# Mental health treatment requirements

<b>Submission date</b> 09/08/2024	<b>Recruitment status</b> Recruiting	[X] Prospectively registered
		∐ Protocol
Registration date	Overall study status	Statistical analysis plan
28/10/2024	Ongoing	☐ Results
Last Edited	Condition category	Individual participant data
26/11/2024	Mental and Behavioural Disorders	[X] 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

#### Contact name

Dr Louise Robinson

#### Contact details

Division of Psychology and Mental Health School of Health Sciences Faculty of Biology, Medicine and Health University of Manchester Jean McFarlane Building Oxford Road Manchester United Kingdom M13 9PL +44 (0)1772 676134 louise.robinson@manchester.ac.uk

#### Type(s)

Public, Scientific

#### Contact name

Dr Kerry Gutridge

#### **ORCID ID**

http://orcid.org/0000-0001-9705-9102

#### Contact details

2nd Floor, Jean McFarlane Building, University of Manchester, Oxford Road Manchester United Kingdom M13 9PL +44 (0)7784 016 900 kerry.gutridge@manchester.ac.uk

# Additional identifiers

#### **EudraCT/CTIS** number

Nil known

#### IRAS number

339957

#### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

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

#### Secondary study design

Scientific realist framework

#### Study setting(s)

Community

#### Study type(s)

Other

#### Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

#### 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 measure

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.

#### Secondary outcome measures

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.

#### Overall study start date

01/02/2024

#### 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

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

### Target number of participants

84

#### 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

England

**United Kingdom** 

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

### Sponsor details

The Lantern Centre
Vicarage Lane
Fulwood
Preston
England
United Kingdom
PR2 8DW
+44 (0)1772773498
farah.lunat@lscft.nhs.uk

### Sponsor type

Hospital/treatment centre

# 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**

#### Publication and dissemination plan

Consultation will be carried out with participants, the Patient and Public Involvement and Engagement (PPIE) panel and SSG to inform the final dissemination strategy, including which information to share with which groups, and the best forms of communication to use. However, plans will include written documents (including lay summaries), posters and videos (produced by PPIE co-applicants), posts on the study website, and social media (including X and the Health and Justice Research Network) as well as conference presentations and academic papers.

Online dissemination events for participants will be held. Short videos and lay summaries will be disseminated on social media, the project website, the Health and Justice Research Network (HJRN) website, mail and email. A press release will be produced for the media.

# Intention to publish date

31/07/2027

### 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