Trial Protocol Front Page

Full title of trial	Development, Feasibility Testing and Pilot Trial of a Crisis Planning and Monitoring Intervention to Reduce Compulsory Hospital Readmissions (the FINCH Study)
Short title	A crisis planning intervention to reduce compulsory admissions
Version and date of protocol	Version 1, 02/08/2021
Sponsor:	University College London (UCL)
Sponsor reference number:	143180
Funder (s):	National Institute of Health Research
IRAS Number:	300671
ISRCTN / Clinicaltrials.gov no:	To be registered before the trial commences.
UCL Data Protection Number:	Z6364106/2021/08/51 health research
Intervention:	A crisis planning psychosocial intervention

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PROTOCOL VERSION HISTORY

Version Stage	Versions Number	Version Date	Protocol updated & finalised by;	Reasons for Update
Previous	0.1	25/05/21	Lisa Wood	
Current	1	02/08/21	Sonia Johnson	Minor amends to study design

DECLARATIONS

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

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

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

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

Chief Investigator:

Signature: Sonia Johnson Date 02/08/2020

Print Name (in full): SONIA JOHNSON

Position: Chief Investigator, Professor of Social and Community Psychiatry

On behalf of the Study Sponsor:

Signature: Eirini Tsitsipa Date: 02/08/2021

Print Name (in full): Eirini Tsitsipa

Position: Sponsorship Officer

STUDY SUMMARY

IDENTIFIERS	
IRAS Number	300671
REC Reference No.	TBC
Sponsor Reference No.	143180
Other research reference number(s) (if applicable)	Funder reference number: NIHR20173 Data protection reference number: Z6364106/2021/08/51 health research
Full (Scientific) title	Development, Feasibility Testing and Pilot Trial of a Crisis Planning and Monitoring Intervention to Reduce Compulsory Hospital Readmissions (the FINCH Study)
Health condition(s) or problem(s) studied	Service users with acute mental health difficulties who have been compulsorily detained under the Mental Health Act (section 2 or 3)
Study Type i.e. Cohort etc	Complex intervention development and a pilot randomised controlled trial
Aim(s) and Objectives:	We aim to develop and test an intervention to prevent compulsory readmission and develop self-management skills among people who have been compulsorily detained under the Mental Health Act. In the first phase of the study, we will adapt an intervention that has shown considerable promise in a trial in a large metropolitan area in Switzerland. This stage includes initial investigation of feasibility and acceptability. The second phase involves a pilot randomised controlled trial, intended to assess whether this intervention can be tested through a definitive trial and to make an initial assessment of its effectiveness.
Type of trial:	A multi-site pilot randomised controlled trial of a crisis planning intervention for those detained compulsorily under the Mental Health Act
Trial design and methods:	Phase 1: The first phase of the study will involve adapting the Swiss intervention by following an iterative process. This will involve examining current evidence, undertaking qualitative interviews with service user (up to n=12) and staff (up to n=12) about the contents of the intervention, and preliminary testing of the intervention with n=6 service users. This preliminary testing will include n=6 service users completing baseline measures, receiving the intervention and then, as well as their key clinicians/practitioners delivering the intervention (up to n=6), being interviewed. Phase 2: A multi-site proof-of-concept pilot randomised control trial will be conducted to investigate recruitment and intervention delivery parameters and obtain initial evidence as to whether trial process and outcomes are consistent with the intervention being potentially effective. In our methodology, we follow recent MRC and CONSORT guidance on feasibility and pilot studies (29-30). Participants will be randomised by an independent statistician at

	University College London who will allocate participants via a computer-generated allocation sequence to intervention or control group in a 1:1 ratio using block randomisation stratified by site and ethnicity (ethnic minority groups at higher risk of detention vs. White/Other). All primary and secondary measures will be collected at baseline, 6-months post randomisation, and 12 months post-randomisation. Compulsory readmission and other service use outcomes will be assessed at 12 and 24-months post randomisation. Qualitative interviews will be undertaken with up to n=20 service users who received the intervention as part of the pilot RCT and up to n=18 clinical key workers/ mental health workers who delivered the intervention.
Trial duration per participant:	24 months
Estimated total trial duration:	43 months
Planned trial sites:	Camden & Islington NHS Foundation Trust, North East London NHS Foundation Trust, Lancashire and South Cumbria NHS Foundation Trust
Total number of participants planned:	Phase 1: N = 18 service user participants; N = 18 staff participants Phase 2: N = 80 service user participants; N = 18 staff participants Total: N = 134
Main inclusion/exclusion criteria:	Eligible patient participants will: have been compulsorily detained during their current hospital admission; be due to receive community mental health care locally post-discharge; be aged 18 and over; have capacity to consent at the time of recruitment. They will be recruited close to the point of discharge.
Statistical methodology and analysis:	**Quantitative analysis:** The focus of the analysis will be on key indicators of feasibility, including participant recruitment, retention in the trial and the intervention, which will be summarised descriptively using frequencies and percentages. Continuous clinical outcome measures will be summarised separately by study arm using means and standard deviations or medians and interquartile ranges, as appropriate for the distribution of the data. Binary outcome measures will be summarised using frequencies and percentages. The quantity of missing data for each clinical outcome will be examined and likewise summarised by study arm. This pilot study will not have sufficient power to assess the effectiveness of the intervention. However, to trial the analysis envisaged for a future, fully powered, effectiveness RCT, clinical outcomes at follow-up time points will be compared between study arms, using linear or logistic regression models as appropriate, and adjusting for the baseline measure of the outcome in question.

	Qualitative analysis: Semi-structured interviews will be transcribed verbatim and analysed using thematic analysis. Analysis will be conducted on NViVo software. Initially each transcript will be read and reread to ensure the researcher is fully immersed in the data, and then initially coded. Codes will be collated together across interviews and grouped together to form analytical themes. Patterns of themes will be explored across the data set focussing on both commonalities and variations and comparing service user and therapist perspectives. The theme structure will be checked with a small number of participants to check it reflects their experiences. The final theme structure will also be discussed with the research team and stakeholder group (including people with lived experience of psychosis and inpatient admission).
FUNDING & OTHER	
Funding	National Institute of Health Research
STORAGE of SAMPLES / DATA (if applicable)	
Data collected / Storage	Dr Mary Birken, Division of Psychiatry, Maple House, 149 Tottenham Court Road
KEY STUDY CONTACTS	
Committees	Trial steering committee (members detailed in relevant section of protocol)
Sub-contractors	Not applicable
Other relevant study personnel	Not applicable

KEY ROLES AND RESPONSIBILITIES

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

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

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

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

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

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

TRIAL PERSONNEL

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

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KEY WORDS

Mental Health Act, crisis intervention, inpatient admission, randomised controlled trial

Contents

1. OVERVIEW OF THE STUDY

The rate of compulsory admission has been rising in the UK. This is highly problematic because of the associated distress and disempowerment, and because mental health care should as far as possible be based on principles of consent and collaboration. People with previous compulsory admissions are at high risk of a repeat compulsory admission, making them an important potential focus for interventions to reduce detentions. We aim to develop and test an intervention to prevent compulsory readmission and develop self-management skills among people being discharged following a compulsory admission. In the first phase of the study, a coproduced approach will be taken to adapting an intervention that has shown considerable promise in a trial in a large metropolitan area in Switzerland. This stage includes initial investigation of feasibility and acceptability, especially to Black/Black British service users. The second phase involves a pilot trial, intended to assess whether this intervention can be tested through a definitive trial and to make an initial assessment of its potential effectiveness. We hope to produce initial evidence as to whether our intervention is feasible and acceptable. We will engage stakeholders throughout by a blog, dissemination events, policy briefs and social media, and will publish scientific papers from both phases describing justified conclusions thus far and their implications. A Gantt chart of study processes can be found in the appendix.

2. BACKGROUND AND RATIONALE

The problem addressed is the relatively high, and recently rising, rate of compulsory psychiatric hospitalisation in England and Wales, a challenge that several other European countries also face (10). Official data suggest use of the Mental Health Act to detain people in hospital increased by 40% between 2006 and 2016 (11). There is also a striking ethnic inequality in risk of being detained, with people from Black and Black British ethnic groups around four times as likely to be detained as White British people (11-13). Currently we lack strategies for preventing compulsory admission that are rooted in evidence and have been successfully implemented as part of standard UK mental health care (14).

High rates of compulsory admission are important because service users and carers recurrently report that this is a distressing and sometimes traumatising experience, which greatly disrupts recovery and therapeutic alliances (15,16). Compulsory admission, and the coercion and disenfranchisement that are inevitably involved, also violates an otherwise highly regarded principle, that mental health treatment should be freely chosen and as collaborative as possible. Thus, there is a strong case for keeping compulsory admissions to a minimum. The experiences of ethnic minority communities are especially important, as high rates of coercive treatment, especially in Black/Black British communities, constitute an important inequality and contribute to mistrust of mental health services. Compulsory admissions are also expensive, recently estimated as costing £18,315 per admission (12). Policy makers and service user advocates thus concur in prioritising prevention of compulsory admission, the focus of the funding call to which we are responding.

Our ultimate aim in our proposed study is to reduce overall levels of compulsory admission through an intervention designed to reduce compulsory **re**admissions and for this to be suitable for and engaging to Black African, Caribbean and British service users due to their overrepresentation in this setting. Our finding in a recent review (17) that past compulsory admission is one of the main risk factors for future compulsory admission provides a rationale for focusing on preventing **repeat** compulsory admission. The proposed pathway is via an individualised crisis planning and monitoring intervention for people who have just had a compulsory admission. Reducing repeat compulsory admissions is one of three main potential pathways to reducing compulsory admissions, the others

being early intervention to prevent the crises that lead to hospitalisation, and diversion to community alternatives at the point of admission.

We suggest that, in order to maximise chances of substantially reducing compulsion, there should be research investment in each. Our plans and chosen strategy for reducing compulsory admissions are rooted in the evidence syntheses that we led to inform the Independent Review of the Mental Health Act in our (SJ and BLE) leadership roles in the NIHR Mental Health Policy Research Unit (MHPRU). We also draw on subsequent consultations, including a large stakeholder event in March 2019: the purpose of this event was for a mixed group, including service users and carers, researchers, clinicians and policy makers, to discuss priority next steps for research to reduce compulsory admission (18). We drew the following conclusions following this work:

- Firstly, our literature syntheses established that there is currently very little evidence on what interventions or service arrangements can reduce compulsory admissions or readmissions (14). Very few trials of psychological, psychosocial or team interventions include compulsory admission as a primary or even secondary outcome. This is unlikely to change imminently: our search of the ISRCTN, ClinicalTrials.gov and EU Clinical Trials Register found no trials in progress with compulsory admission as primary outcome. Thus, there is a long way to go to reach a point where interventions can be rolled out with confidence that they prevent compulsory admission, so that it is very desirable that robust trial evidence is urgently obtained regarding effectiveness and cost-effectiveness of candidate interventions.
- Secondly, when evidence from all available studies is pooled through meta-analysis (19,20), the only kind of intervention that currently has substantial evidence for effectiveness in reducing compulsory admissions is advance planning for crises and collaborative agreements with patients on how to manage them. Such strategies tend to be called crisis plans or advance statements. Based on this evidence, the Independent Review of the Mental Health Act recommends mandatory use of Advance Choice Documents, in which patients record preferences for management of future crises. Compulsory community treatment, for example through Community Treatment Orders, is the approach to preventing compulsory admission that has been most investigated. However, current evidence, as synthesised in our comprehensive review of randomised and non-randomised studies, does not support compulsory community treatment as a means of reducing levels of compulsory admission (21).
- Thirdly, in our systematic review of crisis planning interventions (19), we found that while crisis planning/advance statement interventions appeared effective in reducing compulsory admission when all results of all studies were analysed together through meta-analysis, there was considerable variation between individual studies in size of effect and whether statistical significance was reached. Difficulties in implementing crisis planning interventions effectively were noted in several studies. In particular, in the largest UK trial, a crisis planning model that had initially appeared effective in a single site trial showed little evidence of effectiveness when tested across multiple sites at a larger scale (22-24). This was attributed to clinicians often failing to modify their routine practice to incorporate crisis planning as intended, and to crisis plans rarely being referred to by clinicians or service users in subsequent care or help-seeking. Thus, it is likely that, to be reliably successful in reducing compulsory admission, crisis planning needs to be embedded in a framework that ensures it is delivered in practice, and that the crisis plans that are formulated are subsequently monitored and followed through.
- Finally, one of the trials we identified in our evidence gathering stood out as having a substantially more intensive and developed approach to implementation than the rest, including clear strategies for continued monitoring for signs of crisis and for giving service users a voice. This is the study carried out by Dr Barbara Lay and her colleagues in the

multicultural Swiss city of Zurich (25- 26). This intervention also has the advantage of integrating crisis planning within a framework of supported self-management, with service users provided with education, support and resources to make active plans to manage their own mental health and respond to any early warning signs of deterioration. Supported self-management is an approach for which our recent review (27) finds benefits on several clinical and social recovery outcomes, and it is a natural overall framework in which to embed crisis planning.

Based on this and on subsequent consultations including our stakeholder event, we have identified the Zurich study intervention as the most promising starting point for developing an effective intervention for prevention of compulsory readmissions (25). Developed by leading researchers from German-speaking countries, it is designed to prevent repeat compulsory admissions, and comprises a programme of psychoeducation, crisis planning and monitoring by phone for people who are being discharged following a compulsory hospital admission. The policy recommendation for implementation of Advance Choice Documents, accepted in principle by the Government, fits well within its framework: we will tailor the programme to any emerging policy guidance. Advance Choice Documents are intended to have a relatively narrow focus on the response once a crisis is underway, and especially to direct care once someone has lost decision-making capacity: our study intervention will provide space and structure for service users to formulate this Advance Choice Document and locates it within a broader framework of psychoeducation and of empowering service users to monitor and respond to early warning signs of crisis.

Findings from the Swiss trial of the Zurich intervention were promising: over two years, 28% of people in this programme were compulsorily readmitted compared with 43% of controls receiving standard local care: with adjustment for other differences, the estimated relative risk of compulsory readmission for the treatment group was 0.55 (confidence interval: 0.33-0.94) (26). Thus if similar effectiveness can be achieved in the UK, there is scope for making a substantial reduction in compulsory readmissions. This trial has some important limitations: it did not achieve the statistical power it had specified, and differential drop-out rates create ambiguity in interpreting the statistically significant result. However, in addition to having a promising, if not definitive result, the trial intervention appears carefully designed, with a clear theoretical basis and congruence with well-established principles of crisis planning and of supported self-management, and it has proved acceptable to a diverse sample.

A further advantage is that it already has a tele-medicine component, and in the light of changes in practice during the COVID-19 pandemic, can readily be adapted to include video-calls as an option. In a field where evidence is meagre, there is thus a good case for using this model as a starting point. Our plan is to adapt it for a UK context, explore its feasibility and acceptability, and conduct a pilot trial to establish proof of concept in preparation for larger-scale testing.

3. AIMS AND OBJECTIVES

3.1.Aims

Our overall aim is to examine whether it is feasible and acceptable to deliver, and test through a randomised controlled trial and accompanying qualitative evaluation, an intervention involving psychoeducation, crisis planning and monitoring to reduce the rate of repeat compulsory admissions. We will also obtain initial evidence as to whether outcomes and process measures are consistent with the intervention being effective. This intervention will be delivered by clinical psychologists or similarly qualified mental health workers and draws on an intervention programme developed and evaluated with promising results in Switzerland. We will recruit 50% of participants

from Black, Black British or from another ethnic minority background as these individuals are more likely to be compulsorily admitted to hospital. We therefore need to ensure that this new intervention is suitable for the needs of these people.

The specific aim is to:

- To adapt to a UK context and explore the feasibility and acceptability of the psychoeducation, crisis planning and monitoring intervention developed and tested in Zurich (26).

3.2.Objectives

3.2.1.Development and adaptation of the intervention:

- To conduct qualitative interviews with service users (up to n=12) and staff (up to n =12) regarding recruitment and the content and implementation of the intervention.
- To deliver the intervention to a preliminary group of six participants, allowing us to study their experiences and the process of intervention delivery by interviewing them (up to n=6) along with their key clinicians/mental health workers delivering the intervention (up to n=6).
- To draw together these inputs in a trial protocol, intervention manuals, Theory of Change outline and description of the intervention following the TIDIER (Template for Intervention Description and Replication) checklist (28).

3.2.2.Undertake a pilot randomised controlled trial:

- To recruit 80 participants from inpatient wards in two London Trusts (Camden & Islington NHS Foundation Trust and North East London NHS Foundation Trust) and Trust outside London (Lancashire Care NHS Foundation Trust), with the aim that half are from minority ethnic backgrounds at high risk of detention.
- To randomise 40 to receive the innovative intervention, provided as an addition to routine care, and 40 to treatment as usual with no additional intervention.
- To assess clinical outcomes at 6 months and 12 months. To assess compulsory admission at 12 and 24 months as the primary outcome along with other service-related outcomes.
- To examine whether the recruitment and retention targets are met, and the intervention taken up, and to be desirable in a full trial.
- To undertake qualitative interview with up to n=20 service users who received the intervention, and up to n=18 key clinicians/mental health workers delivering the intervention to identify their experiences of the intervention.
- Also address preceding objectives in relation to over-represented ethnic minority participants, of whom we aim to have at least 20 receiving the intervention.
- To consider the above data with the study co-applicants, the Co-production Group, the funders and an independent advisory group, and reach a decision about whether a full trial is justified and necessary. If it is, to prepare finalised materials for this, including revising the intervention manual and training guidance.

4. STUDY DESIGN

This study is following guidance from the Medical Research Council in developing and evaluating complex health interventions (29).

4.1. Phase 1

The first phase of the study will involve adapting the Zurich intervention by following an iterative process. This will involve examining current evidence, undertaking qualitative interviews with service user (up to n=12) and staff (up to n=12), and preliminary testing of the intervention with up to n=6 service users who will be interviewed about the delivery of the intervention. The practitioners delivering the intervention and clinicians working closely with the service user will also be interviewed (up to n = 6).

4.2 Phase 2

A proof-of-concept pilot randomised control trial will be conducted to investigate recruitment and intervention delivery parameters and obtain initial evidence as to whether trial process and outcomes are consistent with the intervention being effective. In our methodology, we follow recent MRC and CONSORT guidance on feasibility and pilot studies (29-30). Participants will be randomised by an independent statistician at University College London who will allocate participants via a computer-generated allocation sequence to intervention or control group in a 1:1 ratio using block randomisation stratified by site and ethnicity (ethnic minority groups at higher risk of detention vs. White/Other). Clinical outcomes will be collected at baseline, 6-months and 12 months post-randomisation. Compulsory readmission and other service use outcomes will be assessed at 12 months and 24-months post randomisation. The study plan, schedule of participant activities, and study flow diagram are outlined in the appendix. Full Health Research Authority (HRA) and NHS Research Ethics Committee (REC) approval has been sought and the study is sponsored by University College London.

5. SAMPLING METHODS

Participants will be recruited from three sites; Camden & Islington NHS Foundation Trust, North East London NHS Foundation Trust, and Lancashire and South Cumbria NHS Trust. Purposive sampling will be undertaken to ensure that the sample is representative of the service user population. We will aim for half of our participants to be from ethnic minority groups at higher likelihood of being admitted (i.e those from Black, Asian and mixed-race ethnic minority backgrounds).

5.1 Inclusion criteria

5.1.1. Service user participants

Eligible participants will (a) have been compulsorily detained under Section 2 or Section 3 of the Mental Health Act during their current hospital admission, (b) be due to receive community mental health care locally post-discharge, (c) be aged 18 and above, and (d) have capacity to consent at the time of recruitment.

5.1.2. Clinician participants (for intervention development and evaluation)

Eligible participants will be (a) currently working in an NHS mental health service as nurse, psychiatrist, psychologist, social worker, occupational therapist, support worker or assistant psychologist (b) are currently working with service users who are currently or recently (in the last 6 months) detained under section of the Mental Health Act (section 2 or 3).

5.1.3. Personal mental health worker (for intervention evaluation)

Eligible participants will have delivered the adapted intervention to participants in the trial.

5.2 Exclusion criteria

5.2.1 Service user participants

Participants will be excluded if they (a) are already receiving an intensive psychosocial intervention that focuses on crisis reduction (for example, assertive outreach services) (b) have a diagnosis of dementia or a brain injury (c) do not speak sufficient English to take part without an interpreter (d) lack capacity to consent.

5.2.2. Clinician participants (for intervention development and evaluation)

None specified

5.2.3. Personal mental health worker (for intervention evaluation)

None specified

5.3 Recruitment

Participants will be recruited from three NHS Trusts and recruited from acute mental health inpatient wards for adults. The study will be advertised to the inpatient staff teams who will in turn provide information about the study to eligible participants. Staff will be asked to consider the stage of service users' recovery and likely capacity to understand the study purpose and requirements before approaching patients on our behalf. Posters will also be put up, and flyers distributed, on recruiting wards to advertise the study. We will also promote the study on social media related to the trust, and share advertising material with relevant local advocacy and voluntary services within trust's locality. If thought appropriate by staff, we will present the study briefly at community meetings on the ward. We will also liaise with Clinical Studies Officers linked to the R&D departments that are involved in this study, especially those embedded within inpatient teams. This will help the Clinical Studies Officers answer questions about the study and refer interested patients onto the study team. We will aim to recruit participants nearer towards discharge.

Before meeting with potential participants, the research team will firstly discuss with ward staff whether they believe service users are at a suitable stage of recovery and likely capacity for it to be appropriate for informed consent to be sought from them.

If the staff team agree to a particular service user's involvement in the study, the service user will then be contacted or approached by a member of the research team who will share more detailed information and gain informed consent if the service user wants to participate. They can also contact the research team directly via contact details on the recruitment materials. The participant will have adequate time to consider if they want to take part (a minimum of 24 hours).

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

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

5.4 Informed Consent

Full written informed consent will be taken by a member of the research team who is suitably trained and has local NHS approvals. Some participants may prefer to meet with the research team remotely. Participants will be given the Participant Information Sheet (which includes the HRA's GDPR recommended wording) and will have the opportunity to ask questions. Participants will have adequate time to consider if they want to take part (at least 24 hours). Participants will be deemed

to have capacity to consent if they understand the purpose and nature of the research, risks and benefits once going through the information sheet with a researcher and are able to retain the information long enough to make an informed decision.

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

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

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

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

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

5.5 Blinding

Some of the study team will be unblinded so that they are able to deal with any logistical or other issues with intervention delivery as they arise. Other members of the study team, such as the research assistant, will be blind to treatment allocation. This means that they will not know who is receiving the new crisis-planning intervention, and who is receiving treatment as usual. The research assistant will be responsible for collecting much of the outcome data, so this is important in minimising bias. The study team will coordinate with the personal mental health workers delivering the intervention to minimise the likelihood that the blind researchers will be accidentally exposed to information about group allocation (known as 'blind breaks'). Blinding will be monitored, and if any blind breaks occur they will be systematically recorded.

6. INTERVENTION DEVELOPMENT

6.1. Qualitative interviews for the intervention development:

Qualitative interviews will be conducted with up to n=12 service users and up to n=12 clinical staff who meet the eligibility criteria in section 5.1.1. and 5.1.2. to inform the intervention development. These interviews will examine views about what leads to repeat compulsory admission, the potential acceptability of our intervention and how it can best be implemented to prevent compulsory readmission. These interviews will be transcribed and thematically analysed, focusing on content relevant to development of the intervention and of recruitment strategies. They will be conducted a member of the research team or a fully trained member of the coproduction group face to face or online, depending on the participants' preference.

6.2 Piloting of the intervention

A preliminary sample of n=6 meeting the eligibility criteria outlined in section 5.1.1. will be recruited to receive a preliminary version of the intervention. The process of intervention delivery will be studied, as well as running the baseline measures with the group to check the feasibility of taking these measures. The participants (n=6) involved (both the clinicians and practitioners (n=6) delivering the intervention (meeting criteria in section 5.1.2. or 5.1.3) will be interviewed.

7. INTERVENTIONS

7.1 Name and description of intervention under investigation

Crisis psychoeducation intervention: The plan for the intervention is described here but is subject to change following phase 1 of the study.

Each intervention participant will receive:

(a) Up to four initial sessions with a "personal mental health worker" (a clinical psychologist or equivalently skilled worker - terminology, desirable qualifications and characteristics to be reviewed in Phase 1). These will focus on: initial relationship building; individualised education about risk factors for relapse; information about accessing and using services and treatments; information on their specific mental health problem; identification of individual risk and protective factors; exploration of individual recovery goals. Meetings may be conducted in person, or via video-conference depending on current Covid-restrictions and participants' preference. The content of the intervention will be finalised by the coproduction group.

(b) Production, in electronic or paper form, of a crisis plan/advanced statement, outlining warning signs to monitor strengths and resources, a personalised crisis action plan and details of sources of help and support. This will be adapted to incorporate emerging policy guidance on content of Advance Choice Documents regarding preferences for crisis management.

(c) Monthly telephone or video call monitoring over one year, initiated by the personal mental health worker, including checking warning signs and prompting coping responses.

The trial intervention will be provided as an addition to mental health care of usual type and quality, received by members of this groups.

Treatment as usual: This will be the routine care that participants receive. This includes multi-disciplinary care from mental health nurses, nursing assistants, psychiatrists, pharmacists, occupational therapists and psychologists in both the inpatient and community setting.

8. TRIAL PROCEDURES

8.1 Pre-intervention assessments

8.1.1. Primary outcome

Number of participants who had been compulsorily detained or not, which will be taken from medical notes.

8.1.2. Other Clinical Outcomes

Service engagement will be measured through routinely collected data from patient records about all service use during data-collection periods.

The remaining clinical outcome measures will be collected by a research assistant blind to treatment allocation. The measures will be administered during a face to face, or if not possible remote, interview between the participant and the research assistant.

Satisfaction with services will be examined using the Client Satisfaction Questionnaire (CSQ). It is an 8-item scale where participants can rate their satisfaction on a 4-point likert scale.

Personal recovery will be measured by the 15-item Process of Recovery Questionnaire (QPR) (33). Participants can score from 0 (disagree strongly) to 4 (agree strongly) on each item and score a total a maximum of 40 on the scale.

Self-management confidence will be measured using the Mental Health confidence scale (34). Participants rate their mental health confidence on 16-tems on a 6-point likert scale from very non-confident to very confident.

Quality of life will be measured by the REQOL-10 and EQ-5D-5L. They are both widely used measures in clinical trials and has been successfully used with psychosis populations. On the REQOL, participants rate their quality of life on 10-items from 0 to 4. A participant can score a total of 40 (36). For the EQ-5D-5L, participants rate quality of life on 5-items (mobility and self-care) where they can score from 1 –3. A participant can score a total of 15.

Psychiatric symptoms will be assessed using the Brief Psychiatric Rating Scale. Participants are rated by a clinician on 18 items from 0 (not assessed) to 7 (extremely severe) to give an overall score of psychiatric symptoms.

Economic costs will also be assessed using an adapted version the “generic UK mental health” version of the Client Service Receipt Inventory (37). The CSRI has also been adapted to examine service use and service engagement.

We will also record demographic and clinical/service user characteristics,
including Community Treatment Order status, previous admission history and clinical diagnosis.

8.2 Registration/Randomisation Procedures

Randomisation will take place following baseline interviews. An independent statistician at University College London will allocate participants via a computer-generated allocation sequence to either the intervention or control group in a 1:1 ratio using block randomisation stratified by site and ethnicity (ethnic minority groups at higher risk of detention vs White/Other).

8.3 Intervention Procedures

8.3.1.Crisis psychoeducation intervention

Each participant will receive up to four initial sessions with a “personal mental health worker” to undertake the crisis intervention and develop a crisis plan/advanced statement. They will then

receive monthly telephone or video call monitoring over one year, initiated by the personal mental health worker, including checking warning signs and prompting coping responses.

The four intervention sessions will begin on the acute inpatient ward and if needed continue into the community (either remotely or face to face in a community service setting or at the participants home). The therapists will receive a one-to-two-day training package in order to deliver the intervention, which will be manualised in the course of the initial 8 month intervention development phase. The training will be delivered by a clinical psychologist and an expert by experience. All mental health workers will have access to monthly supervision whilst they are delivering the therapeutic intervention.

All mental health workers will record information on the content and delivery of the sessions, including information on the session length, location and types crisis management strategies utilised (e.g. assessment, formulation, relapse prevention) on a pre-defined database.

All therapy sessions will be audio recorded if the participants gives written consent for them to do so. Fidelity to the intervention will be measured using a fidelity checklist which will be finalised in collaboration with the coproduction panel.

8.3.2. Treatment as usual

This will be the routine care that participants receive. This includes multi-disciplinary care from mental health nurses, nursing assistants, psychiatrists, pharmacists, occupational therapists and psychologists in both the inpatient and community setting.

8.4 Subsequent assessments and procedures

8.4.1. Feasibility outcomes

Detailed trial parameters will be recorded. These will include rates of eligibility among those screened, recruitment and acceptance of randomisation, rates and patterns of attrition from treatment and trial, extent of delivery of each intervention component, completion rates for individual outcome measures, and event rates on the outcome of compulsory readmission. As further described below under *Analysis*, we will assess the extent to which targets for progress to a definitive trial have been met.

8.4.2. Primary outcome

Compulsory readmission to hospital will be examined at 12-months and 24-months. These data will be taken from the participants' medical notes.

8.4.3. Secondary outcome measures

All secondary clinical outcomes outlined in section 7.1 will be repeated six months post randomisation and twelve months post randomisation. These will be conducted either face to face or remotely.

Service engagement and service use will be collected from medical records at 12 and 24 months.

8.4.4. Qualitative interview to investigate experiences of receiving the intervention

Qualitative interviews will be conducted with up to 30 consenting intervention group participants (depending when thematic saturation is reached and a representative sample obtained), purposively sampled to include a full range of demographic characteristics and service experiences. between six and nine months after baseline. These will usually be carried out by service user researcher members of the Co-production Group to facilitate empathy and open disclosure, supported by the

research team. Study researchers will interview the "personal mental health workers". Topic guides will explore experiences of the intervention and its acceptability, barriers and facilitators to making use of it, possible mechanisms of effect, potential benefits or harms, and suggested changes. Data collection and analysis will be guided by the Theoretical Framework of Acceptability (38) using thematic analysis, exploring in relation to the intervention the seven domains of acceptability specified in this framework: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and self-efficacy.

8.5 Discontinuation/withdrawal of participants

In consenting to participate in the trial, participants are consenting to intervention, assessments, follow-up and data collection. Participants also consent to the research team continuing to collect data from medical records should they lose capacity at any point during the trial.

Therefore, if a participant loses capacity during the course of the trial, they will no longer be contacted for follow-up assessments. However, their data collected up until that point will be retained and the study team will continue to use data from the participant's medical records.

However, if within a month clinicians judge capacity to have returned, and if participants wish to continue with research assessments, we will try to include the participant again at this stage. If more than a month elapses without a clinician indicating the participant has capacity to continue, we will assume capacity has been lost and stop contacting participants about further research assessments.

We make these allowances because transient relapses are fairly frequent amongst populations of individuals with Serious Mental Illness and we would like to provide the participants the opportunity to fully re-enter the study should they wish.

8.6 If a participant explicitly states they do not wish to contribute further data to the trial their decision must be respected and recorded in the CRF and medical notes.

8.7 Definition of End of Trial

The end of trial is the date of the last visit/ telephone follow up/home visit of the last participant.

9. FINANCE AND SUPPLY OF EQUIPMENT

The research costs for the study have been supported by the National Institute of Health Research. This study was funded £808,077.00 and began on the 1st January 2021. The research team have no financial interests and there are no commercial ties for this study. This study will develop an intervention to help reduce compulsory readmission. This will be made available once the study is completed.

10. DATA MANAGEMENT

10.1 Confidentiality

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

The study will be collecting the following personal data: patient names, address, contact details and GP name, but these will be electronically stored separately from study data.

The Case Report Forms (CRFs) will not bear the participant's name or other personal identifiable data. The participant's initials, date of birth and trial identification number, will be used for identification and this will be clearly explained to the patient in the Patient Information Sheet. Patient consent for this will be sought.

Data on service use, psychiatric diagnosis and related symptoms, risk assessment and hospitalisation will be extracted from medical notes. All information extracted from medical notes will be directly added to the CRF and anonymised through use of a participant number.

All electronic data will be stored on a password protected database. All personally identifiable data will be sorted separately on a password protected database. The core research team will have access to all study data (SJ, BLE, MB, LW and the research assistants). All paper data will anonymised and stored in a locked filing cabinet at in the PIs office. Personal data will be stored 2 years following the completion of the study. Research data will be stored 10 years following the completion of the study. Professor Sonia Johnson will act as Data Custodian.

During the study, it is possible that a participant may disclose a serious risk of harm to themselves or to others. In these instances, participants' confidentiality would be breached to share the necessary information with the relevant clinical team. The participant would be made aware of the need to breach confidentiality in such instances in the Participant Information Sheet. Depending on the circumstances and time permitting, we would firstly discuss our concerns with a care coordinator or other appropriate clinician. However, if the concerns were immediate, we would breach confidentiality and contact the relevant safeguarding advisors and others, such as emergency services, as appropriate. This would be judged on a case-by-case basis, and confidentiality would only be breached for serious disclosures where there is substantial concern about immediate risk to self or others.

10.2 Data collection tools and source document identification

Data will be collected from sites on trial specific case report forms (CRFs) or data collection tools such as electronic CRFs.

Source data are contained in source documents and must be accurately transcribed on to the CRF. Examples of source documents are medical records which include laboratory and other clinical reports etc.

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

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

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

10.3 Completing Case Report Forms

All CRFs will be completed and signed by staff that are listed on the site staff delegation log and authorised by the CI/ PI to perform this duty. The CI/PI is responsible for the accuracy of all data reported in the CRF.

Once completed the original CRFs must be sent to Mary Birken and a copy kept at site. The CRFs must be returned within 7 days of the participant visit.

10.4 Data Handling

In the study, data will be collected from patients in accordance with the patient consent form, patient information sheet and this protocol.

The data will be appropriately sent to the trial manager for the processing of data, and UCL will act as the data controller of such data for the study.

Dr Mary Birken, Division of Psychiatry, Maple House, 149 Tottenham Court Road, UCL will process, store and dispose of all identifiable patient data in accordance with all applicable legal and regulatory requirements, including the Data Protection Act 2018 and any amendments thereto.

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

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

10.5 Personal Data breaches

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

11. STATISTICAL CONSIDERATIONS

11.1 Primary outcome

Compulsory readmission measured at 12-months.

11.2 Sample size calculation

We will aim to recruit eighty participants in line with recommendations by Consolidated Standards of Reporting Trials (CONSORT) for pilot RCTs (Eldridge et al. 2016), forty of which will be randomly allocated to the therapy arm and forty to the TAU arm. A sample of eighty is deemed of sufficient

size to examine the aims of the study. Data (for example, relevant proportions, means standard deviations and confidence intervals) from this study will be used to inform a power calculation for a future, definitive, fully powered effectiveness trial.

11.3 Planned recruitment rate

Baseline recruitment will be conducted from January 2022 to September 2022 with an estimated 10 participants recruited per month.

11.4 Randomisation methods

Randomisation will take place following baseline interviews. An independent statistician at University College London will allocate participants via a computer-generated allocation sequence to either the intervention or control group in a 1:1 ratio using block randomisation stratified by site and ethnicity (ethnic minority groups at higher risk of detention vs White/Other).

11.5 Statistical analysis

11.5.1 Clinical outcome analysis

The study will follow best practice guidance for the reporting of pilot RCTs (CONSORT, Schulz, Altman & Moher, 2010; Eldridge et al., 2016). The focus of the analysis will be on key indicators of feasibility, including participant recruitment, retention and acceptability of the intervention, which will be summarised descriptively using frequencies and percentages. Continuous clinical outcome measures will be summarised separately by study arm using means and standard deviations or medians and interquartile ranges, as appropriate for the distribution of the data. Binary outcome measures will be summarised using frequencies and percentages. The quantity of missing data for each clinical outcome will be examined and likewise summarised by study arm. This pilot study will not have sufficient statistical power to assess the effectiveness of the intervention, although it will allow an assessment of whether the direction and magnitude of any effect found for the proposed primary outcome are consistent with a hypothesis that the programme is effective in reducing repeat detentions. For this reason and to test the analysis envisaged for a future, fully powered, effectiveness RCT, clinical outcomes at follow-up time points will be compared between study arms, using linear or logistic regression models as appropriate, and adjusting for the baseline measure of the outcome in question.

10.5.2. Trial parameters

The thresholds for deciding whether recruitment and retention indicate sufficiently good feasibility and acceptability will be finalised during Phase 1, following review by the Independent steering committee. Regarding follow-up on the clinical outcome compulsory admissions, availability of this measure from electronic case records will allow a high follow-up rate to be attained: our goal in the study will be at least 90%. We will decide on a minimum number of sessions at which the intervention will be deemed to have been delivered as intended, likely to be at least 50%, and will assess how many participants reach this.

12. ASSESSMENT AND MANAGEMENT OF RISK

The table below summarise the risks and mitigations of all test above standard care that are being performed in a table:

Intervention	Potential risk	Risk Management
Assessment measure completion Delivery of therapy	There may be a small possibility that the participant will get upset or emotionally distressed whilst taking part in the assessment measures and therapy.	If participants become distressed whilst completing the outlined assessment tools, the study researcher will use their skills to make sure the participant feels as safe as possible. This will include monitoring the participants' mental state, offering breaks, offering the opportunity to talk through their difficulties (if they want to), providing a safe and containing environment to conduct the research and ensuring a person-centred stance is taken. In the event that the participant becomes distressed and it is not manageable by the/research assistant, the therapist/research assistant will also contact their named nurse/care coordinator if there is concern that they are at a risk to themselves or self-harming intent/suicide is disclosed. The researcher will follow the trusts safe visiting policy. Participants are also free to withdraw at any point. Participants who are deemed high risk by their clinical workers will be seen at the service where additional clinical staff are present

13. RECORDING AND REPORTING OF ADVERSE EVENTS

13.1 Definitions

Term	**Definition**
Adverse Event (AE)	Any untoward medical occurrence in a patient or trial participant, which does not necessarily have a causal relationship with the intervention involved.
Serious Adverse Event (SAE).	Any adverse event that: • results in death, • is life-threatening*, • requires hospitalisation or prolongation of existing hospitalisation**, • results in persistent or significant disability or incapacity, or • consists of a congenital anomaly or birth defect. • Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences

* A life- threatening event, this refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe. ** Hospitalisation is defined as an in-patient admission, regardless of length of stay. Hospitalisation for pre-existing conditions, including elective procedures do not constitute an SAE.

13.2 Assessments of Adverse Events

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

13.2.1 Severity

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

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

13.2.2 Causality

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

Category	**Definition**

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

13.2.3 Expectedness

All SAEs assigned by the Investigator or delegate as suspected to be related to the intervention will be assessed for expectedness as outlined below.

Category	Definition
Expected	An adverse event which is consistent with the information about the intervention
Unexpected	An adverse event which is not consistent with the information about the intervention

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

No AEs or SAEs are expected as a result of the intervention.

13.2.4 Recording of Adverse Events

14. All adverse events will be recorded in the medical records in the first instance. All Adverse events will be recorded in the Case Report Form (CRF) following consent.

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

All serious adverse events will be recorded in the medical records and the CRF, and the sponsor's AE log. The AE log of SAEs will be reported to the sponsor at least once or twice per year. Where the event is unexpected and thought to be related to the intervention, this will be reported by the Investigator to the Health Research Authority within 15 days. Completed SAE forms must be sent within 5 working days of becoming aware of the event to the Sponsor **Email forms to** Uclh.randd@nhs.net

14.2 Managing serious adverse events across research sites

Mental health practitioners delivering the trial intervention, their NHS supervisors, and managers of the participating NHS services will be directed to report any adverse events involving trial participants to the relevant site PI without delay. In addition, the study researcher will contact the mental health practitioner's supervisor and involved NHS service manager at each site at least monthly, to ask them to screen service and patient records for AEs for trial participants. A report of the circumstances of the AE, and the informant's view on causation and severity will be sought from the PI or study researcher, who will then contact the study CI without delay. The study CI (Prof Sonia Johnson), as the trial's Clinical Reviewer and a Consultant Psychiatrist, will complete an SAE form and make final assessments of severity, causality and expectedness, in discussion with the PI where possible. The CI will then send the completed SAE form to the Sponsor and the site PI, and disseminate any necessary safety information to the other site PI.

SAEs will be followed up and screened for each participant until the participant's 6-month follow-up research interview and active involvement in the study are completed.

SAEs will be reported to the sponsor until the end of the trial. Follow-up SAE forms (clearly marked as follow-up) will be completed and emailed to the JRO if required as further information becomes available.

14.3 Unblinding

The CI/PI will document any unblinding and the reasons it on the CRF and unblinding log and will file this, in the site file. It will also be documented at the end of the trial in any final trial report and/or statistical report.

The CI/Investigating team will notify the JRO in writing as soon as possible following the code break detailing the necessity of the code break.

In the absence of a Data Safety Monitoring Committee, the written information will be disseminated to the chair of the Trial Steering Committee for review in accordance with the DSMC Charter.

14.4 Reporting Urgent Safety Measures

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

14.5 Protocol Deviations and 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 trial; or

(b) the scientific value of the trial.

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

14.6 NHS Serious Incidents and Near Misses (if applicable)

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

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

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

14.7 Complaints from research participants

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

15. OVERSIGHT COMMITTEES

15.1 Trial Management Group (TMG)

The TMG will include the Chief Investigator, Co-CI, study co-applicants, and trial staff. The TMG will be responsible for overseeing the trial. The group will meet monthly and will send updates to PIs.

The TMG will review recruitment figures, SAEs and substantial amendments to the protocol prior to submission to the REC. All PIs will be kept informed of substantial amendments through their nominated responsible individuals.

15.2 Other committees

A Trial steering Committee of independent researchers, including: a service user-researcher, a clinical academic, a social scientist and a statistician, will be set up and meet at least six monthly during the course of the study to provide independent oversight and advice. The steering committee will advise on development of the study intervention and trial procedures. The committee will also review serious adverse events thought to be linked to the trial or other concerns regarding the safety of the trial.

A Data Monitoring Committee is not planned for this pilot trial, which is not collecting interim data and has no pre-planned stopping criteria. The study management team will ask the steering committee to review this plan before the start of the trial in the second year of the study and will recruit a DMC if the TSC advises this.

16. REGULATORY REVIEW AND PATIENT AND PUBLIC INVOLVEMENT

16.1 Regulatory Review

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

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

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

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

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

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

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

16.2 Peer 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 National Institute of Health Research to be of sufficient rigour and independence to be considered an adequate peer review.

16.3 Patient and public involvement (PPI)

The PPI lead will be Patrick Nyikavaranda. He will work with BLE and the study post-doc researcher to set up, organise and support the Co-production Group. We include funding for him to have access to a mentor who is an experienced lived experience researcher monthly during the first six months of the study and quarterly thereafter.

The Co-Production group will include around eight people with relevant lived experience, most as service users and at least two as carers. PN will be included along with 2 or 3 other members of the MHPRU to provide continuity with previous work: a further 4 or 5 will be recruited through advertisement. The Co-Production group will meet monthly through the initial eight months of the study to take the key decisions regarding intervention adaptation. This will include reviewing and iteratively refining study materials, including recruitment materials, psychoeducation materials and study manuals.

We also include funding for members of the Co-Production group to conduct the qualitative interviews with service users during the development phase of the project. In preparation, they will receive training sessions based on training already developed and delivered within the PRU and the UKRI Loneliness and Social Isolation in Mental Health Network, in qualitative interviewing skills and in how to participate in qualitative data analysis. We have costed for an expert in qualitative methods training at UCL to deliver this.

In Phase 2, the Co-Production Group will meet less frequently, but will continue to monitor and advise on study recruitment and retention, and to advise on any dilemmas or difficulties encountered. Members of the Co-Production Group with relevant lived experience will again conduct the qualitative interviews during this phase, and finally will review the intervention to recommend any adaptations or refinements prior to a full trial.

17. MONITORING AND AUDITING

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

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

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

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

18. 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.

19. INSURANCE AND INDEMNITY

University College London holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, as this clinical study is being carried out in a hospital, the

hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

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

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

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

20. RECORD KEEPING AND ARCHIVING

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

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

21. INTELLECTUAL PROPERTY

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

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

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

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

22. PUBLICATION AND DISSEMINATION

22.1. Study outputs

The main outputs during the period of funding will be:

1. A co-produced iteratively revised manualised intervention to guide implementation of the crisis planning and monitoring intervention. This will clarify stages of the intervention and include training materials and useful tools and forms to support its delivery (such as psycho-educational materials, a crisis card template and checklist for initial meetings).
2. Detailed and iteratively revised trial operating procedures and statistical analysis plans.
3. Scientific papers, conference presentations, policy briefs, blogs and plain English summaries reporting findings and development work in each Phase, including the intervention development process and qualitative evidence informing it, and pilot trial results.

These outputs will allow rapid progress to a fully powered, definitive, multi-site randomised controlled trial of the programme's effectiveness and cost-effectiveness, if judged appropriate. Our findings from the development phase and qualitative investigation of the implementation of the intervention will also inform other future research, quality improvement and service development on crisis planning in diverse patient groups.

22.2. Engagement with patients, NHS and the wider population

We will aim to engage stakeholders, especially service users and clinicians, with the study throughout, inviting them to comment on study materials and key decisions. Methods for this will include:

- A study blog in which our progress will be described, and stakeholders invited to comment. Study research staff and applicants, clinicians at participating sites and members of the Co-production Group with relevant lived experience will all be invited to contribute to this blog.
- Study social media accounts, as well as our individual and research group accounts, will promote engagement with our outputs and events.
- A newsletter, distributed approximately quarterly will provide news for participating sites and other interested parties.
- Two well-publicised dissemination events, offered both in person and online:
- One around 5 to 6 months into Phase 1 to present progress on development of intervention and methods and obtain stakeholder feedback.
- A second at the end of the study period, informing decisions about further roll-out and testing of the intervention.
- Briefs on key findings for policy makers and senior managers, developed with our partners the Centre for Mental Health in similar style to summaries for policy makers prepared by the MHPRU.
- Presentations to key voluntary sector organisations such as Black Thrive, seeking their views and support in engagement

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

Great attention will be paid, especially in Phase 1, to tailoring the intervention for NHS settings and patients, and the above dissemination events will promote uptake of study findings. A simple on-line

manual will be developed describing step-by-step implementation, and study materials will ultimately be free across the NHS. However, we do not expect to have an evidence base supporting full roll-out in routine settings until a fully-powered multicentre randomised controlled trial of effectiveness and cost-effectiveness has been conducted.

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

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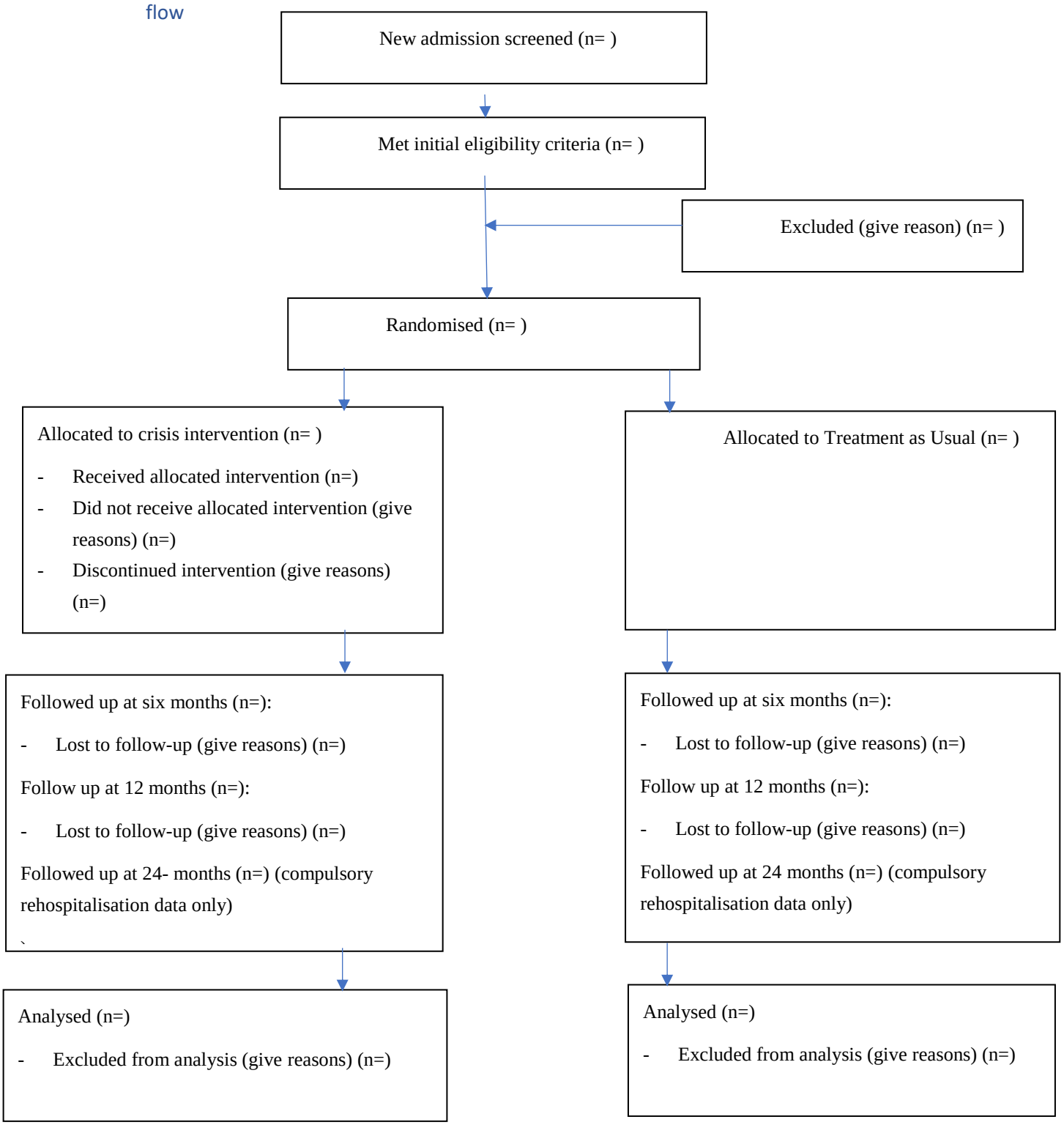
24. APPENDICES

24.1 APPENDICE 1: Schedule of Assessments

	Screening (Pre-treatment assessment)	**Intervention phase**	**6-month post baseline (post-therapy)**	**12-month post baseline (follow-up)**	**24-month post baseline (follow-up)**
	Day 1 to Day -7	Week 1 - 52	Week 24	Week 52	Week 104
Informed Consent	X				
Eligibility confirmation	X				
Randomisation	x				
Compulsory admission				X	X
CSQ	x		x	X	
QPR	X		X	X	
REQOL	X		X	X	
MHCS	X		X	X	
TA	X		X	X	
SE	X		X	X	
CSRI	X		X	X	
Intervention delivery		X			
Qualitative interview (intervention arm participants only)			X*		

CSQ- Client satisfaction Questionnaire; CSRI – Client Service Receipt Inventory; MHCS – Mental Health Confidence Scale; QPR – Process of Recovery Questionnaire; REQOL – Recovering Quality of Life; SE – Service Engagement; TA – Therapeutic Alliance; *will be conducted 6=9 months post randomisation

24.2 APPENDICE 2: Study flow



Finch Study: Development, feasibility testing and pilot trial of a crisis planning and monitoring intervention – Gantt Chart

	Activity	1	3	5	7	9	11	13	15	17	19	21	23	25	27	29	31
	REC approvals (prior to study start – by month 5)																
Phase 1 Months 1-8	Qualitative interviews with service users (n=12) and staff (n=12)																
	Recruitment of service users for intervention testing (n=6)																
	Preliminary testing the intervention with service users (n=6)																
	Qualitative feedback from service users (n=6) on crisis card development and initial crisis monitoring calls																
	Develop theory of change, intervention manual, training																
	Stakeholder event for feedback on plans																
	Trial site set-up																
Phase 2 Months 9-31	Recruit pilot trial participants and collect baseline data (n=80) (Months 12-18)																
	Intervention delivery: including making a crisis plan with each participant (n=40)																
	Intervention delivery: 1-year crisis monitoring with each participant (n=40)																
	Collect 6-month follow-up data from participants (n=80) and health records																
	Collect 1-year follow-up data from participants (n=80) and health records																
	Qualitative interviews with treatment group participants (n=up to 20) and staff delivering the intervention (n=up to 18)																
	Qualitative data analysis																
	Quantitative data analysis																
	Revision of manuals and study write-up																
	Final stakeholder events, decisions regarding further research																
	Coproduction working group meetings (monthly during Phase 1; at 7 meetings during Phase 2)																