QED PILOT TRIAL PROTOCOL

Redthread Youth Violence Intervention Programme evaluation

University of Birmingham

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YOUTH ENDOWMENT FUND

QED Pilot protocol template (includes a control group)

Evaluating institution: University of Birmingham

Principal investigators: Professor Paul Montgomery, Dr Joht Singh Chandan

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Project title[1]	Redthread Youth Violence Intervention Programme evaluation
Developer (Institution)	Redthread
Evaluator (Institution)	University of Birmingham
Principal investigator(s)	Professor Paul Montgomery, Dr Joht Singh Chandan
Evaluation plan author(s)/Co-investigators	Professor Paul Montgomery, Dr Joht Singh Chandan, Dr Emily Evans, Professor Siddhartha Bandyopadhyay, Dr Ioannis Karavias, Alice Burton, Dr Rasiah Thayakaran, Professor Eddie Kane.
Evaluation setting	Hospital / Community
Target group	10- to 17-year-olds presenting at hospital who are impacted by violence, exploitation or vulnerability. Redthread, NHS staff and other professionals at each recruitment site will also be interviewed.
Number of participants	In pilot phase all eligible participants across 4 proposed sites (Birmingham Queen Elizabeth hospital, Birmingham Children's hospital, St Mary's London and Queen Elizabeth

[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).

	hospital, Woolwich) – approximately 350 CYP referred to Redthread and 150 engaged in a longer term programme.

Protocol version history

Version	Date	Reason for revision
1.5	18/8/22	YEF, RT and REC feedback
1.4	26/07/22	YEF, RT and REC feedback
1.3	13/7/22	YEF, RT and REC feedback
1.2	26/5/22	YEF feedback
1.1 [latest]	4/4/22	YEF feedback
1.0 [*original*]	16/12/2021	

Any changes to the design need to be discussed with the YEF Evaluation Manager (EM) and the developer team prior to any change(s) being finalised. Describe in the table above any agreed changes made to the evaluation design, research questions and approach, and the rational for these.

Introduction

Background

The World Health Organization (WHO) state "violence is a universal scourge that tears the fabric of communities and threatens the life, health and happiness of us all."[1] An emerging strategy in the UK to mitigate such negative consequences is to adopt a public health approach to reducing violence which has been led by established violence reduction units (VRU).[2] One element of taking such an approach consists of secondary prevention. In contrast to primary prevention which refers to preventing exposure to violence, secondary prevention occurs when an individual is exposed to violence but where we aim to stop ongoing victimisation or offending patterns to prevent further injury. Diversionary programmes are secondary prevention approaches where children and young people (CYP) are diverted away from behaviours or risk factors which could lead them into a cycle of ongoing violence following initial exposure to a violent injury.

An area of particular note revolves around youth violence attendances in the emergency department (ED).[3] For example, in 2020/21 there were 4,091 recorded attendances to EDs due to assault by a sharp object and of these 17% were aged 18 and under, representing a significant burden of injury.[4] Despite the substantial health burden, historically in the UK, prevention of youth violence has been left to outside the hospital with community and police interventions.[3] However, with the ongoing concerns around hospitalisations related to youth violence, there is a developing trend of interventions where youth workers are integrated into EDs, where they deliver a teachable or reachable moment[2] and have the opportunity to integrate the CYP into a longer term programme to divert them from further victimisation/offending. Numerous examples of programmes of this type are available of which many based in North America.[5–16]

Two recent systematic reviews[3,17] have summarised the existing literature on ED based interventions aiming to reduce revictimization and perpetration in victims of violence. They identified 9 different intervention programmes which, on the whole, appeared to lead to improvements in one or more violence related outcomes. Despite the positive findings, none of the included interventions in either study were UK based and the recommendations of both reviews described the need for larger, more suitably powered studies and for them to take place in the UK. Similarly, The Health Foundation funded research into the adoption

[2] RT use both terms but often prefer reachable as it presents their service less as a lesson they teach the CYP, but more as an opportunity to reach out to the CYP as an equal.

and spread of the RT programme noted as a potential barrier to this, a lack of comparative studies from the UK demonstrating the effect of the service compared to standard care.[28] Therefore, there is an urgent need to undertake a more robust evaluation of these hospital-based interventions (often referred to as navigator programmes). In this proposal, we aim to describe an evaluation of a widely adopted youth violence interruption scheme based in UK EDs.

Intervention

Background to Redthread Youth Violence Intervention Programme

The Redthread (RT) programme is aimed at those aged 11 to 25 years old. The funding for this study is for those aged 10-17 which will be our eligible population for this evaluation. Approximately 300 children (aged under 18) are engaged in a longer term programme by RT per year. By nature, the intervention is a diversionary activity based in a hospital setting aiming to divert individuals away from ongoing violent crime leading to injuries or divert them from at risk settings.

The children and young people (CYP) eligible for the intervention are those who have attended one of the 13 emergency departments (ED) where Redthread's Youth Violence Intervention Programme is embedded as part of standard care, having experienced or been impacted by violence, assault or a risk of violence, whether weapon or non-weapon related, domestic or sexual violence, sexual or criminal exploitation.

In such cases a clinical member of staff refers the CYP to the RT team. They can do this directly to the RT team when they are on shift and on site. Due to Redthread's position in the hospital, honorary NHS contracts, and safeguarding issues this can be done without consent from the CYP. When consent is sought, it is recorded in hospital systems. Referrals can be made face to face, via secure NHS email, phone or other local system e.g., referral button on hospital system, and will include the CYP's hospital number to allow RT to check hospital systems to establish eligibility. In cases where a RT team are not on site or on shift the clinician can complete a referral providing details of the CYP. It is standard practice at these sites for RT to also ask the clinician, to provide a safe number for them to use to contact the CYP, ask whether the CYP has a safe place to be discharged to and to make the usual referrals to hospital safeguarding as necessary. Most often the referral is made by a member of staff within the ED, but could also be a clinician elsewhere within the hospital who becomes concerned about a CYP. Referrals are managed and recorded by the Programme Coordinator and Team Leader of the RT team for each hospital site.

CYP can also be referred should they present in a different part or department of the hospital or if information about their risk factors transpire following their admission. They can also be identified by RT staff using information on hospital systems to ensure eligible CYP are not missed. The intervention is bespoke and led by the CYP's needs at that time. Once clinical needs are dealt with the intervention team continue building trust and a practical plan to help the CYP feel safe in preparation and following their discharge. The cases are closed once the CYP is safer and has engaged with a professional network that can support their longer-term goals, away from violence:

- For CYP who already have effective support of multiple existing agencies and/or a key professional, the intervention can be short-term and involves 'scaffolding' the reachable moment back into that CYP's professional network.
- For CYP who don't have an effective support network who are facing extremely high levels of complex risk or harm, or require further support, RT offer a longer intervention, usually lasting up to three months, although this can be longer. A more comprehensive risk and needs assessment is completed by the youth worker in partnership with the CYP, and a joint action plan is agreed. Actions can include support navigating statutory systems, casework around healthy relationships or managing difficult emotions, support to (re-)engage with education, securing alternative accommodation, accessing mental health or substance misuse support, accessing financial support and welfare benefits, relational referrals to community or statutory partners and diversionary activities, supporting the CYP to advocate for themselves in multi-agency meetings, or goal-setting and aspirational exercises.

When closing a case, RT complete a comprehensive end assessment with each CYP, and follow up six months after case closure with the CYP and other key workers to review progress.

RT provide a dedicated, trained, highly skilled team in each hospital site made up of the following roles (The precise team combination varies per site):

- Programme Manager (oversees teams in each locality, covering multiple sites, safeguarding and partnerships lead);
- Team Leader (manages team, involved in partnership working and multi-agency work, carries a smaller caseload, delivers training to professionals);
- Senior Youth Intervention Practitioners (SYIP) (carries a caseload, delivers training to professionals, leads on projects);
- Youth Intervention Practitioner (YIP) (carries a caseload, delivers training to professionals);
- Programme Coordinator (data and administration lead);
- Counsellor (Birmingham only) (upskills practitioners, carries a small caseload of high risk young people);

- Young Women's Worker (some London sites only) (carries a caseload, specialist support for women, delivers training to professionals);
- Independent Domestic Violence Advocate/Advisor (seconded from Solace Women's Aid to 3 London sites, working in partnership with team to support YP affected by domestic violence).

RT have commissioned a number of evaluations of its programme within different hospital sites. A non-peer reviewed published evaluation undertaken on the programme in St Mary's hospital in London by NPC associates[18,26] showed promising findings, regarding reducing hospital re-attendance rates for violence (a statistically significant fall compared to a pre-programme control group). YP using the service and professionals referring into it were supportive of the programme. However, there were limitations in the study design which affected the ability to draw a causal conclusion. Similarly, an evaluation of the programme in the Queen's Medical Centre undertaken by research staff there[27] showed lower re-attendance rates for YP who participated in the programme (both short term crisis support and full programme of work), compared to those YP who were eligible for the programme but did not engage with it. These results were found for re-attendance for any reason and specifically for violence or assault.

Mechanism for action and key outcomes

During the co-design phase we worked with RT and their partners (Dartington Service Design Lab) to undertake a Theory of Change exercise. This work involved key stakeholders and is on-going but a draft has been produced and is described below. The work has helped clarify what the different components of the programme are and the likely channels which have outcomes for CYP. In turn, this has enabled us to clarify the short-, medium- and long-term outcomes that are expected. As a result, during our sessions, we have considered the outcomes at length in consultation with YEF and RT both separately and as part of a co-design phase. Following the co- design stage, it became clear that the primary outcome should be reattendance coded for a violence or abuse related reason to hospital within 12 months from their initial discharge date. These data are available for both intervention and controls (see detail later) and we are confident that there will be sufficient power to distinguish the two groups. The secondary outcome will be mortality by any cause one year post contact with RT (this will draw on NHS data captured in the Summary Hospital level Mortality Indicator and other data which captures mortality beyond 30 days post discharge).

We also plan to pilot the collection of the strengths and difficulty questionnaire (SDQ) and self-report delinquency scale (SRDS) as outcome measures for the treatment group only. It will not be possible to collect these for the control groups. These validated measures are

described below and used as part of YEF's core measures in evaluating their funded interventions.

- Strengths and Difficulties Questionnaire (SDQ), Self-complete version for children and young people- a brief emotional and behavioural screening questionnaire for children and young people, which can be completed by the young people themselves, their parents or their teacher.
- Self-Reported Delinquency Scale – a broad measure of 'delinquency' from the Edinburgh Study of Youth Transitions and Crime which measures involvement in shoplifting, assault, weapons carrying, burglary, truancy and robbery.

RT will aim to administer the SDQ/SRDS near to the initial assessment and towards the end of the CYP's engagement with RT. They will be completed by CYP with information not shared with RT workers and only with research staff. CYP will use a University of Birmingham approved online platform (Online Surveys- formerly BOS) on which to complete the questionnaires. Participants will be identified by a case ref number assigned to them by RT which will be written on questionnaire forms by RT workers prior to completion. The CYP will then complete the questionnaire independently.

This pilot will allow us to understand what the optimum point to administer the questionnaires is, as the engagement period may be variable per participant. During our co-design phase it was clear that from previous evaluation experiences undertaken by RT that the feasibility of introducing these measures into their routine practice has been problematic (e.g. that it can be clinically difficult for them to do so given the setting in which the CYP are seen). We would continue to do our utmost to ensure as many CYP in the treatment group are administered the questionnaire but we will need to monitor the feasibility of doing this.

The key mechanisms for the RT intervention are assumed to be that once CYP have undergone the initial elements of the intervention, the CYP will feel safer, have safeguarding support around them, have an improved understanding of their health and ongoing connections with required support services. These short-term outcomes, should create improved feelings of wellbeing, self-esteem, confidence and greater independence in the medium term and so reductions in readmission to hospital or further involvement in criminal activity in the long-term. The theory of change can be seen below.

Theory of Change

WHY	***Problem Observation***	Children and Young People (CYP) are presenting to hospital (Major Trauma Centres, MTC and Local Trauma Units, LTU) having experienced or been impacted by: violence, assault or a risk of violence, whether weapon or non-weapon related, domestic or sexual violence, sexual or criminal exploitation. Violence has a negative impact on the health and social wellbeing of children as they become adults. CYP need to be recognised as victims who should be supported. Where support exists this often treats the symptoms (e.g. injury) rather than the root causes of violence (e.g. situation that caused the injury) and their holistic needs
	Need	A number of these CYP are frequently high risk and may have experienced violence and /or exploitation.
WHO	***Target Population***	10 – 17 year olds who present at hospital having experienced or been impacted by: violence, assault or a risk of violence, whether weapon or non-weapon related, domestic or sexual violence, sexual or criminal exploitation. Referrals made by (1) hospital staff member or (2) Redthread identifying an eligible CYP when reviewing the hospital systems Eligibility criteria: 1. Weapon-related injury (with the intention to do serious harm) 2. Concerns that incidents or individuals may be gang affiliated / have been exposed to or experienced violence/abuse 3. Concerns that an individual is at risk of further harm or abuse 4. A victim or perpetrator of a serious assault (with the intention to do serious harm) 5. Concerns or disclosures of domestic violence, sexual violence, including historic sexual violence/abuse 6. Concerns or disclosures of (Child) Sexual Exploitation or (Child) Criminal Exploitation. Planned Scale: approximately 350 CYP referred through 2022 with around 150 engaged in a longer term programme across three locations, Queen Elizabeth Hospital MTC (Birmingham), Birmingham Children's Hospital MTC, Queen Elizabeth Hospital LTU (Woolwich, London) and St Mary's Hospital MTC (Paddington, London).
HOW	***Intervention Activities***	Hospital initiated Violence Intervention Programme delivered by Redthread workers that aims to contact CYP at a "reachable" moment. Following a referral Redthread workers will approach the CYP to seek consent to work with them and for their data to be stored and shared. Short term crisis support - can include safety planning, emotional support, help with understanding medical treatment, attending relevant medical appointments, friends and family liaison, advocacy and signposting to statutory and community agencies, obtaining food vouchers/ clothing/ phone credit, safe travel after discharge, emergency accommodation. Longer term (full programme of work) engagement - risk and needs assessment and joint action plan agreed. Plan can include: making safeguarding referrals as necessary, support navigating statutory systems (including CJS, welfare), casework around healthy relationships/ managing difficult emotions, support to (re)engage in education, securing alternative accommodation, accessing mental health or substance misuse support, accessing financial support and welfare

		benefits, referrals to community or statutory partners or diversionary activities, support CYP to advocate for themselves in multi-agency meetings, goal setting and aspirational exercises. Typically support lasts for up to 12 weeks, with a 6 month follow up with YP and/or keyworker. Engagement in full programme of work includes these stages (post referral): • Engagement – face to face, phone • Joint needs assessment – drawn up with the YP, relevant services are engaged • Planning and Actioning – priorities jointly set, Redthread attend meetings with YP • Positive disengagement
WHAT	***Short Term Outcomes***	• CYP understands their diagnosis/health plan • CYP feel safer • CYP offered appropriate safeguarding support • CYP better able to attend appointments, negotiate services and access support • CYP makes own appointments/plans for specialist ongoing support • CYP experiences successful engagement with specialist services themselves • CYP has onward plan for appropriate services
	Medium Term Outcomes	• CYP gains greater independence (e.g. makes own plans, appointments) • Improved wellbeing, sense of self, and confidence
	Long Term Outcomes	• No readmission to hospital for violence-related incidents for 12 months • Reduced risk of future harm to self and others • Reduced mortality

Logic Model

INPUTS	***What resources are needed?***	Provision of a dedicated, trained, highly skilled team at each hospital site. The size and composition of the team varies based on the extent and nature of the demand at the hospital. The roles which can feature in these teams include: • Programme Manager (oversees teams in each locality, 2-3 sites, safeguarding and partnerships lead); • Programme Coordinator (data and administration lead); • Team Leader (manages team in a site, involved in partnership working and multi-agency work, carries a smaller caseload, delivers training to professionals); • Senior Youth Intervention Practitioners (SYIP) (carries a caseload, delivers training to professionals, leads on projects); • Youth Intervention Practitioner (YIP) (carries a caseload, delivers training to professionals); • Counsellor (Birmingham only) (upskills practitioners, carries a small caseload of high risk young people); • Young Women's Worker (some London sites only) (carries a caseload, specialist support for women, delivers training to professionals); • Independent Domestic Violence Advocate/Advisor (seconded from Solace Women's Aid to 3 London sites, working in partnership with team to support YP affected by domestic violence). Staff are from diverse disciplines Clinician / hospital staff time (to make referrals) and training.
OUTPUTS	***Activities*** *What needs to take place for CYP to accomplish the short term outcomes*	Hospital-based Violence Intervention Programme delivered by Redthread workers that aims to contact CYP at a "reachable" moment. Following a referral Redthread workers will approach the CYP to seek consent to work with them and for their data to be stored and shared. Short term crisis support - can include safety planning, emotional support, help with understanding medical treatment, attending relevant medical appointments, friends and family liaison, advocacy and signposting to statutory and community agencies, obtaining food vouchers/ clothing/ phone credit, safe travel after discharge, emergency accommodation. Longer term (full programme of work) engagement - risk and needs assessment and joint action plan agreed. Plan can include: making safeguarding referrals as necessary, support navigating statutory systems (including CJS, welfare), casework around healthy relationships/ managing difficult emotions, support to (re)engage in education, securing alternative accommodation, accessing mental health or substance misuse support, accessing financial support and welfare benefits, referrals to community or statutory partners or diversionary activities, support CYP to advocate for themselves in multi-agency meetings, goal setting and aspirational exercises. Typically support lasts for up to 12 weeks, with a 6 month follow up with YP and/or keyworker.

		Engagement in full programme of work includes these stages (post referral): • Engagement – face to face, phone • Joint needs assessment – drawn up with the YP, relevant services are engaged • Planning and Actioning – priorities jointly set, Redthread attend meetings with YP • Positive disengagement
	Participation *What outputs must be achieved for the short term outcomes to be achieved.*	10 – 17 year olds who present at hospital having experienced or been impacted by: violence, assault or a risk of violence, whether weapon or non-weapon related, domestic or sexual violence, sexual or criminal exploitation. Referrals made by (1) hospital staff member or (2) Redthread identifying an eligible CYP when reviewing the hospital systems Planned Scale: approximately 350 CYP referred through 2022 with around 150 engaged in a longer term programme across four locations, Queen Elizabeth Hospital MTC (Birmingham), Birmingham Children's Hospital (MTC), Queen Elizabeth Hospital LTU (Woolwich, London) and St Marys MTC (Paddington, London).
OUTCOMES	***Short Term Outcomes***	• CYP understands their diagnosis/health plan • CYP feel safer • CYP offered appropriate safeguarding support • CYP better able to attend appointments, negotiate services and access support • CYP makes own appointments/plans for specialist ongoing support • CYP experiences successful engagement with specialist services themselves • CYP has onward plan for appropriate services
	Medium Term Outcomes	• CYP gains greater independence (e.g. makes own plans, appointments) • Improved wellbeing, self-esteem, and confidence
	Long Term Outcomes	• No readmission to hospital for violence-related incidents for 12 months • Reduced risk of future harm to self and others • Reduced mortality

Underpinning Aspects

ASSUMPTIONS	**EXTERNAL FACTORS**
Redthread can expect to receive referrals in from partner agencies listed above.	Availability of specialist services for Redthread staff to refer on to and thresholds of these organisations.
Eligibility criteria is appropriately applied.	

Research questions and/or objectives

The overarching research question is do CYP who engage with longer term support from RT have a reduced incidence of hospital re-admission for violent injury?

The primary objective of our proposed evaluation is to provide a robust understanding of whether the RT programme targeted at CYP experiencing violence or at risk of abuse/exploitation leads to a reduction in violence/abuse related hospital readmissions in the subsequent one-year period. We aim to undertake a 1) process/implementation evaluation to assess how the well the programme is being delivered and differences between delivery locations and an 2) impact evaluation to assess whether the RT programme leads to a reduction in violence/abuse related hospital admissions and other metrics.

Success criteria and/or targets

As agreed upon with YEF and RT, this project will run in two parts. The first element relates to the successful completion of a pilot phase lasting one year. This pilot will form the first part of an efficacy study, and the data gathered may contribute to the final analyses. Set progression criteria will determine whether the pilot proceeds to the efficacy study. The agreed progression criteria include:

1. Project implementation

    a. UoB and RT are able to make a decision on the use of the SDQ/SRDS – based on RT run pilot (August 2022) and use within the pilot study (if the tools are used).
    b. Intervention aligns with the ToC; if there is misalignment it will be necessary to re-visit the ToC, there is in general no need to stop the intervention but rather understand why the two diverge.
    c. 75% of actions in an agreed action plan with CYP were implemented in a collaborative process involving staff and children; if this falls below 60% (Yellow), we need to discuss why this divergence is occurring and if it reaches 50% (Red) we will refer to YEF.
    d. Personnel records show all youth workers received adequate supervision and support; this will be reviewed by UoB team and significant divergence will be reviewed with RT and YEF.

2. Recruitment and retention

    a. Recruitment on to the intervention and into the control group is at least 60% of planned numbers within the pilot period. Anything below that is cause for concern (Yellow) with a need to pause (Red) if the response is below 40%.
    b. CYP referred to and accepted on to the Redthread programme meet the eligibility criteria (referral form). We would expect the majority of CYP Redthread work with to meet these criteria, anything below 90% would prompt a need to discuss with Redthread.
    c. Redthread are able to retain CYP in support within the intervention to work through the action plan. At least 60% of planned numbers within the pilot period should be retained for a sufficient

period to complete this work. Anything below that is cause for concern (Yellow) with a need to pause (Red) if the response is below 40%.

3. Measurement

   a. Hospital admission records (primary outcome)
   b. Mortality data (secondary outcome)

Follow up data collection will continue for 1 year after the intervention.

It will be important to see how easily data can be matched between NHS and RT records. Not being able to match at least 80% of referrals is cause for concern and needs to be discussed (Amber), anything below a 60% match is serious cause for concern (Red) and may require us to revisit this method of capturing data.

Some key data issues such as incomplete/missing data or noncompliance or higher attrition rates than expected need to be considered. A certain level of missing data can be handled using statistical techniques, but quarterly audits should prevent this from becoming a serious problem.

These ratings relate to the feasibility of the methods of data collection of the pilot. Failure to meet success criteria, does not necessarily mean that the main evaluation should be abandoned, but will suggest that the proposed design or methods require revision. Provided the above are met or feasible alternatives can be found, we will recommend that we proceed to an efficacy trial, which will be completed via a separate ethics application. YEF will then reflect on the evidence the evaluation provides before a decision is made about the transition to the efficacy study.

The progression criteria will remain under review with more specific suggestions made as the evaluation proceeds (e.g. when it is clearer what a realistic proportion of completions of the SDQ might be possible with this cohort). Following the successful completion of this first year then we will focus on developing success criteria for the two-year efficacy study.

Methods

Study design

This study is a mixed-methods quasi-experimental design (QED) using existing observational data. The project is due to consist of two elements (process/implementation and impact). The first year of the project will be a pilot and if successful (see below) will then be extended for a further two years to collect sufficient impact data across further sites. The pilot study will be based in the following settings: Queen Elizabeth

hospital Birmingham, Birmingham Children's hospital, St Mary's hospital London and Queen Elizabeth hospital Woolwich.

Different research activities will require different ethical approvals and so will take place once these have been secured. This is further detailed in the sections below.

Rationale for study design

This design selection (QED) was made after careful consultation at the co-design meetings and follow up discussions with both Redthread and YEF separately. Initially we had planned to conduct an RCT across the multiple sites where RT operates. However, after extensive discussions, it became clear that this was not possible for a number of operational reasons. Firstly, RT has contracts in place with its funders where it has agreed to treat all patients. If treatment were to be withheld to create a control group this would threaten these funding arrangements. Secondly, in sites where RT is already operating, it was considered to be unlikely that NHS ethics committees would agree to the withdrawal of treatment. Thirdly, in discussion with RT field staff, we came to believe that the chances of contamination between treatment and control groups was very high and thus the delivery of a high quality RCT is unlikely. In sum, we concluded that other robust designs needed consideration. Hence we believe that a QED is the most robust design that will provide high quality causal data on this research question by allowing us to compare a treatment a control group.

Participants

During the pilot phase, the participants will be identified across the four hospital sites. For the process evaluation the participants will consist of:

1. RT staff - Staff will be interviewed at the start of the intervention and throughout as part of the process evaluation. Participants will be those working directly on the project (programme managers and a representative of each job role across the four hospital sites). The size of these teams vary by hospital site, we will use a mix of one-to-one interviews and focus groups to ensure we speak with as many members of these teams as possible. This part of the pilot has been reviewed and approved by UoB ethics.

2. NHS clinicians and other staff who refer CYP to the RT teams – We will aim to interview (perhaps in a focus group) around 4-6 individuals in each of the 4 hospital sites. We will ask RT to identify appropriate staff members, provide them with the Adult Participation Information Sheet and gain consent for their contact details to be passed to the study team. Researchers will gain written consent prior to commencing the interview.

3. Community partners –non-hospital personnel who work with Redthread in joint case work, and representatives of organisations receiving onward referrals. We will aim to interview (perhaps in a focus group) around 4-6 individuals in each of the 4 hospital sites. We will ask RT to identify appropriate staff members, provide them with the Adult Participation Information Sheet and gain consent for their contact details to be passed to the study team. Researchers will gain written consent prior to commencing the interview.

4. CYP who are engaged in the intervention. We will aim to interview 10-20 CYP and gather quantitative data from all those taking part in the intervention. The CYP eligible for the intervention are those who have attended one of 4 hospital ED as a result of violence or deemed at risk of exploitation or abuse by a referring clinical member of staff. CYP can also be referred should they present in a different part or department of the hospital or if information about their risk factors transpire following their admission (see eligibility criteria for RT in the theory of change (page 1-introduction for more detail).

For the impact evaluation, the participants will consist of:

1. Intervention group: CYP (aged 10-17) who have undergone the intervention in any of the four sites (see eligibility criteria).
2. Control group: This will consist of CYP (aged 10-17) who either were eligible for the intervention but did not take part (this will include those who could not be contacted by RT following a referral. It should not include those who refused to take part in the intervention) or taken from historic data prior to the introduction of the intervention in each site.

Theory of change:

The initial phase of the evaluation will be to refine the theory of change (ToC) for the programme with the RT senior team. The organisation Dartington Service Design Lab have been commissioned to undertake the ToC with RT. However, they were commissioned to undertake the ToC for the whole service and the programme we are evaluating is only part of the wider RT offer. Therefore, our initial activities will be to undertake 1-2 focus groups consisting of 5-10 individuals remotely of RT senior staff to clarify and finalise the ToC for this project. This will inform data collection, analysis, and interpretation. As the feasibility study progresses, we will continue to consult with RT, clinical colleagues and most importantly CYP eligible for the intervention, about the ToC and Logic model. This part of the study has been reviewed by the UoB ethics committee.

This will include discussions around:

1. Problem Identification

Describing the problem that the project is designed to address. The description of the problem should be based on an analysis of data and relevant information and should be rigorously checked for availability, accessibility, completeness, and accuracy.

2. Response/Resources

How does the intervention address cause of the identified problem? This will include:

- What are the causal links assumed between the project approach and the problem?
- How and why does/will the project approach address the problem?
- Are there parts of the problem the project approach does not address?
- How do any current approaches need modifying to address all aspects of the identified problem? This would include a discussion of the associated dosage (which varies from case to case) and mode of delivery.

3. Outputs

Describing what is expected to be produced as a result of the response. Outputs are not used to evaluate the success of the intervention (as outcomes are), rather they are the measurable elements of project approach and generally describe the amount of activity expected or delivered.

4. Outcomes

Describing the changes expected as a result of the longer term support from RT in the short, medium, and long term. When determining the outcomes, it is essential to:

- Identify the outcome data; it is often the same data used to understand the problem
- Ensure the planned outcomes are SMART (Specific, Measurable, Agreed, Realistic, Time-based)
- Set out clearly and credibly how the outcomes can be measured reliably - what data/information is needed, can it be easily accessed, is it detailed and complete enough? (e.g., can it be linked to the planned outcomes), can outcomes be linked to the response/resources and outputs?

Process/implementation activities:

The process and implementation elements of the study will consist of both qualitative and quantitative data collection. The process evaluation's quantitative data collection activities will describe how the well the programme is being delivered during its first year, including differences between delivery locations. The types of data we aim to include are:

- Fidelity – Information on whether the providers delivered the specified interventions consistently and whether it differed importantly across locations.
- Delivery - number of interventions planned with children and young people, quality of delivery
- Dosage – number of interventions completed with children and young people and topics covered

- Reach – size of target group broken down by referral reason, hospital site, demographics, education
- Health records taken from hospital data including:
    - Readmission and follow up information
    - Clinical outcomes
- Response – completion of the programme and outcomes
- Engagement with support services including education and social care
- Adaptation - are changes needed to accommodate context and population need?

These metrics are largely currently collected by RT as performance metrics for the existing project. However, we will explore the existing data with the RT team and then adapt the standardised data collection tools captured by the RT staff to capture any missing metrics.

We anticipate that analysis of data held by RT, where they are data controller (e.g. from Lamplight) can be undertaken once ethical approval has been gained, in the process described below.

In addition to the description of data above, we aim to undertake qualitative research to investigate the implementation processes and quality of the interventions. We aim to undertake the following activities:

- Interviews / focus groups with local delivery staff and leaders on the implementation and delivery of the project. The topics would cover the ToC and operational processes such as intervention delivery and ongoing support, understanding of the project fidelity, and session quality. We aim to undertake 1:1 semi-structured interviews with each of the programme managers at the four sites, and then focus groups with a representative of each of the remaining job roles (consisting of 4-6 individuals). We expect each interview/focus group to last between 30-60 minutes and will be in person (in their chosen location) or on Zoom/Teams if Covid restrictions again come into place. We would expect the team leads at Redthread to initially approach staff working in their area (no exclusion criteria) to gain consent for their contact details to be passed to the research team. Potential interviewees will be given Participant Information Sheets prior to UoB staff consenting them into the study. Consent statements will be signed in person before the interview takes place. Where interviews take place remotely we will email consent statements in advance and ask them to be returned to us prior to the interview.

- Interviews/focus group with community partners –non-hospital personnel who work with Redthread in joint case work, and representatives of organisations receiving onward referrals to explore their experience of working with Redthread. We will aim to interview around 4-6 individuals in each of the 4 hospital sites.

- One to one interviews with CYP who experienced the RT programme to explore what difference it made to them. We aim to recruit around 5 individuals at each of the 4 sites. We would aim to conduct these interviews towards the end of their time working with their RT youth worker so they are able

to reflect upon it. CYP will be interviewed by experienced University researchers either face to face in local RT offices, or online depending on their preference. All the involved UoB staff are experienced in trauma informed interviewing and working with children. We will seek a maximum variation sample[19] to give us a range of different backgrounds, experiences, referral routes and ethnic backgrounds. We will ask youth workers to refer to us **all** CYP they consider able to consent and communicate in English language to be invited for interview. This will avoid youth workers only referring those young people where they think they've had more success and who are likely to give positive responses. We will ask RT staff to provide CYP and parents/carers with Participant Information sheets (audio and translated version will also be made available) during their initial meeting in hospital. They will be consented into the study during their post-discharge meeting with RT. Researchers will ask the CYP to sign an additional consent statement prior to participating in an interview. It is likely that where consent is needed from parents/guardians for those under 16, this will be obtained via phone or email and recorded appropriately on the consent form. Thank you tokens in the form of shopping vouchers (£20) will be offered to CYP participating. We will ask RT to systematically gather information on those CYP who refuse an interview so we can assess differences between those who agree to and refuse an interview. We will ask RT staff to provide CYP and parents/carers with Participant Information sheets (audio version will also be made available) during their initial meeting in hospital. They will be consented into the study during their post-discharge meeting with RT.

- Interviews / group interviews with clinical staff at the hospital sites who refer into RT. Topics would cover their use and opinions of the RT service, the alternatives to RT locally and the effect it has and ways it could be improved. We aim to conduct one focus group (consisting of 4-6 individuals) per site and the staff are likely to consist of ED doctors, nursing and professional services staff. We would expect the team leads at Redthread to initially approach referral staff to gain consent for their contact details to be passed to the research team. Potential interviewees will be given Participant Information Sheets prior to UoB staff consenting them into the study. We expect each interview/focus group to last between 30-60 minutes and will be in person (in their chosen location) or on Zoom/Teams if Covid restrictions again come into place.

Inclusion/exclusion criteria:

Participant Group	Inclusion Criteria	Exclusion Criteria
Children and Young People (CYP)	Capacity to consent to the Redthread programme.	
	CYP aged (10-17) who have undergone the Redthread programme in any of the four participating sites. *Redthread eligibility criteria:* 10-17 year olds who have presented at hospital having experienced or been impacted by: violence, assault or a risk of violence, whether weapon, or non-weapon related, domestic or sexual violence sexual or criminal exploitation.	
Controls (PSM)	CYP (aged 10-17) who were eligible for the intervention but did not take part; or eligible CYP taken from historic data prior to the introduction of the programme in each site. This will include those who could not be contacted by Redthread following a referral.	CYP who were offered but refused the Redthread programme.
Parents/carers (for CYP under 16 years old)	Capacity to consent to their CYP taking part in the Redthread programme. Where appropriate we will provide the PIS in alternative languages.	None.
Redthread staff	All programme managers and a representative of each job role within the team across the four hospital sites.	None.
Community Partnership staff **NHS Staff**	Consenting non-hospital personnel who work with Redthread in joint case work, and representatives of organisations receiving onwards referrals. Consenting NHS clinicians and other staff who refer CYP to the Redthread teams.	None. None.

We anticipate that interviews with RT staff can take place once ethical approvals have been gained from UoB. Interviewing NHS staff and CYP will require NHS ethical approval.

Data analysis for process evaluation

All interviews and focus groups will be recorded on encrypted digital voice recorders, transferred onto our secure BEAR research data store as soon as possible after returning to campus (when they will be deleted from recorders), transcribed, and analysed using Framework Analysis (FA).[20] This is a qualitative method where data is sifted, charted and sorted in accordance with key issues and themes supported by using Nvivo software (Nvivo aids the organisation and analysis of unstructured and qualitative data such as interviews). Interview recordings will be deleted from the UoB server after transcriptions have been received and checked. We recognise that there may be individuals who are reluctant to be recorded (although in our experience this is highly unlikely) and, in those cases a written record will be made. Informed consent (preferably written, but in cases where that is not possible, oral consent will be obtained and recorded on the consent form) will be sought from each participant following a briefing that will

explain the aims of the research, the terms of participation, reassurances around confidentiality, as well as explanation of support options after involvement in the interview and the process for managing their data.

Impact evaluation activities:

Control group data collection

As highlighted above, we aim to undertake a QED with PSM to ascertain impact. The PSM study will consist of collecting data from the treatment group (from the four RT hospitals) and then, with the support of the relevant health informatics teams at the sites, identify a suitable group of controls who have not used the service from at least one of the existing sites (but who have not refused that service as including those who refuse service would create a selection bias). This could be drawn from contemporaneous or historical data, depending on the processes RT uses to gather referrals; for example, whether there would be a group of suitable CYP not approached by RT. This data will be provided to us without any personal identifying information. The groups will then be propensity score matched to identify the most suitably similar controls based on a variety of demographic and clinical data that we have in both the hospital record and RT dataset. This is likely to include age, gender, severity and nature of their injury, or level of risk to the CYP based on RT's eligibility criteria (weapon-related injury or a serious assault with the intention to do serious harm; concerns that incidents or individuals may be gang affiliated or have been exposed to or experienced violence/abuse; concerns that an individual is at risk of further harm or abuse; concerns or disclosures of domestic abuse, sexual violence, including historic sexual violence/abuse; concerns of (Child) Sexual Exploitation or (Child) criminal exploitation). These variables are chosen because they are related to both the treatment and the outcome and are common in the literature (see e.g. Shibru et al., 2007).

The matching is done by comparing the probability that an individual is assigned to the treatment group. Therefore, a matched pair comprises two individuals with the same probability of being assigned to the treatment group, yet one of them belongs to the control group. This probability is called the propensity score. The first step of PSM is to use logistic regression to calculate the propensity scores of each individual in the sample; the second step is to match these individuals according to their propensity scores. Once a propensity score has been calculated for each observation, we will ensure that there is overlap in the range of propensity scores across treatment and comparison groups by examining the scores graphically. A second check for the quality of matching is that, the propensity scores should have a similar distribution ("be balanced") in the treated and comparison groups. We will obtain an estimate of the propensity score's distribution by splitting the sample by quintiles of the propensity score. Because the number of individuals in the control group might be different than those in the treatment group, we will use kernel-based matching. We prefer the Epanechnikov kernel with a bandwidth of 0.06, which are common choices in the literature (see, e.g., Heckman, Itchimura and Todd, 1997).

We will ensure that there is a data sharing agreement between UoB and RT and UoB and the participating NHS trusts to support these activities.

Outcomes

For contextual information, following a co-design stage working with the intervention providers, it became clear that the primary outcome should be readmission (specifically violence/abuse related) to hospital at 12 months. These data are available for both intervention and controls and we are confident that there will be sufficient power to distinguish the two groups as well providing a comparable estimate with the published literature. The key secondary outcomes will be mortality by any cause one-year post contact with RT (this will draw on NHS data captured in the Summary Hospital level Mortality Indicator and other data which captures mortality beyond 30 days post discharge). We also plan to pilot the collection of the strengths and difficulty questionnaire (SDQ) and self-report delinquency scale (SRDS). However, the latter will be piloted in the opening phases of the study, as it is not likely we will be able to collect this data on control groups.

Control quantitative data

We foresee challenges in the collection of hospital data from the intervention and control sites. However, we have experience in working with NHS trust site directors, health informatics teams, and emergency departments and believe that these challenges are ones that we can address. We have discussed with RT who will provide us with the treatment data and will support our team in the extraction of pseudo anonymised control data supported by the relevant health informatics teams who will assign case IDs to those in the control group.

We will use this phase to explore whether it will be possible to collect control data on current cases, who do not receive support from RT, or whether it will need to be constructed from historic data. Discussions of RT practice during the co-design phase highlighted that RT staff in hospital sites do review hospital admissions to check for missed referrals and that they follow up referrals made when staff are not on duty. This risks contaminating any concurrent control group and reduces the pool of eligible CYP for such a control group.

During this phase we will complete a Template for Intervention Description and Replication (TIDieR) Checklist for the proposed control sample as we have done during the co-design phase for the intervention. This will include defining precisely what Business as Usual (BAU) consists of across sites. Mostly likely, this will be statutory safeguarding practices, although it may well be that this varies from one Trust to another and this will, of course, influence the effect size found in the intervention. The implementation study will aim to track both the intervention and assess what the comparison group receives.

Sample size

During the co-design phase we identified approximately 300 CYP (aged under 18 years) are engaged in a longer term programme annually across all 13 ED sites. Our sampling considerations have been informed by existing literature on the topic.[3,17] Much of the existing literature to date has focussed on criminal justice outcomes with no comparable study examining the risk of re-hospitalisation.

For power calculations, acceptable levels of differences of outcome in the treatment group compared to the control group for the intervention to be considered a success would be established. Our considerations of sample size and minimally acceptable levels would also be informed by the existing literature in this area. A measure for this effect size is Cohen's d,[21] which takes positive values. Cohen suggested that d = 0.2 represents a 'small' effect size, 0.5 represents a 'medium' effect size and 0.8 a 'large' effect size. In the current study, we will aim to detect even 'small' effect sizes, i.e. where d takes values around 0.2. Such effect sizes may be small, but they are meaningful in the current context and are standard in medical research, where sizes in the 0.05 to 0.2 range are frequently encountered. For d=0.2, with power of 80%, and assuming treatment and control groups of similar size, the minimum necessary sample is 392 individuals in each group, to a total of 784. We will aim to use treatment and control samples of similar size. This is likely to be more feasible if constructing the control group from historic data, as there will be more suitable cases to draw on. If treatment and control groups are of unequal size, power calculations can be modified. Thus, the roughly 900 people who are engaged in a longer term programme over the 3 year course will give us adequate power provided the attrition rate is not much more than 50%. This is in line with previous studies conducted.

On its own, the Cohen's d measure of effect size can be used to understand the relative differences between the treatment and the control group. Absolute differences need information on the averages of the outcome variables of interest in the control group. We can illustrate using some figures regarding the average readmissions in the control group from past literature. These figures are based on Cheng et al. (2008), one of the first emergency department studies.[10] Cheng et al. (2008)[10] analysed pupils 10-15 years old with peer assault injury in two large hospital emergency departments in Baltimore US. They find that 7.8% of the pupils in the control group had a repeat injury associated with serious youth violence or exploitation. Assuming that we will see the same resubmissions in a control group (which has 392 individuals), this means that we are expecting that 31 (7.8%) of them will be readmitted to the hospital with repeat injuries. It is straightforward to see that the hospital readmissions variable follows a binomial distribution with mean 31 and variance 28.19. Based on this, unreported calculations show that an intervention with a Cohen's d effect size of 0.2 will have 30 treatment group injury readmissions. If the effect of the intervention is stronger, say d=0.5, then the treatment group readmissions are expected to be 28.

The above analysis depends crucially on the recidivism rate of the control group, which is estimated to be 7.8% in the study of Cheng et al. (2008).[10] In the UK, this rate can be very different because of the different socio-economic conditions. The UK literature currently provides no empirical evidence on outcomes gathered in the UK context.[3] As explained above, these estimates are based on a US study and meant to be illustrative. We will gather historical data on the outcomes of interest e.g. readmission to understand what an effect size translates into in terms of a percentage reductions (or increases) from baseline means. This will allow us to benchmark this in terms of the effect seen in similar programmes.

As a result, we anticipate needing to recruit treatment and control samples from all 13 sites should the project run to a full trial. This will provide us with the maximal opportunity to meet the statistical power needed to assess our primary outcome (re admission). Additionally, where possible and statistical power is met, we will apply the principles of the Cochrane Progress Plus initiative[22] to ensure the findings are reported in a manner applicable to the diverse population in these regions. Hence, during the first year pilot, we will not be able to make causal inferences as to the differences between the groups. However, one of the purposes of the first year is to ensure that data collection approaches are feasible.

Impact data analysis

We anticipate that gathering and analysing SDQ and SRDS measures, and NHS held data (regarding patient outcomes) would require NHS REC and HRA approval.

We will analyse the collected data in the following way. First, we will conduct a pre-treatment analysis, looking at summaries and descriptive statistics of the collected data. Our aim here will be to discover any systematic differences between the treatment and the control group. Second, we will apply propensity score matching to remove the systematic differences which may arise between these groups, due to biases related to the aforementioned observed characteristics. This method will create 'matching pairs' of 'similar' individuals. In each pair, one individual will have received the treatment, and one not. The average difference over all such pairs will constitute a reasonable estimate of the average treatment effect. We will test if this effect is statistically significant using statistical hypothesis testing (t-tests). Furthermore, we will examine if the detected differences are clinically significant, besides being statistically significant.

The pre-determined sample size (see earlier discussion of sampling considerations) needed to get what would be the agreed minimum effect should ensure that the study is sufficiently powered.

Appropriate guidelines will be followed for reporting an observational real world evidence trial: https://www.equator-network.org/reporting-guidelines/consort-spi/

We will aim, as far as possible, to do sub-group analyses. This will depend on, for example, referral source, initial level of risk etc. and it is not possible to know at this stage if the sample size of sub-groups will be sufficient. If not, the results will be indicative, but underpowered. The subgroups of interest will be based on the variables of gender, age and ethnicity.

Some key data issues need to be kept in mind such as incomplete or missing data or the possibility on noncompliance or higher attrition rates than expected. A certain amount of missing data can be handled using a range of possible techniques but we hope that quarterly audits will prevent this from becoming a serious problem.

PSM does not control for the presence of unobserved covariates that can be correlated with both the treatment and the outcome variables. The presence of such unobserved factors could bias our estimates of the average treatment effects. To account for the selection on unobservables, we will use the Rosenbaum (2002)[23] bounds approach. To find out how strongly hidden biases may influence our results, we will thus do a sensitivity analysis following the boundness approach.

Ensuring cultural competence

We will ensure, that the intervention is delivered in a culturally competent way and not excluding people for cultural and linguistic reasons. For example, a common misconception is to consider the BAME population as homogeneous but there are significant cultural and other differences within the BAME populations and we will consider what these differences are and assessing if the mix in the pilot (and efficacy if we progress) provides the diverse mix that is expected for the target population. This will include an understanding of the differences across BAME groups and the diversity in the type of barriers they face. Thus, we will recognise that YP from BAME groups may not be a unified entity and it will be important in the design to incorporate the diversity of opinions and consider if the way the intervention is delivered needs to be tailored to that. That ensures the research design is truly inclusive by accounting for the potential diverse voices (see above section to reference of PROGRESS PLUS framework).[22]

Our research team for this project is reasonably diverse with regards to sex, age and ethnicity. We recognise that we will be speaking to different groups of participants who are also likely to be diverse with regard to their individual characteristics and that the interaction between the researcher and participant can affect the extent and quality of data gathering. The RT intervention is not suitable for the use of peer researchers as CYP do not tend to remain in contact with the service once they have finished their work. As such we will ensure that our researchers are mindful of diversity of the groups being interviewed, and in the case of the CYP, the sensitive nature of the topics covered. However, we will not be able to offer interviewees a choice of interviewer. The training of our staff will be key to our ability to safeguard and protect CYP participating in the study.

Data collection information

Participants	Data collected	Source	Details
CYP	• Personal identifying information • Demographic information • Referral information • Engagement with RT • SDQ/SRDS responses • Reattendance at hospital data • Mortality data	• RT • RT • RT • RT • UoB online survey platform • NHS informatics team/ RT • Summary Hospital level Mortality Indicator	(*All data on CYP will be passed to YEF at which point personal details will be replaced with a Pupil Matching Reference number from the Department for Education- pseudo anonymised).
NHS / RT / Community partner organisation staff	• Contact details/ employer name and Job role	• Provided by staff leads after consent given	For researchers to arrange interview- deleted after contact made and assigned ID to reflect employer / role group.
Controls	• Demographic information • Referral information • Severity and nature of injury/ level of risk to the CYP based on RT's eligibility criteria. • Reattendance at hospital data • Mortality data	• NHS informatics team	To support propensity score matching

Outputs

The output of the pilot trial will include an evaluation report fully summarising the pilot study. It will include details on CYP recruitment, tables and figures providing the collected data, and a statistical analysis comparing the different short-term outcomes between the treatment and the control group. Based on the criteria set on outcomes as well as fidelity to the process, we will make recommendations on (i) whether the pilot indicates that the main study is feasible or not and (ii) any changes needed to make the main study feasible. If necessary, an updated logic model will be provided.

Therefore, the evaluation report will conclude with a statement of progression to the second year of the study and if feasible, an efficacy study protocol if the recommendation is to proceed to the main study.

Additionally, we will offer a presentation to RT and YEF on the main findings of the pilot study.

Publication Policy

The Publications Subcommittee comprised of researchers from the University of Birmingham will review all research outputs following the guidelines given below and report its recommendations to the Steering Committee.

a. Data analysis and release of results

The scientific integrity of the project requires that the data from RT be analysed study-wide and reported as such. All presentations and publications are expected to protect the integrity of the major objective(s) of the study; data that break the blind will not be presented prior to the release of mainline results. Recommendations as to the timing of presentation of such endpoint data and the meetings at which they might be presented will be given by the Steering Committee.

b. Review process

Each paper or abstract, as described below, must be submitted to the Publications Subcommittee for review of its appropriateness and scientific merit prior to submission. The Subcommittee may recommend changes to the authors and will finally submit its recommendations to the Steering Committee for approval.

c. Primary outcome papers

The primary outcome papers are papers that present outcome data. The determination of whether or not a particular analysis represents a primary outcome will be made by the Steering Committee on the recommendation of the Publications Subcommittee.

d. Other study papers, abstracts and presentations

All studies, other than those designated as "Primary Outcome", fall within this category. All papers and abstracts must be approved by the Publications Committee before they are submitted. It is possible that in certain instances RT may be asked to contribute papers to workshops, symposia, volumes, etc.

We will also abide by the YEF Publication Policy.[3]

Cost data reporting and collecting

There are several organisations involved in the delivery of the RT intervention. Clinicians and others working in the NHS will refer into RT. RT will provide the intervention. Referrals by the NHS are part of their standard

[3] https://res.cloudinary.com/yef/images/v1623145471/cdn/16.-YEF-publication-policy/16.-YEF-publication-policy.pdf

operation and therefore no further costs arise for these organisations. Therefore, in the following table we provide cost descriptions from RT's point of view. The table below shows the total costs for RT to provide the intervention. In line with the funding application, below are the budgeted, allocated costs for delivering the programme to under 18 year olds across all 13 Redthread programme sites. The YEF funding is for supporting 10 – 17 year olds, Redthread's normal programme supports 11 – 25 year olds. The YEF funding is a contribution to the costs and is complemented by other funding sources.

Expenditure	Mobilisation	Year 1
Staff costs - delivery		
Youth Intervention Practitioners (existing roles) Inclusive of salaries, National Insurance, pension contributions, training, CPD, trauma-informed clinical supervision	£0.00	£517,050.00
Programme Coordinators (existing roles) as above regarding costs	£0.00	£140,150.00
Team Leaders (existing roles) as above regarding costs	£0.00	£102,510.00
Subtotal staff costs - delivery	£0.00	£759,710.00
Staff costs - central/management/training		
e.g. evaluation project management, operational programme management, data management	£84,502.00	£221,547.00
Subtotal staff costs - central/management/training	£84,502.00	£221,547.00
Equipment and materials		
IT equipment, software, IT support, mobile phones, PPE/Covid-related resources	£970.00	£31,050.00
Subtotal equipment / materials costs	£970.00	£31,050.00
Travel and expenses		
Travel and subsistence for all funded roles	£250.00	£9,000.00
Subtotal travel and expenses costs	£250.00	£9,000.00
Overheads - non-staffing business costs		
Contribution to organisation's overheads	£3,106.00	£74,728.00
Subtotal overheads	£3,106.00	£74,728.00
Expenditure Total	**£88,828.00**	**£1,096,035.00**
Youth Endowment Fund contribution	**£12,903.00**	**£588,859.00**
Other sources	**£75,925.00**	**£507,176.00**

Our approach will be based on five pillars: a) observe employees' work, b) request reports regarding caseloads and time-use, c) employ self-monitoring tools, and d) review progress on a regular basis. The key employees in this intervention are the hospital-based teams. During the pilot study we will focus on four sites and will seek to collect data from all of them. We will work with the programme manager and

programme coordinators in the four sites to ensure consistent data collection. As RT is not a new intervention we do not expect large cost deviations. To understand the resources needed to deliver the intervention, we need to understand the number of CYP who go through the intervention and the associated costs. Our approach to doing this is informed by the Youth Endowment Toolkit, which provides an overview of existing research on approaches to preventing serious youth violence. The toolkit has looked at the evidence underpinning mentoring and pre-court diversion. It finds that the mean effect size of mentoring for juvenile delinquency was d = 0.21. The pilot study should examine the availability of a sample to detect this effect size.

We will collect cost data using the principles articulated in the YEF guidance document, i.e. a bottom up approach estimating the different components of costs for the organisation concerned. We expect to collect the data from RT and include labour costs (these will be the main source of costs), material costs (including licensing), training costs, venue costs where applicable (if this is a regular fixed rental to be paid where say mentoring takes place). There is certainty about some of these costs because RT is an existing intervention.

Ethics and registration

Research into violence and criminality and with CYP has certain ethical and safeguarding challenges. We will ensure all issues like confidentiality, safeguarding, disclosure etc. are fully considered. We have a robust ethics framework in place.

The process evaluation work to be conducted with Redthread staff will be submitted for approval under the UoB ethics committee. The UoB has an overarching Code of Ethics and ethical approval is a requirement of the Code of Practice for Research. All research projects go through the ethical review and approval process. The process includes completion of a self-assessment form. Then, for studies involving human participants such as the current evaluation, stage 2 is to secure ethical approval via the central research ethics committee. Application to securing approval typically takes between 6 and 10 weeks. If amendments are needed (e.g. further development of an interview schedule or the addition of another organization / group of participants to the project) then these can be submitted and processed quickly by the ethics committee.

Any modifications to the protocol which may impact on the conduct of the study, potential benefit of the CYP or may affect CYP safety, including changes of study objectives, study design, patient population, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol. Such amendments will be agreed upon by the University of Birmingham, RT and YEF and approved by the University of Birmingham ethics committee prior to implementation. Administrative changes of the protocol are minor corrections and/or clarifications that have no effect on the way the study is to be conducted. These administrative changes will be agreed upon by the University of Birmingham, RT and YEF,

and will be documented in a memorandum. The University of Birmingham ethics committee may be notified of administrative changes at the discretion of the University of Birmingham research group.
Due to the nature of engagement with NHS patients, staff and NHS data, the data collection involving CYP experiencing the intervention, referral staff at the four NHS sites and control data are due to undergo NHS REC and HRA review. The process from application to securing this approval often can take up to three months. The part of the study undergoing NHS REC and HRA approval will also undergo sponsorship review. The application will then be submitted to the REC and HRA for review and approval. Both non-substantial and substantial amendments will be submitted to the sponsor for approval prior to submission on IRAS for REC/HRA review and approval.

With regard to registration, we intend to publish this protocol in BMJ Open.

All correspondence with the REC will be retained.
It is the Chief Investigator's responsibility to produce the annual reports as required.
The Chief Investigator will notify the REC and sponsor of the end of the study.
An annual progress report (APR) will be submitted to the REC and sponsor within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
If the study is ended prematurely, the Chief Investigator will notify the REC and sponsor, including the reasons for the premature termination.
Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC and sponsor.

Indemnity

The University has in force a Public Liability Policy and/or Clinical Trials policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage.

Data protection

The six lawful bases for processing are set out in Article 6 of the UK GDPR (one of which must apply when data is processed). A relevant basis for processing personal data here is the 'public task' basis.

For qualitative data, the most relevant principle/basis is **consent**; the individual has given clear consent for you to process their personal data for a specific purpose. Informed Consent will be obtained – this is where participants receive information outlining the nature of the research, what they are being asked to do, their

right to refuse to take part without negative consequences and their right to withdraw from the research during the fieldwork and up to two weeks after they finish working with RT.

Regarding **confidentiality**, participants will be informed prior to and post the interview process that the information they provide will be kept strictly confidential and that no identifying information will be available to anyone external to the research team. Confidentiality will be preserved (for quantitative and qualitative data) through steps such as (1) assignment of participant numbers/pseudonyms, (2) deletion of audio files post-transcription, (3) transcripts / consent forms stored in a locked cabinet at the University, and (4) electronic data held on password protected spaces only accessible to researchers.

All study-related information will be stored securely in RT premises or the allocated areas in hospitals from which RT staff work, the RT case management system and University of Birmingham computers. All participant information will be stored in locked file cabinets in areas with limited access. All reports, data collection, process, and administrative forms will be identified by a coded ID [identification] number only to maintain participant confidentiality. All records that contain names or other personal identifiers, such as locator forms and informed consent forms, will be stored separately from study records identified by code number. All local databases will be secured with password protected access systems. Forms, lists, logbooks, appointment books, and any other listings that link participant ID numbers to other identifying information will be stored in a separate, locked file in an area with limited access.

All participant results will be kept strictly confidential, all research activities will be conducted in private rooms, and study staff will be required to sign agreements to preserve the confidentiality of all participants. The final trial dataset will be accessed by the University of Birmingham researchers. They can access the data for a period of 10 years after the conclusion of the trial.

Once we have finished our study, we will share all of the information we have gathered about CYP who have taken part with the Department for Education (DfE). The DfE will replace all identifying information about the young people who have taken part in the study (their name, gender, date of birth, home address) with the young person's unique Pupil Matching Reference number in the DfE's National Pupil Database. Once this has been done, it is no longer possible to identify any individual young person from the study data. This process is called pseudonymisation.

Once information is transferred to the DfE to be pseudonymised, we hand over control to the YEF for protecting personal information. The DfE will transfer the pseudonmyised information to the YEF archive, which is stored in the Office for National Statistics' (ONS) Secure Research Service (SRS). The YEF is the 'controller' of the information in the YEF archive. By maintaining the archive and allowing approved researchers to access the information in the archive, the YEF is performing a task in the public interest and this gives the YEF a lawful basis to use personal information.

Information in the YEF archive can only be used by approved researchers to explore whether Redthread's programme, and other programmes funded by YEF, had an impact over a longer period of time. Using the unique Pupil Matching Reference numbers added to the data by the DfE, it will be possible to link the records held in the YEF archive to other public datasets such as education and criminal justice datasets. This will help approved researchers to find out the long-term impact of the projects funded by YEF because they'll be able to see, for example, whether being part of a project reduces a child's likelihood of being excluded from school or becoming involved in criminal activity.

Data Management Plan

Assessment and use of existing data and creating new data

We will analyse existing routinely collected hospital data and may produce new quantitative and qualitative data alongside the more sensitive individual level data. Ethics approvals will be obtained from the UoB and the NHS REC and HRA where needed that will set out the usage, storage and governance of data. The research team will respect any conditions of usage set forward by the data owners and the informed consent sheets will set out how data that is collected will be used.

For interviews, when prior consent is received, all interviews will be digitally audio recorded. The recorded data will be saved on password-protected and encrypted computers of the research co-ordinator and lead for the study on UoB servers. It will be either transcribed in-house or sent electronically to a transcription agency with a confidentiality agreement in place that complies with the University's data protection policy and agreed security standards set by the funder. The transcripts will be stored on UoB servers in Word Format and will be thematically analysed by the study lead and research fellow. Where interviews are conduced remotely, a UoB teams/zoom account will be used.

Quantitative data will be stored anonymously. If any individual data is collected, participant names will be allocated a research ID number. A separate list detailing the participant name and research ID code will be stored in an encrypted file on UoB servers, separate from the rest of the project files. All UoB laptops have secure encryption which satisfies the requirements of the Data Protection Act 2018. All work involving matching using names will be on UoB encrypted machines by researchers under the PI's supervision.

All data collected will be for the specific purpose of carrying out the different phases of the feasibility studies and will be GDPR compliant.

Quality assurance of data

Data collection will be designed and reviewed to ensure integrity and quality. This will be achieved by having regular project team meetings and consulting research participants on an ongoing basis. Quality assurance of data will form a standing agenda item at all team meetings.

The project manager will have ultimate accountability and oversight for quality assurance of data; however, it will be emphasised to all team members that they have a personal responsibility to produce high quality data. In order to ensure 360-degree oversight, a selection of each lead's work will also be reviewed by the co-leads and research fellow.

Quality assurance in the merged and linked data files will be ensured via the use of clear, consistent coding that will be crosschecked by members of the research team. All provided coding will be clearly annotated so that the purpose of the code is understood by any potential user. Data will also be manually examined by more than one person, either using subsets of the data for complete examination against the original data or running frequencies of the original and newly created data, for inconsistencies and errors.

Back-up and security of data

Each study lead and research fellow will store the data on their encrypted laptop. Further data back-up will be provided by using the UoB's secure network. Backup copies of data are taken at least daily or immediately if needed.

The UoB's Information Security document can be provided upon request. The project team will be mindful of not carrying/ using devices that contain sensitive data (such as personal details of participants) in 'risky' situations e.g., all members of the project team will be made aware of the issues posed by the theft of laptops etc.

This evaluation will comply with YEF's Data Archive guidance, including the collection and long-term archiving of personal data. We have considered YEF's guidance on this and will abide by it.

Data Monitoring

A data monitoring committee (DMC) will be established, which will be independent of the study organisers, the funder and the evaluation team. The DMC will consist of two people, one of which will act as a chair. The frequency of interim analyses will depend on the judgement of the Chair of the DMC, in consultation with the steering committee. However, we anticipate that there might be one interim analysis and one final analysis.

The DMC will have unblinded access to all data and can propose the stopping of the project. The steering committee decides on the continuation of the trial and will report to the central ethics committee.

An audit is planned six months into the pilot, which will include site visits. The audit will be conducted by the DMC committee.

Personnel

Redthread team:

- Project Manager – Strategic management, liaison with all key partners, contract compliance, quality assurance
- Data and Insights Manager and Data Officer - Data Management, coordination of Programme Coordinators and liaison with hospital data teams. Expertise from external GDPR / information governance adviser and other Redthread staff for data governance and consent processes
- Programme Managers across the regions – Redthread delivery staff engagement and management - project implementation, delivery liaison with local stakeholders and adherence to local processes for the evaluation
- Programme Coordinators and Youth Work teams - project delivery at sites, and evaluation tasks.
- Head of Fundraising, Communications and Policy, Statutory Fundraising Manager, Head of Finance (and information governance lead) - funder engagement, interim project management and finance expertise.

UoB evaluation team:

For this evaluation, Professor Paul Montgomery (PM) will be the lead principal investigator, lead for the impact evaluation as well as overall Project Manager. PM will be supported by Dr Joht Singh Chandan (JSC) who will co-lead/manage the project and lead the process evaluation.

Research support:

Dr Emily Evans (EE) will act as the single point of contact for UoB contributing to all phases and supporting PM and JSC in project management as needed. She is a research fellow within the Institute of Global Innovation within at the University of Birmingham.

Dr Rasiah Thayakaran (RT) is a Research Fellow in Health Informatics (Statistics) in the Institute of Applied Health Research, University of Birmingham. His research focuses on propensity score matching for observational data and on survival analysis using extended Cox proportional hazard model with time varying covariates. He will assist in the statistical analysis.

Ms Alice Burton (AB), is a research assistant at the University if Birmingham. She will support both the process and impact evaluation.

Senior supporting project team:

Professor Siddhartha Bandyopadhyay (SB), is based in the Birmingham Business School, and is director for the Centre of Crime, Justice and Policing (CCJP). He will support this project with the impact evaluation and any leading any subsequent economic analysis.

Professor Eddie Kane (EK), leads the Centre for Health and Justice, within the Institute for Mental Health at the University of Nottingham. He will support this project as a co-investigator specifically with the process evaluation.

Academic advisory support:

To provide technical support and sustainability for the principal/co-investigators we have an academic advisory team specific to this project including:

- Dr Shola Apena Rogers (SR) – School of Psychology, University of Birmingham. Will support on co-production. SR has undertaken a number of mixed methods evaluations, with expertise in research with children and young people impacted by violence and/or at risk of offending.
- Dr James Martin (JM) is a lecturer in medical statistics and a statistical advisory to trials at the Birmingham Clinical Trials Unit (BCTU). He will provide research methods support.
- Professor Krishnarajah Nirantharakumar (KN) is Professor in Health Data Science and Public Health at the Institute of Applied Health Research at the University of Birmingham. He will provide epidemiological support for longitudinal datasets.
- Dr Ioannis Karavias (IK) is a lecturer in Financial Economics at the University of Birmingham. He will provide advice on quantitative methods.

The wider team have other expertise relating to public health, econometrics, social sciences, evaluation methods, statistics, and implementation science. These members of staff and senior researchers will form part of a critical friends group to provide independent review and advice as the project progresses.

The team also have a wide network of RAs who could join the team all with expertise in the field of vulnerability and youth violence.

Due to the complex and nationwide nature of the RT interventions we have ensured sufficient research fellow support. Their role will be critical to the success of the evaluation in terms of data collection, analysis, and routine monitoring of the project.

Risks

In order to manage risk and issues we will be using a risk register and maintaining an issues log. We have identified early risks and provided mitigation for these; these are included at the end of this document.

These include project-specific risks such as engagement with stakeholders, unavailability of data, and other risks such as unexpected unavailability of research staff.

We are particularly aware of risk related to Covid-19 and the team and the university has become familiar with secure online working. This includes online meetings, webinars and workshops and the team will have full access to the use of standard software such as Microsoft Teams and Zoom enabling business to be conducted smoothly if face to face meetings and workshops are not possible. All team members have regularly been using such software and are well versed in the functionality of it.

Additionally, given the increased possibility of illness or care duties, a resilient team has been created. Each work package in addition to a lead (or in this case co-leads), has a further senior researcher and research fellow associated with it. We also have a small cohort of experienced persons who have an advisory role (domain/methods experts) who can step in for a team member should there be an unexpected contingency that will make him/her unavailable. All the senior researchers supporting the overall project lead (project manager) have the ability and experience in this area to step in to become overall lead in case of anything unexpected happening that makes the project manager unable to carry on leading the project. Most of the personnel have not only led or co-led complex projects, they were involved in a recent work for the College of Policing to evaluate interventions as part of their vulnerability and violent crime programme and have a history if co-working minimising the risk of any difficulties of a multi-disciplinary team working together.

Our issues log will be used to collate key questions/issues and target the appropriate individual for a response which will be recorded in the log. Our risk register will identify, assess and control risks and uncertainties enabling us to improve the ability of the project to succeed. Our risk management technique, based on PRINCE2 principles, involves:

- Clear understanding of project context
- Establishing clear project objectives
- Regularly assessing and reporting risks
- Defining clear roles/responsibilities
- Establishing a support structure for risk management
- Monitoring for early warning indicators
- Establishing a review cycle, aiming for continual improvement.

Regarding ensuring the safety of the participants, none of the proposed activities for this research poses any risks to their safety beyond disease transmission though all and any government guidelines regards being Covid secure will be complied with. However, the researchers will keep this issue of safety under review during the course of the research and will take advice on the issue from RT staff. Particularly, during the interviews it will be important to note if participants (this includes not just CYP but all participants of our interviews) may be uncomfortable answering certain questions or being observed. In order to

minimise this, we will reassure participants that they are under no obligation to answer every or any question or discuss potentially distressing cases relating to difficulties in their personal life unless they are willing. Where participants feel particular distress, we will stop the interview and guide them to local counselling services which may assist them. We have developed distress protocols that we use routinely in our work and have adapted one specifically for this study. This is included at the end of this document. Also included is a link to Redthread's safeguarding policy.

Where fieldwork occurs in the RT offices, we will do this during hours when other personnel are present in the building to ensure that the environment is safe for the research team. We will also ensure that at least one staff in the building where we are interviewing are aware that we are interviewing. Further, we will create a WhatsApp group for immediate check in/check back after each interview between University staff. These arrangements are consistent with UoB's lone working guidelines (https://intranet.birmingham.ac.uk/collaboration/ctl/Health-and-Safety/Lone-Working.aspx, included below as an Appendix).

We believe this is a low to medium risk project and have identified (and mitigated for) a small number of potential early risks prior to project initiation. The issues log and risk register will be reviewed weekly by the research team. Any issues and/or risks will be shared at the earliest possible opportunity internally for mitigation and where necessary, if these are viewed as major risks, these will be escalated to 'named' project contacts within the Youth Endowment Fund.

Timeline

Dates	Activity	Staff responsible/ leading
Jan–Mar 2022	Project set up – define referral pathways, record management processes Evaluation set up – information sharing agreements, develop evaluation materials, gain ethics approval	RT: project team UoB: PM/JSC
April 2022	Project go live – recruitment of CYP into intervention, begin collecting case monitoring data Begin collecting data	RT: project team and local teams UoB: PM/JSC (lead) and UoB team.
April-December 2022	Project operation Gather quantitative data sources (outcome measures, case monitoring data, administrative data, control group) Gather qualitative data (interviews with staff, referrers and CYP)	RT: project team and local teams UoB: PM/JSC (lead) and UoB team. UoB: EK (lead) and UoB team.
January 2023	Draft interim report	UoB team
March 2023	YEF make decision whether to progress to efficacy study	YEF
May 2023	Submit final report / support YEF publication process	UoB team

References

1 Krug EG, Dahlberg LL, Mercy JA, Zwi AB, Lozano R. World report on violence and health. 2002.http://apps.who.int/iris/bitstream/handle/10665/42495/9241545615_eng.pdf;jsessionid=38974668595BA31895E557DC1CB1EFEC?sequence=1 (accessed 4 Jul2018).

2 Craston M, Balfour R, Henley M, Baxendale J, Fullick S. Process evaluation of the Violence Reduction Units. 2020.

3 Wortley E, Hagell A. Young victims of youth violence: using youth workers in the emergency department to facilitate 'teachable moments' and to improve access to services. *Arch Dis Child - Educ Pract* 2021; **106**: 53–59.

4 House of Commons Library. Knife crime statistics. 2021.https://commonslibrary.parliament.uk/research-briefings/sn04304/ (accessed 29 Mar2022).

5 Walton MA, Chermack ST, Shope JT, Bingham CR, Zimmerman MA, Blow FC *et al.* Effects of a Brief Intervention for Reducing Violence and Alcohol Misuse Among Adolescents: A Randomized Controlled Trial. *JAMA* 2010; **304**: 527–535.

6 Shibru D, Zahnd E, Becker M, Bekaert N, Calhoun D, Victorino GP. Benefits of a hospital-based peer intervention program for violently injured youth. *J Am Coll Surg* 2007; **205**: 684–689.

7 Cooper C, Eslinger DM, Stolley PD. Hospital-based violence intervention programs work. *J Trauma* 2006; **61**: 534–537.

8 Aboutanos MB, Jordan A, Cohen R, Foster RL, Goodman K, Halfond RW *et al.* Brief violence interventions with community case management services are effective for high-risk trauma patients. *J Trauma* 2011; **71**: 228–236.

9 Cheng TL, Wright JL, Markakis D, Copeland-Linder N, Menvielle E. Randomized trial of a case management program for assault-injured youth: impact on service utilization and risk for reinjury. *Pediatr Emerg Care* 2008; **24**: 130–136.

10 Cheng TL, Haynie D, Brenner R, Wright JL, Chung SE, Simons-Morton B. Effectiveness of a Mentor-Implemented, Violence Prevention Intervention for Assault-Injured Youths Presenting to the Emergency Department: Results of a Randomized Trial. *Pediatrics* 2008; **122**: 938–946.

11 Zun L. Violence prevention in the ED: linkage of the. *Am J Emerg Med*; **6757**: 454–7.

12 Zun LS, Downey LV, Rosen J. The effectiveness of an ED-based violence prevention program. *Am J Emerg Med* 2006; **24**: 8–13.

13 Davis A, Arterberry B, Bonar E. Predictors of positive drinking outcomes among youth receiving an alcohol brief intervention in the emergency department. *Drug Alcohol Depend*; **188**: 102–8.

14 Carter PM, Walton MA, Zimmerman MA, Chermack ST, Roche JS, Cunningham RM. Efficacy of a Universal Brief Intervention for Violence Among Urban Emergency Department Youth. *Acad Emerg*

Med 2016; **23**: 1061–1070.

15 Snider CE, Kirst M, Abubakar S, Ahmad F, Nathens AB. Community-based participatory research: development of an emergency department-based youth violence intervention using concept mapping. *Acad Emerg Med* 2010; **17**: 877–885.

16 Dicker RA, Jaeger S, Knudson MM, MacKersie RC, Morabito DJ, Antezana J *et al.* Where do we go from here? Interim analysis to forge ahead in violence prevention. *J Trauma* 2009; **67**: 1169–1175.

17 Brice JM, Boyle AA. Are ED-based violence intervention programmes effective in reducing revictimisation and perpetration in victims of violence? A systematic review. *Emerg Med J* 2020; **37**: 489–495.

18 NPC Associates. St Mary's Hospital Youth Violence Intervention Project Year 2 Evaluation Report. 2017.http://www.redthread.org.uk/wp-content/uploads/2017/03/YVIP-2nd-year-Exec-summary-NPC-Associates-240217-final.pdf (accessed 10 Aug2021).

19 Schreier M. Sampling and Generalization. *SAGE Handb Qual Data Collect* 2018; : 84–97.

20 Shibru D, Zahnd E, Becker M, Bekaert N, Calhoun D, Victorino GP. Benefits of a hospital-based peer intervention program for violently injured youth. J Am Coll Surg. 2007 Nov;205(5):684-9. doi: 10.1016/j.jamcollsurg.2007.05.029. Epub 2007 Sep 10. PMID: 17964444.

21 Srivastava A, Thomson SB. Framework Analysis: A Qualitative Methodology for Applied Policy Research. *Appl Policy Res JOAAG* 2009.

22 Cohen J. Statistical Power Analysis for the Behavioral Sciences. *Stat Power Anal Behav Sci* 1988. doi:10.4324/9780203771587.

23 O'Neill J, Tabish H, Welch V, Petticrew M, Pottie K, Clarke M *et al.* Applying an equity lens to interventions: Using PROGRESS ensures consideration of socially stratifying factors to illuminate inequities in health. *J Clin Epidemiol* 2014; **67**: 56–64.

24 Rosenbaum PR. Observational Studies. 2002. doi:10.1007/978-1-4757-3692-2.

25 Heckman J.J, Ichimura, H. and Todd P.E. (1997). Matching as an econometric evaluation estimator: evidence from evaluationg a job training programme. *Review of Economic Studies*, 64, 605-654.

26 NPC Associates. Redthread Youth Violence Intervention Project: St Mary's Hospital. Executive Summary. 2018.

27 Dickson, E. A., Blackburn, L., Brooks, A. Evaluation of the Redthread Youth Violence Intervention Programme at the East Midlands Major Trauma Centre: An Analysis of Impact on Re-injury and Re-attendance Rates Executive Summary. 2021.

28 The Health Foundation. Redthread YVIP Adoption and Spread: Final Report. 2020.

Distress Protocol for participants

Modified from: Draucker C B, Martsolf D S and Poole C (2009) Developing Distress Protocols for research on Sensitive Topics. Archives of Psychiatric Nursing 23 (5) pp 343-350

Distress

An participant indicates they are experiencing a high level of stress or emotional distress
OR
Exhibits behaviours suggestive that the discussion/interview is too stressful such as uncontrolled crying shaking etc

Stage 1 Response

Stop the interview/discussion
The researcher will offer immediate support
Assess mental health status using the following questions:

- Tell me what thoughts you are having?
- Tell me what you are feeling right now?
- Do you feel able to go on with the interview/discussion?
- Do you feel safe?

Review

If participant feels able to carry on - **Resume the interview/discussion**
If participant is unable to carry on - **Go to stage 2**

Stage 2 Response

Discontinue interview/discussion
Encourage participant to contact their GP or mental health provider or an external support service such as The Samaritans or Childline
OR
Offer with participant's consent for RT worker to do so
OR
With participant's consent contact a member of the health care team treating them for advice/support

Follow up

Follow up participant with courtesy call (with consent)
OR
Encourage the participant to call researcher or RT staff member if they experience increased distress in the hours/days following the interview/discussion.

UoB Lone Working

It is inevitable that at certain times staff, students and visitors will find themselves working alone. This may because of the:

- time of day, e.g. early in the morning, at lunch time or late at night.
- time of the year, e.g. during holiday periods.
- location of the work.
- nature of the work.

Lone working is required to be considered in the overall Risk Assessment for a particular activity. Lone working is an activity where a person has neither visual nor audible communication with someone who can summon up assistance in the case of an accident, emergency or illness.

Levels of Risk

Examples of **low risk** lone working include:

- office, library, lecture theatre and study room based academic work or administration.
- some basic laboratory work (e.g. routine operations such as analysis).
- some basic assembly work in workshops.

Examples of **higher risk** loan working include:

- laboratory work (e.g. research work where the outcome is largely unknown).
- using machinery and electrical equipment.
- using hazardous substances.

Loan workers are prohibited from working with pyrophoric and/or cryogenic substances.

Assessing the Risk

Lone workers should not be exposed to significantly higher risks than those who work together. A number of points need to be considered in order to determine if an activity is suitable and safe to be conducted by a lone worker:

- Are there safe means of egress? e.g. if working out of hours will suitable exits be available.
- Is there a risk to personal security?
- Is the person medically fit to work alone? Anyone can be taken ill whether alone at work or elsewhere. The consequences have to be considered, e.g. how long will it be before they are found if they collapse, what risks are there if they cannot control a piece of equipment etc.
- How competent is the lone worker? The risk associated with an experienced member of staff working alone may be considered acceptable but the risk associated with a student doing the same work my be unacceptable.

- What extra training will lone workers need? e.g. in unusual or emergency situations when they have to make decisions on their own.
- What are the supervision arrangements? Although there will be no direct supervision, arrangements will be have to be made to know what the person is doing and when.

Additional points to consider for **higher risk** lone working:

- Does the workplace present a special risk to the lone worker? e.g. laboratory work etc.
- Does the work activity present a special risk to the lone worker? e.g. working with machinery, hazardous substances etc.
- Can one person handle equipment safely? e.g. items may be heavy, awkward.
- Can one person use or operate the equipment safely? e.g. ladders may need footing, large equipment may need more than one person to operate it.

Link to Redthread Safeguarding Policy:

Redthread Youth Ltd_Safeguarding Poli

Risk Register and Mitigation Plan

RISK TITLE	RISK DESCRIPTION AND IMPACT	RISK CATEGORY	IMPACT LEVEL	PROBABILITY LEVEL	PRIORTITY LEVEL / RISK RATING	MITIGATIONS
Recruitment of staff to UoB	Delay to project start	Recruitment	3	2	6	Timely exchange of contracts. UoB have a pool of staff who can contribute to the early stages of the evaluation until the Research Fellow is recruited.
Recruitment of Redthread staff for interview	Delay/prevent data gathering	Recruitment	5	1	5	Work with YEF, Redthread, and partners to encourage participation. For example, explaining the value of taking part (opportunity to share your views, help to understand how RT is supporting CYP)
Recruitment of CYP for interview	Delay/prevent data gathering	Recruitment	5	2	10	Work with YEF, Redthread, and partners to encourage participation. For example, explaining the value of taking part (opportunity to share your views, help to understand how RT is supporting you etc.); recruit researchers who share key characteristics with CYP - the commonality (e.g. age, ethnicity) would help to build trust; neutral space for interviews to give CYP more confidence to talk openly
Recruitment of stakeholders for interview	Non-RT stakeholders difficult to engage in evaluation and/or find time to participate in interviews; in ability to access data from hospitals (e.g. control sites)	Recruitment	5	2	10	Work with Redthread and partners to devise communication/ engagement strategy directed at relevant stakeholders (e.g. clinicians)
Loss of key evaluation staff	e.g. due to isolation because of covid	Loss of staff	3	2	6	Use of back up researchers to strengthen resilience.

Data access	Access - e.g. unable to access relevant data or data is not available, incomplete, inaccessible or not produced in a timely way. Could impact on quality of evaluation (e.g. what can be measured) and/or delay delivery of data analysis.	Data	4	3	12	Work with the stakeholders to identify relevant data and agree data sharing protocols. Consider alternative data sources.
Ethics approval	Ethics approval is required by UoB and potentially NHS ethics - approval needs to be granted so that the evaluation can start. Any delays cause delays with the start of the evaluation	Ethics approval	5	1	5	Ethics approval application(s) to begin as soon as possible, and be as comprehensive and high quality as possible
Data quantity	Sample size too low to meet research requirement either due to low numbers of referrals or data sharing agreements not in place. This would affect validity and reliability of data	Data	4	2	8	Early identification and communication of any challenges shared by Redthread / UoB. Comprehensive data sharing agreements in place and importance of these communicated with all relevant hospital personnel. Inclusion of all Redthread sites is important to ensure there is enough high quality data
Data quality	Quality - data quality too low to meet research requirement	Data	4	2	8	Data checks and cleaning techniques applied as standard. Potential use of missing data modelling if required.
Data security	Breach of confidentiality and/or data agreements	Data	5	1	5	Data protection guidance in place which outlines how we will collect, store, use, and share data. This will be shared with stakeholders. For qualitative data collection (e.g. interviews) we will provide confidentiality statements to make sure participants feel safe sharing views and information.

Data archive	Archiving - incomplete or incorrectly formatted dataset for archive	Data	2	2	4	Clear remit from YEF about specific information (e.g. variable list) and format neededfor the archive. Data gathering tools to include these variables to facilitate gathering this in the correct format.
Participants unavailable due to time pressure	Delay/prevent data gathering	Practical issues	3	2	6	Opportunity to participate would be provided to a large number of CYP.
Not being able to gather data face to face (e.g. due to covid restrictions)	Delay/prevent data gathering; could impact data quality if CYP don't feel comfortable being interviewed online	Practical issues	4	4	16	Use phone or video teleconferencing. The team has familiarity with online working (including small and large workshops). The university has software (e.g. Teams) to facilitate safe online data collection.
A breakdown in communication	Inhibits the ability for the evaluation to run smoothly	Communication	4	1	4	All partners to have single points of contact.
Psychological safety of research staff	Topic of research causes trauma to researcher staff	Psychological	4	1	4	• The team has significant experience of working with distressing materials/subjects. • Weekly debriefs for all staff and a WhatsApp group for immediate check in/check back. • A senior member of the research team will have a dedicated role on this issue, with planned cover when not available.
Personal security of research staff	Conduct of the study puts research staff at risk	Practical issues	4	1	4	• All data collection will be conducted in line with the UoB lone worker policies. • Data collection will take place at the RT offices or other organisational buildings or online and so staff are unlikely to be alone.

RT staff leaving / recruitment	Staff leaving	Practical Issues	3	2	6	Recruit to the roles as soon as possible following staff announcing their departure. Consider redeployment / secondment to pilot sites where appropriate
Fundraising	Lack of other funding to ensure the programmes continue to be delivered to the same resource level as currently	Funding	3	2	6	Continue to fundraise through a wide range of sources and carry out the actions within the fundraising strategy

YOUTH ENDOWMENT FUND

Impetus

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