Examining the feasibility of a crisis-focused Cognitive Behaviour Therapy (CBT)–informed psychological intervention for inpatients experiencing psychosis (the CRISIS study): results from a pilot randomised controlled trial

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Summary

Background Cognitive Behavioural Therapy for psychosis (CBTp) is a psychological intervention that should be offered in the acute phase of psychosis. However, there is little evidence to guide its delivery. The aim of this study was to examine the feasibility of a randomised controlled trial (RCT) of a crisis-focused CBTp-informed intervention (cCBTp) with inpatients. The intervention was co-produced with a stakeholder group.

Methods Participants were included if they were experiencing psychosis and receiving care from a psychiatric inpatient service at the time of consent. We aimed to recruit n = 60 inpatients and randomise them on a 1:1 ratio to either receive cCBTp plus treatment as usual (TAU) or TAU alone. Follow-ups were conducted at 2, 6, and 12 months. An average of 6–8 sessions of the intervention were offered. The primary objective was to examine indicators of feasibility (recruitment, data collection rates, intervention delivery). The study was prospectively registered (ISRCTN59055607) and is now complete.

Findings Between 1st February 2021 and 28th February 2022, 145 participants were referred to the study and 52 participants were randomised (during the COVID-19 pandemic). 26 were randomly allocated to cCBTp and 26 to TAU. We were able to recruit 87% of our target sample size. The face-to-face data collection rate (measures of symptoms, recovery, quality of life and service use) was 58% at 2 months and 60% at 6 months, which was below the proposed feasibility threshold. Collection of Electronic Health Record (EHR) data (relapse, rehospitalisation, and adverse events) was at 86% at 6 months and 83% at 12 months. Nine (35%) participants in the cCBTp arm and n = 7 (27%) in the TAU arm had an adverse or serious adverse event. None were assessed as related to participation in the intervention or the trial.

Interpretation This study demonstrated that a pilot RCT of cCBTp was feasible with inpatients experiencing psychosis. A further large-scale fully powered trial is required to evaluate its effectiveness and cost-effectiveness, including modified strategies for follow-up data collection.

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Research in context

Evidence before this study

In January 2020, we conducted a systematic review to examine the feasibility, acceptability and effectiveness of cognitive behavioural psychological interventions for people in acute mental health inpatient settings. We searched CINAHL, clinicaltrials.gov, PsychInfo, Embase, and Medline utilising groups of terms relating to psychosis, psychological interventions and inpatient settings and identified 23 studies reporting on 18 trials of interventions such as Cognitive Behaviour Therapy for psychosis (CBTp), Acceptance and Commitment Therapy (ACT), and Metacognitive Therapy (MCT). Our review demonstrated that the interventions were of poor to moderate quality with small improvements in psychotic symptoms at the end of therapy, but not at longer-term follow-up.

Added value of this study

The review of the literature indicated the need for a robust evaluation of a psychological intervention for individuals with psychosis, adapted for the current acute mental health inpatient setting with a focus on crisis reduction. Our study demonstrated that a pilot randomised controlled trial of a crisis-focused CBTp intervention for psychiatric inpatients is feasible. It is the first study examining a coproduced intervention for contemporary ethnically diverse inpatient populations, which are notoriously underrepresented.

Implications of all the available evidence

This highlights that a brief crisis-focused psychological intervention that helps patients understand their crisis, develop coping strategies and safety plans may be useful to inpatients with psychosis. A further definitive Randomised Controlled Trial (RCT) is required.

Introduction

Cognitive Behavioural Therapy for psychosis (CBTp) is a psychological therapy which targets the distress related to experiences of psychosis by focussing on the way an individual thinks and behaves. Although there have been recent reviews challenging the effectiveness of CBTp,[1] the evidence base generally demonstrates that CBTp is an effective intervention, with a small to medium effect size, in improving outcomes for people experiencing psychosis.[2] Clinical guidelines, such as those of the National Institute of Health and Care Excellence [NICE],[3] recommend offering CBTp in the acute phase of psychosis, i.e., during inpatient and crisis care. Despite this recommendation, much of the research examining the effectiveness of CBTp has been done with outpatient community samples or several decades ago in inpatient settings very different from current hospitals, which have higher thresholds for admission and care for more ethnically diverse patients.[4,5]

It is well demonstrated that the acute stage is a crucial time to intervene psychologically as this is when people are in most need of psychological support; are often at risk to themselves (e.g., self-harm or suicide), to others (e.g., violence and aggression) and/or from others (e.g., exploitation); and are experiencing distressing symptoms of psychosis.[4] Psychological therapies offered in crisis can help contain distress, instil hope, and help patients identify appropriate coping strategies.[4] There is evidence that cognitive behavioural interventions can be adapted to be delivered as a brief intervention, i.e., within 6–8 sessions, therefore making them suitable for brief inpatient admissions.[6]

There is an overrepresentation of inpatients from ethnic minority backgrounds, with those from black African and black Caribbean backgrounds being 3.5 times more likely to be compulsorily detained than their white counterparts.[7] There is evidence that patients from ethnic minority backgrounds are less likely to be offered psychological therapies, have more negative experiences of mental health services and have poorer outcomes following a mental health crisis.[7] There is probably a range of reasons for these disparities, and it is essential that acute inpatient psychological interventions are developed to meet the needs of ethnic minority groups if they are to be useful and acceptable in this setting. There is some existing evidence that CBTp can be culturally adapted to be appropriate for ethnic minority populations, with some evidence with inpatient populations.[8]

Recent systematic reviews have been conducted to examine the feasibility, acceptability and effectiveness of cognitive behavioural psychological interventions for people in acute mental health inpatient settings.[4,5] They have demonstrated some initial promise with small improvements in psychotic symptoms at the end of therapy, but not at longer-term follow-up.[5] There is also initial evidence that psychological therapy may have a

small effect on readmission, depression and anxiety. However, the reviews concluded that the quality of research was poor to moderate, and that most psychological therapies had not been specifically adapted for delivery in the acute mental health inpatient setting or focused on crisis management. Moreover, the reviews highlighted the inconsistent use of outcome measures with the majority not being psychometrically validated for this setting. This is a strong indication of a need for a robust evaluation of a psychological intervention for individuals with psychosis, adapted for the current acute mental health inpatient setting with a focus on crisis reduction, using appropriate outcome measures.

We have developed a crisis-focused CBTp-informed intervention (cCBTp) for inpatient settings,[9] which is culturally sensitive, following best practice guidelines from the Medical Research Council (MRC) on complex intervention development.[10] The cCBTp intervention was developed drawing from relevant systematic reviews, qualitative literature and additional stakeholder consultation.[5,9,11] Data from these studies was reviewed by a coproduction group and used to develop a therapy protocol and associated staff training manual. Full detail about the intervention development can be found here.[9]

The aim of this study was to examine the feasibility of a randomised controlled trial (RCT) of the cCBTp intervention for acute inpatients experiencing psychosis. More specifically, our objectives were to:

Assess the feasibility of conducting the RCT, examined by the number of participants who gave informed consent as a proportion of the number identified as eligible, the number of participants randomised, number of participants who dropped out from the trial, number of post-therapy and follow-ups completed.

Examine the feasibility of the intervention to participants, examined by the number of therapy sessions attended, number of sessions declined or not attended, number of people who declined therapy once randomised.

Examine for any adverse effects of the intervention.

Examine the suitability of the outcome measures to examine the efficacy of the interventions, in preparation for a fully powered effectiveness RCT.

Acceptability of the intervention has been assessed through two nested qualitative studies and more detail can be found in the papers.[12,13]

Methods

Study design and participants

This study adopted a single-centre, individually randomised, researcher-blind, parallel-group, RCT design. Participants were randomly allocated to either treatment as usual (TAU) or the crisis-focused CBTp informed intervention (cCBTp) plus TAU in a 1:1 ratio. Outcome measures were carried out at baseline, 2 months and 6 months post-randomisation either face to face or remotely (see Table 1). Relapse, rehospitalisation and adverse event data was collected from electronic health records (EHRs) at 6 and 12-months. This trial is reported following the guidance from the Consolidating Standards for Reporting Trials (CONSORT) guidance.[14] The full trial protocol has been published.[15] The changes to the protocol were not collecting relapse and rehospitalisation data at 2-months due to many participants still being hospitalised on their initial admission and not reporting the outcome data on the CRISIS measure due to it being an unvalidated measure. This trial was undertaken at a single NHS site located in outer London, in the acute mental health inpatient services. The trial was fully conducted during the COVID-19 pandemic.

Recruitment was conducted to ensure that the sample was representative of the patient population, with at least 50% from ethnic minority backgrounds and at least 30% of the total sample from Black African and/or Caribbean ethnic backgrounds.

Participants were included if they were: (i) aged 18 and above; (ii) met criteria for a schizophrenia-spectrum diagnosis (schizophrenia, schizophreniform disorder, schizoaffective disorder, delusional disorder or psychotic disorder not otherwise specified; ICD-10), or met criteria for an early intervention service (EIS) for treatment of psychosis to allow for diagnostic uncertainty; (iii) able to give informed consent and had the capacity to consent; (iv) currently receiving care from an acute psychiatric inpatient team; and (v) able to

	Enrolment	Baseline	Allocation	2-month FU	6-month FU	12-month FU
Eligibility screen	X					
Informed consent	X					
Intervention allocation			X			
Outcomes						
BDI		X		X	X	
GAD-7		X		X	X	
BHS		X		X	X	
QPR		X		X	X	
REQOL		X		X	X	
PANSS-P		X		X	X	
GAF-S		X		X	X	
GAF-F		X		X	X	
TAG		X		X	X	
Relapse					X	X
Rehospitalisation					X	X
SAE/AE					X	X

AE–Adverse Event, BDI–Beck Depression Inventory, BHS–Beck Hopelessness Scale, FU–follow-up, GAD-7–Generalised Anxiety Disorder Measure, GAF-F–Global Assessment of Functioning-Functioning Subscale, GAF-S–Global Assessment of Functioning—Symptoms Subscale, PANSS-P–Positive and Negative Syndrome Scale—Positive Subscale, QPR–Process of Recovery Questionnaire, REQOL–Recovering Quality of Life, SAE–Serious Adverse Event, TAG–Threshold Assessment Grid.

Table 1: **Schedule of events.**

complete the research in English. Exclusion criteria were (i) non-English speakers (due to translation costs and complex procedures required to produce valid translations of the research instruments and intervention), (ii) an acquired brain injury or substance misuse judged to be the acute cause of the psychotic experiences, and (iii) those already undertaking a structured psychological intervention delivered by a psychological professional at the time of the study.

Ethics

Full Health Research Authority (HRA) and NHS Research Ethics Committee (REC) approval was granted (IRAS ID: 272043; 20/LO/0137/AM01) and the study was sponsored by University College London. Full informed consent was obtained from all participants.

Randomisation and masking

The randomisation was undertaken using www.sealedenvelope.com. Randomisation was blocked using the random permute blocks method on a ratio of 1:1 to ensure the groups were balanced periodically. Participant numbers were entered into the Sealed Envelope website by a research assistant psychologist independent from the trial after the research assistant had completed the baseline assessment. The independent research assistant psychologist would then assign participants to their trial group and inform them via telephone of their allocation. Allocations were emailed to the Chief Investigator (LW) who in turn allocated a therapist to commence therapy. All assessments were completed by research assistants who were blind to treatment allocation. Blinding was monitored, and if any blind breaks occurred, they were systematically recorded. The chief investigator (LW) and trial therapists were not blinded to the participant allocations.

Procedures

The study had two arms. The experimental arm was the cCBTp arm. The intervention was delivered by practitioner psychologists working in acute inpatient services who were registered with the UK Health and Care Professions Council and had experience and training in delivering CBTp in inpatient settings.

The intervention was underpinned by a modularised CBTp protocol involving delivery of approximately six to eight therapy sessions to participants.[9] The protocol included six modules: engagement, assessment, and identifying priorities; formulation of the crisis; stabilisation, safety, and problem solving; crisis plans and crisis cards; change strategy work focussing on crisis appraisals and safety behaviours; and discharge, relapse planning, and recovery toolkits. The first two modules (engagement, assessment and identifying priorities, and formulating the crisis) were essential components of the intervention, while the remaining ones were collaboratively chosen based on the participant's priorities. The number of sessions was determined by the collaborative priorities set by the patient and therapist, as well as the length of the admission; therefore, more or fewer sessions could be offered. If only one session was possible, the therapist would prioritise a brief assessment and formulation of the prioritised issue and a simple intervention strategy (e.g., a coping strategy for a distressing voice). The therapy included at least one follow-up session post-discharge to ensure support through the discharge process. The intervention aimed to be culturally competent and also included strategies to involve the individual's network, such as family sessions and formulation sharing with the multidisciplinary team.

The sessions were delivered in a private and quiet room on the inpatient ward or outside the ward if the participant had appropriate leave, for example, in a room off the ward but on the grounds of the hospital. If the participant was discharged before therapy was complete, the sessions continued and were delivered in community settings or remotely (e.g., via phone or video conferencing technology) to ensure continuity post-discharge. More detail about the therapy is published elsewhere.[9]

A total of seven therapists delivered the cCBTp intervention. All therapists were Heath and Care Professions Council (HCPC) registered practitioner psychologist with experience working of delivering CBTp in inpatient settings. The therapists received a training package that involved watching pre-recorded therapy videos (https://www.psychosisresearch.com/cbt-phase-1/) and participating in two days of training specifically focused on cCBTp. The training, delivered by LW, CW, and CD, included an introduction to the cCBTp model, making culturally appropriate adaptations, conducting a crisis-focused assessment, developing a crisis-focused formulation, and using brief crisis-focused intervention strategies. It involved a combination of didactic teaching, role plays, reflective exercises, and group discussions. Therapists also had access to weekly 90-min group supervision while delivering the therapeutic intervention and were required to attend at least on supervision session a month when they were actively delivering the intervention.

All therapy sessions were audio recorded, provided the participant consented. A random selection of 10% of all the sessions were rated using the Cognitive Therapy Rating Scale (CTRS) to ensure adherence to the CBT model (operationalised as a score of 3 or more on each CTRS item).[16] All therapists had at least one session checked for fidelity (where consent to recording allowed). The fidelity scale was applied flexibly considering that the therapy was delivered as a brief intervention with people in an acute mental health inpatient population, which could make some fidelity items harder to achieve. For example, the agenda may have

been brief and included only a single item, and only a simple formulation, making basic links between thoughts, feelings, and behaviours, may have been possible. All rated sessions met fidelity criteria.

Treatment as usual was the routine care that participants received, which typically included multidisciplinary acute inpatient and crisis care. More specifically, participants would have received care from inpatient or crisis home treatment team, and had treatment comprising pharmacotherapy, risk assessment and management, and crisis-focused care plans. TAU also included access to NICE recommended psychosocial interventions, which could involve structured psychological therapies provided by psychological professionals and brief interventions delivered by appropriately trained nurses or occupational therapists. TAU was not standardised across participants but reflect real-word clinical practice.

Participants were recruited from an acute mental health hospital in outer London. The study was advertised to the inpatient staff teams, who provided information about the study to eligible participants. Due to the high patient turnover in acute mental health inpatient wards, staff advertised the research to patients as early as their first day of admission, if appropriate. If the patient consented, they were contacted by a research assistant within 72-h, who provided more detailed information and obtained informed consent. The research assistant completed all clinical measures with the participant (see Table 1). Once complete, the participant was randomised by a researcher independent from the trial. The research assistant then completed follow-up assessments at 2- and 6-months post-randomisation. Data on relapse, rehospitalisation, and adverse events were collected at 6 and 12 months directly from EHRs.

An independent trial steering committee that incorporated the duties of a data management committee, including monitoring adverse events, oversaw the running of the trial. They met every 6 months and monitored the progress, conduct and safety of the trial; advised on scientific credibility; and considered whether the trial should continue, be modified or be stopped. This study was not formally supported by a Clinical Trials Unit (CTU) due to limited financial resource. However, key collaborators were CTU staff and consulted on the trial methodology and analysis throughout. The trial followed University College London's standard operating procedures (SOPs) for clinical trial delivery. The authors based in CTUs did not explicitly use their home CTU SOPs.

Outcomes

Individual patient data was collected by research assistants on a pre-developed sheet adhering to CONSORT guidelines.[14] The feasibility outcomes examined were patient eligibility status, the number of referrals received by ward staff, participants' willingness to consent, and dropout rates. Therapy-specific data was collected on the number of sessions attended, the number of sessions declined or not attended, the number of people who declined therapy after randomisation, and any adverse and serious adverse events. This data was collated by therapists who completed a session summary sheet after each session. Outcome measure collection rates were also examined.

An individual patient demographics sheet was used to collect sociodemographic and patient data to identify the types of people willing to take part in the trial. Participants self-reported their demographic information, including their age and sex.

Clinical outcome measures were completed by a research assistant blind to treatment allocation. No primary or secondary outcomes are identified due to the feasibility nature of the study. Research assistants received half a day training on how to complete the outcome measures with participants. Research assistants also received additional 2-day training on administering the PANSS. No inter-rater reliability coefficients were calculated due to a lack of resource. To reduce participant burden, a combination of self-report outcomes, assessor-rated outcomes and a structured clinical interview were chosen. The measures were administered during a face-to-face, or if not possible, remote interview between the participant and the research assistant. Where possible, short versions or sub-components of the measures were chosen for the same reason.

Depression was measured using the Beck Depression Inventory brief 7-item measure (BDI-7), a self-report tool with good internal consistency.[17] Participants could score from 0 (not present) to 3 (indicating severe) on each item with a possible total score ranging from 0 to 21. A higher score indicates higher levels of depression.

Hopelessness was measured using the short form of the Beck Hopelessness Scale (BHS), a 9-item version validated for psychiatric inpatients.[18] Participants could score 0 (not present) or 1 (present) on each item with a possible total score ranging from 0 to 9. A higher score indicates higher levels of hopelessness.

Personal recovery was measured using the 15-item Process of Recovery Questionnaire (QPR).[19] Participants could score from 1 (disagree strongly) to 5 (agree strongly) on each item with a possible total score ranging from 15 to 75. A higher score indicates higher levels of personal recovery.

Anxiety was measured using the Generalised Anxiety Disorder 7-item (GAD-7) measure.[20] Participants could score from 0 (not at all) to 3 (nearly every day) on each item with a possible total score ranging from 0 to 21. A higher score indicates higher levels of anxiety.

Quality of life was measured using the Recovering Quality of Life (REQOL-10) scale.[21] Participants rated

their quality of life across 10 items, scoring from 0 to 4, with a possible total score ranging from 0 to 40. A higher score indicates higher levels of perceived quality of life.

Service use was assessed using an adapted version of the "generic UK mental health" Client Service Receipt Inventory (CSRI), tailored to reflect local care pathways at the recruitment site.[22] This was completed through participant self-report and information from clinical notes.

Experiences of psychosis were measured using the Positive and Negative Syndrome Scale (PANSS).[23] Only the 7-item positive subscale was used to measure positive symptoms. Participants could score from 1 (absent) to 7 (extreme) on each item with a possible total score ranging from 7 to 49. A higher score indicates more severe psychotic symptoms.

Functioning was assessed using the Global Assessment of Functioning (GAF) measure.[24] GAF scores ranged from 1 (in some danger of hurting self or others) to 100 (absent or minimal symptoms). We used the version that had two separate subscales examining symptoms and functioning respectively and participants would have a separate score for each subscale. A higher score indicates improved functioning and symptoms.

The Threshold Assessment Grid (TAG) is a 7-item measure used to examine the severity of participants' mental health difficulties in three areas; safety, risk, and needs and disabilities.[25] Participants could score from 0 (none) to 4 (very severe) on each domain with a possible total score of 0–28. A higher score indicates increased risk and needs.

EHRs were screened to gather information on the following variables from the point of randomisation and summarised at 6 and 12-months:

Hospitalisation: Total number of days in hospital (variable name "Hospitalisation (days)") and number of hospitalisation episodes (variable name "Hospitalisation (episodes)") respectively.

Relapse (operationalised as care received from crisis services): Total days under the care of acute mental health services (including inpatient wards, crisis home treatment, psychiatric liaison, and acute crisis and assessment teams) (variable name "Relapse (days)") and number of episodes (variable name "Relapse (episodes)") respectively.

Binary outcomes of whether participants were hospitalised (variable name "Hospitalisation (binary)") or relapsed (variable name "Relapse (binary)") or not.

Number of serious adverse events (SAE) and adverse events (AE), including harm to self and others. SAEs were defined as untoward medical occurrence(s) where the intervention (a) results in death, (b) is life-threatening, (c) requires hospitalisation or prolongation of existing hospitalisation, (d) results in persistent or significant disability/incapacity or (e) consists of a congenital anomaly or birth defect. An AE was defined as any untoward medical occurrence in a patient or clinical trial participant administered a medicinal product and which does not necessarily have a causal relationship with this treatment.[26]

Statistical analysis

The trial was registered on the ISRCTN trial registry (ISRCTN59055607). We aimed to recruit sixty participants in line with recommendations by CONSORT for feasibility and pilot RCTs.[27] This sample size allowed for dropouts, which are common in clinical trials in inpatient settings. Some inpatient studies report dropout rates of over 50%, and recruiting a larger sample allowed us to collect adequate data to inform a larger multi-site trial.[4]

As this was a feasibility study, the focus was on examination feasibility outcomes. No primary or secondary outcomes were identified. Data analysis was based on intention-to-treat. The study followed best practice guidance for the reporting of feasibility RCTs (CONSORT).[14,27] The analysis focused on key indicators of feasibility, including participant recruitment, data collection, engagement in the intervention, adverse and serious adverse events, which were summarised descriptively using frequencies and percentages. Where outcome measures had less than 20% of missing data, it was replaced with the mean score. If more than 20% of data was missing, the subscale was removed. Continuous clinical outcome measures total scores (except for the GAF where the subscales of symptoms and functioning were reported individually) were summarised separately by study arm using means and standard deviations. Binary outcome measures were summarised using frequencies and percentages. The quantity of missing data for each clinical outcome was examined and likewise summarised by study arm. This study was not designed to have sufficient power to assess the effectiveness of the intervention or test null hypotheses. All data analysis was undertaken on IBM SPSS Statistics (Version 29).

Pre-set criteria for deciding whether a trial of the CBTp intervention was feasible (determined by examining published CBTp trials)[4,5] were:

A follow-up rate of 75% at 2 months post-randomisation and 60% at 6 months post-randomisation.

Recruitment of ≥80% of the target sample size (n = 60) over the 12-month recruitment period.

Qualitative data from patients and therapists support the intervention/indicate that the intervention is acceptable. This is examined in other publications.[12,13]

Role of funding source

The NIHR had no role in any aspects of this research study. They were not involved in the study design, data

collection, data analysis, interpretation or writing of this manuscript.

Results

A total of 145 people were referred to the study. The first participant was recruited on 19th February 2021 and the last on 21st February 2022 and the final follow up data were collected on 13th October 2022. 145 participants were screened and 52 were randomised, 26 to the cCBTp intervention arm and 26 to the TAU arm (Fig. 1).

Baseline participant characteristics can be found in Table 2 and were mostly balanced across the groups. There appear to be group differences in the ethnicity variable with more people from Black African/Caribbean backgrounds being allocated to the intervention arm and more people from Asian backgrounds being referred to the TAU arm. The mean age was 40.2 years (SD 15.0). In terms of sex, 27/52 (52%) participants were male and 25/52 (48%) were female and 33/52 (63.5%) participants were from ethnic minority backgrounds. Baseline scores on the outcome measures can be found in Table 3.

We were able to recruit n = 52 of our target sample of 60 participants within the study recruitment window (87%). Referral to randomisation ratio was approximately 3:1, with 29/145 referrals being ineligible at initial screening leaving 116/145 potentially eligible participants. Out of the 116 remaining participants, n = 29 became ineligible due to being discharged from the ward before being approached, and n = 35 declined to take part. The reasons for declining were not being interested in the study (n = 7), not being interested in being involved in research (n = 3), the research involving too much time/commitment (n = 3), not being the right time (n = 3) and no reason given (n = 19).

At the end of treatment (2-month follow up), n = 30/52 (58%) participants were retained for the face-to-face outcome measures (n = 16/26 for the cCBTp arm and 14/26 for the TAU arm) and n = 46/52 (88%) participants had their EHR data collected (n = 24/26 from the cCBTp arm and n = 22/26 from the TAU arm). At 6-month follow-up n = 31/52 (60%) participants provided face-to-face outcome measures (n = 19/26 from the cCBTp arm and n = 12/26 from the TAU arm) and n = 46/52 participants (86%) had their EHR data collected (n = 24/26 from the cCBTp arm and n = 21/26 from the TAU arm). This demonstrates that the face-to-face outcome measure completion was lowest as 2-months and slightly improved at 6-month. At 12-month follow-up n = 43/52 (83%) participants had their EHR data collected (n = 24/26 from the cCBTp arm and n = 19/26 from the TAU arm).

Of those allocated to the intervention, 22/26 (85%) received at least one session, which was the minimum to achieve adherence. n = 4 had declined or moved out of area before therapy commenced. The average number of sessions attended was 7.5 (SD: 5.72; range 1–19) and the mode number of sessions was 7. The average number of sessions declined or missed was 4.2 (SD: 2.67; range 1–8). The average therapy session length was 48.3 min (SD: 11.84; 10–70).

In terms of adverse effects, n = 9/26 participants (35%, 35 events) in the cCBTp arm and n = 7/26 participants (27%, 11 events) in the TAU arm experienced an adverse event or serious adverse event (see Table 4). The most common serious adverse events were prolonged psychiatric hospital admission (8/29; 28%), readmission to psychiatric hospital (13/29; 48%), and admission to a physical health hospital (8/29; 28%). The most common adverse events were self-harm attempts (11/17; 65%). None of the adverse or serious adverse events were deemed related to study participation or the intervention.

All results from clinical outcome measures are reported in the Supplementary Material (Tables S2–S5). We were able to complete the CSRI with all participants who were retained (see Supplementary Material Table S6) at 2 and 6 months. CSRI data from clinical notes had a higher collection rate.

Discussion

This study aimed to assess the feasibility of a pilot randomised controlled trial of cCBTp. Overall, the study met the pre-defined feasibility criteria in relation to recruitment. Data collection targets were met at the 6-month follow-up but not at the 2-month follow-up. However, we were able to collect EHR data (>80%) above expected rates for the trial at 6 months and 12 months demonstrating that such data are more feasible to collect for this participant population, as reported in previous studies, and may be more suitable to examine the efficacy of the intervention is a larger fully powered RCT.[4] The intervention and research procedures were also deemed to be safe as there were no serious adverse events or adverse events relating to trial procedures (based on 92% of cCBTp arm participants EHR data).

To our knowledge, this is the first RCT to evaluate the feasibility a cCBTp intervention for inpatients experiencing psychosis. We are tentatively able to demonstrate that inpatients experiencing psychosis are willing to engage in a research trial and in a crisis-focused psychological intervention when receiving acute psychiatric inpatient care. This suggests that an intervention that includes building a therapeutic relationship, helping individuals make sense of their psychotic crisis, finding ways of coping, and supporting discharge may be acceptable to inpatients. The mean number of sessions attended was 7.5, which was in line with the estimated 6–8 sessions outlined in the treatment protocol. However, the range of sessions attended was from 1 to 19, reflecting the diverse needs of the

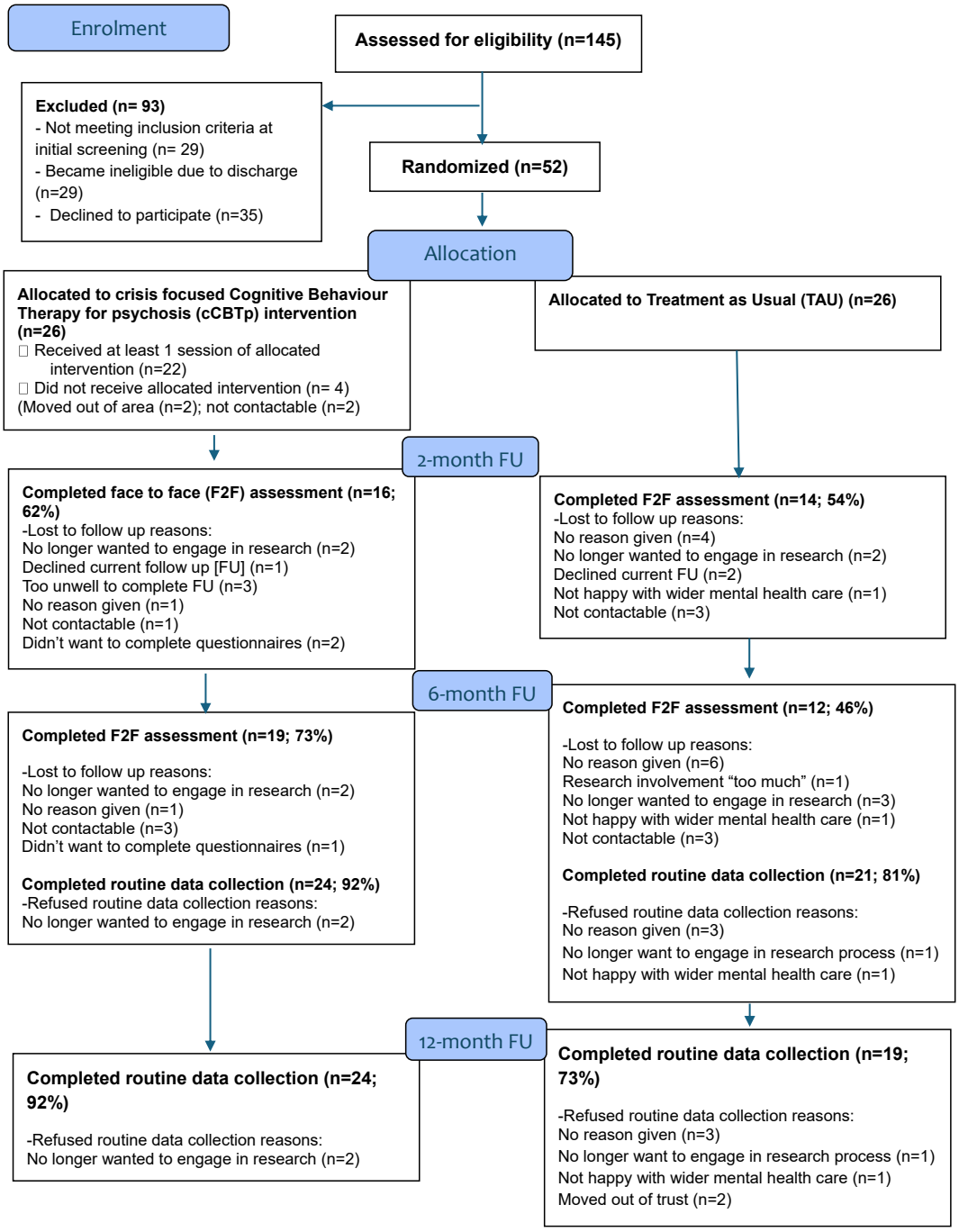

Fig. 1: **CONSORT diagram of participant flow.**

inpatient populations and potentially wide-ranging admission lengths. It was important to allow for varied lengths of sessions to meet participants' needs and having flexibility in intervention delivery would be recommended in future trials. This is supported by qualitative data from both patients and therapists, which outlined that flexibility to therapy delivery was key.[12] A limitation of the intervention was that the first two modules were compulsory, but only one session of therapy was considered an adequate "dose". While it is possible to complete both the assessment and formulation components of the intervention in a single session, this may not always be possible meaning participants may be missing an essential part of the

	Total sample		cCBTp		TAU	
	M (SD)	Range	M (SD)	Range	M (SD)	Range
Age	40.19 (SD: 14.98)	19–70	41.23 (16.96)	19–69	39.15 (12.97)	21–70
Number of previous admissions	3.38 (SD: 5.88)	0–26	2.80 (5.31)	0–26	3.96 (6.42)	0–24
	N	**%**	**N**	**%**	**N**	**%**
Sex						
Male	27	51.9	14	54	13	50
Female	25	48.1	12	46	13	50
Education level						
Secondary	15	28.8	7	27	8	31
Further	19	36.5	11	42	8	31
Higher	17	32.7	7	27	10	38
Missing	1	1.9	1	4	0	0
Employment status						
Employed	5	9.6	3	12	2	8
Student	1	1.9	1	4	0	0
Unemployed	36	69.2	18	69	18	69
Retired	8	15.4	4	15	4	15
Other	2	3.8	0	0	2	8
Marital status						
Single	43	82.7	20	77	23	88
Married/with partner	7	13.5	5	19	2	8
Other	1	1.9	1	4	0	0
Missing	1	1.9	0	0	1	4
Ethnicity						
South Asian	9	17.3	2	8	7	27
Black African/Caribbean	20	38.5	15	58	5	19
Mixed background	4	7.7	0	0	4	15
White	19	36.5	9	35	10	38
Religious beliefs						
Christianity	27	52.9	15	58	12	46
Islam	11	21.2	5	19	6	23
Sikhism	1	1.9	0	0	1	4
Buddhism	1	1.9	0	0	1	4
Atheism	1	1.9	1	4	0	0
Other	8	15.4	3	12	5	19
Missing	3	5.8	2	8	1	4
Primary diagnosis						
Schizophrenia	20	38.5	11	42	9	35
Acute and transient psychotic disorder	7	13.5	3	12	4	15
Schizoaffective disorder	3	5.8	2	8	1	4
Persistent delusional disorder	7	13.5	0	0	7	27
First episode psychosis	4	7.7	2	8	2	8
Psychosis not otherwise specified	2	3.8	1	4	1	4
Bipolar disorder (with psychosis)	6	11.5	4	15	2	8
Missing	3	5.8	3	12	0	0
Admission status						
Informal	7	13.5	3	12	4	15
MHA section 2 admission	8	15.4	2	8	6	23
MHA section 3 admission	13	25	9	34	4	15
Missing	24	46.1	12	46	12	46

cCBTp–crisis-focused Cognitive Behaviour Therapy for psychosis, MHA–Mental Health Act, TAU–Treatment as Usual.

Table 2: **Baseline Sample demographics of trial participants.**

	cCBTp			TAU		
	N	M	SD	N	M	SD
BDI	26	4.65	4.70	26	5.15	5.15
GAD-7	26	7.81	6.17	26	7.23	5.54
BHS	26	2.26	2.51	25	1.60	1.38
QPR	26	59.23	11.99	26	61.92	9.02
REQOL	26	25.88	9.10	26	27.03	8.18
PANSS-P	26	13.91	5.28	26	14.85	5.06
GAF-S	26	32.04	6.07	26	29.42	6.75
GAF-F	26	33.50	4.94	26	34.85	5.99
TAG	26	17.96	3.18	26	16.92	3.54

BDI-7–Beck Depression Inventory, BHS–Beck Hopelessness Scale, cCBTp–crisis-focused Cognitive Behaviour Therapy for psychosis, CI–Confidence Interval for Cohen's d, FU–follow-up, GAD-7–Generalised Anxiety Disorder Measure, GAF–Global Assessment of Functioning, N–Sample size, M–Mean, PANSS-P–Positive and Negative Syndrome Scale—Positive Subscale, QPR–Process of Recovery Questionnaire, SAE–Serious Adverse Event, SD–Standard Deviation, TAG–Threshold Assessment Grid, TAU–Treatment as Usual.

Table 3: **Baseline measures.**

intervention. Upon reflection, it may be important to consider two sessions to be the minimal "dose" of sessions in further large-scale trials of the intervention. In addition, we were not able to demonstrate which specific components of the intervention were most effective or whether the intervention was most beneficial for specific groups of participants. This should be examined in future research focussing on evaluating the implementation of the intervention in a larger definitive trial.

	cCBTp N = 26		TAU N = 26	
	N	%	N	%
Number of participants with an SAE/AE	9	35	7	27
Number of SAE/AE	35		11	
Serious adverse events				
Number of participants with an SAE	8	31	6	23
Number of SAEs	19		10	
Details				
Extended psychiatric hospital admission	4		4	
Readmission to a psychiatric hospital	8		5	
Admission to a physical health hospital	6		1	
Suicide attempt	1		0	
Adverse events				
Number of participants with an AE	2	8	1	4
Number of AEs	16		1	
Details				
Self-harm attempts	11		0	
Reported missing from supported accommodation	5		0	
Accidently taking incorrect prescribed medication	0		1	

AE–Adverse Events, SAE–Serious Adverse Events.

Table 4: **Serious adverse events and adverse events.**

Our study also demonstrated that it is possible to engage patients from ethnic minority backgrounds in research in acute mental health settings. We were able to recruit over 60% of participants from ethnic minority backgrounds and over 30% from black African/Caribbean backgrounds demonstrating that this population is willing to engage in psychological therapy research in inpatient settings. Ethnic minority groups are notoriously underrepresented in psychotherapy research, as well as clinical research more generally, due to factors such as historical and systemic racism leading to mistrust, stigma, broader negative experiences of health services, and lack of cultural adaptation of research processes.[28] We made specific efforts to ensure both the research and intervention were culturally sensitive including working closely alongside an ethnically diverse stakeholder group, having ethnically diverse therapist provision, and adopting the NIHR INCLUDE guidance.[28] However, a limitation in this area was the exclusion of participants who did not speak English. We recommend that future research in this field continues to increase diversity in their participant samples and includes those whose first language is not English, and wider underrepresented groups.

One of the main trial limitations was the high dropout rates from the face-to-face follow up appointments (42% at 2 months and 40% at 6 months) with dropout rates higher in the TAU arm. Ongoing mental distress and challenging symptoms of psychosis, stigma, shame, and traumatic experiences of psychiatric inpatient care may explain the high dropout rates. A further factor may be the burdensome nature of the outcome measures. Although we attempted to minimise the number of outcome measures completed by participants, for example only using the PANSS positive subscale, it was evident that took too long to complete, with an average completion time of over an hour. We implemented several strategies to minimise dropouts including being flexible with follow-up modality (i.e., on the phone, in a local service, or at home), attempting continuity in research assistant, and liaising with clinical teams to support follow-up contact yet dropouts remained high. We suggest minimising the use or face to face outcome measures or utilising shorter versions, such as the PANSS-6,[29] in future clinical trials. Some emerging research has been undertaken to support researchers in improving data collection in psychiatric inpatient clinical trials,[30] however further research is required to identify the specific reasons for disengagement and to identify tailored strategies to improve it. Overall, our follow-up rate was in line with other clinical trials that have been conducted with psychiatric inpatient populations.[4]

As a result of the poor dropout rates, we were not able to collect sufficient outcome measure data to draw conclusions on their suitability for a larger RCT. We were not suitably powered to calculate effect sizes with

the planned sample size, which was further exacerbated by the high dropout rates. However, we were able to successfully collect data from EHRs. This was an encouraging finding as it meant that the majority of those who dropped out of face-to-face assessments still verbally consented for us to continue collecting their routine clinical data. Although people did not want to actively engage in self-report face-to-face assessments, they were willing for their data to still contribute to the research process. As a result, future research trials with this population may want to consider maximising opportunities for the collection of data from EHR where appropriate (for example, hospitalisation and relapse), which was demonstrated to be most feasible for this population and minimise the use of self-report outcome measures.

As a small feasibility trial, with the additional data collection challenges, we were not adequately powered to examine any of the outcomes for significant effect and therefore cannot draw any conclusion regarding the potential efficacy of the intervention. Rehospitalisation and relapse seem like feasible potential primary outcomes for interventions with this population, but the small sample and high variance meant we were unable to find any indication of efficacy on these outcomes. A recent study examining core outcome sets for psychological therapy trials with psychiatric inpatient populations identified that ability to cope, hopefulness, quality of life, psychosis symptoms, mood and self-harm behaviours should be examined as key outcomes for interventions in inpatient settings and therefore should be considered for inclusion in future research.[31]

Another limitation was the trial being conducted during the COVID-19 pandemic, which may have impacted research delivery, recruitment and data collection. Although we were supported by senior clinical leadership at the recruiting site to undertake the trial in the psychiatric hospital during this time, the staff were having to implement additional infection control procedures to minimise contraction of the virus in staff, patients and visitors. This meant ward visiting policies would regularly change, and that staff were exceptionally busy and had increased demands placed on their time. As a result, accessing the wards and engaging staff in study recruitment procedures was challenging and potentially impeded our ability to recruit to target. It may have also impacted upon follow-up data collection with factors such as worsened mental health, participant fears of contamination, self-isolation, and poorer experiences of mental health services (due to stretched resources) impacting, however we were unable to monitor and determine its full effect. It also may mean that our findings may not be fully generalisable to inpatient settings post-pandemic.

A final limitation of the trial was the high number of staff working on the trial. Due to having no dedicated therapists or research assistant resource funded for this trial, we had seven therapists and eight research assistants working on the study. The study was reliant on trial therapists who were clinicians delivering therapy around the demands of their main clinical roles. The therapists also had varied experience and training in delivering CBTp with some having undertaken additional postgraduate training. This may have meant that the quality of the therapy offered varied across therapists and could have impacted therapy engagement and outcome. Similarly, the trial depended on input from Clinical Studies Officers, which are researchers funded centrally by the Clinical Research Network to support NIHR funded trials recruiting across NHS trusts in the UK. This meant that we had over eight staff members working on the trial throughout its duration, which made inter-rater reliability of the outcome measures a particular concern. We were also not able to calculate inter rater reliability on research administered outcome measures due to the volume of research assistants and lack of study resource which may have reduce measurement consistency and validity. This also likely impacted on follow-up completion as participants were not able to build relationships with research and maintain continuity. Future research should attempt to minimise staff turnover and prioritise regular training and integrate inter-rater reliability assurances into such trials.

In summary, this study, along with support from the additional qualitative components published elsewhere,[12,13] has demonstrated that it is potentially feasible to undertake a pilot randomised controlled trial of a crisis-focused CBTp-informed psychological intervention with inpatients experiencing psychosis. A large definitive trial of the intervention is suggested which primarily uses data from EHRs to monitor outcomes of the intervention. However, further refinement of a recruitment and data collection plan is required.

Contributors

Conceptualisation: LW, APM, CW, SJ.
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Formal analysis: LW, CoC.
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Investigation: LW, PF, CN.
Methodology: All authors.
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Writing original draft: All authors.
Writing-review and editing: All authors.
Study data were accessed by all authors and verified by CoC.
All authors read and approved the final version of the manuscript.

Data sharing statement

This clinical trial data can be requested by any qualified researchers who engage in independent scientific research and will be provided following review and approval of a research proposal. For more information on the process, or to submit a request contact the following: l.wood@ucl.ac.uk.

Declaration of interests

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.eclinm.2025.103380.

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