AD-CARE

Acute day units as crisis alternatives to residential care

Acute Day Units as Crisis Alternatives to Residential Care
AD-CARE

Chief Investigator:
Professor David Osborn, UCL

Supported by:
NIHR HS&DR 15/24/17

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2 20/12/16

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Study Registration Number:

UCL McPin Foundation Transforming mental health research WARWICK THE UNIVERSITY OF WARWICK Camden and Islington NHS NHS Foundation Trust

PROTOCOL VERSIONS

Version Stage	Versions No	Version Date	Protocol updated & finalised by;	Appendix No detail the reason(s) for the protocol update
Previous	1	25/10/16	Danielle Lamb	N/A
Current	2	20/12/16	Danielle Lamb	1

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 Research Governance Framework 2005 (as amended thereafter), the Trust Data & Information policy, Sponsor and other relevant 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 clinical investigation without the prior written consent of the Sponsor.

I (investigator) also confirm that an honest accurate and transparent account of the study will be given; and that any deviations from the study as planned in this protocol will be explained and reported accordingly.

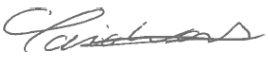
Chief Investigator:

Signature:..... Date...../...../.....

Print Name(in full):.....

Position:.....

On behalf of the Study Sponsor:



Signature: ..... Date 15/11/2016

Print Name(in full): Tania West.....

Position: Research Portfolio Coordinator.....

STUDY SUMMARY

Identifiers	
IRAS Number	201627
REC Reference No	
Sponsor Reference No	16/0576
Other research reference number(s) (if applicable)	
Full (Scientific) title	Acute Day Units as Crisis Alternatives to Residential Care
Health condition(s) or problem(s) studied	
Study Type i.e. Cohort etc	Observational cohort study, and qualitative study
Target sample size	Cohort study: n=800, qualitative study: n=55
STUDY TIMELINES	
Study Duration/length	Three years
Expected Start Date	01/07/16
End of Study definition and anticipated date	30/06/19
Key Study milestones	IRAS form submitted, REC attended, first participant recruited, final participant recruited
FUNDING & Other	
Funding	NIHR HS&DR
Other support	
STORAGE of SAMPLES (if applicable)	
Human tissue samples	N/A
Data collected / Storage	N/A
KEY STUDY CONTACTS	Full contact details including phone, email and fax numbers
Chief Investigator	Professor David Osborn 0207 679 9028 d.osborn@ucl.ac.uk

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 has to 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 or not he/she is an investigator at any particular site.

The CI role is to complete and to ensure that all relevant regulatory approvals 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 RE of the end of the study, including the reasons for the premature termination. 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.

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.

PARTNERS: The research partners include the McPin Foundation, and the University of Warwick. The research partners will attend study group meetings, and contribute advice and support as appropriate.

KEY WORDS

Acute Day Unit; Mental health;

LIST OF ABBREVIATIONS

AE	Adverse Event
AR	Adverse Reaction
CI	Chief Investigator
CRF	Case Report Form
CRO	Contract Research Organisation
DMC	Data Monitoring Committee
GAfREC	Governance Arrangement for NHS Research Ethics
HTA	Human Tissue Authority
IB	Investigator Brochure
ICF	Informed Consent Form
MD	Medical Device
ISRCTN	International Standard Randomised Controlled Studies Number
PI	Principle Investigator
PIS	Participant Information Sheet
QA	Quality Assurance
QC	Quality Control
RCT	Randomised Clinical Study
REC	Research Ethics committee
SAR	Serious Adverse Reaction
SAE	Serious Adverse Event
SDV	Source Data Verification
SOP	Standard Operating Procedure
SSI	Site Specific Information
TMF	Trial Master File

CONTENTS

1 INTRODUCTION, BACKGROUND, AND RATIONALE

There are well-established and publicised problems in acute mental health care for people experiencing crises. This includes poor experience, lack of provision of recommended interventions, delays in accessing care, poor continuity of care, over-reliance on restriction and the current reduced bed capacity. There are a range of reports regarding the need for better crisis care including the Schizophrenia Commission report[1] in 2012, the Chief Medical Officer's report in 2013[2] and the 2015 interim Crisp report for the Commission on Acute Adult Psychiatric Care[3].

We need to provide better, more efficient, acceptable, empowering community responses to acute mental health crises. Inpatient psychiatric care is unpopular, expensive and sometimes detrimental for individuals and their families. There are also criticisms of crisis resolution/home treatment teams (CRTs) in terms of the limited interventions they provide, the time-limited assessment/treatments they can offer, and the lack of consistency in staff due to the need to provide 24 hour care via a shift system.

Acute Day Units (ADUs) are services which have the potential to address these needs and overcome problems in both inpatient and crisis/home treatment settings. ADUs are available to enhance mental health crisis care in some English catchment areas (about 1 in 5 English crisis teams have access to ADUs). These units offer intensive, short term community responses to mental health crises, and aim to reduce costly and unpopular admissions, either avoiding them or facilitating early discharge.

ADUs (called day hospitals in the past) have been a component of adult mental health services for decades, especially across Europe[4] but their provision and function in the UK has been highly variable, and research is relatively lacking[5]. They also did not form a core part of the NHS Service Framework. A survey conducted in 2001 (pre-crisis teams) identified 102 such services in England providing a mixture of care models, including i) an alternative to

admission, ii) more chronic care and iii) services for those for whom outpatient care was insufficiently intensive[6] Cochrane systematic reviews have compared acute day hospitals to both outpatient and inpatient care[7,8]. We will only focus on acute units which crisis teams have access to for supporting urgent mental health crises. We found 41 such units in The NIHR CORE programme grant survey in 2013. The limited available evidence is heterogeneous in terms of study participants, design and outcomes, making conclusions difficult. A meta-analysis of four randomised controlled trials concluded that mental health day units were superior in terms of clinical outcomes (symptoms) and were less costly[4]. However the most recent British RCT, involving one London acute day unit in 2006, reported that while symptom improvement and satisfaction were greater, the costs were also greater[9].

Service users and crisis team staff tell us that ADUs can be very valuable but they need to be safe and to include effective psychological and pharmacological interventions, peer support (as recommended by NICE[10]) and a smooth care pathway including interface with external user-empowering agencies in the community. The integration of the acute system seems key, as well as its ability to target the right people at the right time and to be value for money. Local evaluations suggest ADUs have high levels of satisfaction and they fit with many aspects of the NHS plan such as patient empowerment and innovative models of acute care[11].

There is a dearth of information regarding modern ADUs such as their models of care, effectiveness, place in the acute pathway and service user acceptability and experience. The research we propose addresses problems identified by a range of recent publications and policies regarding acute mental health care. The Crisis Care Concordat[12] includes crisis care and acute day care within its domains. ADUs address many of the ambitions of the NHS 5 year plan[13], including improvements in acute care, personalised care, empowerment and efficiency.

2 Workpackage 2.1 – Cohort Study

3 OBJECTIVES

In this stage of the AD-CARE study, we aim to:

1. Describe the clinical and socio-demographic characteristics of people who use each of five ADUs selected for the in depth case studies
2. Determine their pathways into the ADU, length of stay, treatments received, experience, empowerment, loneliness and readmissions at 6 months
3. Compare these characteristics to a cohort of people who receive acute crisis care without ADU input

4 STUDY DESIGN

This will be a cohort study. Five ADUs will be identified from the national survey carried out in WP1. We will invite people aged 18 and over who are consecutively admitted to each ADU to participate in baseline interviews and then telephone/internet follow-up 8-12 weeks after baseline, with administrative outcome data collected at 6 months.

We will invite people form the same crisis pathway to participate in the parallel non-ADU cohort. They must be receiving CRT home treatment when recruited, but could previously have been admitted to an inpatient ward during this episode.

We aim to recruit 80 people who receive ADU care and 80 people who do not, in the locality of each ADU chosen for the mixed-method case studies. This gives a total of 400 in each 'arm', and a combined total of 800.

5 STUDY SCHEDULE

At baseline, ADU staff will screen all service users consecutively admitted to their service from the start date. All service users who meet the inclusion criteria will be approached by ADU staff and asked if they are willing to be contacted by researchers to discuss participation further (except at sites where service users have already given consent to be contacted directly about research projects: in this circumstance, researchers will contact service users directly once their eligibility and any risk-related safety requirements have been established). The researchers will keep a record of potential participants to be contacted and the date and the name of the clinician with whom this was agreed. Researchers will ask the clinician who spoke to each service user to note the patient's agreement to be contacted by a researcher in their patient records. Those who agree will be contacted by a researcher with an information sheet and offer to answer any questions. Potential participants will be given at least 24 hours to consider whether they would like to take part, and then if still interested they will be consented by a researcher, who will also collect the baseline data.

Participants will be contacted by phone 8-12 weeks after baseline to be asked if they are willing to complete the questionnaire again. If so, the researcher will collect the data required from them. If a participant does not wish continue at follow up they are free to decline.

If any participant wishes to withdraw at any point they are free to do so without any detriment to their current or future care. Unless participants inform researchers that they do not want their data used, any data collected before withdrawal will be used.

The study will be completed by 30/06/2019, with the recruitment of 800 participants.

6 CONSENT

As noted above, data will be collected by study researchers and Clinical Research Network (CRN) staff (hereafter collectively referred to as 'researchers'). At baseline, ADU staff will screen all service users consecutively admitted to their service from the start date. All service users who meet the inclusion criteria will be approached by ADU staff and asked if they are willing to be contacted by researchers to discuss participation further (except at sites where service users have already given consent to be contacted directly about research projects: in this circumstance, researchers will contact service users directly once their eligibility and any risk-related safety requirements have been established). The researchers will keep a record of potential participants to be contacted and the date and the name of the clinician with whom this was agreed. Researchers will ask the clinician who spoke to each service user to note the patient's agreement to be contacted by a researcher in their patient records. Those who agree will be contacted by a researcher with an information sheet and offer to answer any questions. Potential participants will be given at least 24 hours to consider whether they would like to take part, and then if still interested they will be consented by a researcher, who will also collect the baseline data.

In order to include those whose first language is not English, any local provision by NHS Trusts for translators will be used. However, where there are no translators provided locally it will not be possible to include non-English-speaking participants.

7 ELIGIBILITY CRITERIA

7.1 Inclusion Criteria

Inclusion criteria are as follows:

- 18 years old or older
- Have used the ADU for at least one week
- Can read and understand English (or there are translation services in place to enable communication)
- Have capacity to provide informed consent
- Do not pose too high a risk to others or themselves to participate

7.2 Exclusion Criteria

We will exclude patients who are too unwell to consent, but otherwise aim to be inclusive to gain a fully representative sample, including using local interpretation facilities when necessary.

8 RECRUITMENT

As noted above, researchers will recruit participants. At baseline, ADU staff will screen all service users consecutively admitted to their service from the start date. All service users who meet the inclusion criteria will be approached by ADU staff and asked if they are willing to be contacted by researchers to discuss participation further (except at sites where service users have already given consent to be contacted directly about research projects: in this circumstance, researchers will contact service users directly once their eligibility and any risk-related safety requirements have been established). The researchers will keep a record of potential participants to be contacted and the date and the name of the clinician with whom this was agreed. Researchers will ask the clinician who spoke to each service user to note the patient's agreement to be contacted by a researcher in their patient records. Those who agree will be contacted by a researcher with an information sheet and offer to answer any questions. Potential participants will be given at least 24 hours to consider whether they would like to take part, and then if still interested they will be consented by a researcher, who will also collect the baseline data. Participants will be offered £20 in cash as a thank you for taking part (£10 for the baseline interview, and £10 for the follow up interview at 8-12 weeks after baseline). If participants decline this money it will be returned to the study. Participants will be contacted by phone by a researcher 8-12 weeks after baseline in order to collect follow up data. At 6 months after baseline, participant data will be collected from patient records and clinical notes.

While many people find talking about their experiences to be helpful, some people may find that completing the questionnaire brings up issues that cause emotional distress. In this case the researcher will provide immediate emotional support to the participant, offer to pause or postpone the interview, and, if the participant asks, will contact a person of the participant's choice (e.g. current care coordinator, carer, friend, family member, colleague) for them.

If service users or carers report any untoward feedback, the researcher conducting the interview will confirm with the participant whether or not they would like the researcher to pass this on to the service or other relevant person. If the untoward feedback is of a nature that leads the researcher to be concerned for the safety of others, the participant will be informed that the feedback will be passed on to the relevant service or person to be addressed, but that if desired and possible they will remain anonymous.

9 STATISTICAL METHODS

We will provide descriptive statistics comparing the baseline characteristics of the CRT cohorts with and without ADU care within each of the five case studies and also for the

sample as a whole. We will explore baseline differences in demographics, diagnoses and symptom severity, severity of past mental health history and pathways into the crisis service using parametric and non-parametric tests as appropriate.

For the primary outcome we will compare the risk of readmission in the groups who do and do not receive ADU care using logistic regression adjusting for age, gender, main diagnostic group and a measure of severity.

We will compare satisfaction/ experience mean CSQ-8 scores in the two cohorts and use linear regression to adjust for important covariates. We will adjust for cluster (sampling unit being the ADU), and also test for effect modification by individual ADU. We will not make head to head comparisons of outcomes between ADUs.

For the economic evaluation we will also extract health service usage from clinical notes and apply unit costs from the sources described above, to estimate the costs incurred by participants during the 6-month follow-up period, and compare mean costs per patient with or without ADU care, controlling for confounders using baseline data.

We have calculated sample size to detect a 12-13% absolute reduction in the main outcome of re-admissions to the acute pathway at 6 months after baseline (using admission figures from our previous CRT research). Our CORE programme grant1 in crisis teams is powered at 80% to detect a 15% difference between trial arms (50% versus 35%). Recent data from London crisis services suggest baseline re-admission rates could be lower, at 40%. We have explored various sample size calculations, including different assumptions regarding this baseline readmission rate. These show that 310 people in each arm would afford 90% power to detect differences such as 50% versus 36.8%, 45% versus 32.0% or 40% versus 27.4%. Inflating for a design effect by 30% to accommodate the clustered study design requires 400 per arm. These numbers also afford greater than 90% power to detect an effect size or difference of 0.3 standard deviations in the client experience measure CSQ-8 (crisis team mean CSQ = 25, sd 6).

10 DATA HANDLING AND MANAGEMENT

Hard copy consent forms and questionnaires will be completed on site at ADUs. CRN researchers will return hard copy data directly to their CRN office and store in locked filing cabinets between regular visits from UCL researchers, whereupon the hard copy data will be taken to UCL. Questionnaires will be identified by an ID number, and participant identifiers will be kept in a separate document in a locked filing cabinet in a locked storage room in the Division of Psychiatry at UCL. The participant identifier document will be kept in a separate filing cabinet to the questionnaires.

If the questionnaire is completed over the phone, the consent process will be audio recorded using a Dictaphone. Recordings will be transferred to secure UCL servers immediately after the interview and the Dictaphones subsequently wiped of recordings. All electronic data will be stored on secure UCL systems.

11 Workpackage 2.2 – Qualitative Study

12 OBJECTIVES

In this stage of the AD-CARE study, we aim to:

1. Explore the views of service users, carers and practitioners regarding the strengths and weaknesses of ADUs and their component interventions
2. Explore service user, carer, and practitioner views concerning the role of ADUs in the acute care pathway
3. Integrate these findings with those from WP2.1 to generate theory around how outcomes are achieved
4. Develop a set of recommendations outlining best practice in this field

13 STUDY DESIGN

This will be a qualitative study. Five ADUs will be identified from the national survey carried out in WP1. At each site five service users, three carers, and three members of staff will be interviewed. The sample will be purposively sampled, based on those willing to participate in the interview process.

14 STUDY SCHEDULE

Service users: We will interview five service users from the WP2.1 cohort in each case study site, assuming 5 sites, or 25 people in total. During WP2 baseline data collection participants will be asked if they would be interested in taking part in an interview with a peer researcher about their experiences. Interview participants will be purposively sampled from those who have expressed an interest and sampling will be carried out that ensures diversity in terms of gender, ethnicity, diagnosis, satisfaction with ADU and site. We do not seek representation of views but maximum diversity among participants based upon key characteristics. Interviews will take place up to one month after the service user has been discharged from the ADU, to allow enough time for reflection, but close enough to the point of discharge that there will not be any difficulty recalling experiences of the service.

Carers: We will interview three carers of people accessing ADUs in each case study site (n= 15) recruited through convenience sampling. Service users will need to give permission for

the research team to approach their carer. When permission is granted the unit staff will approach the carer and those interested will be asked to either contact the research team themselves, or give permission for the research team to contact them. These interviews will seek to explore carers' own experiences of ADUs and the potential benefits to them, and so we will not be recruiting service user-carer pairs. Interviews will occur post discharge but the timing post discharge will be more variable and up to 6 months. We want to encourage reflection and gain a perspective on the role of the ADU in context to other supports and provision.

If service users or carers report any untoward feedback, the researcher conducting the interview will confirm with the participant whether or not they would like the researcher to pass this on to the service or other relevant person. If the untoward feedback is of a nature that leads the researcher to be concerned for the safety of others, the participant will be informed that the feedback will be passed on to the relevant service or person to be addressed, but that if desired and possible they will remain anonymous.

Staff: We will interview three members of staff working within ADUs in each case study site (n= 15). We will aim to interview a sample of staff from a broad range of disciplines (e.g. lead psychiatrist, team leader, recovery worker, peer supporter, psychologist), representative of the team structures identified during WP1 mapping. Interviews will occur at any point during the WP2 data collection period.

While many people find talking about their experiences to be helpful, some people may find that the interview brings up issues that cause emotional distress. In this case the researcher conducting the interview will provide immediate emotional support to the participant, offer to pause or postpone the interview, and, if the participant asks, will contact a person of the participant's choice (e.g. current care coordinator, carer, friend, family member, colleague) for them.

Typically, interviews will take place in a room booked by the researcher at the site the participant has previously used (as a service user, carer, or staff member). All interviews will take place in person, at a time and place mutually agreed by the participant and the researcher to ensure the location is easy to travel to, provides privacy, and is safe and comfortable. Any participant travel costs will be reimbursed, or paid for in advance. Researchers will adhere to local lone-working procedures (e.g. 'checking-in' phone calls upon completion of the interview). All service user interviews will be conducted by a peer researcher (someone with lived experience of using mental health services). Carer and staff interviews are likely to be conducted by the peer researcher, but may be conducted by other study researchers in the event that the peer researcher is unavailable.

If any participant wishes to withdraw at any point they are free to do so without any detriment to their current or future care. Unless participants inform researchers that they do not want their data used, any data collected before withdrawal will be used.

The study will be completed by 30/06/2019, with the recruitment of 25 service user participants, 15 carer participants, and 15 staff participants.

15 CONSENT

As noted above, the consent process and interviews will be conducted by study researchers. Initially, ADU staff will screen all service users consecutively admitted to their service from the start date of the study. All service users who meet the inclusion criteria will be approached by ADU staff and asked if they are willing to be contacted by researchers to discuss participation further (except at sites where service users have already given consent to be contacted directly about research projects: in this circumstance, researchers will contact service users directly once their eligibility and any risk-related safety requirements have been established). The researchers will keep a record of potential participants to be contacted and the date and the name of the clinician with whom this was agreed. Researchers will ask the clinician who spoke to each service user to note the patient's agreement to be contacted by a researcher in their patient records. Those who agree will be contacted by a researcher with an information sheet and offer to answer any questions. Potential participants will be given at least 24 hours to consider whether they would like to take part, and then if still interested a time and place will be agreed for the interview, and researchers will consent the participant before starting the interview.

In order to include those whose first language is not English, any local provision by NHS Trusts for translators will be used. However, where there are no translators provided locally it will not be possible to include non-English-speaking participants.

16 ELIGIBILITY CRITERIA

16.1 Inclusion Criteria

Inclusion criteria are as follows:

- 18 years old or older
- Have used the ADU for at least one week
- Can read and understand English (or there are translation services in place to enable communication)
- Have capacity to provide informed consent
- Do not pose too high a risk to others or themselves to participate

16.2 Exclusion Criteria

We will exclude patients who are too unwell to consent, but otherwise aim to be inclusive to gain a fully representative sample, including using local interpretation facilities when necessary.

17 RECRUITMENT

As noted above, study researchers will recruit participants. At baseline, ADU staff will screen all service users consecutively admitted to their service from the start date. All service users who meet the inclusion criteria will be approached by ADU staff and asked if they are willing to be contacted by researchers to discuss participation further (except at sites where service users have already given consent to be contacted directly about research projects: in this circumstance, researchers will contact service users directly once their eligibility and any risk-related safety requirements have been established). The researchers will keep a record of potential participants to be contacted and the date and the name of the clinician with whom this was agreed. Researchers will ask the clinician who spoke to each service user to note the patient's agreement to be contacted by a researcher in their patient records. Those who agree will be contacted by a researcher with an information sheet and offer to answer any questions. Potential participants will be given at least 24 hours to consider whether they would like to take part, and then if still interested they will be consented by a researcher, who will also collect the baseline data. Participants will be offered £20 in cash as a thank you for taking part. If participants decline this money it will be returned to the study.

While many people find talking about their experiences to be helpful, some people may find that completing the questionnaire brings up issues that cause emotional distress. In this case the researcher will provide immediate emotional support to the participant, offer to pause or postpone the interview, and, if the participant asks, will contact a person of the participant's choice (e.g. current care coordinator, carer, friend, family member, colleague) for them.

If service users or carers report any untoward feedback, the researcher conducting the interview will confirm with the participant whether or not they would like the researcher to pass this on to the service or other relevant person. If the untoward feedback is of a nature that leads the researcher to be concerned for the safety of others, the participant will be informed that the feedback will be passed on to the relevant service or person to be addressed, but that if desired and possible they will remain anonymous.

18 ANALYSIS METHODS

The interviews will be analysed by the peer researcher, directly supervised by the study qualitative leads, with input and support from the SURG and the wider research team. We will use thematic analysis and will elicit detailed descriptions of the perceived strengths and weaknesses of ADUs to inform the development of best practice recommendations, and will aim to generate theory around the processes through which ADUs might impact on recovery, as well as the outcomes measured during WP2. The qualitative data analysis software NVivo will be used to assist the management of data and facilitate systematic examination of the interview transcripts.

19 DATA HANDLING AND MANAGEMENT

Hard copy consent forms will be completed at the interview. Interviews will be recorded on Dictaphones, transferred to secure UCL systems directly after the interview, and the Dictaphones immediately wiped. Electronic files will be identified by an ID number. Transcripts of each interview will be identified by an ID number, and participant identifiers will be kept in a separate document in a locked filing cabinet in a locked storage room in the Division of Psychiatry at UCL. The participant identifier document will be kept in a separate filing cabinet to the transcripts.

20 Workpackages 2.1 and 2.2

21 PATIENT AND PUBLIC INVOLVEMENT (PPI)

Patients and the public will be actively involved in this research programme and have been resourced appropriately to cover their planned roles. There are three key involvement mechanisms:

- Employment of a researcher who will draw on their lived experience of mental health problems within their role as a peer researcher. They will be a central member of the multi-disciplinary research team.
- We are building a Service User Research Group (SURG sometimes called Lived Experience Advisory Panel- LEAP) with six members including coverage of the sites selected. The McPin Foundation will convene and coordinate the SURG. The SURG will work closely with the peer researcher to deliver the case study work – planning data collection, directly promoting the study in the sites and being part of the synthesis phase as well as the overall study analysis phase integrating data from all work packages.

- We will build a network of people and organisations to help us build a dissemination strategy including practitioners, carers and service users as well as organisations involved in the improvement of acute care services. This network will emerge through the contacts we build to deliver the research programme.

The lead coordinator of our involvement approach will be Vanessa Pinfold, research manager from McPin Foundation who is an expert in acute care and the Crisis Care Concordat.

22 FUNDING AND SUPPLY OF EQUIPMENT

The study funding has been reviewed by the UCL/UCLH Research Office, and deemed sufficient to cover the requirements of the study. NHS costs will be supported via UCLH and/or the Local Clinical Research Network.

The research costs for the study have been supported by the NIHR HS&DR programme grant 15/24/17.

23 PEER AND REGULATORY REVIEW

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

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

24 ASSESMENT AND MANAGEMENT OF RISK

While many people find talking about their experiences to be helpful, some people may find that completing the questionnaire brings up issues that cause emotional distress. In this case the researcher will provide immediate emotional support to the participant, offer to pause or postpone the interview, and, if the participant asks, will contact a person of the participant's choice (e.g. current care coordinator, carer, friend, family member, colleague) for them.

If service users or carers report any untoward feedback, the researcher conducting the interview will confirm with the participant whether or not they would like the researcher to pass this on to the service or other relevant person. If the untoward feedback is of a nature that leads the researcher to be concerned for the safety of others, the participant will be informed that the feedback will be passed on to the relevant service or person to be addressed, but that if desired and possible they will remain anonymous.

In the event that the researcher feels concerned for their own safety they will be advised to bring the interview to an end. All face-to-face interviews will be conducted on NHS premises, and local safety policies and protocols should be adhered to by all researchers (e.g. informing local staff at the start of an interview, and again once the interview has been completed).

25 RECORDING AND REPORTING OF EVENTS AND INCIDENTS

15.1 Definitions of Adverse Events

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a patient or study participant, which does not necessarily have a causal relationship with the procedure 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
*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.	

25.2 Assessments of Adverse Events

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

15.2.1 Severity

Category	Definition
Mild	The adverse event does not interfere with the participant's daily routine, and does not require further procedure; it causes slight discomfort

Moderate	The adverse event interferes with some aspects of the participant's routine, or requires further procedure, 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

15.2.2 Causality

The assessment of relationship of adverse events to the procedure 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 AE Log and 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 procedure). 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 procedure). There is another reasonable explanation for the event (e.g. the participant's clinical condition).
Not related	There is no evidence of any causal relationship.
Not Assessable	Unable to assess on information available.

15 .2.3 Expectedness

Category	Definition
Expected	An adverse event which is consistent with the information about the procedure listed in this protocol.

Unexpected	An adverse event which is not consistent with the information about the procedure listed in this protocol.

25.3 Recording adverse events

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

25.4 Procedures for recording and reporting Serious Adverse Events

All serious adverse events will be recorded in the medical records, and the study AE form, and the sponsor's AE log.

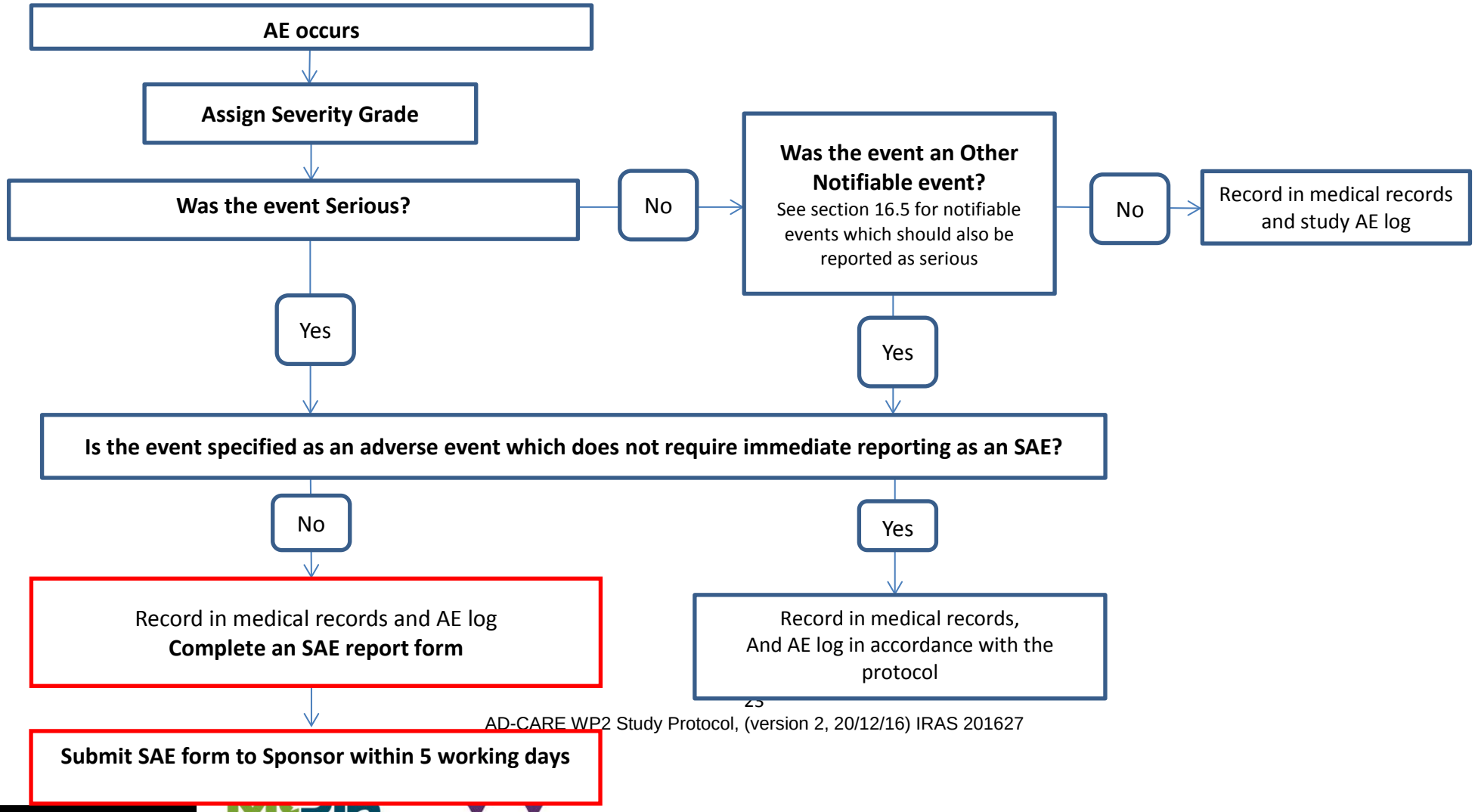
All SAEs (except those specified in section 16.5 as not requiring reporting to the Sponsor) must be recorded on a serious adverse event (SAE) form. The CI/PI or designated individual will complete an SAE form and the form will be preferably emailed to the Sponsor within 5 working days of becoming aware of the event. 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 procedure this must be reported by the Investigator to the Health Research Authority within 15 days.

Completed forms for unexpected SAES must be sent within 5 working days of becoming aware of the event to the Sponsor

Email forms to Research-incidents@ucl.ac.uk

Flow Chart for SAE reporting (this simple flow chart is for single site study, please amend in line with study specific requirements)



25.6 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 to the relevant REC and Sponsor of the measures taken and the circumstances giving rise to those measures.

25.7 Protocol deviations and notification of protocol violations

A deviation is usually an unintended departure from the expected conduct of the study protocol/SOPs, which does not need to be reported to the sponsor. The CI will monitor protocol deviations.

A 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 CI and sponsor will be notified immediately of any case where the above definition applies during the study conduct phase.

25.9 Trust incidents and near misses

An 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.

Incidents and near misses must be reported to the Trust through DATIX as soon as the individual becomes aware of them.
A reportable incident 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 of loss or damage.

26 MONITORING AND AUDITING

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 have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

27 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.

28 INTELLECTUAL PROPERTY

All intellectual property rights and know-how in the protocol and in the results arising directly from the study, but excluding all improvements thereto or clinical procedures developed or used by each participating site, shall belong to UCL. Each participating site agrees that by giving approval to conduct the study at its respective site, it is also agreeing to effectively assign all such intellectual property rights ("IPR") to UCL and to disclose all such know-how to UCL, with the understanding that they may use know-know gained during the study in clinical services and teaching to the extent that such use does not result in disclosure of UCL confidential information or infringement of UCL IPR.

29 INDEMNITY ARRANGEMENTS

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, if 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.

30 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 will archive the study master file at UCL for the period stipulated in the protocol and in line with all relevant legal and statutory requirements.

31 PUBLICATION AND DISSEMINATION POLICY

Dissemination will be carefully planned with The McPin Foundation and NHS England to ensure high quality peer review of our outputs and stakeholder engagement and information sharing.

We will provide the usual full scientific reports, peer reviewed papers, powerpoint presentations, conference talks, and web output. We will also consult with our PPI and NHS management colleagues to disseminate our findings across a range of NHS and health provider platforms. We will produce our summary documents in a range of formats suitable for different audiences.
We will develop an AD-CARE website hosted at UCL. All ADUs and crisis services will be sent links to the website. Twitter will be used for distributing publications to a variety of audiences and findings more widely once published in open access journals.
We will hold an expert consensus meeting/conference in the final two months of the project.

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Appendix 1

Version 2 of the protocol includes changes requested by the London (Bloomsbury) Research Ethics Committee:

- Clarification that data to be archived 1 year after the end of the study, and destroyed after 20 years, includes audio recordings
- The REC felt it was unnecessary to re-consent participants at follow up, and so this has been dropped from the protocol.