UCL Sponsored Studies: SHARE Study Protocol

(*Version 1, 14/07/2025)*

Full title of trial	PhD study to co-design a novel intervention to support discussion between mental health staff and a service user after a Mental Health Act assessment
Short title	SHARE Supporting Honest And Reflective Engagement after MHA assessment
Version and date of protocol	DRAFT Version 1, 26/06/2025
Sponsor:	University College London (UCL)
Sponsor reference number:	179749
Funder (s):	National Institute of Health Research
IRAS Number:	353351
UCL Data Protection Number:	**Z6364106/2025/02/103 health research**
Intervention:	Intervention development and preliminary testing

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PROTOCOL VERSION HISTORY

Version Stage	Versions Number	Version Date	Protocol updated & finalised by;	Reasons for Update
Current	DRAFT 0.1	23/03/2025	Louise Blakley (Ms.)	DRAFT submitted for review
Previous				

DECLARATIONS

The undersigned confirm that the following protocol has been agreed and accepted and that the investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the U.K. Policy Framework for Health and Social Care Research 2017 (3rd edition) (as amended thereafter), the EU General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018), Sponsor SOPs and applicable Trust policies and legal frameworks.

I (investigator) agree to ensure that the confidential information contained in this document will not be used for any other purposes other than the evaluation or conduct of the research investigation without the prior written consent of the Sponsor.

I (investigator) agree to ensure that no research activity or recruitment will commence at participating research sites until the appropriate regulatory approvals and NHS confirmations of Capacity and Capability have been issued, and Sponsor green light confirmed.

I (investigator) also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest, accurate and transparent account of the study will be given. Any deviations from the study as planned in this protocol will be explained and reported accordingly.

Chief Investigator:

Signature: 

Date11/09/2025

Print Name (in full): BRYNMOR LLOYD-EVANS

Position: Professor of Mental Health and Social Inclusion, Division of Psychiatry UCL

On behalf of the Study Sponsor:

Signature:  **Date: 12/08/2025**

Print Name (in full): PUSHPSEN JOSHI

Position: RMG & MANAGER- UCLH/UCL JRO

STUDY SUMMARY

IDENTIFIERS	
IRAS Number	353351
REC Reference No.	
Sponsor Reference No.	
Other research reference number(s) (if applicable)	**UCL Data Protection Number: Z6364106/2025/02/103 health research**
Full (Scientific) title	Co-designing a novel intervention, to support discussion between mental health staff and a patient after a Mental Health Act assessment
Health condition(s) or problem(s) studied	Service users assessed under Mental Health Act
Study Type i.e. Cohort etc	A qualitative, multi-site, participatory co-design study with preliminary feasibility testing
Aim(s):	To develop a new intervention for mental health staff and service user after a Mental Health Act (MHA) assessment to increase service user's understanding and sense of fairness, reduce distress and inform their future care.
Objectives:	The **primary objectives** include: 1. Exploring service users' experiences of MHA assessments and post-assessment support. 2. Understanding staff perspectives on barriers and facilitators to these discussions. 3. Co-designing a prototype intervention with stakeholders. 4. Testing and refining the intervention based on participant feedback. **Outcome measures** include thematic analysis of interviews and focus groups, evaluation of the co-design process, and participant feedback on the prototype.
Type of trial:	A qualitative, multi-site, co-design study involving service users, carers, and mental health professionals to develop and refine a post-Mental Health Act (MHA) assessment support intervention
Trial design and methods:	This study is **not a trial** but follows a **phased, participatory design** using interviews, focus groups, co-design workshops, and preliminary testing across multiple NHS sites. It involves testing the

	prototype intervention with 6 services users under mental health care. This study has three work packages: 1. **Interviews and focus group**: Twenty service users and twenty staff will share their experiences of MHA assessments and the support afterwards. 2. **Workshops**: Service users, carers, and staff will collaborate to design a draft type of support using creative methods. 3. **Testing**: Staff will pilot the new type of support l in role-play and then, in real-life settings with six service users. Feedback will guide refinements.
Trial duration per participant:	Maximum of eight weeks for workshop participants if attend both. For other participants the duration will be between consent and arranging the interviews/ or focus groups up to a month.
Key Study milestones	study submission 4/2025 WP1 first Service user and staff recruitment 8/2025 WP1 last participant recruitment 4/2026 WP1 analysis finished 6/2026 WP2 Workshops completed 3/27 WP2 protype intervention developed 6/27 WP3 recruitment to testing 7/27 WP3 final recruitment 12/27
Estimated total trial duration:	From 8/25 - 9/28
Planned trial sites:	multi-site North London NHS Foundation Trust, Sussex Partnership NHS Foundation Trust, Hampshire & Isle of Wight Healthcare NHS Foundation Trust
Total number of participants planned:	WP1 Service user = 20, Staff = 20 WP2 Workshop one = 20, workshop two= 20 WP 3 User testing = 6 staff Real World testing = 6 staff and 6 service user 100 Participants
Main inclusion/exclusion criteria:	For WP1 and WP 3 Service users assessed under MHA adults under 65 with capacity Staff either involved in assessment or care afterwards.

	For WP2 wider stakeholders involved in MHA assessments. People with lived experience need to have prior involvement in collaborative projects.
Statistical methodology and analysis:	No Statistical analysis as not a full clinical trial. Thematic and collaborative analysis od data collection in WP 1. The testing of protype intervention will use Instant Data Analysis for initial refinements for WP 3.
FUNDING & OTHER	
Funding	NIHR Academy 21 Queen Street Leeds LS1 2TW academy@nihr.ac.uk / Henry Mbawa Jr
Other support	Hampshire and IOW NHS Healthcare Foundation NHS Trust - Employer of Louise Blakley and NHS site sponsor
STORAGE of SAMPLES / DATA (if applicable)	
Human tissue samples	Not applicable
Data collected / Storage	Not Applicable
KEY STUDY CONTACTS	
Chief Investigator	**Prof Brynmor Lloyd-Evans** (BLE) **Professor of Mental Health and Social Inclusion** **University College London** **Maple House** **Wing A, 4th Floor 149 Tottenham Court Road** **London** **W1T 7NF** **b.lloyd-evans@ucl.ac.uk** **02076799428**
Study Coordinator	Louise Blakley (LB) PhD student Division of psychiatry **University College London** **Maple House** **Wing A, 4th Floor 149 Tottenham Court Road** **London** **W1T 7NF**
Committees	Thesis committee will act as the Project Management Group (PMG) and Trial Management Group for the study and meet at least six monthly. Chief Investigator, PhD student, Professor Johnson (SJ), Professor Morant (NM)(qualitative methodology expert), member of the Lived experience Advisory Panel (LEAP), and other members

	depending on stage of the study who will bring research or MHA assessment expertise.
Sub-contractors	
Other relevant study personnel	Data Custodian Professor Llyod-Evans Date Processor Louise Blakley

KEY ROLES AND RESPONSIBILITIES

SPONSOR: The sponsor is responsible for ensuring before a study begins that arrangements are in place for the research team to access resources and support to deliver the research as proposed and allocate responsibilities for the management, monitoring and reporting of the research. The Sponsor also must be satisfied there is agreement on appropriate arrangements to record, report and review significant developments as the research proceeds, and approve any modifications to the design.

FUNDER: The funder is the entity that will provide the funds (financial support) for the conduction of the study. Funders are expected to provide assistance to any enquiry, audit or investigation related to the funded work.

CHIEF INVESTIGATOR (CI): The person who takes overall responsibility for the design, conduct and reporting of a study. If the study involves researchers at more than once site, the CI takes on the primary responsibility whether he/she is an investigator at any particular site.

The CI role is to complete and to ensure that all relevant regulatory approvals and confirmations of NHS Capacity and Capability are in place before the study begins. Ensure arrangements are in place for good study conduct, robust monitoring and reporting, including prompt reporting of incidents, this includes putting in place adequate training for study staff to conduct the study as per the protocol and relevant standards.

The Chief Investigator is responsible for submission of annual reports as required. The Chief Investigator will notify the REC and JRO of the end of the study (including the reasons for premature termination, where applicable). Within one year after the end of study, the Chief Investigator will submit a final report with the results, including any publications/abstracts to the REC and JRO.

PRINCIPLE INVESTIGATOR (PI): Individually or as leader of the researchers at a site; ensuring that the study is conducted as per the approved study protocol, and report/notify the relevant parties – this includes the CI of any breaches or incidents related to the study.

OTHER: Supervisors of PhD student.

TRIAL PERSONNEL

See protocol cover page for Chief Investigator and Sponsor contact details.

Study Coordinator

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KEY WORDS

Mental Health Act assessments, Collaborative study, intervention development study, Qualitative research, lived experience.

LIST OF ABBREVIATIONS

Abbreviation	Full Term
AMHP	Approved Mental Health Professional
BLE	Professor Brynmor Lloyd-Evans – Supervisor and Chief Investigator
CI	Chief Investigator
CRF	Case Report Form
CRPD	Convention on the Rights of Persons with Disabilities
HRA	Health Research Authority
IDA	Instant Data Analysis
LB	Louise Blakley – PhD student, main researcher and experienced Mental Health Practitioner in acute and crisis work
LEAP	Lived Experience Advisory Panel
MHA	Mental Health Act
NHS	National Health Service team or staff
NIHR	National Institute for Health Research
NM	Professor Nicola Morant – PhD supervisor
PIS	Participant Information Sheet
PMG	Project Management Group
PN	Dr Patrick Nyikavaranda – LEAP lead
R&D	Research and Development

REC	Research Ethics Committee
SAE	Serious Adverse Event
SJ	Professor Sonia Johnson – PhD supervisor
WP	Work Package

Contents

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1. INTRODUCTION

This research study focuses on improving the post-assessment experience of service users who undergo Mental Health Act (MHA) assessments, a critical but often distressing and confusing process in mental health care. The study is motivated by the growing concern over the rising number of mental health detentions and the poor experiences of service users during these assessments. Previous research shows that discussions between mental health staff and service users after MHA assessments are rare, despite the potential benefits of post-event reviews in improving understanding, service user-staff relationships, and service users' sense of procedural justice. Procedural justice refers to the perception that a legal process is fair, conducted with appropriate authority, and involves the service user meaningfully.

The study aims to co-design an intervention to facilitate discussions between mental health staff and service users following MHA assessments. The intervention is intended to increase service users' understanding, sense of fairness, and improve their future care. The study will unfold in three phases called Work Packages (WP). First, qualitative data will be collected through interviews with service users and focus groups with mental health staff to explore their experiences and perspectives (WP1). Next, workshops will be held to co-design a prototype intervention based on these findings (WP2). Finally, the prototype will be refined through user testing and real-world application (WP3). Involving service users throughout the process, the study anticipates that the intervention will enhance service user well-being, improve engagement with mental health services, and reduce the likelihood of readmission. Findings will be disseminated through publications, presentations, and collaborative networks.

This research study is part of Louise Blakley's (LB) doctoral research project which is being fully funded by through National Institute of Health Research fellowship. The NIHR Doctoral Clinical Practitioner Academic Fellowship (DCAF) supports health and social care professionals in pursuing PhDs while continuing clinical development and practice. This fellowship funds high-quality research training, allowing recipients to develop research expertise and advance evidence-based practice in their fields. It is highly competitive and aims to foster the integration of clinical and academic roles to improve service user care.

2. BACKGROUND AND RATIONALE

What is the problem being addressed

Internationally there is a call for mental health services to reduce the coercion, and to ensure that when coercion cannot be avoided, any possible measures to reduce its impact are taken (Gooding et al., 2018). Coercion in mental health includes admitting a person to a mental health hospital without their consent, known as involuntary admission, and other acts like restraint and seclusion, where a service user is restricted to one room alone. Involuntary admission is an ethically challenging and controversial aspect of health care ((Iudici et al., 2022). Up to 60% of service users disagree with the decision to detain them, even when asked retrospectively (O'Donoghue et al., 2011)(Priebe et al., 2009).Service user's views can become more positive over time, suggesting potential to change them (Akther et al., 2019).

A finding from coercion research is that service users distinguish between what is done to them and how it is done, so that the way someone views an act of coercion can be improved even if they disagree with the act (Gooding et al. 2018).

An under-researched area is the Mental Health Act (MHA) assessment in which professionals decide whether to involuntarily admit service users (Akther et al., 2019). This involves two doctors and a specially trained mental health professional (Approved Mental Health Professional (AMHP) interviewing the service user, often together. There is scant research on service users' experiences of the MHA assessment process and factors influencing them, despite growing evidence regarding experiences of involuntary stays in hospital(Akther et al., 2019). Louise Blakley (LB) has published the first study exploring these experiences based on interviews with 10 service users(Blakley et al., 2022) .These service users had little understanding of what had happened, felt they had little voice, and limited participation in this process which is deciding their liberty. Even when experiences had been distressing or traumatic, most had no subsequent opportunity to discuss them with mental health staff (Blakley et al., 2022).

This research study will fill this gap by increasing understanding of these assessment experiences and designing a post-assessment intervention to help service users reduce distress. The evidence suggests that a service user's views can change over time, so after is ideal for an MHA assessment intervention. Also, during the assessment, the service user can be acutely unwell and possibly unable to understand what is happening entirely, however well it is explained. This intervention will support a structured discussion between service users and staff so service users can understand their experience, feel assured of a fair process, and let their views known for future MHA assessments. The immediate impact of this intervention will be to improve the service user's well-being and care experience. A further benefit will be increasing clinical understanding of service user experience, which could inform future MHA assessment practices. Long-term benefits may include lowering subsequent assessment and the likelihood of readmission.

Importance of research

Service user experiences of the Mental Health Act (MHA) has become a critical area for policy and reform with a growing recognition of negative effects on service user well-being and engagement with services(Hughes et al., 2009). A crucial finding from the 2018 Independent MHA Review was that service users: "understood in retrospect why they needed to be detained… but not why it was such a needlessly unpleasant experience… if we cannot improve the experiences of people who are detained, we have failed."(Wessely et al., 2019). In qualitative studies exploring involuntary admission and advocacy, the MHA assessment experience is described as bewildering and confusing, (Newbigging et al., 2015; Smyth et al., 2016; van den Hooff & Goossensen, 2014) with service users advocating for improvements(Murphy et al., 2017). Forceful removal from your home and being deprived of your liberty can have a lasting negative effect on a service user and their family.

A growing area of coercion research is development of interventions to mitigate these negative impacts (Braun et al., 2023; Gaillard et al., 2023; Gooding et al., 2018; Iudici et al., 2022; Roche et al., 2014; Wullschleger et al., 2021). This study will build on learning from other forms of coercion to develop such an intervention tailored to MHA assessments. Such interventions typically include a structured discussion after restraint or seclusion, and formulation of an advance care plan, documenting service users' wishes in any future relapse (Gaillard et al., 2023; Wullschleger et al., 2021). The impact of these interventions has included an increased sense of feeling processes were fair(Wullschleger, et al., 2021), a better therapeutic relationship with staff (Gaillard et al., 2023; Wullschleger, et al., 2021), service user satisfaction in care (Iudici et al. 2022), and an increased sense of participation (Braun et al., 2023; Gaillard et al., 2023)

This research has potential to yield a route to reducing repeat detentions. The continuous rise in number of detentions in England is a major concern, with 53,239 in 2020-21(Smith et al., 2020) and these admissions are more expensive than the alternatives costing the NHS £1.0 billion in 2015/16

(Walker et al., 2019)]. Detention has limited clinical benefits, and a high social cost for service users, including negative impacts on relationships, housing, and employment (O'Donoghue et al., 2011). The biggest risk factor for detention is previous involuntary admissions (Walker et al., 2019)and the proposed intervention will have a possible mechanisms to reduce this risk. As it will be designed to improve the therapeutic relationship between staff and service users and a better relationship linked with fewer readmissions.

This study will develop an intervention which improves service user wellbeing and increases staff understanding, leading to better therapeutic relationships, and through the expression of wishes for next time, leading to reduced likelihood of MHA assessments and future detentions. (Bone et al., 2019; Iudici et al., 2022)

Review of existing evidence

This research is timely as there is a legal and policy focus on involuntary admissions. The new Mental Health Bill emphasises improving service users' experience and increasing their rights(Wessely et al., 2019). A priority in research and policy is becoming consistent with the United Nations Convention on the Rights of Persons with Disabilities (CRPD) which states that service users have rights in all decision-making even when acutely unwell (Braun et al., 2023; Burn et al., 2019; Iudici et al., 2022).

This research brings together three areas of research –post-restraint and seclusion intervention, procedural justice as the framework for improving the MHA assessment process, and advance care planning for mental health service users.

A post-incident review (PIR), after coercive events such as seclusion and restraint, is supported by NICE guidelines as good practice but a scoping exercise with 30 service users and 20 staff found little or no discussion following MHA assessments Participants advocated more discussion, cohering with literature on coercion (Bolsinger et al., 2020; Krieger et al., 2018). Service users have further highlighted the importance of communication when they are detained(Akther et al., 2019). The research study will explore why these discussions are rarely happening to inform a clear process for facilitating them in practice.

PIR can reduce the negative effects of these experiences of restraint and seclusion (Asikainen et al., 2023; Hammervold et al., 2022a; Wullschleger et al., 2021): the proposed intervention is intended to do similar with MHA assessments. PIR is a structured conversation between service users and staff (Asikainen et al., 2023). Outcomes of a randomised controlled trial of PIR included better therapeutic relationships following a mutual reflective process, significant reductions in trauma symptoms, and increased sense of procedural justice(Wullschleger et al., 2021). Evidence suggests service users feel more coerced with involuntary hospital admission than with restraint and seclusion (Iudici et al., 2022), but no similar intervention is offered as good practice.

Increasing service users' feeling of procedural justice has been shown to reduce feelings of coercion and negativity about involuntary admission(Monahan et al., 1995). The key factors are feeling assured of the neutrality and trustworthiness of the people carrying out the coercive act, being treated with respect and "voice" - having a chance to express your views (van den Hooff & Goossensen, 2014). The proposed intervention will help the service user express their views as well understand what happened to them. This discussion may enhance their confidence in the fairness and neutrality of the process as it has been evidence with PIR(Wullschleger et al., 2021). An international systematic review of the process for involuntary admission found that procedural justice was important to service users at this time (van den Hooff & Goossensen, 2014). Each of these findings has informed the need for this proposed study.

Advance care planning is the only intervention that has reduced involuntary admissions and is widely supported by service users (Bone et al., 2019; Gaillard et al., 2023). Even though respect of advance statements is legally required, recent research found that they are not currently standard practice (Abbott, 2022). All the participants in LB's previous research study raised some suggestions to make

their future assessment better, for example one participant want her mother present to ensure it was done fairly(Blakley et al., 2022). The draft MH Bill is supporting the creation of these plans and increasing their role (Wessely et al., 2019). Although not yet in legislation, practice is changing, and this proposed research could inform implementation.

The proposed intervention will combine two elements of a post-coercion discussion and advance care planning. The anticipated impacts are firstly increasing the service users' feelings of procedural justice. Secondly it will bring insights into the MHA assessment similarly to the outcomes of PIR, which encouraged learning on a service level and changed practice (Asikainen et al., 2023; Hammervold, 2021; Hammervold et al., 2022a)). Thirdly through increased dialogue and involvement in decision the service user becomes more active participants and more in line with their rights through CRPD (Braun et al., 2023; Gaillard et al., 2023; Hammervold et al., 2022a)

3. OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

3.1Primary Objective

To co-design a novel intervention to support discussion between mental health staff and service users after a Mental Health Act assessment to increase service users' understanding and sense of procedural justice and inform their future care.

3.2 Secondary Objective(S)

1. To conduct interviews to gain an understanding of a broader range of service user's lived experience of MHA assessment, what support they received afterwards, and their suggestions for a post-MHA assessment intervention. (WP1)

2. To conduct focus groups to explore mental health staff's views and to identify the facilitators and barriers to post-MHA support (WP1).

3. To facilitate workshops to co-design a prototype intervention with stakeholders for post-MHA assessment. (WP2)

4. To refine this prototype intervention through preliminary testing (WP3)

4. TRIAL DESIGN

The study design is an intervention development study over four years as a part-time PhD. It will follow a sequential and systematic co-design approach using the Medical Research Council framework for developing complex interventions (Skivington et al., 2021).

One major criticism of post-intervention reviews is that they have developed with little service user involvement. Consequently, there is no standardised version (Hammervold et al., 2019), and practicalities are not informed by service user preferences(Hammervold, 2021; Wullschleger et al., 2021). This study will develop an intervention using a collaborative approach with service users and carers using a tested framework. This methodology has been chosen as it uses knowledge from service users on how best to do the intervention and staff to advise on systemic issues and how to embed in good practice (O'Cathain et al., 2019; Skivington et al., 2021).

The intervention is envisaged to consist of two elements to be developed and specified in an intervention manual:

1) Practicalities and content - to optimise staff and service user involvement. Including areas like the timing, number of sessions and areas to cover in the discussion.
2) Resources for staff - as guidance and training resources which will enable staff to facilitate the structured discussion.

Patient and Public Involvement

This study will involve input into the research planning, data collection and analysis from people with lived experience of MHA assessments, recruited to a LEAP. Additionally, LEAP members will be funded and trained to become Lived Experience Researchers. Full details see Section 15.3.

4.1. Work package 1 (WP1) evidence gathering

The first work package will involve gathering evidence to inform the development of novel intervention. This will include examining the current evidence, undertaking qualitative interviews with service users (up to n=20) and 4-5 focus groups with clinical staff (up to n=20). If low recruitment of a particular professional, then individual interviews will be offered.

4.2. Work package 2 (WP2) Co-designing workshops with stakeholders

In this work package, there will be 2 creative-based workshops with up to n=20 attendees at each event (n= 40). The first workshop will share the findings from WP1and through using techniques like mapping, brainstorming and story boards to engage attendees and create a few potential ideas for the intervention. The second workshop will refine these ideas using their collective knowledge of setting and MHA assessment experience. These workshops will also develop a programme theory to understand the mechanism of change that the intervention is targeting. The LEAP and project management group (see15.2) will oversee and support prototype development. At the end of this work package, there will be a prototype.

4.3. WP3 testing and refining prototype

This work package has two stages using a cyclic process and after each test, feedback is gained from participants to use for refinement of the intervention.

1. User testing of the prototype intervention using an adapted talking aloud method n=6 clinical staff participants.
2. Real-world testing with n=6 service user participants and their clinical staff n=6.

5. SAMPLING METHODS

5.0.1. Sampling service user participants for WP1

Participants will be recruited from three sites: North London NHS Foundation Trust, Hampshire and Isle of Wight Healthcare NHS Foundation Trust, and Sussex Partnership Trust. Purposive sampling will ensure that the sample is representative of the service user population who experience MHA assessments. We will aim to disproportionately recruit men and people from minoritised ethnic groups, to reflect the demographics of the population who are assessed. Purposive sampling will be used to ensure a broad range of experiences are represented, including regard to outcomes (detention, voluntary admission or no admission), time since assessment (ranging from initial weeks to longer periods) and number of previous detentions (first time and multiple).

5.0.2. Sampling staff participants for WP1

Purposeful sampling will be used to ensure the representation of both inpatient and community settings, different Trusts and professional groups. Focus groups have been chosen to reflect the multi-disciplinary nature of assessments, aiming to highlight differences and commonalities across Trusts with the potential to inform choices regarding the intervention (O'Cathain et al., 2019; Skivington et al., 2021).

Additional individual interviews will be used to include professionals not represented in the focus group. Purposeful sampling will be used to ensure the representation of both inpatient and community settings, different Trusts and professional groups.

5.0.3. Sampling for Stakeholder participants for WP2

Sampling for the workshops will ensure representation of different MHA act assessment perspectives including people with lived experience of MHA assessment, carers, clinical staff involved in these assessments like Approved Mental Health Professionals and Section 12 Doctors, staff working in community and inpatient mental health teams, managers, mental health leads, voluntary sector and policymakers. We will also seek demographic variation if possible and target recruitment.

5.0.4. Sampling for staff and service user participants for WP3

Sampling for Staff and Service user participants will be from the three NHS sites. We will aim to make sure we include some men and some people from minoritised ethnic groups at highest risk of detention within our small sample of service user participants

5.1 Inclusion criteria

5.1.1. Service user participants WP1

Eligible participants will:
(a) have experienced and remember the Mental Health Act assessment
(b) be able and willing to discuss this experience,
(c) be aged 18 and over and under 65
(d) have the capacity to consent at the time of recruitment.

5.1.2. Staff participants WP1

Eligible participants will be:

(a) currently involved in MHA assessments as an Approved Mental Health Professional or Section 12 Doctor or Consultant psychiatrist
or (b) working with service users who have experience MHA assessments and work within a Crisis, community mental health team or inpatient unit as a nurse, psychiatrist, psychologist, social worker or occupational therapist.

5.1.3. Staff, stakeholder and lived experienced participants (for WP2 workshop)

Eligible participants will be:

(a) stakeholder in Mental Health Act assessment includes as person with lived experience, carer (e.g. partner, family or close friends), staff with direct service user contact, mental health clinical leadership and management, policy maker or charity and voluntary organisation.
(b) willing and able to attend either one or both of the workshops.

Additional criteria for lived experience participants:

Previous experience of using their lived experience, whether as a service user or unpaid carer, in research, educational or service development setting and have experience of a MHA assessment.

5.1.4. Staff participants WP3 testing and refining

The eligible staff participants will be:
a) staff that work in role and setting which is relevant to prototype intervention being designed in WP2.
b) be willing to be trained and test the prototype intervention,
c) be willing to be interviewed after the testing and share thoughts and ideas.

User testing criteria: Staff participants to be new to the prototype intervention, i.e. not a participant in any other WP.

Real-world testing criteria: Staff participants may or may not have been involved in previous work packages.

5.1.5. Service user participants WP3 testing and refining

Eligible participants will:

(a) have experienced a Mental Health Act assessment within the last year
(b) be able and willing to discuss this experience using the prototype intervention
(c) be aged 18 and over and under 65
(d) have capacity to consent at the time of recruitment.

5.2 Exclusion criteria

5.2.1 Service user participant (for WP1 and WP3)

Participants will be excluded if:
(a) they have a diagnosis of dementia or a brain injury
(b) over 65 years old
(c) do not speak sufficient English to take part without an interpreter
(d) lack capacity to consent
(e) no memory of MHA assessment.

5.2.2 Staff, stakeholder and lived experienced participants (for WP2 co-design workshops)

Participants will be excluded if:
(a) have a diagnosis of dementia or a brain injury
(b) over 65 years old
(c) do not speak sufficient English to take part without an interpreter
(d) lack capacity to consent

5.2.3. Staff participants (for WP1 and WP3)

None specified

5.3 Recruitment

Overview

Participants will be recruited from three NHS Trusts: North London NHS Foundation Trust, Sussex Partnership NHS Trust, and Hampshire and Isle of Wight Healthcare NHS Foundation Trust for WP1 and WP3. These sites include urban and rural areas to ensure a diverse participant population. Recruitment strategies will vary based on participant type (service users, staff, and stakeholders) and work package (WP1, WP2, WP3). WP2 will adopt a distinct recruitment strategy, extending beyond the three study sites to include national recruitment. WP2 will specifically recruit individuals with lived experience of Mental Health Act (MHA) assessments who have prior experience collaborating with professionals in research, education, or service development.

Recruitment of Service Users (WP1 and 3)

Methods of Recruitment:
Service users will be recruited from acute inpatient wards, community mental health teams, and service user and carer groups. Recruitment strategies include:

- Information Sharing via NHS Staff**:** Staff will be informed about the study through Trust R&D departments, service managers, and Research Delivery Staff. Staff will identify and approach eligible service users, providing basic study information and recruitment materials (posters, flyers, participant information sheets).
- Direct Self-Referral: Service users who see study advertisements (e.g., posters, social media, advocacy networks) can contact the research team directly When they contact, they will be asked permission to contact their care team to confirm suitability and capacity.
- Targeted Databases: In sites where service users have pre-agreed to be contacted about research, R&D staff will reach out to those who meet the inclusion criteria.
- Use of Patient Record System: Depending on the record system, it may be possible, to identify NHS staff working with eligible service users to target recruitment through using data analytics. This method was used in LB's previous research and does not involve any screening of personal identifiable data.
- Community Engagement: The research team will liaise with advocacy organisations and voluntary sector groups to promote the study.
- Lived Experience Researchers involvement in recruitment: Where appropriate, to increase recruitment LEAP members will be trained and paid to support recruitment by attending

community meetings on wards and other mental health settings. This approach been used successful in other studies and will be used if difficulties in recruitment.

- Diverse sample: To ensure that participants represent the population that are assessed/ detained under the MHA, there might be targeted recruitment and adaptation of materials. For example, men and black people are overrepresented in detention figures.

Recruitment of Staff Participants (WP1 and 3)

Methods of Recruitment:

Staff participants will be recruited through:

- Email Invitations: Trust R&D teams, senior managers, and service leads will distribute recruitment emails with study details with their approval.
- Advertising within trust communication channels.
- Workplace Promotion: The research team will attend staff meetings to introduce the study and answer questions.
- Targeted Outreach: If the patient record system allows identification of staff working with service users recently assessed under the MHA, they may be sent study information directly by R&D team.
- Following agreement of staff participants in other work packages and if meet criteria, then emails invitation sent about the real-world testing stage of WP3.
- Self-referral or via information shared by managers.

Recruitment for Work Package 2 (WP2) – Co-Design Workshops

Methods of Recruitment:
WP2 involves a wider range of stakeholders, including people with lived experience, unpaid carers, staff with direct service user contact, senior and leadership staff within mental health, policymakers, and voluntary sector representatives. Recruitment methods include:

- Social media and Professional Networks: Study advertisements will be shared on NHS Trust websites, Mental Health Policy Research Unit (UCL), research networks, national organisations, social media sites, and national and local mental health groups.
- Email Invitations: Individuals in the research team's network and those identified as key stakeholders will receive study information.
- Self-Referral: Interested individuals can register their interest online.
- Follow-Up Contact: Those who register interest will receive an email with further details and we will offer a phone/video call to discuss participation dependent on potential participants knowledge of the study and workshop.
- People with lived experience and carers will all be offered a phone or video call to discuss participation

Recruitment Timeline and Approval

Participant recruitment at a site will only commence when the trial has:

1. Been confirmed by the Sponsor (or it's delegated representative), and
2. Been issued with Confirmation of Capacity and Capability from each participating site (where applicable).

Participant Expenses and Compensation

All participants in WP 1 and WP3 will receive a £20 voucher as a thank-you for their time. In WP2 the co-design workshops the lived experience participants will receive £40 in vouchers to acknowledge the additional time commitment. Travel expenses for participants will be reimbursed where applicable.

5.4 Informed Consent

Service user participants

Screening, Eligibility and Initial Contact:

NHS staff will discuss the study with service users and confirm permission to share their details with the research team. Their contact details will be sent via secure email. If the service user directly contacts, permission will be sought to speak to the care team or staff member to check whether they believe service users are at a suitable stage of recovery and likely to have capacity to agree to be a participant.

The research team will arrange a meeting via telephone or video conferencing and provide further information on the study, share Participant Information Sheet, and answer any questions. The researcher will discuss that if they take part in study then their care team and GP will need to be informed. Eligibility will be confirmed by checking basic details, for example, experiences of MHA assessment, and, if service user agrees then, arrange a meeting to obtain consent. A minimum of 24 hours will be given for participants to decide whether to take part.

Staff Participants

Screening and Eligibility

Interested staff will receive the Participant Information Sheet and be invited to discuss the study further with research team. Staff can self-refer to the research team. Eligibility will be confirmed by checking role and, if agree agrees then, arrange a meeting to obtain consent. A minimum of 24 hours will be given for participants to decide whether to take part.

Consent for all participants

Full written informed consent will be taken by a member of the research team who is suitably trained with local NHS approvals and will have been delegated this duty by the CI/ PI on the Staff Signature and Delegation of Tasks. Some participants may prefer to meet with the research team remotely. Participants will be given the Participant Information Sheet (which includes the HRA's GDPR recommended wording) and will have the opportunity to ask questions. Participants will have adequate time to consider if they want to take part (at least 24 hours). Participants will be deemed to have capacity to consent if they understand the purpose and nature of the research, risks and benefits once going through the information sheet with a researcher and are able to retain the information long enough to make an informed decision.

The researcher will explain that participants can choose freely whether they wish to enter the study and that they can withdraw at any time during the study, without having to give a reason and without prejudicing his/her further treatment. Data collected up to the point of withdrawal will only be used after withdrawal if the participant has consented for this, which is outlined in the consent form. The participant will be offered a chance to choose a pseudonym name for the research outputs, and this will be added to consent form. This name will be part of the participant ID.

No study procedures, including the collection of identifiable participant data will be conducted prior to the participant giving consent by signing the Consent form. Consent will not denote enrolment into study.

If the participant meets with the study researcher remotely, consent will be obtained via taking an audio-recording of participants' verbal agreement with each clause in the consent form. Audio-recordings of consent to take part in the study will be separately and securely stored in the protected UCL online system. Participants will also be sent a copy of the consent form in advance, giving them time to read the statements and providing them with a copy of the sheet for their records. Medical records will be updated to show participation in the study.

For those who meet with the study researcher in person, a copy of the signed Informed Consent form will be given to the participant. The original signed form will be retained in the Investigator Site File and a copy placed in the medical notes.

Staff will be offered an online consent form to assist with recruitment process and reduce burden for busy staff to be able to participate.

WP2 Workshops

Screening and eligibility:

Interested people will be able to register their interest online and fill in information about the group they belong to (such as a person with lived experience, carer, or staff), experience of MHA assessments, knowledge of study, previous experience in collaborative workshops, a brief reason for wanting to attend and email details. The first approach will be via email, where the Participant Information Sheet will be shared. The information completed on online form will assist with screening and eligibility. A follow-up call or video conference will be offered to provide more

detailed information and answer any questions to all people with lived experience including carers and other stakeholders with limited knowledge of the study.

Persons with Lived Experience and carers: Before confirming their participation in the workshops, individuals with lived experience will be offered a telephone or video call with research team. This meeting will provide an opportunity to discuss the workshop's purpose, structure, and expectations. It will also ensure that participants are eligible through having prior experience in applying their lived experience collaboratively with professionals in research, service development, or educational settings. Engaging in workshops alongside professionals and other stakeholders can be complex and potentially overwhelming. Prior experience ensures that participants feel confident in contributing meaningfully to discussions, have had previous opportunities to engage with staff, and are prepared to share insights based on their experiences in a collaborative setting. This preparatory discussion aims to support informed participation and ensure that individuals feel confident and prepared for engagement in a multi-stakeholder environment.

To include a wide range of perspectives, extra interviews or group meetings will be held with stakeholders who can't attend the co-design workshops. These sessions will cover the same topics as the workshops, with Workshop 1 focusing on generating ideas and Workshop 2 refining those ideas and addressing practical challenges. This ensures that the final design will be practicable and acceptable.

Participants will have at least 24 hours to consider their involvement before providing informed consent.

Consent

Interested individuals will register for the event via an online system, providing their contact email, the group they belong to (e.g., people with lived experience, unpaid carers, staff with direct service user contact, senior and leadership staff within mental health, policymakers, and voluntary sector representatives.), and a brief explanation of why they would like to attend. This information will support the sampling strategy. The relevant Participant Information Sheet will also be shared with them.

Informed consent will be obtained in three possible ways:

1. Via a meeting with the study team.
2. Through an online consent form.
3. Using a paper consent form prior to the event.

The study team will decide the most appropriate method based on the need for a discussion with potential participants to explain the purpose and format of the workshops and to address any queries. For individuals with lived experience and carers, a meeting will be offered via video conferencing, and consent will be obtained online.

For staff, representatives, and other professionals, the study team will exercise discretion in deciding whether a meeting with a researcher is necessary. One key consideration will be whether the individual has sufficient prior knowledge of the study. Online consent will be offered as a standard option, and if the online form is not completed before the workshop, consent can be obtained at

registration on the day of the event. This flexible approach ensures that busy staff are enabled to attend the workshop without unnecessary barriers.

Consent will be checked that it has been completed prior to participants involvement in workshop.

After consent has been completed, participants will be asked to fill in a non-identifiable demographic form.

1. Meeting with the research team to complete consent, then researcher can assist with completion of demographic form. This option will be offered if anyone struggles with filling in forms.
2. Online- the consent form will include a link to the demographic form to be completed electronically
3. At Workshop –Paper demographic form will be completed subsequently to any paper consent form.

For whole study

The researcher will explain that participants are under no obligation to enter the study and that they can withdraw at any time during the study, without having to give a reason and without prejudicing his/her further treatment. Data collected up to the point of withdrawal can only be used after withdrawal if the participant has consented for this. Any intention to utilise such data should be outlined in the consent form.

The PIS and consent form will be reviewed and updated if necessary throughout the trial (e.g. where new safety information becomes available) and participants will be re-consented as appropriate.

6. PRODUCT/INTERVENTIONS

6.1. Intervention being developed

As this is an intervention development study, the specific details of the intervention will be determined based on evidence gathered in Work Package 1 (WP1) and through a collaborative, creative co-design process in Work Package 2 and 3 (WP2/3).

The intervention aims to support a structured clinical discussion between staff and service users following a Mental Health Act (MHA) assessment. It is envisioned that the intervention will have two key components:

1. **Practicalities and Content:**
    a. Designed to optimise staff and service user participation.
    b. Will address factors such as the timing of the discussion, the number of sessions required, and the key topics to cover.
2. **Resources for Staff:**
    a. Includes guidance and training materials to help staff facilitate the structured discussion effectively.

Drawing on principles from other post-coercion interventions, the proposed intervention may include similar elements, such as:

- Providing service users time to share their perspectives and reflect on their experiences.
- Offering emotional support to service users.
- Reviewing the event and factors leading up to the coercion.
- Identifying lessons for staff and the organisation.
- Collaborating with the service user to develop a plan for managing future crises (based on approaches by (Goulet & Larue, 2016; Hammervold et al., 2022b))

The exact staff responsible for delivering the intervention and the timing of its implementation will be explored further in the WP2 workshops. These decisions will consider practical factors and stakeholder expertise.

Currently, the intervention is anticipated to be a short-term measure, delivered over one or two structured sessions.

6.2. Qualitative interviews and focus groups for the intervention development:

Qualitative interviews will be conducted with up to n=20 service users and focus groups and if needed individual interviews with up to n=20 clinical staff who meet the above criteria (Section 5.1.1, 5.1.2 and5.2.1) and to inform the intervention development.

The topic guide for the service user interviews (WP1) will build on LB's previous research (Blakley et al., 2021) and will be co-designed in collaboration with the Lived Experience Advisory Panel (LEAP). It will focus on three primary areas:

1. **Assessment experiences**: Exploring experiences related to procedural justice components, including service user involvement, respect from staff, the fairness of the process, and the impact of assessments.
2. **Post-assessment reflections**: Investigating perceptions of support, opportunities for discussion, and future planning provided after the assessment.
3. **Suggestions for improvement**: Understanding what participants would have preferred to happen and gathering their suggestions to inform intervention development.

The topic guide for the staff focus groups will be developed in collaboration with the supervisors and the Chief Investigator (CI), drawing on their clinical expertise. These guides will incorporate initial themes emerging from service user interviews to facilitate discussion.

The topic guide for WP3 interviews will be developed following WP2, once the purpose and components of the intervention are clarified. LEAP and the project management group (see 15.2) will actively contribute to this process.

Draft topic guides have been developed for the sponsorship and ethic approval process (see

These interviews and focus groups will be conducted by LB as part of her PhD, with the following arrangements:

1. **Service user interviews**: If participants consent, interviews will be conducted jointly with a member of the LEAP group. The LEAP member will receive training in qualitative interviewing and analysis. For the initial interviews, LB will take the lead, transitioning to a more supportive role as the LEAP member's skills develop.
2. **Focus groups**: LB will facilitate the focus groups, supported by a member of the research team to ensure effective delivery and discussion management.

Recognising that, for many service users, this may be the first time they have discussed their experiences, it is important to offer them the opportunity to receive their interview transcripts. Participants in Work Packages 1 and 3 will be given the option to be sent an anonymised transcript of their individual interview, either via email or by post, according to their preference

Participants will be offered a high street shopping voucher of £20 as thank you for the time given and travel expenses will be reimbursed.

Analysis

These interviews will be transcribed and thematically analysed, focusing on content relevant to development of the intervention. The team will use a thematic analysis (Braun et al., 2018) facilitated by NVivo software and a collaborative approach using Saunders (2023). To minimise bias and ensure emerging themes are valid, development of codes and themes will be done collaboratively, led by LB with input from supervisory team and trained LEAP members. With further validity, through a supervisory team member conducting a second coding of 20% of transcripts and the use of reflexive diary by LB and field notes after each interview/ focus group. To ensure transparency, a clear audit trail will be saved on NVivo. Data analysis will be conducted in collaboration with lived experience researchers and the LEAP group, following best practice guidelines to ensure a rigorous and inclusive approach (Jennings et al., 2018; Saunders et al., 2023) .

6.3. WP2 Co-design Workshops

Intervention design will be based on a creative co-design approach through 2 workshops with N= 20 participants for each workshop. Two stakeholder workshops will be organised and facilitated by the research team and Lived Experience Advisory Panel (LEAP) members. The workshop's objective is to produce a prototype of the intervention for testing. A co-design approach has meaningful service user involvement (Slattery et al., 2020) and is advocated for "groups who are often excluded from research" s (Moll et al., 2020; O'Cathain et al., 2019; Slattery et al., 2020b). Using creative methods overcomes challenges like power, language, and time. The creative methods such as mapping, brainstorming, concept posters and storyboards to engage participants and share and develop ideas for innovative solutions(Langley, n.d.; Moll et al., 2020; O'Cathain et al., 2019) Extra support will be given to service user and carer participants to help them attend and participate.

For the co-design workshops, it is critical to include a wide variety of perspectives from diverse stakeholder groups. However, recognising that some interested individuals may not be able to attend due to scheduling conflicts or other barriers, supplementary interviews or small group meetings will be conducted. These additional sessions will aim to gather input from underrepresented stakeholder groups, ensuring their perspectives and ideas are incorporated into the development process.

The supplementary interviews or meetings will cover the same areas as the workshops. For **Workshop 1**, this will involve generating intervention ideas, discussing the findings from WP1, and brainstorming potential solutions. For **Workshop 2**, the focus will shift to refining proposed interventions, addressing implementation challenges, and discussing the feasibility of ideas. These sessions will help ensure the intervention design reflects a broad range of experiences and needs.

Workshop 1 – Idea generation

The first workshop will involve generating intervention ideas and drafting the logic model. Key findings from WP1 will be shared. Areas covered may include the impacts on service users of the MHA assessment, such as aspects resulting in confusion and perceived unfairness. Current practice will be compared with service user and carer views about what would ideally post MHA. Both service users and staff participants will be encouraged to make suggestions for the intervention. The LEAP will help develop easy-to-understand visual representations of findings data analysis.(Grindell et al., 2020a; Langley, n.d.; O'Cathain et al., 2019) . Intervention ideas will be refined through a series of activities and polls (Grindell et al., 2020a; Langley et al., 2018)

By the end of the workshop, attendees will have voted on the best intervention ideas. the research team will produce a mock-up of one or two top ideas, highlighting key elements and alternative options for Workshop 2 discussion. A storyboard and/or draft resource will represent the ideas, providing a tangible focus for further development (Grindell et al., 2020b)

Workshop 2 – further designing and selecting for prototype

In Workshop Two the draft logic model with key components will be shared and discussion and agreement on key intervention components. Then the participants will refine the intervention and assess ease of use and practicality. Ideas for the manual for the intervention will then be discussed, as well as implementation challenges.]. An accompanying draft logic model will also be produced from this workshop.

The research team will further draft the intervention manual incorporating ideas from Workshops. The Template for Intervention Development and Replication (TIDieR) checklist will be used to ensure key ingredients are all specified(Hoffmann et al., 2014).

The outputs from this Work package will be, a prototype intervention including accompanying draft resources and a logic model.

7. TRIAL PROCEDURES

This study involves a novel clinical intervention; however, it is not a full clinical trial. The intervention will be delivered on a small scale to a maximum of six individuals using NHS services, primarily to test feasibility, acceptability, and usability in a real-world setting. The purpose at this stage is not to evaluate clinical efficacy or compare outcomes against a control group, but rather to refine the

intervention and understand its implementation in practice. It does appear to fall under the definition of a clinical trial as outlined by the Medicines for Human Use (Clinical Trials) Regulations 2004 as it involves administration of novel clinical intervention.

As the study has no pre-intervention assessments as not assessing clinical efficacy. The following section will look at procedures for Work Package 3 (WP3), which focuses on testing and refining the intervention

7.1.1 Intervention Procedures

The primary outcomes of WP3, are to ensure its acceptability and practicality and to explore participants' experiences with the intervention through qualitative interviews.

In WP3, the research team will iteratively test and refine the prototype intervention. This will begin with **User Testing** (see Section 5.0.2 for Sampling of Clinical Staff and 5.2.2 for Inclusion Criteria) involving staff participants, followed by **Real-World Testing**, which includes both staff and service user participants (see Section 5.0.1 for Sampling and 5.1.1 for Inclusion Criteria) (O'Cathain et al., 2019). This process is designed to ensure the final intervention is acceptable, feasible, and engaging.

Real-world testing often highlights unexpected challenges in implementation (O'Cathain et al., 2019; Joe et al., 2015). Identifying and addressing these issues during the testing phase helps to refine the intervention and resolve problems before moving to more costly and time-intensive feasibility trials. A small sample size is sufficient for this phase, as the goal is to evaluate intervention acceptability and usability rather than generalizability.

The **Instant Data Analysis (IDA)** process will be used to maximize the usefulness of testing sessions (Joe et al., 2015). This approach combines interviews and brainstorming immediately after testing, allowing the team to address issues while they are fresh in participants' minds. Simple changes will be rapidly incorporated into the intervention between testing cycles, while more complex refinements will be reviewed and agreed upon with the research team and the Lived Experience Advisory Panel (LEAP).

'User testing' cycle

Staff participants = 6 will test the prototype intervention and accompanying intervention manual in role plays with a person with lived experience of MHA assessment from the LEAP group. This testing will be recorded and observed by a member of research team. They will receive the intervention and any training resource in advance of the testing. An adapted 'thinking aloud' (Joe et al., 2015; O'Cathain et al., 2019) procedure will be used, inviting participants to share thoughts and comments on the intervention as they use it. Minor amendments will be made prior to the next user testing.

''Real-world testing' cycle

This testing cycle will involve evaluating the prototype intervention with a staff participant and a service user participant. The staff participant will receive the intervention and any training resource in advance of the testing.

Staff participants will identify service users they work with who meet the sampling criteria (Section 5.1.1). If a service user agrees to participate, they will be consented either together with the staff participant or separately. If both parties are agreeable, the testing session may be recorded; this recording is optional.

The follow-up interviews can take place immediately after the intervention or on a later date, depending on what can be arranged. Staff and service user participants will be interviewed separately to ensure free expression of their views. If both parties agree and it is practical, a joint interview may also be conducted. All interviews will be recorded and will focus on engagement, usability, and the value of the intervention, as well as suggestions for improvement.

As part of user testing, minor refinements to the intervention will be made after each testing session, while more complex adjustments will be undertaken in consultation with the research team.

Following the completion of WP3, interview recordings and field notes will be reviewed to refine a logic model, describing the key components of the intervention, contextual factors affecting how it is delivered, it's perceived impacts and the mechanisms by which they are achieved. Together with a description of the iterative development of the intervention will be written up as an academic paper.

7.2 Discontinuation/withdrawal of participants

In consenting to participate in the trial phase (WP3), participants are consenting to testing the and interview following. It is a one-off session.

It is always within the remit of the physician responsible for a service user to withdraw the service user from a trial (or certain aspects of the trial) for appropriate medical reasons, adverse events or new information gained about an intervention. A participant may be withdrawn from this WP whenever continued participation is no longer in the participant's best interests, but the reasons for doing so must be recorded. Reasons for discontinuing may include deterioration in mental health.

The decision to withdraw a participant from treatment will be recorded in the CRF and medical notes/electronic health record system. If a participant explicitly states they do not wish to contribute further data to the trial their decision must be respected and recorded in the CRF and medical notes. Any inclusion of collected data needs to be used in accordance with GDPR and HRA guidance.

7.3 Definition of End of Trial

The expected duration of the trial is 2.5 from recruitment of the first participant.

The end of trial is the date of the last testing session of the last participant in WP3.

8. FINANCE AND SUPPLY OF EQUIPMENT

The research costs for this study and LB's doctoral program have been supported by the National Institute for Health Research (NIHR) Academy through the Doctoral Clinical and Practitioner Academic Fellowship award. The award provides £ 320,00 and covers all research costs, service user and public involvement (PPI), PhD fees, and LB's salary. The doctoral study commenced in October 2024 to October 2028.

The research team has no financial interests or commercial ties related to this study. The study aims to develop an intervention to reduce distress, enhance service users' understanding and increase future involvement through advance care planning. The resulting intervention will be made freely available upon the study's completion.

There is no conflicting interests.

The staff time spent delivering the intervention will be considered an excess treatment cost associated with the study, which will be calculated and reported in a SoECAT form. The WP3 intervention will be delivered by currently employed practitioners as part of their regular work schedule, requiring no additional staffing.

9. DATA MANAGEMENT

9.1 Confidentiality

The study is compliant with the requirements of the General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018). All Investigators and study site staff will comply with the requirements of the General Data Protection Regulation (2016/679) with regards to the collection, storage, processing and disclosure of personal information, and will uphold the Act's core principles. UCL is the data controller; the UCL Data Protection Officer is Alex Potts (data-protection@ucl.ac.uk). The data processors are UCL research team and NHS staff.

Personal Data will be collected directly from participants and no data from the medical record systems by the UCL research team.

The study will be collecting the following personal data:

All participants:

- Name
- Contact details for arranging interview/ focus group/ workshops or testing (email or telephone details).
- Contact (address or email if the participant requests research findings, dissemination events or further information on study).
- Demographic information (gender, age, ethnicity).

For service users participants:

- GP and care team details.

- Mental health history (self-reported diagnosis, duration of contact with mental health services).
- Experience of MHA assessments (number of assessments, outcomes such as detention or voluntary admission).

For staff participants:

- Professional role (e.g., Approved Mental Health Professional, Psychiatrist, Community Mental Health Nurse).
- Work setting (e.g., inpatient, community mental health, crisis services).

Data Storage

Depending on the data it will be stored differently and is summarised below.

a) Forms and data with **participant names and other identifiable details** will be stored electronically with UCL Data Safe Haven or paper consent in locked storage. Only research team members who need access and they will have contracts or honorary UCL contracts and be trained on data protection and Data Safe Haven.

   For example, i) Participant name and ID list. All participants will have chosen a pseudonym name for the study and the ID will be this name and a number.
   ii) Participant name and contact details for arranging participation in study. For staff information on team. For service users in WP1 and WP3, GP and care team details for informing them of participation in the study.
   iii) Participant name and email/ postal address for sharing further information on study, dissemination events and report/ findings (if participant agrees on Consent Forms).
   iv) Consent Forms – Paper stored in locked storage and will be scanned to Data Safe Haven, or an electronic recording will be stored similarly.
   v) Recordings of interviews or focus groups prior to transcribing.

b) Forms with **Pseudo-anonymised** information will be stored in a separate folder (electronically on UCL Data Safe Haven or paper in locked storage). This data will be kept separate from personal identifiable data to further safeguard confidentiality.

   For example, i) Case Report Form (see list of details on the form below)

   ii) Demographics forms with Participant ID (age, ethnicity, gender, service users - mental health service information and staff – role and profession).

c) **Anonymised** research data will be stored on UCL one drive and/ or UCL NVivo data analyst software, and all paper information will be scanned or photographed. This data will be shared with research team including members of the LEAP. Access to the folders on One drive and NVivo will be limited accessed to named people and not available to wider UCL staff. During the interview and focus group, researchers will refrain from using participants names. Transcripts will be checked for any identifiable information by lead researcher (e.g. removing names of any people, organisations or places from the text).

   For example, i) Anonymised transcripts.
   ii) Notes and data from workshops
   iii) Reflective memos after interviews/ focus groups.
   iv) Drafts of intervention.

Other data recording, NHS staff will add a note to medical records of service user participants in WP1 and WP3. NHS sites will manage any paper or electronic data in secure facilities as described in their Standard Operating procedures or policies.

If any paper documents with Personal Identifiable Details will be in a locked bag if being moved between buildings from interview or focus group setting to the secure storage at UCL.

Information on Case Report Forms

The Case Report Forms (CRFs) will not bear the participant's name or other personal identifiable data. The forms will have the participant ID number. These CSF will include participant demographic and mental health diagnosis and MHA assessment or role details, work package, consent type, researcher observations from interviews, focus group or testing session, participant suggestion, any emotional responses, any adverse events and any post-session actions or support provided.

Data custodian is Professor Brynmor Lloyd-Evans (BLE).

Data transfer

This will happen in two instances

a) Between NHS sites and research team via secure email
b) Interview and focus group recordings will be transferred to an approved UCL transcription provider.

Data maintenance responsibility is UCL research team.

Data storage timelines

Forms with participant names and contact details for arranging data collection (interviews, focus groups, workshops and testing sessions) will be stored for i) deleted immediately if person decides not to participate in study, ii) at the end of recruitment stage of each work package, if not participating, iii) at end of study or iv) after findings and dissemination shared if participant agreed.

Research data will be stored for 10 years in line with UCL policy. This data will include consent forms/ recordings, transcripts and other research documents,

Breaches in confidentiality

During the study, it is possible that a participant may disclose a serious risk of harm to themselves or to others. In these instances, we would seek participants' consent to share the necessary information with the relevant clinical team. If this consent was not given, the participant would be made aware of the need to breach confidentiality in such instances in the Participant Information Sheet. Depending on the circumstances and time permitting, the researchers will seek advice from more senior research staff like the supervisors (Professor Sonia Johnson (SJ) and Professor Brynmor Lloyd-Evans (BLE)who are qualified mental health practitioners). Where the need to breach confidentiality was confirmed, the researcher would then contact a care coordinator or other appropriate clinician involved in the participant's care. However, if the concerns were immediate, we would breach confidentiality immediately, and contact the relevant safeguarding advisors and others, such as emergency services, as appropriate. This would be judged on a case-by-case basis, and confidentiality would only be breached for serious disclosures where there is substantial concern about immediate risk to self or others

9.2Data collection tools and source document identification

Data will be collected from participants by the research team and will be recorded specific case report forms (CRFs) or data collection tools such as electronic CRFs.

Where participant data is collected remotely through videocalls, we will leave a file note on the CRF documenting where (on the UCL Data Safe Haven) the audio-recorded data are stored. Similarly, any paper copies of forms (e.g. consent and demographic forms) location will also be recorded on CRF.

In this study, there is little source data and documents like the demographic information will be transcribed onto the CSF.

A source document list will be implemented prior to the start of the trial to identify:

- which data is to be recorded directly onto the CRF.
- which data is recorded firstly into source documents, such as medical notes, and then transcribed into the CRF; and
- which data is not to be recorded in the CRF but only recorded in source documents, e.g. participant questionnaires.

It is the responsibility of the investigator to ensure the accuracy of all data entered in the CRFs. After the delegation log will identify all those personnel with responsibilities for data collection and handling, including those who have access to the trial database.

For this study the data contained in CRF will be only taken from the participants and probably include the following:

- Demographic information and diagnosis
- Basic information about experience of MHA assessments, outcomes and other mental health history
- Roles and profession
- Type of consent given either on paper or an audio file for online.
- Who interviewed or which focus group attended (WP1)/ Workshop attended (WP2)/ Test session (WP3) with whom
- If any distress/ emotional response experienced in the interview
- Any adverse events
- Any details of the support plan agreed by the research team member and the participant.

Transcripts of Interviews and Focus Groups (WP1 and WP2) After the interviews and focus group data are transcribed, then the lead researcher LB will fully anonymise them through removing any direct or indirect personal identifiable details, for example, mention of named hospital or teams. Fully anonymised versions of the transcripts will be analysed using NVivo software and saved on UCL online drives with access limited to the research team, including Lived Experience Researchers (LEAP members) and the supervisory team.

9.3Completing Case Report Forms

For this study, the CRF will be completed by the UCL research team and will be stored immediately on UCL Data Safe Haven electronically.

9.4Data Handling

In the study, data will be collected from service users in accordance with the service user consent form, participant information sheet and sections [9.1] of this protocol.

The data will be collected by the UCL research team and NHS staff and UCL will act as data controller will act as the data controller of such data for the study.

Louise Blakley, Division of Psychiatry, Maple House, Wing A, 4th Floor 149 Tottenham Court Road, London, W1T 7NF will process, store and dispose of data in accordance with all applicable legal and regulatory requirements, including the Data Protection Act 2018 and any amendments thereto. Data which either personal data or pseudonymised will be stored centrally electronically on Data Safe Haven or in locked storage at UCL.

The data will not be transferred to any party not identified in this protocol and are not to be processed and/or transferred other than in accordance with the patients' consent.

Direct access to the data will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit study-related monitoring, audits and inspections, in line with participant consent.

9.5 Personal Data breaches

Personal data breaches will be immediately reported to the UCL Information Security Group (ISG) and the UCL Data Protection Officer Alex Potts (data-protection@ucl.ac.uk), and to the Sponsor via the UCL JRO research incident reporting form (as per form and guidance: https://www.ucl.ac.uk/legal-services/guidance/reporting-loss-personal-data). The following information will be provided: full details as to the nature of the breach, an indication as to the volume of material involved, and the sensitivity of the breach (and any timeframes that apply). Sites will additionally follow their Trust incident reporting mechanisms and will document this within their Trial Master File and Investigator Site File.

The study has robust procedures in place to manage risks associated with participant disclosures of harm. If a participant discloses a serious risk of harm to themselves or others, the research team will follow an established distress protocol. Where possible, researchers will seek explicit consent before sharing concerns with a mental health professional. However, if a significant risk remains and the participant withholds consent, confidentiality may need to be breached in line with safeguarding laws.

10.STATISTICAL CONSIDERATIONS

None in this study.

11.ASSESSMENT AND MANAGEMENT OF RISK

The table below summarise the risks and mitigations for testing the intervention above standard care that are being performed in a table:

Intervention	Potential risk	Risk Management
Interview of service user participants WP1 Real Word Testing and interviews following WP3	There may be a small possibility that the service user participant will get upset or emotionally distressed whilst taking part in the interviews and testing of intervention.	What the study involves will be clearly explained to participants in the study information sheet and by researchers, and written informed consent will be received before participants join the study. The interview topic guides will be developed with the study Lived Experience Advisory Panel (LEAP) that will consist of people with lived experience of MHA assessment. If participants become distressed the study researcher will use their skills to make sure the participant feels as safe as possible. The lead researcher LB is an experienced mental health worker and has expertise in dealing with distress. The researchers will use guidance from sensitive subject research. This will include monitoring the participants' mental state, offering breaks, offering the opportunity to talk through their difficulties (if they want to), providing a safe and containing environment to conduct the research and ensuring a person-centred stance is taken. A distress protocol will be developed with the LEAP group to guide if a participant becomes upset. A debriefing time will be offered after to discuss any emotions and questions raised in the interview and this time was viewed as valuable in a previous study. Service user participants will be given a sheet with local and national support services for mental health (see Support Resources Sheet) for them to use after the interview if needed. We will also provide information on MHA assessments which the LEAP will develop. For WP1, the participants will be asked to provide details of a support person- mental health worker, friend or family who they can talk to after if needed. Contact details will be requested at beginning of interview. In the unlikely event that the participant becomes distressed, and it is not manageable by the researcher, will also contact their support person if there is concern that they are at a risk to themselves, or self-harming intent/suicide is disclosed. Each participant will be given a list of contacts if feeling any distress following the interview

		or testing of intervention. This list has been devised with LEAP members. The researcher will follow the trusts safe visiting policy. Within WP3, a member of their care team will be a participant as well and will be responsibility for any ongoing support needs. Participants will be reminded that also free to withdraw at any point. Participants who are deemed high risk by their clinical workers will be seen at the service where additional clinical staff are present.
Real world testing on clinical staff and service user participants		If there is any distress or effect after the testing, then a harms log will be completed which will use information received from the service user or clinical team. This information will be discussed with supervisors and CI and advice sought about any requirement to modify the study procedures or the intervention, or pause the intervention phase of the study, in the event of concerns.

12.RECORDING AND REPORTING OF ADVERSE EVENTS

12.1 Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a patient or trial participant, which does not necessarily have a causal relationship with the intervention involved.
Serious Adverse Event (SAE).	Any adverse event that: • results in death, • is life-threatening*, • requires hospitalisation or prolongation of existing hospitalisation**, • results in persistent or significant disability or incapacity, or • consists of a congenital anomaly or birth defect. • Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences
* A life- threatening event, this refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe. ** Hospitalisation is defined as an in-patient admission, regardless of length of stay. Hospitalisation for pre-existing conditions, including elective procedures do not constitute an SAE.	

12.2 Assessments of Adverse Events

WP1 and WP2 involve one-off interviews and stakeholder meetings, with no intervention. We do not propose to formally monitor SAEs in these phases of the study.

WP3 involves clinical staff using our novel intervention with six service user participants. It is possible in theory that service users could experience the intervention negatively and this could result in a serious adverse event. We will monitor SAEs in WP3 through feedback from the involved clinical and service user participants at the time of the intervention and in the follow-up interview.

In addition to SAE monitoring, we will also keep a Harms Log, recording any reported negative experiences of the interviews or intervention across all three Work packages. We will report the nature of the harm, which participant was affected, action taken to resolve the harm, and any actions planned to prevent recurrence. This harms log will be reviewed at least monthly by LB and her clinically qualified supervisors SJ and BLE, and by the wider project management group (see 15.2) at scheduled meetings. It will be available for review by the sponsor as requested. For this study, there will only be Adverse Events and Serious Adverse Events for work package 3.

Each adverse event (AEs) will be assessed for severity, causality, seriousness and expectedness as described below.

12.2.1 Severity

The generic categories below are given for use as a guide. You may have a more specific scale that you want to use related to the disease (e.g. CTCAE criteria), amend as required.

Category	**Definition**
Mild	The adverse event does not interfere with the participant's daily routine, and does not require further intervention; it causes slight discomfort
Moderate	The adverse event interferes with some aspects of the participant's routine, or requires further intervention, but is not damaging to health; it causes moderate discomfort

Severe	The adverse event results in alteration, discomfort or disability which is clearly damaging to health

12.2.2 Causality

The assessment of relationship of adverse events to the intervention is a clinical decision based on all available information at the time of the completion of the case report form. The differentiated causality assessments will be captured in the trial specific AE Log and/or SAE form. The following categories will be used to define the causality of the adverse event:

Category	**Definition**
Related	A causal relationship between the intervention and an adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out.
Not related	There is no reasonable possibility of a causal relationship between the intervention and an adverse event.
Not Assessable	Unable to assess on information available.

12.2.3 Expectedness

All SAEs assigned by the Investigator or delegate as suspected to be related to the intervention will be assessed for expectedness against as outline below. No AEs or SAEs are expected because it is a one-off intervention testing.

Category	Definition
Expected	An adverse event which is consistent with the information about the intervention listed in the current SmPC, Manual of Operation (amend as appropriate) **or clearly defined in this protocol.**

Unexpected	An adverse event which is not consistent with the information about the intervention listed in the current SmPC, Manual of Operation (amend as appropriate) * **or clearly defined in this protocol.**

** This includes listed events that are more frequently reported or more severe than previously reported.*

12.2.4 Recording of Adverse Events

All adverse events will be recorded in the medical records in the first instance.

All Adverse events will be recorded in the CRF following consent.

12.3 Procedures for recording and reporting Serious Adverse Events (SAEs)

All serious adverse events will be recorded in the medical records and the CRF, and the sponsor's AE log. The AE log will be reported to the sponsor at least once or twice per year and reviewed by the Project Management Group.

Where the event is unexpected and thought to be related to the intervention, this will be reported by the Investigator to the Health Research Authority within 15 days.

Completed SAE forms must be sent within 5 working days of becoming aware of the event to the Sponsor Email **forms to** Uclh.randd@nhs.net

12.4 Managing serious adverse events across research sites (if applicable)

SAEs will be reported to the Sponsor until the end of the trial.

12.5 Reporting Urgent Safety Measures

If any urgent safety measures are taken the CI/ PI shall immediately and in any event no later than 3 days from the date the measures are taken, give written notice in the form of a substantial amendment to the relevant REC and Sponsor of the measures taken and the circumstances giving rise to those measures.

12.6 Protocol Deviations and Violations

The Sponsor will be notified immediately of any protocol violations during the trial conduct phase (WP3) by completion of the online JRO Research Incident Reporting Form: https://redcap.slms.ucl.ac.uk/surveys/?s=NE5dypTdFo. All protocol violations must be recorded on the Protocol Violation Log and filed in the site file.

12.7 NHS Serious Incidents and Near Misses (if applicable)

A serious incident or near miss is any unintended or unexpected event that could have or did lead to harm, loss or damage that contains one or more of the following components:

a. It is an accident or other incident which results in injury or ill health.
b. It is contrary to specified or expected standard of patient care or service.
c. It places patients, staff members, visitors, contractors or members of the public at unnecessary risk.
d. It puts the Trust in an adverse position with potential loss of reputation.
e. It puts Trust property or assets in an adverse position or at risk.

Serious Incidents and near misses will be reported to the Sponsor and Trust Quality & Safety department as soon as the study team becomes aware of them.

12.8 Complaints from research participants

In the first instance, research participant complaints (service user or staff) will be reported to the CI/PI to investigate, as documented in the patient information sheet(s), and to the Sponsor via research-incidents@ucl.ac.uk, following the *UCL Complaints from Research Subjects about UCL Sponsored Studies and Trials* policy. For participants who are NHS service users, complaints will be reported to the NHS Complaints Manager at the Trust where the recruitment and study procedures were undertaken. Complaints from NHS patients are handled under NHS complaints policies and procedures, with involvement from PALS and the Sponsor where necessary.

13.OVERSIGHT COMMITTEES

13.1 Trial Management Group (TMG)

LB's PhD thesis committee will act as the Project Management Group (PMG) and the roles of the Trial Management Group for this study. The PMG will include the Chief Investigator (BLE), LB, SJ, qualitative expert Professor Nicola Morant (NM), other academics with method or subject expertise for the work package, representative from the Lived Experience Advisory Panel. The PMG will be responsible for overseeing the trial phase (WP3) and the whole study. It will meet at least 6 monthly throughout the study. It will provide independent oversight and advice on all work packages and ensure protocol and ethics procedures being adhered to. The PMG will review recruitment figures, SAEs and substantial amendments to the protocol prior to submission to the REC. All PIs will be kept informed of substantial amendments through their nominated responsible individuals. The PMG will advise on development of the study intervention and trial procedures. The PMG will also review adverse events thought to be linked to the study or other concerns regarding the safety of the trial.

This PMG will act as the Trial Management Group for the testing work package (WP3) of the study The PMG will review recruitment figures, SAEs and substantial amendments to the protocol prior to submission to the REC. As there will be more regular meetings between the CI and lead researcher LB then monthly supervision meetings will also complete this role (see 13.2). All PIs will be kept

informed of substantial amendments through their nominated responsible individuals. The PMG will monitor data collection and there is no separate Data monitoring committee.

13.2 Monthly Academic supervision

Academic supervision will be from BLE and SJ as well as specialist supervision from NM on qualitative aspects and SC about collaborative research with LEAP and Lived Experience Researchers. These meetings will be held at least monthly with BLE who is CI and will continue throughout the study. Other supervision will depend on needs of study and LB.

They provide academic oversight, ensuring that research aligns with ethical and methodological standards. Supervisors also offer mentorship, assist with problem-solving, and help navigate regulatory and institutional requirements, including data protection, ethics, confidentiality, and compliance with UCL policies and HRA. The academic supervision will review recruitment figures, harm logs, SAEs and substantial amendments to the protocol prior to submission to the REC. All PIs will be kept informed of substantial amendments through their nominated responsible individuals and have updates from this meeting as needed.

14.REGULATORY REVIEW AND PATIENT AND PUBLIC INVOLVEMENT

14.1 Regulatory Review

The Sponsor will ensure that the protocol, participant information sheet, consent form, GP letter and submitted supporting documents have been approved by the appropriate research ethics committee, prior to any participant recruitment. The protocol, all other supporting documents including and agreed amendments, will be documented and submitted for ethical and regulatory approval as required. Amendments will not be implemented prior to receipt of the required approval(s).

The study was deemed to require regulatory approval from the following bodies (NHS REC Favourable Opinion and HRA Approval). **Before any site can enrol patients into the study,** the Chief Investigator/Principal Investigator or designee will ensure that the appropriate regulatory approvals have been issued, and NHS Confirmations of Capacity and Capability and Sponsor green lights are in place.

For any amendments to the study, the Chief Investigator or designee, in agreement with the Sponsor, will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments as well as the study delivery team) to confirm ongoing Capacity and Capability for the study.

All correspondence with the Sponsor, REC and HRA will be retained. The Chief Investigator will notify the Sponsor and REC of the end of the study.

It is the Chief Investigator's responsibility to produce the annual progress reports when required; an annual progress report (APR) will be submitted to the Sponsor and REC within 30 days of the anniversary date on which the favourable opinion was issued, and annually until the study is declared ended.

Within 90 days after the end of the trial, the CI will ensure that the main REC is notified that the trial has finished. If the trial is terminated prematurely, those reports will be made within 15 days after the end of the trial.

Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the Sponsor and to the REC and HRA.

14.2 Peer Review

This study is being conducted as part of LB's PhD project, funded by the National Institute of Health Research (NIHR) through a prestigious Doctoral Clinical Practitioner Academic Fellowship (DCAF). The award process was highly competitive, involving a rigorous two-stage review that included thorough evaluation by a panel of three independent reviewers during both the application and interview phases. The DCAF selection committee, composed of academic experts from diverse fields within health and social care, assessed the application for its research rigor and potential impact.

As part of this process, the project plans underwent detailed independent peer review during the funding stage. Feedback from reviewers has been carefully incorporated into the study plans reported in this protocol, ensuring alignment with high standards of academic and ethical research practice (see Peer review report).

The study has been peer reviewed in accordance with the requirements outlined by UCL.

The Sponsor considers the procedure for obtaining funding from NIHR to be of sufficient rigour and independence to be considered an adequate peer review.

14.3 Patient and public involvement (PPI)

The PPI work will be led by the lead researcher LB and Dr Patrick Nyikavaranda (PN) to set up, organise and support the Lived Experience Advisory Panel (LEAP). To support this work, there is specialist supervision for LB with an experienced lived experience researcher two monthly through this study. PN has experience in leading a PPI group from other nationally funded mental health research projects. PN will be offered check-ins by LB and by LB's supervision team, which comprises clinicians and lived experience academics.

The LEAP group will include around eight people with relevant lived experience, most as service users and at least two as carers. PN will be included along with 1 or 2 peer members of the initial study completed by LB (Blakley et al., 2022) to provide continuity with previous work: a further 6 or 7 will be recruited through advertisement. The LEAP group will meet approximately bi-monthly through the study depending on the work package.

This group will play a crucial role in providing advice and impact on key decision in the following:

- **WP1**: Advising on the development of the interview topic guide, recruitment processes, and ethics application.
- **WP2**: Reviewing findings from WP1 and advising on their presentation in workshops. They will ensure effective participation of service users and carers in workshops and have paid opportunities to facilitate these sessions with appropriate training.
- **WP3**: Supporting the testing and further development of the intervention with mental health staff.
- **Dissemination**: Assisting with dissemination events and presentations to ensure findings reach relevant audiences.

The LEAP will provide a service user and carer perspective to address the potential researcher/ clinical staff bias and advise on any dilemmas or difficulties encountered on the study.

Additionally, LEAP members will be funded and trained to become Lived Experience Researchers

- **WP1**: assisting in Service User participant recruitment and conducting interviews with LB and then co-analysing all the data from WP1.
- **WP2**: presenting findings and co-facilitating the workshops.
- **WP3**: Role-play to support user testing of prototype intervention and analysis of interviews to inform refinements to this intervention.

The LEAP will play a vital role in reducing researcher and clinical bias by providing authentic perspectives grounded in lived experience. Their contributions will ensure the study remains person-centred, ethically robust, and reflective of real-world needs. Additionally, they will help shape the intervention to be practical, effective, and genuinely beneficial for service users.

To ensure that LEAP members receive comprehensive support throughout this study, the following measures will be implemented:

PPI strategy: costs, meetings, roles and responsibilities, and member's needs will be discussed in initial meetings (Jennings et al., 2018).

Support and Reflection: Researching sensitive topics, such as experiences with (MHA assessments, can evoke strong emotions in all involved, making it essential to acknowledge and address this impact, particularly for members of the LEAP group). The LEAP meetings will foster an environment for open and honest communication, with dedicated time for debriefs in each session and check-ins provided by LB or PN as needed (Wood et al., 2024). Additionally, funded reflective sessions led by LB or PN will be offered throughout the study, giving LEAP members a structured, supportive space to discuss how hearing other service users' experiences is affecting them. These sessions are designed to provide both emotional support and the opportunity to reflect on the impact of shared narratives within the group.

Training program will include access to research courses provided through the academic host's program for lived experience researcher like qualitative interviewing and analysis. Any additional training will be offered as needed by NM, a qualitative expert or one of the supervisors. Funding is

allocated to address the needs of both the group and the individual peer researchers so will different training provide through the study(Jennings et al., 2018).

15.MONITORING AND AUDITING

A trial specific oversight and monitoring plan will be established for studies. The trial will be monitored in accordance with the agreed plan. The degree of monitoring will be proportionate to the risks associated with the trial. Risk will be assessed on an ongoing basis by the Chief Investigator, and adjustments made accordingly (in conjunction with the Sponsor).

The Chief Investigator will be responsible for the day to day monitoring and management of the study. The Chief Investigator will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting and ensure adequate data quality.

The Chief Investigator will inform the Sponsor should he/she have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

The UCLH/UCL Joint Research Office, on behalf of UCL as Sponsor, will conduct random audits on a selection of studies in its clinical research portfolio. Monitoring and auditing will be conducted in accordance with the UK Policy Framework for Health and Social Care Research, and in accordance with the Sponsor's monitoring and audit policies and procedures.

16.TRAINING

The Chief Investigator will review and provide assurances of the training and experience of all staff working on this study. Appropriate training records will be maintained in the study files.

17.INSURANCE AND INDEMNITY

University College London holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, as this clinical study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

Participants may also be able to claim compensation for injury caused by participation in this clinical study without the need to prove negligence on the part of University College London or another party. Participants who sustain injury and wish to make a claim for compensation should be advised to do so in writing in the first instance to the Chief Investigator, who will pass the claim to the Sponsor's Insurers, via the Sponsor's office.

NHS trusts selected to participate in this clinical study shall provide clinical negligence insurance cover for harm caused by their employees and a copy of the relevant insurance policy or summary shall be provided to University College London upon request.

Additionally, UCL does not accept liability for sites such as GP surgeries in primary care; investigators/collaborators based in these types of sites must ensure that their activity on the study is covered under their own professional indemnity.

18.RECORD KEEPING AND ARCHIVING

UCL and each participating site recognise that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol). The Chief Investigator confirms that he/she will archive the Trial Master File at Division of Psychiatry, Maple House for the period stipulated in the protocol and in line with all relevant legal and statutory requirements. The Principal Investigator at each participating site agrees to archive his/her respective site's study documents in line with all relevant legal and statutory requirements. Study documents will be archived for a minimum of 5 years from the study end, and no longer than 20 years from the study end.

The Trial Master File will be archived at UCL, in accordance with the UCL Retentions Schedule. It will be archived for a minimum of 5 years from the study end, and no longer than 20 years from study end.

19.INTELLECTUAL PROPERTY

All background intellectual property rights (including licences) and know-how used in connection with the study shall remain the property of the party introducing the same and the exercise of such rights for purposes of the study shall not infringe any third party's rights.

All intellectual property rights and know-how in the protocol, the study data and in the results arising directly from the study, but excluding all improvements thereto or clinical procedures developed or used independently of the study by each participating site, shall belong to UCL. All intellectual property rights deriving or arising from the material or any derivations of the material provided to UCL by the participating site shall belong to UCL. Each participating site agrees that by giving approval to conduct the study at its respective site, it agrees hereby to effectively assign all such intellectual property rights ("IPR") to UCL and to disclose all such know-how to UCL.

Each participating site agrees to, at the request and expense of UCL execute all such documents and do all acts necessary to fully vest the IPR in UCL.

Nothing in this section shall be construed so as to prevent or hinder the participating site from using know-how gained during the performance of the study in the furtherance of its normal activities of providing or commissioning clinical services, teaching and research to the extent that such use does not result in the disclosure or misuse of confidential information or the infringement of an intellectual property right of UCL or its funder. This does not permit the disclosure of any of the results of the study, all of which remain confidential.

20.PUBLICATION AND DISSEMINATION

20.1. Study outputs

The main outputs during the period of funding will be:

1. A co-produced iteratively revised intervention and accompanying resources. It is envisaged there will be proforma for the discussion and then a training resource for clinical staff. These items will form the manual and include any other resources that support its delivery (such as psycho-educational materials, information leaflets and checklist for initial meetings).
2. Scientific papers, conference presentations, policy briefs, blogs and plain English summaries reporting findings and development work in each work package, including the intervention development process and qualitative evidence informing it

These outputs will allow rapid progression to a feasibility and pilot study. Our findings from the qualitative interviews (WP1) and the co-design development and refining (WP2 and 3) of this novel intervention will also inform other future research, quality improvement and service development on Mental Health Act assessments.

All proposed publications will be discussed with and reviewed by the Sponsor prior to publishing other than those presented at scientific forums/meetings. Resulting publications and/or abstracts will be emailed to the JRO.

20.2. Engagement with patients, NHS and the wider population

We will aim to engage stakeholders, especially service users, carers and clinicians throughout, inviting them to comment on study materials and key decisions.

a) Social Media and Online Presence

Throughout the study, we will maintain a social media and web presence to build a network of interested staff, service users, and organisations. This network will help us invite participants to stakeholder workshops (WP2) and dissemination events.

b) Dissemination Event

We will hold a well-publicised event to share findings and the intervention, as well as provide guidance on potential implementation. It will bring together all parties involved in MHA assessments, including service users, carers, advocates, inpatient and community teams, AMHP, commissioners, and other stakeholders. This will be an opportunity to showcase good practices to an audience well-positioned to advocate for improvements in clinical practice. Based on service user consultation, we plan to offer live streaming for greater reach and improved accessibility for service users via social media.

c) Service users

We will create a brief newsletter, article, or lay summary of the findings and details about the intervention for service users, which will be shared through our connections within service user organisations. This newsletter will enhance the visibility of MHA assessments and foster service user understanding.

20.3. Entry of our outputs in the health and care system

Great attention will be paid, especially, to tailoring the intervention for NHS settings and service users to support an easy adoption of the intervention. The dissemination event and plans will promote uptake of study findings. A simple on-line manual will be developed describing step-by-step implementation, and study materials will ultimately be free across the NHS. However, we do not expect to have an evidence base supporting full roll-out in routine settings until a further evaluation trial has been conducted.

Briefs on key findings for policy makers and senior managers, developed with our partners the Centre for Mental Health in similar style to summaries for policy makers prepared by the MHPRU.

Findings may include other ways to improve the MHA assessment experience, and these will be shared within professional networks of research team, at conference and blogs which target the core professional in the MHA assessment process.

21.REFERENCES

Abbott, S. (2022). Decision Making by Practitioners in the Social Professions Involved in Compulsory Admission to Mental Health Hospital: A Scoping Review. *British Journal of Social Work*, *52*(4), 1916–1933. https://doi.org/10.1093/bjsw/bcab164

Akther, S. F., Molyneaux, E., Stuart, R., Johnson, S., Simpson, A., & Oram, S. (2019). Patients' experiences of assessment and detention under mental health legislation: systematic review and qualitative meta-synthesis. *BJPsych Open*, *5*(3). https://doi.org/10.1192/bjo.2019.19

Asikainen, J., Vehviläinen-Julkunen, K., Repo-Tiihonen, E., & Louheranta, O. (2023). Use of debriefing following restrictive practices in forensic psychiatric care. *Journal of Forensic Practice*, *25*(1), 46–56. https://doi.org/10.1108/JFP-08-2022-0040

Blakley, L., Asher, C., Etherington, A., Maher, J., Wadey, E., Walsh, V., & Walker, S. (2022). 'Waiting for the verdict': the experience of being assessed under the Mental Health Act. *Journal of Mental Health*, *31*(2), 212–219.

Bolsinger, J., Jaeger, M., Hoff, P., & Theodoridou, A. (2020). Challenges and Opportunities in Building and Maintaining a Good Therapeutic Relationship in Acute Psychiatric Settings: A

Narrative Review. In *Frontiers in Psychiatry* (Vol. 10). Frontiers Media S.A. https://doi.org/10.3389/fpsyt.2019.00965

Bone, J. K., McCloud, T., Scott, H. R., Machin, K., Markham, S., Persaud, K., Johnson, S., & Lloyd-Evans, B. (2019). Psychosocial Interventions to Reduce Compulsory Psychiatric Admissions: A Rapid Evidence Synthesis. *EClinicalMedicine*. https://doi.org/10.1016/j.eclinm.2019.03.017

Braun, V., V. Clarke, G. Terry, and N. Hayfield. 2018. *"Thematic Analysis."* In Handbook of Research Methods in Health and Social Sciences, edited by P. Liamputtong, 843–860. Singapore: Springer.

Braun, E., Gaillard, A. S., Vollmann, J., Gather, J., & Scholten, M. (2023). Mental Health Service Users' Perspectives on Psychiatric Advance Directives: A Systematic Review. In *Psychiatric services (Washington, D.C.)* (Vol. 74, Issue 4, pp. 381–392). NLM (Medline). https://doi.org/10.1176/appi.ps.202200003

Burn, E., Conneely, M., Leverton, M., & Giacco, D. (2019). Giving Patients Choices During Involuntary Admission: A New Intervention. *Frontiers in Psychiatry*, *10*. https://doi.org/10.3389/fpsyt.2019.00433

Domecq, J. P., Prutsky, G., Elraiyah, T., Wang, Z., Nabhan, M., Shippee, N., Brito, J. P., Boehmer, K., Hasan, R., Firwana, B., Erwin, P., Eton, D., Sloan, J., Montori, V., Asi, N., Dabrh, A. M. A., & Murad, M. H. (2014). Patient engagement in research: A systematic review. In *BMC Health Services Research* (Vol. 14). https://doi.org/10.1186/1472-6963-14-89

Gaillard, A. S., Braun, E., Vollmann, J., Gather, J., & Scholten, M. (2023). The Content of Psychiatric Advance Directives: A Systematic Review. In *Psychiatric services (Washington, D.C.)* (Vol. 74, Issue 1, pp. 44–55). NLM (Medline). https://doi.org/10.1176/appi.ps.202200002

Gooding, P., Mcsherry, B., Roper, C., & Grey, F. (2018). *Alternatives to Coercion in Mental Health Settings: A Literature Review*.

Goulet, M. H., & Larue, C. (2016). Post-Seclusion and/or Restraint Review in Psychiatry: A Scoping Review. In *Archives of Psychiatric Nursing* (Vol. 30, Issue 1, pp. 120–128). W.B. Saunders. https://doi.org/10.1016/j.apnu.2015.09.001

Grindell, C., Tod, A., Bec, R., Wolstenholme, D., Bhatnagar, R., Sivakumar, P., Morley, A., Holme, J., Lyons, J., Ahmed, M., Jackson, S., Wallace, D., Noorzad, F., Kamalanathan, M., Ahmed, L., & Evison, M. (2020b). Using creative co-design to develop a decision support tool for people with malignant pleural effusion. *BMC Medical Informatics and Decision Making*, *20*(1). https://doi.org/10.1186/s12911-020-01200-3

Hammervold, U. E. (2021). *Participation in Post Incident Reviews after Restraint in Mental Health Services A qualitative study*. www.uis.no

Hammervold, U. E., Norvoll, R., Aas, R. W., & Sagvaag, H. (2019). Post-incident review after restraint in mental health care -a potential for knowledge development, recovery

promotion and restraint prevention. A scoping review. In *BMC Health Services Research* (Vol. 19, Issue 1). BioMed Central Ltd. https://doi.org/10.1186/s12913-019-4060-y

Hammervold, U. E., Norvoll, R., & Sagvaag, H. (2022a). Post-incident reviews after restraints—Potential and pitfalls. Patients' experiences and considerations. *Journal of Psychiatric and Mental Health Nursing*, *29*(3), 472–483. https://doi.org/10.1111/jpm.12776

Hammervold, U. E., Norvoll, R., & Sagvaag, H. (2022b). Post-incident reviews after restraints—Potential and pitfalls. Patients' experiences and considerations. *Journal of Psychiatric and Mental Health Nursing*, *29*(3), 472–483. https://doi.org/10.1111/jpm.12776

Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., Altman, D. G., Barbour, V., Macdonald, H., Johnston, M., Kadoorie, S. E. L., Dixon-Woods, M., McCulloch, P., Wyatt, J. C., Phelan, A. W. C., & Michie, S. (2014). Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide. *BMJ (Online)*, *348*. https://doi.org/10.1136/bmj.g1687

Hughes, R., Hayward, M., & Finlay, W. M. L. (2009). Patients' perceptions of the impact of involuntary inpatient care on self, relationships and recovery. *Journal of Mental Health*. https://doi.org/10.1080/09638230802053326

Iudici, A., Girolimetto, R., Bacioccola, E., Faccio, E., & Turchi, G. (2022). Implications of Involuntary Psychiatric Admission: Health, Social, and Clinical Effects on Patients. In *Journal of Nervous and Mental Disease* (Vol. 210, Issue 4, pp. 290–311). Lippincott Williams and Wilkins. https://doi.org/10.1097/NMD.0000000000001448

Jennings, H., Slade, M., Bates, P., Munday, E., & Toney, R. (2018b). Best practice framework for Patient and Public Involvement (PPI) in collaborative data analysis of qualitative mental health research: Methodology development and refinement. *BMC Psychiatry*. https://doi.org/10.1186/s12888-018-1794-8

Joe, J., Chaudhuri, S., Le, T., Thompson, H., & Demiris, G. (2015). The use of think-aloud and instant data analysis in evaluation research: Exemplar and lessons learned. *Journal of Biomedical Informatics*, *56*, 284–291. https://doi.org/10.1016/J.JBI.2015.06.001

Krieger, E., Moritz, S., Weil, R., & Nagel, M. (2018). Patients' attitudes towards and acceptance of coercion in psychiatry. *Psychiatry Research*, *260*, 478–485. https://doi.org/10.1016/j.psychres.2017.12.029

Langley, J. (n.d.). *Participatory design : co-creation | co-production | co-design combining imaging and knowledge*. http://shura.shu.ac.uk/14631/

Langley, J., Wolstenholme, D., & Cooke, J. (2018). "Collective making" as knowledge mobilisation: The contribution of participatory design in the co-creation of knowledge in healthcare. In *BMC Health Services Research* (Vol. 18, Issue 1). BioMed Central Ltd. https://doi.org/10.1186/s12913-018-3397-y

Moll, S., Wyndham-West, M., Mulvale, G., Park, S., Buettgen, A., Phoenix, M., Fleisig, R., & Bruce, E. (2020). Are you really doing a € codesign'? Critical reflections when working with vulnerable populations. *BMJ Open*, *10*(11). https://doi.org/10.1136/bmjopen-2020-038339

Monahan, J., Hoge, S. K., Lidz, C., Roth, L. H., Bennett, N., Gardner, W., & Mulvey, E. (1995). Coercion and commitment. Understanding involuntary mental hospital admission. *International Journal of Law and Psychiatry*, *18*(3), 249–263. https://doi.org/10.1016/0160-2527(95)00010-F

Murphy, R., McGuinness, D., Bainbridge, E., Brosnan, L., Felzmann, H., Keys, M., Murphy, K., Hallahan, B., McDonald, C., & Higgins, A. (2017). Service Users' Experiences of Involuntary Hospital Admission Under the Mental Health Act 2001 in the Republic of Ireland. *Psychiatric Services*. https://doi.org/10.1176/appi.ps.201700008

O'Cathain, A., Croot, L., Duncan, E., Rousseau, N., Sworn, K., Turner, K. M., Yardley, L., & Hoddinott, P. (2019). Guidance on how to develop complex interventions to improve health and healthcare. *BMJ Open*, *9*(8). https://doi.org/10.1136/bmjopen-2019-029954

O'Donoghue, B., Lyne, J., Hill, M., Larkin, C., Feeney, L., & O'Callaghan, E. (2011). Physical coercion, perceived pressures and procedural justice in the involuntary admission and future engagement with mental health services. *European Psychiatry*, *26*(4), 208–214. https://doi.org/10.1016/j.eurpsy.2010.01.014

Priebe, S., Katsakou, C., Amos, T., Leese, M., Morriss, R., Rose, D., Wykes, T., & Yeeles, K. (2009). Patients' views and readmissions 1 year after involuntary hospitalisation. *British Journal of Psychiatry*, *194*(1), 49–54. https://doi.org/10.1192/bjp.bp.108.052266

Roche, E., Madigan, K., Lyne, J. P., Feeney, L., & O'Donoghue, B. (2014). The therapeutic relationship after psychiatric admission. *Journal of Nervous and Mental Disease*. https://doi.org/10.1097/NMD.0000000000000102

Saunders, C. H., Sierpe, A., Von Plessen, C., Kennedy, A. M., Leviton, L. C., Bernstein, S. L., ... & Leyenaar, J. K. (2023). Practical thematic analysis: a guide for multidisciplinary health services research teams engaging in qualitative analysis. *Bmj*, *381*.

Skivington, K., Matthews, L., Simpson, S. A., Craig, P., Baird, J., Blazeby, J. M., Boyd, K. A., Craig, N., French, D. P., McIntosh, E., Petticrew, M., Rycroft-Malone, J., White, M., & Moore, L. (2021). A new framework for developing and evaluating complex interventions: Update of Medical Research Council guidance. *The BMJ*, *374*. https://doi.org/10.1136/bmj.n2061

Slattery, P., Saeri, A. K., & Bragge, P. (2020a). Research co-design in health: A rapid overview of reviews. In *Health Research Policy and Systems* (Vol. 18, Issue 1). BioMed Central Ltd. https://doi.org/10.1186/s12961-020-0528-9

Slattery, P., Saeri, A. K., & Bragge, P. (2020b). Research co-design in health: A rapid overview of reviews. In *Health Research Policy and Systems* (Vol. 18, Issue 1). BioMed Central Ltd. https://doi.org/10.1186/s12961-020-0528-9

Smith, S., Gate, R., Ariyo, K., Saunders, R., Taylor, C., Bhui, K., Mavranezouli, I., Heslin, M., Greenwood, H., Matthews, H., Barnett, P., & Pilling, S. (2020). Reasons behind the rising rate of involuntary admissions under the Mental Health Act (1983): Service use and cost impact. *International Journal of Law and Psychiatry*, *68*. https://doi.org/10.1016/j.ijlp.2019.101506

van den Hooff, S., & Goossensen, A. (2014). How to increase quality of care during coercive admission? A review of literature. In *Scandinavian Journal of Caring Sciences*. https://doi.org/10.1111/scs.12070

Walker MBBS, S., Sheridan Rains, L., Leverton, M., Dalton-Locke, C., Lloyd-Evans, B., Johnson, S. D., Trevillion, K., Johnson, S., Walker, S., Mackay, E., Barnett, P., Sheridan Rains, L., Leverton, M., Dalton-Locke, C., Trevillion, K., Lloyd-Evans, B., & Johnson, S. (2019). *Division of Psychiatry Clinical and social factors associated with increased risk for involuntary psychiatric hospitalisation: a systematic review, meta-analysis, and narrative synthesis*. www.thelancet.com/psychiatryVol

Wessely, S., Lloyd-Evans, B., & Johnson, S. (2019). Reviewing the Mental Health Act: delivering evidence-informed policy. *The Lancet Psychiatry*, *6*(2), 90–91.

Wood, L., Rowe, A., Persaud, K., Nyikavaranda, P., Malde-Shah, N., Guerin, E., ... & Birken, M. (2024). Reflections on the coproduction of a crisis-focused intervention for inpatient settings underpinned by a Cognitive Behavioural Therapy for psychosis (CBTp) model. *Psychosis*, *16*(3), 313-324.

Wullschleger, A., Vandamme, A., Mielau, J., Renner, L., Bermpohl, F., Heinz, A., Montag, C., & Mahler, L. (2021). Effect of standardized post-coercion review session on symptoms of PTSD: results from a randomized controlled trial. *European Archives of Psychiatry and Clinical Neuroscience*, *271*(6), 1077–1087. https://doi.org/10.1007/s00406-020-01215-x

Wullschleger, A., Vandamme, A., Mielau, J., Stoll, L., Heinz, A., Bermpohl, F., Bechdolf, A., Stelzig, M., Hardt, O., Hauth, I., Holthoff-Detto, V., Mahler, L., & Montag, C. (2021). Effect of standardized post-coercion review on subjective coercion: Results of a randomized-controlled trial. *European Psychiatry*, *64*(1). https://doi.org/10.1192/j.eurpsy.2021.2256

22.APPENDICES

Include here a list of the supplementary information and documents that will support the protocol and information contained therein, e.g. PIS, ICF, schedule visit, assessment tools, delegation log, case report forms, questionnaires, scales, tables, charts, diagrams, manufacturer's brochures.

It is not advisable to insert copies of documents such as the PIS and ICF due to version control and document management issues. You may wish to list the document titles here, or delete if unnecessary.

Include the schedule of assessments (Appendix 1) and references.

22.1 APPENDICE 1: Schedule of Assessments

	Screening (Pre-treatment assessment)	**Intervention phase**					**Final visit**
Visit No:	1	2	3	4	5	6	8
	Day – X to Day -X	Day 1	Day 7	Day 14	Day 21	Day 28	Day 42/ Early Discontinuation visit
Window of flexibility for timing of visits:			e.g. +/- 2 days	e.g.+/- 2 days	E.g..+/- 3 days	e.g.+/- 3 days	e.g.+/- 3 days
Informed Consent	X						
Medical History	X						
Physical Examination							
Vital Signs							
Eligibility confirmation	X	X					
Add ALL Protocol Assessments including intervention, bloods/urine, ECGs, scans, c as applicable both trial specific and routine (include separate row for each assessment)							
Randomisation	X						
Adverse Events review	X	X	X	X	X	X	X
Concomitant Medication review (if applicable)	X	X	X	X	X	X	X

22.2 APPENDICE 2: Associated Documents

Include here supplementary information and documents that will support the protocol and information contained therein.

E.g. data dictionary

Document Name	Document Version	Document Date