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Empowered Together (coordinated social care in prison)

Submission date
01/09/2025

Recruitment status
Recruiting

Registration date
03/10/2025

Overall study status
Ongoing

Last Edited
19/11/2026

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Social care helps people who struggle with everyday tasks because of physical or mental health problems. This includes help with cleaning, washing, dressing, using special equipment, and staying connected with others. There hasn't been much research into how social care works in prisons, but what we do know suggests it's not as good as it is outside prison. To help improve this, researchers have created a new approach called Empowered Together. The study will test whether this approach works well in prisons.

Who can participate?
Men in selected prisons can take part if they are aged 18 years or older, have at least 7 months left on their sentence, are thought to have high social care needs, and can give their consent to take part.

What does the study involve?
The study has three parts.
In part one, researchers will work with people who have lived in prison to create training for staff, tools to measure how well Empowered Together works, and a short film, event, and website.
In part two, Empowered Together will be tested in two men's prisons. Seventy-six men with social care needs will take part. Half will receive Empowered Together and half will get usual care. Researchers will test different questionnaires, interview 20 men and 26 staff, and explore the costs of Empowered Together.
In part three, a larger group of 426 men will take part. Half will get Empowered Together and half will get usual care. Researchers will compare the two groups using questionnaires, interview 32 men and 56 staff, observe 16 men, and collect information about costs and how well the approach was delivered.

What are the possible benefits and risks of participating?
The study could help improve social care for future prisoners who need support.
Some people might feel upset during interviews when talking about their daily challenges. If this happens, they can speak to the researcher, prison staff, healthcare staff, or a trained listener. Support and advice will be offered if needed.

Where is the study run from?
Part two will take place in HMP Liverpool and HMP Risley (UK). Part three will be in six to eight prisons, which haven't been chosen yet.

When is the study starting and how long is it expected to run for?
February 2025 to January 2030.

Who is funding the study?
Lancashire and South Cumbria NHS Foundation Trust (UK)

Who is the main contact?
Dr Katrina Forsyth, katrina.forsyth@manchester.ac.uk

Contact information

Type(s)
Scientific, Principal investigator

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Integrated Research Application System (IRAS)
361615

Central Portfolio Management System (CPMS)
57609

Protocol serial number
LSCFT-RD24002

Study information

Scientific Title
Empowered Together (coordinated social care in prison): A feasibility and definitive randomised controlled trial, with embedded realist informed process evaluation

Acronym
ET

Study objectives
Empowered Together is more effective in reducing the number of unmet social care needs of men in prison than care as usual.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 01/09/2025, Wales REC 3 (Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 2922941107; Wales.REC3@wales.nhs.uk), ref: Reference number not provided

Primary study design
Interventional

Study design
Two-site parallel individually randomized controlled trial feasibility and definitive study

Study type(s)
Efficacy, Screening, Treatment

Health condition(s) or problem(s) studied
Social care needs of adult men in prison who are at risk of having unmet needs

Interventions
ET Screening: All individuals living in the prison(s) are screened using the ET tool. This was adapted for prison use from one used in the community. It is aligned with the Care Act and briefly asks whether individuals: 1. consider themselves to have any physical or mental health condition/impairment or to be neurodiverse 2. experience difficulties in any of the following social care domains in prison: food, hygiene, toileting, clothing, safety, family relationships. A series of probing questions relevant to these social care in prison domains will be used.
If individuals report they may have difficulties in two or more social care domains they will go on to receive an ET assessment.
ET Assessment: A strengths-based assessment of social care need, conducted by an ET worker. Strengths and assets-based approaches to assessment and care-planning focus on people's capabilities, explore help available from wider support networks, and take account of issues of importance to the individual. Care needs change over time, therefore follow-up assessments should occur at least twice yearly with clear review dates identified in response to changing needs follow-up assessments should be conducted, with changes to care-plans being jointly agreed.
ET Care Coordination: ET worker coordinates care for those meeting criteria for of social care provision under the Care Act 2014. The ET Worker will coproduce a care plan with the individual /family member/peer carer. This will consider placement in the prison (e.g. vulnerable prisoner wing, healthcare wing, adapted cell) and the support required. All domains of the Care Act 2014 will be considered including adaptations to cells and other parts of the prison (e.g. handrails; hygiene equipment, meal trays); support with maintaining personal relationships; coordination of peer support; necessary changes to the regime; and details of any personalised care.
ET is delivered by an ET coordinator, qualified to a minimum of Health and Social Care level 4. The ET workers will receive social care management and clinical supervision monthly. Their role as a prison social care specialist will include conducting screening, assessments, and care co-ordination. They will liaise with prison, health and external social care staff, making referrals where appropriate, improving communication and aiming to ensure that individuals' needs are met. The role of the ET worker will involve acting as an advocate for the person in prison, and this will include referring for, feeding into and attending the Care Act Assessment conducted by the local authority. They will also liaise with prison authorities, whose responsibilities include adaptation of the environment for social care.

The control will be care as usual in the prison.

As part of a previous programme delivery grant (PDG) we conducted:
1. A realist synthesis to develop the initial programme theory, logic model and intervention delivery platform for Empowered Together
2. A systematic review of suitable outcome measures
3. Development of patient, public involvement and engagement (PPIE)

The proposed study builds on the work conducted in the PDG. It contains three work packages:

WP1: Development of:
1. Training manual
2. Bespoke outcome measure
3. Fidelity scale
4. Immersive film, audio, blog, event and webpage

WP2: Feasibility study/embedded formative process evaluation
1. Feasibility RCT
2. Cost-effectiveness feasibility
3. Realist-informed formative process evaluation (including implementation fidelity)
4. Review of progression criteria

WP3: Definitive RCT and embedded summative process evaluation
1. Definitive RCT
2. Cost-effectiveness analysis
3. Realist-informed summative process evaluation (including implementation fidelity)
4. Development of future funding application to adapt Empowered Together for women

Timelines for Delivery
Months
0 – 12: Set up
0 – 6: WP 1
6 – 20: WP2
20 – 54: WP3
54 – 60: Impact and Dissemination

For the feasibility RCT, this 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.
The feasibility RCT will include follow-ups at 42-days (six weeks) and 90-days (three months) (±7 days) post-baseline.

For the definitive trial, the duration of the intervention will also be 9 months, and the follow ups will be at six weeks and six months.

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.
Again, for the definitive trial, following screening for eligibility, participants will be randomised 1: 1 to receive ET or CAU. This will be achieved using block randomisation stratified by prison and age group.

Intervention Type
Other

Primary outcome(s)
Feasibility study:
Unmet needs of men in prison will be measured using Camberwell Assessments of Needs-Forensic Research CANFOR-R at baseline, 6 weeks, and 3 months

Definitive study:
Unmet needs of men in prison will be measured using Camberwell Assessments of Needs-Forensic Research CANFOR-R at baseline, 6 weeks, and 6 months

Key secondary outcome(s)
At baseline, 6 weeks, and 3 months in the feasibility trial:
1. Social care related quality of life measured using the Adults Social Care Outcomes Toolkit (ASCOT SCT4)
2. Health related quality of life measured using EQ-5D-5L
3. Wellbeing measured using ICEpop CAPability measure for Adults (ICECAP-A)
4. Recovery outcomes measured using ReQol-10

At baseline, 6 weeks, and 6 months in the definitive trial:
1. Social care related quality of life measured using the Adults Social Care Outcomes Toolkit (ASCOT SCT4)
2. Health related quality of life measured using EQ-5D-5L
3. Wellbeing measured using ICEpop CAPability measure for Adults (ICECAP-A)
4. Recovery outcomes measured using ReQol-10

Completion date
31/01/2030

Eligibility

Key inclusion criteria
1. Resident in one of the study prisons
2. Serving a sentence with at least 7 months until release date
3. Over 18 years of age
4. Has mental capacity to consent or appropriate personal or independent consultee who can provide assent (as assessed by researchers in consultation with prison staff)
5. Scores positively on the ET screen

Participant type(s)
Service user

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit

18 Years

Upper age limit
100 Years

Sex
Male

Total final enrolment
426

Key exclusion criteria
1. Unsafe for researchers to interview alone
2. In current receipt of a social care package under the Care Act
3. Insufficient knowledge of English to complete assessment and outcome measures

Date of first enrolment
01/08/2025

Date of final enrolment
26/02/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hmp Liverpool
68 Hornby Road
Liverpool
England
L9 3DF

Study participating centre
Hmp Risley
Warrington Rd, Risley, Croft, Warrington
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Sponsor information

Organisation
Lancashire and South Cumbria NHS Foundation Trust

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1	30/06/2025	10/09/2025	No	No