Feasibility testing and preliminary trial of a crisis planning and monitoring intervention to reduce compulsory readmissions: the FINCH Study

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Abstract

Background: Compulsory admissions to psychiatric hospital have been rising in England and some other higher income countries. Patients and families often find such admissions distressing, disempowering, and traumatising. Evidence on how to prevent compulsory admissions is still very limited. Collaborative crisis planning currently appears the most promising way of reducing compulsory readmissions, but can be challenging to implement.

Methods: The overall aim of the FINCH (Feasibility trial of an INtervention to reduce Compulsory Hospitalisation) study was to develop a crisis planning and monitoring intervention to prevent repeat compulsory admissions, and to investigate the feasibility and acceptability of testing it through a randomised controlled trial. Drawing on a promising intervention developed in Switzerland and on qualitative interviews with service users and carers, a team including researchers, service users, carers and clinicians co-designed an intervention. This included formulating personalised plans for preventing and managing crises, with follow-up contacts over a year to support participants in implementing these. We carried out a feasibility randomised controlled trial of the intervention, with 80 participants recruited towards the end of compulsory hospital admissions in three areas of England.

Results: Eighty participants were recruited within our target timeframe, 40 (as planned) from ethnic groups at disproportionately high risk of compulsory admission. Data were obtained for 86% of participants on compulsory admission, identified as a potential primary outcome for a full trial, but only for 51% on secondary outcomes measured at interview. Twenty-five of the 38 experimental group participants (66%) received at least three intervention sessions and developed a crisis plan of some kind. Qualitative data obtained from participating service users and carers suggested the intervention was acceptable and feasible, but that a high level of persistence and flexibility and considerable time were needed to deliver it.

Conclusions: We were readily able to recruit to this study, including from ethnic groups who are at high risk of compulsory admission, and delivery of our study intervention was feasible at least in a minimum form. Given the high financial and human costs of compulsory admission, there is an ethical and practical requirement for more research in this area: larger-scale research based on a refined version of our intervention has potential to contribute.

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Keywords: compulsory admission; involuntary admission; psychiatric inpatient; psychiatric hospital; mental health legislation; self-management; crisis planning

Background

Compulsory detentions in mental health inpatient units have increased over several decades in England, and similar trends are observed in some other higher income countries (1). A particular concern in England is a large ethnic inequality in compulsory admissions: people from Black and Black British ethnic groups are about four times more likely to be detained compared to White British individuals, with several other minoritised ethnic groups also at higher risk (2, 3).

Compulsory admissions may be clinically the best option in some circumstances, especially for people who are acutely ill and lack capacity to make decisions about their own care, but they are inherently coercive and should be avoided whenever feasible. Service users and carers frequently report that compulsory admissions are distressing and traumatising, disrupting recovery and therapeutic alliances (4-6). Human and financial burdens on clinicians and the healthcare system are also considerable, with little evidence that such admissions improve longer term outcomes (7).

Evidence-based approaches to preventing compulsory admissions have yet to become a standard part of care in the UK or elsewhere. Surprisingly few trials have been conducted with compulsory admission as a primary or even secondary outcome measure (8). People who have been detained at least once are at high risk of being detained again (9), making them a promising focus for efforts to reduce compulsory detentions. One approach has been continuing compulsion into the community, such as through Community Treatment Orders in England. However, current evidence does not support this as an effective means of reducing compulsory admissions (10), and use of such orders is disproportionately high in Black and Black British ethnic groups (11).

When evidence from all available studies internationally is pooled through meta-analysis (12, 13), the only types of intervention that currently show substantial effectiveness in reducing compulsory admissions are advance planning for crises (often called crisis plans) and collaborative agreements (advance statements) with patients about what should happen if they become unwell in the future (14,15). Such strategies were recommended for national roll-out in the Independent Review of the Mental Health Act (MHA) in England, published in 2018 (16).

In our group's review of relevant literature (12), we found that while pooled meta-analysis indicates overall effectiveness for interventions based on crisis planning, there has been considerable variation between studies in effect size and in whether statistical significance was reached. Challenges in implementing crisis planning strategies so that they have a sustained impact have been recurrently noted. For example in the largest UK trial, a joint crisis planning model initially effective in a single-site trial showed little evidence of effectiveness when tested across multiple sites, and it was noted that crisis plans were made but rarely referred to in subsequent care or help-seeking (17-19). Thus, to be successful, crisis planning needs to be embedded in a framework that ensures plans remain salient in subsequent care, especially at the time of any future crisis.

Within our systematic review (12), we identified one study that appeared to have a more developed approach to implementation than the others, including strategies for continued monitoring for

signs of crisis. This study, conducted in Zürich in Switzerland (20, 21), involved initiation of a crisis planning intervention in hospital, delivered by a "personal mental health care worker" who was a psychologist separate from the patient's usual care team and responsible for delivering the intervention over a two year period (20). Components included three or four sessions dedicated to discussing the nature of each patient's mental health problems and risk factors for relapse, and to reinforcing their self-management skills and adherence to treatment. A crisis care plan was formulated, following which participants were monitored for two years, additional to any other mental health care provided. During this monitoring stage, personal mental health care workers contacted participants every four weeks by telephone and discussed risk factors and early warning signs for the crisis, aiming to detect an incipient relapse and to prompt action to avert it. Thus this intervention was designed to avoid the often-identified problem of crisis plans being developed but subsequently forgotten(17).

Findings from implementing this Swiss model were promising: over two years, 28% of participants in this programme were compulsorily readmitted compared to 43% of patients in the control arm who received standard local care. The adjusted relative risk of compulsory readmission was 0.55 (95% confidence interval 0.33–0.94) in favour of the treatment group (20). However, differential risks of drop-out created ambiguity in interpreting this statistically significant result. Robust research is rare in this field, and the results appeared sufficiently promising to provide a starting point for our intervention. Results from a further trial conducted in France and published after start of the current study were also in keeping with previous evidence, showing that a peer-facilitated advance statement was effective in reducing compulsory readmission (22).

Building on these foundations, the overall aim of the FINCH study was to design an intervention to reduce repeat compulsory admission, drawing on the Zürich intervention and adapting it to a UK context, and to examine the feasibility and acceptability of delivering the intervention and testing it through a randomised controlled trial.

We have reported in previous papers on our co-designed intervention development process (23) and the qualitative studies that informed it (24, 25). Specific objectives for the research reported in the current paper were:

1. To conduct a feasibility randomised controlled trial (RCT) in order to assess the feasibility of delivering the FINCH intervention and of investigating its effectiveness and cost-effectiveness through an RCT.
2. To assess the magnitude and direction of the difference in the risk of having at least one compulsory admission within 12 months (the proposed primary outcome for a future definitive trial) for participants in the control arm versus those in the intervention arm, and to measure potential clinical and social secondary outcomes and health economic measures.

3. To assess recruitment and retention rates for the trial measures, describe how far the intervention was received as planned, and investigate via qualitative interviews the acceptability of the intervention to participating service users and clinicians.

Methods

Full Health Research Authority (HRA) and NHS Research Ethics Committee (REC) approval was granted by the London-Bromley Research Ethics Committee (IRAS: 300671; Protocol number: 143180; REC reference: 21/LO/0734). The trial sponsor was the Joint Research Office for UCL and UCLH (Ref: 143180). The trial was pre-registered as ISRCTN11627644.

Purpose and design

We conducted a feasibility trial, whose primary purpose was to assess the feasibility of recruitment, retention and randomisation in a trial of the intervention developed in the earlier part of the FINCH study (23). We also planned to obtain the difference in risk of compulsory readmission between the experimental and control arms so as to provide the parameters for the sample size calculation of a subsequent parallel arm superiority study (compulsory readmission within a year was identified as potential primary outcome for such a full trial). An embedded qualitative study was included in order to further explore acceptability of the intervention and potential refinements ahead of a potential full trial. The trial was designed and conducted following standard guidance for feasibility trials (24,25). **Additional File: Online Appendix A** provides a summary of the study.

The Study Coproduction Group and PPI input

The Finch Study Coproduction Group was convened at the start of the intervention development phase of the study and was involved in decision making and interpretation of findings throughout all phases. The group included people who had relevant lived experience of being detained under the Mental Health Act and/or of supporting close family and friends who had experienced this. It also included clinicians and researchers, and some members had more than one role. Our PPI lead (PN), an experienced researcher as well as an expert by experience, was a study co-applicant involved in planning the study from the initial grant application onwards. Six of our 11 Lived Experience Researchers (LERs) (including PN) were from Black ethnic backgrounds and five from White backgrounds, with a mix of ages, genders and regions of the country. Eight members of the group were clinicians, qualified in psychiatry, clinical psychology, occupational therapy, nursing and social work, several also with research and/or policy backgrounds: they were also diverse in terms of ethnic group, age and gender. The group met mainly online via video-call to provide input to each phase of the study. During intervention development (23), they met twice monthly to receive evidence and make recommendations to shape the intervention. During the feasibility trial reported in the current paper, they met approximately monthly and discussed challenges in conducting the study such as how to present it to potential participants. They also helped to shape interpretation of findings and writing of the Discussion section of this paper. For the qualitative

study, they participated in topic guide development, interviews with service user participants, and analysis and interpretation of findings.

Setting

Participants were recruited from the acute psychiatric inpatient wards of three NHS mental health Trusts in England; one in inner London, one in outer London, and one covering a mixture of non-metropolitan areas in the North-West of England. Both London Trusts have very ethnically diverse catchment areas.

Participants and sample size

Eligible participants were current inpatients who:

a) Had been compulsorily detained under Section 2 or Section 3 of the Mental Health Act during their current hospital admission (Section 2 allows for 28 days' detention for assessment and Section 3 for a renewable 6-month detention);
b) Were due to receive community mental health care locally post-discharge;
c) Were aged 18 or above;
d) Had the capacity at the time of recruitment to give informed consent to participate in the trial and receive the study intervention.

Participants were excluded if they:

a) Were already receiving an intensive psychosocial intervention that focused on crisis prevention.
b) Had a diagnosis of dementia or a brain injury (no mental health conditions resulted in exclusion).
c) Did not speak sufficient English to participate without an interpreter.

We aimed to recruit 80 participants, with at least half from ethnic groups at greater risk than the general population average of being compulsorily detained, according to recent NHS data (26). These included Black African, Caribbean, British and Other, Asian Pakistani, Asian Bangladeshi and White Other ethnic groups. White Other is a category used in UK official data collection to include all White groups other than White British and White Irish, the largest groups being from other European countries, North America and Australasia. We aimed to recruit 30 participants from each London centre (one Inner London and one suburban Mental Health Trust) and 20 from the Trust in the North-West of England. Our planned sample size was deemed sufficient to examine the primary aim of the study, which was to assess feasibility parameters to inform decisions about a future fully powered confirmatory trial.

The study had a statistical power of 80% (with a two-sided alpha of 5%) for detecting a reduction in the risk of compulsory readmission from 50% to 20%. Such a large difference was not considered

likely, but we planned to use the true difference observed from this study to help with the future sample size calculation of a future definitive trial (if considered feasible).

Recruitment

Participants were recruited from acute mental health wards by methods including discussions with ward staff, screening by NHS-employed research support staff, and advertising through posters and flyers on the ward. Staff considered whether patients were likely to be able to make an informed decision about study participation before introducing the study to them. Interested and potentially eligible patients were seen by a researcher and given an overview of the study and a participant information sheet, with at least 24 hours to consider participation. If they remained interested, their capacity to consent was assessed, the option to withdraw at any stage was explained, and they were enrolled after giving written informed consent.

Allocation

Randomisation took place following the completion of baseline measures. Researchers at University College London who were independent of the study allocated 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 (3:3:2 ratio inner London: outer London: North-West England) and ethnicity (people from ethnic minority groups at higher risk of detention vs lower risk groups 1: 1 ratio).

Some of the study team, including the study manager (MB), remained unblinded so that they could oversee and assess intervention delivery. Other members of the study team, such as the study research assistants who were collecting follow-up outcomes, were kept blind to treatment allocation as far as possible.

Interventions

Intervention group: Participants randomised to the intervention group received the co-designed FINCH intervention, alongside usual acute and post-discharge care. As described in more detail in our previous paper (23), our starting point was the approach developed and tested by Lay and colleagues in their Zürich study (21). Our study Coproduction Group took key decisions about our intervention's content and delivery, informed also by reviews of relevant literature on crisis planning and self-management for severe mental illness (12, 27, 28), by a crisis planning and recovery intervention previously developed by our group (29), by our qualitative interview studies with service users and clinicians on their views about what could prevent compulsory admission (30, 31), and by initial testing with six participants (23). Intervention development was guided by the Medical Research Council (MRC) Framework for Developing Complex Interventions (32, 33) and the TIDIER (Template for Intervention Description and Replication) checklist (34).

The resulting manualised FINCH intervention was delivered by Personal Mental Health Workers (PMHWs): most PMHWs were clinical psychologists, but a mental health nurse and an occupational therapist, both with experience of delivering structured interventions to people with significant mental health problems, also took this role. The intervention consisted of four initial

sessions with a PMHW, followed by monthly check-in sessions for the remainder of a year. PMHWs aimed to complete as many as possible of the initial sessions, each lasting up to an hour, while participants were inpatients, and if necessary to complete the remainder in the community following discharge.

The key tasks which PMHWs aimed to complete over four initial sessions were:

- Development of a collaborative formulation about the pathway by which the participant came to be compulsorily detained
- Creation of a personalised crisis plan, identifying early warning signs of a crisis and ways of responding, potentially including obtaining support from family, friends, and professionals. A choice of crisis plan formats was offered, including digital or paper or both. This included an opportunity to develop a "Message to future self" in written or recorded form, which could include advice on how to manage an incipient crisis or reminders of important aspirations.
- Development of an advanced statement recording treatment preferences to be followed if participants became unwell in the future and lost capacity to make and communicate their wishes.
- Exploration of aspirations and recovery goals for the future.

There was considerable flexibility in the order in which these activities were undertaken, in keeping with a generally adaptable and individualised approach.

In the monthly check-in sessions which were offered over the following year, PMHWs' aims were to provide support, complete and revisit elements of the content of the first four sessions, and check for and prompt responses to warning signs of a crisis. The initial four sessions were mainly delivered face-to-face; phone was the main modality for subsequent check-in sessions but face to face contact, video calls and text or WhatsApp messaging were also used to maintain contact and accommodate individual preferences and circumstances.

PMHWs initially received two half-day sessions training and access to a draft manual, followed by monthly supervision with a senior clinician. Key considerations emphasised in PMHW training and supervision included the centrality of therapeutic engagement, the need for flexibility and individualisation in the intervention, including in working with different explanations of mental health and of the pathway to being compulsorily detained, and the importance of recognising and discussing impacts of culture, ethnicity and racism.

PMHWs recorded details of sessions on a database, including length and location. Recording included a bespoke fidelity checklist designed to report which elements of the intervention were delivered. Participants were also invited to have intervention sessions recorded: however, given the engagement challenges in this study and feedback from our lived experience researchers, recording was presented to participants as an optional addition to the study and in practice rarely used.

Control group*:* Control group participants received usual care only, usually involving discharge to the care of a generic community mental health team, or a specialist team such as those supporting people with early psychosis or a personality disorder diagnosis.

Measures

Descriptive data

Demographic data from participants and casenote data on diagnosis were collected at baseline to characterise the sample.

Outcomes

The primary goal was to assess feasibility-related outcomes. Data on candidate outcomes for a future randomised controlled trial of the intervention were also collected, allowing assessment of the feasibility of collecting these outcomes and best approaches to doing so, collection of data to inform a power calculation for a definitive trial, and a preliminary assessment of the likelihood of a positive result from a definitive trial.

Feasibility Outcomes

Feasibility parameters included recruitment rates, acceptance of randomisation, rates and patterns of attrition from treatment and trial assessments, delivery of each intervention component, completion rates for individual outcome measures, and rates of serious adverse events in each arm of the trial.

Candidate trial outcomes

Candidate trial outcomes were measured via clinical records and interviews. Interviews were conducted by the research team at baseline prior to randomisation, and at 6 and 12 months after randomisation. A final follow-up point at 24 months (which will be reported elsewhere) involves health record data only.

Primary Trial Outcome

The planned primary outcome for a future definitive trial was whether the participant had been compulsorily detained in hospital under Section 2 or Section 3 of the Mental Health Act within one year of randomisation.

Secondary outcomes

The following candidate secondary outcomes were assessed at interview by a researcher at baseline and at 6 and 12 month follow up where consent was given for a further interview:

a) Satisfaction with services was examined using the Client Satisfaction Questionnaire (CSQ) (35). This is an 8-item scale where participants can rate their satisfaction with various aspects of their care on a 4-point Likert scale.

b) Self-rated recovery was measured using the 15-item Questionnaire about the Process of Recovery (QPR) (36). Participants can score from 0 (disagree strongly) to 4 (agree strongly) on each item and score up to a maximum of 60 on the scale, high scores indicating good self-rated recovery.
c) Self-management confidence was measured using the Mental Health Confidence scale (37). Participants report their confidence in managing their mental health for 16 items rated on a Likert scale from very non-confident to very confident.
d) Health-related quality of life was measured using the REQOL (Recovering Quality of Life)-10 (38) and EQ-5D-5L (EuroQol 5-Dimension 5-Level) (39). Both measures are used to derive quality-adjusted life years (QALYs). The REQOL is specifically designed for mental health studies and participants rate their quality of life on 10 items from 0 to 4. The EQ-5D-5L, is a generic measure and more commonly used. It contains five domains (mobility, self care, usual activities, pain/discomfort, and anxiety/depression) with each rated between 1 (no problems) and 5 (extreme problems). . Both the REQOL and EQ-5D-5L are converted to a weight with 1 representing full health. This weight can be used to derive QALYs.
e) Psychiatric symptoms were assessed using the Brief Psychiatric Rating Scale (BPRS) (40). Participants were rated by a researcher on 18 items from 1 (not present) to 7 (extremely severe) to give an overall score for psychiatric symptom severity.
f) Service use data were collected using an adapted version of the Client Service Receipt Inventory (CSRI) (41). Costs were calculated by combining this information with appropriate unit costs. The costs of the intervention were calculated from information on staff time and other requirements, resulting in a unit cost for the therapy sessions.

Analysis

The following steps were carried out, adhering to an analysis plan published online ahead of analyses being conducted (42).

Descriptive Statistics

Baseline characteristics were summarised for all patients in the study. Summary measures were presented as mean and standard deviation for continuous (approximately) normally distributed variables, medians and interquartile ranges for non-normally distributed continuous variables, and frequencies and percentages for categorical variables.

Feasibility outcomes: recruitment, retention and intervention delivery

Recruitment rate, retention in experimental and control groups and rates of collection of candidate primary and secondary outcome measures and intervention delivery parameters were also summarised descriptively. Progression criteria were established for consideration of whether progress to a full trial was warranted (23). These stipulated that achieving the goals below in full would indicate trial protocols and procedures were suitable for a full trial, while falling short by up to 20% on any parameter would indicate a need to consider what improvements could be made to make a full trial achievable, and falling short by more than 20% would suggest a need for major changes and a further feasibility trial prior to any full trial:

- Recruitment within 9 months of 80 trial participants.
- At least 50% of these participants to be from ethnic backgrounds associated with an elevated risk of being compulsorily admitted.
- At least 85% data completeness on candidate primary outcome measure for trial (repeat compulsory admission within a year of randomisation)
- At least 60% data completeness for secondary outcomes at 1 year
- At least 75% of intervention participants to have developed a crisis plan and have received at least 3 intervention sessions (our study definition of receiving minimum *per protocol* treatment).

Analysis of candidate primary outcome for a trial

This feasibility study did not have sufficient statistical power to assess the effectiveness of the intervention with precision but allowed an assessment of whether the direction and magnitude of any effect found for the proposed primary outcome was 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, the primary outcome at follow-up was compared between study arms using appropriate multi-level models. Hierarchical multi-level modelling, allowing for clustering of residuals between centres by introducing the variable coding for centres as a random intercept was utilised. We entered all other stratification variables as fixed effects. This analysis was also conducted for those in ethnic groups at higher risk of compulsory admission alone.

Adverse Events

Adverse events were summarised in terms of the number of (serious) adverse events and the number of participants with any (serious) adverse events in each randomised group.

Qualitative Study to investigate experiences of receiving and delivering the intervention

Sample

We aimed to interview up to 20 participants who were allocated to receive the FINCH intervention, as well as the PMHWs at each site who delivered the intervention. If a choice of participants were available, we aimed to use purposive sampling to ensure a full range of demographic characteristics and service experiences were included.

Interview guide

The interview topic guide for patient participants allocated to receive the FINCH intervention was developed collaboratively by the Coproduction Group and the FINCH research team. The core research team developed the topic guide for the PMHWs delivering the intervention. With each group, we aimed to explore experiences of intervention delivery, most and least helpful elements, and perceived influence on recovery. **Additional File: Online Appendix B** shows the topic guides.

Interviews were conducted between November 2022 and January 2024. Capacity was assessed and informed consent was sought to audio- or video-record all interviews and have them transcribed verbatim by an external transcription agency approved as secure by UCL. All audio-transcripts were then checked by the researchers and any potentially identifying information was anonymised. Interviews with participants allocated to receive the FINCH intervention were conducted by an LER from the Coproduction Group who had received training in qualitative interviewing, and those with clinicians by FINCH researchers.

Interviews were analysed deductively using Framework Analysis (42), a form of thematic analysis designed for team analysis. The framework consisted of themes derived from the seven constructs of the Theoretical Framework of Acceptability of Healthcare Interventions (43), which are affective attitude, burden, intervention coherence, ethicality, opportunity costs, perceived effectiveness, and self-efficacy.

Results

In this section, we report the findings from the feasibility trial and accompanying qualitative study conducted as part of the FINCH study. For the trial, we first report sample characteristics and feasibility outcomes, including rates of recruitment and randomisation, delivery of the intervention, and completion of outcome measures. We then report findings on the candidate measures for a full RCT, including repeat compulsory detention as the proposed primary outcome, as well as data on health economic measures and on serious adverse events in each arm. Finally we describe qualitative findings on acceptability of the intervention from staff and service user perspectives.

Findings of feasibility trial

Feasibility outcomes

Recruitment

Eighty participants were recruited and gave informed consent to participate in the trial: 30 from each participating London Trust and 20 from the northern Trust. Recruitment took place over a 9-month period, as had been specified in the trial protocol and the planned sample was achieved for each participating Trust.

Randomisation

Thirty-eight participants were randomly assigned to receive the intervention and 42 to the control condition. Figure 1 (the Consort diagram) shows flow through the study. It should be noted that the 590 identified as potential participants were a minority of potentially eligible inpatients compulsorily detained in the participating wards during the study period: recruitment on these wards took place intermittently, reflecting the availability of researchers and of PMHWs who could deliver the intervention.

Figure 1 about here

Sample characteristics and diversity

Table 1 shows sample characteristics for each arm of the trial. Two participants asked for all data to be withdrawn and are shown as missing in the table below. A feasibility goal for the study was to recruit at least half participants from groups at elevated risk of compulsory admission, including Black or Black British, Asian Bangladeshi or Pakistani, White Other and some Mixed groups. Forty of the 80 participants were from such groups.

Table 1 about here

Completion of candidate measures for a full RCT

Proposed primary outcome for trial

Data were collected for the candidate primary outcome for a full trial, whether participants had been compulsorily detained again by the one-year follow-up point, for 69/80 (86%) of participants. Six participants withdrew from the study and asked that further data not be collected from their clinical records (including the two who also asked us to remove baseline data). A further five participants moved out of the catchment areas in which the study was conducted and we were unable to obtain data on subsequent service use. Data for potential outcome measures for a full trial are reported below.

Secondary measures

At six-months follow-up, secondary outcome data were collected on interview measures for 46/80 participants (58%). Among the 34 with no follow-up data, 17 participants declined to provide follow-up data, 13 were not contactable after several attempts, 3 were unwell/readmitted at time of follow-up, and one participant was felt not to be suitable for follow-up as recovering from a distressing experience (not study-related).

At 12 months, secondary outcome data were collected for 41/80 participants (51%). Of the 39 not interviewed, 21 declined to provide follow-up data for researchers, 14 were not contactable after several attempts, of whom 3 had moved out of area, and 4 appeared to be too unwell to participate in an interview.

Intervention Delivery

Initially, seven clinicians, two in two centres and three in the third centre, were employed as PMHWs to deliver the FINCH intervention and were provided with the draft manual and two half days training in delivering the intervention. The initial PMHWs were six clinical psychologists, three of whom worked on adult acute inpatient wards, and an occupational therapist. Four left the role before the planned end date (including two for maternity leave), following which a further three clinicians, a psychiatric nurse and two clinical psychologists, were recruited to continue delivering the intervention. Several participants experienced a delay in starting the intervention due to lack of PMWH availability or a change of PMHW towards the end of intervention delivery. It was noted that the relatively small time allocations (often just a half day a week) for working on this feasibility trial seemed to make it difficult to recruit clinicians to this role and for them to be sufficiently flexible in

how they delivered the intervention. Our manual recommended that the initial four sessions be delivered as far as possible while participants were still inpatients, with several in a week if feasible and acceptable. However, in practice our PMHWs' limited available time meant that most participants received sessions only weekly, with the initial four sessions often continuing after discharge.

Receipt of intervention

Of the 38 participants allocated to receive the FINCH intervention, six did not start. Three of these participants moved out of area on discharge following randomisation (despite the research team seeking to exclude people who were about to move) and three were quickly discharged from the ward following randomisation and did not subsequently respond to multiple attempts to contact them.

Of the remaining 32 participants allocated to the intervention group, seven participants asked to withdraw from receiving the intervention at varying stages during its delivery: three of these had not yet received the four initial sessions, while the other four had received all initial sessions and up to eight follow-up contacts. Thirty-two participants attended the first session, after which two participants were lost to follow-up following hospital discharge having received only one session. Twenty five of the 38 intervention group participants (66%) received at least three intervention sessions and had at least partially developed a written crisis plan: this was the pre-specified minimum for participants to be classified as having received the intervention. Fifteen of these participants were from ethnic groups at high risk of being detained under the MHA.

Delivery of intervention components

Table 2 shows which components of the planned intervention were delivered. PMHWs were encouraged to prioritise completion of crisis plans.

Table 2 about here

Follow-up sessions

For those who participated in at least one follow-up check in session, the median number of follow-up contacts was four, with the total number ranging from one to ten. Sessions did not reliably take place on a monthly basis as in the protocol for reasons related to both participant and clinician availability.

Table 3 about here

Findings on candidate trial outcomes

Findings for proposed primary outcome measure

Regarding the candidate primary outcome measure for a full trial, at 12 months' follow-up from randomisation, 49 of the 69 (71.0%) for whom data were available on the primary outcome had not

been compulsorily detained again (**Table 3)**. Twenty-three (67.6%) of those allocated to the control group for whom follow-up data were available had not been detained again, while 26 (74.3%) of those who had been allocated to the intervention group had not been detained again. Those who received the intervention had an increased odds ratio of avoiding detention of 1.378 (95% confidence interval: 0.480 to 3.955) versus those randomly allocated to the control arm: the number needed to treat to prevent one detention was estimated as sixteen.

When only members of ethnic groups at a high risk of compulsory admission were included, at 12 months follow-up, 10 (58.8%) of those who had been allocated to the control group and had data available had not been detained vs. 12 (70.6%) of those who been allocated to the intervention group (Table 5). This corresponded to increased odds of not being detained of 1.680 (95% CI: 0.405 to 6.962) for the group receiving the intervention. Number needed to treat within this sub-group to prevent one detention was estimated as nine. No findings reached the threshold for statistical significance, as anticipated with the small sample size and very limited power in this feasibility trial.

No analysis involving diagnosis was planned: however, given different rates in the general population, members of the research team raised the question *post hoc* of whether patterns of diagnosis were markedly different between high risk and low risk ethnic groups. In the high risk ethnic groups, 36/39 of those with an available casenote diagnosis had psychosis or bipolar, compared with 30/39 in the low risk group.

Further details regarding distribution of the primary outcome, including risk differences between arms are found in the **Additional File**: **Appendix C (Tables C1 and C2).**

Findings for proposed secondary outcome measures

Table 3 shows findings for the main candidate secondary measures for a full trial that were collected at interview and **Additional File: Appendix D** shows scores on individual items of the BPRS, for which no total scores were computed because observer-rated items could not be collected for many people as data were often gathered by phone. No statistical analyses beyond descriptive statistics were planned for these measures given the status of the trial as a feasibility study. It should also be noted that there was considerable attrition for these measures.

Serious adverse events

Table 3 shows Serious Adverse Events (SAEs) in each arm, identified from PMHW reports and from case notes. Almost all SAEs were hospital admissions and were not suspected to be study-related. One SAE was discussed with the sponsor and independent chair of the Trial Steering Committee as possibly study-related, but the conclusion from these discussions was that this was unlikely.

Health economic findings

Additional File : Online Appendix E presents the health economic findings in full. Costs were measured using the Client Service Receipt Inventory (CSRI) (38) and covered the six-month periods prior to baseline and 6- and 12-month follow-up, encompassing primary and secondary care and social care services. Mean total costs for the combined follow-up period are compared with bootstrapped 95% confidence intervals generated around the cost difference between the two groups. We included the EQ-5D-5L (36) as a measure of health-related quality of life to be used in health economic analyses, although as with all interview secondary measures there was substantial attrition on this measure.

Total costs could be computed from the CSRI for 40 (95.2%) control group and 36 (94.7%) intervention group participants at baseline, 36 (85.7%) control group and 37 (97.4%) intervention group participants at 6-month follow-up, and 29 (69.0%) control group and 34 (89.5%) intervention group participants at 12-month follow-up.

All participants had inpatient stays in the six months prior to baseline, and most also in the first six months of follow up, as discharge did not usually occur immediately after randomisation. In the six months prior to the 12-month follow-up point there were fewer in the intervention group who had inpatient stays. Use of GPs was slightly more likely for the intervention group prior to baseline, but prior to the 12-month follow-up this had switched with more of the control group seeing a GP. Contacts with psychiatrists, mental health nurses, and other mental health workers were common for both groups in each period but without major differences between groups.

The mean (SD) cost for the FINCH study intervention was £583 (£404) for the intervention group, with a range of £0 to £1385. Other care costs were dominated by inpatient costs. The total mean (SD) cost over the combined follow-up period, including the intervention, was £41,840 (£29,068) for the control group and £35,962 (£38,020) for the intervention group. The mean incremental cost was −£5872 (i.e. lower for the intervention group) with a bootstrapped 95% confidence interval of −£22,204 to £9781, showing the difference not to be statistically significant.

Findings of qualitative study investigating experiences of receiving and delivering the intervention

Informed consent to participate in a recorded interview regarding experiences of receiving and delivering the intervention was obtained within the timeframe available from eight service users who had received the intervention, and nine of the PMHWs who had delivered it. If a larger number of service user participants had been available, we would have sampled purposively to ensure inclusion of the main demographic and diagnostic groups participating in the study, but limited numbers meant we included all who consented. These data were analysed in relation to the constructs in the Theoretical Framework of Acceptability, which provides a structured approach to exploring the main asects of acceptability (43). The following is a brief summary: a more detailed description of the sample and analysis will be published separately.

Affective Attitude

This construct assesses overall perceptions of the intervention and its content. Positive comments from service users included feeling supported and able to express their views openly, gaining a greater understanding of their illness, and benefiting from the crisis planning process.

> "*It has been a positive experience because it has put my… put where I'm at in my illness to some sort of reality so to speak. I don't know whether that makes sense. It has made me get more insight into my illness basically.*" (Service User Participant)

The opportunity to form a strong and consistent relationship with PMHWs was also valued, with some seeing PMHWs as akin to "friends" or "peers," with less than usual power imbalance. PMHWs also reported a positive overall view of the intervention, finding the manual content useful and the opportunity to spend time forming a therapeutic relationship at this important stage valuable. Suggestions for improvement included offering the intervention sooner so that a larger proportion was delivered on the inpatient ward, and more frequent follow-up sessions (although few in practice took up all that were offered).

Burden

This construct examines the effort required for intervention engagement. Most service users found the intervention manageable, although one reported a substantial interruption due to staff unavailability and another financial barriers to participating. PMHWs saw the intervention as time-consuming, especially because of the efforts needed to keep in touch and engage with service users following discharge. The time allocated to deliver the intervention in the study was seen by most as insufficient for the persistent efforts required:

> "*It's been frustrating… I think it's been quite time consuming. Making some space to see someone and then they don't turn up, then chasing to see if they're okay. If a phone call doesn't work, sending a text and putting lots of reminders in my calendar, 'Contact this person if they don't reply in a week.' There are a couple I tried. One said they weren't interested and one just never really…*" - (PMHW Participant)

Ethicality

This construct focuses on how well the intervention aligns with the participants' values. The moral and ethical consequences of the intervention were not discussed by many participants. One participant reported that the intervention made them feel as though they mattered, whilst another felt that the intervention would only be useful for those wishing to recover.

> "*It was something that I wasn't expecting that is good. To be completely honest, I don't believe that it would work on everybody. I think that it has to be individual on a certain level of capacity to appreciate those sessions, somebody who wants to recover. It cannot be somebody who is ready to fall into problems again.*" (Service User Participant)

Intervention coherence

This describes the extent to which participants understand the intervention and how it is intended to work. Both PMHWs and service users felt they had a good understanding of the purpose and content of the intervention:

"*Building a crisis plan and increasing self-awareness…*" (Service User Participant)

"it gave me the tools that I needed at the time and now to… know when I'm having episodes or… put things in place where it won't go to that level of going back to hospital, hopefully." (Service User Participant)

" *it does focus on their experience of being sectioned, the reasons why they've come into hospital and what can be done to support them before them being re-admitted*." (PMHW Participant)

Opportunity costs

This describes the extent to which benefits, profits, or values must be given up to engage in the intervention. Interviewed service users did not describe such opportunity costs. PMHWs, for whom in most cases delivering the intervention was a relatively small part of their overall job role, found it difficult to fit in, especially if they were persistent and flexible in making contact with service users, as the intervention manual requires:

"Obviously, trying to work this around I've got a full diary of things that I need to do. It was scheduled at a time where… I'm doing this on the bank, I'm not doing this as part of my job. That has been a bit challenging. If I'm attending that in work time, I have to work it back." (PMHW Participant)

Attending the monthly group clinical supervision sessions also was challenging due to other clinical roles.

Perceived effectiveness

This describes how far the intervention is seen as likely to achieve its purpose.

Interviewed service users described changes in their self-management strategies following receiving the intervention:

"*I've noticed I'm more aware of my triggers. And the choices I'm making now. Like don't drink, don't take any illicit drugs, like weed and stuff, because I used to think that was helping me, but really and truly it wasn't helping."* (Service User Participant)

Clinicians delivering the intervention also believed that the intervention had potential to achieve its purpose:

"*Actually, going through some of things that others can do, what they can do, thinking about the signs and triggers. It feels to me that it's been quite helpful for them. The few who have engaged really well have said it's not something that they've done before and it's quite helpful to have."* (PMHW Participant)

Self-efficacy

This construct captures how far participants are confident that they can carry out their role in the intervention. Clinicians were confident in their ability to deliver the intervention after the training, provided they could engage participants.

"*it was really helpful to get an overview of the intervention. And then, the supervision sessions have been really helpful in terms of if any questions have come up, or thinking about having to adapt it and tailor it a bit more, then that's been really supportive, to think more about it there as well.*" (PMHW Participant)

Some recipients of the intervention reported having acquired skills that would enable them to mobilise self-management skills better in future:

"*I think I could make my own crisis plan now if I needed to. I understand, which is something I used to find overwhelming. In fact, I found doing crisis plans very difficult because then I wouldn't be able to think of things. So I feel like I've learnt how to do crisis plan better*." (Service User Participant),

Discussion

Main findings

The main aim of this study was to assess the feasibility and acceptability of delivering and evaluating through an RCT a co-designed crisis planning intervention. We published a set of progression criteria in our protocol paper (23), stating that progress to a full trial would be fully justified if these criteria were met in full, and that a shortfall of less than 20% would indicate potential to progress to a full trial after reviewing and addressing difficulties identified in the feasibility trial. Our feasibility trial's performance in relation to these progression criteria was as follows:

Recruitment within 9 months of 80 trial participants: this was achieved within the acute wards of the three study catchment areas.

At least 50% of these participants to be from ethnic backgrounds associated with an elevated risk of being compulsorily admitted: this was also achieved.

At least 85% data completeness on primary outcome measure for trial (repeat compulsory admission within a year): this was achieved with 69/80 having complete data on the primary outcome (86%). While our target was reached, this level of missingness is still challenging for reliable inference for a trial: in a future confirmatory trial, we would take additional steps to ensure completeness such as obtaining patient consent to track outcomes via the national Mental Health Services Data Set for those leaving the area.

At least 60% data completeness for secondary outcomes at 1 year: this was not achieved, with measures completed for 41/80 participants at a year (51%). Data completeness was however within 20% of our target (41/48: 85% of target). This level of missingness is a significant challenge

for the trial, prohibiting reliable inference regarding secondary measures. We will consider further strategies to address this, for example omitting outcome measures recorded at interview from secondary measures or including only very few very brief ones.

At least 75% of intervention participants to have developed a crisis plan and received at least 3 intervention sessions: this was not reached, with 25/38 (66%) of participants receiving at least three sessions of the intervention and developing a crisis plan. However, the number reaching this minimum target for being defined as having received the intervention was within 20% of our goal (25/28.5, 88%).

Thus, progression criteria were either met, or within 20% of being met: according to our a priori criteria, this justifies considering progressing to a full trial after considering and implementing improvements that could be made in trial methods and procedures.

The accompanying qualitative study also suggested good acceptability, although the number of participating service users was very small and may well not have been representative (trial participants tended to be reluctant to take part in an interview that was recorded). A number of potential improvements to trial intervention, methods and procedures were identified during the study, supported especially by qualitative findings. These included ensuring that interventionists (PMHWs) have sufficient time to deliver the intervention, avoiding a situation in which it makes up only a small part of their job plan, and ensuring that they are experienced acute care clinicians who are linked to wards, as well as finding ways to prioritise the crisis planning element of the intervention, and making use of the national Mental Health Services Data Set to avoid loss to follow- up. Also of note, recruitment to the study began early in 2022, when the impact of COVID-19 on service delivery and on many aspects of community living was still marked: the team's impression was of continuing disruption to establishing effective community support and meeting practical needs, which may have made the intervention more difficult to deliver effectively.

Expert opinion varies regarding the extent to which conclusions should be drawn from findings on potential trial outcomes in feasibility studies such as FINCH which do not have sufficient statistical power to expect a statistically significant finding. The direction of odds ratios in the analysis of primary outcomes favoured the intervention, more so in the sub-group analysis including only people from ethnic minority backgrounds at higher risk of compulsory detention (although any attempt to interpret this observation is impeded not only by small numbers but also by different patterns of diagnosis by ethnic group). The health economic analysis also favoured the intervention, but without reaching statistical significance and with a caveat that inpatient use was already higher at baseline in the control group. These signals suggesting the intervention may prove effective in a larger trial do cohere with the findings of the small existing body of relevant evidence including the original trial in Switzerland (20, 21) and systematic reviews of the literature on approaches to preventing compulsory admissions (12, 13 17). The indication that a greater effect might be anticipated in groups at higher risk of compulsory admission is similar to the finding in a previous randomised controlled trial of advance statements for prevention of compulsory

admission, in which larger numbers of Black participants appeared to avoid compulsory admission with an advanced statement, but with insufficient power for investigation of this sub-group (19).

Limitations

Some limitations to conclusions that can be drawn were inherent in the feasibility study design: statistical power was not sufficient to conduct any definitive analysis of differences in outcomes between groups and the confidence intervals on the estimate of the difference in the candidate primary outcome are wide. The composition of the underlying population from which our sample was recruited is uncertain as recruitment took place intermittently depending on researcher and interventionist availability, and the research team were aware of the target ethnic composition, although in our diverse inpatient population this was achieved without much effort by researchers to recruit from specific groups. Blindness was limited by the small research team and was sometimes broken in extracting the study primary outcome from case notes (although this is possibly less important than for questionnaire ratings as documentation of compulsory detention in clinical records was usually clear). As already described, some progression criteria were not met. Drop out from the follow-up interviews for secondary measures was considerable.

Difficulties in delivering the intervention as planned particularly related to PMHW turnover, with two dropping out and two others going on maternity leave during the study period, while others had only very limited time to deliver the intervention. PMHWs strongly believed that insufficient time had been allocated for the intervention (the time allocated was determined before the study when an application was made for funding to support treatment costs for the study).

The sample of participants willing to take part in a recorded interview for the Phase 2 qualitative study was small. and may have been skewed towards people who had engaged with and had a positive view of the intervention, and analysis of these data was a rapid one carried out with the Theoretical Framework of Acceptability (43) as an a priori framework approach to organising the analysis.

Implications of study findings

A degree of reserve is needed in discussing study implications, given its preliminary nature. However, a very important finding is that recruiting compulsorily detained patients in hospital to a trial is feasible: at a time (in the later stages of the COVID-19 pandemic) when many studies have reported difficulty recruiting (44), our recruitment was to time and target, and informal impressions were that both clinicians and inpatients were often very sympathetic to the aims of the study. The literature on how to reduce unnecessary compulsory admissions is very limited in contrast to the importance of this question (8): perceived difficulties in conducting studies with this population are likely to be an important impediment, but our study suggests that research at this stage is feasible (and indeed necessary). The feasibility of recruiting participants from ethnic groups at high risk of detention is also a key finding.

Drop-out rates from both the intervention and the follow-up interviews for secondary outcomes were substantial, and for secondary outcomes would preclude reliable inference in analyses. This is not perhaps a surprise, given that people who have experienced compulsory detention may well have negative views of what mental health services offer and tend not to be well-engaged with services: it was comparable to another recent multicentre trial where a mental health inpatient sample was followed up after discharge (45). However, using a service use-based primary outcome (the obvious one in view of trial aims) helped us achieve relatively high follow-up rates on this outcome. Two thirds of participants received a trial intervention that reached our pre-specified minimum threshold for classifying the intervention as received, formulating a crisis plan and receiving some further check in sessions, again perhaps not an unduly discouraging outcome in this population. Those participants (only a small minority) with whom we were able to conduct a qualitative interview found the intervention acceptable, as did clinicians delivering it except for lack of time, a potentially remediable difficulty.

Thus findings suggest that this research direction is worth pursuing, especially as results cohere with previous evidence and there is a pressing need to understand how to reduce numbers of coercive, distressing and expensive compulsory inpatient admissions. Inspection of findings on the primary outcome suggests a possibility that the intervention may be more successful among people from ethnic backgrounds at high risk of compulsory admission, which might be explained in terms of this group currently being under-served and too often regarded as unlikely to engage with psychosocial interventions that may in reality be helpful if offered. Calculations of the number needed to treat suggest a full trial may also be more feasible in this group, with an estimate that the intervention needs to be offered to 9 people for a compulsory detention to be prevented. Delivering the intervention for this degree of benefit is likely to be worthwhile given its relatively low cost and the great benefits associated with avoiding compulsory admission, a goal no other type of evidence-based strategy currently achieves. However, a large sample size is likely to be needed for good power to detect an effect in a full trial, with attention also to the potential improvements to trial and intervention processes suggested by this feasibility study.

Approaches worth considering for a full trial include assessing only routinely recorded outcomes such as compulsory hospitalisation, and increasing PMHW time and flexibility for delivering the intervention. Further consideration of who delivers the intervention may also be helpful: following our Swiss model, our initial preference was for clinical psychologists to deliver the intervention. However, we experienced some difficulties in recruiting and retaining them, leading us to deploy other professionals: our impression was that it was less important for interventionists to belong to a specific profession and more

important that they had confidence in working flexibly with a population with relatively severe difficulties who are often ambivalent towards mental health services, and experience in delivering structured interventions. A recently published study from France successfully engaged peer support workers to deliver an intervention based on advance statements (22), and a previous study from our group found a peer support worker-delivered intervention to be effective following discharge from crisis resolution teams (46). We considered intervention delivery by peer support workers in the current study, but eventually decided to follow previous studies, especially our Swiss model, in employing qualified professionals. Our concerns included that working with a high level of independence with a patient group potentially at high risk of relapse and of losing capacity might exceed reasonable expectations regarding peer support worker roles (47). However, peer support workers increasingly work in a wide range of mental health settings and may have particular strengths in engaging a population who tend to be disillusioned with mental health services, so that their involvement in interventions to prevent compulsory re-detention seems well worth considering further.

In relation to service planning, supported self-management (26) and crisis planning (12) already have substantial supporting evidence: our study suggests that delivering such interventions around the time of discharge is feasible and acceptable for at least some inpatients. Even in a system characterised by brief admissions and a tendency for patients on wards to be acutely unwell, obtaining the informed consent of inpatients to receive structured interventions proved to be feasible and may present a good opportunity to initiate therapeutic relationships and treatment engagement (22), fostering hope that repeat compulsory admission can be avoided and meaningful recovery achieved in future.

Conclusions

Despite the concerns of service users, carers, clinicians and policy makers regarding the human and economic cost of compulsory detention, evidence is still very limited on how to prevent detention whenever this is feasible and safe. This may reflect the considerable challenges of recruiting to and conducting a trial in this context. However, in our feasibility trial of an intervention based on crisis planning, we were successful in recruiting a diverse sample of recently detained inpatients as planned. We also met our feasibility trial target for the primary outcome. Our target for intervention delivery was narrowly missed, with some potentially remediable obstacles identified through qualitative interviews, whilst low rates of completion for secondary outcomes suggested that the value of interview-based secondary measures needs careful consideration in this population. Given that some evidence is already available internationally for the effectiveness of similar approaches to preventing compulsory admission, we propose that further refinement and large-scale

testing is indicated to make progress towards achieving the very important target of reducing compulsion in mental health care.

Additional File contents: Online Appendices

Online Appendix A: Intervention and research activities in the FINCH trial as reported in the current paper

Online Appendix B: Phase 2 Interview Topic Guides

Online Appendix C: Findings for proposed primary outcome for whole sample and for groups at higher risk of compulsory detention

C1. Findings for whole sample

C2. Findings for ethnic minority groups at higher risk of compulsory detention only

Online Appendix D: Proposed trial secondary outcomes

D1 Means for BPRS items at each timepoint where available

Online appendix E: Health economic analysis

Table E1. Number and % using services in 6 months prior to baseline and each follow-up.
Table E2 Mean and SD contacts for those using services in 6 months prior to baseline and each follow-up.
Table E3 Mean and SD service costs in 6 months prior to baseline and each follow-up (2021/2 £s).

Abbreviations used in paper in order of appearance in the text:

FINCH: Feasibility trial of an Intervention to reduce Compulsory Hospitalisation (acronym used to describe study)

MHA: Mental Health Act

RCT: Randomised Controlled Trial

PPI: Patient and Public Involvement

LER: Lived Experience Researcher

PMHW: Personal Mental Health Worker

TIDIER: Template for Intervention Description and Replication

CSQ: Client Satisfaction Questionnaire

QPR: Questionnaire about the Process of Recovery

REQOL: Recovering Quality of Life

EQ-5D-5L: EuroQol 5-Dimension 5-Level

BPRS: Brief Psychiatric Rating Scale

CSRI: Client Service Receipt Inventory

Declarations

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Consent for publication

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Data availability

On request from lead author

Author Contributions: SJ and BLE were principal and co-principal investigators and obtained funding and led the study throughout. RG was study statistician, designing and implementing statistical plans. MB was study manager throughout, contributing to intervention development and protocol development, implementation of processes, and analysis of feasibility and qualitative data. AK and JP were researchers on the study, contributing to intervention design, implementation of study procedures and data collection, and analysis of feasibility and qualitative data. PN was lead lived experience researcher, contributing coproduction expertise throughout and co-ordinating lived experience contributions at all stages. JH, MKH, LM, JS, CS AND VCW were lived experience researchers on the study, involved in protocol and intervention manual development and reviewing study processes and outcomes throughout. LB and LW contributed clinical researcher expertise at all stages of design and implementation of processes and manuals. BL contributed to intervention design as lead on the previous study on which we drew, NF was senior statistician and trials expert providing guidance throughout. HM-B contributed expertise on cultural appropriateness and on training and real-world implementation, PMcC was the study health economist, leading throughout on design and analysis of the health economic component. FL led the northern site and contributed expertise on intervention and trial design throughout. SJ initially drafted the

manuscript: all authors contributed to and reviewed it. All authors read and approved the final manuscript.

Competing interests

The authors have no conflicts of interest to declare.

Ethics approval and consent to participate

Full Health Research Authority (HRA) and NHS Research Ethics Committee (REC) approval was granted by the London-Bromley Research Ethics Committee (IRAS: 300671; Protocol number: 143180; REC reference: 21/LO/0734). The trial sponsor was the Joint Research Office for UCL and UCLH (Ref: 143180). All participants gave written informed consent.

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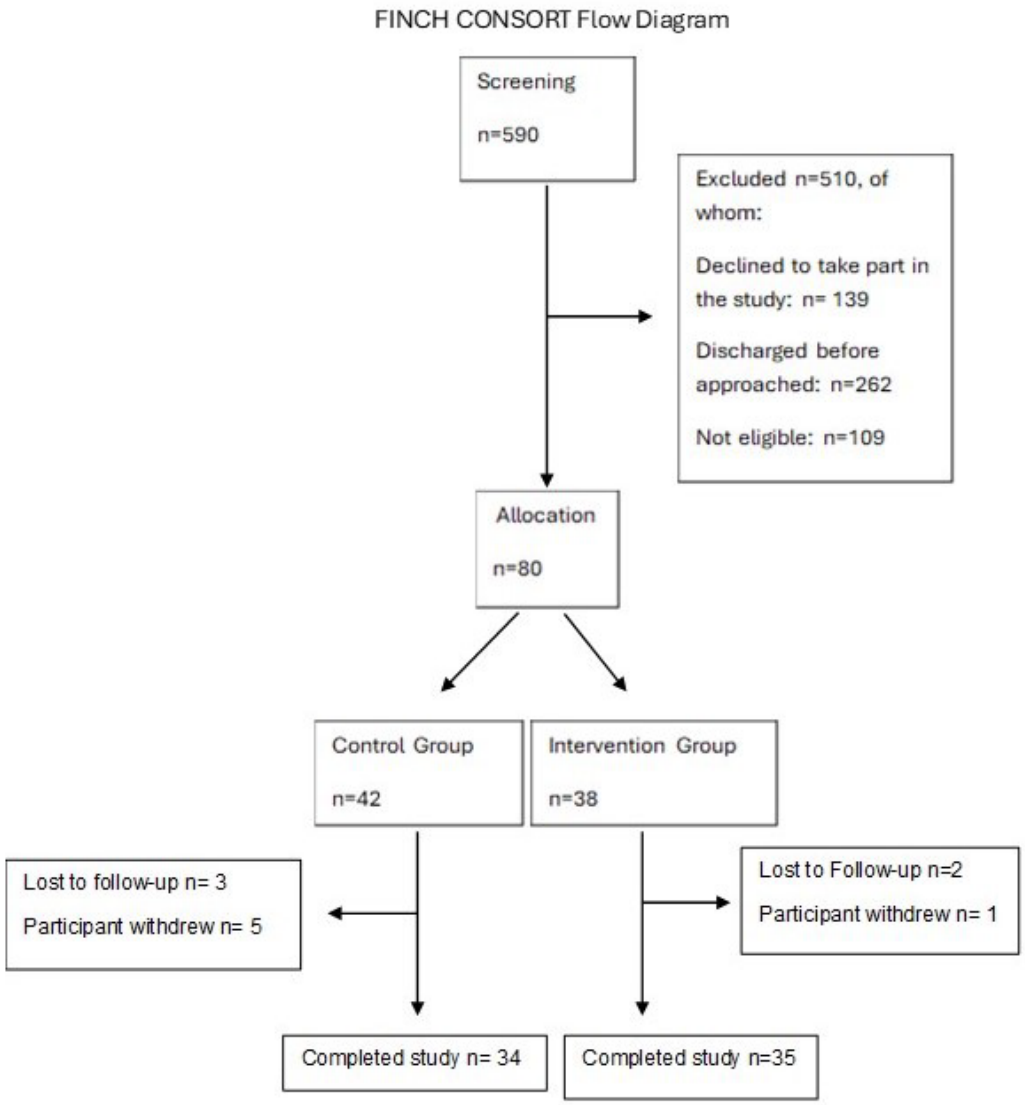

Figure 1: Flow diagram

Table 1: Baseline characteristics of intervention and control groups

	Allocation					
	Control N = 42 (52.5%)		Intervention N = 38 (47.5%)		Total N = 80 (100%)	
	n	(%)	n	(%)	n	(%)
Age/years						
20/29	7	(16.67)	16	(42.11)	23	(28.75)
30/39	14	(33.33)	12	(31.58)	26	(32.50)
40/49	13	(30.95)	2	(5.26)	15	(18.75)
50/59	3	(7.14)	6	(15.79)	9	(11.25)
60/65	3	(7.14)	2	(5.26)	5	(6.25)
Missing	2	(4.76)	0	(0)	2	(2.50)
Gender						
Male	18	(42.86)	21	(55.26)	39	(48.75)
Female	21	(50.00)	13	(34.21)	34	(42.50)
Other	0	(0)	4	(10.53)	4	(5.00)
Not declared	1	(2.38)	0	(0)	1	(1.25)
Missing	2	(4.76)	0	(0)	2	(2.50)
Ethnicity						
White	19	(45.24)	21	(55.26)	40	(50.00)
Mixed	4	(9.52)	6	(15.79)	10	(12.50)
Asian	3	(7.14)	4	(10.53)	7	(8.75)
Black	12	(28.57)	7	(18.42)	19	(23.75)
Other	2	(4.76)	0	(0)	2	(2.50)
Missing	2	(4.76)	0	(0)	2	(2.50)
Marital Status						
Single	32	(76.19)	32	(84.21)	64	(80.00)
Married/Cohabiting	4	(9.52)	4	(10.53)	8	(10.00)
Separated/Divorced	2	(4.76)	2	(5.26)	4	(5.00)
Widowed	2	(4.76)	0	(0)	2	(2.50)
Missing	2	(4.76)	0	(0)	2	(2.50)
Centre						
Inner London	15	(35.71)	15	(39.47)	30	(37.50)
North-West England	11	(26.19)	9	(23.68)	20	(25.00)
Outer London	16	(38.10)	14	(36.84)	30	(37.50)

	n	(%)	n	(%)	n	(%)
Clinical diagnosis						
Psychosis	25	(59.52)	21	(55.26)	46	(57.50)
Bipolar Disorder	9	(21.43)	11	(28.95)	20	(25.00)
Depression/Anxiety	2	(4.76)	1	(2.63)	3	(3.75)
“Personality Disorder”	4	(9.52)	4	(10.53)	8	(10.00)
Other	0	(0)	1	(2.63)	1	(1.25)
Missing	2	(4.76)	0	(0)	2	(2.50)
National risk of being detained for participant’s ethnic group						
From a higher risk group	21	(50.00)	19	(50.00)	40	(50.00)
From a lower risk group	21	(50.00)	19	(50.00)	40	(50.00)
On a Community Treatment Order						
No	32	(76.19)	33	(86.84)	65	(81.25)
Yes	4	(9.52)	3	(7.89)	7	(8.75)
Missing	6	(14.29)	2	(5.26)	8	(10.00)
No of previous compulsory Admissions						
0	15	(35.71)	16	(42.11)	31	(38.75)
1	7	(16.67)	10	(26.32)	17	(21.25)
2-3	8	(19.05)	4	(10.53)	12	(15.00)
4-6	7	(16.67)	5	(13.16)	12	(15.00)
7-27	3	(7.14)	3	(7.89)	6	(7.50)
Missing	2	(4.76)	0	(0)	2	(2.50)
Sexual Orientation						
Heterosexual	33	(78.57)	27	(71.05)	60	(75.00)
Bisexual	1	(2.38)	8	(21.05)	9	(11.25)
Gay	2	(4.76)	2	(5.26)	4	(5.00)
Not declared	4	(9.52)	0	(0)	4	(5.00)
Other	0	(0)	1	(2.63)	1	(1.25)
Missing	2	(4.76)	0	(0)	2	(2.50)

	n	(%)	n	(%)	n	(%)
Employment Status						
None/other	27	(64.29)	24	(63.16)	51	(63.75)
Employed (>= 16h/week)	3	(7.14)	5	(13.16)	8	(10.00)
Employed (< 16 h/week)	3	(7.14)	2	(5.26)	5	(6.25)

Voluntary work	3	(7.14)	2	(5.26)	5	(6.25)
Education (>= 16h/week)	2	(4.76)	2	(5.26)	4	(5.00)
Fulltime Carer	2	(4.76)	2	(5.26)	4	(5.00)
Missing	2	(4.76)	1	(2.63)	3	(3.75)
Housing Status						
Independent Permanent	33	(78.57)	21	(55.26)	54	(67.50)
Independent Temporary	4	(9.52)	5	(13.16)	9	(11.25)
Supported	0	(0)	7	(18.42)	7	(8.75)
Homeless/Hostel	2	(4.76)	3	(7.89)	5	(6.25)
Other	1	(2.38)	2	(5.26)	3	(3.75)
Missing	2	(4.76)	0	(0)	2	(2.50)
Living Situation						
Lives Alone	24	(57.14)	20	(52.63)	44	(55.00)
Lives with other adults & no children	9	(21.43)	12	(31.58)	21	(26.25)
Lives with other adults & dependent children	6	(14.29)	4	(10.53)	10	(12.50)
Lives with dependent children only	1	(2.38)	1	(2.63)	2	(2.50)
Missing	2	(4.76)	1	(2.63)	3	(3.75)
Education						
No Qualifications	5	(11.90)	0	(0)	5	(6.25)
GCSEs/NVQs	11	(26.19)	11	(28.95)	22	(27.50)
A-Levels	9	(21.43)	9	(23.68)	18	(22.50)
Higher National Diploma	2	(4.76)	3	(7.89)	5	(6.25)
University (no degree)	4	(9.52)	3	(7.89)	7	(8.75)
Degree	5	(11.90)	8	(21.05)	13	(16.25)
Postgraduate level	4	(9.52)	4	(10.53)	8	(10.00)
Missing	2	(4.76)	0	(0)	2	(2.50)
Client Satisfaction Questionnaire 8 - Total Score						
Low	28	(66.67)	25	(65.79)	53	(66.25)
Moderate	9	(21.43)	10	(26.32)	19	(23.75)
High	5	(11.90)	3	(7.89)	8	(10.00)
	Mean	**(sd)**	**Mean**	**(sd)**	**Mean**	**(sd)**
Mental Health Confidence Scale - Total Score	63.40	(19.50)	61.55	(21.00)	62.50	(19.96)

The Process of Recovery Questionnaire - Total Score	40.51	(13.84)	41.49	(12.01)	40.99	(12.91)
Brief Psychiatric Rating Scale - Total Score	49.82	(15.96)	49.57	(14.53)	49.7	(15.10)

Table 2 Delivery of components of the intervention

.	Formulation completed about how crisis developed	Crisis plan developed	Advanced statement recorded	Recovery goals recorded
Completed	24	22	14	11
Partially completed	5	5	1	9
Declined to complete	0	1	5	1
*Did not complete but not declined	3	4	12	11

* excludes six participants who did not start intervention

Table 3: Results from proposed outcomes for a full trial and serious adverse events

Proposed primary outcome for full trial				
	Control Group n=42		Intervention N=38	
Not compulsorily detained again in 12 month follow-up period	23 (67.6%)		26 (74.3%)	
	Odds ratio: 1.378 (95% CI 0.480-3.955), p=0.551			
	Control group n-21		Intervention group n = 19	
Not compulsorily detained again in 12 month follow-up (high risk ethnic groups only)	10 (58.8%)		12 (70.6%)	
	Odds ratio 1.680 ((0.405 to 6.962)			
Proposed secondary outcome measures for full trial				
	Mean	(sd)	Mean	(sd)
Client Satisfaction Questionnaire Baseline	20.35 n=40	(6.29)	19.92 n=38	(6.31)
Client Satisfaction Questionnaire 6 months	20.00 n=26	(6.45)	24.95 n=20	(5.22)
Client Satisfaction Questionnaire 12 Months	20.43 n=24	(8.03)	24.75 n=17	(5.13)
Mental Health Confidence scale Baseline	63.4 n=40	(19.15)	61.55 n=38	(21)
Mental Health Confidence scale 6 months	60.92 n=26	(19.10)	58.33 n=20	(11.17)
Mental Health Confidence scale 12 months	61.17 n=24	(17.39)	58.06 n=17	(18.35)
The Process of Recovery Questionnaire Baseline	40.51 n=40	(13.84)	41.49 n=38	(12.01)
The Process of Recovery Questionnaire 6 months	34.58 n=26	(14.56)	36.59 n=20	(9.92)
The Process of Recovery Questionnaire 12 months	37.12 n=24	(14.22)	38.35 n=17	(14.42)

Serious adverse incidents		
	Control group Data available for full period: 34/42	Intervention group Data available for full period: 35/38
Incidents in group	25, of which: -Psychiatric hospital admission: 17 -General Hospital admission: 8	17, of which: -Psychiatric hospital admission: 11 -General hospital admission: 6
Number of participants with at least one incident	14	11