The NEST Study Protocol

Nurturing Environments for Shaping Trauma-informed care and recovery

A Realist Co-production Development Study

FUNDED BY
NIHR | National Institute for Health and Care Research

NHS Pennine Care NHS Foundation Trust

Salford City Council

Manchester Metropolitan University

University of Oxford

University of Cumbria

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Contents

i. Abbreviations

ii.

AE	Adverse Event
ACAMH	The Association for Child & Adolescent Mental Health
CI	Chief Investigator
CAMHS	Child and Adolescent Mental Health Services
Co-CI	Co-Chief Investigator
CMO	Context-mechanism-outcome
CMOC	Context-mechanism-outcome configurations
CLA	Care Leavers Association
CPMS	Central Portfolio Management System (CPMS)
CRF	Case Report Form
CRN	Clinical Research Network
CYP	Children and young people
EBCD	Experience-Based Co-Design
GCP	Good Clinical Practice
GDPR	General Data Protection Regulations
GM	Greater Manchester
GMMH	Greater Manchester Mental Health NHS Foundation Trust
HEI	Higher Education Institution
HRA	Health Research Authority
HS&DR	Health and Social Care Delivery Research
LEAG	Lived Experience Advisory Group
NHS	National Health Service
NICE	The National Institute for Health and Care Excellence
NIHR	National Institute of Health and Care Research
non-CTIMP	Research in human subjects other than Clinical Trials of Investigational Medicinal Products
PCFT	Pennine Care NHS Foundation Trust
PID	Personal Identifiable Data
PIS	Participant Information Sheet
PPIE	Personal and Public Involvement and Engagement
R&D	Research and Development
R&I	Research and Innovation
REC	Research Ethics Committee
RMD	Routine monitoring data
RP	Research Practitioner
SAE	Serious adverse event
SAB	Stakeholder advisory board
SDQ	Strengths and Difficulties Questionnaire
TIC	Trauma Informed Care

iii. Project summary

Study Title	**N**urturing **E**nvironments for **S**haping **T**rauma-informed care and recovery

	Trauma-informed Care in Children's Homes: A Realist Co-production Development Study
Internal ref. no. (or short title)	The NEST Study
Clinical Phase	Pilot and evaluation
Design	Realist synthesis Pilot and realist evaluation Co-production of iterative dissemination workstream
Study Participants	Cared for children and young people (up to 18 years old) Staff working in homes for cared for children Stakeholders associated with homes for cared for children and out of home placements
Planned Sample Size	N CYP = up to 150 N Staff = up to 60 N Stakeholders = up to 30
Planned Pilot Period	September 2025 – August 2026
Planned Study Period (Study start and end date)	1st December 2024 – 30th April 2027
Research Questions and Objectives	**Aim:** To co-produce, pilot, and evaluate a new trauma-informed care intervention for use in children's homes to promote wellbeing and recovery. **Research Question:** How, when, and why can a theoretically informed evidence-based trauma-informed care intervention tailored for children and young people in children's homes improve care quality and experience? **Objectives:** 1. Co-produce a new tailored intervention for children's home care through a rapid realist review (Ws1) and experience-based co-design (Ws2). 2. Pilot and evaluate the intervention across local authority and privately run homes in Greater Manchester, using a realist evaluation approach to identify how, why, and in what contexts the intervention could support the recovery and wellbeing of young people in care (Ws3a). 3. Develop an implementation toolkit for wider use and further evaluation (Ws3b). 4. Promote positive change for children's homes and vulnerable young people through an appropriate dissemination, impact, and communications strategy.

iv. Funding and support in kind

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this trial)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
NIHR RfSC	£350,000.00
Excess Treatment Costs	£30,278.00

v. Role of study sponsor and funder

The proposed project has been reviewed by an NIHR funding panel as part of the NIHR competitive funding process and was recommended for funding in February 2024. The project's Sponsor is Pennine Care NHS Foundation Trust (PCFT). The CI is responsible for setting up research sites on behalf of PCFT) as sponsor. The CI (or delegate) will provide sites with the necessary documentation in line with agreed site set-up processes and ensure appropriate approvals and permissions for activities taking place at external organisations are in place prior to the research commencing at the site.

The NIHR and the Sponsor have no direct involvement in the selection of the study design, conduct of the research, data analysis and interpretation or dissemination of results. The analysis, interpretation and preparation of outputs will be sole responsibility of the Chief Investigator (CI; Dr Parry), Co-Chief Investigator (Co-CI; Prof Duxbury), Research Centre Manager (Dr Zarah Eve) and the project team. The views expressed will be those of the authors and not necessarily those of the NIHR, the Department of Health and Social Care, PCFT or other collaborating trusts.

vi. Roles and responsibilities of study management committees/groups & individuals

The independent oversight committee, on behalf of the Sponsor and the NIHR, will ensure that the project is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice. The independent oversight committee will 1) provide advice on all appropriate aspects of the project; 2) review the progress of research against the project timeline, monitor adherence to the protocol and the consideration of new information of relevance to the research question; 3) review issues related to patient safety (e.g. any SAE) and ensure that, throughout the project, the rights as well as safety and well-being of the participants will be prioritised over the interests of science and society; 4) agree proposals for substantial protocol amendments and provide advice to the Sponsor and NIHR regarding approvals of such amendments.

vii. Core Project Team

Sarah Parry, University of Manchester, and Pennine Care NHS Foundation Trust
Joy Duxbury, Cumbria University
Geoff Wong, University of Oxford
Elaine Craig, Manchester Metropolitan University
Emma Ford, Warrington Borough Council
Zarah Eve, Pennine Care NHS Foundation Trust
Sadie Rodell, Pennine Care NHS Foundation Trust
David Graham, The Care Leavers' Association

viii. Patient & Public Involvement and Engagement (PPIE)

The project will be supported by a Lived Experience Advisory Group (LEAG; N=6) of young care leavers who will meet with the project team every six months. PPIE with care experienced young people, frontline staff, and wider stakeholders between 2020 and 2023 has directly informed the design of this application. We will also appoint an independent oversight committee (SAB; N=6) of independent professionals, researchers, policy makers and commissioners to offer critical reflections and recommendations throughout the study.

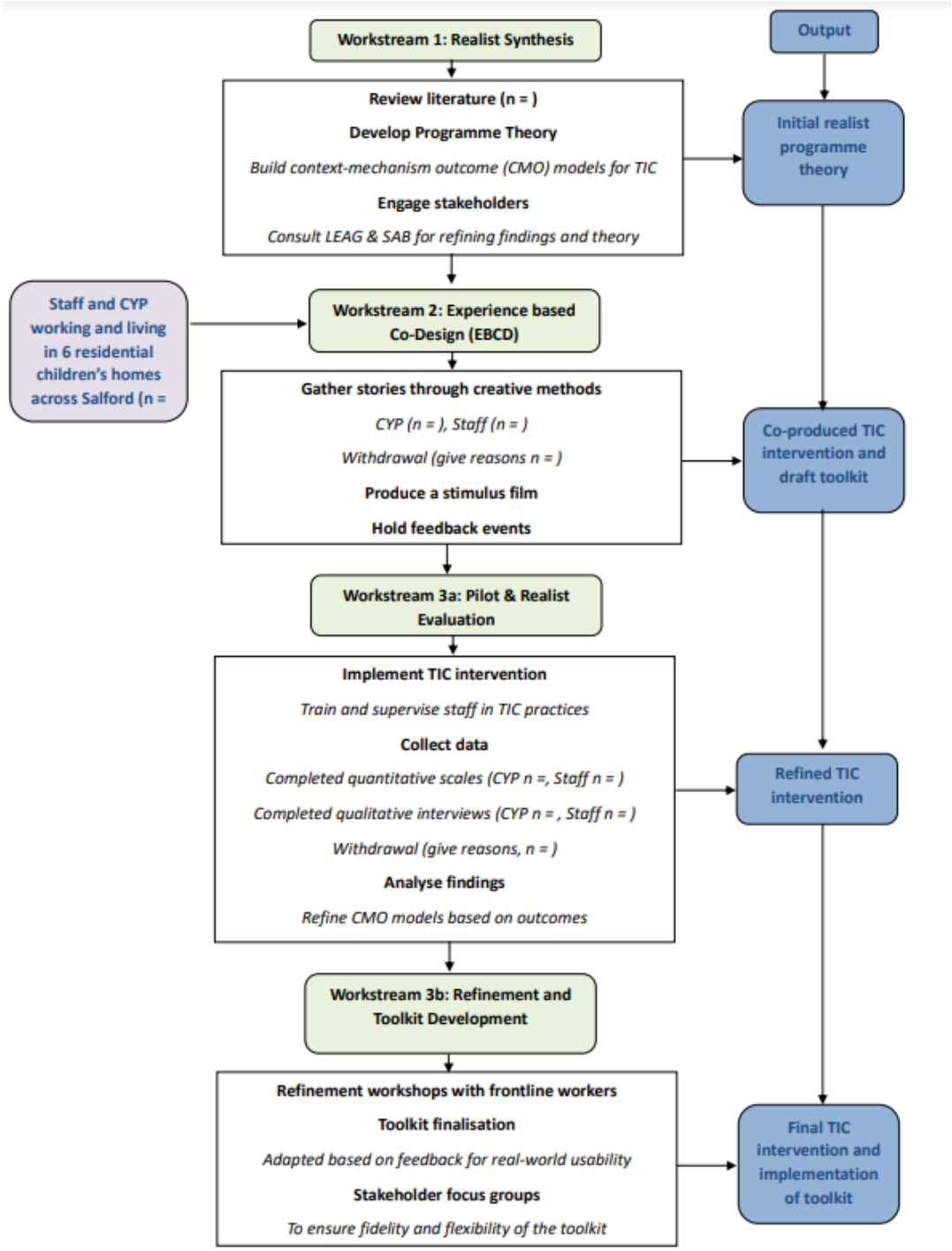
ix. Protocol contributors

Dr Parry (CI) was responsible for the drafting of the protocol on the basis of the Detailed Project Plan of the grant application submitted to NIHR and reviewed through two competitive rounds by committee. The wider research team have supported further development, in consultation with our NIHR programme manager.

x. Key words

Trauma-informed care; cared for children; out of home placements; realist methods; Experience based co-design (EBCD).

xi. Study flow chart



1. Background and rationale

What is the problem?

Young people entering the care system have often experienced multiple traumas and loss. Entering the care system itself can be traumatic as a child is removed from the care of people they know and placed in an unfamiliar and unpredictable environment. Of the 82,000 children in care in England, the 12,898 young people in one of 2,873 children's homes are some of the most vulnerable in society. The number of children's homes has increased each year since 2019, with over a quarter of placements located in Northwest England.

What can be done?

Trauma-informed care is an approach that understands and responds to the impact of trauma for a person. Trauma-informed practice aims to provide physical and emotional safety for both the young person who has experienced trauma and their carers to create opportunities to rebuild a sense of safety, empowerment, and form safe relationships to support a fulfilling future. If children who have experienced many adversities do not experience safety in relationships during youth, the risks of exploitation, revictimization and poor health outcomes remains high. Unfortunately, due to a lack of clinical guidance and governance, there are no agreed standards for delivering trauma-informed care specifically for children's homes. Suitable guidance could be developed through collaboration with young people and stakeholders, leading to a new trauma-informed care resource for use in practice.

What will we do?

In this project, we will co-design and pilot a trauma-informed intervention toolkit across six children's homes in the Northwest. The toolkit will provide clear guidance for staff training, trauma-informed supervision, trauma-aware care, and organisational governance to embed trauma-informed thinking into each element of a home's operations. The project has the potential to enhance service quality and improve outcomes for young people, staff, and care providers.

How will we do it?

Firstly, we will bring together existing information from the evidence base for trauma-informed care for young people to look at what works. Secondly, we will hear stories from experience from young people and staff in the children's homes. Learning from these two activities will help us develop the new trauma-informed

care intervention toolkit especially for use in children's homes. This intervention will be piloted across the children's homes over 12 months. Information from the staff and children will help us understand the impact of the intervention for positive change. Finally, we will share the resulting toolkit and research findings with care providers, local authority commissioners, and policy makers to promote system wide reflection, to raise standards, and increase the transparency of trauma-informed care. We will then develop a larger-scale project to test the intervention across a greater range of care providers, offering new opportunities for sector wide learning, development, and improvement.

Assessment and management of risk

- The proposed intervention offers a novel, tailored and theoretically informed trauma-informed approach to support young people and frontline staff in homes for cared for children already in the care of Salford Council and commissioned providers. Compared to normal standard practice, the proposed trauma-informed approach should pose less risk as its development has been theoretically informed and co-produced throughout primary and secondary research.
- A dedicated and highly trained research team will ensure that the trauma-informed approach is delivered and evaluated to the highest quality, with participant care in mind at all times.

This study is categorised as: Type A = No higher than the risk of standard medical care.

2. Objectives and Outcome Assessments

2.1 Aim

To co-produce, pilot, and evaluate a new trauma-informed care intervention for use in children's homes to promote wellbeing and recovery.

2.2 Research Question

How, when, and why can a theoretically informed evidence-based trauma-informed care intervention tailored for children and young people in children's homes improve care quality and experience?

2.3 Objectives

1. Co-produce a new tailored intervention for children's home care through a rapid realist review (Ws1) and experience-based co-design (Ws2).
2. Pilot and evaluate the intervention across local authority and privately run homes in Greater Manchester, using a realist evaluation approach to identify how, why, and in what contexts the intervention could support the recovery and wellbeing of young people in care (Ws3a).

3. Develop an implementation toolkit for wider use and further evaluation (Ws3b).
4. Promote positive change for children's homes and vulnerable young people through an appropriate dissemination, impact, and communications strategy.

2.4 Outcome Assessments

1. RCADS - Self-Reported (8-18 years old)
2. RCADS – Parent version
3. Therapeutic Alliance Scale for Children, Revised (TASC-R)
4. Trauma-Informed Care Pen Portrait Template
5. Resilience Scale for Care Experienced Young People
6. Sense of Community in Adolescents Scale (Chiessi, Cicognani & Sonn, 2010)
7. The strengths and difficulties questionnaire (SDQ) (Goodman, 1997; for children and key workers)
8. Professional Quality of Life Scale (Stamm, 2005)

3.a. Realist Synthesis (Workstream 1)

A rapid realist review will identify how, why, for whom, in what contexts and to what extent TIC that includes consideration of adversity and resilience *works* for children in residential care. TIC is a complex intervention, and an initial scoping review has revealed the literature is heterogenous, hence a realist review is appropriate. The realist review protocol will be registered with PROSPERO.

Our review will follow RAMESES quality and reporting standards (Wong et al, 2014). We will synthesise evidence from diverse sources (i.e., academic/grey literature, policy, related theory) to build an initial programme theory of a recovery-focused TIC intervention for children's homes. We will be able to achieve this within the timeframe as we have already conducted primary and secondary research into TIC, resilience, and post-traumatic growth, and will be including publications such as the 'Using Logic Models Grounded in Theory of Change to Support Trauma-Informed Initiatives' (U.S. Department of Health and Human Services, Administration for Children and Families, & Office of the Assistant Secretary for Planning and Evaluation, 2020), which is focused upon children and families, in the review. Our job will not be to reinvent TIC, but to extrapolate understanding from relevant literature in relation to TIC and children's homes to formulate an initial programme theory.

We have taken the following steps to enable us to conduct the realist review in a timely fashion:

1. The review process will benefit from the expertise of our Young People's Mental Health Research Centre specialist librarian Stephen Edwards, who will support the literature searching and selections process at no financial cost to this project.
2. We will aim to build directly upon the Principles of Care for Children with Complex Needs published by the Nuffield Foundation in September 2023,

working closely with their team to move from principles to implementation.

3. We have a head start preparing for implementation thanks to the excellent August 2023 publication by Katherine Saunders and colleagues, A scoping review of trauma informed approaches in acute, crisis, emergency, and residential mental health care.

Dr Saunders has kindly offered to join our SAB to further guide the implementation process. We will also be able to seek guidance from Dr Paul Wilson of the University of Manchester Implementation Science research centre through our collaboration with the GM ARC.

Our five-step rapid realist review is adapted from Pawson's suggested steps, achievable in our given timeframe because our focus is very narrow; to develop an initial, rather than a highly detailed 'finalised', programme theory, building upon the aforementioned developments in this field.

Step1: Locate existing theories - Translate existing literature into concepts that will inform our initial programme theory by holding two half-day workshops with all members of the project team, SAB and LEAG, using their content expertise to generate potential realist causal explanations, which fit with the existing theory of change in relation to TIC, but specific to children's homes.

Step 2: Search for evidence - Undertake highly focused searches of electronic databases (e.g., PubMed, CINAHL, PsycINFO) and keyword searches on Google Scholar, NIHR and other relevant websites to identify documents that contain data to refine the initial programme theory developed in Step 1. We will identify relevant policy/practice guidance from online searches of NHS, social care, and mental health service websites. We will download documents to bibliographic software. Under GW's guidance, the Research Practitioner (RP) will screen using the inclusion and exclusion criteria in two-stages: first screening by title and abstract and then by full text. To ensure the screening process is consistent, GW will check a 10% random subsample for systematic errors. We will include documents that: i) relate to TIC for young people; ii) focus upon good quality care in children's homes; iii) contain empirical data. We will only run additional searches if required, to identify data to address specific gaps or refine specific aspects of the initial programme theory.

Step 3: Select articles - The RP will select and appraise documents, applying the following criteria to documents included at the full text stage:

- Relevance: Are sections of text within this document relevant to programme theory development?
- Rigour: Are these data sufficiently trustworthy to contribute to programme theory development?

Step 4: Extract data - The RP will extract data from relevant documents as follows: i) descriptive data describing the included documents (e.g., date, type of document,

study design, etc.), which will be tabulated in Excel; ii) extracts of relevant data from full text documents, which will be uploaded into software that assists qualitative data analysis (e.g., NVivo). GW will check a 10% random sample for systematic errors.

Step 5: Synthesise data - The RP will lead data analysis and synthesis with regular discussions with the research team to challenge and debate interpretations. A realist logic of analysis to develop potential context-mechanism-outcome (CMO) configurations will explain when, why and how TIC might lead to intended (and unintended) outcomes in children's homes. To operationalise this logic, we will ask these questions:

1. Interpretation of meaning: do the contents provide data that may be interpreted as functioning as context, mechanism, or outcome?
2. Interpretations and judgements about context-mechanism-outcome configurations (CMOCs) e.g., what is the CMOC for the data that has been interpreted as functioning as context, mechanism, or outcome?
3. Interpretations and judgements about programme theory e.g., how does this CMOC relate to the initial programme theory?

We will seek data to inform the interpretation of the relationships between CMOs across documents. Interpretive cross-case comparison will be used to understand and explain how and why observed outcomes have occurred.

Engaging the LEAG and SAB

In two two-hour online meetings, facilitated by GW, SP, EF, and DG, we will share and discuss the developing findings (based on the CMOCs) with the LEAG and SAB groups. The two consultation events will present the same findings, will be open to all members from both advisory groups, and will be conducted on different days and times to maximise attendance. Discussions will take place in online breakout rooms of up to six people to gather the variety of perspectives and experiences. One facilitator will be allocated to each online breakout room to present findings using materials, such as vignettes and visual illustrations, that set out the CMOCs in an accessible format.

Facilitators will support engagement with discussions, make notes and feedback to all attendees at the end of the breakout groups. With permission from breakout groups, discussions will also be audio recorded to support notetaking. Notes from discussions, comments posted on the event chatroom or comments offered after the event will be collated and discussed between the event facilitators and the rapid realist review team to identify if there are key areas of divergence and/or agreement with the developing programme theory. This deliberation process will allow us to assess how far and where findings may resonate with group members' diverse experiences and assumptions.

WS1 Output: a realist programme theory of the intersections between TIC, adversity, resilience and residential care, which will iteratively feed into the development of the new intervention in WP2, informing likely key performance indicators.

3.b. Pilot Design (Workstream 2)

Experience Based Co-Design (EBCD) is a participatory action research approach that draws upon creative and inclusive design tools and ways of thinking to bring practitioners and experts-by-experience together to improve quality of care (Donetto et al, 2015). EBCD enables the development of a touchpoint/stimulus film that amplifies the child's voice, enables professionals to view the service through young people's eyes, and stimulates discussion to identify priorities for change and intervention. To achieve this, we will conduct the following 8 stages:

Stage one: Interview 10 young people aged 16-18 from the homes to source stories of their experience. Locations and privacy will be arranged on an individual basis. PPIE suggests mealtimes and private spaces within the homes will be preferred for this age group.

Stage two: Co-produce 10 x individual case study films with the participants aged 16-18 that will firstly be edited into individual case study films; secondly, into an age specific EBCD collective voice film; finally, it will be integrated into the EBCD collective voice film with all age range data. To do this, participants will have four choices over the level of anonymity they wish to have in the interviews. They can choose: 1) a face to camera filmed interview (participants face and voice are captured), 2) concealed face interview (the participants face will be disguised but the voice will be their own), 3) concealed face and actors voice interview, 4) audio interview only (no filming). If participants change their mind and would like to be anonymised at a later date, this choice can easily be amended during the editing prior to the film being shown. All participants will be given the opportunity to co-create their individual films with the film editor (EC). This is to ensure they are happy with how their experience is portrayed and give them the opportunity to edit out anything they do not want to be shared.

Stage 3: Employ creative methods and research-informed conversations with 10-15 children aged 11-15 in the homes, e.g., photographs, poetry, Lego, modelling clay, and artwork to elicit their experiences. This process will be accompanied by a graphic illustrator to record and theme discussions and outputs into a cohesive visual story, accessible for the children. PPIE suggests mealtimes and facilitated play times within the homes will be preferred for this age group, although 1-2-1 opportunities will also be available. We will then collate, anonymise then edit the young people's data (inclusive of pictures of visual outputs) into an age-specific EBCD collective voice film for participants aged 11-15 years.

Stage 4: Co-produce the final EBCD film by collating all the filmed data of both age ranges to be integrated into the final EBCD collective child's voice film.

Stage 5: Show the films to young people and frontline workers from the homes (N=40). During this we will gather responses from the children through message cards, research-focused conversations over mealtimes, and provide the option of 1-2-1 research conversations with a member of the research team. We will also conduct 1-2-1 interviews with staff and older children where they prefer, to gather a rich understanding of their response to the stimulus film and broader perspectives and analyse all data to formulate an overarching narrative.

Stage 6: Present the overarching narrative and the findings of WP1 and WP2 through EBCD feedback events in each of the four homes, inviting reflective feedback, which will be audio recorded.

Stage 7: Collate feedback from the four events into the final emancipatory narrative, which will inform the key components for the intervention.

Stage 8: Co-ordinate intervention development workshops in the four homes to finalise and name the intervention and draft the initial toolkit, which will be further developed from experience of the pilot in WP3.

The Analysis

- Anonymised verbatim transcripts from participants will be analysed.
- **Realist Logic Analysis**: Identifying common themes, recommendations, and challenges across the qualitative data will inform further development of the CMOCs and programme theory from WS1. This analysis will highlight key areas for improvement and opportunities for trauma-informed care.
- **Stakeholder Interpretation Discussions**: Collaboratively interpreting findings with stakeholders and discussing potential solutions. Their insights will help refine our theory and recommendations to ensure they address user needs.
- **Comparative Analysis**: Comparing findings from the pilot with existing literature will enable us to identify best practices and innovative approaches that could be adapted across other homes for cared for children.

Finally, we will draw upon the realist programme theory of the intersections between TIC, adversity, resilience, and residential care with the findings from the EBCD process to develop the new TIC intervention and implementation toolkit for WP3. We will hold two half day events with the LEAG and SAB, as described in WP1, to gather feedback on the drafted new TIC intervention and implementation toolkit and make final amendments. Together, the perspectives offered through the interpretation of data presented to these groups will provide opportunities for meta-learning on the process, factors for decision making, and insights into how the intervention might operate within the children's home environment.

The residential nature of the homes and enthusiasm from the partner will ensure there are no delays with recruitment as all parties are already on-site. Additionally, if we need to extend this part of the research process, we can do, with little impact on WP3 as all activities are being undertaken in the same locations.

WS2 Output: A new TIC intervention with an implementation toolkit tailored for the unique context of children's homes, piloted and evaluated in WP3.

4. Pilot and Evaluation

Workstream 3a: Realist Evaluation

WP3a aims to test and refine the programme theory from WP1 and our new TIC intervention and implementation toolkit across the homes, evaluated using realist evaluation (Flynn et al, 2019, Pawson and Tilley, 1997). Our hypothesis is that the intervention will bring about observable change in terms of creating a culture of resilience, community cohesion and community spirit, as well as enhancing individual wellbeing, attainment, and resilience in the face of stressors, transitions, and adversity. We envision WP1 and WP2 will inform:

- Key performance indicators, identified and developed through WP1 and 2, and will help set clear SMART goals for the home managers and staff.

- A theoretical induction in resilience, recovery, adversity, and TIC specifically in relation to children in care, taught to staff at all levels through three training days, team formulation sessions and ongoing supervision, supported by SP, EF, and the RP.

- The TIC intervention will be taught to staff, who will be supported in implementation through training, supervision, and support workshops. This process will also help the research team build the implementation toolkit around the intervention as it is used, collecting stories from practice, reflective case examples, and problem/solution-based learning examples.

- An integrity checklist, implemented through peer observation and support from the research team.

- An embedded schema for team formulation meetings and supervision for the frontline staff that will initially be run by members of the research team, learnt by the home staff, and then adopted so it can be continued after the pilot has finished.

- SP and EF are experienced trainers and consultants within children's homes, and will conduct the training, supervision, and team formulation sessions, supported by the RP and, in time, home managers.

Data collection will include:

- Personal demographics of all participants at the start of the study or when a new member of staff or young person joins each home.
- Tabulated data from the monthly routine monitoring data (RMD), which all children's homes routinely collect in relation to child development, educational attainment, incidents of concern, and their wellbeing.
- A TIC conversation tool of 10 implementation domains from Scotland's Trauma-informed practice toolkit, conducted with house managers and senior staff at the start and end of the study.
- Quantitative data to track children's development and wellbeing at the start, middle and end of the pilot:

1. RCADS - Self-Reported (8-18 years old)
2. RCADS – Parent version
3. Therapeutic Alliance Scale for Children, Revised (TASC-R)
4. Trauma-Informed Care Pen Portrait Template
5. Resilience Scale for Care Experienced Young People
6. Sense of Community in Adolescents Scale (Chiessi, Cicognani & Sonn, 2010)

- The strengths and difficulties questionnaire (SDQ) will be given to children and their key workers at the beginning and end of the pilot, or when the child leaves the home if before the end of the pilot. This plan has been discussed with stakeholders and appears acceptable.
- Key workers and home managers will keep a fortnightly pen portrait documenting intervention integration, integrity, and implementation, which will be accompanied by supportive Microsoft Teams and in-person supervision with a member of the research team.
- At the start, middle and end of the pilot, all staff members will be asked to complete the Professional Quality of Life Scale (Geoffrion et al, 2019), and a brief TIC self-assessment reflective exercise, which will be created by the research team during WP1. This process will help us identify any changes and tentatively explore relationships between the implementation of the TIC intervention and compassion satisfaction, burnout, and secondary traumatic stress.
- Spoken narrative data from the children's key workers, designated social workers and home managers will be collected every eight weeks to elicit their stories and experiences of the intervention.
- Young people from the homes will be invited to feedback events at the start, middle and end of the pilot to share their thoughts and views on the experience of the TIC intervention through semi-structured interviews and/or reflective group discussions, depending upon preference.
- We will also create an anonymous Qualtrics platform for written feedback in case there are points staff and young people do not wish to say aloud or in front of others. A member of the research team will be available to support

engagement with this feedback route and the young people will be able to ask for help from an adult they trust within their home as well.

Table One: Data collection timetable

Month / **Data**	1	2	3	4	5	6	7	8	9	10	11	12
RMD												
TIC implementation domains												
SDQ												
Quant CYP measures												
ProQOL												
TIC self-assessment												
Staff narratives												
CYP narratives												

Setting: Four local authority homes in Salford and two privately run homes in Stockport have elected to collaborate on this project to enhance their service delivery. The initial phases of the EBCD approach and baseline assessments taken at the start of the evaluation will inform interpretations of the findings to support theoretical transferability across a fractured and under-performing sector.

Data analysis

Qualitative data analysis software NVivo will be used to manage qualitative transcribed verbal and text data. We will analyse the data using the same realist logic of analysis as in WP1 and qualitative data will be analysed as set out in WP2. Our analysis will enable us to further refine our understand of the new intervention, which will be captured in a refined programme theory. Additionally, we will use the following forms of reasoning to make sense of the data:

- **Juxtaposing data:** for example, where data about behaviour change in one source enables insights into data about outcomes in another source.
- **Reconciling data:** where data differs between apparently similar circumstances, it is appropriate to seek potential explanations for these differences having occurred.
- **Adjudicating data:** terms of methodological strengths or weaknesses.
- **Consolidating data:** where outcomes differ in particular contexts, constructing an explanation of how and why these outcomes occur differently.

Quantitative data will be analysed using descriptive statistics and regression analysis, which will be the likely suitable analyses based on expected participant numbers. However, this approach will be reviewed at regular points during the research process. Where relevant, quantitative data will be drawn on to inform programme theory development.

Workstream 3b: Refinement of Intervention and Implementation Toolkit

The increased understanding in our programme theory from WP3a will inform the refinement of the intervention and implementation toolkit, reflecting learning throughout the evaluation. The intervention and implementation toolkit revisions will be presented to staff and young people across the homes for feedback before being finalised. The final draft will then be presented to the LEAG and SAB for final edits.

1. Refinement Workshops with Frontline Workers (N=20) and PPIE Groups

- Purpose: To refine the intervention elements and gather practical insights into how TIC can be effectively implemented within children's homes.
- Activities:
    - Facilitated sessions to discuss practical challenges, adaptability, and barriers in the proposed TIC protocol.
    - Evaluation of toolkit components, with feedback on usability and relevance to daily care practices.

2. Interpretation Focus Groups with Stakeholders

- Purpose: To explore feasibility and ensure that the toolkit's design maintains fidelity during practical implementation while remaining adaptable to specific contexts.
- Activities:
    - Detailed discussions on toolkit integrity during application, including role-playing or scenario-based testing to evaluate flexibility.
    - Analysis of potential risks and adaptations required to maintain TIC principles while adjusting to specific organisational or situational demands.

3. Programme Theory Development

- Purpose: To finalise the programme theory by incorporating insights from the workshops and focus groups, achieving a thorough understanding of the 'what works, how, why, and when' of the TIC intervention.
- Activities:

- Consolidation of insights and case examples from frontline staff and PPIE participants on specific elements of TIC interventions that are effective in supporting children's resilience.

- Examination of causal mechanisms (e.g., psychological safety, trust-building) within TIC practices and conditions under which these mechanisms best support outcomes.

Outputs:

1. A well-refined intervention and implementation toolkit that is grounded in frontline experience and practical needs, ensuring its usability and acceptability in real-world settings.
2. A new approach for TIC in children's homes that is shaped by a record of toolkit feasibility, ensuring that fidelity to trauma-informed principles can be maintained despite situational challenges.
3. A comprehensive programme theory that articulates how the TIC intervention can be successfully implemented in children's homes, guiding stakeholders on factors impacting its effectiveness and sustainability in diverse contexts.

5. Participant Eligibility Criteria

5.1 Inclusion criteria: Every person eligible to take part will be offered the same opportunities, regardless of any protected characteristics. Due to our aim to recruit children, young people and their parents/carers, our age range for the study is 11-99 years. Any young person aged eleven years old and over who has been placed in the care of one of the six participating homes for cared for children will be eligible to take part. Frontline staff, home managers, associated social workers, and other care staff involved in the day to day running of the homes and delivery of care will have the opportunity to take part. Due to the systemic nature of this study, if a young person at any of the homes does not want to take part in the study as a participant, they do not need to opt-in to take part in data collection directly. However, as the homes have agreed to take part in this study to improve the standard of care, there may be an indirect impact on that young person's care. For example, the people who care for that young person are likely to be engaging in additional training, supervision, and record keeping activities, so routine outcome measure data routinely collected for that child may anonymously feed into monitoring data contributed to the study.

Data on protected characteristics will be collected through standard demographic surveys from all participants and members of the research team, including stakeholders. Within our end of study reports, we will provide tabulated summaries of demographics of the research team, stakeholders, and participants to ensure transparency and accountability. We will follow the NIHR INCLUDE Guidance throughout.

5.2 Exclusion criteria: Generally, young people with no connection to the six homes where the study is based will not be invited to participate as participants in this study, directly or indirectly. We do not anticipate young people under the age of 16-years-old will be involved as stakeholder advisors. We will develop study specific distress protocols and signposting information for young people and families, and colleagues throughout the study to support wellbeing.

6. Study Procedures

Recruitment

We will follow guidance from HRA on Research involving children, requesting consent from people aged 16-years and over, and assent and parental/legal guardian consent for anyone under 16-years-old. SP is experienced in working with young people experiencing mental health distress and in undertaking research with young people. AT will also provide support as PPI lead, and all assistants will have training in a compassionate and inclusive approach to recruitment and research-focused communication.

To aid recruitment, we will also engage the help of the clinical research network (CRN) as our study qualifies as a portfolio study, and our project is registered on the Central Portfolio Management System (CPMS), who may also be able to share the consent to contact form to families who have opted into the CRN.

6.2 Study participant support

6.3 Payments, rewards, and recognition: We have followed the INVOLVE guidance on renumeration for stakeholders and participants, outlined in the detailed budget and cost justification.

6.4. Taking Informed Consent

Assent and Consent

Following enrolment and assent/consent, participants will be asked to complete a questionnaire assessing relevant demographic information (Laurens et al., 2020) (e.g., age, gender, ethnicity, family circumstances) and brief clinical history information (history of past service use, any comorbid diagnoses etc.).

Engagement process for participants

At the beginning of research engagement, the research study will be explained to potential participants in person, via Teams, or by telephone, depending upon the preference of each participant or appropriateness of setting. For example, most engagement activities with young people will be in person, whereas many meetings with staff will be conducted via Teams as this is generally more convenient for practitioners. Consent (participants aged 16-years-old and over) and assent (participants aged 15-years-old and under, with parental/caregiver consent also required) to participate will be obtained during initial meetings that will take place in each of the homes. Following this, as new staff and young people come into the home environment, assent/consent will be taken at a suitable point, in agreement with the home managers.

Following enrolment, participants will be asked to complete a questionnaire assessing relevant demographic information (Laurens et al., 2020) (e.g., age, gender, ethnicity, family circumstances). Pen portraits for each participating young person will also be developed based on their records held by the care provider (i.e., the placement provider).

Following gaining consent/assent, baseline (T1) data will be collected from all participants. At all research assessments, young people will be asked whether they prefer to speak to the researcher alone or in the presence of their primary caregiver, or another trusted adult (e.g., social worker, mentor, advocate, key worker, etc.). Staff will be asked if they would like to speak with the researcher privately, or with their child present. The same process will be followed at each data collection point (table one).

6.3.1 Additional consent provisions for collection and use of participant data

The consent form used for the study will include optional items of consent related to additional collection and use of participant data. It will be made clear that these additional consent options are non-mandatory and that declining additional consent will not prevent them from taking part.

Based on prior experience of working in this field and anticipated media interest in this study, we will also ask participants aged 16 years and over to separately consider providing consent to be passed information about prospective media opportunities (e.g., radio or TV interviews). This approach will mean that consent for the research study is clearly separate from consent to be contacted about media opportunities, although participants who wish to be contacted will have the choice. In previous studies conducted by the research team, participants were often keen to talk about their experiences within media features, which is why we include this element in the protocol, to offer participants the option.

All participants will also be asked whether they give permission for: 1) some of the assessment to be audio recorded for quality checking and for improving study

procedures and assessments; 2) the recordings to be used for supervision/teaching/training; 3) their anonymised data to be used for secondary analysis research; 4) their anonymised data to be made available for data-sharing with other research teams; 5) being contacted at a later stage for participating in further studies related to this area of research; 6) being contacted at a later stage to receive a summary of the study findings; and 7) having their participation in the study recorded in their clinical notes.

6.3.2 Withdrawal of consent and withdrawal criteria

Participants will be free to withdraw from the study at any time. If a participant chooses to do so before the EBCD final collective child's voice film is made, any data collected will be completely removed from the study, deleted, and not used for analysis or dissemination. Should someone wish to withdraw after the EBCD collective child's voice films are made (both age specific and the final combined age film), will fully anonymise that participant's data either by removing that participant from the films altogether and/or concealing/blurring the person's identity and replacing the persons voice with an actor's voiceover so the participant will be unidentifiable. If a participant is deemed to lose the capacity to assent/consent to research while taking part in the study, the participant will be withdrawn from the study. A participant may be withdrawn if the research team are notified of a significant potential threat to the safety of a member of the research team or if a participant displays aggressive or abusive behaviour towards a member of the team. These decisions would be made in consultation with appropriate clinical colleagues and would occur on a case-by-case basis.

6.4.1. Measures

6.4.1. Measures Ws3a

Participant group	Measures	Frequency	Time point (month number 1-12)
Children/young people	- Demographics	Once	1
	-RMD	Monthly (12)	1-12
	- Revised Children's Anxiety and Depression Scale (RCADS)	Three times	1, 6, 12
	- The Bounce Forwards Scale	Three times	1, 6, 12
	- Sense of Community in Adolescents Scale	Three times	1, 6, 12
	- Therapeutic Alliance Scale for Children (TASC-r)	Three times	1, 6, 12
	- SDQ CYP		

	-Pen portrait - Interviews and/or reflective group discussions -Qualtrics written feedback	 Twice Fortnightly (24) Three times Three times	 1 & 12 1-12 1, 6, 12 1, 6, 12
Residential Staff	-Demographics - Professional Quality of Life Scale (ProQOL) - Brief TIC self-assessment reflective exercise (developed in Ws1) -TiC conversation Tool -Narrative data	Once Three times Three times Twice Bi-monthly (6)	1 1, 6, 12 1, 6, 12 1 & 12 2, 4, 6, 8, 10, 12
Social Workers	-Narrative data (every 8 weeks)	Bi-monthly (6)	2, 4, 6, 8, 10, 12

Assessments for children and young people

Instrument used in the proposed evaluation	**Number of items**	**Indicative completion time**
Strengths and Difficulties Questionnaire Self-Report version for 11-17 year olds (Goodman et al., 1998)	25	10-15 minutes
Revised Children's Anxiety and Depression Scale (RCADS)	47	10-15 minutes
The Bounce Forwards Scale	34	10-15 minutes
Sense of Community in Adolescents Scale (SOC-AS; Chiessi et al., 2010)	36	15-20 minutes
Therapeutic Alliance Scale for Children (TASC-r; Creed& Kendall, 2005)	12	5-10 minutes

Instrument used in the proposed evaluation	Suitability for the study
Strengths and Difficulties Questionnaire (Goodman et al., 1998)	The SDQ is a brief behavioural and emotional screening questionnaire, routinely employed across youth mental health services to collect baseline data, usually at the point of referral. The SDQ captures information about children aged 2–17-year-olds. There is a version for young people aged 11-17-years-old that they can complete on their own, and a parent version and teacher version. Only the parent/carer version and young people's version will be used in the NEST study. Research with children and young people supports the use of the self-report SDQ with young people aged 8-17-years-old and is therefore appropriate to our study.
Revised Children's Anxiety and Depression Scale (RCADS)	The Revised Children's Anxiety and Depression Scale (RCADS) is a 47-item self-report questionnaire designed for children and young people aged 8 to 18. It assesses symptoms across six subscales: separation anxiety, social phobia, generalized anxiety, panic disorder, obsessive-compulsive disorder, and major depression. This tool is appropriate for the NEST Study because it helps identify and track anxiety and depression symptoms, which are common in young people who have experienced trauma. By administering the RCADS before, during, and after the intervention, the study can evaluate the effectiveness of trauma-informed care in improving mental health outcomes. Its comprehensive nature and validated use in diverse settings make it a reliable measure for informing and tailoring trauma-informed practices in children's homes.
The Bounce Forwards Scale	The Bounce Forwards Scale is a resilience-focused assessment tool designed to measure young people's ability to adapt positively to challenges and adversity. This scale is appropriate for the NEST Study because it aligns with the project's goal of promoting trauma-informed care, helping assess how well the intervention enhances resilience and emotional recovery in children who have experienced trauma. By tracking changes in resilience, the scale provides valuable insights into the effectiveness of the trauma-informed toolkit being implemented in children's homes.

Sense of Community in Adolescents Scale (SOC-AS; Chiessi et al., 2010)	The SOC-AS is a psychological tool designed to measure adolescents' perceived sense of belonging, connection, and support within a specific community, such as their school, neighbourhood, or peer group. This scale evaluates how well adolescents feel integrated and valued within their community, which is particularly important during adolescence—a developmental stage where social connections play a key role in emotional well-being and identity formation. This scale is particularly useful in contexts like residential care settings or schools, where fostering a sense of belonging can significantly improve adolescents' well-being and engagement.
Therapeutic Alliance Scale for Children (TASC-r; Creed& Kendall, 2005)	The TASC-r is a 12-item self-report measure designed to assess the quality of the therapeutic relationship from the child's perspective. The scale evaluates both positive and negative aspects of the therapeutic alliance, including goal agreement, task collaboration, and emotional bond. This measure is appropriate for the NEST study as it assesses the quality of the therapeutic relationship, which is crucial in trauma-informed care settings like residential homes. The NEST Study focuses on creating nurturing environments for young people who have experienced significant trauma, and building a strong therapeutic alliance is essential to fostering a sense of safety, trust, and empowerment—key components of trauma-informed care.

Quantitative ssessments for residential staff

1. Professional Quality of Life Scale (ProQOL) - 30 items (5-8 minutes)

Informed Assent/Consent for Interviews

As for other stages of the study, informed assent and/or consent will be obtained prior to the start of the qualitative interviews. Participants will be provided with multiple options to confirm and document their informed consent, depending on whether contact with the research team will be face-to-face or via remote means. These will include: 1) signing a hard copy of the consent form during face-to-face meetings with research workers; 2) returning a signed hard copy of the consent form to the research team via standard mail (using a pre-paid return envelope provided by the research team); 3) returning a signed electronic copy of the consent form to the research team via email, or 4) providing audio-recorded consent (this will be recorded by research workers using an encrypted recording device and stored separately from any research data collected from study participants).

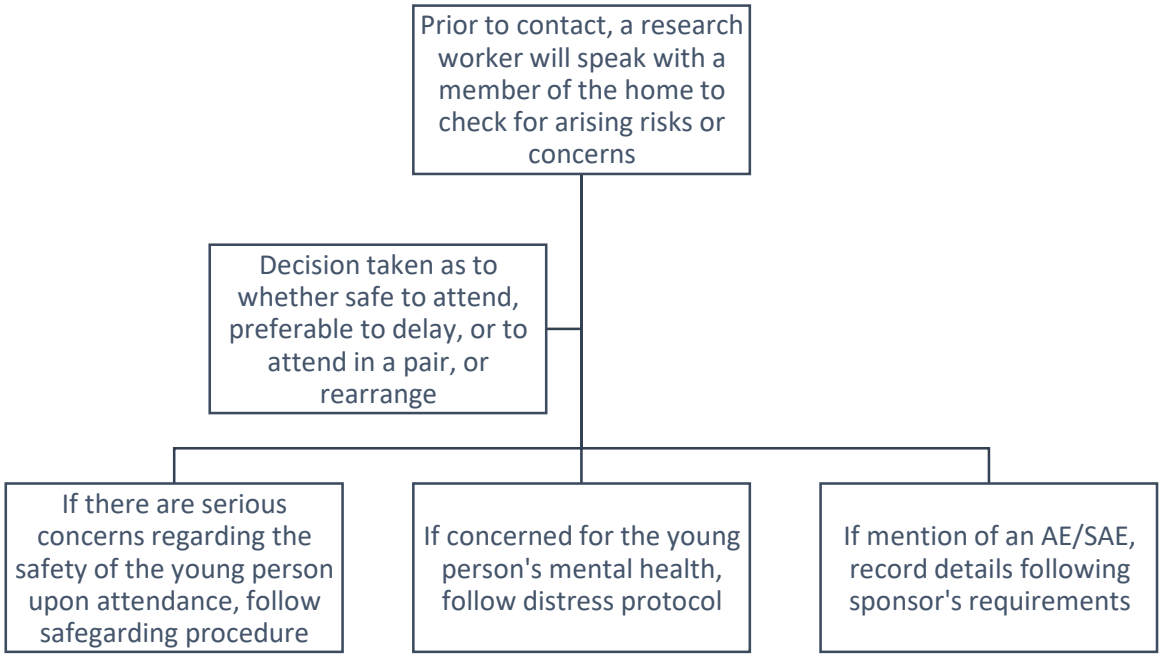
Following consent, the research workers will conduct semi-structured interviews according to the draft topic guides included with this NHS ethics/health research authority (HRA) application. The topic guides used to inform the qualitative interviews will be a living document, updated according to emerging findings from earlier interviews, new published literature in this area and feedback from our ongoing stakeholder consultations.

Interviews may take up to 90 minutes, depending upon how much or little participants wish to say, and will be recorded using encrypted recording devices. Participants will be asked if they would like to receive copies of their interview transcripts and a summary of the emerging findings of the study, for the purposes of ensuring accuracy and contribute to 'member checking' procedures to ensure the trustworthiness of the study findings.

6.6 Keeping in touch calls.

To promote retention in the study, the research workers will contact the link person at each of the homes approximately two weeks before each data collection point and then again a few days prior. These brief telephone calls will be an opportunity for the research workers to remind participants (usually staff) of upcoming research engagement and to resolve pragmatic barriers that may delay or hinder the participant's timely engagement in the follow-ups.

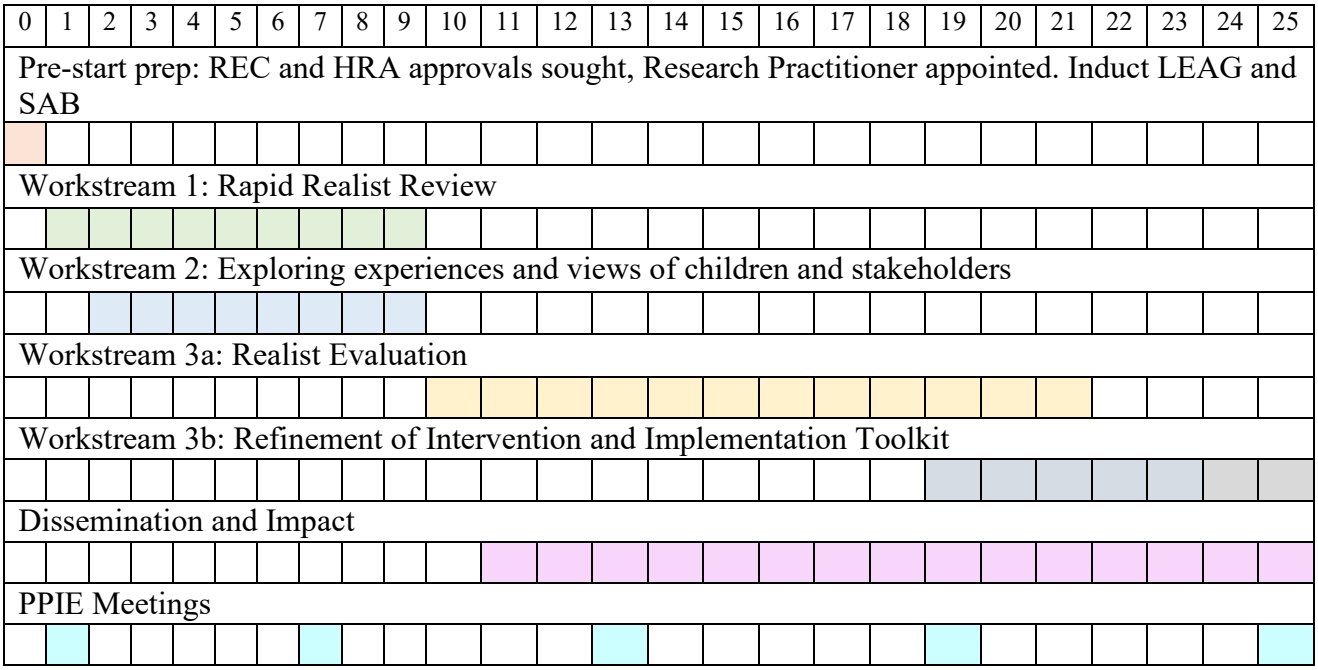
6.7 Safeguarding



Co-investigator Emma Ford is an expert in Child Safeguarding and will advise the team on complex issues or ethical dilemmas that emerge during the study regarding safeguarding. In most instances, Salford's child safeguarding procedures will be followed, in collaboration with the Salford Safeguarding Children Partnership.

7. Definition of end of study

The intervention period is due to end by 31st August 2026, data collection is due to complete by 30th September 2026, and the study will close on 30th April 2027.



8. Ethical and regulatory considerations

8.1 Approvals

Before the start of the intervention period, a favourable opinion will be sought from an NHS Research Ethics Committee (REC) for the study protocol, informed assent forms (children aged 15-years-old and younger) consent forms (participants 16-years-old and over) and other relevant study documents. All components of the research involving data collection from research participants will commence following satisfactory NHS Ethics and HRA approval, as well as local Capacity and Capability approval from participating NHS Trusts. The study will be conducted in full conformance with all relevant legal requirements and the principles of the Declaration of Helsinki, Good Clinical Practice (GCP) and the UK Policy Framework for Health and Social Care Research 2017. Where young people are in the care of Salford City Council, depending upon the nature of the care order, consent for a young person's participation will be gained from the placement provider, social worker, or child's named parent/caregiver, as appropriate.

8.2 Regulatory Review & Compliance

Before any site can enrol patients into the study, the CI or designee will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance.

For any amendment to the study, the CI or designee, in agreement with the Sponsor, will submit information to the appropriate body (REC, HRA, Sponsor and participating sites) for them to issue approval for the amendment. The CI or designee

will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

All correspondence with the REC and HRA will be saved in the Study Master File. The CI or designee will be responsible for the submission of annual reports and safety reports to the REC, the final REC project report / end of study notification and the prompt notification of the premature interruption of the study, should this be warranted.

8.3 Protocol compliance

Thorough training of all research staff at the study onset and subsequent weekly supervision of all research workers (e.g., assistant, therapist, ClinPsyD trainees) throughout their involvement in the study will minimise risk of deviations from protocol. However, accidental deviations from protocol can happen at any time; these will be documented and recorded in a protocol deviations log, which will be saved in the Study Master File. All deviations from protocol will be brought to the attention of the project CI, and promptly communicated to the study Sponsor, so that corrective actions could be promptly implemented. The protocol deviations log will also be reviewed at regular meetings with the experienced research team and professional steering groups for additional scrutiny and suggestions of corrective actions.

8.4 Assessment and management of risk

All digital and face-to-face contact with research participants will be conducted in accordance with bespoke standard operating procedures (SOPs) to manage any risk uncovered as part of the planned research assessments. These will comply with national and local policies for safeguarding children and vulnerable adults. In case our research assessments will uncover significant safeguarding issues or risks, participants' confidentiality may be breached to comply with safeguarding best practice and ensure the safety of all parties. This might involve disclosure of clinical and risk information to the participants' clinical teams and relevant safeguarding teams, as guided by local frameworks and policies for safeguarding children and vulnerable adults. All participants will be informed of the boundaries and limits of confidentiality at the onset of the evaluation.

The study will include the collection and discussion of sensitive topics, and some participants may find these upsetting or potentially distressing. In our experience, severe distress caused by the proposed research procedures will be highly unlikely. Nonetheless, to mitigate risk of distress, all contact with research participants will be conducted according to SOPs to manage assessments in a sensitive and respectful way. We will also follow tried-and-tested protocols for recognising and responding to potential signs of distress during and following contact with research participants. These procedures include, amongst other steps, 1) pausing of any data collection /

interview procedures should a participant become distressed; 2) offering breaks and opportunities for reassurance; 3) reminding participants that their participation is voluntary and of their right to withdraw at any point, without any detriment to them; 4) procedures for signposting participants to appropriate sources of support or summon emergency services in cases of extreme risk to the participant or the public. All participants will be provided with debriefing information that will include the contact details of relevant local support services that participants could access in the event of a crisis. This debriefing document will be updated regularly to ensure that information and resources are as up to date as possible throughout the study.

All research workers contributing to data collection activities will receive regular supervision from a senior researcher within the team as well as access to line management supervision and other ad-hoc supervision and guidance from clinically qualified NHS professionals. All contacts with research participants will take place at pre-specified times agreed by project's CI or individual with delegated responsibility, and according to a 'clinical cover rota' that will guarantee that RAs within the host research centre have prompt access to clinically qualified members of the research team for initial risk management advice.

It is expected that a considerable amount of contact with research participants will be via remote means (e.g., telephone or digital platforms/software approved by the participating NHS organisations, e.g., Microsoft Teams). Risks to the physical safety of the investigator are therefore minimal in these circumstances. Any necessary face-to-face contact will be conducted in full compliance with the lone working policies of the participating NHS Trusts and Higher Education Institutions (HEIs) where the research workers and other research workers will be based, which will include locally adapted safety checking for lone workers SOPs.

8.5 Adverse event reporting and harms

Throughout the participants' involvement in the study, best practice, professional guidelines, and local NHS policies for monitoring mental state and risk for participants will be followed and will be facilitated by close liaison with clinical teams. Any adverse event (AE), clinically significant deterioration in the participants' mental state or change in risk information will be promptly communicated to responsible clinicians to ensure appropriate monitoring and provision of support.

Any AE observed over the course of the research will be documented and reported according to bespoke SOPs that will fully comply with appropriate HRA safety reporting procedures for non-CTIMP studies, Sponsor's requirements, and local R&D policies of participating NHS organisations. For example, all research contacts will be recorded in clinical notes and signed consent forms will also be uploaded/attached to clinical notes.

The occurrence of AEs will be monitored and systematically recorded by study staff. Research workers may become aware of an AE in a variety of ways, including

participants' prompted or unprompted disclosure, information received from responsible clinicians, information extracted through clinical notes and usual monitoring of the participants' mental health and welfare as part of therapy sessions delivered as part of the trial. To ensure active surveillance of harms, at each follow-up assessment, the research workers will actively check for the occurrence of specific AEs using a structured checklist completed with the participant.

AEs are defined in line with standard HRA guidance as any untoward medical occurrence, unintended disease or injury, or untoward clinical signs in participants, whether or not related to the treatment, which require additional support or input from health professionals. Any clinically significant increase in presenting difficulties reported by participants (i.e., operationalised as an unresolved exacerbation in distress/mental health symptoms requiring increased involvement from the care team, e.g., a change in treatment plan) and reports of distress or complaints associated with therapy or other study procedure would also constitute AEs.

AE forms will be sent to the project CI (or another clinically qualified person with delegated responsibility) and assessed for:

- *Severity* (i.e., classified as mild, moderate, and severe according to the impact of the event on the person at the time, irrespective of whether the event also meet 'seriousness' criteria).
- *Relatedness* (i.e., whether the event resulted from administration of any of the research or therapy procedures, according to available information, e.g. temporal proximity to a study procedure; according to the report of the participant and the opinion of the clinical team).
- *Expectedness* (rated only in cases where the event is judged as related to the study procedures and intervention, and pertaining to whether the nature and severity of the observed reaction appears inconsistent with those expected from the study procedures.
- *Seriousness* (i.e., whether the outcome of the event meet criteria for a SAEs, including death and life-threatening events, incidents which acutely jeopardise the health or psychological well-being of the individual, events resulting in immediate hospital admission and/or persistent or significant disability or incapacity, and events resulting in injury requiring immediate medical attention, including A&E visits for mental health reasons).

Only SAEs judged to be unexpected and related to the study will be reported to the REC as per standard HRA procedures, within 15 days of the CI first becoming aware of the event. This means the REC will be notified based on the initial report, even if the final report is pending. <u>All reportable SAEs will be reported to the Sponsor in accordance with timelines and procedures mandated by Sponsor-specific guidelines and SOPs.</u>

All completed AE forms will be stored locally in site master files, and a central AE log will be maintained as per HRA guidance to ensure effective safety monitoring. Throughout the trial, AEs and SAEs will be regularly audited at monthly team

meetings to monitor trends in AE/SAE and their implications for the ongoing delivery of the study procedures. The Sponsor and Funder will immediately be notified on receipt of any information that raises material concerns about safety of the study procedures and interventions.

Any required urgent safety measures (i.e. steps taken by the CI and/or research team in the event that there is an immediate risk to a participant or participants, without the prior approval of the NHS REC/HRA) will be notified by the CI must to the REC immediately by telephone and then follow-up with a substantial amendment within 3 days outlining the measures that have been taken and its rationale. A copy of the amendment will be submitted to the Sponsor for expedite review and sponsor authorisation of the amendment before being submitted to the NHS REC/HRA.

8.6 Data protection and management

The processing of all personal and research data will be in full compliance with the Data Protection Act 2018 and the European Union's General Data Protection Regulation (GDPR). Any personal information, with the exception of participant's who have chosen an identifiable option for the filmmaking, will be deleted and/or safely destroyed at the end of the study e.g., through confidential waste management services available at our HEIs and NHS organisation. This will include pseudonymisation keys, i.e., data will be fully anonymised at the end of the study. All anonymised research data will be kept in anonymised format and retained for a minimum of five years following the end of the study. All final locked datasets will be kept in encrypted files on robust and automatically backed up on Pennine Trust servers.

With regards to the films, a DPIA data transfer agreement will be drawn up between NHS, Pennine Care and Manchester Metropolitan University (MMU) specific to the film data. In short, this agreement will outline that the film data is captured via MMU's cameras using password protected, encrypted SD cards. Ethical procedures to data handling outline that the filmed interview data is transferred on location straight after filming from the camera SD cards to MMU's editing suit. This is again using a password protected, unique identifier MMU Mac Laptop to be edited by the filmmaker EC. At this point, the film data is deleted from the SD cards. The un-edited films are then backed up and saved onto a designated MMU RDS drive until the films are created. When created and approved by the participants and the research team, these unedited films are then deleted from the RDS Drive and only the approved edited versions are kept.

Participants over 16 years, will have the opportunity to co-edit their individual case study films with the research team before it gets integrated into the child's collective voice film. At this stage they will also be given a second chance to change their anonymity choice should they wish to and to edit out anything they do not want to be included in the final film. The EBCD films will be edited using FinalCut ProX software using the themes emerging from the thematic analysis. The individual case

study films will be uploaded to MMU Tube for the purpose of research dissemination and will be active as long as the webpage is active. This will be password protected and locked, only accessible to be viewed and shared by the MMU co-applicants on the team. Storage of the collective voice films will be reviewed annually by the project CI (SP) for relevance as per GDPR guidance. If anyone who has chosen an identifiable option for filming wishes to withdraw after the EBCD final collective child's voice is made and uploaded, the research team will delete their individuals case study film (if aged over 16) remove from the MMU Tube site and fully anonymise that participant's data from the age specific and final collective child's voice film before uploading the amended version. Robust data security measures will be implemented throughout the study, in full compliance with national policies and relevant data management and information governance policies and procedures of the participating HEIs and NHS organisations. Hard copies of participant questionnaire data and interview transcripts will be stored in safe lockable cabinets on Trust premises. Hard copies of signed consent forms will be stored in a similar way and will be kept separate from research data collected as part of the study. Signed consent forms will be stored in line with PCFT policies. Study participant consent forms will be stored for five years after the study end date, and healthcare professional consent forms will be stored for 5 years after the study end date.

Any digital / electronic copies of research measures, interview transcripts and audio recordings will be encrypted and stored on secure and automatically backed up serves available at PCFT sites. All research data will be pseudonymised and unique study IDs will be used instead of participant names / Personal Identifiable Data (PID). Whenever possible, interviews will be conducted using recording devices enabling data encryption at the point of data collection, to provide additional data security. All interviews will be pseudonymised at the point of transcription, and all identifying details removed. Audio-recorded consent (including participants' names) will be recorded on a separate audio file so that this information could not be directly linked with interview transcripts or audio-recordings. Digitally encrypted audio recordings of the interviews (but not identifying consent data, see above) will be transferred to an external company for transcription. Transcripts will be returned to the central research team using digitally encrypted files. Any audio or video recording of therapy sessions undertaken for the purposes of supervision and treatment fidelity/adherence checks will not be retained and will be permanently deleted as once reviewed/rated by a therapy supervisor. Data will be fully anonymised at the end of the study by destroying pseudonymisation keys.

The transfer of research data amongst participating sites will be managed via a secure web-based database system hosted on Trust servers, or alternative safe data transfer systems approved by the Sponsor. Access to the database will be restricted to members of the project team involved in data entry and analysis, using an in-built secure system to grant access and data management privileges that can be authorised only by the project CI/Co-CI.

At the end of the study, all study data, the Project Master File, and all site files will be forwarded for archiving with the study Sponsor.

9. Peer review

This protocol has been robustly reviewed by NIHR HS&DR funding panels.

10.Statement of Indemnity

PCFT is the project sponsor. NHS indemnity applies for this NHS Trust sponsored trial. The Universities involved in this project also have insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

11. Access to the final study dataset

Future requests to access our data will be via the project's CI (Dr Parry) and will be only approved on a case-by-case basis when sharing of data will not incur in any risk of participant identification, and only when secondary users will be from a bona fide research organisation and have been granted suitable regulatory approval to further interrogate our data.

12. Publication and dissemination policy

No professional writers will be involved in the production of the final project report and other peer-reviewed publications that will result from the research activities conducted as part of the project. Authorship of various project outputs will be informed by authorship criteria proposed by The International Committee of Medical Journal Editors or equivalent criteria endorsed by specific peer-reviewed journals where manuscripts will be submitted. Exact authorship decisions, including any time limits and review requirements by co-authors, will be agreed by the research team over the course of the project.

All publications and outputs arising from the project will comply with the NIHR's publication requirements, including advance output notifications to NIHR, standard NIHR funding statements and NIHR / disclaimers.

Following completion of the study, participants will be provided with an accessible summary of the study findings (if they consented to this). The findings of the project will be written-up as a series of papers to be submitted for publication in peer-

reviewed journal. Further dissemination will be via conference presentations at national and international academic conferences, as well as training seminars, mainstream and social media, and accessible public forums (e.g., blogs and ACAMH) to share findings in a range of accessible mediums.

To disseminate and promote the intervention and toolkit across the sector, a multimedia dissemination package will include a short film, illustrated toolkit, implementation section with case studies, and stories from experience. We will work with the LEAG and SAB on integrated knowledge translation to ensure our materials are suitable for a range of audiences. In line with EBCD methodology, a celebration event will thank participants and promote our findings through all mainstream and social media channels to increase visibility and impact. A minimum of four high impact journal papers will be generated: (1) Rapid Realist Review, (2) EBCD commentary, (3) Realist Evaluation, (4) Intervention and Implementation Toolkit publication with policy and practice recommendations. We will present our findings to the Policy Team of the DfE and Ofsted to share key findings relevant across the sector. We will promote the toolkit though the Children's Homes Association to ensure uptake and further feedback across the sector. SP has provided information, upon invitation, to the Policy Team of the DfE regarding workforce training and support for residential care workers in recognition of current shortfalls. Accordingly, key stakeholders are already engaged in this process.

A large dissemination event will be held at Salford Civic Centre, including webcast via Microsoft Teams/Zoom for an online audience, to disseminate findings from the study. All stakeholders will be invited and members of the LEAG and SAB will be invited to present their reflections. Young people from the homes and LEAG will be supported as is needed so they can participate, or not, as fully as they would like. Local and national press will be engaged with the event to promote the reach of the findings.

Planned outputs:

- A policy document and practitioner briefing for frontline workers in children's homes, home managers and directors, with an addendum for commissioners.
- High quality journal publications from WP1-3.
- Accessible media outputs in digital magazines with no paywall (e.g., CYP Now, a multimedia portfolio that will include the implementation toolkit).
- Based on PPIE conducted so far, we envisage the implementation toolkit will include the intervention protocol for practitioners to apply the TIC intervention, supplemented by stories from experience developed through the study, case studies to illustrate how to apply the elements of the intervention, reflections on practice to demonstrate learning and progress over time, and visual summaries to help practitioners discuss the intervention with young people. We will also include a section on research-based learning and 'social stories' for future research and service development initiatives

that wish to build on this study. For example, reflections and recommendations for overcoming likely challenges or adjustments.
- Sector wide webinars to share findings.

Anticipated Impact and Future Research

If the findings from the proposed study suggest that a future trial is warranted, we will design a feasibility Randomized Controlled Trial across local authority and privately owned homes in Northwest England to establish the parameters for a large-scale multi-site definitive trial. Currently, it is not clear how trial conditions could be operationalised within these environments, although this study will provide learning in relation to these methodological challenges.

Equality, Diversity, and Inclusion

The process of recruiting people to the LEAG, SAB and research participants will be informed by an awareness of inclusive practices for research participation. We are committed to hearing from a diverse range of young people and stakeholders, which will help us assess the cultural sensitivity of our interpretations of data and implementation toolkit planning. We will draw on guidance and recommended practices within the Race Equality Framework, addressing the 50 questions attending to the five domains of the self-assessment. Further, benefitting from the anonymous feedback forum, we will employ the four components of the Patient–Public Partnership Model as a model to structure our presentations to and conversations with the LEAG and SAB to reflect upon our application of the Race Equality Framework within the context of the study. Pennine Care NHS Foundation Trust will cover costs of interpreters and translators as needed, and we are exploring commissioning training through the Proud Trust on promoting culturally sensitive engagement with young people identifying as LGBTQ+. Additionally, we are in touch with Paul Deemer, Head of Diversity and Inclusion for NHS Employers and Steven Weeks, Policy Manager of NHS Employers to see how we could adapt NHS EDI monitoring processes for this study. Finally, we have an existing programme of knowledge exchange work ongoing with the GM ARC Young People's Advisory Group in relation to tackling health inequalities, which will further guide this project.

Success criteria and barriers to proposed work

Establish an **effective inter-disciplinary team**. We have spent considerable time pre-application building relationships, networks, and co-developing an iterative process of research with a range of professionals and stakeholders across the sector, which should ensure effective collaboration between ourselves and colleagues throughout the project.

Develop a manageable range of initial **programme theories** in workstream one for testing in workstreams 2-3, building upon the Nuffield Foundation's recent Principles of Care for Children with Complex Needs. The time and flexibility we have accounted for in our plan and methods, alongside considerable expertise in the team and costed RP support, will ensure the timely success of these workstreams. These iterative workstreams should lead to a **piloted and robustly evaluated trauma-informed care intervention** for homes for children, which has the potential to significantly improve the care children receive, the wellbeing and retention of staff, and the future developments of the sector.

Recruitment of volunteers and participants: Based on the recognised need for a theoretically informed trauma-informed care framework to guide care in homes for children and buy in from identified organisations and homes, we do not anticipate recruitment will be a challenge. A challenge for the team will be to communicate with each young person and staff member individually and confidentially to discuss informed assent/consent for their participation in both the intervention and evaluation. Initial stakeholder consultations indicate there is a wish and desire for this project in each of the homes. However, if a critical mass of staff and/or young people within each of the homes later withdraw their interest, we would need to discuss how viable it is that home is included in the study. Whilst unlikely given all current indicators, this is nonetheless a consideration the team are aware of. Equally, it may be that a small number of individuals are happy to take part in the intervention but not all research procedures. These instances will be discussed within the team and consent will be viewed as a process, not an event, over the full course of the pilot intervention. In the unlikely event a plan B is needed, a nearby local authority has offered to host the study in part or full depending upon need, ensuring the study would go ahead in another area of need, offering value and much needed research input.

Retention of participants: The proposed project will benefit from the existing and strong partnerships and relationships between the project team and stakeholders across the children's homes sector. Retention to workstreams two and three will be supported by the permanence of the research environment within the homes and a flexible process of participation that suites individual young people and staff (i.e., offering interview spaces outside of typical office hours and a commitment to offering engaging research activities).

Staff engagement and training: Another benefit of engaging with our project for staff is the training they will receive in trauma-informed theory and care. This is a key priority for children's services across Greater Manchester, with the Deputy Director of Public Health stating in July 2023 that, "It is therefore critical for Manchester to have a strategic approach to ACE aware, trauma informed and responsive practice, to tackle health inequalities and achieve the ambition of Making Manchester Fairer". This strategic alignment will further support buy in, maintaining ambition, and the success of the project. The Greater Manchester Health Scrutiny Committee currently recommends people "Advocate for trauma informed practice wherever possible."

Finally, it is essential our research has a **strong impact**. We have involved key stakeholders at all levels who have a role in guiding the future design and delivery of better care for care experienced young people. The nature of our dissemination strategy means we will reach people through multimodal platforms and collaborate with other researchers working in this field to amplify our collective findings, to drive change in relation to youth emergency mental health services and formulate new relationships and infrastructure to support implementation. We will develop a mailing list for the project and add key people from the policy teams of the DHSC, the Greater Manchester Integrated Care Partnership, NHSE, and ICBs. We will offer quarterly online feedback and consultation events, which PI SP is experienced in hosting. The RP will also be tasked with developing and sharing a quarterly newsletter for the mailing list, which we will also share more broadly with potential 'friends' of the project.

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WP Activities	ASSIGNED TO	Pre-start:	Dec-24	Jan-25	Feb-25	Mar-25	Apr-25	May-25	Jun-25	Jul-25	Aug-25	Sep-25	Oct-25	Nov-25	Dec-25	Jan-26	Feb-26	Mar-26	Apr-26	May-26	Jun-26	Jul-26	Aug-26	Sep-26	Oct-26	Nov-26	Dec-26	Jan-27	Feb-27	Mar-27	Apr-27
Set up	SP																														
Ethics application & digital infrastructure	SP																														
Recruit RP	SP																														
Appoint to LEAG & SAB	SP, DG																														
Formulate RR searches	GW, SP, Librarian																														
Site visits	SP, JD																														
WP1 Realist Review																															
Step1: Locate existing theories	GW, RP																														
Step 2: Search for evidence	GW, RP																														
Step 3: Select articles	GW, RP																														
Step 4: Extract data	RP																														
Step 5: Synthesise data	GW, RP																														
Discuss CMOCs with LEAG & SAB	GW, SP, RP, DG																														
Discuss emerging initial prog theory with EBCD groups	GW, SP, RP, DG, JD																														
WP2 EBCD																															
Interview 16-18-year olds	JD, RP, DG																														
Research/creative conversations with 11-15-year olds	JD, SP, RP, DG																														
Develop and show stimulus film	EC, JD, DG																														
Gather reflective narratives	RP, JD, SP																														
Develop and show final narrative stimulus film	EC, JD																														
Gather final reflective narratives + feedback on PT in WP1	RP, JD, SP																														
Intervention development workshops	GW, SP, RP, DG, JD																														
WP3 Realist Evaluation																															
Staff training in intervention	SP, GW, DG																														
Formulation and supervision meetings	SP, RA																														
Data collection (table in research plan)	RP (+SP, GW)																														
Data analysis	RP, SP, GW, JD																														
WP3.b.	SP, GW, JD																														
Dissemination and Impact																															
Iterative dissemination of emerging findings and feedback	SP, DG																														
Development of multimedia portfolio and toolkit design	GW, SP, RP, DG, JD, EC																														
Research outputs and policy briefing	SP, GW, JD																														
EBCD celebration events	JD, EC, SP																														
Dissemination events with stakeholders	GW, SP, RP, DG, JD, EC																														