (TISUK): Admissions and Operations Co-ordinator - Processing training applications, tracking attendance, assisting delegates to make up missed days, sending out handouts and feedback form.

Derrick Hopf (TISUK): Business and Project Development Manager - Financial Monitoring

11. Risks

Table 8 sets out the risks for both the evaluation and delivery team with the respective mitigation measures.

Table 8 Risks and mitigation measures

Risks	Assessment	Mitigation strategy
Missed deadlines due to potential delays in data collection	Likelihood: 4 Impact: 3	Full details of roles and responsibilities to be communicated to all team members. Ipsos and University of Kent to conduct early tests at both baseline and follow up stage to confirm data is as required - as well as anticipating particular risks likely to arise in data analysis. School liaison officer role will be established (Ipsos) to track response rates (formal response rate tracking will be completed weekly), and directly work with schools should there be slow take up of baseline and follow up data collection. School liaison officer will be responsible for providing ongoing guidance and support to ease survey administration process.
Failure to recruit target number of schools	Likelihood: 4 Impact: 3	TISUK have pursued additional locations to improve regional coverage. Initial briefing notes sent to schools include eligibility criteria and partners, who know the schools well, are filtering them based on this, so almost all EOIs should come from eligible schools. In addition, there is a buffer in terms of recruitment to the minimum sample required and the power calculations have been done to assess the impact on MDES by different scenarios of attrition at school and CYP level.
Attrition due to burden of training on school/ difficulties with implementation/ change in leadership	Likelihood: 2 Impact: 3	Training is designed so that school staff can join different cohorts and do not need to be released at the same time. Where possible, any missed days can be made up on alternative courses. Network consultancy to support implementation and provide a point of contact to participating school staff should concerns be raised. MoU and information briefings clear about responsibilities and time demand for schools and teachers. There will be financial incentives for all schools.
Attrition due to burden of evaluation	Likelihood: 3 Impact: 3	Baseline data collection will be carried out before randomisation so that control schools will have already taken part in 50% of surveys when they are informed of control status. There will be a financial incentive for all schools to stay engaged and this will be increased for case study schools with a higher

		time burden. School liaison officer responsible for coordination and communication with schools – any dips in completion rates below expected levels will be flagged with senior project leadership. Information sessions (e.g. early engagement webinars) to school to promote the importance of the project and outline plans for data collection. The approach to data collection has been informed by co-production activities with school staff who have provided feedback on data collection activities and tools. Ipsos specialised email management services to pool more resource to and increase responsiveness of communications and troubleshooting with schools. Ipsos to create project specific email address with direct access to the Ipsos project team. For longitudinal interviews with staff - we will oversample by 10% for interview 1 (24 rather than 20 interviews) to account for some drop off. In addition, we will conduct short surveys with SLT across schools in the control group to map BAU but also to monitor engagement. This short survey will happen after 6 and 12 months from starting the intervention.
Poor data collection engagement from schools (trial)	Likelihood: 3 Impact: 3	Parental consent will be opt-out rather than opt in to avoid low take up from parents who simply do not return the forms. Email comms to schools at strategic times (Tuesday or Thursday scheduled 6am or 7am). No data collection activities planned for between June and August which present challenging times for schools to engage with research activities. School liaison officer will also be in direct, and ongoing engagement and will actively track response rates on a fortnightly basis.
Adverse events	Likelihood: 2 Impact: 4	We will monitor any iatrogenic or adverse events and create a reporting system. Any event that is potentially a consequence of the trial will be reviewed by the senior core team and where appropriate an independent third party, who will decide regarding continued conduct of the trial. Co-production of research materials with young people to identify risk of harm.

Changes to BAU	Likelihood: 1 Impact: 3	We will need to monitor changes in the policy environment as well as schools individually to determine the effect of new programmes and interventions which may influence outcomes. For intervention schools, this will be monitored by TISUK trainers and consultants who will have direct contact with school staff for the duration of the intervention. For schools in the control arm, we will conduct a survey at baseline, 6 and 12 months (after baseline) to gather information regarding other mental health, wellbeing and trauma-informed training available to school staff.
School staff absence	Likelihood: 5 Impact: 2	Information sessions will outline an expectation of 100% attendance on all aspects of the implementation. If school staff do miss training input then: for the whole school training, they can attend a different date; for diploma training or reflective supervision training, they can make up the missed day(s) on a different training course; for SLT training, delegates can attend a different date; for network supervision meetings, a different member of staff who has completed diploma/SLT can attend and post-meeting notes and the development plan can be shared. Where necessary, delegates can join existing training on national and regional courses (external to YEF project). Missed webinar content can be watched at another time. Additional webinars covering similar content to training can be provided if a staff member misses and cannot make up training.
Unprocessed trauma destabilising a delegate and/or a delegate feeling threatened by the content of the training and de-stabilising group	Likelihood: 2 Impact: 4	Schools supported in the selection of appropriate delegates prior to the training. We also have a delegate contract with includes a very specific relational transaction policy. A robust evidence base (over 800 peer reviewed studies) is made available to delegates and the network consultancy will support schools to identify and change trauma uninformed practice within settings. Where there is a concern about a delegate, one to one trainer - delegate meetings take place at the earliest opportunity. If there is a delegate who is triggered by materials, they will be provided with a 1:1 session with a psychotherapist who can identify strategies and signpost to support so they can continue with training.

Staff retention	Likelihood: 3 Impact: 2	In the early part of training, TISUK will accommodate an alternative member of staff on a different training cohort where possible, but the project also has sufficient reach to allow for some staff leaving the school as multiple staff will be trained. Staff moving between schools within the project will be monitored by evaluation team to avoid data corruption. TISUK will ensure communication with evaluation if this situation arises. If the impact of moving between schools is deemed to compromise the validity of the data, then the receiving school will be removed from the trial.
Delegate retention	Likelihood: 2 Impact: 3	This is a low risk; delegates almost always complete training and report that it is highly valued due to its personal and professional impact. The expectation that delegates complete training will be made clear to schools during information briefing so that they can choose staff appropriately. TISUK will endeavour to offer places on alternative cohorts should delegates drop out but this will depend on availability and timing. Sufficient staff will be trained that if one delegate does not complete the training, the school will still meet the fidelity requirements.
Coordination issues	Likelihood: 2 Impact: 4	Roles and responsibilities will be agreed at the start of the trial with regular updated from the delivery team to the evaluators. Senior team members from each organisation will hold regular contacts on monthly –and if needed– on bi-weekly basis.
Insufficient number of CYP in Yr8 receiving individual support to reach required numbers for QED	Likelihood: 2 Impact: 4	With an average year group size of 200, it is likely that there will be more children, on average, receiving targeted intervention than needed for the QED (approx. n= 10-15). Much of the targeted support will be provided by diploma delegates and guidance given to the school regarding the selection of staff for the 11-day practitioner diploma will specify that at least one of these staff members should work directly with Y8 and Y9.
Disruption to training activities as a result of school strikes	Likelihood: 3 Impact: 3	TISUK will accommodate staff onto other training days to make up for missed ones where possible. Webinar viewings and surveys can be completed at a time convenient for the school and the expectation that all relevant staff and students should be involved will be made clear in information briefings so that they strive to avoid any strike dates. Interviews

		can be arranged around strike dates. Where necessary, delegates can join existing training on national and regional courses (external to YEF project). Missed webinar content can be watched at another time. Additional webinars covering similar content to training can be provided if a staff member misses and cannot make up training.

12. Timeline

Table 9 shows the timetable including specification of who is responsible for completing each task.

Table 9 Timelines and milestones

Dates	Activity	Staff responsible/ leading
When?	**What?**	**Who?**
Phase 1 – Pre-intervention (Co-design)		
Jun-23	TIP co-production with young people	TONIC
Jun-23	Development of Research Tools (RCT & IPE)	IPSOS UK
Jun-23	Protocol draft submission	IPSOS UK
Jul-23	Protocol submission to GECo	IPSOS UK
Aug-23	Ethics application	IPSOS UK
Sep-23	Writing and publication of protocol and SAP (including	IPSOS UK
June-23 to Sep-23	Engaging and recruiting schools	TISUK
Aug-23 to Oct-23	Data sharing agreements	ALL
Oct-23 to Dec-23	Baseline survey and checks – batch 1	IPSOS UK
Dec-23 to Jan-24	Baseline survey and checks – batch 2	IPSOS UK
Dec-23	Randomisation batch 1	IPSOS UK
Jan-24	Randomisation batch 2	
Phase 2 – Intervention		
Dec-23 to Mar-25	Managing monitoring data (cleaning, following up)	IPSOS UK
Mar-24 to Jun-24	T1 interviews with delivery team	IPSOS UK
Mar-24 to Jan-25	T2 school staff longitudinal interviews	IPSOS UK
Jun-24 to Dec-24	Short surveys across schools in control group	IPSOS UK
Jan-24 to Dec-24	Observations	IPSOS UK
	Delivery of intervention by the delivery team	TISUK
Jan-24 to Mar-24 (s1) & Sep-24 to Nov-24 (s2)	Whole staff training - 2x3 hours (2 sessions)	TISUK
Feb-24 to May-24	Senior lead training - 2 days	TISUK
Jan-24 to Oct-24	Diploma training - 11 days	TISUK
May-24 to Feb-25	Network consultancy - 3 meetings	TISUK

Sep-24 to Jan-25	Reflective supervision workshops - 4 days	TISUK
Sep-24 to Feb-25	Webinar input 1x for staff and 3x for staff/pupils	TISUK
Phase 3 – Post-intervention		
Mar-25 to May-25	Case studies	IPSOS UK
Mar-25 to Apr-25	Follow-up survey (dependent on delivery timeline)	IPSOS UK
May-25 to Jun-25	Analysis and triangulation	IPSOS UK
Jul-25 to Sep-25	Final report drafting	IPSOS UK
Aug-25 to Dec-25	Publication process	IPSOS UK
Aug-25 to Dec-25	Dissemination and presentation	IPSOS UK
Aug-25 to Dec-25	Data archiving process	IPSOS UK

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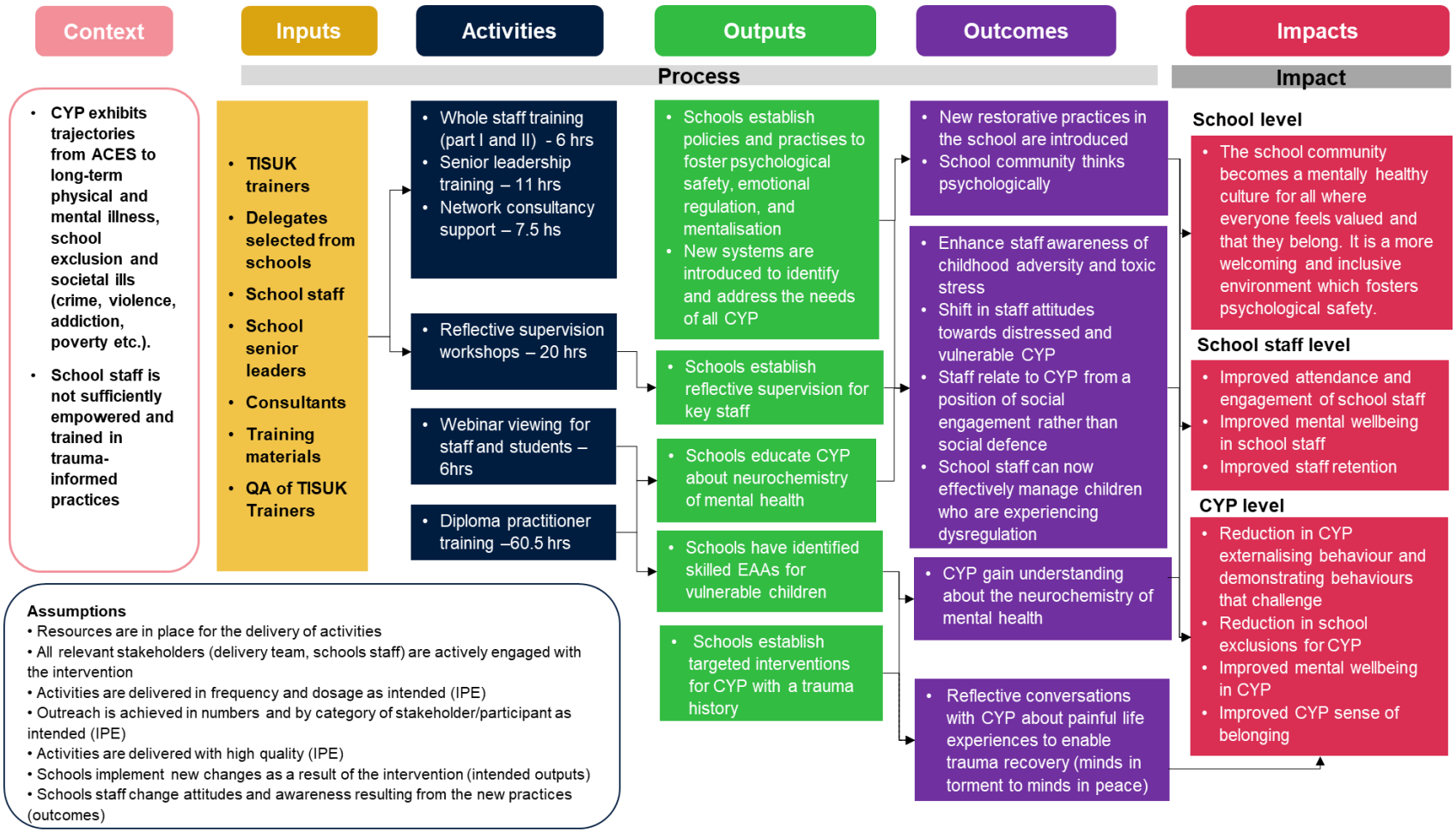
14. Appendix 1: Theory of change



15. Appendix 2: QED initial study plan

Appendix - Table 1 QED design

Design		Propensity score matching
Unit of analysis **(school, pupils)**		Pupils (outcomes are measured at CYP level)
Number of units to be included in analysis **(Intervention, Comparison)**		1,500 (without weighting), (750 intervention, 750 control)
Primary outcome	**variable**	**(CYP) Externalising behaviour**
	measure (instrument, scale, source)	**SDQ – Combined conduct and hyperactivity scale scores (0-20) (Survey)**
Secondary outcome(s)	**variable(s)**	**(CYP) Internalising behaviour** **(CYP) Prosocial behaviour** **(CYP) Total difficulties** **(CYP) Non-psychotic psychological distress** **(CYP) Well-being** **(CYP) Sense of connectedness** **(CYP) Exclusions & suspensions** **(CYP) School attendance**
	measure(s) **(instrument, scale, source)**	**(CYP) Internalising behaviour:** SDQ – Combination of emotional regulation and peer problems (0-20) (Survey) **(CYP) Prosocial behaviour:** SDQ – sub-dimension of prosocial behaviour (0-10) (Survey) **(CYP) Total difficulties:** SDQ – Combination of sub-dimensions of conduct, hyperactivity, emotional regulation, and peer problems (0-20) (Survey)

		(CYP) Non-psychotic psychological distress: General Health Questionnaire (GHQ12) (0-12) (Survey) **(CYP) Well-being**: Short Warwick Edinburgh Mental Well-being Scale (7-35) (Survey) **(CYP) Sense of connectedness:** School Connectedness Scale (Survey) **(CYP) Exclusions & suspensions:** administrative records **(CYP) School attendance:** administrative records
Baseline for primary outcome	**variable**	**(CYP) Externalising behaviour**
	measure (instrument, scale, source)	**SDQ – Combined conduct and hyperactivity scale scores (Survey)**
Baseline for secondary outcome	**variable**	**(CYP) Internalising behaviour** **(CYP) Prosocial behaviour** **(CYP) Total difficulties** **(CYP) Non-psychotic psychological distress** **(CYP) Well-being (CYP) Sense of connectedness** **(CYP) Exclusions & suspensions** **(CYP) School attendance**
	measure (instrument, scale, source)	**(CYP) Internalising behaviour: SDQ – Combination of emotional regulation and peer problems (0-20) (Survey)** **(CYP) Prosocial behaviour: SDQ – sub-dimension of prosocial behaviour (0-10) (Survey)** **(CYP) Total difficulties: SDQ – Combination of sub-dimensions of conduct, hyperactivity, emotional regulation, and peer problems (0-20) (Survey)** **(CYP) Non-psychotic psychological distress: General Health Questionnaire (GHQ12) (Survey)** **(CYP) Well-being: Short Warwick Edinburgh Mental Well-being Scale (Survey)**

		(CYP) Sense of connectedness: School Connectedness Scale (Survey) **(CYP) Exclusions & suspensions: administrative records** **(CYP) School attendance: administrative records**

Appendix - Table 2: Sample size calculations - QED

		PARAMETER
Minimum Detectable Effect Size (MDES)		0.17
Pre-test/ post-test correlations	level 1 (participant)	n/a
	level 2 (cluster)	n/a
Intracluster correlations (ICCs)	level 1 (participant)	n/a
	level 2 (cluster)	0.03
Alpha[18]		0.05
Power		0.8
One-sided or two-sided?		Two
Average cluster size (if clustered)		12
Number of clusters[19]	Intervention	50

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

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

		PARAMETER
	Control	50
	Total	100
Number of participants	Intervention	600
	Control	600
	Total	1,200 (without weighting)

A QED study, using a propensity score matching design, will be embedded within this trial to examine the targeted element of the intervention. In the intervention arm, some staff are given advanced training (Diploma level) to identify a more vulnerable CYP subgroup and provide extra targeted support. This individual intervention is estimated to be provided to about 75 CYP per school, 15 CYP per year group. In the overall analysis, this group of CYP would become subsumed into the overall intervention group. Staff who participate in the diploma training will already have identified most young people who would potentially benefit from more intensive support and, in the early stages of training, will be provided with tools to identify any additional young people. By the time of follow-up, at 15 months, this cohort of young people would have been identified and received at least nine months of intervention.

Selection of the comparison group and identification assumptions

An issue that arises is that while we can identify members of this group in the intervention arm of the study by asking for the details of those who receive additional support at six monthly intervals, we cannot identify members in the control arm because there are no set parameters regarding who would be eligible for additional support. As such, we do not have two randomised groups to compare. To address this, we propose to use a quasi-experimental approach, Propensity Score Matching (PSM), to derive an appropriate group for comparison.

The propensity score is the probability of receiving the intervention conditional on measured participant covariates. It is, in essence, a balancing score. If we have two populations, the intervention and control populations, both of which have a similar propensity score, the distribution of baseline covariates will be the same in the intervention and control groups. Hence, we can remove the effects of confounding by comparing participants who share a propensity score, this is analogous to that induced by randomisation in RCT's.

A counterfactual control group will be derived using PSM to draw causal inferences of the relative effect of the intervention. A probit regression model will be employed, blind to group source. Callipers of width 0.2 of the standard deviation of the width of the logit propensity score will be employed to maximise matching. Once the propensity scores have been generated, they will be incorporated into the primary and secondary analysis using inverse propensity score weights (IPSW) because this will reduce the sample size required for the control group.

Sample size estimation and assumptions

The sample size calculation is designed to detect a difference of 0.2[20]. To detect this difference with 80% power, an alpha of 0.05 and a two-sided test require 527 in each group, a total of 1,054.

For the PSM, the sample size estimations starts from the assumption of 15 CYP on average per school at baseline, assuming a follow-up rate of 80% to account for attrition and consent. The harmonic mean of CYP per year in a group receiving more intensive support is estimated to be 15. We can use this and our ICC of 0.03 to estimate the clustered design effect as 1.45. This inflates our required sample to 1,528. With 100 schools, 15 participants per class provide a sample of 1,500. Incorporation of the inverse propensity score weights will reduce the size of the control group by a conservative estimate of 30%. Therefore, an overall sample of 1,070 would be required.

Appendix Table 3 indicates the impact of different group sizes on the number of schools needed in the intervention arm of the study. We focus on the intervention arm because the control arm is only derived after the follow-up has been completed. The table indicates that with 15 pupils per cluster, we require data from at least 36 intervention schools. At the other extreme, with ten pupils per cluster, we would require data from 48 schools. If the follow-up rate is 80% as anticipated, 12 pupils per school will be available, requiring circa 42 schools in each arm of the study. While we aim to maintain 50 schools in each arm, we should consider these conservative estimates. At the point where the PSM is conducted, we will be able to estimate the pre- and post-test correlation for the primary outcome and incorporate it into the sample size calculation.

[20] This is the MDES required by YEF in efficacy trials

Appendix - Table 3 Impact of differential cluster size on the proportion of schools retained for the intervention group

Pupils	15	14	13	12	11	10
Base sample	527	527	527	527	527	527
Design effect (DE)	1.45	1.42	1.39	1.36	1.33	1.30
Adjusted sample	764	748	733	717	701	685
Sample adjusted for IPW	535	524	513	502	491	480
Number of intervention schools	36	37	39	42	45	48

The primary **research question** is:

- What is the mean difference in externalising behaviour, measured by the Strengths and Difficulties Questionnaire (SDQ) subdomains of Conduct Problems and Hyperactivity, between CYP in intervention settings receiving TISUK training and CYP in control settings receiving business as usual at follow-up?

The secondary **research questions** are:

- What is the mean difference in internalising behaviour, measure by the Strengths and Difficulties Questionnaire (SDQ) subdomains of Emotional Problems and Peer Problems, between CYP in intervention settings receiving TISUK training and CYP in control settings receiving business as usual at follow-up?
- What is the mean difference in prosocial behaviour, measured by the Strengths and Difficulties Questionnaire (SDQ) subdomain of Prosocial behaviour, between CYP in intervention settings receiving TISUK training and CYP in control settings receiving business-as-usual at follow-up?
- What is the mean difference in Total Difficulties, measured by the Strengths and Difficulties Questionnaire (SDQ) subdomain of Conduct Problems, Hyperactivity, Emotional Problems and Peer Problems, between CYP in intervention settings receiving TISUK training and CYP in control settings receiving business-as-usual at follow-up?

- What is the mean difference in non-psychotic psychological distress, measured by the General Health Questionnaire (GHQ), between CYP in intervention settings receiving TISUK training and CYP in control settings receiving business as usual at follow-up?
- What is the mean difference in well-being, measured by the Short Warwick Edinburgh Well-being Scale (SWEMWBS), between CYP in intervention settings receiving TISUK training and CYP in control settings receiving business as usual at follow-up?
- What is the mean difference in the sense of connectedness, measured by the School Connectedness Scale, between CYP in intervention settings receiving TISUK training and CYP in control settings receiving business as usual at follow-up?
- What is the mean difference in the percentage of exclusion between CYP in intervention settings receiving TISUK training and CYP in control settings receiving business as usual at follow-up?
- What is the mean difference in the percentage of suspensions between CYP in intervention settings receiving TISUK training and CYP in control settings receiving business as usual at follow-up?
- What is the mean difference in the percentage of attendance between CYP in intervention settings receiving TISUK training and CYP in control settings receiving business as usual at follow-up?
- What is the mean difference in all primary and secondary CYP outcomes between CYP in intervention settings who received TISUK training and CYP in control settings who received business as usual, considering sub-group analysis by sex, ethnicity, and free school meal (FSM) eligibility?

The analysis will be conducted using an analysis by intention to treat (ITT) and will include all available data, maintaining participants as members of their allocated group. The primary analysis will likely be a linear regression model adjusted for baseline stratification covariates (above/below the median FSM6) and the baseline value of the outcome. As there is variation in business as usual (BAU) across sites, a multi-level model will be applied, allowing for pupils to be nested within schools. Individual outcomes will be incorporated into the model with an inverse propensity weight for each participant.

Secondary outcomes will be assessed similarly by establishing diagnostic plots to identify the most appropriate regression approach, including stratification factors and baseline covariates within a multi-level model.

As the generation of intervention and comparison groups occurs after the final follow-up, we do not account for missing data.

We will not conduct any Complier Average Causal Effects (CACE) analysis for this strand of the study. The nature of the targeted support for this sub-group presents significant challenges in measuring compliance, such as the whole school intervention. This targeted intervention is highly personalised and adaptable to the individual needs of each student, which means that the intensity and frequency of engagement can vary greatly.

Sub-group analysis will be conducted to estimate how the treatment effects vary within groups. This means estimating heterogeneous effects, namely, conditional average treatment effects (CATE). The groups consist of sex, ethnicity and FSM. After passing the balancing test and robustness checks, the approach will achieve a matched sample, thus obtaining the average treatment effect. Then, we will condition the ATE on the respective group variables to obtain treatment effect by stratum, namely the CATE.

16. Appendix 3: Engagement tool

Delivery Element and Engagement Standard	**Engagement Scoring**	**TOTAL POINTS: 100**
Individual Training		
Number of staff on SLT & Diploma courses	0: no staff completed the SLT or Diploma training 10: at least one member of staff completed either the SLT or the Diploma training 20: Ratio on the completed diploma should be at least 1:250 staff/pupils with 1-3 members of additional staff on either the SLT or diploma training OR between 1:250 and 1:350 staff/pupils completed the diploma with at least 2 members of staff on the SLT training. 30: Ratio on the diploma completed 1:250 staff/pupils, and at least 4 additional members of staff on either SLT or Diploma training	Total points available: **45**
Followed guidelines for staff involvement:	0: none 5: 1 school senior leader attended either the Diploma or the SLT training 10: 2 school senior leaders attended either the Diploma or the SLT training	

Senior (Head, Dept/Assistant Head, SENCO,)	15: At least 3 school senior leaders attended either the Diploma or the SLT training	
Whole Staff Training		
Attended full 6hrs	0: Had no training 5: 1-2 hours training received 10: 3 hours of training received 15: 4 hours of training received 20: 5 hours training received 25: 6 hours training received	Total points available: **25**
Consultancy		
Attendance at all termly meetings (expected to attend 3 meetings)	0: none 5: attended 1 - 2 10: attended all 3	Total points available:

Followed guidelines for staff involvement.	0: less than 2 members of staff attend OR 2 staff not in leadership attend 5: 2 members of staff attend (who have done diploma or SLT, and one should be in leadership position)	**15**
Reflective Supervision		
Number of staff on course	0: no attendance 2: at least 1 member staff completed 1 day 4: at least 1 member staff completed 2 day 8: at least 1 member staff completed 3 day 10: at least 1 member staff completed full training (attends all 4 days)	Total points available: **10**
Webinars		
Webinars utilised by school	0: have shared / viewed no webinars 3: have shared / viewed 1-3 webinars 5: have shared / viewed all 4 webinars	Total points available: **5**

Total		**100%**

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