Mental Health Joint Response Car Protocol

Evaluating the Implementation of a Mental Health Joint Response Car with Young People and Families

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Version Control

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V1.5	04.04.2025	
V1.6	29.04.2025	To reduce data collection time points from three to two, to add Snapchat as a contact option, to streamline the repeat consent process, to add a survey option for participation, and to extend the immediate period following a crisis through which young people and parents can take part from 4 weeks to 12 weeks.

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i. Contents

ii. Abbreviations 4
iii. Project summary 5
iv. Funding and support in kind 8
v. Role of study sponsor and funder 8
vi. Roles and responsibilities of study management committees/groups & individuals 8
Patient & Public Involvement and Engagement (PPIE) 9
Stakeholders and Project Staff 9
vii. Protocol contributors 10
viii. Key words 10
ix. Study flow chart 11
1. Background and rationale 11
2. Objectives and Outcome Assessments 17
3.a. Realist Synthesis 18
3.b. Pilot Design 20
4. Setting 21
Nested Case Study Design 21
5. Participant Eligibility Criteria 22
6. Study Procedures 23
6.4. Taking Informed Consent 31
6.3.1 Additional consent provisions for collection and use of participant data 35
6.3.2 Withdrawal of consent and withdrawal criteria 35
6.4 Data Collection 36
6.4.1. Measures 37
6.4.2. Qualitative Interviews 2
Qualitative interviews for TAU and Care Responders delivered during the pilot window 2
Qualitative interviews for past-TAU participants and case study participants 2
Qualitative interviews with practitioners 3
6.4.3. Health Economic Evaluation 4
6.5 Realist Data Analysis 5
6.6 Health Economic Data Analysis 6
6.7 Keeping in touch calls 8
6.8 Safeguarding 8
7. Definition of end of study 9
8. Ethical and regulatory considerations 10
8.1 Approvals 10
8.2 Regulatory Review & Compliance 10
8.3 Protocol compliance 10
8.4 Assessment and management of risk 11
8.5 Adverse event reporting and harms 12
8.6 Data protection and management 14
9. Peer review 15
This protocol has been robustly reviewed by NIHR HS&DR funding panels 15
10.Statement of Indemnity 15
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 . 15
11. Access to the final study dataset 15
12. Publication and dissemination policy 15
15. References 17

ii. Abbreviations

AE	Adverse Event
CBT	Cognitive Behavioural Therapy
CI	Chief Investigator
CAMHS	Child and Adolescent Mental Health Services
Co-CI	Co-Chief Investigator
CFT	Compassion focused therapy
CMT	Compassionate mind training
CRF	Case Report Form
CRN	Clinical Research Network
CSO	Clinical Studies Officer
CYP	Children and young people
GCP	Good Clinical Practice
GDPR	General Data Protection Regulations
GM	Greater Manchester
GMMH	Greater Manchester Mental Health NHS Foundation Trust
GMP	Greater Manchester Police
HEI	Higher Education Institution
HRA	Health Research Authority
HS&DR	Health and Social Care Delivery Research
HTA	Health Technology Assessment
IAPT	Improving Access to Psychological Therapies services
JRC	Joint Response Car
LEAG	Lived Experience Advisory Group
MFT	Manchester University NHS Foundation Trust
MRC	Medical Research Council
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
PCG	Parent and caring companions group
PCFT	Pennine Care NHS Foundation Trust

PIC	Participant Identification Centre
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
RW	Research workers
RCT	Randomised Control Trial
REC	Research Ethics Committee
REDCAP	Research Electronic Data Capture
SAE	Serious adverse event
SAB	Stakeholder advisory board
TAU	Treatment as Usual
UoM	The University of Manchester

iii. Project summary

Study Title	Evaluating the Implementation of a Mental Health Joint Response Car with Young People and Families
Internal ref. no. (or short title)	Mental Health Joint Response Car
Clinical Phase	Pilot and evaluation
Design	Realist synthesis Pilot and realist evaluation Health economic evaluation Co-production of iterative dissemination workstream
Study Participants	TAU – N CYP = 100 TAU – N P/C = 100 JRC – N CYP = 100 JRC – N P/C = 100 Staff – N = 20
Planned Sample Size	Children = up to 200 Parents/carers = up to 200 Staff – up to 30
Treatment duration	1 x first response call out of around 30-90 minutes

Follow up duration	Up to 6 months post contact with first response service
Planned Pilot Period	August 2024 – February 2026
Planned Study Period (Study start and end date)	1st March 2024 – 31st March 2027
Research Questions and Objectives	**RQ1. What are the impacts of introducing a MHJRC for children and young people experiencing mental health crisis resulting in a 999 call? How, why, in what contexts, and for whom are these impacts generated? (Aim and Workstream 1).** **Objectives** 1a. Develop theories of the underlying generative mechanisms by which, and contexts within which, a joint response between a police officer and mental health practitioner impact on mental health, options

	for care, and wellbeing outcomes for young people in mental health crisis. **<u>RQ2.</u> What are the roles of police officers and mental health practitioners within the MHJRC model, and how do they impact young people in mental health crises? (Aims 2-3 and Workstreams 2-3).** **Objectives** 2a. Develop a theory to understand the roles of police officers and mental health practitioners, how they vary in different contexts across call outs, and how they impact young people across emerging adolescence, mid-adolescence, and emerging adulthood. 2b. Test and refine the theories through qualitative enquiry with young people and their families, police officers, mental health practitioners, and other connected first responders. 2c. Employ a cost-consequence approach to identify multiple effects across different sectors of the MHJRC and compare with the costs of the intervention. **<u>RQ3.</u> How can evidence-based theories of joint responses by police officers and mental health practitioners inform best practice guidance and support? (Aim 4 and Workstream 4).** **Objective** 3a. Test and refine the theories through qualitative enquiry with young people, parents/carers, practitioners, and wider stakeholders (e.g., commissioners). 3b. Co-design effective outputs to share new learning about a MHJRC for young people and engage national stakeholders to carry recommendations forwards.

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 HS&DR	£953,791.00
GM CRN (excess treatment costs)	£247,667.00

v. Role of study sponsor and funder

The proposed project has been reviewed by an NIHR funding panel as part of the NIHR HS&DR competitive funding process and was recommended for funding in October 2023. 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), 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 professional steering groups will be responsible for the independent oversight of the project on behalf of the Sponsor and the NIHR and 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 steering groups 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.

Core Project Team

1. Sarah Parry, Chief Investigator, Consultant Clinical Academic and Clinical Psychologist
2. Prathiba Chitsabesan, National Clinical Director for Children and Young People's Mental Health
3. Debbie Robinson, Strategic Lead for Urgent and Emergency Care
4. Karina Lovell, Professor of Mental Health, Nursing and Midwifery
5. Fiona Lobban, Professor of Clinical Psychology
6. Geoff Wong, Associate Professor of Primary Care Health Sciences, GP
7. Heather Brown, Professor of Health Inequalities
8. Zarah Eve, Research Centre Manager

Patient & Public Involvement and Engagement (PPIE)

A lived experience advisory group (LEAG, N=8), and parent and caring companions group (PCG N=8) will be appointed. An independent oversight group (N=8) and implementation advisory group (N=12) will be appointed, following NIHR Guidance. Stakeholder group meetings will ensure voices are integral to the project from the start.

Stakeholders and Project Staff

We will ensure we have our data systems established and consult with our learning technicians at the Trust and University libraries regarding work on our realist synthesis. Workstreams are timed to be as efficient as possible and will overlap where suitable to conduct tasks in parallel, promoting the pollination of ideas and reflection across workstreams to enrich the process. If funding is approved, we will immediately meet with members of the PCFT MHJRC team, MHUT, and GMP to develop a standard operating procedure (SOP) for the youth MHJRC service and thoroughly integrate plans for the pilot into the developing modelling MHUT are conducting now. We will also consider options for secondment or recruitment to a 1.0FTE equivalent (likely 2 x 0.5FTE/0.4FTE + 0.6FTE) band 8a CAMHS practitioner to work on the MHJRC. Learning from the adult MHJRC has demonstrated that designated mental health practitioners, rather than bank staff, are essential for optimal implementation. Meetings will be chaired by our PPIE Lead and at least one member of the core research team.

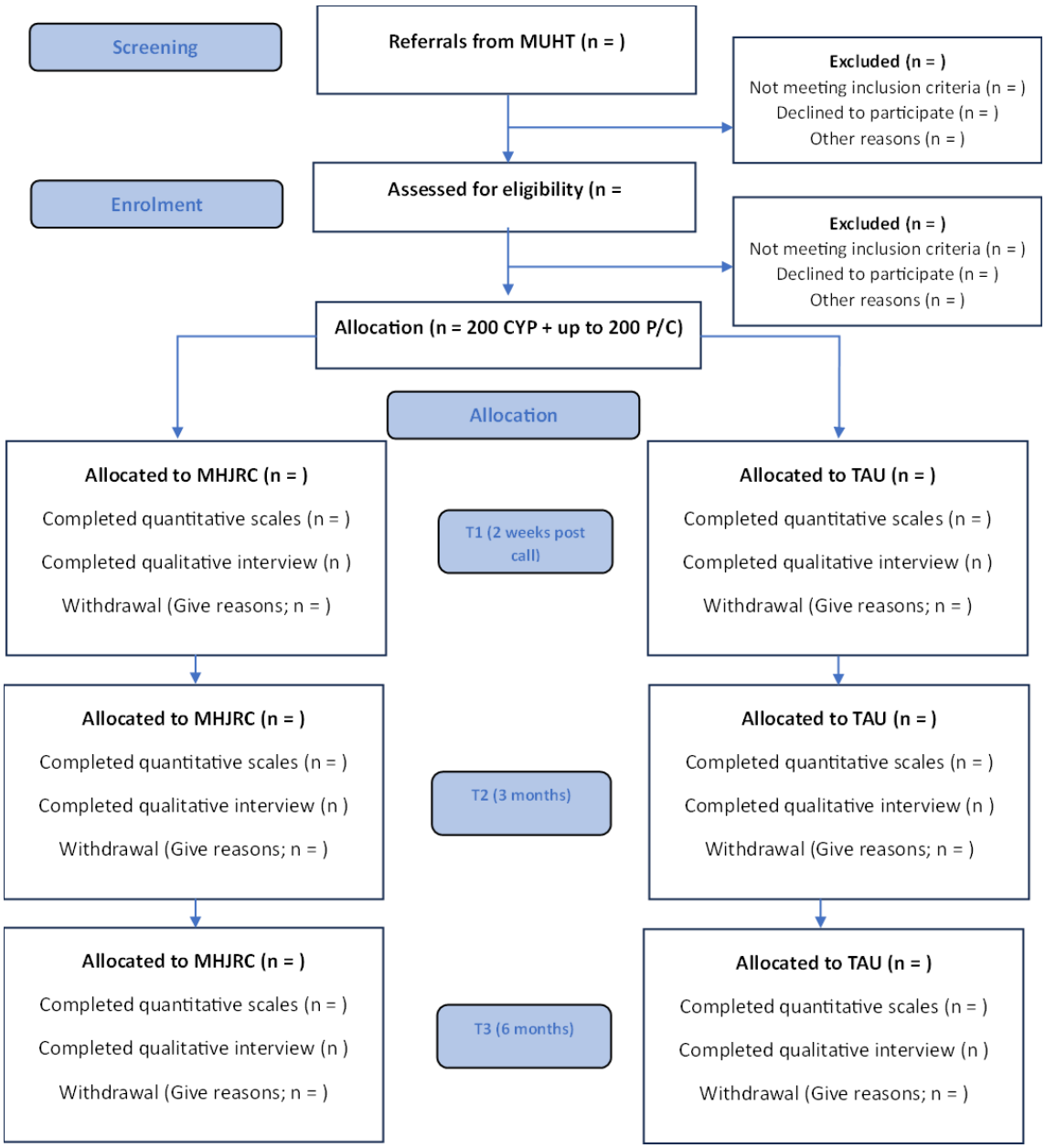
vii. Protocol contributors

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. Adele Terry and Reagan Blyth have advised specifically on PPIE matters and have been directly involved in the development of this project over the last two years.

viii. Key words

Brief intervention; first response; child/adolescent mental health

ix. Study flow chart



1. Background and rationale

Challenge: Children and young people are experiencing increasing challenges to their mental health, with services "constantly firefighting" to meet demand (Health and Social Care Committee, 2022). Pathways to mental health care for young people are under-researched (MacDonald et al., 2018) and poorly understood. In February 2023, it was identified the NHS is not reaching targets to increase access and reduce waiting times for young people's mental health services (Department for Health and Social Care, 2023). Data collected by Greater Manchester Police (GMP) shows youth

mental health care plans developed by police officers attending to 999 calls have increased by 14.2% between 2021 and 2022. Police officers often feel ill-equipped to provide mental health support, especially to children and young people experiencing a mental health crisis (Jackson et al., 2019)

Potential solution: Our evaluation would provide the necessary evidence to establish a high-performance intervention model across England through a robust evaluation of the pilot implementation of a MHJRC. In 2022, GMP and Pennine Care NHS Foundation Trust (PCFT) piloted a MHJRC with adults experiencing mental health crises across five Greater Manchester boroughs. The MHJRC involves a police officer and mental health practitioner attending collaboratively to people in crisis who have made a 999 call: combining the response speed of the police and mental health expertise of the practitioner. The MHJRC for adults demonstrated police officers and mental health professionals can collaborate effectively to support people in crisis (Blyth, 2022).

Collaborations nationally, usually between the police and paramedics, have demonstrated joint response approaches reduce the inappropriate use of mental health legislation and hospital admissions, increase user engagement, strengthen relationships between the police and health services (Blyth, 2022), and reduce costs to public services (Lancaster, 2016). The 2022 Greater Manchester pilot of the MHJRC involved 1,484 adult patients. As a result of the collaborative response of the MHJRC, 673 cases were recorded in which an A&E referral was avoided, 521 Section 136s (S136) were avoided, and in instances where a S136 was required, attendance of the MHJRC enhanced this crisis pathway and improved the process for patients. A S136 is part of the Mental Health Act that gives police emergency powers to take a person to a place of safety, where their mental health is assessed. A detention in a place of safety under a S136 can last for up to 24 hours; sometimes extended for another 12 hours.

Theoretical rationale

Information from the existing literature, research currently in progress, and in relation to current affairs indicates our research is highly timely. Nationally, conversations continue as to what role the police should play in responding to people in mental health crisis. In May 2023, Sarah Hughes, CEO of Mind, stated: “mental health is core police business, for example, only the police can publicly section people in mental health crisis. The police can only properly help people with the right support from the whole system. The NHS needs sufficient resourcing so that people in crisis are treated quickly and in a therapeutic environment.” Our project speaks directly to collaboration, creating a therapeutic response to young people in crisis, and whole system change.

In June 2023, the *Hear Me Speak* UK-based campaign was launched, founded by mental health and anti-racism activist António Ferreira, with support from *Beyond.* Beyond is a youth mental health charity tackling the growing mental health crisis

affecting young people in the UK. António Ferreira is an award-winning campaigner and has his own experience of adolescent mental health crises and involvement with police and CAMHS. The campaign aims to 'strengthen legislation, guidance and training around policing within a mental health crisis'. If funded, we will aim to collaborate with *Hear Me Speak* and *Beyond* to amplify dissemination activities and provide evidence from our study to their campaigns and legislation development in the near future.

Young people's mental health difficulties have increased in scale and complexity in recent years, with COVID related school closures and social media-based bullying cited as recent aggravating factors (Newlove-Delgado et al., 2022). There are increases in the need for emergency mental health care, but little research has been conducted with young people and their families to explore what this emergency support would look like and how it could be operationalised. According to GMP records, the number of S136's for young people under 18-years-old rose from 77 between 01/04/20-31/03/21 to 115 between 01/04/21-31/03/22. However, despite a clear need for supportive emergency care for young people in mental health crisis, emergency care is extremely limited and generally experienced as unsupportive. A recent survey (Buchanan et al., 2022) found:

- 54% of respondents to a satisfaction questionnaire reported child and adolescent mental health services (CAMHS) for emergency care were 'poor' or 'awful'.
- 40% reported emergency care had worsened in 'service quality' over the last 3 years.
- 64% of respondents reported no service availability after 17:00.
- Two thirds of respondents reported waiting times of over 24 hours for a hospital bed, with free text comments indicating some patients had waited 5 days.

CAMHS often operate during typical working hours (8am-6pm), which has meant that it is difficult to integrate paediatric emergency services into existing CAMHS structures. This lack of service integration has a significant impact upon service quality and child safety. Epidemiologic studies in relation to care pathways of mental health and self-harm emergencies attended by first responders are scarce, even though between 10% (NHS Digital, 2015) and 40% (Data Analytics Lab, 2020) of calls to emergency services relate to a mental health crisis. Therefore, we have a limited understanding of who helps people outside of typical working hours when they are most in need, especially for children.

Data is especially scare in relation to young people in crisis. Enquiries with NHS Digital and NHS England have identified that national data on the frequency of S136s and 999 calls for mental health emergencies is not aggregated by age. Therefore, it is not clear how many young people nationally call 999 in a mental health emergency, or what the consequences of those calls may be. What national data does show us is that people experiencing a mental health crisis receive inconstant and poor-quality care, compared to what is experienced for a physical health emergency (Duncan et al.,

2019). Further, mental health difficulties amongst adults and young people are increasing, and the care people receive when they seek emergency help appears less than satisfactory (NHS Digital, 2021); and young people are particularly disadvantaged by current systems and services.

A recent qualitative synthesis identified that most first responders to adult mental health crises in the community are police and ambulance staff (Xanthopoulou et al., 2022). Factors that influenced the care people received included stigmatised attitudes in relation to mental health, arbitrary training, and a lack of sensitivity. Two recommendations from the review were to improve communication between family carers and first responders, and to improve procedures to remove barriers for efficient care.

In London, UK, a pilot of joint responding to mental health crises for adults between the Metropolitan Police Service and London Ambulance Service NHS Trust demonstrated a decrease in need for hospitalisation and reduced on-scene waiting times from an average of 36 minutes to seven minutes for police officers (Zipfel et al., 2016). Further, when police officers and mental health professionals work together to triage a person's needs, the outcome can be a reduced need for use of the Mental Health Act or police custody (Puntis et al., 2018). Encouraging forecasts were also provided regarding cost savings.

Although up to 40% of police time is spent responding to mental health crises (Hallett et al., 2021), there are concerns as to whether police officers have access to suitable training to work on the frontline of mental health (Rodgers et al., 2019). There is also a need to hear the perspectives of service users, investigate outcomes, and explore how co-response interventions work within the wider health service. Specifically, there is a lack of evidence in relation to how police-related mental health triage options could benefit service users (Rodgers et al., 2019).

What evidence we do have for MHJRCs mainly relates to adults. However, the police force has been cited as a 'useful multi-agency partner' who could collaborate with health services to identify children locally who may be at risk, and intervene early (NHS Confederation, 2021). With increased demand for mental health services and limited resources within any one service, it is likely that services will need to collaborate to effectively respond to people of all ages in mental health crisis in the future. Therefore, interventions such as a MHJRC are needed to meet demand at an individual level, and in response to how services will need to collaborate and transform to reduce pressures upon emergency and hospital-based care. Within Greater Manchester (GM), the Mental Health Urgent Triage (MHUT) group has recently been developed (due to launch towards the end of 2023) to link up the three GM NHS Trusts and GMP, to develop an all-age service to 999 calls for mental health distress. SP (PI) and AT (PPI Lead) met with Gary Flanagan, Strategic Lead for Mental Health Crisis and Liaison within MHUT in preparation for this stage two application. MHUT are eager to learn from this project if funded, recognising there is

little youth-focused evidence-based information to draw upon for service modelling and delivery at present.

We have seen the MHJRC works well for adults; we now need to know if it can work well for young people to meet a growing and urgent need. The proposed study would draw upon our unique geographical setting, experienced research team and public co-applicants, novel learning from the Greater Manchester Health and Social Care Partnership (GMHSCP), and the existing partnership between GMP and PCFT to pilot a MHJRC for young people experiencing mental health crisis to find out what works, how, for whom, and in what contexts through a realist evaluation with an embedded health economic evaluation.

Since our stage one application, we have been in close contact with the teams leading projects NIHR128359 (Crisis responses for children and young people: an evidence synthesis of service organisation, effectiveness and experiences) and NIHR151811 (Crisis care for children and young people with mental health problems: national mapping, models of delivery, sustainability and experience) to establish a partnership that will support a sequential programme of collaborative research to optimise our three projects. Our proposed realist review will build upon their systematic narrative review, and their mapping exercises. We have also arranged for the MHJRC in PCFT for 18-25-year-olds to be one of their eight case study sites towards the end of 2023, which will lay helpful foundations for our study with young people aged under 18-years-old. We will benefit from their case study findings and use this information to support the early stages of our evaluation, co-presenting the findings of the NIHR151811 team to our stakeholder groups to 'set the scene' and facilitate an informed and timely start to our project. We have further plans for collaboration, discussed in workstream four.

Further, themes found in NIHR128359 (Evans et al., 2023) will expedite our realist synthesis and support our focus upon exploring *how* to overcome the barriers they have identified in a UK context. We will use the six identified goals for crisis services identified in their review to structure our stakeholder discussions during the interpretation stage of the realist synthesis to inform our developing programme theory. Members of the NIHR128359 and NIHR151811 teams will also join us for reflective discussions during this time while we share information across our projects.

Health/Care need: Suitable, timely, and proportionate on-scene intervention can reduce distress, the likelihood that restrictive practices are necessary, and improve outcomes for patients in the short- and long-term. Within the MHJRC intervention, the mental health practitioner assesses the person's needs and considers appropriate community-based care options, reducing the need for A&E or a secure S136 suite. Through our study, the pilot MHJRC for young people will be funded by GMP and

fully supported by GMHSCP and PCFT, in recognition of the urgent need for improved emergency care.

Expressed need: The NHS Mental Health Implementation Plan states "There will be 100% coverage of 24/7 age-appropriate crisis care […] including mental health professionals working in ambulance control rooms, Integrated Urgent Care services, and providing on-the-scene response in line with clinical quality indicators". Our study could be a helpful step in realising this ambition. A recent meta-analysis found an increase in emergency department visits among girls since the onset of the pandemic and admissions for self-harm have increased among older children (Madigan et al., 2023). Better crisis care is needed for young people, and it is urgently needed now. Young people are facing increasing challenges to their mental health, which are being compounded by the pressures of the cost-of-living crisis. Good quality emergency care is essential. PCFT records show it is inappropriate for the majority of 12-18-year-olds brought to hospital by the police to be admitted to hospital (88%) or referred for acute support (65%), which perhaps suggests a lack of mental health awareness at the point of triage when the police respond to an emergency. Immediate on-scene mental health support by an attending officer and mental health practitioner, drawing on deescalation and coping strategies, could be a suitable and proportionate alternative to an otherwise traumatic admission to hospital. The minimum cost of a CAMHS hospital bed is over £700/person per day. The MHJRC has the potential to provide young people support when they need it, reducing unsuitable referrals, offering an efficient alternative to current practice.

Sustained interest and intent: The 2022 PCFT pilot demonstrated the MHJRC for adults is an acceptable and effective intervention with high satisfaction ratings. Young people should have access to good quality emergency mental health care too. Nationally, NHS England are working with regional teams and Integrated Care Boards to support innovations that reduce pressure on youth emergency pathways, highlighting the timeliness of our research.

Capacity to generate new knowledge: There is a consensus that services need to work differently: police training in mental health needs to improve and we need to learn from lived experiences of young people to improve access to services. We will pilot a MHJRC for young people in a geographically and contextually unique area. GMHSCP and commitment from GMP enables us to bring together a triangle of expertise of the police, health, and social care services to drive innovation for young people's mental health, which will inform service development across England, aligning with future plans for regional devolution.

Generalisable findings and prospects for change: Greater Manchester is one of the UK's largest metropolitan areas, with a diverse population of 2,867,800 people, nearly 200 languages; with 40% of Manchester's young people reporting to be multilingual. The five boroughs served by PCFT are **Bury** (urban; population 552,000), **Stockport** (urban, population 294,800), **Oldham** (rural and semi-rural; population

242,100), **Tameside** (urban centre, rural footprint; population 231,100) and **Hayward, Middleton, Rochdale** (HMR, includes high-density urban areas, semi-rural and rural open countryside; population 223,800). Whilst there are areas of affluence and rapid economic growth, such as parts of Bury and Stockport, 21% of Heywood and Middleton is classed as "highly deprived". 50% of children in Rochdale's most deprived areas are living in poverty (Greater Manchester Poverty Action's Monitor, 2022). Overall, 28% of children living across Rochdale live in poverty, 8% higher than the national average. Therefore, although this study is based across the single site of PCFT, there will be opportunities for exploring how, why and for whom the MHJRC works for young people across a diverse and culturally rich area. The study will offer transferrable learning across urban and semi-rural areas, informing wider learning around cultural sensitivity in relation to how first responders attend to mental health crises across communities. We will therefore be able to collect data to test our theories in relation to a range of geographical locations, from metropolitan highdensity areas to countryside and moorland on the edge of the Peak District National Park; exploring how the MHJRC works, or not, for a variety of people, places, and communities.

1.1 Assessment and management of risk

- The proposed intervention offers a novel, tailored and theoretically informed approach to support for children and young people already seeking crisis care. Compared to normal standard practice, the proposed intervention should pose less risk as its development has been theoretically informed and co-produced throughout primary and secondary research, and co-production.
- Due to the brief nature of the proposed intervention, the frequency of risk should be lower than current practice, which is non-tailored, not standardised, and variable in quality and impact.
- A dedicated CAMHS practitioner and highly trained research team will ensure that the intervention 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 Aims

1. Develop a programme theory of the impacts (positive and negative) of a MHJRC for young people experiencing a mental health crisis and their families (workstream 1).

2. Draw upon the programme theory, lived experience, and realist evaluation to critically consider how a MHJRC can integrate into existing service infrastructures to best serve young people in crisis (workstreams 2 and 3).
3. Identify the costs and effects of the MHJRC for young people, their families, professionals, and systems (workstream 3).
4. Use the programme theory and evaluation outcomes to develop best practice tools for implementation and identify opportunities for integrating the MHJRC within young people's mental health and social care services (workstream 4).

2.2 Objectives

1a. Develop theories of the underlying generative mechanisms by which, and contexts within which, a joint response between a police officer and mental health practitioner impact on mental health, options for care, and wellbeing outcomes for young people in mental health crisis.

2a. Develop a theory to understand the roles of police officers and mental health practitioners, how they vary in different contexts across call outs, and how they impact young people across emerging adolescence, mid-adolescence, and emerging adulthood.
2b. Test and refine the theories through qualitative enquiry with young people and their families, police officers, mental health practitioners, and other connected first responders.
2c. Employ a cost-consequence approach to identify multiple effects across different sectors of the MHJRC and compare with the costs of the intervention.

3a. Test and refine the theories through qualitative enquiry with young people, parents/carers, practitioners, and wider stakeholders (e.g., commissioners). 3b. Co-design effective outputs to share new learning about a MHJRC for young people and engage national stakeholders to carry recommendations forwards.

3.a. Realist Synthesis

A realist review emphasises understanding context specific causation, represented by the heuristic context+mechanism=outcome. It is an interpretative, theory-driven approach used to synthesise evidence from various sources, including published studies, policy documents, and grey literature. Realist review recognises that interventions may be effective in some contexts but not others, for some people but not others, highlighting the importance of *context*. Our realist review starts with initial programme theories that describe our current understanding of emergency responses to young people experiencing mental health crises.

At the end of this Workstream, our programme theory will aim to explain causation based on mechanisms; thus, it is likely to be transferable to similar interventions in different settings and can guide the design and implementation of a complex coresponse intervention for mental health crises in complex environments. To develop and test our programme theory, we will draw on two sources - data from documents included in our review and anonymised and unattributed data from interpretation workshops with stakeholders (professional stakeholders N=20; people aged over 18 years old with lived experience N=20). The combined interpretation process with members of the research team and stakeholders will ensure the review benefits from diverse perspectives. This testing involves iterative processes, such as abductive reasoning and retroduction, leading to the development of a better refined realist programme theory (Wong et al., 2013).

The purpose of using interpretation workshops and discussions with professional stakeholders and people with lived experience during a realist review is to develop programme theories by incorporating diverse perspectives and expertise. This approach ensures that the review is grounded in real-world contexts and is more likely to produce actionable insights. Through our existing professional networks around the Care Responders study, we will identify 20 relevant stakeholders, including healthcare professionals, police officers, and other non-researcher contributors, and up to 20 people with lived experience engaged with our PPIE activities, who will be able to opt-in to the interpretation discussions through our regular correspondence around the study (e.g., our newsletter). Stakeholders will have a direct interest or expertise in relation to responding to mental health crises. Stakeholders will have the option of discussing their perspective individually with a member of the review team or to join an online discussion forum or workshop. Discussion will last approximately 50-90 minutes and will focus on interpreting the emerging programme theory, rather than individual experience of crisis services.

In preparation for the discussions, accessible summaries of relevant literature and initial programme theories will be provided and updated after each discussion, in preparation for the next. A clear agenda and objectives will be set. Discussions will be held with a focus on open dialogue and collaborative exploration of the literature. Stakeholders will be encouraged to share their experiences and insights, highlighting practical implications and contextual factors. A semi-structured discussion guide will ensure consistency while allowing flexibility for emergent topics. Discussions will be recorded and transcribed for transparency via transcription software, record keeping, and thorough analysis. Data will be analysed using the same realist logic of analysis as in Step 5 of the realist review. Iteratively, we will refine initial programme theories based on the analysis, integrating stakeholder feedback (Wiltshire & Ronkainen, 2021).

Preliminary findings and revised programme theories will be shared with stakeholders for validation. Overall, feedback will then be incorporated to further refine the theories, ensuring they accurately reflect the collective insights and are

grounded in real-world contexts. We will document the process and outcomes of the workshops and discussions, including how stakeholder input influenced the development of programme theories. This approach will enhance the relevance and applicability of the realist review, ensure a better understanding of complex interventions and their contexts, and promote stakeholder buy-in and the implementation of findings (Abrams et al., 2021). The evolving programme theory will be shared at regular intervals with the research team and stakeholder groups, in written and diagrammatic form for ongoing refinement, integration and prioritisation of aspects to take forward for testing in a realist evaluation that will follow on from this realist review.

3.b. Pilot Design

A realist evaluation using mixed methods for data collection will enable us to codesign best practice guidance tools through theory and experience for a MHJRC for young people. Realist philosophy asserts that complex social interventions in health have intended and unintended impacts (outcomes - O) through the way in which people respond to the resources offered through the program (mechanism - M). Mechanisms are triggered by the presence or absence of specific elements in the environment in which the programme is delivered (context- C). Understanding what achieves particular outcomes in relation to the MHJRC, and why the MHJRC results in different outcomes for different people, and in different contexts (i.e., the development of CMO configurations) requires in-depth theory building and testing (i.e., confirmation, refutation and refinement). The realist approach has been chosen because it most readily addresses our research questions and the complexity of the MHJRC as a service (Skivington et al., 2021). A realist approach is suitable to understand complex interventions by explaining the influence of context, who might (might not) benefit, and how outcomes have arisen (Pawson, 2013). Using this approach will also enable us to produce potentially transferable knowledge. Based on PPIE conducted with young people since 1st March 2024, the pilot service will be called the **Care Responders** project. The logo design is currently under PPIE review with two young people's groups.

Theoretical framework

We will develop a programme theory to explain the impacts of the MHJRC for young people and their families. To do this, we will be guided by existing theories around first responders, especially in connection to the limited publications focusing upon young people and families (Rumping, et al., 2022).

1. Theories will be developed through workstream one to guide the development of our initial programme theory.
2. The initial programme theory will be further tested in workstream 2.
3. A health economic evaluation, drawing where possible on realist principles, will be undertaken through workstream 3.

4. Our final programme theories and co-production will be used to inform the development of best practice tools for services and first responders, which will be applied to mobilise, communicate, and apply this new learning in Workstream 4.

4. Setting

The pilot and evaluation will be based in Greater Manchester, with participant identification, recruitment and treatment for participants of the pilot Care Responders car taking place through the new MHUT model, the police triage unit, and any other triage centre in Greater Manchester responding to 111/999 calls. MHUT links with Greater Manchester Police (GMP), Greater Manchester Mental Health NHS Foundation Trust (GMMH), Pennine Care NHS Foundation Trust (PCFT), and Manchester University NHS Foundation Trust (MFT) to coordinate emergency care and crisis care pathways. We are already liaising with the Strategic Lead for Mental Health Crisis and Liaison for Greater Manchester, senior members of GMP, and the Greater Manchester integrated care system (ICS) to ensure outputs are useable, feasible and supported through to implementation with the support of the newly formed MHUT, which is currently being set up, to work alongside existing triage centres with a view to MHUT accepting all 999/111 calls in time.

Nested Case Study Design

We have received additional funding from the NIHR to include a nested case study for a non-intervention data gathering case study site in Merseyside. This nested case study employs a qualitative approach, aligned with Priya's (2021) assertion that case study methodology enables an in-depth exploration of complex phenomena within real-life contexts. The focus is upon CAMHS crisis care in Merseyside, allowing for nuanced insights into personal experiences and the contextual factors influencing the effectiveness of mental health crisis interventions in this additional setting. This design incorporates flexibility to adapt to specific elements critical to the effectiveness of the model in Merseyside, with findings transferable to Greater Manchester (GM).

The study will involve a detailed examination of Merseyside's 24/7 CAMHS crisis care model. Where possible, we will explore police and clinical data sets to assess the effectiveness of interventions and inter-agency collaboration. This will be complemented by focus groups and interviews with stakeholders, including young people, families, and healthcare providers. Document reviews will provide additional context, ensuring a comprehensive understanding of existing policies and practices. Methodological triangulation will enrich the understanding of the studied phenomena, capturing the complexities of interactions between young people, their families, and healthcare providers (Wyatt et al., 2021).

Data Collection and Analysis

Data collection will involve multiple sources to provide a holistic perspective:

- **Police and Clinical Data Sets**: Evaluating the effectiveness of crisis interventions and inter-agency collaboration.
- **Interviews and Focus Groups**: Engaging patients and stakeholders to explore personal experiences and inter-agency working.
- **Document Reviews**: Contextualising findings within existing policies and practices.

Data analysis will include:

- **Realist Logic Analysis**: Identifying common themes and challenges across qualitative data collected through semi-structured interviews and focus groups will inform our existing study in GM, informing CMOCs and the programme theory. This analysis will highlight key areas for improvement in service delivery and crisis intervention.
- **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 case study site with existing literature and our GM pilot to identify best practices and innovative approaches that could be adapted to local, regional, and national 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 5-99 years. Any young person who has accessed an emergency response to a mental health crisis (our Care Responders pilot and treatment as usual), and their parents/carers, will be eligible to take part. 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, people with no connection to emergency mental healthcare or experience of a mental health crisis, directly or indirectly. We do not anticipate young people under the age of 16-years-old will be involved as stakeholders, although young people under 16-years are welcome to become

participants, according to appropriate guidelines and ability to provide informed consent/assent. 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

6.1 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.

Summary - How to Take Part in the Care Responders Study

Young people, parents, caregivers, and professional practitioners can take part in the Care Responders study in different ways, depending on how they have engaged with crisis and emergency services. Accessible information, such as that presented in this summary box, will be shared on Participant Information Sheets and the study website to help people decide how to get involved.

Pathway 1

If a young person is supported by the **Care Responders team** (a police officer and a mental health practitioner), they **will be invited** to join the study during or after this visit via their parent/caregiver. At this point (known as **T1, within 12 weeks of the crisis**), participants will be asked about their experiences and offered surveys and interviews to reflect on their situation.

Pathway 2

Anyone who has received **emergency mental health care in the last 2 years** might hear about the study through **social media**, the **NHS**, or via **letters**. If interested, they can contact the research team to take part. Participants will be invited to complete an interview or survey about their experiences, depending upon whether they would prefer to talk to a research or write about their experiences in private.

Pathway 3

If a **first responder visits a young person during a mental health crisis**, a parent/caregiver will be given a consent to contact form to give permission for the research team to contact the family about the research study. Parents/caregivers will be asked if they would like to take part to talk about their own experiences, including stress levels, satisfaction with services, and what they would like to see from crisis services. Participants will be invited to complete a series of measures and take part in an interview within 12 weeks of the crisis (**T1**) and again **6 months later (T2)**, to help compare different crisis services and understand people's experiences over time.

Pathway 4

In **Merseyside**, information about a case study within the wider study will be shared in **crisis services** and online. Participants can choose to opt in if you're interested and take part in surveys, interviews, and reflective workshops, either in person, online via email or Teams, or via a Qualtrics survey to provide an offer with greater anonymity.

Pathway 5

Participants can also choose to complete a **safe, anonymous online survey** using a link shared on flyers, social media, NHS webpages, or by first responders. If participants have taken part in the study within 12 weeks of their point of crisis, participants will be invited to complete a series of measures and take part in an interview within 12 weeks of the crisis (**T1**) and again **6 months later (T2)**, to help compare different crisis services and understand people's experiences over time.

Contact the Team

The research team can be contacted by **email, text (SMS)**, or **Snapchat** to ask questions, express interest, or sign up to take part.

Consent & Support

Everyone taking part will be asked for **consent** (or **assent with parental consent for under 16s**) before joining the study. Participation is voluntary, and individuals can stop at any time. Support will be available throughout from the research team and crisis helplines.

Thank You Voucher - Participants will receive a thank you voucher at different points in the study, usually at T1 and T2 surveys or interviews.

What Will Participants Be Asked to Do?

At different stages (**T1** and possibly **T2, 6 months later**), participants will be asked to: reflect on their wellbeing, relationships, and coping skills; complete questionnaires; and join interviews or an online survey to share their experiences. The information gathered will help the research team understand what works, what doesn't, and how crisis care services could be improved.

Due to the varied nature of emergency care and the footprint of our study, there are four recruitment pathways for potential participants:

Pathway One: Care Responders Response

Young people and parents/carers who access support, via central triage, from the Care Responders project staff (police officer and mental health practitioner), will be recruited to the study via their engagement with the Care Responders response. Data will be collected as outlined in table one. Further details on consent for treatment and consent for evaluation participation are discussed in section 'Informed Consent'.

Pathway Two: Long-term Treatment as Usual

Young people and parents/carers who have accessed treatment as usual (TAU) over the last two years will need to hear about the study before they know whether they can participate in the evaluation, based on their engagement with an emergency response following a mental health crisis. Therefore, we will share information about the study through media, social media channels, information letters, and NHS webpages, sharing the study's designated email address and phone number, so people can contact us if they wish to opt-in and take part. Following an amendment to the original protocol, practitioners and their delegates in young people's NHS services will also gather consent to contact from eligible families, so the family do not need to take the first step to contact the research team.

Pathway three: Short-term Usual Care Reporting

For potential participants who engage with TAU over the course of the study, we will ask attending first responders offering TAU to share a consent to contact form developed for this study with the parent/caregiver (not the young person) when they attend to young people experiencing a mental health crisis. Through the consent to contact form, parents/carers can opt-in to being contacted to hear more about the study. Young people will not be directly addressed about research participation at the time of the call out but, if parental/caregiver approval is in place to be contacted, the research team will be able to share information about the study with the young person at a later date to ask if the young person would like to be involved in the evaluation. If the young person has asked for information about the study, but consent to contact is not in place from the parent/caregiver, the parent/caregiver will be contacted to ask if their child (aged under 16 years old) can be provided with information about the study, in case the family wishes to support the young person to take part. Information flyers about the study and consent to contact forms will be shared by first responders and practitioners across Greater Manchester Police, the three Greater Manchester Trusts involved in the study when they respond to a mental health crisis call out in any of the ten Greater Manchester boroughs. Data will be collected as outlined in table one.

Pathway four: Mersey Care Nested Case Study

Information about the nested case study will be shared via practitioners, administrators, posters and leaflets across the 24/7 crisis service in Merseyside. Information will also be shared through local media and social media. Once in possession of the information about the study and contact details of the research team, potential participants will be able to opt-in. A member of the research team will then undertake a short eligibility check over the phone or by email, before the participant is consented into the study.

Pathway five: Participation via Online Qualtrics Survey

In addition to the pathways outlined above, a fifth route to participation will be made available to young people and parents/caregivers through an online Qualtrics survey. This option has been designed in response to feedback received during the study so far, which highlighted that some young people and families may feel uncomfortable or reluctant to discuss experiences of mental health crisis directly with a researcher whom they do not know. Concerns have been raised by clinical and VCSE colleagues around the potential for shame, stigma, and judgement associated with crisis experiences discouraging potential participants, as well as the additional emotional burden of recounting these events in a one-to-one research conversation so soon after the event.

To address these barriers and improve the acceptability and accessibility of participation, families will be given the option to complete a secure, self-administered online survey, hosted via Qualtrics. Data will be collected as outlined in table one. Participants will be able to access the survey via a web link provided on study information materials distributed by first responders, NHS services, crisis response practitioners and the research team. The link will also be made available through the study's designated web page, NHS partner websites, and via social media posts from participating services.

This route offers participants a degree of anonymity and flexibility, allowing them to complete the survey at a time and location of their choosing, and at their own pace. This option removes the need for direct interaction with a researcher at the initial data collection stage, thereby creating a space in which young people and families may feel more able to reflect openly on their experiences without fear of judgement or perceived consequences. It also reduces the burden on families who may be managing multiple appointments and competing demands on their time.

For young people aged under 16, parental or caregiver consent to participate will be sought through the same mechanisms described in Pathway Three, with an option for parents/caregivers to consent for their child to complete the online survey independently where appropriate. Information about the online participation option will be included in all study recruitment materials to ensure families are aware of this additional, confidential, and flexible route for contributing to the evaluation.

Finally, on a case-by-case basis, if a young person does not feel comfortable to participate in person, over the phone, or may struggle to engage with the Qualtrics platform, a research worker will guide the participant to complete the steps of the Qualtrics based survey via email. This adjustment will need to be approved by the CI before being actioned and this adjustment will be recorded in the participant tracker to aid transparency.

Flow Chart: Participant Journey Through Qualtrics Survey

Start: Access Survey Link

↓

Landing Page:

Brief introduction to the study

Explanation of purpose, confidentiality, and voluntary nature

Age verification question:

Are you aged 16 or over?

Yes → Go to Consent Page

No → Go to Parent/Caregiver Consent Page

↓

If aged 16 or over:

Online Participant Information Sheet

Consent form tick-boxes (consent to participate, consent for data use, option to withdraw)

Click **'I agree to take part'** to proceed

↓

If under 16:

Page asking: *Do you have your parent/caregiver's permission to take part?*

Yes → Parental Consent Page

No → Information message explaining parental consent is needed before continuing. Option to exit survey.

↓

Parental Consent Page (for under 16s):

Online Information Sheet for Parent/Caregiver

Consent form tick-boxes for parent/caregiver consent to their child's participation

Tick box for child's assent

Click **'I agree for my child to take part'** to proceed

↓

Survey Questions:

Data collection items will be presented as outlined in Table One.

↓

End of Survey Page:

'Thank you' message

Information about support services

Option to withdraw data (with explanation of time limits for doing so)
Confirmation of data submission

↓

Finish

To aid recruitment, we will also engage the help of the ICB and their communication channels, and 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.

Additionally, following discussion with stakeholders during the study, for the second year of our study, we will include a **Snapchat** option for participants to contact the research team. The link to the Care Responders Snapchat account will be made available through existing flyers and other digital materials. The communication and engagement procedure for this platform will be as follows.

Young Person/Potential Participant	**Research Team**
Sees Snapchat Story or advert	Posts recruitment Stories or adverts on Snapchat
Sends a direct message (DM) expressing interest	Receives DM and sends standardised welcome and information message
Receives information about the study, eligibility criteria, and what happens next	Provides clear information on who they are, what the study involves, eligibility, and assent/consent process
Confirms interest and eligibility by replying to the message	Screens eligibility based on reply and further discussion if needed
Receives information to participate (appointment with researcher or a secure link to an online survey).	Provides information to young person and/or parent/caregiver by email/post/in person and confirms eligibility
Completes an assent/consent form (with parent if under 16)	Undertakes assent/consent procedure
Receives instructions on how to take part in the research (survey or interview)	Sends participation instructions or research access link after assent and consent are received, or arranges in person data collection meeting
Takes part in the research activity	Follows appropriate data collection and management procedure

Receives incentive after participation, if applicable	Issues thanks and vouchers(s)
Process complete	Reviews recruitment progress and any issues in RTM

The local ICB are currently running a Snapchat pilot, and we will continue to engage with the ICB to learn from each other about how to effectively employ this communication and recruitment channel.

6.2 Study participant support: Participants will have support from all members of the

Summary of Consent Procedures

Consent for the Care Responders Response

When a 111/999 call is made, service users give **verbal consent** for an emergency response vehicle to attend. At the scene, police officers go in first to check safety before a mental health practitioner (MHP) enters. The Care Responders pilot will follow this same process, supporting young people in crisis with a specialist CAMHS clinician.

Assent and Consent Process for All

At the scene of a crisis, the attending MHP will ask if the parent/carer (and young person aged 16–18 if appropriate) would like to be contacted about the study. If the situation is too distressing, no consent will be taken, but information will be left for the family.

There are **multiple options** for families to give informed consent or assent later:

- ☑ Sign a form in person
- ☑ Return a form by post
- ☑ Email a signed form
- ☑ Give recorded verbal consent
- ☑ Provide assent and consent via the consent form on Qualtrics

Consent will always be checked before any data is collected, and again at 6-month follow-up, where appropriate, to make sure everyone's still happy to take part.

Other Participation Options

1. Families who have engaged with emergency or crisis services for a young person's mental health crisis in the past 2 years can choose to join reflective interviews the online Qualtrics survey .
2. The nested case study with Mersey Care will also invite 20 young people, 20 parents/carers, and 20 practitioners to share their experiences through the same participation options.

research team, including AT (PPIE lead), the peer research assistant, and the Head of Patient and Carer Experience and Engagement at Pennine Care. If a participant is considering leaving the study earlier than planned, all efforts will be made to explore a support plan for their engagement, collaboratively with the participant. All young people will have access to the Pennine CAMHS Mental health helpline and supportive resources for families and young people

(https://www.penninecare.nhs.uk/camhs/urgent-help). A similar approach will be taken for stakeholders involved in the study. Relevant helplines (e.g., Mind, Samaritans, Papyrus) will also be offered as points of support external to the Trust and research team. The Trust has a range of support services available for employees, which will be shared with colleagues at relevant points throughout the study.

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

Consent for the intervention from service users.
Based on the existing NHS Standard Operating Procedure (SOP), service users provide verbal consent for an emergency response vehicle to attend during their 111/999 call. The current practice for a MHJRC joint response is that "Police Officers will enter the scene first and assess the situation prior to the mental health practitioner entering the address or interacting with the individual(s). Only when the officer deems it safe to do so will the practitioner exit the police vehicle and enter the address/location. It is appreciated that situations can however be very dynamic, and officers will respond accordingly, having due regard for the safety of the practitioner. It should be remembered that the practitioner will not be wearing a protective vest because they are not attending in the role of an emergency first responder, but of a mental health practitioner." (SOP, 2022, p.7). As the only change for our study is that the car is attending a younger population with the specialist expertise of a CAMHS Band 7/8 practitioner, most likely a clinical psychologist, we will follow the same process as outlined in the original SOP. Once in attendance, the Police Officer and MHP will follow standard processes for risk assessment and clinical decision making, drawing upon evidence-based practices to diffuse tension and risk, providing a compassionate space to hear from the young person in crisis and other people on scene, and discuss next steps with the young person and any responsible adults present.

Consent for the evaluation from prospective participants
As per the existing SOP, "Service user's verbal consent to engage with the evaluation will be gathered on scene by the attending MHP and will be captured within clinical documentation… Following MHJRC callout, where a service user has consented to engage with the evaluation process, they will be contacted by a member of the research team and, where confirmed to be consenting once more, will engage in the evaluation." (SOP, 2022, p.15). We will follow this process for data collection at T1 (within 12 weeks of the first contact with emergency services). We will only gain consent to contact from parents/caregivers, not young people at the point of the response. Due to the distress young people and parents/carers may experience during mental health call outs, we propose two options for gaining informed consent

for research participation in the evaluation for young people who access the Care Responders pilot.

Potential participants who hear about the study and wish to hear more will be able to contact the research team via email or phone. Once in touch, the research team will follow the assent/consent process outlined below.

Overall, informed assent and/or consent will be obtained prior to any data collection. Before the first point of data collection, 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). The research worker will sign the consent form on behalf of the participant as instructed to do so during the consent taking process of the call. The research worker will note the consent process briefly on the consent form, alongside the date and time consent was taken.

Due to the distress young people and parents/carers may experience during mental health call outs, we propose four options for gaining informed assent/consent for research participation in the evaluation.

Care Responders Option 1: Young people aged under 16 years old who receive support from the Care Responders pilot will not be asked by the attending team if they consent to being involved in the study as a research participant. If the attending mental health practitioner considers a young person aged 16-18 years old and/or the parent/caregiver able to read and understand the consent to contact request form, ask questions, and consent to being contacted in future, they will be able to do so. This decision will depend on the mental health and wellbeing assessment undertaken as part of the response. If the young person aged 16-18 years old and/or the parent/caregiver is considered too distressed to consent to being contacted, the attending practitioners will only leave information about the study with the family for them to consider in their own time. Information about participation through pathways one and five will be provided.

Care Responders Option 2: If it is considered the potential participants (young people of all ages and parents/caregivers) are too distressed to discuss consent to contact for the research study, contact information will be stored securely by the attending Care Responders practitioners according to data storage procedures for the

study. A follow up phone call will be made a few days later to see if the parent/caregiver (if the young person is aged under 16 years old) and or parent/caregiver or young person (aged 16-18) would like to discuss research participation in the evaluation. Additionally, an information flyer about the study will be left in the family's home when the Care Responders practitioners leave. The young person and/or parent/carer can then contact the research team and opt-in if they would like to later in the recruitment window (within 12 weeks of contact). Information about participation through pathways one and five will be provided.

TAU Option 1: For potential participants who access TAU, the responders who attend to them will provide a consent to contact form. If the parent/carer would like to hear more about the study, they can complete the consent to contact form, return it to the responder, who will store it securely at their base (e.g., police station, NHS premises) and notify the Care Responders team to collect it. Hard copies will therefore be collected by a member of our research team within two weeks of notification. Additionally, once consent to contact has been established, the administrator at the responder's base will send a digital copy of the form to the research team, so the young person and/or parent/carer can be contacted quickly. Digital copies will be stored securely by the research team and paper copies and digital copies will then be destroyed by the base team. Again, if it is not appropriate to follow this process (e.g., a young person needs to be referred immediately for emergency hospital care), the responsible adult will be given a contact and information leaflet. The young person and/or parent/carer can then contact the research team and opt-in if they would like to later in the recruitment window (within 12 weeks of contact). Information about participation through pathways three and five will be provided.

TAU Option 2: Due to the dynamic nature of emergency care and relatively ambitious recruitment target we have for TAU; we will offer an opportunity for potential participants who hear about the study and wish to take part to opt-in to reflective interviews about their past experiences. This participation will need to operate differently to offer more flexibility. For these participants, they will need to have engaged in a youth emergency response for mental health crisis within the last two years, as a young person or parent/carer. These participants will hear about the study through the aforementioned routes, contact the research team, declare their interest to participate, and provide basic information so a member of the research team can assess eligibility. Once eligibility is confirmed (via email, phone or Teams), a member of the research team will arrange to send an information sheet and arrange an in person or digital appointment to discuss and take consent. Once assent/consent has been taken, the participant will take part in a reflective qualitative interview about their experience at a convenient time and place for the participant or the participant will be able to take part through the Qualtrics survey.

Nested Case Study: Young people (N=20), parents/carers (N=20) and practitioners (N=20) will opt-in to take part in reflective qualitative discussions about their

experiences of child and adolescent crisis care in Merseyside. Once eligibility is confirmed (via email, phone or Teams), a member of the research team will arrange to send an information sheet and arrange an in person or digital appointment to discuss and take consent. Once assent/consent has been taken, the participant will take part in a reflective qualitative interview about their experience at a convenient time and place for the participant.

At any subsequent time points of data collection, the research worker will ask if the participant still provides their assent/consent and will mark the participant's confirmation of assent/consent on the CRF. If the participant wishes for more information, the research worker will go through the original documentation. Data collection will only go ahead following the giving of informed assent/consent.

Concluding details on assent/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.).

For participants engaging with the Care Responders intervention evaluation:
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 parent/carer, or another trusted adult. Parents/carers will also be asked if they would like to speak with the researcher privately, or with their child present. The same process will be followed at 6-month (T2) follow-up, to ensure the assent/consent giving process is based upon ongoing review, consideration, and freedom of choice.

Engagement process for participants

At the beginning of research engagement, the research study will be explained to potential participants in person, via Teams, email, or by telephone, depending upon the patient's preference. 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 an initial meeting if the patient would like to take part or via Qualtrics if the participant has opted to take part through the online survey option.

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) and brief clinical history information (history of past service use, any comorbid diagnoses etc.).

Following gaining consent/assent, baseline (T1) data will be collected from all participants. At this point, it will be noted on the participant tracker how many weeks have passed since the crisis for which the young person sought help. This will help us review the data in the context of the number of weeks that have passed (maximum 12 weeks for pathways one and three) since the crisis. At all research assessments, young people will be asked whether they prefer to speak to the researcher alone or in the presence of their parent/carer, or another trusted adult. Parents/carers will also be asked if they would like to speak with the researcher privately, or with their child present. The same process will be followed at 6-month (T2) follow-up, to ensure the assent/consent giving process is based upon ongoing review, consideration, and freedom of choice.

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 in the trial.

Based on prior experience of working in this field and anticipated media interest in this study, we will also ask participants 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 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 Data Collection

At T1 and T2, participants will be asked to complete a battery of measures and take part in semi-structured interviews about their experiences and, later, reflections upon those experiences.

Methodologically, exploring the MHJRC through a realist evaluation (workstream 2) will offer a nuanced view of how the MHJRC works as an intervention for the communities it serves. We will expand and refine our programme theory from workstream one (realist synthesis) and consider the differences between current practices and the MHJRC by exploring how existing approaches relate to people's lived experiences of the MHJRC through the collection of qualitative and quantitative data. Our realist programme theory will be tested (confirmed, refuted, or refined) through a realist evaluation using mixed methods data.

Data collection from young people and, where possible, their parents/carers, will be tailored based on the findings of workstream one. However, for the purposes of ethical review, we can confirm data collection will include:

1. Contextual features, identified in Workstream 1, that influence service user experiences.
2. Demographic characteristics, feedback on relationships, and individual satisfaction ratings.
3. Exploring relationships between quantitative measures of outcomes and contextual factors.
4. In-depth qualitative exploration of processes underpinning the deeper causal relationships between the variables from the quantitative survey, which will ensure that demi-regularities between variables across the sample are not in themselves assumed to be causal. Exact interview questions will be finalised based on workstream one, although an indicative topic guide formulated through our initial literature review and stakeholder discussions is provided for ethical review.

Quantitative surveys of service user experiences of the MHJRC (N=100, recruited through the MHJRC) and people who have engaged with traditional services to a 111/999 call (N=100, recruited through the MHUT) will be collected at the start (T1, within 12 weeks of the first contact with emergency services (i.e., traditional response to a 999 call or the MHJRC)and 6-month (T2) follow-up.

6.4.1. Measures

The Strengths and Difficulties Questionnaire (SDQ; routinely employed screening and outcome measure in CAMHS) will be used at T1 and T2. The SDQ is a brief behavioural screening questionnaire for 2-17-year-olds. This single-informant measure assesses child-wellbeing and is used by clinicians at the point of referral and exit in CAMHS. Our choice of other questionnaires will be finalised by the programme theory but will likely include:

T1

Analysis of routine data sets held by GMP and PCFT (e.g. care plans, A&E admissions, acute care pathway referrals) in relation to each contact who has engagement with the MHJRC, with an additional EDI lens to evaluate whether the routine data points capture information about the context of the individual that could inform greater cultural sensitivity and accessibility. Experience of Service Questionnaire (ESQ)
Child Self-report for 9–11-year-olds, ESQ Child Self-report for 12-18-year-olds, ESQ Parent/carer report
Therapeutic Experience Scale with young people, parents/carers, and staff (STAR-P and STAR-C)
KidCOPE scale 7-12, KidCOPE scale 13-18
Child and Youth Resilience Measure-Revised (CYRM, 5-9-years-old; CYRM, 10-23years-old)
Parental Stress Scale (PSS)
Session Rating Scale (SRS)
Short Mood and Feelings Questionnaire (sMFQ)
EQ-5D-Y-3L child-friendly EQ-5D version (EQ-5D-Y)

MHJRC PCFT staff will keep tabulated records of how time is spent. The study team will collaborate with members of the adult MHJRC team to develop a ‘heat map’ of youth and adult need/call outs across the service footprint, considering location, frequency, and key timings.

T2

Repeat ESQ, KidCOPE, CYRM-R, PSS.
These measures will address the research questions by gathering data on the impact of the MHJRC on wellbeing, service experience, therapeutic nature of relationships,

coping ability over time, and stress. This data will be enriched through the collection and analysis of qualitative data from the interviews.

Time point / Participant group	**In person/video call T1** (within 12 weeks of engagement with MHJRC/TAU)	~~**In person/ video call T2** (3-month follow-up)~~	**In person/ video call T2** (6-month follow-up)	**Qualtrics Survey T1** Route 1: within 12 weeks of engagement with MHJRC/TAU Route 2: Within two years	**Qualtrics Survey T2** (Only if Route 1: T1 was within 12 weeks of engagement with MHJRC/TAU)
Children/young people	Personal context Nature of crisis Demographics SDQ – CYP ESQ SRS sMFQ CYRM-R KidCOPE Interview EQ-5D-Y	~~ESQ~~ ~~KidCOPE~~ ~~CYRM-R~~ ~~EQ-5D-Y-3L~~ ~~Interview~~	ESQ KidCOPE CYRM-R sMFQ Interview/Workshop	Personal context Nature of crisis Demographics SDQ – CYP ESQ SRS sMFQ CYRM-R KidCOPE Interview questions EQ-5D-Y	Personal context Nature of crisis Demographics SDQ – CYP sMFQ CYRM-R KidCOPE Interview questions
Parent/Carer	Interview SDQ – Parent version PSS STAR-P SRS EQ-5D	~~ESQ~~ ~~PSS~~ ~~STAR-P~~ ~~EQ-5D~~ ~~Interview~~	ESQ SDQ and PSS STAR-P EQ-5D Interview/Workshop	Interview questions SDQ – Parent version PSS STAR-P SRS EQ-5D	Interview questions SDQ – Parent version PSS
First Responders/Practitioners	Demographics Interview STAR-C	-	Reflective interview in last two months of pilot. STAR-C	Demographics Interview STAR-C	N/A

Table Two: Assessments for children and young people

Instrument used in the proposed trial	**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
Experiences of Services Questionnaire (Brown et al., 2014)	12 items, and 3 free text sections	8-10 minutes
KidCOPE (Spirito et al., 1998)	11 items	5-7 minutes
Child and Youth Resilience Measure (separate versions for 5-9 year olds, and 10-23 year olds) (McGarrigle & Ungar, 2019)	17	10-15 minutes
Session Rating Scale (Miller et al., 2000)	4	5-8 minutes
EQ-5D-Y (Wille., 2010)	5	5 minutes

Table Three: Instrument Summary and Rationale

Instrument used in the proposed trial	**Evidence of suitability in different age/educational groups considered in the trial**
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 11-17years-old that they can complete on their own, and a parent version and teacher version. Only the parent version and young people's version will be used in the JRC study. Research with children and young people supports the use of the selfreport SDQ with young people aged 8-17-years-old and is therefore appropriate to our study.

Experiences of Services Questionnaire (Brown et al., 2014)	The ESQ is a brief questionnaire routinely employed across services to collect data relating to service satisfaction within Child and Adolescent Mental Health Services. The ESQ
	captures information about children aged 9-18-years-old. There is a version for children aged 9-11-years-old, a version for young people aged 12-18-years old, and a parent/carer version. All three version will be used within the JRC study.
KidCOPE (Spirito et al., 1998)	KidCOPE is a brief, clinical checklist designed to screen behavioural and cognitive coping in children and adolescents. The items focus on areas of coping such as problem solving, social support, social withdrawal, self-criticism, and emotional expression which are relevant to the current research. There are two age appropriate versions (7-12-years-old and 13-18years-old).
Short Mood and Feelings Questionnaire (sMFQ)	The Short Mood and Feelings Questionnaire (SMFQ) is a brief, self-report tool designed to assess depressive symptoms in children and adolescents. It consists of 13 items that evaluate mood-related symptoms, such as sadness, irritability, and low energy, over the past two weeks. Respondents rate the severity of each symptom on a 3-point scale, ranging from "not true" to "true." The SMFQ is commonly used in both clinical and research settings to help identify individuals who may be experiencing depression. It is a condensed version of the longer Mood and Feelings Questionnaire, offering a quicker and more accessible screening option.
Child and Youth Resilience Measure-revised (separate versions for 5-9 year olds, and 10-23 year olds) (McGarrigle & Ungar, 2019)	The CYRM-R is a screening tool used to explore the resources (individual, relational, communal, and cultural) available to young people which can aid their resilience. Therefore, the CYRM-R sees highly appropriate for the age group of the JRC study and due to the focus on resilience following crisis care.
Session Rating Scale (Miller et al., 2000)	The SRS is a simple, four-item visual scale used to assess dimensions of effective therapeutic relationships. The SRS has been used with children 6-12-years-old, and young people 13years-old to adults.
EQ-5D-Y (Wille et al., 2010)	The EQ-5D-Y facilitates the description and measurement of child and adolescent health status, which combined with preference weights can be used to calculate utility to inform economic evaluations. It is widely used in HE evaluations (Hastings et al., 2020).

Assessments for parents/carers (estimated completion time = 55 minutes)

1. SDQ-parent version (Mathai et al., 2002) – 10-15 minutes
2. Parental Stress Scale (Berry et al., 1995) – 8-10 minutes
3. Session Rating Scale (Miller et al., 2000) – 5-8 minutes
4. Experience of Services Questionnaire (Brown et al., 2014) - 8-10 minutes
5. STAR-P, therapeutic experience scale with parents/carers (McGuire-Snieckus et al., 2007) – 5 minutes
6. EQ-5D, records the patient's self-rated health on a vertical visual analogue scale where the endpoints are labelled for health economic data collection.

Throughout, participants will have no obligation to answer all questions / measures captured in the baseline assessments and will not be obliged to state their reasons for skipping certain items of measure.

6.4.2. Qualitative Interviews

Qualitative interviews for TAU and Care Responders delivered during the pilot window

Qualitative data will include semi-structured interviews at T1 and T2 with service users and parents/carers. Qualitative inquiry with children involved in research is important to inform service design (Martin-Kerry et al., 2019).

Semi-structured interviews exploring experience, acceptability and subsequent wellbeing will be held by the research team at suitable locations (e.g., CAMHS, familiar youth group support setting, or the service user's home or school, depending upon their preference). There will be an option for the young person to attend in person or online through Teams, and they may invite a trusted adult to accompany them if they so wish. Adults will be encouraged to attend interviews alone when possible. Data will be transcribed verbatim by software and then checked by a senior member of the research team. Transcripts will then be anonymised and analysed under the close supervision of SP. SP, GW, FL, KL and ZE will hold regular interpretation meetings with the research workers during the analytic period to offer a space for reflection and to critically assess the reflexivity and transparency of the ongoing analysis.

Qualitative interviews for past-TAU participants and case study participants

Semi-structured interviews exploring experience, satisfaction and subsequent wellbeing will be held by the research team at suitable locations (e.g., CAMHS, familiar youth group support setting, or the service user's home or school, depending upon their preference). There will be an option for the young person to attend in person or online through Teams, and they may invite a trusted adult to accompany them if they so wish. Adults will be encouraged to attend interviews alone when possible. Data will be transcribed verbatim by software and then checked by a senior

member of the research team. Transcripts will then be anonymised and analysed under the close supervision of SP. SP, GW, FL, KL and ZE will hold regular interpretation meetings with the research workers during the analytic period to offer a space for reflection and to critically assess the reflexivity and transparency of the ongoing analysis.

Qualitative interviews with practitioners

Research interviews will also be held with the MHPs and Police Officers working on the MHJRC throughout the research study to collect iterative data on their experiences. Service leads and relevant practitioners (e.g., CAMHS crisis care pathway and emergency triage; GM N=30; Merseyside N=20) will also be interviewed at relevant stages of piloting and evaluation to explore their perspectives on the process and implementation. Again, staff participants will have the option of attending in person at a convenient location (i.e., their place of work/home) or online through Teams.

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 and 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.

6.4.3. Health Economic Evaluation

The MHJRC is a complex intervention that will have impacts on multiple sectors. Cost consequence analysis (CCA) has been recommended for complex interventions that have multiple effects and for public health interventions which have an array of health and non-health benefits that are difficult to measure in a common unit (NICE, 2013a; Shah et al., 2012). Unlike cost-effectiveness and cost-benefit analyses, CCA does not require the research team to impose a specific disciplinary or professional perspective on the analysis, and instead allows decision makers to examine the impact of different perspectives. We will use a micro costing approach. This methodology uses detailed data on resource utilisation from NHS digital and unit cost data (available from: https://www.pssru.ac.uk/project-pages/unit-costs/) to generate precise estimates of economic costs. By clearly outlining all the costs occurred, other trusts can identify potential differences in costs related to roll-out. Data collection will largely be from PCFT and GMP intranet data and routine outcome measures, with additional demographic and impact questions (e.g., days missed from school/work) added to data collection points within the realist evaluation. As this is an acute/crisis intervention, a marker of success is the prevention of admission to hospital and increase in recovery focused measures at follow up. Co-applicant GW is involved in the REEM project (NIHR 135102), which seeks to develop methods for realist economic evaluations. He will be able to share any relevant findings from the REEM project as they emerge, hence potentially informing the conduct of workstream 3.

CCA will be informed by workstream 1 and, where possible, will test and refine theories in relation to economic evaluation, service resilience, and other key factors of importance identified. The analysis is likely to employ cost data on health service utilisation from NHS records of emergency admissions, over-night stays in hospital awaiting assessment, and section 136s. The evaluation will collect data on and assess:

1. Costs of delivering the MHJRC, offering learning on police, emergency department, and wider NHS spending and potential savings.
2. Changes in cost-of-service usage compared to a non-joint response.
3. Average change in cost per person between the MHJRC and care as usual.
4. Time off work/school. NHS costs will be obtained from questionnaires to caregivers and young people at T1 and T2.
5. Time spent attending to emergencies compared to indirect work (note keeping, updating records), systemic liaison (e.g., safeguarding), and other duties, compared with idle time.
6. The cost implications of journey times in boroughs that are more rural and/or that present additional obstacles for the vehicle (e.g., busy one-way systems in intensely urban areas, rural roads with poor road surface conditions, the impact of climate at specific time points, etc.).

A micro costing approach will enable the analysis of detailed data on resource utilisation from NHS digital and unit cost data (available from: https://www.pssru.ac.uk/project-pages/unit-costs/) to generate precise estimates of economic costs. By clearly outlining all the costs occurred, other trusts can identify potential differences in costs related to roll-out. We will include the location of callouts, time to drive to and from each location, and qualitatively explore the perceived impact of location upon the service from the perspective of the attending first responders as a core part of workstream 3.

6.5 Realist Data Analysis

Initially, quantitative data will be entered into SPSS. Depending upon the completion of data sets and whether we achieve our recruitment targets, we will either conduct a descriptive analysis or regression analyses. Advice will be sought from HB in statistics, and the statisticians in the MASH Centre at Lancaster University. NVIVO will store and categorise anonymised transcribed data. Data analysis will be concurrent with data collection, in line with realist interviewing conventions (Brönnimann, 2022). Data analysis will help us understand and explain why the MHJRC works in the way it does for young people and families when called to a mental health crisis, in which contexts and to what extent. This will allow us to develop an in-depth, realist understanding and explanation of the impacts observed. Each new element of relevant data will be used to refine aspects of the programme theory. As it is refined, data sources will be re-scrutinised to search for data relevant to the revised programme theory that may have been missed initially. Transcripts will be uploaded to NVivo. Relevant sections of transcripts that have been interpreted as related to contexts, mechanisms and/or their relationships to outcomes will also inform our analysis. This coding will be both inductive (codes created to categorise data identified through the analysis process) and deductive (codes created in advance of data extraction and analysis as informed by the initial programme theory, which will also hold in mind the results of the NIHR128359 (Evans et al., 2023) review).

Relevant data (qualitative and quantitative) will initially be analysed into conceptual themes. We will then use the realist logic of analysis (Brönnimann et al., 2022; Pawson & Tilley, 1997; Pearson et al., 2015; Ritchie & Lewis, 2003) to develop context-mechanism-outcome-configurations (CMOCs) that bring together the different sources of data to provide causal explanations for outcomes of importance with our programme theory. In addition, we will apply a range of reasoning processes associated with realist analysis (Pawson, 2013) to these data, such as juxtaposing data, unpicking conflicting data, and consolidating data, to explain why differences may arise across settings, and how and why identified outcomes have occurred (or not). Our ongoing application of a realist logic of analysis will be guided by a series of questions that members of the team have used in other realist projects:

1. Is this a piece of data that is relevant to programme theory development?

2. If so, do its contents provide data that may be interpreted as functioning as context, mechanism, or outcome?
3. For data that has been interpreted as functioning as context, mechanism or outcome, which CMOC does it belong to?
4. Are there further data to inform this particular CMOC - contained within this source or other sources? If so, which other sources?
5. How does this particular CMOC relate to others that have already been developed?
6. How does this particular CMOC relate to the programme theory?
7. In light of this particular CMOC and any supporting data, does the programme theory need to be changed?

We will then use this in-depth understanding and explanation as a starting point of our discussions with the stakeholder groups to refine the final theory.

To ensure active surveillance of harms, the research workers will also actively check for the occurrence of specific AEs during the follow-up period. Participants will be offered flexibility regarding length of follow-up assessment meetings, including the option of having regular breaks and multiple, shorter testing sessions. To reduce the likelihood of missing data, a member of the research team will be able to make multiple attempts to contact participants to engage with aspects of the study up until the time a participant withdraws. Data can be gathered in person or over the phone, Teams, or post. Spurious data will be discussed within the research team, who will decide upon an appropriate response (i.e., deletion, checking, repeated data collection).

6.6 Health Economic Data Analysis

We will perform a cost-consequence analysis of the MHJRC Service as a whole, as well as considering distributional impacts if data allows by age group, gender, sexual orientation, and ethnicity. We will provide, where appropriate, monetarised valuation of the effects of the programme and detail of who experiences them (younger person, young person's family, health service, police services). Heath and care utilisation can also be assigned a monetary value by applying NHS Reference Costs and the PSSRU unit costs. Health and wellbeing outcomes can be monetarised if appropriate. These can include calculating healthy life expectancies and disability free life years (NICE, 2013a; Shah et al., 2012).

Consequences will focus on the health and well-being impacts of the programme as well as impacts on the health service, including wait times for CAMHS services, attendance at A&E for mental health emergencies, police service call outs, to give a few examples, but this list is not exhaustive. Data for the benefits will come from the quantitative surveys in workstream two. We will supplement this data with data on health outcomes such as A&E attendance and waiting times from NHS digital and

data on contacts with the police using police data. We will compare these to the costs of implementing the programme, which will be obtained from The Greater Manchester Health & Social Care Partnership (GMHSCP) and PCFT. This will include considering costs around waiting times between call outs (e.g., costs for staff involved during the whole shift). Costs and consequences will be compared to the baseline scenario of service provision before the introduction of the MHJRC.

We will consider the short-term cost and consequences of the MHJRC using the estimated ex-poste effects from data collected in the quantitative surveys through workstream two. Additional consequences on outcomes related to changes in service usage and contact with the police using data from NHS digital and the police will be obtained by estimating a quasi-experimental model such as difference-indifference or interrupted time series which Co-I HB has extensive experience with (Brown et al., 2022; Thomson et al., 2020). Ex-ante longer-term costs and consequences to young people and their families, health services, and police will be estimated using evidence from the review of the literature from workstream one. We will explore different time horizons given what data is available from the literature and discussions with stakeholders and the public. If data allows, we will also explore feasibility of roll out in less urban areas by thinking about longer drive times and greater waiting times between call outs. Discount rates of 3.5% will be used, as per guidelines (NICE, 2017).

The analysis will be conducted following well-established guidelines (HM Treasury, 2018; Hunter & Shearer, 2014). Missing data will be imputed. Subgroup analysis (distributional cost consequence analysis) will be conducted on samples large enough to identify any effects. In line with recommendations, uncertainty will be incorporated using a combination of scenario based deterministic sensitivity analysis, threshold analysis, and/or probabilistic sensitivity analysis (NICE, 2013b). All parameter estimates will include 95% confidence (or, where appropriate credible intervals), and these will be calculated by applying bootstrapping techniques. We will avoid making a summary assessment of effectiveness and instead enable decision makers to form an overall judgement based on the relative weights they apply to the different consequences. Costs and effects will be disaggregated to allow decision makers to assess the trade-off between costs and effects for each dimension compared to a non-joint response. We will work with local partners to accurately audit the need and associated costs the MHJRC could address, in terms of the numbers of referrals, call outs, and admissions to A&E/s136s. Following vetting and with permission and support from Greater Manchester Police, the health economist team will review police records for data relating to the following factors:

- Data on call outs to mental health crisis for under 18s
- Care plans developed by police for young people due to mental health
- Outcome data on responses to mental health crisis
- Any data on complexity of cases
- Data on officer training in mental health

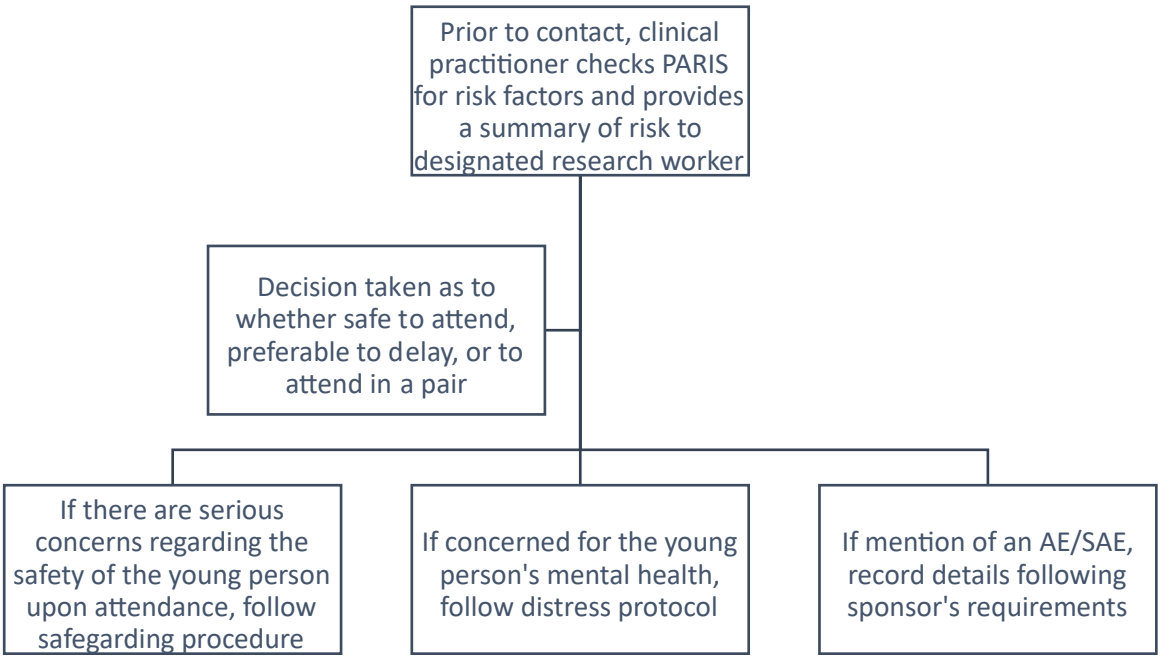
- Costs of the various call outs/responses/outcomes (e.g., hours waiting in A&E)
- Data on co-responses or joint responses with NHS mental health/ambulance/social services - comparing outcomes between police only and joint responses
- Distances travelled to mental health crisis call outs
- The time call outs and responses take
- Locations/settings of call outs (home, school, out of home placements, inpatient wards, etc.)
- Data on how mental health presentations are recorded
- Liaison between services by officers after a call out (e.g., NHS, social services, safeguarding, etc.).

6.7 Keeping in touch calls.

To promote retention in the study, the research workers will contact research participants a few days before each appointment to confirm details, and then again two weeks prior to T2. These brief telephone calls will be an opportunity for the research workers to remind participants (usually the parent/caregiver bringing the young person to the appointment) of upcoming research engagement and to resolve pragmatic barriers that may delay or hinder the participant's timely engagement in the follow-ups (e.g., ensuring that participant contact details and preference for face-to-face or remote meetings are up to date).

6.8 Safeguarding

At time points T1 andT2, we will follow the following plan to assess and manage risk:



The Greater Manchester Safeguarding Partnership is a cooperative partnership of the 10 Local Safeguarding Boards of Greater Manchester. Each of the 10 Local Authorities across the city have a nominated member on the Greater Manchester Safeguarding Partnership. If there are safeguarding concerns about any children in the study, the CI will be notified and will contact the appropriate safeguarding team for that child's place of residence, which will usually be the First Response team. However, if a member of the team is concerned about an immediate risk to a child, the Emergency Duty Team will be called. A list of phone numbers for the First Response teams and Emergency Duty Teams across the ten boroughs will be held by the CI, Co-CI, RA, and MHPs.

7. Definition of end of study

The intervention period is due to end by 31st January 2026, data collection is due to complete by 31st March 2026, and the study will close on 31st March 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 16years-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.

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. Furthermore, in case of future pandemic events, any contact will be in full-compliance with all relevant COVID-19 risk mitigation policies and procedures of participating NHS organisations (or related policies/processes for other unforeseen pandemic events) and will only be conducted following approval by the CI and/or project manager following the completion of any recommended local infection control risk assessment.

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 followup 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; in the case of the JRC study, only mild and transient exacerbation in negative affect and distress are expected following a therapy session or an assessment appointment, and all other reactions will be regarded as unexpected.
- *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 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.

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 peerreviewed 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.

Co-production of Live Performances

Made By Mortals will produce content for three live performances (Manchester, London, and Cardiff) in late 2026. The performance will promote the benefits and impact of the new approach explored within the research. The performance will be coproduced by young people (aged 16-25-years) with lived experience of crisis care as well as mental health practitioners, and police (involved in the study), and family members. The performance will bring 'real people's' lived experience to life to support policymakers and other stakeholders to understand the human impact of the new approach. Through an interactive workshop, it will also give them knowledge and space needed to consider the changes and commitments they need to make in-order to implement the new approach into their systems. Made by Mortals have their own process for gaining informed consent from people engaging in their productions as a participatory arts organisation. Where people opt-in to solely take part in the co-production and performance process, they will follow the Made by Mortals consent process. Participants of the study who are aged 16-years and over will also have the option to check the box on their consent form for the research study to hear about the Made by Mortals project within the study. If they decide to get involved, they will then follow the Made by Mortals process for providing their consent. Made by Mortals are highly experienced in working with young people in relation to mental health narratives and have a variety of engagement options available to promote choice within the development process.

Made By Mortals will provide all creative and technical staff to deliver the performances. They will also produce social media assets, photographs, and blogs to promote the project. Made By Mortals will produce a shorter presentation-style

performance for conference events to support dissemination. The process will be broken down into five interconnected phases. Co-production workshops can be delivered in-person or online to best meet the needs of the lived experience groups. MBM will make payments to stakeholders for their contribution, as per INVOLVE Guidelines.

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