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Empowered Together (Coordinated Social Care In Prison): A Feasibility And Definitive Randomised Controlled Trial, With Embedded Realist-informed Process Evaluation.

Protocol for Work Packages 1 and 2 (feasibility study)

This study is funded by the NIHR Programme Grants for Applied Research (PGfAR) (NIHR206795), National Institute for Health and Care Research (NIHR). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

This protocol has regard for the HRA guidance.

FULL/LONG TITLE OF THE STUDY

Empowered Together (Coordinated Social Care In Prison): A Feasibility And Definitive Randomised Controlled Trial, With Embedded Realist-informed Process Evaluation.

SHORT STUDY TITLE / ACRONYM

Empowered Together (Coordinated Social Care in Prison)/ ET.

WORK PACKAGES COVERED BY THIS PROTOCOL

Work Package 1 (WP1): Preliminary Work

Work Package 2 (WP2): Feasibility Study And Embedded Formative Process Evaluation

VERSION CONTROL TABLE

Version	**Name**	**Role**	**Date**
V1.0	Clare Scollay	Research Associate	30/06/25

RESEARCH REFERENCE NUMBERS

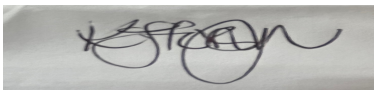
IRAS Number:	**361615**
ISRCTN Number:	*Pending*
SPONSOR Number:	LSCFT-RD24002
FUNDER's Number:	NIHR206795

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, Good Clinical Practice (GCP) guidelines, the sponsor's (and other relevant) standard operating procedures (SOPs), and other regulatory requirements as amended.

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

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

For and On Behalf Of the Study Sponsor: Signature:    Name: Farah Lunat Position: Research Operations Manager Date: 01/08/2025
Chief Investigator (CI): Signature:    Name: Dr. Katrina Forsyth Position: Research Fellow Date: 01/08/2025
Statistical oversight: Signature:    Name: Professor Victoria Allgar Position: Professor of Medical Statistics and Director of Peninsula Clinical Trials Unit (PenCTU) Date: 01/08/2025

KEY TRIAL CONTACTS

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Trial Data Monitoring and Ethics Committee Chair	Dr Daisy Gaunt daisy.gaunt@bristol.ac.uk
Patient and Public Involvement and Engagement Group	The members' list is available in the study Masterfile.

ABBREVIATIONS

AE	Adverse Events
AR	Adverse Reactions
CI	Chief Investigator
Co-CI	Co-Chief Investigator
CRF	Case Report Form
DHSC	Department of Health and Social Care
DMEC	Data Monitoring and Ethics Committee
ET	Empowered Together
GCP	Good Clinical Practice
HMPPS	His Majesty's Prison and Probation Service
HRA	Health Research Authority
ICF	Informed Consent Form
IPT	Initial Programme Theory
ISF	Investigative Site File
LSCFT	Lancashire and South Cumbria NHS Foundation Trust
MHRA	Medicines and Healthcare Products Regulatory Agency
NRC	National Research Committee
PenCTU	Peninsula Clinical Trials Unit
PGfAR	Programme Grants for Applied Research
PI	Principal Investigator
PIS	Participant Information Sheet
PPIE	Patient And Public Involvement and Engagement
R&D	Research and Development
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Events
SAR	Serious Adverse Reactions
SOP	Standard Operating Procedure
SPM	Senior Programme Manager

TMG	Trial Management Group
TSC	Trial Steering Committee
WP	Work Package

TRIAL SUMMARY

Trial Title	Empowered Together (coordinated social care in prison): A feasibility and definitive randomised controlled trial (RCT), with embedded realist-informed process evaluation.
Internal Ref. No. (short title)	Empowered Together (coordinated social care in prison) (ET).
Trial Design	**WP1:** Preliminary (development) work. **WP2:** Feasibility RCT and embedded formative process evaluation. The RCT will be a pragmatic, two-site, parallel arm, individually randomised RCT over nine months. Those in the control arm will receive social care as usual.
Aims and Objectives	The overarching aims and objectives of both WPs are to implement ET across two prison sites and assess the acceptability and feasibility of this intervention and of conducting an RCT. This will allow refinement of the design of the full effectiveness and cost-effectiveness RCT. The detailed aims and objectives of each WP are: **WP1: Primary Objectives** Development of study materials, including: 1. Training and supervision manual for ET workers 2. Fidelity of implementation tool 3. Immersive film, audio, blog, event and webpage **WP2: Primary Objectives** Determine the acceptability and feasibility of a full RCT, including through: 1. Conducting a feasibility RCT. We will: • Implement ET in two prisons • Assess rates of recruitment and outcome measure completion • Determine intervention adherence and fidelity • Assess rates of retention and transfer or release during follow-up 2. Conducting a cost-effectiveness feasibility evaluation. We will: • Estimate resource use and delivery costs for ET • Develop and test methods for undertaking a cost-effectiveness analysis alongside a full trial 3. Conducting a realist-informed formative process evaluation. We will:

	• Explore barriers to the acceptability and feasibility of intervention and trial design and develop methods to overcome these where possible • Evaluate risk of bias or contamination • Evaluate the fidelity of intervention delivery • Explore the mechanisms of action of ET: what aspects work, in what circumstances for whom and how, and evidence of activation to refine the Initial Programme Theory (IPT) 4. Reviewing findings against progression criteria. We will: • Review findings against progression criteria • Develop protocol for definitive evaluation (if met) or review alternative methods of evaluation (if not met) **WP2: Secondary Objectives** • Assess the acceptability of the outcome measures
Trial Participants	**WP1 Activities:** Training and supervision manual development for ET workers (2 workshops facilitated by the core research team): • Experts by experience, healthcare staff, occupational therapists (OTs), prison staff, and social workers Audio, film, and blog development (6-8 workshops facilitated by Made by Mortals[1] in collaboration with co-applicant Paula Harriott and the core research team): • Individuals with experience either of being in prison with social care needs, or of supporting a peer in prison with social care needs. The other activities in WP1 will be completed by the research team, without participant involvement. **WP2 Activities:** Feasibility RCT: • Adult prisoners in one of two male prisons in North West England with social care needs who would meet the threshold for assessment and support under the Care Act[2], as assessed using the brief ET screening tool, and meet the exclusion and inclusion criteria below.

[1] Made by Mortals is a Community Interest Company managed by and for individuals with lived experience of services and underserved populations including the NHS and/or social care.
[2] There are three stages in determining eligibility under the Care Act: it must be shown that the person's needs relate to a physical or mental impairment or illness; the person must be unable to achieve at least

	Realist-informed formative process evaluation: • Adult prisoners from the control and intervention arms of the RCT, including those who have withdrawn. • ET workers (coordinators) involved in assessment and care coordination and their professional supervisors. • Healthcare, prison, and local authority staff involved in delivering or supporting the social care of those in the intervention and control groups. The other activities in WP2 will be completed by the research team, without participant involvement.
Planned Sample Size	**WP1 Activities:** Training and supervision manual for ET workers (2 workshops): • 12 participants Audio, film, and blog development (6-8 workshops): • 8 participants **WP2 Activities:** Feasibility RCT: • Anticipated N to screen will be between 150 and 250 with a current estimate of 190; with 76 of these then recruited into the feasibility RCT (38 per arm) Realist-informed formative process evaluation: • An estimated 48 participants will be recruited: o 20 prisoners from the control and intervention arms o All ET staff: 2 ET workers and 2 supervisors o 24 healthcare, prison, and local authority staff
ADDITIONAL INFORMATION SPECIFIC TO THE WP2 FEASIBILITY RCT	
Treatment Duration	The feasibility RCT will last nine months in total. Recruitment will occur during the first six months to allow the final participants time to complete the three-month intervention.
Follow-Up Duration	The feasibility RCT will include follow-ups at 42-days (six weeks) and 90-days (three months) (±7 days) post-baseline.
Planned Trial Period	The feasibility RCT will last nine months in total.
Outcome Measures	**Primary[3]:** 1. Implementation of ET at each site 2. Recruitment (numbers screened, eligible, and recruited)

two of ten outcome domains of the Care Act (e.g., dressing, toileting); and it must be shown that the inability to achieve these outcomes has a significant impact on the person's wellbeing.

[3] See section 2.2 for the detailed traffic light criteria for each outcome.

	3. Outcome measure completion rates 4. Intervention adherence and fidelity (based on bespoke fidelity tool) 5. Retention (proportion of participants retained for full trial) 6. Proportion transferred or released during follow-up
	Secondary: 1. Acceptability the following outcome measures: a. CANFOR-R: unmet needs in forensic settings (1) b. ASCOT SCT4: adult social care outcomes (2) c. EQ-5D-5L: health-related quality of life (3) d. ICECAP-A: capability (4) e. ReQoL-10: recovery after mental health service use (5) f. Resource usage (based on care plans, case notes, and questionnaires)
Inclusion Criteria	• 18 years or over • Resident in one of the two study prisons • Serving a sentence with at least seven months to earliest date of release (with no upper limit) • Mental capacity to consent or appropriate personal or independent consultee who can provide assent • Scores positively on ET screen (needs in two or more domains)
Exclusion Criteria	• Insufficient knowledge of English to complete the assessment or outcome measures • Unsafe for researchers to interview alone
Investigational Product(s)	In addition to social care as usual, those in the intervention group with higher-level needs will receive ET (a manualised and structured intervention designed to allow the social care needs of people in prison to be met) whilst those with lower-level social care needs will receive signposting to resources. ET involves integrated, person-centred, trauma-informed social care for people living in prison. It includes systematic assessment and social care coordination across complex systems in health, local authority, prison, and third sector organisations. Signposting to resources involves providing participants with tailored advice and information about the social care services available to them in their prison and how to access them.

FUNDING AND SUPPORT IN KIND

FUNDER	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
NIHR Programme Grants for Applied Research Address: NIHR Coordinating Centre, Grange House, 15 Church Street, Twickenham, TW1 3NL. Contact Person: Andrea Yanez-Cunningham Contact Email: andrea.yanez-cunningham@nihr.ac.uk Contact Phone: 020 3692 7887	£2,642,478.36
Research Design Network katherine.Jobson@nihr.ac.uk	
NHS Health and Justice Commissioning Team Etc.helpdesk@nihr.ac.uk Triagehelpdesk@nihr.ac.uk	£87689.50

ROLE OF THE TRIAL SPONSOR AND FUNDER

As study sponsor, Lancashire and South Cumbria NHS Foundation Trust (LSCFT) assumes overall responsibility for the initiation and management of the study. As such, the sponsor will oversee the initial study design phase including ethical applications, study implementation and conduct, data analysis and its interpretation, and dissemination and reporting procedures.

The funder NIHR Programme Grants for Applied Research (PGfAR) will similarly take an oversight role. They will ensure the study team are working in line with their determined milestones and will support reporting procedures.

The project team will work with the sponsor to ensure the study design is appropriate throughout the protocol development and prior to the submission of ethical applications. Where necessary the sponsor will provide feedback and revisions. The funder will ensure that the study design is in agreement with the study design in the approved grant application.

In the instance where the project team wishes to submit an amendment, the sponsor and funder will be consulted prior to any amendments being submitted to the appropriate review boards.

The sponsor will ensure the project team is working in accordance with the study trajectory (see Study Flowchart). The project team will submit regular project updates to the sponsor at pre-agreed time points. If the sponsor identifies a problem during the implementation, they will contact the CI or delegated research team member for resolution.

The funder will oversee study implementation and lifecycle through regular progress updates. The funder will provide feedback to the CI or delegated research team member.

The sponsor will not take an active role in the data analysis and interpretation. However, they will ensure that data management procedures are met. Similarly, the funder will not take an active role in data analysis.

The sponsor and funder will ensure that the Dissemination Plan (see Section 13), outlined in the protocol, is delivered in line with the study timescale.

ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITTEES/GROUPS

Trial Management Group

The Trial Management Group (TMG) will usually meet once a month to monitor all aspects of the conduct and progress of WP1 and WP2. It will include all co-investigators and chaired by KF and/or LR.

Independent Trial Steering Committee

The Trial Steering Committee (TSC) will monitor progress, provide overall supervision of WP1 and WP2 and advise on scientific credibility. The TSC will comprise an independent chair, statistician, and one other independent member. In addition, the TSC will include at least one service user representative. The study leads (KF and LR) will attend as required.

The TSC will act in accordance with NIHR research governance guidelines: https://www.nihr.ac.uk/documents/research-governance-guidelines/12154

Independent Data Monitoring and Ethics Committee (DMEC)

The DMEC will independently monitor data as it is obtained. The committee will recommend if there are any ethical or safety reasons for discontinuing the study.

Patient and Public Involvement and Engagement (PPIE) Group

The PPIE Group will comprise individuals who have lived experience in prison and/or have social care needs. The Group will convene on a timetable allied to key milestones to ensure their timely contribution to progress. They will contribute to key study activities, such as the development of a short film, webpage, documentation, data collection, data analysis, and dissemination. Whilst the PPIE Group will develop the content of the film, they will not appear in it, as professional actors will be employed for this purpose. We will explore the possibility of up to two PPIE Group members collecting data; however, this will depend on gaining appropriate approvals.

Meetings will be held online on a secure video conferencing platform to accommodate members' schedules. However, at least two face-to-face meetings will be offered during the project. All PPIE participants will be re-imbursed for their time in line with NIHR guidance.

Patient and Public Involvement and Engagement (PPIE) Professionals Group

The PPIE Professionals Group will contain a range of professionals, including healthcare, prison, and local authority staff. The group will meet every six months (or more frequently as needed) to provide input into core elements of the study. This will include providing advice for dealing with problems that arise during implementation, and input into dissemination materials.

CORE RESEARCH TEAM

The core research team comprises members of the project team who will oversee and undertake the day-to-day delivery and management of WP1 and WP2. The team will usually meet weekly, chaired by KF and/or LR, with actions and minutes circulated by team members.

Changes to the core research team will be updated here and reported as an amendment.

Name	Email	Position
Dr Katrina Forsyth	Katrina.forsyth@manchester.ac.uk	Chief Investigator Senior Trial Manager
Dr Louise Robinson	louise.robinson@manchester.ac.uk	Co-Chief Investigator
TBC	TBC	Research Associate, Junior Trial Manager
Clare Scollay	clare.scollay@manchester.ac.uk	Research Associate
Jasmine Lamonby	jasmine.lamonby@manchester.ac.uk	Research Assistant
Emily Egan	Emily.egan@manchester.ac.uk	Research Assistant
Matilda Minchin	matilda.minchin@manchester.ac.uk	PhD Student

PROTOCOL CONTRIBUTORS

Name	Responsibility	Full-Time Equivalent
Dr. Katrina Forsyth	KF will co-lead and project manage WP1 and WP2. This includes co-leading PPIE; ensuring milestones are met to time and budget; line managing research associates and assistants; managing all aspects of the study; overseeing qualitative data collection and analysis; and contributing to outputs.	0.35
Dr. Louise Robinson	LR will co-lead WP1 and WP2. This includes ensuring milestones are met to time and budget; providing supervision to researchers; and contributing to outputs.	0.10
Dr. Charlotte Lennox	CL will advise on the realist-informed formative process evaluation in WP2.	0.05
Prof. Catherine Robinson	CR will be the capacity building and social care lead for WP1 and WP2. This will include ensuring that PPIE group members and PhD candidates receive training and support.	0.05
Mr. Ryan Cowley-Sharp	RCS will provide advice and support in relation to social care, contribute to outputs, and assist with the recruitment of ET workers for WP2.	0.05

Prof. Victoria Allgar	VA will provide oversight of trial management and quantitative analysis for WP2.	0.05
Prof. Rachael Hunter	RH will manage the health and social care economics for WP2, including line managing the research associate completing these tasks. RH will also contribute to outputs.	0.05
Ms. Paula Harriott	PH will co-lead PPIE for WP1 and WP2, including recruiting experts by experience and supporting them throughout the process. PH will also contribute to outputs.	0.05
Prof. Jennifer Shaw	JS will mentor KF and LR for WP1 and WP2.	0.05
Dr. Emma Plugge	EP will provide advice and guidance to the core research team for WP1 and WP2. EP will also co-supervise the research assistants (in the south of the country) in future WPs and support dissemination.	0.05
Dr. Debbie Buck	DB will provide advice and guidance for intervention implementation in WP2. DB will also co-produce the training and supervision manual for WP2, conduct qualitative and quantitative analysis for WP2, and contribute to all outputs.	0.50
Dr. Wendy Dyer	WD will provide advice and guidance for intervention implementation in WP2, and support dissemination.	0.05
Mr. Adam O'Neill	AON will advise on data collection for WP2 and contribute to meetings and outputs for WP1 and WP2.	Ad-Hoc
Experts-by-experience: two experts-by-experience will be invited to be members of the research team.		
Dr Clare Scollay	Research Associate	variable
Jasmine Lamonby	Research Assistant	1
Emily Egan	Research Assistant	1
Matilda Minchin	PhD Student (formative process evaluation)	1

KEY WORDS

Social care; prison; feasibility study; realist; randomised control trial.

STUDY FLOW CHART

Empowered Together (ET) Intervention

ET follows the **TIP** principles: 1. **T**rauma informed; 2. **I**ntegrated; 3. **P**erson-centred.

WP1: Preliminary Work – Months 1-6

1.1. Development of supervision and training manual for ET workers
1.2. Development of fidelity scale
1.3. Development of immersive film, event, blog and website

Capacity building
PPIE meetings and evaluation
Immersive film, event, blog and website development
Steering group meetings

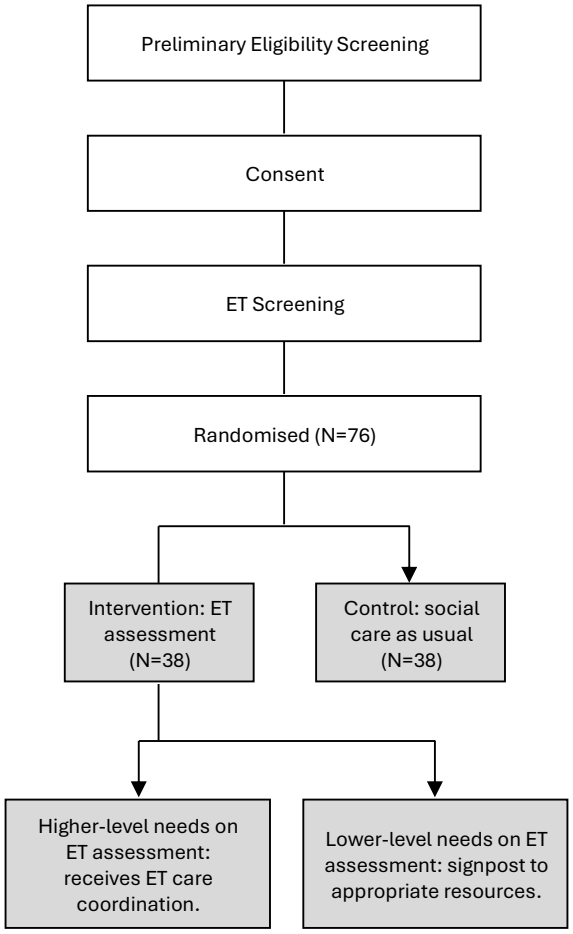
WP2: Feasibility RCT and Embedded Process Evaluation – Months 7-16

2.1 Feasibility RCT
- *Preliminary Eligibility Screen:* 18 years or over; resident in one of two study prisons; serving a sentence with at least seven months to release; capacity to consent or personal or independent consultee to provide assent; sufficient English to complete assessment or outcome measures; safe for researchers to interview alone.
- *ET Screen:* consent to ET screen and scores positively on ET screen (needs in two or more domains)
- *Feasibility Outcomes:* see 2.4 below

2.2 Cost effectiveness feasibility analysis
- Completeness of care plans, case notes, and resource use questionnaires; potential cost of ET; feasibility assessment of a budget impact analysis; list of suitable variables for a social return on investment analysis
- ASCOT SCT4, EQ-5D-5L, or ReQoL-10 to calculate QALY and ICECAP-A to calculate YFC

2.3 Realist informed formative process evaluation
- Semi-structured interviews with prisoners (N=20, approx.), ET workers (N=2, approx.) and supervisors (N=2, approx.); and healthcare, prison, and local authority staff interviews (N=24, approx.)
- Refinement of the IPT, logic model, and intervention delivery platform

2.4 Review of progression criteria
- An assessment will be made against the feasibility outcomes: delivery of ET at each site; number screened, eligible, and recruited into trial; measure completion rates; intervention adherence and fidelity; retention rates; and proportion transferred or released during follow-up.



Dissemination, and Impact – months 17-18
Checkpoint report; academic journal articles and conference presentations; immersive short film; podcast; presentations and policy meetings; prison newspaper article; prison radio; social media; and dissemination event.

Potential Progression to Full RCT

1. BACKGROUND AND RATIONALE

1.1 Background

Prisons hold some of the most socially disadvantaged people in society (6). Prevalence of neuro-diversities (7), and mental and physical health problems, is higher amongst those living in prison than the general population (6,8,9). Those aged 60 and over are the fastest growing subgroup in prison; there are now three times as many as there were in 2002 (10). Consequently, those residing in the prison are highly likely to have complex social care needs (11). The Care Act 2014 (12) that required local authorities to be responsible for meeting social care needs in prison.

Under the terms of the Care Act and accompanying statutory guidance, from April 2015, local authorities in England have had a legal obligation to assess the need for social care to eligible people in prison and provide it accordingly. Determination of the eligibility of a person's identified needs is a three-stage process. First, it must be shown that the person's needs relate to a physical or mental impairment or illness (as opposed to, for example, their criminal record). Secondly, the adult must be unable to achieve at least two of the ten outcomes set out in the national eligibility criteria as a result of these needs. Thirdly, it must be shown that the inability to achieve these outcomes has a significant impact on the adult's wellbeing. Where a person has needs that do not meet the threshold for eligibility under the Care Act, local authorities must provide information and advice to the individual on how these can be met and prevented from getting worse.

Our previous social care needs prevalence study in men's prisons found that 8 percent of the total sample reported health problems that impacted on daily living; 10 percent of younger prisoners and 21 percent of older prisoners in the total sample reported problems maintaining activities of daily living; and 24 percent of the sample reported that their mental health had an everyday impact on their behaviour (13). Processes to identify and meet these social care needs varied considerably (13,14). There was a lack of active case finding, referral follow-up, and integration between services (13,14). Despite the Care Act, local authority involvement in care remains limited (14). A combination of pressures on local authorities (15) and a lack of active case finding and screening (16) means that few assessments and care packages are delivered, leaving many with presumed unmet care needs (13).

1.2 Literature Review

There are few data relating to the social care needs of people in prisons (17,18). Of the few studies that have explored health needs of older prisoners, one found that half of them considered their personal care needs to be unmet (18). Other studies reported a lack of access to education and workshop, recreational, and shower facilities in this group (19,20). Overall, a recent systematic review of social care for older prisoners found a lack of empirical research (21).

There is also little research on provision of prison social care and no information on the costs and benefits of prison social care models (22). In England and Wales, models of social care provision in prisons are not evidence based, variable (13,23), and inferior to those used in the community (24). Nonetheless, there is mounting recognition that social care needs in prison and on release are poorly identified, and that when these are detected they are often inadequately met (25–28). Although unresearched, it appears likely that early identification and meeting the social care needs of people in prison could prevent later, more costly crisis presentations.

There have been a few examples of good social care practice in prison settings, including 'light work' activities for older prisoners (28); sociable activities to overcome isolation in older prisoners (29); and well-supported and well-trained peer support systems (16,30). Whilst these initiatives are encouraging, there is no consistency or guarantee of equivalence of care for people in prison compared to people living in the community, with inspectors reporting a "mixed picture" (16). Advocates are calling for prisoners to have access to the same level of care as their community-dwelling counterparts (27,29,31), thereby meeting human rights obligations (27,32).

The literature also suggests that the key mechanisms to ensuring that initial and emerging social care needs are identified in prison include accessible self-referral processes, active case finding, and standardised but customisable screening tools (33). Good practice for assessing social care needs includes adopting a 'strengths and assets'-based approach, such as the "3 Conversations model", to explore individuals' priorities and needs. To adequately meet social care needs in prison, individuals should be actively engaged in co-production of care plans and reviews (33).

1.3 Rationale

Evidence from the community indicates that social care improves individuals' health, quality of life, and well-being (34). Despite a lack of robust studies, this appears to generalise into prisons, where social care programmes have a positive impact on prisoners including where there are unmet needs linked to health complications (21,35,36). Strong social care delivery can also ease compound pressures on the NHS (37) and reduce rates of recidivism (38,39). Our proposed study aligns with key NIHR, Department of Health and Social Care (DHSC), His Majesty's Prison and Probation Service (HMPPS), and government priorities, including improving the lives of people with long-term conditions and the underserved prison community (40), reducing re-offending (41), and improving integrated social care (45). As older adults are the fastest growing population in prisons (42), social care is becoming a growing concern (17). Evidence from this study could revolutionise social care in prison system within the next 10 years.

To our knowledge, there have been no previous RCTs of a social care intervention in prison. This study is therefore uniquely placed to evidence what effective social care in prison looks like and how it can be successfully integrated with healthcare. The first part (WP1) will result in an optimal package of tools both for implementing the package and assessing it, followed by a feasibility RCT and embedded formative process evaluation (WP2).

1.4 The Intervention

As part of a Programme Development Grant (202610), we used the findings of a realist review to develop an IPT and logic model of co-ordinated social care in men's prisons (33). The realist synthesis allowed us to explore what works for whom and in what circumstances (43) through examination of the community and prison-based literature, and stakeholder engagement workshops. Our expert by experience group named the intervention 'Empowered Together' (ET). ET has potential to lead to direct service user benefit by providing systematic assessment and coordination of social care. The ET intervention follows the three principles of being:

- Trauma Informed
- Integrated
- Person-centred

Trauma informed care: Individuals in prison have often experienced significant trauma in their lives and through the process of imprisonment (44). Trauma-informed practice is an approach to interventions that is grounded in an understanding that exposure to trauma can impact a person's biological, neurological, psychological and social development (45). It acknowledges the need to see beyond an individual's presenting behaviours and ask, 'What does this person need?' rather than, 'What is wrong with this person?'. Its key principles include choice; collaboration; cultural considerations; empowerment; safety; and trustworthiness (46).

Integrated care: It has been evidence that that the way in which prison health and social care is delivered is impeded by silo working (47). Integrated care joins up the health and care services required by individuals to deliver care that meets their personal needs in an efficient way. For individuals with social care needs in prison, this will include coordinating care with criminal justice, health, social care, third sector, families, peers, and the individual themselves.

Person-centred care: Individuals living in prison often feel extremely limited in their choices regarding their health and social care (48). Being person-centred is about focusing care on the needs of the individual, ensuring that people's preferences, needs and values guide clinical decisions, and providing care that is respectful of and responsive to them (49).

1.5 Assessment and Management of Risks relating to this study

The risk of harm in this study is small, as activities will take place with assenting and consenting participants who have the capacity to understand the situation, and in a regulated environment (a prison, with prison staff aware of the research activities). Nevertheless, we acknowledge that participants may have mental disorders or other vulnerabilities and so might become distressed during research activities, and that their reasons for being in prison may include a propensity for violence. We have considered how to respond in the unlikely event of serious distress or threats.

Risks to Participants

There is a possibility that participants might experience discomfort or distress during workshops, feasibility RCT activities, or interviews. Participant Information Sheets (PIS) that describe ethical rights as well as the relevant research activities will be given to participants to help prepare them and minimise burdens and risks as far as possible. All activities will be carried out by experienced, trained researchers and staff, in conjunction with robustly trained experts by experience where possible. Researchers and staff will be aware of the sensitivities surrounding the activities and will carefully choose their approach to prioritise the comfort and ease of participants.

If a participant becomes distressed, researchers will draw on the approach outlined in Jefferson and Holloway (50), who advise that their role is one of emotional containment. For the workshops and interviews, this will involve offering participants the option to take a short break, and being guided by them as to whether to continue with the session. Researchers will have training to aid them in this decision. If a participant becomes significantly upset, researchers will adhere to the study safeguarding protocol. The consent process will make it clear that if a participant tells the researcher that they intend to harm themselves or someone else, confidentiality will be broken and relevant services will be informed immediately. Researchers who conduct interviews with people in prisons are also obligated to report the following and will make this clear to prospective participants in the PIS:

- Behaviour that is against prison rules
- Information that either indicates a risk or harm to the participant or others
- Information on previously undisclosed illegal acts or plans to commit a new crime
- Information that raises concerns about terrorist, radicalisations, or security issues
- Information about poor or unacceptable practices by the prison staff or by an outside organisation

Risks to Staff (ET Workers and Researchers)

Although risks of harm to researchers are small, we will take every step to ensure that prison staff are fully aware of our whereabouts at all times while we are in the prison and we will complete University of Manchester (UOM) training on identifying and managing risks, as well as prison induction training, which covers corruption prevention, health and safety, security measures, and safer custody procedures. Whilst interacting with prisoners, researchers will be based in an environment where there is an alarm and where prison staff will be on duty nearby at any given time. In advance of meeting the researcher, the potential participant will have been screened by the prison contact for level of risk to the researcher.

Psychological risks are low but include discomfort or distress from working with a traumatised population in challenging environment. To mitigate this, clinicians within the research team will be available to guide and support staff throughout the project. Regular meetings between the fieldworkers and senior researchers will include discussion of data collection processes to provide a safeguarding framework and identify changes to procedures if needed.

2. OBJECTIVES AND OUTCOME MEASURES

The aims of WP1 (development work) and WP2 (feasibility RCT and embedded formative process evaluation) are to address the following research questions:

1. Can we implement the ET intervention in two men's prisons?
2. Is it acceptable and feasible to conduct an RCT to assess whether ET improves the number of met social care needs for adults in prison who are likely to have unmet needs after six weeks and three months, in comparison with care as usual?

2.1 Objectives

Primary Objectives

WP1: to develop communication, training, and trial materials, including a training and supervision manual, fidelity of implementation tool, and audio, blog, event, film, and webpage content.

WP2: to determine the acceptability and feasibility of a full RCT, including through:

- Conducting a feasibility RCT. We will implement ET in two prisons and then assess rates of recruitment and outcome measure completion; intervention adherence and fidelity; and rates of retention and transfer or release during follow-up.
- Conducting cost-effectiveness feasibility evaluation. We will estimate resource use and delivery costs for ET, and develop and test methods for undertaking a cost-effectiveness analysis alongside a full trial.

- Conducting a realist-informed formative process evaluation. We will explore barriers to the acceptability and feasibility of intervention and trial design (and develop methods to overcome these where possible); evaluate risk of bias or contamination; evaluate fidelity of intervention delivery; and explore mechanisms of action of ET (i.e., what works, in what circumstances, for whom, and how).
- Reviewing findings against progression criteria and if met developing a final RCT protocol. If not met, alternative methods of evaluation will be reviewed.

Secondary Objectives

WP2: to collect patient outcomes data to inform a full RCT, including assessing the acceptability of the measures used.

2.2 Outcome Measures

Primary Outcomes

WP1:

- A training and supervision manual (nine months after project commencement)
- A fidelity of implementation tool; this will be completed by a researcher in WP2 at the end of the three-month intervention to assess whether the intervention has been delivered in accordance with the protocol and manual, and to evaluate the quality of delivery
- Audio, blog, event, film, webpage content (18 months after project commencement)

WP2:

For the feasibility RCT, the below traffic light criteria will be used in the decision-making process. However, outcomes will be reviewed as a whole, such that amber or red ratings on one or more of the objectives will not necessarily prevent progression to a full trial:

- Delivery of ET at each site (at end of feasibility RCT)
    - Green: both sites able to deliver ET
    - Amber: one site able to deliver ET
    - Red: no sites able to deliver ET
- Number screened, eligible, and recruited into trial (once marked eligible from screening)
    - Green: 60% of participants recruited
    - Amber: 40-60% of participants recruited
    - Red: <40% of participants recruited
- Outcome measure completion rates (at 42- and 90-days ±7 days post-randomisation)
    - Green: 80% of participants have completeness of >60%
    - Amber: 60-80% of participants have completeness of >60%
    - Red: <60% of participants have completeness of >60%
- Intervention adherence and fidelity (at end of feasibility RCT)
    - Green, amber, and red ratings will be based on the bespoke fidelity tool; as such, the progression criteria will be developed once the tool has been finalised.
- Retention rates (at 90-days ±7 days post-randomisation)
    - Green: 60% of participants
    - Amber: 40-60% of participants

- Red: <40% of participants
- Proportion transferred and/or released during follow-up (at 42- and 90-days ±7 days post-randomisation)

Outcome measures for the cost-effectiveness feasibility analysis will include:

- Completeness of care plans, case notes, and resource use questionnaires
- Potential cost of ET (based on data from the Personal Social Services Resource Unit)
- Assessment of the feasibility of conducting a Budget Impact Analysis (BIA)
- List of suitable variables for a social Return On Investment (ROI) analysis

Outcome measures for the realist-informed process evaluation will include:

- Refined IPT, logic model, and intervention delivery platform.

Secondary Outcomes

WP2:

The acceptability of the measures in the following table will be assessed. These measures were determined using a literature review (PDG, NIHR 202610):

Outcome	Measurement Tool	Measurement Method	Baseline	42-Days (±7 days)	90-Days (±7 days)
Unmet needs in forensic settings	CANFOR-R	Researcher completes in person with prisoner	✓	✓	✓
The Camberwell Assessments of Needs-Forensic Research (CANFOR-R) is a semi-structured interview schedule assessing need in 25 domains. Each domain has 4 sections, covering the absence or presence of needs, formal and informal help needed and received, overall satisfaction with help, and links between need and offending. The CANFOR-R has been used in previous RCTs in prisons settings (35). It is the only measure that: has adequate evidence for content validity, development, and relevance for our population, and has been designed as a progress measure (51). However, the tools ability to measure change in need has not been fully assessed (51). We will explore its responsivity, including an analysis of domains relevant to this population, such as needs relating to communication, day-time activities, education, physical health, selfcare, and social contact. We will apply the Met Needs Index to CANFOR-R scores for relevant domains (52).					
Adult social care outcomes	ASCOT SCT4	Researcher completes in person with prisoner	✓	✓	✓
The Adult Social Care Outcomes Toolkit (ASCOT) SCT4 is a 32-item self-complete measure of adult social care related quality of life across eight dimensions: accommodation cleanliness and comfort, control over daily life, dignity, food and drink, occupation, personal cleanliness and comfort, personal safety, and social participation and involvement. Each question has					

four response options relating to four outcome states (ideal, no needs, some needs, high-level needs). Raw scores are then converted into numbers that reflect the relative value of that outcome to the general population. Scores range from -0.17 to 1.00, with higher scores indicating better quality of life. We will use this measure to assess adult social care outcomes. We will also assess its suitability to calculate incremental cost per quality adjusted life year (QALY) for a full economic evaluation. This will include analysing data to estimate parameters (means and standard deviations) and explore responsivity. We will also evaluate the extent to which this measure aligns with changes in the CANFOR-R.					
Health-related quality of life	EQ-5D-5L	Researcher completes in person with prisoner	✓	✓	✓
EuroQol's EQ-5D 5 level (EQ-5D-5L) is a 5-item self-complete measure of health-related quality of life covering the five domains of anxiety/depression, discomfort/pain, mobility, self-care, and usual activities. Each of these has five response levels: no problems, slight problems, moderate problems, severe problems, unable to/extreme problems. The scale generates a five-digit number representing the health profile, which is then converted into a single index score using a scoring algorithm and a value set. The EQ-5D-5L also includes the EQ visual analogue scale (EQ VAS) in which participants self-rate their health on a line with endpoints labelled 'The best health you can imagine' and 'The worst health you can imagine'. We will use this measure to assess health-related quality of life. We will also assess its suitability to calculate incremental cost per QALY for a full economic evaluation. This will include analysing data to estimate parameters and explore responsivity. Finally, we will evaluate the extent to which this measure aligns with changes in the CANFOR-R.					
Capability	ICECAP-A	Researcher completes in person with prisoner	✓	✓	✓
ICEpop CAPability measure for Adults (ICECAP-A) is a 5-item self-complete questionnaire that assesses five capabilities important to wellbeing, these being feeling settled and secure; love, friendship, and support; being independent; achievement and progress; and enjoyment and pleasure. Each is scored on a scale from 1 (full capability) to 4 (no capability). These individual scores are then converted to a single capability index score between 0 and 1 using a UK population value set. We will use this measure to assess capability. We will also assess its suitability to calculate years of full capability (YFC) for a full economic evaluation. This will include analysing data to estimate parameters and explore responsivity. Finally, we will evaluate the extent to which this measure aligns with changes in the CANFOR-R.					
Recovery after mental health service use	ReQoL-10	Researcher completes in person with prisoner	✓	✓	✓

The Recovering Quality of Life (ReQoL-10) is a 10-item self-report measure assessing quality of life during recovery for people with different mental health conditions. Items have been drawn to cover areas of quality of life that are important for service users, such as activity (meaningful), belonging and relationships, choice, control and autonomy, hope, self-perception, well-being, and physical health. Each item has five response options, which are allocated scores between 0 and 4. The ReQoL-10 is scored by summing scores across questions. Total scores range from 0 to 40, where a higher score indicates a better quality of life. We will use this measure to assess recovery. We will also assess its suitability to calculate incremental cost per QALY for a full economic evaluation. This will include analysing data to estimate parameters and explore responsivity. Finally, we will evaluate the extent to which this measure aligns with changes in the CANFOR-R.					
Resource Usage	Resource Use Questionnaires	Routine Data and discussion in person with prisoner	✓	✓	✓
Resource use questionnaires that have previously been developed and tested in community samples (53) will be used to assess receipt of health, personal, and other care services. These will be completed based on care plans, case notes, and discussions with prisoners.					

2.3 Table of Endpoints and Outcomes

Objectives	Outcome Measures	Timepoints of Evaluation
WP1: Primary Objective: to develop communication, training, and trial materials	Training and supervision manual for ET workers	9 months after project commencement
	Fidelity of implementation tool	9 months after project commencement
	Audio, blog, event, film, and webpage content	18 months after project commencement
WP2: Primary Objective: to determine the acceptability and feasibility of a full RCT	Delivery of ET at each site	At end of nine-month feasibility trial period
	Number screened, eligible, and recruited	At end of feasibility trial period
	Outcome measure completion rates	Baseline, 42-days (±7 days), and 90-days (±7 days) post-baseline
	Intervention adherence and fidelity (based on bespoke fidelity tool)	At end of nine-month feasibility trial period
	Retention rates	90-days (±7 days) post-randomisation
	Proportion transferred or released during follow-up	At end of nine-month feasibility trial period
	Completeness of care plans, case notes, and	18 months after project commencement

	resource use questionnaires	
	Potential cost of ET	18 months after project commencement
	BIA feasibility assessment	18 months after project commencement
	List of suitable variables for a social ROI	18 months after project commencement
	Refined IPT, logic model, and delivery platform	18 months after project commencement
WP2: Secondary Objective: to collect patient outcomes data to inform a full RCT, including assessing the acceptability of the measures used	CANFOR-R	Baseline, 42-days (±7 days), and 90-days (±7 days) post-baseline
	ASCOT SCT4	Baseline, 42-days (±7 days), and 90-days (±7 days) post-baseline
	EQ-5D-5L	Baseline, 42-days (±7 days), and 90-days (±7 days) post-baseline
	ICECAP-A	Baseline, 42-days (±7 days), and 90-days (±7 days) post-baseline
	ReQoL-10	Baseline, 42-days (±7 days), and 90-days (±7 days) post-baseline
	Resource usage	Baseline, 42-days (±7 days), and 90-days (±7 days) post-baseline

3. STUDY DESIGN

An exploratory framework will be used to gather preliminary information about the ET intervention and feasibility of conducting a full-scale trial. The study will include:

WP1: preliminary work, including development of communication, training, and trial materials.

WP2: a feasibility RCT and embedded formative process evaluation. The RCT will be a pragmatic, two-site, parallel arm, individually randomised RCT. Prison systems will be reviewed to identify people who meet the initial inclusion and exclusion criteria. These people will then be invited to take part in the study. Prisoners who consent will complete an ET screen (this timepoint will be defined as 'baseline'). Those scoring positively on the ET screen will be eligible for the feasibility RCT and will be consented to the study before being randomised to the intervention or social care as usual. Prisoners randomised to the intervention will undergo a full ET assessment, and those with higher-level social care needs will be allocated to ET, whilst those with lower-level social care needs will be signposted to appropriate resources. ET will be delivered for three months. Follow-up will be for a total of three months with outcomes assessed at baseline, 42-days post-baseline (±7 days), and 90-days post-baseline (±7 days). A sample of prisoners who participate in the RCT will be invited to participate in interviews as part of the embedded process evaluation, along with the ET workers and their supervisors, and healthcare, prison, and local authority staff. At the end of the study, findings will be reviewed against progression criteria.

4. STUDY SETTING

The study will be delivered at two male prisons in England, each of which houses adults serving prison sentences. All activities will involve participants from both sites.

5. PARTICIPANT ELIGIBILITY CRITERIA

WP1:

Development of training and supervision manual and audio, blog, and film content:

Inclusion Criteria (experts by experience):

- Aged 18 or over
- Capacity to consent to participate in the study
- Experience of being in prison with social care needs or of supporting a peer in prison with social care needs

Inclusion Criteria (professionals):

- Aged 18 years or over
- Healthcare, OT, prison, or local authority staff

WP2:

Feasibility RCT and formative process evaluation:

Preliminary Inclusion Criteria (prisoners):

- Aged 18 years or over
- Resident in one of the two study prisons
- Serving a sentence with at least seven months to earliest release date (with no upper limit)
- Capacity to consent or personal or independent consultee who can provide assent[4]

Preliminary Exclusion Criteria (prisoners):

- Insufficient knowledge of English to complete the assessment or outcome measures[5]
- Unsafe for researchers to interview alone

Additional Feasibility RCT Inclusion Criteria (prisoners):

- Scores positively on ET screen (needs in two or more domains)

Inclusion Criteria (ET workers and professionals):

- Aged 18 years or over

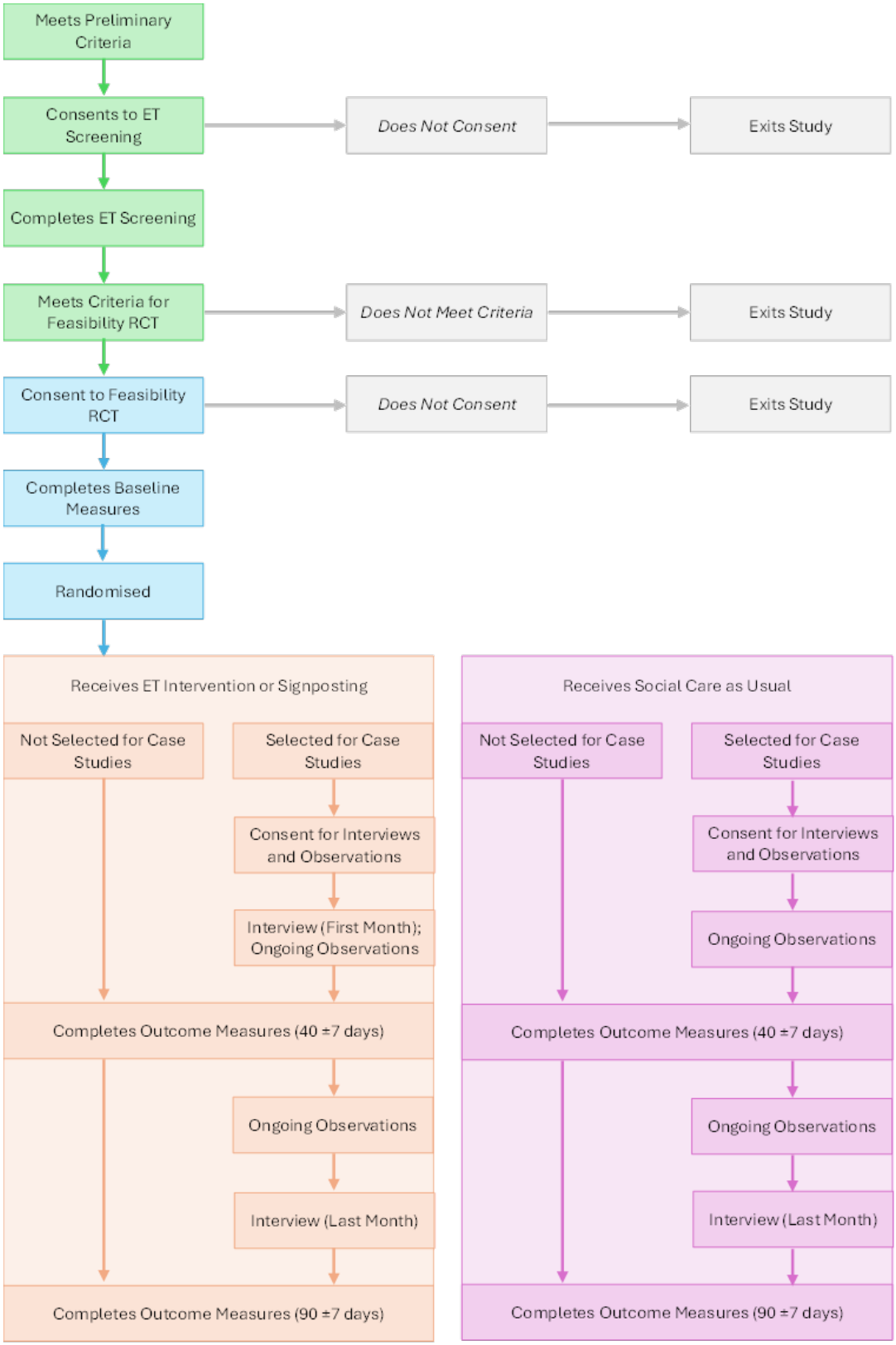
[4] Prisoners with high social care needs include those with cognitive impairments who lack the capacity to consent to participating in research and as such as often under-represented in research. Excluding people who lack capacity, and who are likely to have the most complex needs and be the most vulnerable, would introduce significant bias. Their exclusion would mean that we are unable to understand the impact of the intervention on the target population or meaningfully generalise our results. As a result, we consider that it is important to avoid excluding such participants from the research.

[5] This is due to challenges associated with getting translators into prison to administer the measures. There is a translator service available on some telephones in prisons; however, prior experience has shown that this is not reliable, and accessing it is exceptionally challenging. We will record the number of participants that are ineligible due to insufficient knowledge of English.

- ET worker or healthcare, prison, or local authority staff

6. STUDY PROCEDURES

Participant journeys through the study are mapped below and described in the following sections:



6.1 Recruitment

Participant Identification and Screening

WP1:

The workshops focused on developing the training and supervision manual for ET workers will be advertised through the Association for the Director of Adult Social Services (ADASS), the Health and Justice Research Network at UOM, and social media platforms. The workshops focused on developing the audio, blog, event, film, and webpage content will be promoted through the ADASS Care and Justice Network, the Health and Justice Research Network, the Prison Reform Network, Shaping Our Lives, and social media platforms. Individuals interested in attending the workshops will contact the research team, who will confirm their eligibility before inviting them to take part.

WP2:

For the feasibility RCT, identification of prisoners eligible for participation will occur in two stages. First, the research team will review prisoner lists with prison staff to identify those who meet the following preliminary exclusion and inclusion criteria (see section 5). This group will be weighted with those aged over 50 2:1 to reflect the likely distribution of social care needs in this population. These individuals will be provided with a PIS and Informed Consent Form (ICF) and asked to consent to an interview using the brief ET screening tool (see section 6.2). This tool is aligned with the Care Act and has been adapted from the community for prison settings.

Next, those who consent will complete the brief ET screening tool which asks prisoners whether they (a) consider themselves to have any mental or physical health conditions or impairments or be neurodiverse, and (b) experience difficulties in social care domains such as clothing, food, hygiene, toileting, safety, and family relationships. A series of probing questions relevant to these domains are also asked. The ET screening will be carried out by a researcher to avoid bias from the ET worker developing a relationship and understanding of the needs of participants who later enter the control arm. Those scoring positively on the tool will be eligible for the feasibility trial and will be approached to take part in a further consent process. All participants in the trial will receive an ET screen; this does not, therefore, form part of the intervention, but the acceptability and feasibility of this element will be included in the study.

For the formative process evaluation, first, purposive sampling will be used to identify prisoners from the control and intervention arms of the feasibility RCT who are diverse in terms of their ages, disability statuses, ethnicities, mental and physical health conditions, offence types, sentence lengths, and social care needs. From among these individuals, an estimated ten case studies will be selected (six from the intervention arm and four from the control arm). In the applied scientific realist approach, there is no optimum sample size or saturation point and, as such, the final and proposed numbers of case studies might differ depending on the information obtained. Staff and prisoners will be contacted directly by the research team and invited to take part in interviews as part of these case studies. Additional consent will be sought to make field observations. A further ten prisoners from this group will be invited to interview to discuss the feasibility of the trial design. Attempts will also be made to interview those who have withdrawn from the feasibility RCT, for example due to being released or transferred. To do this, the research team will gain consent from all participants to obtain their locations from Offender Management Services at the prison. The

team will also procure the appropriate permissions from the governor of the new prison and the local research and development (R&D) department.

Second, a purposive sample of an estimated N=2 ET workers, N=2 ET supervisors, N=10 prison staff, N=10 healthcare staff, and N=4 local authority staff will also be identified. These will cover a wide range of employers, locations, and roles in the prisons. The final and proposed numbers of participants may differ, depending on the knowledgeableness of interviewees and information obtained. Once some staff members have been identified through purposive sampling, we will ask them to name other staff who are knowledgeable about the interview topics to ensure that the most relevant people are interviewed (snowball sampling). All potential participants will be contacted directly by the research team and invited to take part in an interview. The study will adopt a realist approach, which assumes that the same intervention will not work in the same way everywhere and for everyone, and focuses on what works, for whom, in what way, and how. A key part of the realist approach involves ensuring the most appropriate people are interviewed; as a result, should the team find that our chosen informants are not the best placed to provide information or that more information is required, we will increase the number of interviews.

No advertising materials will be used for WP2.

Participant Payment and Reimbursement

WP1:

Expert-by-experience participants will be paid £25 per hour in line with NIHR and INVOLVE rates (if they are not currently in prison or on probation, consistent with HMPPS rules). Professionals will not be compensated for their time. All compensation arrangements will be outlined in the PIS.

WP2:

We are not permitted under HMPPS rules to provide people in prison with financial compensation for their time, even if they have left prison but were recruited in prison. There will also be no travel or refreshment expenses for this group, as researchers will be visiting them onsite. Professional participants will not receive compensation for their time or for travel expenses. All compensation arrangements will be outlined in the PIS.

6.2 Consent

Consent for participation in WP1 and WP2 will be sought by a member of the research team, who will act in accordance with the ethically approved protocol, principles of Good Clinical Practice (GCP), and Declaration of Helsinki. All people authorised to take consent will be recorded in the delegation log.

WP1:

Individuals expressing an interest in attending the workshops for developing the manual for ET workers will be provided with an ICF and PIS. These documents will be produced in collaboration with experts-by-experience. Communication and literacy issues will be taken into consideration, and researchers will read the documents aloud to expert-by-experience participants to minimise embarrassment, unless prompted not to. After receiving the ICF and PIS, individuals will be given at least 24 hours to decide whether they want to take part in the workshops. If they have questions about the consent process or the study, they will be able to contact the research team

using an email address provided in the PIS. If an individual does decide to take part, they will be asked to complete the ICF prior to the workshop and email it to a member of the research team (or ask someone else to email it on their behalf).

WP2:

Feasibility RCT

For the feasibility RCT, the preliminary eligibility screen (using the prison lists) will be conducted without prior consent. Individuals who are eligible to participate will be provided with an ICF and PIS by a member of the research team to help them to understand the study. The PIS will explain to participants that they are able to decline or withdraw from the study without giving a reason and without prejudice to future care. It will also outline the limits of confidentiality, making it clear that this will be broken if participants disclose that they intend to harm themselves or others, or share information that researchers in prison settings are obligated to report (see section 1.5). Given that prisoners often have lower literacy levels and higher rates of cognitive impairment than people in the community, the ICF and PIS will be designed in an easy-to-read format that is produced in collaboration with experts-by-experience. In addition, the research team will read the documents aloud to potential participants to minimise embarrassment, unless prompted not to. Potential participants will be given adequate time to consider if they want to take part, and will be given an opportunity to discuss the study with a member of the research team before making a decision.

If concerns about capacity to consent arise, a senior member of the research team will conduct a review, and an opinion will be sought from healthcare staff where required. The research team will receive training on the principles of the Mental Capacity Act and its Code of Practice (54) and GMC guidance will be followed (55). Where prisoners do have capacity, audio or written informed consent will be sought. The consent process will be completed in a face-to-face meeting between the potential participant and the researcher. In this meeting, the researcher will work through the ICF and ask if the participant has any questions. Participants who consent to involvement will complete two separate ICFs, with one held by the research team and one retained by the participant. If an individual lacks capacity but indicates a wish to take part in the study, the research team will attempt to identify a 'personal consultee' as defined by the Mental Capacity Act to receive study information and advise on participation. In cases where this is not possible, we will seek advice from a nominated (professional) consultee in the prison. We will discuss the study with the person themselves in a way appropriate to their understanding, take account of their expressed wishes, and not include them in research if they do not assent. For participants recruited in this way, no actions will be taken during any part of the study if the participant appears to object (unless these are vital to protect them from harm), researchers will consider the interests of the participant above all else, and the person will be withdrawn if they give any indication that they do not want to take part. Capacity will be assessed at each contact and monitored in an ongoing manner for all participants. The ICF will include an option to indicate a preference 'for' or 'against' continued participation should an individual lose capacity during the study. Similarly, if an individual regains capacity during the study, they will be reconsented.

This process will be followed for the initial ET screening and the full feasibility RCT. We will ask participants to provide a variety of contact details in case they are released or transferred. We will consult with our PPIE groups about acceptable information to ask for, however this is likely to include friends and family members, and community probation workers. Consent to contact

participants in the community and/or through the National Probation Service in the event that they are released or transferred will also be sought at this stage.

Embedded Formative Process Evaluation

Prisoners participating in the embedded formative process evaluation will be given an additional ICF and PIS for the interviews, as well as for the observations (for those selected for the case studies), by a member of the research team. PISs will explain to participants that they are able to decline or withdraw from this element of the study without giving a reason and without prejudice to future care. These will also outline the limits of confidentiality, making it clear that this will be broken if participants disclose that they intend to harm themselves or others, or share information that researchers in prison settings are obligated to report including risk to the safety of themselves and others. As prisoners often have lower literacy levels and higher rates of cognitive impairment than people in the community, the ICFs and PISs will be designed in an easy-to-read format produced in collaboration with experts-by-experience. The researchers will also read the ICFs and PISs to potential participants to minimise embarrassment, unless prompted not to. Potential participants will be given adequate time to consider if they want to take part and will be provided with an opportunity to discuss with a member of the research team before making a decision. Concerns about capacity will be addressed in the same way as in the feasibility RCT.

Staff participating in the process evaluation will similarly be provided with an ICF and PIS, which explain that they are able to decline or withdraw from the study without giving a reason. After receiving the ICF and PIS, individuals will be given at least 24 hours to decide whether or not they want to take part in the workshops. If they have questions about the consent process or the study, they will be able to contact the research team using an email address provided in the PIS. If an individual does decide to take part, they will be asked to complete the ICF prior to interview, and email it back to a member of the research team.

6.3 Randomisation

The feasibility RCT will involve randomisation. Following consent and the completion of the brief ET screening tool and baseline assessments, participants will be individually randomised 1:1 to intervention versus social care as usual, stratified by prison (prison 1, prison 2) and age group (<50, ≥50). Randomisation should occur as soon as possible after baseline, but within one week.

The randomisation sequence, using variable blocks sizes, will be generated by a statistician independent to the trial team and implemented through a secure web-based system on REDCap, which will ensure concealment of allocation to blinded members of the research team. Only site staff who have been delegated the role of randomisation on the delegation log will be able to access the randomisation system. An automated confirmation email will be generated when a participant is randomised and sent to the CIs and other delegated members of the study team.

Prisoners allocated to the intervention arm will then complete the ET assessment. This strengths-based assessment of social care need will be conducted by an ET worker. Strengths and assets-based approaches to assessment and care planning focus on capabilities, explore help available from wider support networks, and take into account issues important to the individual (56). Those with higher-level social care needs based on the ET assessment will receive the ET intervention, whilst those with lower-level social care needs will be given tailored advice and information about appropriate resources or services. We will clarify the definitions of higher and lower level social

care needs as part of our preliminary training development workshops. This definition will also be dependent on the individual processes established at the prison.

6.4 Blinding

In the feasibility RCT, blinding of care providers and participants will not be possible because of the differences between the intervention and social care as usual. Research staff conducting the quantitative data collection and entry at 42- and 90-days (±7 days), as well as those performing the health economic and statistical analysis, will be blinded. At the start of each data collection session, participants will be asked not to discuss the intervention they received with the research team. If unblinding does occur, this will be recorded on the participant's Case Report Form (CRF).

Safety reporting will be managed by the PIs and is unlikely to lead to unblinding of data collection, entry, and analysis staff. Emergency unblinding will not be required in this study.

6.5 Quantitative Assessments

In WP2, an ET Screening will be completed for all participants at baseline (before randomisation) while an ET Assessment will be conducted with those in the intervention arm after randomisation and before allocation to either the ET intervention or signposting. Data from these screenings and assessments will be analysed as part of the intervention adherence and fidelity checks.

Quantitative assessments will be conducted according to the following schedule:

Assessment	Baseline (Day 0)	Six Weeks (Day 42 ±7 days)	Three Months (Day 90 ±7 days)
Demographic Data	✓		
Current Offence Data	✓		
Medical History	✓		
CANFOR-R	✓	✓	✓
ASCOT SCT4	✓	✓	✓
EQ-5D-5L	✓	✓	✓
ICECAP-A	✓	✓	✓
ReQoL-10	✓	✓	✓
Resource Usage	✓	✓	✓

First Assessment: Day 0 (Baseline)

Within 14 days of the preliminary eligibility screen, eligible and consented participants will attend a face-to-face baseline assessment at their prison. During the assessment, demographic data will be collected, including age and birth year, ethnicity, gender identity and birth sex, and length of sentence. Participants' current offence information and medical histories will also be gathered, including existing disabilities and mental or physical health conditions, as well as prior contact with social care. Finally, the study measures, the CANFOR-R, ASCOT SCT4, EQ-5D-5L, ICECAP-A, and ReQoL, will be completed. Within seven days, participants will be randomised to the

intervention arm (ET or signposting) or social care as usual (Section 6.3) and their 42-day (±7 days) appointment will be scheduled.

Second Assessment: Day 42 (±7 days)

Participants will attend a second face-to-face assessment visit on Day 42 (±7 days). During this visit, the researchers will complete the CANFOR-R, ASCOT SCT4, EQ-5D-5L, ICECAP-A, and ReQoL with the participants, and enter these into the study database. The researcher will also collect participants' care plans, as well as notes made by health, prison, or local authority staff.

Third Assessment: Day 90 (±7 days)

Participants will attend a face-to-face visit on Day 90 (±7 days). This will be a repeat of the Day 42 visit. The same data will be collected and entered into the study database by the researcher.

6.6 Participant Retention

Attrition will be minimised by asking for transfer holds for all participants for the duration of their time in the feasibility RCT (with their consent) and requesting community contact details and/or permission to contact them through the National Probation Service. If prisoners are transferred, we will attempt to follow them up in other prisons in the estate. If prisoners are released into the community, we will offer them options for completing the study measures through digital means, face-to-face or telephone interviews, or on paper. We will also measure numbers of participants who exit the study through release or transfer, as this will inform the feasibility of a full RCT.

6.7 Qualitative Interviews

Qualitative interviews will be conducted for the process evaluation to inform the development of case studies and an understanding of the barriers and enablers to acceptability and feasibility of the RCT. Interviewees will include prisoners from both the control and intervention arms (N=20), ET workers (N=2) and supervisors (N=2), and healthcare, prison, and local authority staff (N=20).

Development of Case Studies

Individual case studies will be developed for approximately N=10 prisoners in the feasibility RCT (N=4 in the ET intervention group, N=2 in the ET signposting group, and N=4 in the control group). Case studies will be based on both realist-informed interviews and observations. Purposive sampling will be used to identify prisoners who are diverse in terms of their age, disability status, ethnicity, mental and/or physical health conditions, offence types, sentence length, and social care needs. Prisoners within the ET intervention group will be invited to interview once in their first month of receiving ET and once in their last month. Those within the ET signposting group will be invited to interview once in their first month of receiving signposting and again around two months later. Prisoners in the control arm will be interviewed once during the study period. For each individual case study, one member of prison staff (N=10 total) and one member of healthcare staff (N=10 total) will be interviewed. In addition, approximately two members of local authority staff will be spoken to at each site (N=4 total). These interviews will take place around the same time as the second interview for prisoners in the intervention arm and the sole interview for prisoners in the control arm. Finally, ET workers (N=2) and their supervisors (N=2) will be interviewed twice, once within the first three months of the ET delivery period, and once within the last three months. Staff will be identified through a mix of purposive and snowball sampling.

The case studies will allow us to capture in-depth information about those in the intervention and control groups, from their own and staff perspectives.

For case studies relating to the intervention arm, interviews will first focus on the 'theory gleaning' phase of realist evaluation, where the IPT is tested in a real-world setting (57). Questions will ask about if the ET intervention or signposting has been delivered as intended (feasibility and fidelity), how it has been received (acceptability) and what outcomes prisoners and staff have experienced. These questions will not be explicitly realist in their phrasing, but will aim to elicit answers about the context, mechanisms, and outcomes of the intervention. Additional questions will focus on the 'theory refinement' phase, where a teacher-learner cycle is adopted between the interviewer and participant (57). The previously outlined context, mechanisms, and outcomes, and initial IPT (58) will be presented to participants, who will then accept, reject, or update these theories. This will allow us to better understand what aspects of the intervention work, in what circumstances, for whom, and how. Second interviews for prisoners and ET staff will comprise similar questions, but will ask about any changes since the first interview. This will allow us to understand whether identification and delivery of social care under ET changes over time.

For case studies relating to the control arm, interviews will focus on how social care is delivered in prisons. Similar to the ET arm, the interviews will focus on whether social care is delivered as intended, how it is accepted by people in prison, who it works for, how, and why.

Case studies will also be informed by focused and time-limited ethnographic observations of the case study participants. Additional consent for these observations will be sought from prisoners and staff members involved in the case studies. Focused observations will be conducted of each person undertaking discrete, time-limited activities or tasks (for example, educational activities, exercise, focused work, mealtimes, and interactions with ET and prison staff, as appropriate) and detailed field notes will be made. Field notes will record the place, time, and setting of the activity or task, and what happened during the observation. The researchers will ensure that only details from observations concerning consented individuals will be recorded; field notes will not detail actions, interactions, or speech with prisoners or staff who do not provide consent. Observations will add context to the experiences of people who may not be able to fully express themselves through interviews, and highlight experiences that may be avoided or overlooked.

Understanding Barriers and Enablers

A further five prisoners at each site will participate in interviews that explore barriers and enablers to acceptability and feasibility of the intervention and trial design (e.g., randomisation, outcome measures, and potential contamination between the control and two intervention groups). This will enable the evaluation of the research design, and refinement of the delivery platform.

Participation will be entirely voluntary, and the researchers conducting the process evaluation will differ from those collecting baseline data and other study assessments.

6.8 Withdrawal Criteria

For WP1 and WP2, the PIS will explain that participants are able to decline or withdraw from the study if they wish to, without giving a reason and without prejudice to future care. The reasons for deciding to withdraw are varied; participants may, for example, find that they are no longer willing to engage in the research, or have other programmes that they would prefer to prioritise. Their

reasons for discontinuation will be requested and recorded in REDCap in a withdrawal form, but their right not to state a reason will be respected. Data collected from the participant prior to their withdrawal will remain on REDCap. The characteristics of the participants who withdraw or are lost to follow-up will be compared with those that remain within the trial.

For the feasibility RCT, participants might also withdraw from the study due to being transferred or released. However, attempts will be made to minimise attrition (Section 6.6). In addition, early discontinuation will be allowed, and participants that withdraw their consent for the treatment element of the feasibility RCT can still be invited to complete the outcome measures. In addition, participants who withdraw their consent for the feasibility RCT element of WP2 can still be invited to take part in the process evaluation element of WP2.

For WP2, for participants lacking capacity to consent, if there is any indication that they do not want to take part, the researchers will prioritise their interests and withdraw them from the study. No participants lacking capacity to consent will be recruited for WP1.

6.9 End of Trial

The end of the feasibility RCT is defined as the completion of the final participant's final outcome measures. The end of the study is defined as the conclusion of the final participant's last interview or visit. At this point, the research team will submit a checkpoint report based on the progression criteria. If the minimum success criteria for key feasibility aims and objectives are achieved, the programme will progress to a full RCT. The sponsor delegate will notify the REC of the end of the trial within 90 days of completion. The final report will be written within 12 months of the end of the trial. If the trial terminates early for any reason, the CI will notify the REC of early termination (including reasons for this) or end of trial in accordance with the required timelines.

7. STUDY INTERVENTION

WP1: no intervention will be administered.

WP2: ET is the treatment that will be administered in the feasibility RCT. It aims to allow the social care needs of prisoners to be met through an integrated, person-centred, trauma-informed intervention. It is a manualised, structured programme that usually includes three core elements of screening, assessment, and social care coordination. In this study, screening will occur before randomisation (Section 6.1), with individuals allocated to the intervention or social care as usual. Assessments will then be conducted with prisoners in the intervention group post-randomisation (Section 6.3), and those with higher-level social care needs will receive social care coordination, whilst those with lower-level social care needs will be given tailored advice and signposting.

Care coordination involves ET workers coproducing care plans with prisoners and/or their carers, family members, or peers. These care plans consider placement in the prison (e.g., adapted cell, healthcare wing, vulnerable prisoner wing) and the support required. All domains of the Care Act are considered, including adaptations to cells and other parts of prisons (e.g., handrails, hygiene equipment, meal trays); coordination of peer support; necessary changes to the regime; support with maintaining personal relationships; and supplementary details of personalised care. The ET workers then coordinate across the complex systems of health, local authority, prison, and third sector organisations to deliver on care plans. A core part of the role of the ET worker is therefore to liaise with health, prison, and local authority staff, making referrals where appropriate, and

aiming to ensure prisoner needs are met (including via improved communication). ET workers act as advocates for the person in prison, including by referring for, feeding into, and attending the Care Act Assessment conducted by the local authority. They also liaise with prison authorities, whose responsibilities include the adaptation of the prison environment for social care.

Signposting to appropriate resources involves providing the participants with tailored advice and information about social care services available to them. These might include (but are not limited to) helplines, healthcare services, or peer support. Information will be developed in consultation with the PPIE panel and individual prisons, and provided in both verbal and written formats.

8. SAFETY MONITORING

8.1 Definitions

Term	Definition
Adverse Event (AE)	An AE is an unfavourable or unintended disease, sign, or symptom that is temporally associated with the intervention, whether or not it is related to that intervention.
Adverse Reaction (AR)	An AE that, in the opinion of the CIs, has the potential to be related to the intervention (i.e., its relationship to the intervention cannot be ruled out).
Serious Adverse Event (SAE)	A SAE is an untoward response that: • results in death • is life-threatening • requires hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability or incapacity • consists of a congenital anomaly or birth defect Other events may be considered SAEs if they jeopardise the participant or require an intervention to prevent one of the above consequences.
Serious Adverse Reaction (SAR)	A SAE that, in the opinion of the CI, is believed with reasonable probability to be due to the intervention, based on the information provided.

8.2 Recording and Reporting

The safety reporting period will commence at the point of consent and end at the final study visit. The intervention (ET and signposting) is extremely low risk and therefore unlikely to result in AEs or SAEs. However, as participants are people with social care needs, it is possible that AEs, SAEs, and other safeguarding concerns unrelated to the intervention may arise. The ET workers and the researchers will record the dates and details of any concerns and incidents in a Safeguarding Log. The ET worker or researcher will then notify the CIs, who will review the log and, utilise their experience and judgement to determine if there is a causal relationship between the incident and the study (i.e., if it is an AR or SAR) and if further action is needed. This includes determining if the incident needs to be escalated as an SAR. Actions decided and taken will be recorded in the Log.

If an incident is determined to be an AR or SR, it must be entered into REDCap within 24 hours of the research team first becoming aware of it, even if not all information is available at the time of

reporting. The sponsor will be automatically notified when an SAE is entered. Change in condition and new follow-up information should be entered on the digital PenCTU SAE resolution form as soon as it is available or at least within 24 hours of the information becoming available.

8.3 Responsibilities

ET workers and researchers:

- Record AEs, SAEs, and safeguarding concerns in the Safeguarding Log
- Notify the CIs that a new concern or incident has been added to the Log

CI or their delegate:

- Maintain the Safeguarding Log
- Review concerns or incidents added to the Safeguarding Log
- Ensure concerns or incidents are added to participants' notes on SystemOne as required
- Use experience and judgement to assign causality and determine actions required
- Ensure that all SAEs are recorded and reported to PenCTU and the Sponsor
- Ensure that actions decided on are taken
- Report safety information to the DMEC and TSC

DMEC and TSC:

- Conduct periodic reviews of safety information
- Liaise with one another regarding safety issues

8.4 Notification of deaths

All deaths should be reported to PenCTU within the electronic CRF (eCRF). 'Death' is not an SAE, but the outcome of an SAE, and should be reported in line with Section 8.2.

9. STATISTICS AND DATA ANALYSIS

9.1 Sample Size Calculation

WP1:

The estimated sample size for the workshops for developing the manual for ET workers is N=12, whilst that for the workshops for developing the audio, blog, and film content is N=8. These group sizes will allow for effective communication, diverse perspectives, and meaningful participation.

WP2:

For the feasibility RCT, the target sample size target is N=76 (N=38 per arm). This has been derived from use of a traffic light system to determine whether an RCT is feasible. It is based on the feasibility objectives in relation to the RAG criteria that tests against being in the RED zone (unacceptable outcome) based on an expectation of being in the GREEN zone (acceptable outcome), along with the sample size to give high power to reject being in the RED zone if the GREEN zone holds true (3). The three key feasibility objectives are to assess: (i) recruitment uptake (percent of screened patients recruited), (ii) treatment fidelity, and (iii) participant retention (follow up):

i. Based on the recruitment rate, if we assume the upper boundary of the RED zone is 40% and the lower boundary of the GREEN zone is 60% (designating unacceptable and

acceptable recruitment respectively), the sample size required for analysis given 80% power and one-sided 5% alpha would be at least N=42 (total screened participants).

ii. Based on treatment fidelity (defined as having completed the ET assessment and having a written management plan or having been given written resources), if we assume the upper boundary of the RED zone is 60% and the lower boundary of the GREEN zone is 80%, the sample size required for analysis given 80% power and one-sided 5% alpha would be at least N=38 (intervention only).

iii. Based on follow-up at 90 days, if we assume the upper boundary of the RED zone is 60% and the lower boundary of the GREEN zone is 80%, the sample size required for analysis given 80% power and one-sided 5% alpha would be at least N=38 (total randomised).

The sample sizes across criteria (i)-(iii) are at different levels; (i) is at the level of screened patients, whereas (ii)-(iii) are at the level of recruited patients. To meet criteria (i) we need ns ≥ 42 (although we will screen approx. ns ≥ 190 (i.e. (1/0.40) × nr (76)) where 0.40 is the expected proportion uptake of the total number screened), and for (ii)-(iii), we need nr = 76 (38 per arm) based on (ii)).

For the embedded formative process evaluation, the estimated sample size is N=48; this includes prisoners from the control and intervention arms (N=20), as well as the ET workers (N=2) and their supervisors (N=2), and other healthcare, prison, and local authority staff (N=24). In the applied scientific realist approach, there is no optimum sample size or saturation point reached through interviews, and it might be more informative to interview a knowledgeable participant multiple times rather than trying to ascertain the experiences of all. As such, final and proposed sample sizes might differ depending on the knowledgeableness of participants.

9.2 Statistical Analysis Plan

WP1:

The workshops for developing the training and supervision manual for workers will be recorded. The data will be analysed using realist-informed thematic approach (see below for further detail) and, along with information from a prior realist review, used to generate the manual.

WP2:

The feasibility RCT will be reported in accordance with the CONSORT 2010 statement extension to pilot and feasibility trials (59). Descriptive statistics will be reported for feasibility outcomes: numbers screened, eligible, and recruited; retention rates; measure completion rates and data quality; intervention delivery and fidelity (including univariate and bivariate analysis to assess the bespoke fidelity checklist developed in WP1); and attrition during follow-up. The data will inform a potential full RCT, with variability in candidate primary and secondary measures calculated and a sample size (power calculation) for the full RCT estimated for each. Moreover, missing data will be investigated in the feasibility RCT to determine why these are missing and what can be done to minimise missingness in the future full RCT. Simple descriptive analyses will identify the extent of missing data for various questions and questionnaires in the dataset, and models will be fitted to see whether the probability of missingness is linked to baseline characteristics. No statistical comparisons between treatment groups will be undertaken on baseline or follow-up data, as the study is not designed to test effectiveness. Adverse events will be summarised descriptively.

For the cost-effectiveness feasibility analysis, descriptive statistics including data completeness will be reported for each source. The potential cost of ET will be calculated based on information

collected using the bespoke fidelity tool about time spent on training, supervision, developing care plans and other components of intervention delivery. Staff time will be costed based on unit costs from the Personal Social Services Resource Unit (60). The team will also investigate the suitability of the ASCOT SCT4, EQ-5D-5L, or ReQoL-10 to calculate the incremental cost per QALY, and the ICECAP-A for YFC gained as part of a full economic evaluation. The extent to which each outcome measure aligns with changes in the CANFOR-R and meeting of social care needs will also be evaluated.

Data will be reported on the number of participants at each stage of the study (screened, eligible, recruited, randomised, completed measures). Their characteristics and the outcome measures will be summarised through means (SD), medians (interquartile range), or Ns (%). For the ASCOT SCT4, EQ-5D-5L, ICECAP-A, and ReQoL-10, ceiling or floor effects for the summary utility score will be examined, and the proportion of participants at each level in each domain will be reported. Appropriate statistical models to determine relationships between the different patient reported outcome measures and social care outcomes will be developed to determine suitability for use in a full RCT. Descriptive statistics for resource cost and use, along with the proportion of missing data for different methods to collect resource use, will be reported to inform a full RCT.

For the process evaluation, a realist logic of analysis will be used with codes developed as linked dyads and triads directly from narratives (61). A realist-informed thematic approach to analysing field notes and transcripts will be taken (61,62). Interviews will be analysed thematically using a framework method (63). In this method, data is sifted, charted, and sorted in accordance with key issues and themes using five steps: familiarisation; identifying a thematic framework; indexing; charting; and mapping and interpretation. This produces a matrix of summarised data, providing a structure to analyse and reduce this data. It also allows for systematic constant comparisons across participants' transcripts to refine themes. It is frequently used in applied research studies where research questions are predefined. The team will produce a table of explanatory accounts. Wherever possible, expressed explanatory accounts will be in the form of ‘If... then’ statements that specify the context and the mechanism. The explanatory accounts will form a ‘narrative’ (coherent linear description of how each stage of the intervention should be refined, if applicable) which will be used to refine our logic model and intervention delivery platform.

Finally, thematic analysis (64) will be used to understand necessary modifications to evaluation design. Braun and Clarke's thematic analysis method is an iterative process consisting of six key steps: becoming familiar with the data, generating codes, generating themes, reviewing themes, defining and naming themes, and locating exemplars.

9.3 Procedure(s) to Account for Missing or Spurious Data

Reasons for being unable to collect data during assessments will be recorded on the eCRF where appropriate. eCRFs will be assessed for missing data by PenCTU, and the research team will be regularly asked to follow up missing data. The CTU will maintain a record of site compliance with eCRF completion. If data completion is poor, a monitoring visit may be scheduled.

The eCRFs will include mandatory fields and automatic flags will be displayed to users if the form is saved without these being completed. Where questions might need to be left blank, options such as ‘Not Applicable’ or ‘Prefer not to say’ will be available, to differentiate these from missing

data. Validations will be written into the study database to raise queries with specific data fields, for example, flagging if the date of a visit does not correspond to the correct timepoint.

The PenCTU data manager will write a series of R scripts to perform data tasks that will aid data completeness. These will include checking overall completeness by field of all CRFs, checking all visits have been recorded in a logical order and checking SAE forms have been completed. The scripts will be run on a weekly basis and any concerns will be raised individually with sites.

10. DATA MANAGEMENT

10.1 Data Collection Tools

For the WP1 workshops and the WP2 formative process evaluation, data will be collected through workshop recordings, and interview recordings and observational fieldnotes, respectively.

For the WP2 feasibility RCT, the REDCap database will be used to collect participants' screening and outcome data, and to perform SAE reporting. It will be a fully validated web-based system that is compliant with the ALCOA+ principles and Medicines and Healthcare Products Regulatory Agency (MHRA) guidance. Data will be captured in accordance with the best principles of clinical data management and the relevant standard operating procedures on Clinical Data Management System Specification and Validation. PenCTU will be responsible for the database build and for system validation. Inbuilt validation features will be utilised alongside post-entry monitoring, performed using validated R scripts to ensure data quality and completeness. Data will be hosted externally by ARO on MS Azure data centres located in the UK (Liverpool, England). ARO are NHS DSP Toolkit compliant, and hold ISO27001 and Cyber Essentials Plus certifications. Microsoft Azure data centres are Service Organisation Control (SOC) type 1 and 2 compliant. Data will be stored on hardware dedicated to PenCTU's instance of REDCap. All electronic data are regularly backed up and stored with a full audit trail.

10.2 Source Data and Documentation

WP1:

Data and documents will include ICFs and workshop recordings. Participants will be asked not to share identifiable information during the workshops. However, if a name or other identifiable information is mentioned, the researcher will make a note of the time on the recording. The sound file can then be edited using open-source Audacity Software so that the name is cut out prior to the recording being sent to the transcriber. Due to the nature of a workshop, participants must be comfortable with the audio recording process in order to participate. If a participant becomes uncomfortable with this, they will be given the opportunity to withdraw and leave the workshop. Each participant will be allocated a unique study identifier and an electronic identification key linking their name to this number will be created. The password-protected spreadsheet will be saved on the UOM research data storage (RDS) drive, in a different folder to the ICFs.

WP2:

For the feasibility RCT and cost-effectiveness feasibility analysis, the source data for participants will comprise demographic data, current offence data, medical records (for medical histories), participant-completed documents (ICFs and outcome measures), care plans, case notes, resource use questionnaires, and PenCTU eCRFs and paper worksheets. ET workers at each site

will ensure that information about participation in the feasibility RCT is added to prisoners' health and medical records. At a minimum, this will include the following:

- Eligibility and consent for feasibility RCT
- Dates of all study visits and follow ups
- Completion or discontinuation of study
- AEs, SAEs, and safeguarding concerns logged

Data (including participant-completed documents) will be recorded on either the eCRF or paper forms that will then be entered into the REDCap eCRF. Identification on the eCRF will be through a unique study identifier. A password-protected screening log linking names to study identifiers will be generated by the researchers who conduct the ET Screen. This will be saved on the UOM RDS, and is the responsibility of the CI. As such, participants cannot be identified from eCRFs. The CI and research team will ensure that participants' identities are protected at every stage of the feasibility RCT, according to the Caldicott principles. If any information needs to be sent to a third party, pseudo-anonymous participant parameters will be maintained in correspondence.

CRFs will be stored on a Clinical Data Management Application (CDMA) developed by PenCTU. The PenCTU Data Manager or a nominated designee will continually monitor completeness and data quality in CRFs and will correspond regularly with the CI and/or the research team with the aim of capturing any missing data where possible and ensuring continuous high quality of data. The CTU will verify source data and documents as stipulated in the study monitoring plan (Section 12). The investigator will also keep a record of all participants and original signed ICFs. Any paper forms completed by site staff or participants should be retained in the Investigative Site File (ISF).

For the embedded formative process evaluation, participant data will consist of ICFs interview recordings, and field notes. Participants will be asked not to share identifiable information during the interviews. However, if a name or other identifiable information is mentioned, the researcher will make note of the time on the recording. The sound file can then be edited using open-source Audacity Software so that the name is cut out prior to the recording being sent to the transcriber. If participants decline to be recorded, then notes will be taken by the researcher. These notes will not contain personal information. Each participant will be allocated a unique study identifier and an electronic identification key linking their name to this number will be created. This password-protected spreadsheet will be saved on the UOM RDS drive, in a different folder to the ICFs.

10.3 Data Handling and Record Keeping

WP1:

Participant data will be stored on a UOM RDS drive on the UOM server that can only be accessed by members of the research team via password protected computers. Paper ICFs will be stored in a locked filing cabinet inside a lockable office on a corridor with keycard access. The workshops will be audio-recorded using an encrypted recording device (if they are in person) or using MS Teams or Zoom software (if they are online) with the recording process explained in the CIF and PIS. Face-to-face workshops will be conducted by members of the research team within a secure environment where discussions cannot be overheard. For online workshops, the team will encourage participants to ensure that their space is private. If the researchers believe there is a risk of a data breach during a remote workshop, the participant will be asked to leave the area or workshop. Following the workshops, the audio recordings will be saved to the UOM RDS drive,

the researchers will check that the transfer has been successful (i.e., the audio recording opens and plays), and the original recording will be deleted. Transcriptions will be written up as soon as possible following the workshops and pseudonymised using study identifiers. Transcribers will either be contracted external transcribers, including LSCFT transcribers, or UOM staff. If university approved external transcribers are used, audio files and transcripts will be transferred in password-protected files, with passwords sent separately or via the approved transcribers secure processes. When transcripts have been completed and have been checked by a member of the research team, the recording will be deleted. Transcripts will then be transferred and stored on the secure UOM server ready for analysis.

WP2:

For WP2, data will be handled and stored as described in Section 10.2.

10.4 Access to Data

Staff involved in conducting the study, namely the core research team, will have access to study data. Direct access to investigator site records will be granted to authorised representatives from the host institution, the sponsor, and the regulatory authorities to permit trial-related monitoring, audits and inspections, in line with participant consent. Secure anonymised electronic data will also be released to the health economist(s) and study statistician(s) for analysis.

The core research team may not disclose or use for any purpose other than performance of the study any data, record, or other confidential or unpublished information disclosed to them for the purposes of the study. Prior written agreement from the sponsor or its designee must be obtained for the disclosure of such confidential information to other parties.

10.5 Archiving

Essential data will be retained for a period of at least five years following publication. Archiving will be authorised by the sponsor after the submission of the checkpoint report (for the feasibility RCT) or final report (for the full RCT). The sponsor will be responsible for archiving the data and the Trial Master File in a secure location for at least five years after publication. The Junior Trial Manager will prepare the Trial Master File for archiving according to requirements of the sponsor's SOPs and under the CI's supervision. PenCTU will also prepare a copy of the final dataset for archiving in accordance with the requirements of the CTU's SOPs. Authorisation will be requested from the sponsor to destroy the documentation at the end of the archiving period.

CIs will be responsible for archiving ISFs and feasibility RCT data generated at the site according to local policy. No trial-related records should be destroyed unless or until the sponsor gives their authorisation to do so. Medical records containing source data or other trial related information should be labelled, physically or electronically, so as to ensure retention until the sponsor gives authorisation to destroy (for example, 'keep until dd/mm/yyyy', where the date given is five years after the last participant's final visit).

11. MONITORING, AUDIT, AND INSPECTION

The trial will be coordinated by the TMG, who will meet once per month to monitor all aspects of the conduct and progress of the trial. The Independent TSC will meet once per quarter to monitor progress, provide overall supervision, and advise on scientific credibility. The DMEC will

independently monitor data as it is obtained and highlight if there are any ethical or safety reasons for discontinuing the trial. The PenCTU Data Manager or nominated designee will be responsible for monitoring completeness and data quality in the CRFs. However, this will remain the overall responsibility of the CI. Queries will be resolved by the CI or delegated research team member.

A study-specific Delegation Log will be prepared for each site to detail the responsibilities of each research team member working on the trial. These research team members will also be required to document study training on a study-specific training log. The trial may be subject to additional auditing or monitoring by an IEC, the sponsor, its designee, Regulatory Authorities, or the REC.

Central monitoring will include close supervision of participant recruitment rates, attrition rates, data completeness (missing data), data quality (using range and consistency checks), protocol non-compliance, and calendar checks (to identify deviations from participants' visit schedules).

12. ETHICAL AND REGULATORY CONSIDERATIONS

12.1 Research Ethics Committee Review and Reports

The research team will obtain ethical approvals from the national Research Ethics Service (RES), including from a Research Ethics Committee (REC) and HMPPS's National Research Committee (NRC). The team will also obtain approvals from the Health Research Authority (HRA), all relevant NHS Trusts, and the governors of the participating prisons. The ET workers and researchers will require security clearance and prison induction training (security and risk). Parties will conduct the study in accordance with these approvals.

The REC will be notified of all substantial amendments, as well as non-substantial amendments that result in a change to the documentation. Substantial amendments that require a favourable opinion from the REC will not be implemented until this opinion is obtained. All correspondence with the REC will be retained in the study's master file. The research team will also notify the REC of any serious breaches of the GCP or protocol, and urgent safety concerns that arise.

An annual progress report will be submitted each year to the REC by the research team until the end of the study. This report will be submitted within 30 days of the anniversary date on which the original favourable ethical opinion was granted. It is the CI's responsibility to provide annual reports as required. The CI will notify the REC of the early termination (including reasons for this) or end of trial in accordance with the required timelines. Within one year after the end of the trial, the CI will submit a final report with the results, including abstracts and publications, to the REC.

12.2 Peer Review

The study has undergone a high quality and thorough peer review process and has been approved by the sponsor. Prior to commencement, the study will have been subject to multiple peer review stages, including: (a) feedback on the initial and full grant application from the NIHR Programme Grants for Applied Research panel, (b) sponsor review, (c) NHS REC review, and (d) HMPPS NRC review. On completion, the checkpoint report will be subject to peer review, and any subsequent manuscripts will be submitted to peer-reviewed journals.

The study has several management groups, including the TMG, independent TSC, independent DMEC, PPIE panel, and PPIE Professionals panel. Each group consists of individuals with different areas of expertise who will be consulted with at each stage of the study.

12.3 Public and Patient Involvement

PPIE Group

A PPIE group was established and consulted in the preparation of the grant application. The group is comprised of seven core members who have previously experienced prison, including several with social care needs. Their contribution to the grant included naming the intervention, advising and commenting on study design, and coproducing the Plain English Summary.

Two members of the PPIE group will be invited to join the research team as co-investigators. These members will be appointed as honorary Research Assistants at UOM if deemed appropriate and acceptable by all parties. In this role, they will attend bespoke training, have direct input into study direction, and coproduce outputs. These co-investigators have worked closely with the research team to develop the PPIE strategy.

Throughout the study, the core PPIE group will meet at key points of the study. We will adhere to UK standards for public involvement and follow the INVOLVE NIHR guidance for coproduction. The group will meet online on a secure video conferencing platform at times that align with PPIE members' schedules. The group will also aim to meet face-to-face approximately twice during the project and as needed. Discussions will differ depending on the phase of the study that the meeting is in. For example, during the ethics application phase, PPIE groups will be asked to screen ICFs, PIS, and other materials to ensure appropriateness. PPIE co-investigators will take a more involved role and produce documentation in collaboration with the research team. They may also be involved in data collection and analysis, as appropriate. Dissemination will also be jointly conducted with PPIE collaborators.

PPIE participants will be reimbursed for their time in line with NIHR guidance. Ongoing evaluation will take place, with regular confidential feedback forms distributed to collaborators to establish what is working well, what could be improved, and what changes participants would like to see. The research team will also explore options for certificates of participation.

PPIE Professionals

A PPIE Professionals group comprised of healthcare, prison, and local authority staff will also be developed during the study. This group will meet every six months (or more frequently as needed) to provide input into core elements of the study. This might include providing advice for dealing with problems that arise during implementation, and input into dissemination materials.

12.4 Regulatory Compliance

The study will not commence until there is a favourable REC opinion. Approvals from the HMPPS NRC, NHS Trusts, and prison governors will also be required. Any substantial amendments that require review by NHS REC will not be implemented until that review is in place, along with other mechanisms to implement at site. The sponsor delegate will notify the REC of the end of the trial within 90 days of completion. The final report will be written within 12 months of the end of the trial. If the trial terminates early for any reason, the CI will notify the REC of early termination (including reasons for this) or end of trial in accordance with the required timelines.

12.5 Protocol Compliance

Any deviations, non-compliances, and breaches of the protocol will be reported to the CIs and the sponsor. A record of the incident will be documented in the site file. The core research team will follow instructions from the sponsor.

The research team understands that deviations from the protocol which frequently recur are not acceptable and require immediate action and could potentially be classified as a serious breach. The research team understands the importance of complying with the protocol.

12.6 Notification of Serious Breaches to the GCP or Protocol

A serious breach is defined any breach that is likely to affect to a significant degree:

- the safety or physical or mental integrity of the subjects of the study; or
- the scientific value of the study

If a serious breach of the GCP or protocol occurs in relation to the feasibility RCT the sponsor will be alerted immediately. A record of the incident will be documented in the site file, and the core research team will follow instructions from the sponsor. The research team will notify the REC of any serious breaches of the GCP or protocol, and urgent safety concerns that arise.

12.7 Indemnity

LSCFT are the research sponsor; therefore, the NHS Indemnity Scheme will apply. Appropriate contractual arrangements will be put in place with all third parties.

12.8 Amendments

The core research team will prepare the amendment and update the protocol and other materials as needed. Preparing the amendment will be the responsibility of the CIs and can be delegated to other members of the core research team. The prepared amendment will then be submitted to the sponsor. It is the responsibility of the sponsor to determine if an amendment is substantial.

If an amendment is substantial, the sponsor will submit a valid notice of amendment to the REC for consideration. The REC will provide a response on the amendment within 35 days of receiving the notice. Substantial amendments will not be implemented until the REC issue an acceptance. If an amendment is not substantial, the CI or delegee will notify the REC.

Amendments and revised materials will also be sent to the HMPPS NRC, and NHS amendments will be notified to the participating NHS R&D offices. The CI or delegee will work with the sites to confirm their support for the amended study and to implement the amendments. Although core responsibility for the decision and submission of amendments will lie with the research team, co-investigators will be consulted. The TMG, TSC, DMEC, PPIE panel, and PPIE professionals panel will also be consulted about amendments and their feedback requested as appropriate.

Amendment history will be recorded in the protocol (Appendix 2) and can be cross-referenced with the Protocol Version Control Table. Amendments will also be recorded on the NIHR REALMS platform and NIHR permission will be required for amendments to the study protocol.

12.9 Post-Trial Care

For the feasibility RCT, those in the intervention arm will receive social care as usual in addition to ET or signposting. Although no provision for the continuation of ET will be made by the research

team or sponsor, participants in the intervention arm will continue to receive social care as usual. Participants in the control arm will also continue to receive social care as usual.

12.10 Access to the Final Trial Dataset

During the study, the PenCTU data team will have access to the dataset, including to identifiable participant data. Other members of the research team will be given restricted access to pseudo-anonymised data. Access to the dataset will be granted to the host institution and the sponsor on request, to permit study-related audits, inspections, and monitoring. Access will be overseen by the CTU data manager. Access to the final dataset will be provided to the health economist(s) and study statistician(s) for analysis.

Once reporting is complete, the anonymised individual participant data that underlie the results will be available on request from the CI and sponsor, along with supplementary files as required (for example, analysis code, blank data collection forms, data dictionaries, and so on). Data will be shared with (or access to the data will be provided to) requestors whose proposed use of the data has been approved by the CI and sponsor, under an appropriate data sharing agreement. It will not be possible to identify participants personally from any information shared. The dataset will not be made freely available.

13. DISSEMINATION POLICY

13.1 Dissemination Policy

Checkpoint Report

At the end of the study (18 months post-commencement) a checkpoint report will be submitted to the funder based on the progression criteria. If minimum success criteria for feasibility aims and objectives are achieved, the programme will progress to full RCT. In this case, the checkpoint report will include ET worker recruitment and health economics methods for the full RCT.

Dissemination to the Academic Community

Our aim is to publish papers on the feasibility RCT and embedded formative process evaluation. Data collected through the study may also contribute to a paper on PPIE involvement. We intend to reach social care and criminal justice audiences by publishing in journals such as the British Journal of Social Work; the British Medical Journal; Health and Justice; Health and Social Care in the Community; and the Journal of Forensic Psychology and Psychiatry. We may also present our findings at conferences such as BASW Conferences and the Health and Justice Summit.

Dissemination to Decision-Makers, Prisoners, Prisoner Families, and Practitioners

A comprehensive dissemination and impact strategy will be employed to ensure that our findings are shared with relevant stakeholders, including prisoners, prison and local authority staff, prison and social care managers, policy makers, and the public. The strategy has been developed based on guidance from the PPIE group. It will include co-produced outputs for, and engagement with, professional and lay audiences. The key outputs will include:

- An immersive short film and corresponding launch event and training webpage
- An ‘easy read’ article in prison newspaper ‘Inside Times’
- A podcast with ‘Secret Life of Prison’ accessible to those currently living in prison.

- A piece for prison radio
- A twitter account
- Presentations at key policy meetings
- A dissemination event to embed our findings into policy and practice in conjunction with the Ministry of Justice, and Health and Social Care HMPPs Partnership board.

13.2 Authorship Eligibility Guidelines

Checkpoint Report

Authorship for the checkpoint report will be granted to protocol contributors, providing they have contributed as per their outlined study role, and that they subsequently review and contribute to drafts of the report in defined timescales. Other researchers who have significantly contributed to the delivery, evaluation, or write up of the study will be given opportunities to attain authorship on the checkpoint report. Acknowledgment will be made to the funder in the report.

Publication of Manuscripts

The core research team will oversee subsequent manuscripts in line with their involvement and expertise. One person will be assigned to lead on each manuscript, with drafts reviewed by co-investigators according to defined timescales. As first author, the lead researcher will liaise with co-investigators and order of authorship will be defined based on level of involvement in the specific manuscript.

Other Articles for Dissemination

It is anticipated that articles prepared as part of the dissemination policy will be authored by the core research team with oversight from co-investigators and the management groups as required.

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APPENDIX 1: AMENDMENT HISTORY

Details of all protocol amendments are listed below. Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made