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Mental health treatment requirements

Submission date
09/08/2024

Recruitment status
Recruiting

Registration date
28/10/2024

Overall study status
Ongoing

Last Edited
26/11/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Many people who attend court have severe and complex mental health problems. They often find it difficult to access treatment. They can face stigma, homelessness, financial and substance problems. A prison sentence can make these problems worse and does not help their mental health.
A Mental Health Treatment Requirement (MHTR) can be given instead of a short prison sentence by courts in England and Wales if the person agrees. It means that they must attend for treatment of their mental health problem as part of a community sentence. Secondary MHTRs (SC-MHTR) are for people who need specialist mental health care. Until now, courts have ordered very few SC-MHTRs. The NHS has given money to three courts in England, called 'proof-of-concept' sites, to investigate whether more people could benefit from SC-MHTRs. They think that this could improve their mental health and reduce the number of people with severe mental health problems going to prison. The NHS would like to see an increase in SC-MHTRs across the country and needs to learn the best way to go about this. There is no research evidence about how to increase use of SC-MHTRs. We also do not know if they affect health, or if they can work for different people and in different places.
This study will examine how people use SC-MHTRs at the proof-of-concept sites and at a Welsh site. The researchers want to know if SC-MHTRs are working, who for, how and why. This will let them tell the NHS the best way to introduce them across the country. They also aim to develop a way to measure their effect on health and on NHS costs across the country in future.

Who can participate?
Adult patients aged 18 years and over who are under an SC-MHTR, carers of patients under an SC-MHTR, commissioners, policymakers and staff involved in the creation and implementation of SC-MHTRs.

What does the study involve?
The researchers will get information in three ways:
1. Review documents about people's expectations about SC-MHTRs
2. Hold interviews with people who designed the SC-MHTR, staff, patients, and their families
3. Examine NHS records that describe patients on SC-MHTRs and SC-MHTR numbers
They will use this information to:
1. Find out how SC-MHTRs are being delivered
2. Explain how SC-MHTRs work (or do not work) for which patients and in what circumstances

3. Tell the NHS about the best way to increase SC-MHTRs across the country and overcome problems
4. Design a way to evaluate a future national SC-MHTR programme.

What are the possible benefits and risks of participating?
There is no direct benefit to research participants, but participants taking part in interviews /workshops may benefit from being part of the research process and contributing to the evaluation of SC-MHTRs. For example, being able to discuss their experiences and 'be heard' may have a positive effect on participants.
The study involves the discussion of sensitive topics. There will be a safeguarding protocol in place to minimise the risk of participant distress.

Where is the study run from?
Lancashire and South Cumbria NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2024 to July 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) Health and Social Care Delivery Programme (UK)

Who is the main contact?
Dr Kerry Gutridge (Project Manager), kerry.gutridge@manchester.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
339957

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
LSCFT-RD23010, CPMS 64720

Study information

Scientific Title
An evaluation of secondary care mental health treatment requirements

Acronym
SC-MHTR

Study objectives
To develop a Secondary Care Mental Health Treatment Requirements (SC-MHTR) programme theory that would facilitate understanding of need, barriers to take-up and delivery, and solutions, and form the basis for a full evaluation of SC-MHTRs in anticipation of a national programme rollout across England and Wales.

Research questions:
1. How is the SC-MHTR being delivered?
2. What works, for whom at each of the study sites, and what are the mechanisms that underpin this?
3. What can we learn from the sites about improving delivery across different geographic, socio-economic and organisational contexts?
4. How should we evaluate a future national SC-MHTR programme?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/10/2024, Wales REC 4 (Health and Care Research Wales, Castlebridge 5, 15-19 Cowbridge Road East, Cardiff , CF11 9AB, United Kingdom; +44 (0) 2922 941119, 2922 940989; Wales.REC4@wales.nhs.uk), ref: 24/WA/0267

Study design
Scientific realist framework

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Secondary care mental health treatment requirements

Interventions
The SC-MHTR is a complex intervention that may be offered after conviction in a magistrates' or Crown court to tailor a community or suspended sentence. It involves assessment by probation and health personnel and explanation to the offender, assessment, agreement between them and, if agreed, a recommendation to the court, sentencing and then the management of the arrangement and delivery of treatment, with return to court if in breach. Thus, the parties come from very different training and professional backgrounds and co-operation must be achieved between them across separately commissioned services. The NIHR/MRC framework for developing and evaluating complex interventions has informed our research approach.

A Scientific Realist Framework will be adopted. A realist approach assumes that the same intervention will not work in the same way everywhere and for everyone, and focuses upon 'what works, for whom, in what way, and how'. The Government recognises the importance of this approach for evaluating interventions at early stages and to understand how to adapt them to new contexts to understand how and why differences occur.

Here, the plan fits with a four-step process within two work packages. In Work Package 1, the researchers will:
1. Formulate an initial programme theory by drawing on extant documents and interviewing central policy staff
2. Conduct preliminary testing of this model with NHS routine data and proof of concept and Wales site staff, patients, and carers
3. Consolidate the programme theory
In Work Package 2, the researchers will design the large-scale evaluation

Intervention Type
Other

Primary outcome(s)
Views and experience of staff, patients and carers on secondary care MHTRs collected from 01 /10/2024 to 31/01/2026. Data will be analysed using a realist approach to thematic analysis and descriptive statistics, using realist methods to develop an Initial Programme Theory to describe how secondary MHTRs work, in what way and for whom.

Key secondary outcome(s))
Quantitative analysis of routine health and justice datasets collected from 01/10/2024 to 31/01/2026. Data will be analysed using a realist approach to thematic analysis and descriptive statistics, using realist methods to develop an Initial Programme Theory to describe how secondary MHTRs work, in what way and for whom.

Completion date
31/07/2026

Eligibility

Key inclusion criteria
Patients:
1. Adults aged 18 years or over
2. Capacity to consent to participate in the study
3. Recommended for, under, or recently (within 3 months) under an SC-MHTR

Carers:
1. Adults aged 18 years or over
2. Capacity to consent to participate in the study
3. Family member or informal caregiver of someone recommended for, under, or recently (within 3 months) under an SC-MHTR

Professionals:
1. Aged 18 years or over
2. Have working knowledge of how SC-MHTRs operate

Participant type(s)
Patient, Health professional, Carer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Patients:
1. Aged 17 years and under
2. Lacking the capacity to provide informed consent to participate
3. Not recommended for, under, or recently (within 3 months) under an SC-MHTR
4. Considered by staff not safe to interview due to their current risk assessment

Carers:
1. Aged 17 years and under
2. Lacking the capacity to provide informed consent to participate
3. Not a family member or informal caregiver of someone recommended for, under, or recently (within 3 months) under an SC-MHTR

Professionals:
1. Aged 17 years and under
2. Do not have a working knowledge of how SC-MHTRs operate

Date of first enrolment
01/02/2025

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
Midlands Partnership NHS Foundation Trust
Trust Headquarters
St Georges Hospital
Corporation Street
Stafford
United Kingdom
ST16 3SR

Study participating centre
Gloucestershire Health and Care NHS Foundation Trust
Edward Jenner Court
1010 Pioneer Avenue
Gloucester Business Park
Gloucester
United Kingdom
GL3 4AW

Study participating centre

Swansea Bay University Local Health Board
Tonna Hospital
Tonna Uchaf
Tonna
Neath
United Kingdom
SA11 3LX

Study participating centre
East London NHS Foundation Trust
Robert Dolan House
9 Alie Street
London
United Kingdom
E1 8DE

Study participating centre
North East London NHS Foundation Trust
West Wing
C E M E Centre
Marsh Way
Rainham
United Kingdom
RM13 8GQ

Study participating centre
Central and North West London NHS Foundation Trust
Trust Headquarters
350 Euston Road
Regents PLACE
London
United Kingdom
NW1 3AX

Study participating centre
Barnet, Enfield and Haringey Mental Health NHS Trust
Trust Headquarters St Ann's Hospital St Ann's Road
London
United Kingdom
N15 3TH

Study participating centre
Camden and Islington NHS Foundation Trust
St Pancras Hospital
4 St Pancras Way
London
United Kingdom
NW1 0PE

Study participating centre
Oxleas NHS Foundation Trust
Pinewood House
Pinewood PLACE
Dartford
United Kingdom
DA2 7WG

Study participating centre
South West London and St Georges Mental Health NHS Trust
Trinity Building, Springfield University Hospital, 15 Springfield Drive
London
United Kingdom
SW17 0YF

Study participating centre
West London NHS Trust
1 Armstrong Way
Southall
United Kingdom
UB2 4SD

Study participating centre
South London and Maudsley NHS Foundation Trust
Bethlem Royal Hospital
Monks Orchard Road
Beckenham
United Kingdom
BR3 3BX

Study participating centre
Tavistock and Portman NHS Foundation Trust
The Tavistock Centre

120 Belsize Lane
London
United Kingdom
NW3 5BA

Sponsor information

Organisation
Lancashire and South Cumbria NHS Foundation Trust

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research - Health and Social Care Delivery Research Programme

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
The datasets generated during and or/analysed during the current study are not expected to the made available due to restrictions included in the data sharing agreements and the specificity of the data.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes