1. PROTOCOL FULL TITLE Advance Choice Document Implementation IRAS 346853

Protocol Short Title/ Acronym: ACDI

Trial Identifiers

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REC Number:	25/WM/0117		
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2. STUDY SUMMARY / SYNOPSIS

TITLE OF STUDY:	Advance Choice Document Implementation
Protocol Short Title/ Acronym:	ACDI
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UKCRN Number:	

REC Number:	
Medical Condition or Disease Under Investigation:	Severe mental illness
Purpose of study:	To evaluate the effectiveness of Advance Choice Document implementation in an NHS Mental Health Trust
Primary Objective:	To evaluate the effect of Advance Choice Document implementation on rates of detention under the Mental Health Act
Secondary Objective(s):	To evaluate the effect of Advance Choice Document implementation on: (i) rates of restraint, seclusion, and involuntary medication (ii) safety events (violence, self-harm, consequences of self-neglect and other serious untoward incidents) (iii) acute mental health and emergency services use (iv) criminal justice service involvement (v) trust in mental health services To evaluate key aspects of ACD implementation: Completion; access; honouring; and review. See detail in section 8.2.
Design:	Mixed methods evaluation: Consultation on adaptation for forensic, older adults and child and adolescent mental health (CAMHS) services Retrospective matched cohort study Pre-post evaluation
Sample Size:	**Work package 1:** Older Adults: 10- 20 service users 10-20 carers 10-20 professionals CAMHS users: 10- 20 service users 10 -20 carers 10 - 20 professionals **Total = 60 - 120** **Work package 2: ACD creation & follow up** General adult mental health service users: n=40 Forensics service users: n=20 Older adults service users: n=10 CAMHS users: n=20

	Service users to be interviewed only post expected ACD application: n=15 (from any of general adult, older adult, forensic or child and adolescent services). Parents/people with parental responsibility for CAMHS service users: n=20 Carers of adults completing ACDs; Staff of the South London and Maudsley Trust and of the acute NHS Trusts, local authorities, advocacy services, relevant voluntary sector services and primary care practices serving the Trust catchment area n=60 **Total: 170**
Summary Of Eligibility Criteria:	Service users - Currently under the care of South London and Maudsley NHS Foundation Trust - Previously detained under the Mental Health Act (MHA) - Aged ≥ 16 years Carers / Informal supporters - Aged ≥ 16 years - A relative or friend of a service user who is eligible for the study, although the service user does not have to be a study participant Professionals - Professional involved in supporting the completion of ACDs (i.e., ACD facilitators, community mental health team (CMHT) staff, advocates, peer support workers) - SLaM NHS professional potentially involved in referring to ACDs (i.e., inpatient and emergency department, home treatment, place of safety and street triage staff); Approved mental health professionals (AMHPs) and Section 12 (MHA) approved doctors; General Practitioners; advocates
Intervention (Description, frequency, details of delivery)	Advance Choice Document
Comparator Intervention:	No ACD
Maximum Duration Of Treatment Of A Subject:	As the Trust has committed to the rollout of ACDs, there is no maximum duration of treatment. Instead, service users completing an ACD may have one for as long as they wish. Maximum duration of participation in the pre-post evaluation= 21 months
Version And Date Of Final Protocol:	v.1.1 16.07.25
Version And Date Of Protocol Amendments:	v2.0 25.09.25; SA01

3. Revision History

Document ID - (Document Title) revision X.Y	Description of changes from previous revision	Effective Date

4. PROTOCOL CONTENTS

5. STUDY MANAGEMENT

5.1 Role of Study Sponsor and Funder

South London and Maudsley NHS Foundation Trust and King's College London are joint sponsors.

This study is funded by the Maudsley Charity.

The Co-Principal Investigators have overall responsibility for the study and shall oversee the study management. Both Co-Principal Investigators and the Research associate will have weekly meetings for the entire duration of the study.

5.2 Study Management Committees

1. Study Steering Committee: The steering committee will consist of policy stakeholders nationally. They will meet every 6 months once the study has begun, and will advise on implementation, dissemination, and the overall process of the study.
2. Co-Applicants: The co-applicants will meet at least every two months to receive feedback from the co-principal investigators and research associate on the progress of the study and provide input.
3. Patient and Public Involvement (PPI) / Lived Experience Advisory Groups: Five groups will be convened and will be chaired by experienced facilitators

- Black people with a previous experience of detention under the MHA while aged over 18 to South London and Maudsley (SLaM) general adult inpatient unit, and relatives and carers of such service users:
- Any service user with previous experience of detention as above, and relatives and carers of such service users:
- Adults who have previously been detained under the MHA in SLaM forensic services, and relatives and carers of such people.
- Adults who are current or former users of SLaM Older Adults services and were detained under the MHA in an inpatient unit for Older Adults, and relatives and carers of such people.
- People aged 16 or over who are current or former users of SLaM CAMHS and were detained under the MHA while aged under 18, and relatives and carers of such people.

The lived experience advisory groups will meet every 2-3 months and will advise on engagement at all stages of the study to optimise both the recruitment and participation of service users.

6. STUDY BACKGROUND & RATIONALE

The evidence base and policy position regarding Advance Choice Documents

The UK government committed to legislating for Advance Choice Documents[1] following their recommendation by the Independent Review of the MHA (2018) [2]. This recommendation is based on ethical and legal arguments as well as evidence from systematic reviews and meta-analyses of randomised controlled trials (RCTs)[3–5] of interventions variously termed Joint Crisis Plans or Psychiatric Advance Directives. These trials show such interventions are associated with a reduction (25%, RR 0.75, CI 0.61-0.93) in compulsory psychiatric admission[3,4]. They are yet to be implemented in routine practice despite this evidence and indications of high demand in England and elsewhere[6,7]. The joint parliamentary scrutiny committee of the Mental Health Bill recommended a statutory offer of an ACD be made to anyone who has previously been detained under the MHA and, in line with the research interventions, that support to create one be provided by someone independent of the treating team. The 2024 King's Speech, made as the new government came to power, highlighted an intention to amend the MHA with a view to "strengthening the voice of patients by adding statutory weight to patients' rights to be involved with planning for their care, and to make choices and refusals regarding the treatment they receive"[53].

The current NHS England position is:
1. NHSE Patient and Carer Race Equality Framework reporting requirements include: (i) ACD completion by race/ethnicity and (ii) experience of completion on the part of people from minoritized groups.

2. The guidance: Acute inpatient mental health care for adults and older adults states:

"From the point of presentation to within 72 hours of admission:
Holistic assessment conducted to understand the person's needs. This assessment should build on information contained within the person's EPR, including any recorded advance choices and reasonable adjustments."

"Decision reached, considering as fully as possible the person's preferences (including any ACDs), those of their chosen carer/s, and the views of relevant partner services, that the person's needs can only be met in an inpatient setting and cannot be supported in the community."

"Formulation review completed to gain an in-depth understanding of the person, the circumstances leading up to their admission and what will help them to recover. This, together with recorded ACDs should be used as the basis to co-develop a personalised care plan with the person and their chosen carer/s, which should then be uploaded to the person's EPR."

"At and following discharge:
Prompt access provided to all planned post-discharge support included in the person's discharge plan. The person should also be supported to develop ACDs and a crisis plan, if they were not developed ahead of discharge."

This guidance suggests that ACDs should be created while someone is an inpatient or post discharge. However, the two trials of advance statements developed during inpatient stays showed negative results in terms of compulsory hospitalisation[1,2] and service users have expressed a clear preference to create them when in the community [3]. This may differ in forensic settings however, where patients may have significantly longer stays due to sentencing. In such cases, the better option may be to create an ACD while the person is still receiving inpatient treatment and is well, for example in a low secure or rehabilitation setting.

As the trials took place in countries without specific legislation for ACDs for mental healthcare, it might be expected that legislation would lead to widespread implementation. However, in countries with such legislation (USA and Scotland), uptake has been slow and remains low[11]. In England and Wales there is little evidence that service users have the opportunity to use the advance planning provisions under the Mental Capacity Act (MCA)[7]. Research in the USA, Scotland, and England suggests barriers at service user, clinician, and service levels [7,11].

Completing an ACD involves asserting advance wishes and preferences as requests and/or refusals for treatment and other aspects of care when one has the capacity to do so. US research shows that the majority of service users need support to do this[7,8]. This is also demonstrated by a survey[7] of people with bipolar disorder in England. Among the third who were aware of the MCA, unrealistic expectations about advance planning and misunderstanding about the different forms (advance treatment refusals, advance statements, and power of attorney) were common. Among the 10% who had made an advance refusal, only half were written down (of these, many were not given to anyone else and almost all were described as being ignored during MHA detention). Scottish evidence suggests some service users are sceptical about whether ACDs will be followed by staff, while others do not acknowledge their relevance[9].

At the clinician and service levels, mental health professionals express reservations about being able to access ACDs and honour the person's wishes[10–12]. In the CRIMSON trial of JCPs, co-lead Henderson et al. identified three barriers: (1) lack of recognition of the benefits of advance statements; (2) not recognising the need for a change in the clinician-patient relationship including discussing treatment options and supporting patient choice; and (3) difficulties in implementation arising from working across the system[13]. Moreover, while some clinicians believed the external JCP facilitator was necessary for empowering service users to participate in shared decision making, senior clinicians – namely psychiatrists – feared losing control of their role in patients' care [14].

Service users, clinicians and carers view ACDs as potentially offering positive outcomes including: reduced coercion or trauma associated with compulsory treatment; building therapeutic alliance[8,13]; earlier presentation; avoiding harms; enhancing communication; empowering service users; and improving clinician confidence[15,16]. The above guidance on ACDs creates an implementation gap, and there remains a need for an evidence-based approach to ensure effective implementation. In the protocol we will henceforth use the term ACD.

The Importance of ACDs to Black people

Detention rates of Black people (defined as people of Black African and Caribbean heritage, including those of mixed Black ethnicity) are disproportionately (>3 times) higher than those of White British people and they have poorer care experiences and outcomes[18,21]. They are more likely to access mental healthcare via the criminal justice system than through primary care[22] or have police involved in their detention[23]. Their treatment involves increased use of compulsion, longer admissions and more detention in secure settings[24]. Black people of Caribbean heritage are more likely to be re-admitted or repeatedly detained than White people[18], and less likely to be referred for specialist mental healthcare[25]. This pattern incurs increased service costs[26] – the current unit cost/day for caring for someone with a psychotic relapse in the community is £146, compared with £455 in hospital. The current rate of detention of Black people has been conservatively estimated to cost ~£158 million/year[2].

Black people with severe mental illness (SMI) therefore benefit more than other groups from ACDs: the CRIMSON trial showed greater cost-effectiveness of JCPs for Black people compared with White and Asian participants[13], arising from reduced inpatient service use. In a US study[6], completing an ACD was a more empowering experience for African Americans compared with other ethnic groups[17] and demand for these was higher among non-White people[6]. Lack of trust in mental health services may create a high demand for ACDs among Black people in England[18–20].

Almost half (47%) of the explanations for these variations in care have no or limited supporting evidence. Interventions based on these explanations are likely to fail[27], and current methods of supporting Black people previously detained under the MHA are insufficient[2]. In contrast, ACDs are the only evidence-based intervention to reduce compulsory psychiatric admission overall, with particular benefit for Black people due to their higher likelihood of being detained under the MHA because of racial stereotyping and discrimination [3,28]. ACDs thus represent a way to reduce unwarranted variation by intervening in a negative cycle of dissatisfaction with services[29], impaired therapeutic alliance and trust, disengagement from services, reduced help seeking[25,30] and repeated compulsory admissions, associated with reduced quality of life.

In our previous study, Advance Statements for Black African and African Caribbean People (AdStAC) we developed an implementation resource for ACDs developed with and for Black people. Our rationale was: 1) Strategies that support successful implementation of ACDs will enable better access and delivery of mental health services for Black people; and 2) if the most marginalised groups, who are least engaged, can be supported with these strategies, then these strategies are likely to work for other people with SMI.

The resource developed and tested includes an ACD template, a manual for the independent facilitator professional leading the process of creating the ACD (ACD facilitator), and trainings provided by the SLaM Recovery College and Maudsley Learning simulation team respectively. The resources will be used in the present project and adapted as necessary for specific services.

This project will also benefit from the following work undertaken by the applicants and their associated NHS trusts:

- A study led by Henderson[32] suggests that services need to be flexible, allowing service users to choose not just the content of an ACD but also when and where to complete one and whom to involve.
- The process and documents for producing ACDs in the form of JCPs (Henderson) were developed with input from service users[14] and a manual was developed for the trials[13,33].
- Qualitative work during CRIMSON (Henderson) identified the processes to ensure shared decision making about the content of JCPs and the positive impact of these processes on therapeutic relationships[15], as well as difficulties ensuring consistency[14].

- Recent focus group and consultation work in England indicates that successful implementation requires: user-friendly templates and supporting materials; attention to the legal framework; NHS Trust support, health professional training and time; third sector engagement; and service user 'readiness'[16]. A template and guidance for advance statements was developed for people with bipolar disorder (Owen)[5,16].
- The Crisis Plus service at South London and Maudsley (SLaM) NHS Foundation Trust comprises a team of psychologists helping people frequently admitted to hospital to develop crisis plans. This service addresses some of the barriers to accessing and honouring plans identified during CRIMSON[14].
- A minimally viable product (MVP) for digitising ACDs for deployment in clinical settings (https://kclpure.kcl.ac.uk/ws/portalfiles/portal/239348291/Thalamos_KCL_Digital_ACD_Discovery_Document.pdf p48)

7. STUDY AIM AND OBJECTIVE

7.1 AIM

To evaluate the effectiveness of Advance Choice Document implementation in an NHS Mental Health Trust

7.2 PRIMARY OBJECTIVE

To evaluate the effect of Advance Choice Document implementation on rates of detention under the Mental Health Act

7.3 SECONDARY OBJECTIVE(S)

A) To evaluate the effect of Advance Choice Document implementation on:

(i) rates of restraint, seclusion, and involuntary medication

(ii) safety events (violence, self-harm, consequences of self-neglect and other serious untoward incidents)

(iii) acute mental health and emergency services use

(iv) criminal justice service involvement

(v) trust in mental health services

B) To evaluate key aspects of ACD implementation: Completion; access; honouring; and review

8. OUTCOME MEASURES / ENDPOINTS

8.1 PRIMARY OUTCOME MEASURE / ENDPOINT

Admission to hospital under a section of the MHA

8.2 SECONDARY OUTCOME MEASURE(S) / ENDPOINT(S) (i – iv measured by case note review)

Case Note Review:

(i) episodes of restraint, seclusion, and involuntary medication

(ii) safety events: episodes of violence, self-harm, consequences of self-neglect and other serious untoward incidents

(iii) compulsory transport to hospital/place of safety using Section 135 or 136 of the MHA; length of stay for informal and formal psychiatric admissions; presentation at Emergency Departments

(iv) contact with police related to use of acute mental health services; imprisonment; length of time in prison

Single Item:

(v) Trust in mental health services, measured by a single item *'Generally you can trust mental health staff and services*' with response options ranging from strongly agree to strongly disagree. This item is adapted from a measure previously employed in research on social capital[46]

Implementation outcomes:

These will be assessed via case note review and recordings of meetings given consent, for all those who express an interest in creating an ACD across the services where implementation is taking place (i.e. not only research participants).

Completion:

- Fidelity of the process: attendance, participation, efforts to complete all ACD sections, completion of capacity statement
- Completion procedures to allow costing: setting/location, duration and number of sessions, time preparing for meetings and finalising the ACD
- Reasons for non-completion following initial expression of interest
- ACD content (types of requests and refusals[35])
- Distribution of hard and electronic copies

Accessing:

- Rates of access to ACD by service users during follow-up for: Approved Mental Health Professional team; emergency department, home treatment team; recovery house staff; inpatient staff.
- Participant use of the ACD during use of an acute service

Honouring:

- Proportions of ACDs in which one or more choices were honoured/not honoured
- Rate of documentation of reasons for choices clearly not honoured
- Content of choices not honoured and reasons given

Reviewing:

- Proportion of ACDs reviewed and reason for review
- Proportion revised after review
- Types of revisions made

On ACD completion and after use of an acute service, service users who have consented to take part in the study, and staff who have been involved in their care, will be interviewed about their views on:

a. **Acceptability**: the aspects which participants found acceptable about the processes of completion, access and use of ACDs acceptable,
b. **Appropriateness**: the aspects about the processes of completing an ACD which participants found to be suitable for their needs, using the Intervention
c. **Feasibility**: the aspects of the processes of completing an ACD that are possible. Additionally, we will assess the barriers and facilitators of implementing Advance Choice Documents across the different services in SLaM by analysing audio recordings of ACD implementation group meetings, the minutes and the action tracker.

Evaluation of ACD creation and use:

The primary outcome and secondary outcomes (i-iv) will be ascertained using a retrospective cohort study supported by the SLaM Clinical Records Interactive Search (CRIS) database following approval by the BRC CRIS oversight committee (Work package 3). Secondary outcome (v) and all implementation outcomes will be ascertained using interviews and record reviews of samples of those referred to ACD facilitators who in addition provide informed consent to take part in the research: service users under the care of general adult, forensic, older adults services and CAMHS (Workpackage 2).

9. STUDY DESIGN

Summary

Work package 1: Focus groups and stakeholder consultation for Older Adults and CAMHS implementation

Work package 2: Prospective study of ACD completion and use

Work package 3: Retrospective controlled study of ACD creation and its relationship to service use and routinely collected outcomes

Work package 4: Pilot retrospective study of ACD use and its relationship to: ACD content, service user and service characteristics, and to service use and routinely collected outcomes

Study Design

WP1: Focus groups and stakeholder consultation for Older Adults and CAMHS implementation

Adaptation for older adults' services and CAMHS: The research team will run focus groups with service users and carers from those groups using services for which adaptation is needed. We will also run focus groups with staff who work with people from each of these groups, from SLaM and other organisations (e.g. social care and advocacy). All focus groups will be audio recorded.

The purpose of these focus groups will be:

a) To inform service users, carers, and staff about ACDs

b) To understand aspects of ACD creation that may be unclear, especially in relation to the specific needs of different groups

c) To understand any concerns or barriers that stakeholders may have in relation to ACD creation

d) To ensure that the ACD resources (i.e. ACD creation template) have been suitably adapted (where necessary) for use in older adults' services and CAMHS.

e) To understand the barriers and facilitators for ACD implementation for staff across different mental health services (e.g. CMHT, inpatient wards, staff working with service users on Community Treatment Orders etc).

WP 2: Prospective study of ACD completion and use

Trained ACD facilitators will be in post across SLaM to facilitate the implementation of ACDs. When service users are referred to facilitators to create an ACD, they will be asked if they would like to participate in a research study. If they wish to participate, they will speak with a member of the research team who will go through the consent process (see 10.6). ACD facilitators will also refer service users who expressed interest in participating in the study but have already created their ACDs. Once the participant has provided written consent, they will complete a baseline single item regarding their level of trust in mental health care services and socio-demographic information. Participants will also be asked for information about their treating team.

Where ACDs are created, we will seek *optional* consent to record the ACD creation meeting (from service users, carers, and all staff present at the meeting). This recording will be used for fidelity purposes. Participants who complete ACDs will also be asked to complete a single item regarding their level of trust in mental health care services and questions on their satisfaction with and perceived value of their ACD. We will also seek optional consent from participants to contact them about future research on ACDs and send a letter to their GPs, to notify them that the service user is taking part in the study.

The research team will follow up participants based on their clinical notes. In the event that their ACD is, or should have been, used the research team will seek to interview the service user about this experience.

Situations in which an ACD should be used or reviewed will include:

- Zoning (where a service user's care team increase contact due to concern about their mental health)
- Referral for an MHA assessment
- An MHA assessment
- Home Treatment Team (HTT) referral
- A&E presentation, where they are seen by the mental health liaison team
- Admission to inpatient ward, crisis house, or place of safety
- Any transfer of care to another team
- Discharge from their care team

As the project progresses, these criteria will be reviewed and changed as necessary. Additionally, facilitators will identify service users whose ACDs are expected to have been applied in the above events, either through their care teams or other appropriate channels, and will invite them to participate in the study to explore their experiences of the expected use event.

The research team will invite participants to take part in an interview based on advice from the participant's care team, to ensure that they are well enough to be contacted and to give informed consent. When participants are interviewed, they will also be asked to again complete the questionnaire measure of trust.

We will also seek to interview SLaM Trust clinical staff involved with the event that led to the use of the ACD, as well as the facilitator who led its creation and review. SLaM clinical staff will have the option to answer interview questions via email correspondence in cases when an interview is not possible.

Facilitators will also be interviewed about their perspectives on integration of their role within SLaM mental health services. With participants' consent, research staff will be given access to participants' clinical records for ongoing observation regarding use / non-use of their ACD.

We will conduct up to eight focus groups covering inpatient, CMHT, liaison and home treatment team and all of CAMHS, OA, general adult and forensics about their experience of ACD completion and use. Staff who cannot join a focus group will be invited to do an interview instead.

WP3: Retrospective controlled study of ACD creation and its relationship to service use and routinely collected outcomes

The CRIS (Clinical Record Interactive Search) database is a de-identified case register extracted from the SLaM electronic health record[54]. Using the CRIS database, following approval from the SLaM BRC oversight committee, we will aim to use anonymised routinely collected data to create a retrospective cohort study where we will aim to compare service users who hold an ACD to those who are eligible for one but have not created one.

Data from the Clinical Record Interactive Search (CRIS) database at SLaM will be used, with the intention of creating a retrospective cohort to evaluate the impact of ACDs on primary and secondary outcomes. Permission to perform the evaluation will be sought from the SLaM CRIS Oversight Committee and all data will be accessed within the SLaM trusted research environment. Data will be extracted six months before the end of the study (date of completion of data analyses: 31/09/26) to ensure there is an adequate follow-up period to assess the impact of ACDs on outcomes. We aim to use the CRIS database to create an anonymised cohort of ACD holders and potential control participants. These potential control participants will comprise SLaM service users who have been detained under the MHA more than once and last discharged from SLaM within 24 months. We aim to match ACD holders with service user controls based on sociodemographic (age, gender) and clinical variables (e.g. primary diagnosis) using propensity score matching. For ACD holders, the study follow-up period will begin when the ACD is recorded on their electronic health record. Each matched control will have the same follow-up period as their corresponding ACD holder. This study design has been applied previously to evaluate an intervention, namely recovery colleges, as part of the RECOLLECT programme[52].

Work package 4: Pilot retrospective study of ACD use and its relationship to: ACD content, service user and service characteristics, and to service use and routinely collected outcomes

ACDs as identified through Work package 3 will have content extracted in preparation for coding and further analysis as described under 9.2.

End of study

The study will end on the date when all data analyses are completed (predicted end date is 31/03/27). The Research Ethics Committee (REC) will be notified of the study's conclusion within 90 days of the end date, and a final study report will be submitted within 12 months of the study's end date. We will also inform the host sites of the study's completion and request them to communicate this information to participants recruited at their respective sites. Lastly, the study's findings will be published in peer-reviewed journals using open-access mechanisms.

9.1 STUDY SETTING

South London and Maudsley NHS Foundation Trust

9.2 DATA ANALYSIS

All data analyses will be undertaken by the research team at the Institute of Psychiatry, Psychology and Neuroscience, King's College London and within SLaM.

Qualitative data (Workpackages 1 and 2):

Following transcription, framework analysis[36] will be used to code the transcripts and identify key themes from:

Workpackage 1 focus groups to adapt the ACD resources and processes.

Workpackage 2 interviews with service users, people in parental roles, and carers, and staff on expected ACD use events.

Workpackage 2 staff focus groups on ACD implementation.

Quantitative data (Workpackages 2 and 3):

Primary outcome and secondary outcomes (i-iv)

- Primary and secondary outcomes (i-iv) will be analysed using inferential statistics (e.g. regression models) to assess differences between participants and controls using the CRIS data (Workpackage 3 data)
- Pre and Post comparisons of the question asked to research participants about trust in services will be undertaken. The statistical test used will depend on the scoring distribution.
- Baseline comparison comparisons on trust in mental health services will be conducted to compare differences between service users who complete ACDs and those who do not.

Workpackage 4: Analysis of ACD Content: Coding frameworks developed through previous research will be applied to the content of the full ACD sample available within the Trust via both manual records review, and automated methods to include topic modelling, measures of textual similarity, and information extraction. Output of these reviews will be analysed using descriptive statistics. Differences in content by service user race/ethnicity (Black African and African Caribbean heritage or mixed heritage vs all other) will be tested for. We will also look at differences in content between different service user groups (i.e. young people/older adult/forensic).

10. SELECTION OF PARTICIPANTS

10.1 ELIGIBILITY CRITERIA

Gender: Participants of any gender.

Lower age limit: 16 years

Upper age limit: No upper age limit

Location: Lambeth, Lewisham, Croydon or Southwark

Language: Participants who do not speak English, or who feel more comfortable expressing themselves in their first language, will be able to participate in the study with the assistance of an NHS interpreter.

10.1.1 INCLUSION CRITERIA

WP1: Focus Groups

Service users

Young people

a) Aged ≥ 16
b) Experienced detention under the MHA while in the care of CAMHS
c) Currently under the care of community mental health services (CAMHS / EI / CMHT)

Older adults

a) Experienced detention under the MHA while under services for Older Adults
b) Currently under the care of older adult community mental health services

Carers / Informal supporters

a) Aged ≥ 16 years
b) A relative or friend of a service user who is eligible for the study

Professionals

a) Professional potentially involved in supporting the completion of ACDs (i.e., community mental health team (CMHT) staff, advocates, peer workers)
b) SLaM professionals potentially involved in referring to ACDs (i.e., inpatient and emergency department liaison mental health staff, home treatment, place of safety and street triage staff)
c) Approved mental health professionals (AMHPs) and Section 12 (MHA) approved doctors involved in detention.
d) Ambulance, prison mental health and Emergency Department staff
e) General Practitioners, including mental health leads, or other primary care professionals who care for people with SMI discharged from secondary services

WP 2: Prospective study of ACD completion and use

Service users

All service users: accepted referral to an ACD facilitator for ACD creation

Young people

a) Aged ≥ 16

b) Experienced detention under the MHA while in the care of CAMHS

c) Currently under the care of community mental health services (CAMHS / EI / CMHT/)

d) Accepted referral to an ACD facilitator for ACD creation; including participants who decline to complete and ACD after referral to an ACD facilitator.

Older adults

a) Experienced detention under the MHA while under services for Older Adults

b) Currently under the care of older adult community mental health services

c) accepted referral to an ACD facilitator for ACD creation

General Adult:

a) Aged ≥ 18 years

b) Previously detained under the MHA

c) Under the care of community mental health services (CMHT or EI)

Forensic

a) Aged ≥ 18 years

b) Experience detention under the MHA into forensic services

c) Currently under the care of forensic mental health services

***Carers*:** relative or friend of someone referred to an ACD facilitator

Professionals: SLaM staff involved in the care of a participant with an ACD whose ACD is expected to have been consulted because they were: involved in a transfer of care, placed in zoning, referred for a MHA assessment or to a home treatment team, attended an Emergency Department or Place of Safety, admitted to a psychiatric inpatient unit or imprisoned.

The interviews conducted with service users and staff after the expected use event will also include questions about satisfaction with and perceived value of the process of completing, distributing, accessing, honouring, and reviewing an ACD.

10.1.2 EXCLUSION CRITERIA

Service users

a) Aged under 16 years
b) Lacking capacity to provide consent and/or is unwilling to do so
c) Currently detained under the MHA in psychiatric hospital
d) Currently under the care of eating disorder services

Carers/informal supporters

a) Aged under 16 years
b) Is not a relative or friend of a service user who is eligible for the study

Professionals

a) Is not a mental health professional or Section 12 (MHA) approved doctor
b) Is not a professional involved in supporting the completion of ACDs
c) Is not a General Practitioner or mental health lead caring for people with SMI discharged from secondary services.

10.2 SIZE OF SAMPLE

WP 1: Focus groups

This sample size will enable us to capture diverse perspectives that will allow us to adapt ACD resources and processes for CAMHS and older adults' services. We will hold 3-6 focus groups for both CAMHS and older adults. These will be specifically focused on the barriers and facilitators for ACDI implementation in SLaM.

1-2 Older Adults service users' focus groups = 15-20 participants (max 10 per group)

1-2 CAMHS service users' focus groups = 15-20 participants (max 10 per group)

1-2 Older Adults carers / informal supporters' focus groups = 15-20 participants (max 10 per group)

1-2 CAMHS carers / informal supporters' focus groups = 15-20 participants (max 10 per group)

1-2 CAMHS professionals' focus groups = 15-20 participants (max 10 per group)

1-2 older adults professionals' focus groups = 15-20 participants (max 10 per group)

Total = up to 90-120

Work package 2: Prospective study of ACD completion

The sample size for the numbers of participants allows for estimation of implementation outcomes and the potential effectiveness with respect to the outcome of trust in mental health services.

General adult mental health service users: n=40

Forensics service users: n=20

Older adults service users: n=10

CAMHS users: n=20

Service users to be interviewed only post expected ACD application: n=15 (from any of general adult, older adult, forensic or child and adolescent services.

Parents/people with parental responsibility for CAMHS service users: n=20

Carers of adults completing ACDs n=10

Staff interviews: This will be determined by the eligibility criterion above, i.e. all staff involved in the care of a participant with an ACD whose ACD is expected to have been consulted, max n=58

Staff focus groups: up to eight focus groups each with maximum 12 participants max n=96

Total: 289

10.4 SAMPLING TECHNIQUE

WP1: Purposive sampling will be used with the aim of recruiting all staff types, and service users of Black African and Caribbean vs other heritage, of at least cis-male and cis-female genders, of varying ages (between 16-25 for CAMHS group). For CAMHS we will aim to include young people looked after by the local authority, as well as those who are not. For Older Adults, we will aim to include service users who have experience creating other planning documents such as LPAs, and ACPs.

WP 2: we will recruit in order of referrals made, with purposive sampling used if required to achieve our sample size for each group of interest.

10.5 RECRUITMENT

WP 1: Focus Groups

Professionals:

Recruitment will take place through presentations to clinical teams, service directors and other services within SLaM and consent for contact (c4c) list.

Service users and carers/informal supporters:

- Presentations to clinical teams, other groups within SLaM including the Patient and Carer Race Equity Framework groups for each directorate, recovery colleges and peer support services, service user groups, carer groups, relevant voluntary sector organisations.
- Informal coffee mornings/events for service users
- Identification of interested mental health service staff to discuss involvement with service users, carers and their clinical colleagues, including service PPI leads, existing research champions or professionals with particular interest in the project.
- Flyers, to be distributed throughout participating Trust sites and to groups and organisations listed above.
- A webpage (hosted by SLaM) providing study information for service users, informal supporters and Trust staff.
- Through the Recovery College
- Social media – X/Twitter, TikTok, Instagram, and a brief YouTube video, to signpost people to the webpage.
- Contact with local media including radio, newspapers, and podcasts.
- Presentations at research clubs, including the one hosted by the SLaM Recovery College

A search for eligible participants using the Clinical Records Interactive Search system (CRIS) in collaboration with the Maudsley Biomedical Research Centre (BRC), thus study information can be sent to those who have provided Consent for Contact (c4c). The Maudsley BRC will provide the research associate and research assistants with the details of potentially eligible patients who have provided Consent for Contact within the BRC's trusted environment.

The potential participants will be contacted by a member of the research team who has a Letter of Access. In cases where the participant is yellow lit, the researcher will contact the patients' care team to make sure it would be an appropriate time to contact the potential participant. If it is not (e.g., due to patient hospitalisation, relapse, in crisis, or the individual is not contactable), it will be arranged with the care team whether or when to contact them again. If the care team says that the potential participant can be contacted, the researcher staff or facilitator clinical research staff member, will contact the potential participant via email or post, or the person will be contacted by phone to arrange the provision of the Participant Information Sheet depending on the patient's stated preferences on the consent to contact system. Service users currently not living in the community due to hospital admission, incarceration, or being out of the country will not be contacted until they are living at the usual address again. Those waiting for a Mental Health Act Assessment will also not be contacted.

WP 2: ACD Referral

Service users referred for ACD creation and their carers/informal supporters:

Facilitators and the administrator working with facilitators will ask service users referred to them and carers attending ACD creation meetings for permission to pass their contact details to the research team.

Professionals involved in the care of a participant with an ACD whose ACD is expected to have been consulted:

Professionals will be identified via review of the records of participating service users who have given their consent for their records to be accessed as part of the study. They will be contacted for recruitment via their professional email account or workplace telephone or address.

10.5.1 Participant payment / compensation

Service users and their carers/informal supporters will be compensated for their time with vouchers or cash provided either in person, electronically, or posted, dependent on preference. They will also be reimbursed for any travel expenses.

Voucher prices per service user/carer participant:

- WP1 Focus Groups: £20
- WP2 Interviews: £15 per interview

10.6 CONSENT

All participants will provide written consent. For WP1 Focus groups, the research associate or research assistants will obtain written consent from all participants. The consent form will be signed and dated by the participant before they participate in the study.

For WP2, *Consent will be sought to a) Interview participants following ACD referral b) access service users' clinical records and c) contact participants in the event that ACD is or should have been used.* The Consent Form (CF) will be signed and dated by the participant before they participate in the study. There will be an opportunity for potential participants to ask questions. Mental capacity will be confirmed by the facilitator. However, it will again be evaluated by researchers during interactions with service users, to ensure capacity to consent and understanding of the research process. If researchers are unsure if participants have the capacity to consent, they will not progress with the consent process. Instead, they will suggest meeting another day and speak to the facilitator who referred the participant, in addition to a member of the care team if appropriate. Electronic consent may be taken in some instances e.g. if service users prefer to communicate over the phone or remotely using MS Teams. If any phase of the study must take place online, consent will be taken through over the phone and/or MS Teams.

A Participant Information Sheet (PIS) will be provided before consent is taken, ensuring that the participant has sufficient time to consider participating or not. The participant will be given the opportunity to ask any questions they may have has concerning study participation.

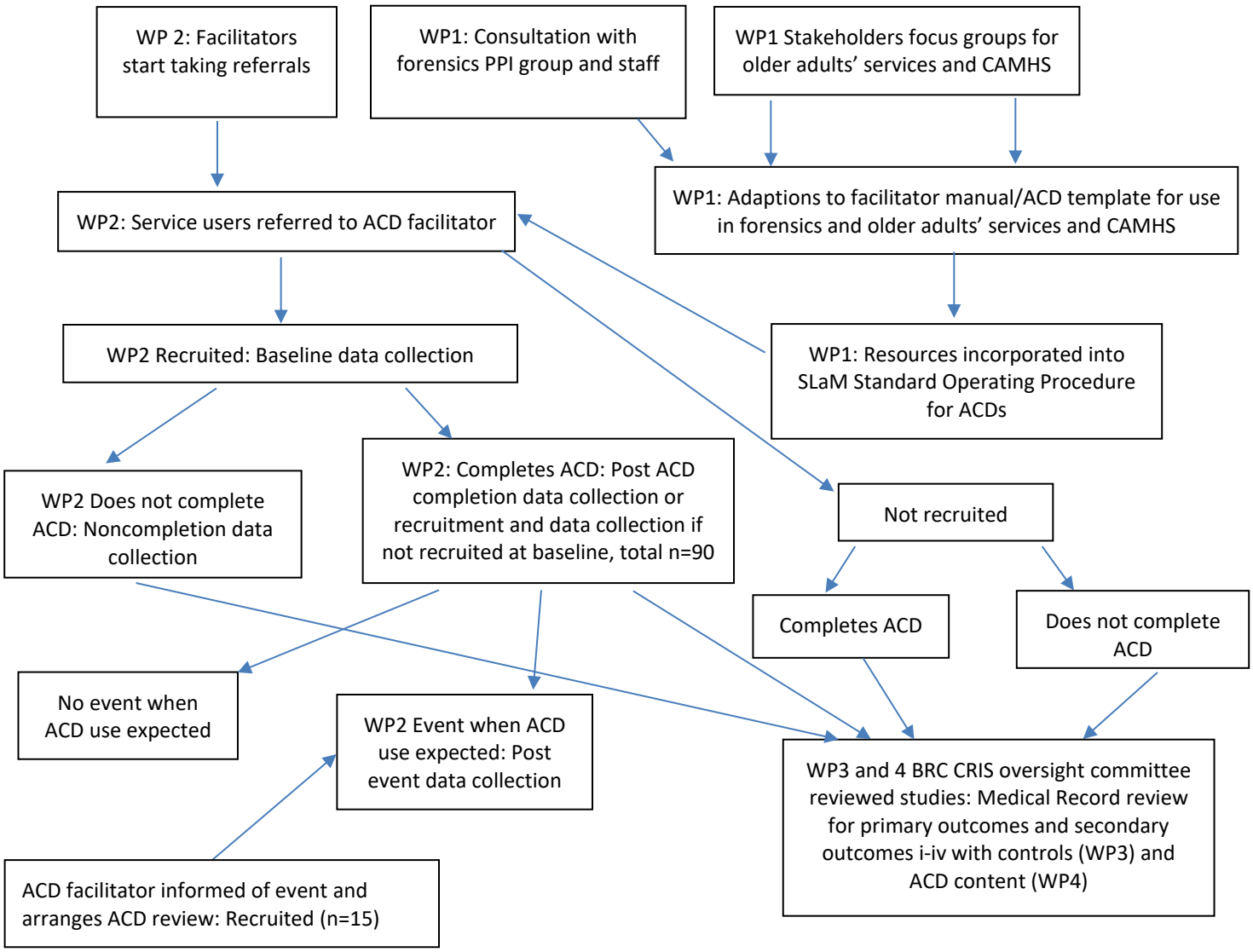
The Research Associate and Research Assistants will confirm participant consent verbally at follow-up if the interview is done in person at settings, including outpatient care locations, low secure forensic facilities, forensic rehabilitation settings, and participants' homes. Additionally, consent will be confirmed electronically via email or audio recording on the phone when setting up a remote follow-up interview.

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP), and any other regulatory requirements that might be introduced. The co-principal investigators, the research associate or research assistants and the participant or other legally authorised representative shall both sign and date the CF before the person can participate in the study.

Informed consent will be collected from each participant before they participate in each part of the study. One copy of the CF will be kept by the participant, one will be kept by the research team. Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the study, continuing consent will be obtained using an amended CF which will be signed by the participant.

11. STUDY PROCEDURES

11.1 STUDY FLOWCHART



11.2 METHODS

Work package 1: Focus Groups

Focus groups with staff, carers, and service users will be led by the research team, where a brief presentation will explain:

- What is an ACD
- Process of completing ACDs, and which stakeholders (professionals, staff and carers/informal supporters) are involved
- The Trust project to roll out the use of ACDs, why it is doing this and why this way

A facilitated discussion will follow, where participants will view and discuss the current ACD template developed through AdStAC. Questions will cover completing, accessing, honouring and reviewing advance statements.

Data collection: The focus groups will be recorded and transcribed.

Analysis: Data will be analysed using framework analysis.[36]

Output: Results of the focus groups will be discussed with the respective advisory groups and the SLaM ACD implementation project working group and used to inform the SLaM SOP for the respective service.

Work package 2: Prospective study of ACD completion.

The measures and other data to be collected at each time point, plus the sources of data, are summarised in Table 1.

Table 1. ACD creation and use data collection: measures, time points and sources:

	Baseline	**Post ACD completion**	**Post event when ACD use expected**	**End of study**
Demographic & clinical data;	Service users			
Trust in services	Service users	Service users	Service users	
ACD completion log		EPJS notes		
Satisfaction with and perceived value of ACD		Service users' interviews	Interviews with: Service users Carers/informal supporters involved in completion SLaM Staff involved in completion and/or event	
Reasons for completion and non-completion*		Interviews with service users and facilitators		
Distribution of hard & electronic copies		ACD facilitator Clinical notes	Service user interview	
ACD access and honouring			Service users SLaM Staff involved in the event Carers/informal supporters involved in completion (interview)	
ACD review frequency, and revisions			Facilitator notes on ePJS/interviews with service users	
Staff feedback				SLaM staff involved in completion and/or use including facilitators
Primary outcome and secondary outcomes i-iv				Electronic record review
ACD content				Electronic record review

**Non-completion will be determined as having occurred at 3 months post baseline or if the participating service user decides against completion before this.*

WP3 Retrospective controlled study of ACD creation and its relationship to service use and routinely collected outcomes

To maximise data collection on access to, honouring and review of ACDs a variable follow-up period will be used. Follow-up duration will depend on when the participant is recruited. We will collect all follow-up data leaving 6 months for analysis and dissemination at the end of the study period.

11.3 SCHEDULE OF PROCEDURES

Gantt Chart of schedule of procedures and see **Table 2**.

11.4 WITHDRAWAL

Participants may be withdrawn from the study either at their own request or at the discretion of the Co-Principal investigators. The participants will be made aware that this will not affect their future care.

Participants will be made aware (via the PIS and CF) that should they wish to withdraw the data collected once it has been analysed, their anonymised data may not be erased in accordance with King College London's Research Privacy Notice and information given in the PIS and may still be used in the final analysis.

12. ETHICAL AND REGULATORY CONSIDERATIONS

12.1 ASSESSMENT AND MANAGEMENT OF RISK

Sensitive nature of this research

This project includes people from vulnerable groups who have a SMI diagnosis and have also been detained under the MHA. Due to this, the research will need to be accomplished with skill and sensitivity. At all times, we will use listening and non-judgemental techniques to create an open yet confidential safe space for people to freely discuss their views and recommendations.

Experience of research leads and research team

The study will be carried out by an experienced research team who have the appropriate clinical research expertise and experience with working with vulnerable groups. The Co-Principal Investigators (Prof Claire Henderson and Dr Shubulade Smith) are the co-leads for this study. Both are experienced clinicians, academics and have successfully run and completed projects that have involved co-production, evaluation and working with marginalised and vulnerable groups. Prof Henderson also has topic expertise having led the first randomised controlled trial of joint crisis plans, a type of ACD[33]. She also collaborated on the multisite RCT of Joint Crisis Plans[13] and led a consensus study on the implementation of Mental Health Advance Directives in the US Veterans Health Administration[32.]. Prof Henderson and Dr Smith co-led the AdStAC project.

WP1

The focus groups are not expected to raise any significant ethical issues; however, they may cause distress or make participants upset. This is due to the focus groups being centred around opinions on ACDs. Participants who are service users or carers/informal supporters may find discussing their experiences of mental healthcare or mental illness distressing or upsetting. During the focus groups, should participants become upset, distressed or wish to leave, their needs will be accommodated. Should they wish to leave

the focus group/discussion. they can do this for as long as needed. They will have the option to withdraw or re-join the discussion depending on their preference. The Co-Principal investigators are both experienced clinicians who have experience working with marginalised and vulnerable groups. The research team are trained in, and have experience of, working with vulnerable people and facilitating sensitive mental health discussions.

During discussions participants may disclose past criminal or other activity on the part of staff that indicates risk to participants or others including thoughts or actions related to self-harm. If this happens, the research team member will inform the participant that they will have to inform the co-principal investigators of the disclosure. From here, the co-principal investigators will take action based on Trust safeguarding policy.

It is not anticipated that participants will feel marginalised during the focus groups, as recommendations from our Staff and Lived Experience Advisory groups will be obtained to inform and guide the research team on using an appreciative and open approach where all participants' views are valued. Participants will be made aware that the focus groups will be recorded, and their consent for this will be obtained both before and during the focus group.

Consent will be obtained in written format before the focus groups, and again in verbal format on the day of the focus groups.

WP2

As ACD creation and use is to be led by SLaM clinicians employed by the Trust to implement ACD use per a Trust SOP, the ACD facilitators and their supervisor will be responsible for the wellbeing of service users during the process of ACD creation. This section will therefore cover the research data collection processes only.

Service users and staff will both be informed that participation is entirely voluntary, and that there is an option to withdraw at any stage of the study, although the research team may contact participants to explore reasons for non-completion.

Follow-up

Risks and burdens for participating service users

There are two potential follow up points: in addition to post ACD completion, we propose to ask service users whether their ACD was used and honoured as soon as practicable and appropriate after an event during which the ACD should be used i.e. contact with acute services.

We are aware that after admission/detention under the MHA it may take time for service users to discuss this especially if they had a negative experience, or their wishes in the ACD were not honoured. We will not interview service users who have lost capacity to participate in the research and will wait until this has been regained following discussion with treating staff. We aim to discuss with the Lived Experience Advisory Groups and ways in which this process can be approached, in order to gather sufficient and useful data from service users regarding feasibility of the process of completing ACDs, if their ACD was not honoured. We aim to do this without over-burdening service users at a difficult time. If service users do not wish to meet following an event during which the ACD should be used, we will instead wait until the ACD review to invite them to an interview about the event.

Service users will also have the option of having a carer/supporter or a mental health professional support them by sitting in on any interview they take part in.

Potential burden on mental health professionals and carers/informal supporters

To minimise burden on carers/informal supporters and staff we will conduct one follow up interview to gain their perspectives on the feasibility, acceptability and appropriateness of the process of completion, and on any experience they have had of accessing and using the ACD. Other follow up data to be collected will only occur when record review indicates an event which should entail access to the ACD.

Personal information / data confidentiality

Participants' identifiable details will be pseudonymised during the study, and then anonymised once the study has completed, and will be stored securely on the King's College London SharePoint study site on computers at the Institute of Psychiatry, Psychology and Neuroscience, King's College London, and on laptops administered by the institution. All audio files gained from each part of the study will use either an encrypted recording device (face-to-face) or Microsoft Teams (online) and will be saved to the study folder on the King's College SharePoint study site , to which only the research team has access. Transcriptions of recordings will be done by a transcription service that has an existing data sharing agreement with King's College London. Once the research team have approved the transcription, the audio files will be deleted. We will abide by the Data Protection Act and the NHS Code of Confidentiality.

Only the research team will have access to the study documentation and final data set, which will be retained for 10 years after the study has completed.

Inclusivity

This study will aim to be as inclusive as possible. We will be guided by our Lived Experience Advisory Groups (Public and Patient Involvement) and who will advise on appropriate approaches to every part of the study, where all participants views will be valued and acknowledged throughout. The LEAG chairs will meet between group meetings to support each other and confer about advice to be given to the research team.

Individual participant medical information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted. Medical information may be given to the participant's medical team and all appropriate medical personnel responsible for the participant's welfare

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the Co-Principal Investigators and where appropriate report according to Trust safeguarding procedures.

12.2 ADVERSE EVENTS

We will actively collect information at each assessment of the study about adverse events and serious adverse events. These will be recorded in the standard way. There are standard operating procedures for reporting serious adverse events to the Project Steering Committee (PSC), sponsor, funder, and NHS Research Ethics Committee (REC).

RECORDING AND REPORTING ADVERSE EVENTS

Recording adverse events

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

Procedures for recording adverse events will be reviewed by the research team, and ethics committee approval sought for any proposed changes before the beginning of the pre-pilot study.

Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a patient or 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
* 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 acute in-patient admission, regardless of length of stay. Hospitalisation for pre-existing, non-mental health conditions, including elective procedures, do not constitute an SAE.	

Assessments of Adverse Events

Each adverse event will be assessed for severity, causality, seriousness and expectedness as described below:

Severity

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

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 study specific AE database and the SAE form.

The following categories will be used to define the causality of the adverse event:

Category	**Definition**
Definitely:	There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out.
Probably:	There is evidence to suggest a causal relationship, and the influence of other factors is unlikely
Possibly	There is some evidence to suggest a causal relationship (e.g. the event occurred within a reasonable time after administration of the study intervention). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant events).
Unlikely	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the study intervention). There is another reasonable explanation for the event (e.g. the participant's clinical condition, other concomitant treatments).
Not related	There is no evidence of any causal relationship.
Not Assessable	Unable to assess on information available.

Expectedness

There are no anticipated expected adverse events from the study processes. However, due to the nature of the participant group – people with severe mental illness, the following serious adverse events are not considered to be unexpected per se: admission to mental health acute care; attempted suicide or suicide. Harm to others perpetrated by the participant does constitute an unexpected adverse event.

Procedures for recording and reporting Serious Adverse Events

All serious adverse events will be recorded in the medical records and the CRF. SAEs will also be recorded in an SAE database throughout the study, allowing a line-listing of SAEs to be easily extracted for review.

All SAEs (except those specified below as not requiring reporting to the Sponsor) must be recorded on a serious adverse event (SAE) form. The Chief or Principal Investigator will respond to any SAE queries raised by the sponsor as soon as possible.

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

Reporting lines for SAEs

The study researcher will screen records for AEs for participants during follow up. A report of the circumstances of the AE, and the informant's view on causation and severity will be sought by the study researcher, who will then contact the study team without delay. The study Co-PI Henderson (a clinician) will complete an SAE form and make final assessments of severity, causality and expectedness. She will then disseminate any necessary safety information to the rest of the research team.

SAEs will be reported to the sponsor until the end of the study.

Serious Adverse Events that do not require reporting

SAEs involving a psychiatric hospital admission for a participant which occur in the context of a relapse of an existing mental health condition and are assessed as unlikely to be causally related to the study will not be reported to the Sponsor, unless unusual in frequency or severity. Readmissions to hospital are likely to occur for a number of participants, given the study participant group – people with severe mental illness. These events will however be recorded in the medical records, CRF and the study AE database.

Additionally, only SAEs which require reporting to the REC and HRA need be reported to the sponsor.

No other notifiable events for immediate reporting to the sponsor have been identified for this study.

Reporting Urgent Safety Measures

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

NOTIFICATION OF REPORTABLE PROTOCOL VIOLATIONS

A reportable protocol violation is a breach which is likely to effect to a significant degree:

(a) the safety or physical or mental integrity of the participants of the study; or

(b) the scientific value of the study.

The sponsor will be notified immediately of any case where the above definition applies during the study.

12.3 ETHICS REVIEW AND COMPLIANCE

The study shall not commence until the study protocol, information sheets and consent forms have been reviewed and approved from a Research Ethics Committee.

12.4 FUNDING

The project has received funding from the Maudsley Charity.

12.5 PUBLIC & PATIENT INVOLVEMENT

The study will involve extensive patient and public involvement (PPI) through the Lived Experience Advisory Groups. In addition to this, Mr Steve Gilbert who will chair the Lived Experience advisory group is a co-applicant of this project, as well as being a member of the Staff advisory group.

Initial involvement:

The consent forms and participant information sheets given to participants at different stages of the study, to ensure that both forms/sheets are participant friendly will be reviewed by the Lived Experience Advisory Group chairs.

Planned on-going involvement:

The Lived Experience Advisory Groups will consist of people who are both service users with experience of detention under the MHA in the respective service (general adult, forensics, older adults and CAMHS) and carers/informal supporters of such service users. They will meet every 2-3 months to ensure the study is conducted sensitively and has a people-centred and culturally sensitive approach, in addition to:

- Reviewing and inputting advice on initial results from interviews of ACD holders
- Advising on dissemination of results within and beyond the Trust.

The chairs of each Lived Experience Advisory Group will confer between meetings to share learnings and support each other. We will hold a thank you and feedback session for all LEAG members and chairs at the study midpoint and at the end.

12.6 PROTOCOL COMPLIANCE

This study will be conducted in accordance with this protocol. Accidental protocol deviations may occur at any time. Accidental protocol deviations will be adequately documented on the relevant forms and reported to the Co-Principal Investigators, and the Sponsor immediately. Any amendments or accidental protocol deviations will also be reported to the Research and Ethics committee.

13. DATA PROTECTION AND SERVICE USER CONFIDENTIALITY

All study staff and investigators will comply with the principles of the Data Protection Act (2018) in protecting the rights of study participants with regards to the collection, storage, processing, and disclosure of personal information and will uphold the Act's/Regulations core principles.

A Data Protection Agreement between the Institute of Psychiatry, Psychology and Neuroscience, King's College London and South London and Maudsley NHS Foundation Trust has been signed by the Co-Principal Investigators.

Each participant will be assigned a study identity number, for use in obtaining contact details and linking the datasets, i.e., personal information (dataset 1) and research data (dataset 2).

Personal data, research data and the linking identity number will be stored in the same physical location – a secure locker in the IoPPN, King's College London building, which the research team only have access to. When stored electronically, this will include encrypted digital files within the KCL study SharePoint site which the research team only have access to. Personal information will be stored separately to research data and will be kept secure and maintained.

Personal data will be stored for 6 months after the project end date, so that the Co-Principal Investigators may provide participants with a summary of the research and follow up.

Data generated as a result of this study will be available for inspection on request by the participating clinicians, King's College London representatives, SLaM representatives, the REC, local R&D Departments and the regulatory authorities.

14. INDEMNITY

Mandatory text: Insurance and indemnity for trial participants and trial staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but trial participants may have recourse through the NHS complaints procedures.

14.1 ACCESS TO THE FINAL DATASET

The Co-Principal Investigators (Dr Claire Henderson and Dr Shubulade Smith, Research Associate (Mariam Namasaba) and research assistants (Jonathan Simpson and Riddhi Daryanani) will have access to the final dataset. The dataset will be pseudonymised. At the end of the study all data will be anonymised by destroying the dataset containing participant contact details.

15. DISSEMINATION POLICY

The data custodian will be the Co-Principal Investigators on behalf of the Institute of Psychiatry, Psychology and Neuroscience, King's College London and SLaM. The findings will be disseminated within SLaM, in peer reviewed scientific journals, internal report, conference presentations, publication on the SLaM website and other publications. We will invite participants and other SLaM staff, service users and carers to a knowledge mobilisation event to feed back the findings and present the implementation resource.

15.1 Authorship eligibility guidelines and any intended use of professional writers

We will follow the ICMJE authorship guidelines. We do not intend to use professional writers.

16. SIGNATURES

__ _____Claire Henderson_____ 25/09/2025_____

Chief Investigator Date

Print name

_____ _____

Statistician (if applicable) Date

Print name

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