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Developing and testing a strategy to prevent involuntary psychiatric hospital admissions

Submission date
19/05/2022

Recruitment status
No longer recruiting

Registration date
25/05/2022

Overall study status
Completed

Last Edited
22/02/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Backgrounds and Study Aims
More and more people are being admitted to psychiatric hospitals without consent (compulsorily admitted or "sectioned"). Patients and families often find such admissions distressing, disempowering and traumatising. Ethically, treatment should involve collaboration and consent except when truly unavoidable. Strategies for reducing compulsory admissions are therefore urgently needed. People who have had at least one compulsory admission are at particularly high risk of future compulsory admissions. In this study the researchers therefore focus on them in their plans for reducing compulsion. This proposal comes from researchers who led on inputting evidence to the Independent Review of the Mental Health Act. Evidence on how to prevent compulsory admissions was thin, but it was concluded that strategies involving collaborative planning for crises (also called advance statements) are most promising. However, such crisis planning can be hard to put into practice in real-world settings, resulting in some studies in which it has not worked as intended. The researchers have therefore identified as the most promising starting point a study from a metropolitan area of Switzerland, in which crisis planning was part of a well-developed programme designed to prevent compulsory re-admissions. This included individualised strategies for monitoring for early signs of crisis, and for empowering patients to develop and put into practice crisis prevention plans. A trial evaluating this programme had promising findings: the researchers plan to build on this work. Their aim is to develop and test an intervention to prevent people from getting "sectioned" again once they are discharged from hospital. The intervention will involve service users who have been "sectioned" working with a personal mental health worker (a clinical psychologist or equivalently qualified practitioner) to develop a crisis plan and improve their self-management skills. The researchers will then follow up with these service users when they have been discharged from hospital and track their outcomes over 24 months. This study will help the researchers to understand whether the intervention is seen as acceptable and relevant, by both service users and NHS staff. The researchers will also gather some early evidence for the effectiveness of the intervention in reducing the likelihood of service users getting "sectioned" again.

Who can participate?
Service users on inpatient wards, including patients who may still be compulsorily detained in hospital. The researchers are especially interested in people from Black and Black British backgrounds as a high-risk group for compulsory admission. A big focus will be making sure the

programme is relevant and engaging for them. The study will recruit in diverse areas in and around London, aiming for half our participants to be people identifying as Black or Black British.

What does the study involve?
There are two core phases of this study. Phase One involved adapting the swiss programme to the UK. A co-production group, in which people with relevant lived experience, clinicians and researchers work together on an equal basis, will steer the adaptation of the Swiss programme to a UK context and will finalise methods to test it in an initial trial. Inputs to this will include interviews with service users and staff with relevant experience, and learning from trying out the programme with six people. Any new policy guidance will be incorporated into the programme.
Phase Two will be an initial trial of the programme. This is the vital first step towards a large multi-site study giving a more definite answer as to whether it prevents compulsory admissions and is good value for money. The researchers will find out whether they can recruit people to take part in a trial, and whether they stick with the programme and find it helpful. They will get some idea of whether the programme seems likely to be effective and whether it should be tested further.
For Phase Two, there will be an initial preliminary testing with six service users from the London sites, all of whom will receive the intervention which is described in detail below.
Following this, the researchers will recruit eighty participants for the pilot trial, where half the people taking part are allocated by chance to be offered our new type of support, in addition to their usual care; while the other half are not offered the new support but continue to receive their usual care. They will find out whether it is possible to deliver the new type of support and test it in a research trial. They will hear from people taking part whether the new support is acceptable and feels helpful, and they will get a first indication about whether it may be effective in helping to reduce the likelihood of people being “sectioned” again in the future.
All people taking part in the study (whether or not they are allocated by chance to be offered the new type of support) will be asked to meet with a researcher three times over the following 12 months. Participants medical records will also be assessed at 24 months.
The three meetings will take place following this timeline:
Meeting 1: Start of the study
Meeting 2: 6 months from the start
Meeting 3: 12 months from the start
Meeting 1 will take place on the hospital ward, Meetings 2 and 3 will take place either remotely (via video or telephone), or at the participant's local community mental health service or at their home address. Participants will be asked to complete some questionnaires about their mental health recovery and their views on the NHS services they are receiving. If they take part in the crisis-planning support, they may also be invited to an in-depth interview where they will be asked questions about their experiences of receiving this support. This in-depth interview would be additional to completing the questionnaires and would take up to an additional 60 minutes.
After the first meeting with a researcher, the study researcher will let participants know whether they have been allocated by chance (“randomised”) to receive the new crisis-planning support intervention in addition to their usual care, or to continue to have their normal treatment without receiving the new type of support. This means that not everyone who is taking part in the study is receiving the new type of support. A computer will allocate participants by chance to one group or the other. This is the best way to compare people who are receiving the new support to those who are not, so that the researchers can make conclusions about it.
Participants who are randomly allocated to the group of people who will be offered the new type of support in addition to their usual care, which will consist of the following:
1. Four individual sessions with a personal mental health worker (who will be a clinical psychologist or another member of staff with equivalent skills). These sessions will focus on

discussing risk factors for relapse, providing information about treatment and services and exploring recovery goals. The initial sessions will be conducted on the hospital ward, but once discharged they will be conducted via telephone or video-calling software.
2. Participants will work with the personal mental health worker to create an individualised crisis plan, which they can use once they have been discharged from hospital.
3. Consent will be taken for these sessions to be audio-recorded, which is optional for the participant. This is so that the researchers can check that the personal mental health worker is delivering the new type of support in the same way for everyone.
4. Participants will also be offered a call from the personal mental health worker each month over the next year (either on the telephone or using video-calling software). They will discuss how the participant is coping and how they have been applying the plan in their life and whether it needs any changes.
For participants not randomly allocated to receive the new crisis-planning type of support, they will continue with your usual treatment. This will include their current care and treatment in hospital, and whatever support and treatment the NHS has arranged for them when they leave hospital.

What are the possible benefits and risks of participating?
The benefits of taking part in the study include all participants receiving a £20 voucher as a token of appreciation for each assessment interview they complete. Furthermore, for participants who receive the intervention, if it turns out to be helpful and effective in reducing compulsory admission (as previous investigations suggest it may be), this may be a substantial benefit from participating in the study.
Possible risks could be related to the sensitive nature of the topic being discussed. This includes discussing events prior to the participant getting “sectioned” and thinking about things which may be difficult in the future when they leave hospital. It is possible that talking about their personal experiences could sometimes lead to feeling upset. However, the personal mental health worker will be sensitive of participants' needs as they have experience working with people with upsetting or distressing emotions. Participants are also able to withdraw from the study at any point and this will not affect the ongoing care they are currently receiving.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
March 2021 to December 2024

Who is funding the study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
Prof. Sonia Johnson
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Study website
https://www.ucl.ac.uk/psychiatry/research/epidemiology-and-applied-clinical-research-department/finch-study

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
300671

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 50801, IRAS 300671

Study information

Scientific Title
Development, feasibility testing and pilot trial of a crisis planning and monitoring intervention to reduce compulsory hospital readmissions (the FINCH study)

Acronym
FINCH

Study objectives
The final hypothesis that the researchers aim to test is that a crisis planning intervention can reduce the rate of repeat involuntary admissions among people discharged following an involuntary hospitalisation. This is a feasibility trial, in which the aim is to develop and test interventions and methods for the final trial.

In more detail: More and more people are being admitted to psychiatric hospitals without consent (compulsorily admitted or “sectioned”). Patients and families often find such admissions distressing, disempowering and traumatising. Ethically, treatment should involve collaboration

and consent except when truly unavoidable. Strategies for reducing compulsory admissions are therefore urgently needed.

People who have had at least one compulsory admission are at particularly high risk of future compulsory admissions. The researchers therefore focus on these people in the plan they have developed for reducing compulsory hospital admissions.

Not much relevant research has been done, but the little there is suggests the best approaches involve making a plan for how to respond to a future crisis to avoid someone being “sectioned”.

A promising study was carried out in a metropolitan part of Switzerland. Here crisis planning was part of a programme designed to prevent compulsory readmissions. It included individualised strategies for monitoring for early signs of crisis, and for empowering patients to develop and put into practice crisis prevention plans.

The researchers have adapted this strategy to an NHS context, working with experts by profession and experience. It will involve four sessions around the time of hospital discharge with a personal mental health worker (a clinical psychologist or someone equivalently skilled) then monthly phone or video calls.

The researchers are carrying out initial tests of this strategy to reduce sectioning. They are doing this mainly by carrying out a pilot feasibility randomised control trial of 80 service users, in which chance will decide whether people get our new strategy or usual treatment. They will find out whether they can recruit people to take part in a trial, whether they stick with the programme and find it helpful. The aim is to get some idea of whether the programme seems likely to be effective and whether it should be tested in a bigger trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/12/2021, London - Bromley Research Ethics Committee (Postal address: not available; +44 (0)207 104 8105; bromley.rec@hra.nhs.uk), ref: 21/LO/0734

Study design
Randomized; Interventional; Design type: Treatment, Prevention, Education or Self-Management, Psychological & Behavioural, Management of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied
Mental health

Interventions
One way to try and reduce use of the Mental Health Act is to offer people a bespoke form of support after they are discharged to prevent them from being readmitted again. Therefore, the aim of this study is to develop and test an intervention to reduce the rate of compulsory readmission to hospital following discharge using a method called a “pilot trial”.

The intervention will include elements of crisis-planning and self-management skills, as well as monthly follow-up calls (via video-calling or phone) over a twelve-month period. Working with a clinical psychologist, the service user will receive education and support to develop a plan to better manage their day-to-day mental and learn to identify their early warning signs of deteriorating mental health.

Participants will be randomly allocated to either receive this new intervention or their usual treatment (in the control group with which a comparison is made). Participants will complete questionnaire measures several times during a one-year period to investigate the impact of the new intervention, especially on whether people entering the study are "sectioned" again. Medical records will be used to assess the intervention at 12 and 24 months. The researchers are especially interested in making sure they can recruit people from those ethnic minority backgrounds where people are more likely to be “sectioned” compared to White British people.

The research will take a ‘co-produced’ approach throughout, meaning that people with lived experience of being “sectioned” and family and friends who support them will provide input into the intervention and also help to conduct and analyse the results of the study.

A two-phased approach
There have been two phases in this study. Throughout both phases, the researchers are working alongside a co-production group of eight individuals with lived experience of mental health problems or caring for someone with a mental health problem, and often also experience of the research process. This Patient and Public Involvement (PPI) group is currently collaborating with the research team and a group of relevant clinicians on the initial stages of adapting the study intervention (as well as shaping and commenting on the current ethics application). This group will steer the development of the intervention, as well as feeding into the research planning, implementation and analysis. For example, in Phase One, members of the co-production group will act as the interviewers in interviews with service users and then take part in the analysis and write-up of the findings. Involving the co-production group throughout is vital in ensuring our intervention and research reflects the views and needs of service users.
The two-phased approach enables the researchers to maximise service user involvement in carefully developing the intervention before they begin the pilot randomised controlled trial. The initial steps of consulting with the co-production group, interviewing service users and staff, and conducting preliminary testing of the intervention are key to developing an intervention that best meets service users’ needs.

Phase one
Study design:
For the first part of the study, the research team has already been working on adapting the Swiss intervention developed by Lay and colleagues, with PPI input from our Co-production

group of researchers with relevant lived experience and clinicians. The researchers are developing a draft intervention drawing on Dr Lay's experiences (she is their collaborator), and on other relevant evidence and tools, especially advance statements developed in relation to the Mental Health Act.

The first phase of data collection in this application involves refining this developing intervention, firstly by exploring how well it fits with service user and clinician views on the pathway to being "sectioned" and refining it based on this, and secondly through preliminary testing with six service users.

These six service users will complete the initial baseline questionnaire measures, receive the intervention sessions and then they will be interviewed to share their experiences. Those clinicians/practitioners delivering the intervention will also be interviewed (n = 6).

Procedure:
a. Qualitative interviews to inform intervention development
The researchers will recruit up to 12 individuals with experience of being "sectioned" under the Mental Health Act (section 2 or 3) for an interview.

They will be recruiting from three NHS Trusts, two in London and one in Lancashire (North-East London NHS Foundation Trust, Camden & Islington NHS Foundation Trust and Lancashire and South Cumbria NHS Trust). They will recruit patients who are close to being discharged from acute mental health inpatient wards for adults and older adults, where they have been detained under Section 2 or Section 3 of the Mental Health Act for at least part of their hospital stay. The study will be advertised in various ways:

1. It will be advertised to the inpatient staff teams, who can then provide information to eligible patients on the ward.
2. Posters will also be displayed on recruiting wards.
3. Advertising materials will be shared on social media platforms related to the trust.
4. Advertising materials will be shared with relevant local advocacy and voluntary services within the trust's locality.
5. Where appropriate, the researchers will share information about the study at community group meetings on the ward and/or staff meetings on the ward.

The researchers 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.

If participants are interested, and their clinical team agrees that they are eligible, they will be contacted by a research assistant who will share more detailed information and gain informed consent if the service user gives informed consent to participate. The participant will have at least 24 hours to consider if they want to take part after the initial contact.

The purpose of having up to 12 interviews with service users is to hear about their experiences of being "sectioned" and better understand what they feel would have helped to prevent them being "sectioned", exploring whether this fits with our proposed intervention. The researchers will also outline their draft crisis-planning intervention and ask the service users what they see to be the benefits, drawbacks or areas for development for its design and implementation.

The researchers will also conduct interviews with up to 12 members of NHS staff who have experience of working with those who have been "sectioned", both on inpatient wards and in the community. They will make contact with staff directly via email and/or via attendance at staff meetings (by agreement with the relevant team manager) where they will briefly describe the study. If staff members are interested in participating, the researchers will then meet with them (either in-person or remotely) to fully explain the Participant Information Sheet and to answer any questions that might arise. If at this point the staff member still wishes to participate, the researchers will take written informed consent.

The purpose of the interviews with NHS staff members is to gather their perspective on why people get readmitted to mental health services, as well as their input into the intervention. For the interviews with service users, members of our coproduction group will be involved in both conducting the interviews and analysing the data. The researchers have selected their coproduction group based on their lived expertise of mental ill-health or caring for someone with a mental health problem. Many of the coproduction group members also have relevant research experience, and the researchers will also provide training in qualitative research methods for those without experience. This group will inform key research decisions and their involvement throughout is crucial to making sure the final intervention reflects service user needs and perspectives.

b. Preliminary testing

The final part of Phase One will involve recruiting six individuals from mental health hospitals in up to three NHS Trusts for preliminary testing of the intervention. The researchers will recruit these individuals by making site visits and firstly speaking to inpatient staff who will initially decide whether or not a patient is suitable for involvement in the study, and make initial contact with them. They will also advertise the preliminary testing through other means: distributing posters and flyers on inpatient wards, sharing relevant advertising material on social media and with relevant local advocacy or volunteer organisations, and attending meetings on the ward as appropriate. They 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.

Patients who are interested in taking part will be met by a researcher, who will explain the study in detail and provide a Participant Information Sheet. Potential participants will then have at least 24 hours to consider whether they want to participate. If they decide to take part, written informed consent will be taken by the research assistant.

Participants will firstly meet with the researcher in a private environment to complete initial baseline questionnaire measures. This could be on the hospital ward, in a community mental health centre, at the participant's home or remotely, depending on what works best for the participant and what is advised as suitable by the clinical team. This will take approximately one hour and will involve answering questions about mental health symptoms, recovery and their view on the NHS services they are currently receiving.

The intervention that these participants will then receive may change according to what the researchers find from speaking with service users and staff members, and based on the steer of the coproduction group. However, as it stands, each intervention participant will receive:

1. Four individual sessions with a "personal mental health worker" (who will be a clinical psychologist or someone with equivalent skills). These sessions will focus on exploring with each individual the risk factors for relapse and for being compulsorily detained rather than voluntarily

admitted, and providing information about accessing services and treatment options, identifying individualised risk and protective factors and exploring the individual's recovery goals.
2. An individualised crisis plan/advanced statement, which outlines warning signs to monitor strengths and resources, a personalised crisis action plan designed to avert compulsory detention if at all possible and details of sources of help or support.
3. Monthly telephone or video call monitoring over one year with the personal mental health worker, including checking warning signs and prompting coping responses.

The initial four sessions will likely take place in the hospital where the participant is admitted, at a time that suits them and the clinician. The four sessions will take place close to the patient being discharged. There is a chance that the patient is discharged before the conclusion of the four sessions. In these instances, the four sessions will continue remotely via video call.

The researchers will seek permission to record these intervention sessions from participants. If they consent, this will enable us to monitor the content of the intervention and whether the intended areas have been covered (the 'fidelity' of the intervention). After the four initial sessions, the six participants and six NHS clinicians who have received this preliminary version of the intervention will be invited to an interview. This meeting will take place in a location that is most convenient to the participant, which could be a local NHS service, remotely (via telephone or video-conferencing software) or at their home if considered safe following discussion with clinical teams. This interview will focus on service users' experience of receiving the intervention and NHS clinicians' experience of delivering the intervention. The findings of Phase One will inform any necessary adaptations that need to be made to the intervention.

Phase Two
Study design:
A multi-site pilot randomised controlled trial will be conducted to investigate the feasibility and acceptability of recruitment, retention and intervention delivery and to obtain initial evidence as to whether the trial process and outcomes fit with the intervention being potentially effective. Three sites have been chosen for the study in two culturally diverse London Trusts (North-East London NHS Foundation Trust and Camden & Islington NHS Foundation Trust) and one non-metropolitan Trust outside London (Lancashire and South Cumbria NHS Trust).

Sample:
Eighty participants will be recruited from inpatient wards across the three NHS Trusts. The researchers will select their sample intentionally (this is known as 'purposive sampling') in order to ensure that the sample is representative of the service user population. They will aim for half (50%) of our participants to be Black or Black British or from another of the minority ethnic backgrounds at increased risk of being "sectioned".

Recruiting eighty participants is in line with recommendations by Consolidated Standards of Reporting Trials (CONSORT) for pilot RCTs (31). Forty participants will be randomly allocated to receive the new intervention and forty will be allocated to receive their treatment as usual (the control group). A sample of eighty is deemed of sufficient size to examine the aims of the study. Data (relevant means and standard deviations) from this study will be used to inform a power calculation for a future larger multi-site trial. A power calculation is a statistical procedure that helps researchers design studies with sufficient sample sizes to make robust conclusions about effectiveness.

Randomisation:
In this study, the randomisation will take place following all participants' baseline assessments. An independent statistician at University College London will allocate participants via a

computer-generated allocation sequence to either the intervention or control group using a 1:1 ratio, with block randomisation stratified by site and ethnicity (ethnic minority groups at higher risk of detention vs White/Other).

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.

Procedure
a. Pre-assessment and baseline measures
The researchers will be recruiting patients who are close to being discharged from acute mental health inpatient wards for adults and older adults. The study will be advertised in various ways:
1. It will be discussed with the inpatient staff teams, who will be asked to provide information (verbally and in the form of a flyer) to eligible patients on the ward.
2. Posters will also be displayed on recruiting wards.
3. Advertising materials will be shared on social media platforms related to the trust.
4. Advertising materials will be shared with relevant local advocacy and voluntary services within the trust's locality.
5. If appropriate, and with permission from ward staff, the researchers will share details of the study at community groups and/or staff meetings on the ward.

The researchers 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.

If someone is interested in taking part in the study, the researcher will arrange to meet with them on the ward. At this meeting, the researcher will take the participant through a comprehensive Participant Information Sheet and answer any questions. The participant will then have at least 24 hours to decide if they would like to take part in the study. If they do wish to take part, they will provide written informed consent.

The research assistant will then meet with the participant in the hospital to complete the baseline measures. In total, there are seven baseline measures to complete (see Materials below).

b. Intervention delivery
Following the completion of baseline measures, participants will be randomized to either receive the intervention or treatment-as-usual. Those who receive the intervention will receive four individual sessions with a clinical psychologist (or equivalently skilled clinician). The 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 participant's home). They will also receive monthly check-in calls with the personal mental health worker for 12 months. The stages of the intervention as it currently stands are detailed in the Procedure for Phase One. This is subject to change after Phase One based on the results of the interviews with

service users and NHS staff and based on the interviews after the intervention is preliminarily tested.

The researchers will seek permission to record these intervention sessions from participants. If they consent, this will enable us to monitor the content of the intervention and whether the intended areas have been covered.

c. 6-month post-baseline (and post-therapy) follow-up
Six months following the completion of the baseline measurements, the researchers will contact participants again to complete the next round of questionnaire assessments. They will continue to try and make contact with participants for up to two months, therefore the 6-month assessment could take place between six and eight months after the initial baseline measurements.

This meeting will take place in the location that is most convenient to the participant, which could be a local NHS service, remotely (via telephone or video-conferencing software) or at their home. The participant will complete the seven measures listed in the Materials section again. In addition, qualitative interviews will be carried out with up to 20 consenting intervention group participants; these participants will be chosen intentionally ('purposively sampled') to include a full range of demographic characteristics and service experiences. The interviews will usually be carried out by service user researcher members of the coproduction group to facilitate empathy and open disclosure, supported by a researcher. Service user researcher members of the co-production group will receive full training and support in conducting the interviews.

The interviews 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. This framework breaks down 'acceptability' into seven different components:

1. Affective attitude (feelings)
2. Burden (reasons for dropout)
3. Perceived effectiveness
4. Ethicality (any associated negative side-effects)
5. Intervention coherence (the 'fit' between different parts of the intervention)
6. Opportunity costs (anything that had to be given up to take part in the intervention)
7. Self-efficacy (confidence in your ability to control yourself and your environment)

d. 12-month post-baseline follow-up
Twelve months after the initial baseline measures, the researcher will meet with the participant again. This meeting will take place in a location that is most convenient to the participant, which could be a local NHS service, remotely (via telephone or video-conferencing software) or at their home. The participant will complete the seven measures listed in the Materials section again. At this stage, data to do with compulsory readmission to hospital will be collected. The number of participants who have been compulsorily detained within the 12 months following baseline measurements being taken will be gathered from medical notes.

e. 24-month post-baseline follow up
24 months after the initial baseline measures, medical records for all participants will be re-examined. The researcher will record the number of participants who have been compulsorily detained between 12 and 24 months.

Materials:
The measures that participants will complete at baseline, and at 6 and 12 months post-baseline will be measures of:
1. Satisfaction with services (Client Satisfaction Questionnaire)
2. Personal recovery (Process of Recovery Questionnaire)
3. Self-management confidence (Mental Health Confidence Scale)
4. Symptoms of mental ill-health (Brief Psychiatric Rating Scale)
5. Quality of life (Recovering Quality of Life; REQOL-10)
The research assistant will be fully trained to administer these measures.

Economic costs will also be assessed using an adapted version of the "generic UK mental health" version of the Client Service Receipt Inventory.
Service engagement will be measured through routinely collected data from patient records about all service use during data-collection periods. The researchers will also record demographic and clinical/service user characteristics, including Community Treatment Order status, previous admission history and clinical diagnosis.

Analysis of quantitative data:
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 feasibility study will not have sufficient power to assess the effectiveness of the intervention definitively but the researchers will make a preliminary estimate of the effect of the intervention on this outcome by fitting a logistic regression model with study arm as the main explanatory variable and adjusting for site and ethnicity (the two stratification factors).

Analysis of qualitative data:
Semi-structured interviews will be transcribed verbatim and analysed using thematic analysis. Analysis will be conducted on qualitative analysis software called 'NViVo'. 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).

Intervention Type
Other

Primary outcome measure
Compulsory readmission to psychiatric in-patient services measured by checking the medical records of participants at 12 months

Secondary outcome measures
Measured at baseline, 6 months post-randomisation, and 12 months post-randomisation unless stated otherwise:

1. Satisfaction with services assessed using the Client Satisfaction Questionnaire
2. Personal recovery assessed using the Process of Recovery Questionnaire
3. Self-management confidence assessed using the Mental Health Confidence Scale
4. Symptoms of mental illness assessed using the Brief Psychiatric Rating Scale
5. Quality of life assessed using Recovering Quality of Life (REQOL-10)
6. Economic costs assessed using an adapted version of the “generic UK mental health” version of the Client Service Receipt Inventory
7. Service engagement measured through routinely collected data from patient records about all service use during data-collection periods at 12 and 24 months post randomisation
8. Compulsory readmission to hospital measured by checking the medical records of participants at 24 months
9. Demographic and clinical/service user characteristics, including Community Treatment Order status, previous admission history and clinical diagnosis

Overall study start date
01/03/2021

Completion date
16/12/2024

Eligibility

Key inclusion criteria
Service user participants:
Eligible participants will:
1. Have been compulsorily detained under section of the Mental Health Act (section 2 or 3) during their current hospital admission
2. Be due to receive community mental health care locally post-discharge
3. Be aged 18+ years
4. Have the capacity to consent at the time of recruitment

Clinician participants (for intervention development and evaluation):
Eligible participants will be
1. Currently working in an NHS mental health service as a nurse, psychiatrist, psychologist, social worker, occupational therapist, support worker or assistant psychologist
2. Currently working with service users who are currently or recently (in the last year) detained under section of the Mental Health Act (section 2 or 3)

Personal mental health worker (for intervention evaluation):
1. Eligible participants will have delivered the adapted intervention to participants in the trial

Participant type(s)
Patient, Health professional

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
Planned Sample Size: 91; UK Sample Size: 91

Total final enrolment
80

Key exclusion criteria
Service user participants:
Participants will be excluded if they:
1. Are already receiving an intensive psychosocial intervention that focuses on crisis reduction (for example, assertive outreach services)
2. Have a diagnosis of dementia or a brain injury
3. Do not speak sufficient English to take part without an interpreter
4. Lack capacity to consent

Staff participants and personal mental health workers:
Does not meet the inclusion criteria

Date of first enrolment
27/05/2022

Date of final enrolment
28/02/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Pancras Hospital
St. Pancras Way
London
United Kingdom
NW1 0PE

Study participating centre
Highgate Acute Mental Health Centre
Dartmouth Park Hill
London
United Kingdom
N19 5JG

Study participating centre
Goodmayes Hospital - Main Building
157 Barley Lane
Ilford
United Kingdom
IG3 8XJ

Study participating centre
Royal Blackburn Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
Chorley and South Ribble Hospital
Preston Rd
Chorley
United Kingdom
PR7 1PP

Study participating centre
Ormskirk and District General Hospital
Wigan Road
Ormskirk
United Kingdom
L39 2AZ

Sponsor information

Organisation
University College London

Sponsor details
Gower Street
London
England
United Kingdom

WC1E 6BT
+44 (0)7747691139
c.hutchings-hay@ucl.ac.uk

Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR201739

Results and Publications

Publication and dissemination plan
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. The 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.

Intention to publish date
16/12/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository.

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 study will be collecting the following personal data: patient names, address, contact details and GP name, but these will be electronically stored separately from the 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 informed 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. All paper data will anonymised and stored in a locked filing cabinet at UCL (in the Division of Psychiatry) or at Lancaster University (at the Department for Health Research). 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.

The core research team will have access to all study data. Furthermore, study data and material may be looked at by individuals from UCL, from regulatory authorities or from NHS trusts, for monitoring and auditing purposes, and this may include access to personal information.

All data analysis will take place at UCL. Statistical analysis will be conducted by members of the research team supported by the study statisticians (RJ and NF) and qualitative analysis will be conducted by members of the research team and members of the Co-Production Group.

In order to write up the data for publication, it is anticipated that research data will be kept for 10 years. This is in line with the 1988 Data Protection Act. All data kept will be anonymous data.

Consent forms will be retained as essential documents, but items such as contact details will be deleted as soon as they are no longer needed.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Service users pilot trial version 2	22/11/2021	25/05/2022	No	Yes

Participant information sheet	Service users pilot trial interviews version 2	22/11/2021	25/05/2022	No	Yes
Participant information sheet	Staff participants pilot trial interviews version 2	22/11/2021	25/05/2022	No	Yes
Protocol file	version 1	02/08/2021	25/05/2022	No	No
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	version 1	06/02/2024	06/02/2024	No	No
Protocol article		20/02/2024	22/02/2024	Yes	No