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Accelerating the development of a psychological intervention to restore treatment decision-making capacity in patients with schizophrenia-spectrum disorder: An umbrella trial

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ABSTRACT

Introduction: Many individuals with schizophrenia-spectrum disorder ('psychosis') lack capacity to make decisions about psychiatric treatment ('incapacity'), however we lack robust evidence from clinical trials on interventions to improve it. To accelerate their development, we tested whether an 'umbrella' trial was feasible. This involved running multiple randomised controlled 'interventionist-causal' trials (IC-RCTs) concurrently. Each tested the effect on incapacity of targeting an individual psychological mechanism.

Methods: We did 3 assessor-blind, multi-site, pilot IC-RCTs. Each compared 6 sessions of psychological therapy for either self-stigma (SS), low self-esteem (SE) or the jumping-to-conclusions (JTC) bias, to 6 sessions of collaborative assessment of the causes of incapacity (control). Adults with psychosis, incapacity and ≥1 target mechanism could participate. Primary outcomes were recruitment feasibility, and data retention on the MacArthur Competence Assessment Tool-Treatment (MacCAT-T).

Results: We recruited 57 participants and performed 60 randomisations (3 patients participated in 2 trials); 82 % provided post-treatment data. Standardised mean differences (Hedges' g) for MacCAT-T 'understanding' were g = 0.35 (SS; 95 % CI −0.51, 1.22), g = 0.41 (JTC; −0.55, 1.38) and g = 0.74 (SE; −0.73, 2.21), with positive values favouring treatment. For 'reasoning', they were −0.20 (SS; −1.05, 0.66), 0.79 (JTC; −0.20, 1.79) and 0.79 (SE −0.69, 2.27). For 'appreciation' they were −0.39 (SS; −1.25, 0.48), 1.76 (JTC; 0.62, 2.90) and 0.57 (SE; −0.87, 2.02). Four control participants had 9 serious adverse events between randomisation and post-treatment; two intervention participants had 2.

Discussion: An umbrella trial of psychological interventions to improve capacity in psychosis is feasible. A definitive trial is warranted.

Trial pre-registration: NCT04309435.

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1. Introduction

Losing capacity to make one's own decisions about treatment ('incapacity'), is prevalent in schizophrenia-spectrum disorder ('psychosis'), affecting up to 80 % of inpatients (Owen et al., 2008), but also potentially reversible (Larkin and Hutton, 2017; Turner et al., 2019). Definitions of incapacity vary, but most involve significant impairments in the ability to understand decision-relevant information and communicate one's decision. Many also involve impaired abilities to retain, use and weigh relevant information, and/or appreciate it (Berg et al., 1995).

Capacity has been referred to as the 'gatekeeper of autonomy' (Donnelly, 2010), and in many jurisdictions clinicians are obliged to respect the treatment preferences of those who retain it. However, taking autonomy seriously also means we have a positive obligation to help people regain or retain it, which includes providing patients with support to regain or retain capacity (Beauchamp and Childress, 2001). In many countries, including the UK, this ethical imperative is mandated by law (Davidson et al., 2016) and professional regulations (General Medical Council, 2024). However, support for treatment decision-making in psychosis remains rare [e.g., (Martin et al., 2021)] and has been the subject of relatively little research (Larkin and Hutton, 2017). This is at odds with the deep importance many people with psychosis attach to being involved in treatment decision-making (Byrne and Morrison, 2014) and the observation that many will, at some point, need support to do so (Larkin and Hutton, 2017). Our limited knowledge of factors affecting capacity in psychosis means that it could take decades to develop an effective psychological intervention to restore it (Larkin and Hutton, 2017). To reduce this, we need to rethink the traditional process of intervention development, and consider alternative, more efficient paradigms.

One recent innovation is the 'umbrella trial', an approach which has successfully accelerated the development of interventions for cancer (Meyer et al., 2020), but has yet to be used in mental health (Meyer et al., 2020). It involves running multiple randomised controlled 'interventionist-causal' trials (IC-RCTs) (Freeman, 2011) at the same time, under one infrastructure. An individual IC-RCT aims to target a single factor or 'mechanism' hypothesised to cause or maintain a particular problem (Freeman, 2011). Umbrella trials aim to maximise the advantages of IC-RCTs (i.e., their ability to produce information on efficacy, safety *and* aetiology) while offsetting their relatively higher cost. This extra cost is inversely related to mechanism prevalence; the less prevalent it is, the more people need to be assessed for one to be randomised, which in turn needs more resources. Running several IC-RCTs at the same time, under one 'umbrella', increases a person's chances of being eligible for at least one.

In this article, we report the results of the 'DEcision-making Capacity: Intervention Development and Evaluation in Schizophrenia-spectrum disorders' (DEC:IDES) umbrella trial (Hutton et al., 2023). DEC:IDES involved assessing the feasibility and acceptability of running three IC-RCTS concurrently. Each tested the effect of modifying an individual mechanism which prior work suggested might contribute to impaired capacity in psychosis; these were self-stigma, low self-esteem and the jumping to conclusions (JTC) bias. Each mechanism is included in our theoretical model of impaired capacity (supplementary Fig. 2), which is in turn informed by a range of prior studies (Dudley et al., 2016; Larkin and Hutton, 2017; Morrison et al., 2016; Murphy et al., 2017, 2018; Turner et al., 2019). We specifically predicted that self-stigmatising beliefs about illness may motivate a person to reject the possibility they have a need for care, that low self-esteem may fuel treatment-related distrust and paranoia, and that individuals with a 'jumping to conclusions' bias may struggle to gather sufficient information about treatment before accepting or rejecting it. These particular mechanisms are also highly prevalent in psychosis (Dudley et al., 2016; Gerlinger et al., 2013; Murphy et al., 2018) and brief psychological interventions capable of selectively modifying them already exist (Freeman et al., 2014; Morrison et al., 2016; Turner et al., 2019).

2. Methods

The protocol and statistical analysis plan for DEC:IDES trial have been published previously (Hutton et al., 2023). We provide an abridged version here.

2.1. Study design and participants

We ran a single (rater) blind umbrella trial across three NHS sites in the United Kingdom; one in Scotland (Lothian) and two in England (Pennine and Lancashire). Our primary goals were to demonstrate feasibility of recruitment and retention of participants. We used UK National Institute of Health Research (NIHR) guidance (Hooper, 2013) to calculate that 60 participants were required to estimate a post-treatment data non-retention rate of 15 % to within a 95 % confidence interval of +/− 9 %.

To minimise cost, we planned to recruit 75 % of participants from our lead site, Lothian. Participants entered one of three IC-RCTs, each comparing treatment as usual plus a psychological intervention designed to address one of the hypothesised mechanisms (self-stigma, low self-esteem or the JTC bias) to treatment as usual plus an attention control condition (Fig. 1). Each trial required its own control group to ensure participants within each trial were equivalent with respect to their mechanism profile. Assessments were carried out at 0 (baseline), 8 (end-of-treatment; EoT) and 24 weeks (follow-up; FU). Due to limited resources and because our intention at this stage is simply to demonstrate the feasibility of retaining participants for follow-up, only those randomised in the first 5 (England) to 23 (Scotland) months are eligible for the 24-week assessment.[1] DEC:IDES was registered prospectively on clinicialtrials.gov on 16 March 2020, prior to the first randomisation (registration number NCT04309435).

Service-users could take part in DEC:IDES if they were aged 18–65, diagnosed with schizophrenia-spectrum disorder and assessed as lacking capacity to make decisions about taking antipsychotic medication or receiving psychiatric inpatient care by both their referring clinician and the research team. They needed to be a current patient of mental health or social care services, and have either low self-esteem, defined as a score of $<$15 on the Rosenberg Self-Esteem Scale (RSES) (Rosenberg, 1965), high self-stigma, defined as a score of $\geq$60 on Internalised Stigma of Mental Illness Inventory (ISMI) (Ritsher et al., 2003) and/or a JTC bias, defined as selecting $\leq$2 beads on the Beads Task (85:15 version) (Dudley et al., 2016). Exclusion criteria are detailed in the published protocol (Hutton et al., 2023), and included presence of moderate to severe learning disability or psychosis secondary to an organic condition (e.g. brain injury).

Participants could be referred by their care team, or they could self-refer. Participants lacking capacity to consent to research could take part if they assented and did not show any signs of distress, discomfort or unwillingness to participate, and either proxy consent (Scotland) or advice (England) was obtained from an appropriate representative, indicating they would wish to take part if they had capacity.

We gathered baseline information on demographics, legal status, offending history, medication regime stability, level of service engagement, alcohol/drug use and receipt of other treatments. The Clinical Interview for Psychotic Disorders (CIPD) (Martins et al., 2015), and the Brief Neurocognitive Assessment (BNA) (Fervaha et al., 2015), were used to confirm diagnosis and assess baseline cognitive functioning, respectively.

[1] The number of participants eligible for follow-up increased when the trial was extended to mitigate the impact of the COVID-19 pandemic. See CONSERVE checklist.

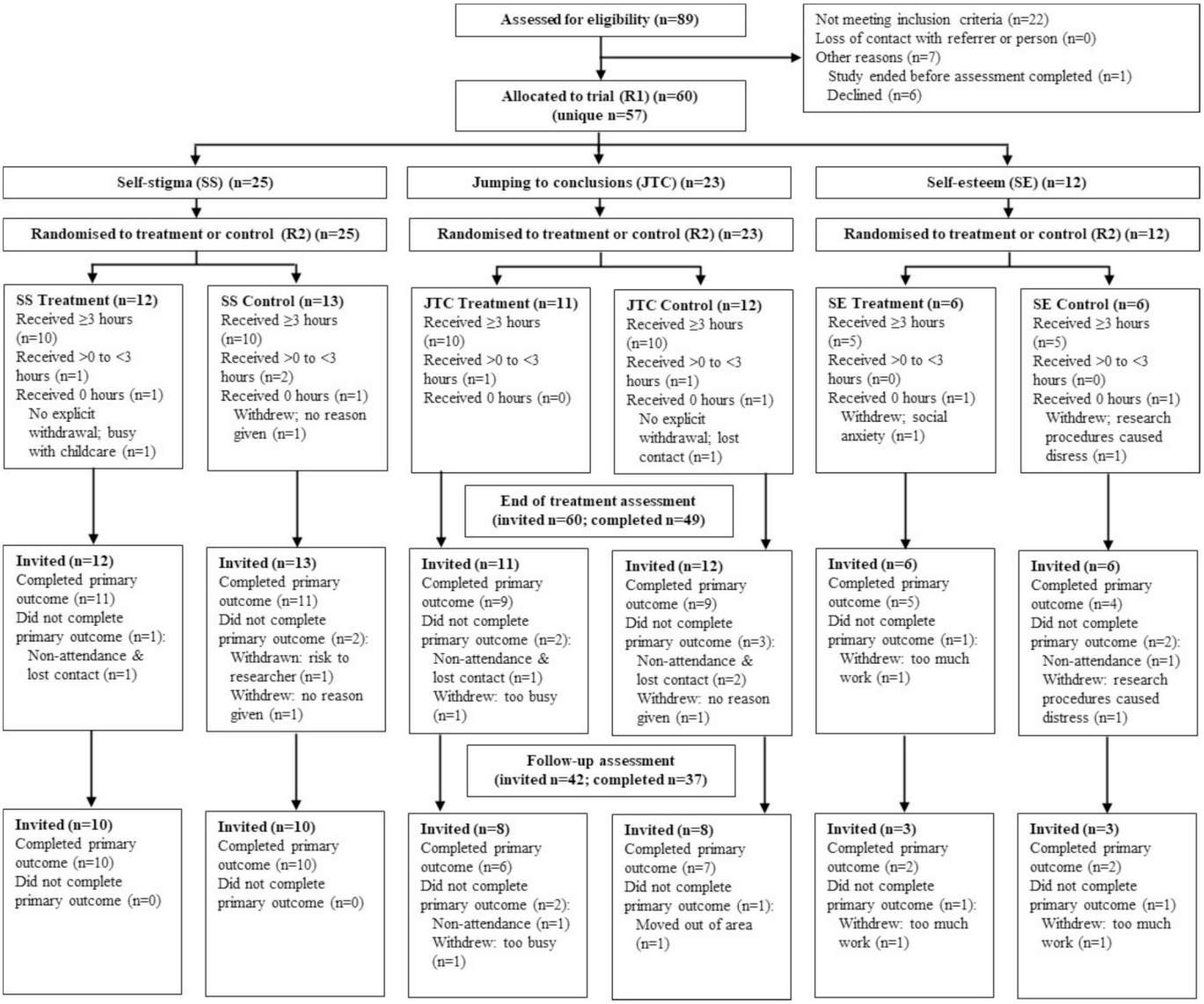

Fig. 1. CONSORT diagram (abbreviated).

2.2. Randomisation and masking

Participants who presented with only one target mechanism were allocated to the relevant trial. Participants with two or more were randomly allocated to a trial via the Sealed Envelope online service, according to random allocation sequences which were generated by Sealed Envelope and inaccessible to the research team. Once allocated to a trial, randomisation to intervention or control ('R2') was normally completed at the beginning of the participant's first meeting with their therapist [see protocol for further information; (Hutton et al., 2023)]. We did this to minimise the risk of non-ignorable missing data from participants who left the study before treatment or control began (Turner et al., 2019). All efficacy outcome assessments were completed by fully trained research assistants who were masked to R2 (allocation to treatment or control) but not R1 (allocation to trial). Concealing the results of R1 was unnecessary because no between-trial comparisons were planned. Masking was protected by various means, including assessors and therapists having separate offices, phone numbers and filing systems. Assessors continually reminded participants at the start of each post-treatment assessment not to discuss which group they were in. In the event that unmasking occurred, we planned to replace that assessor with an assessor who remained masked to allocation.

2.3. Interventions and control procedures

The interventions and control procedures ('clinical procedures') were designed to provide participants with equivalent amounts of engagement, listening, positive regard, empathy, collaboration, structure and between-session activity. Each were delivered by the same therapists, who were either clinical psychologists trained in cognitive behavioural therapy (CBT), or CBT therapists accredited by the British Association for Behavioural and Cognitive Psychotherapies. Training and supervision was provided by the CI, local site Principal Investigators (PIs) and the lead therapist in the Lothian site (CH). Sessions were recorded where feasible and a random sample was assessed for adherence and competence.

The interventions were informed by the principles and methods of cognitive therapy (Morrison and Barratt, 2010) and metacognitive training (Moritz and Woodward, 2007). They were highly manualised[2] to ensure replicability and minimise therapeutic drift. They were 6 h long, and deliverable over an 8-week period, typically with weekly 1-hour sessions.

[2] Copies of the intervention and control manuals are available upon request.

Each intervention, but not the control condition, involved collaborative goal setting around the target mechanism, a psychological formulation of the relationship between it and capacity, information on the mechanism (e.g., structured self-help material), practice of new strategies and development of a shared plan to maintain any improvements. The self-stigma intervention involved a variety of strategies to weaken stigmatising beliefs about psychosis and psychotic symptoms and build and strengthen non-stigmatising replacement beliefs (e.g. normalisation, anti-stigma data logs). The self-esteem intervention also involved information-giving, experiments and data-logs, but here their focus was on weakening self-criticism and negative-self beliefs and building self-kindness and positive self-beliefs. The JTC intervention was an extended version of a brief (1 h) intervention used in a previous trial (Turner et al., 2019), with a number of extra elements added, including goal setting, formulation, and strengthening positive beliefs about gathering additional information and considering alternative explanations before making decisions.

The control condition was also manualised, agenda-driven, 6 h long and deliverable over 8 weeks. It involved cognitive assessment of factors which may have caused or maintained the person's decision-making difficulties, structured interviews (e.g., Abbreviated Scale to assess Unawareness of Mental Disorder) (Michel et al., 2013), psychometric assessments and self-report measures (e.g., Life Events Checklist) (Gray et al., 2004). Therapists were encouraged to be warm, empathic and collaborative, and to provide participants with time to 'tell their story.' They were precluded from engaging in psychological formulation, socratic questioning, or any other strategies which are commonly used to improve a person's cognitive and/or metacognitive awareness and understanding of their difficulties. All control group participants were invited to meet with the therapist after their final research assessment to develop a psychological formulation of their impaired decision-making capacity and recommendations for supporting it, based on the information they provided during the clinical and research assessments. We tested the acceptability and safety of this overall approach in a previous case series (Murphy et al., 2017). More information on the interventions and control procedures is provided in the published protocol (Hutton et al., 2023).

All participants continued to receive their usual care, throughout the trial. In the UK this involves prescription of antipsychotic medication, either in an inpatient or outpatient setting, assessment and monitoring by medical and nursing staff, and in some cases CBT (Royal College of Psychiatrists, 2018). They were unlikely to receive psychological support focused on restoring decision-making capacity (Martin et al., 2021).

2.4. Outcomes

Our primary outcomes were (1) the number of participants recruited and (2) the number of participants who provided end-of-treatment (week 8) data on the MacArthur Competence Assessment Tool for Treatment (MacCAT-T) (Grisso and Appelbaum, 1998), which is a widely used, reliable and valid measure of treatment decision-making capacity (Larkin and Hutton, 2017; Owen et al., 2008; Wang et al., 2017) and our planned primary outcome in a future trial. The MacCAT-T assesses participants on 4 domains of treatment decision-making capacity: (i) 'understanding', scored 0–6 (3 items); (ii) 'reasoning', scored 0–8 (4 items); (iii) 'appreciation', scored 0–4 (2 items); and (iv) 'expressing a choice', scored 0–2 (1 item) (Grisso and Appelbaum, 1998), with higher scores indicating greater capacity in each domain. We made an a priori decision that a definitive trial would be feasible if we achieved our target recruitment figure ($n = 60$) over the recruitment window, and acquired end-of-treatment (8 week) MacCAT-T data from ≥75 % of those randomised (Xia et al., 2009).

Our secondary outcomes were data completion rates on the MacCAT-T at follow-up (week 24), and on a range of additional clinical measures at end-of-treatment and follow-up. These were the Positive And Negative Syndrome Scale (PANSS) (Kay et al., 1987) to assess psychotic symptom severity, the Questionnaire on the Process of Recovery (QPR) (Neil et al., 2009) to assess subjective recovery, the Schizophrenia Quality of Life scale (SQoL) (Wilkinson et al., 2000) to assess quality of life, the Client Service Receipt Inventory (CSRI) (Beecham and Knapp, 2001) to assess service use, the Beck Anxiety Inventory (BAI) (Beck et al., 1988) to assess anxiety, the Brief Core Schema Scale (BCSS) (Fowler et al., 2006) to assess negative schemata about self and others, and the Calgary Depression Scale for Schizophrenia (CDSS) (Addington et al., 1993) to assess depression. We also examined data completion rates at end-of-treatment and follow-up on our measures of self-esteem (RSES) (Rosenberg, 1965), data-gathering (Beads Task) (Huq et al., 1988) and self-stigma (Structured Interview Measure of Stigma; SIMS) (Wood et al., 2016). We also assessed feasibility of rater-masking, defined as the number of reported blind-breaks.

We planned to report group differences on outcome measures at post-treatment and follow-up, for each trial separately. We decided in advance to treat all estimates as exploratory, given the feasibility/pilot aims of the project.

We used an adapted version of a previously used protocol to measure and record serious adverse events (SAEs) (Klingberg et al., 2012), which included suicidal crisis without attempt, severe symptom exacerbation, suicide and death. Moderate adverse events (e.g., lower mood, increased anxiety) were assessed using a self-report measure. Further details are provided in the protocol (Hutton et al., 2023).

2.5. Statistical analysis

A statistical analysis plan (SAP) was prepared and published before data was analysed (Hutton et al., 2023). All outcomes are reported in line with the Consolidated Standards of Reporting Trials (CONSORT) 2010 Statement, including relevant extensions (Eldridge et al., 2016; Ioannidis et al., 2004; Montgomery et al., 2018). Analyses of group differences within each trial were performed on both the (i) 'as randomised' (intention-to-treat; ITT) population, and (ii) those randomised who also received ≥3 h of their allocated clinical procedures (per protocol; PP) population. Unstandardised and standardised effect sizes for continuous outcomes were derived from individual linear regressions, incorporating (i) group allocation and (ii) baseline values of the outcome as predictors. Standardised mean differences were calculated by dividing the unstandardised regression coefficients by the pooled SD of the baseline values. A Hedges' g adjustment was applied to account for the small sample sizes. When the total sample size for a comparison was <8, we did not conduct regression or compute effect sizes (Jenkins and Quintana-Ascencio, 2020). The relative and absolute risks of benefit or harm, together with numbers needed to treat are reported for all binary outcomes, together with 95 % CIs. Analyses of continuous outcomes were conducted on observed cases. In small samples, this approach has been shown to perform at least as well as various multiple imputation strategies in relation to type 1 error, power and bias, particularly when missing data is 20 % or less and satisfies the Missing At Random assumption (McNeish, 2017). For binary outcomes, we used the randomised N as the denonominator and assumed missing events, whether beneficial or adverse, did not occur.

2.6. Changes to protocol

All changes to the study protocol introduced between public registration on 16 March 2020 and the first R2 randomisation involved mitigation of pandemic-related health risks to participants and staff. See supplementary Tables 3 and 6. Most subsequent changes involved mitigation of the effects of the pandemic on recruitment. In particular, we extended the recruitment period in the Lothian site, increased the numbers allowed to take part in the individual trials, and allowed previous trial completers to return to take part in one of the other trials, if eligible. Preferential allocation to the self-esteem trial was introduced late in the trial, primarily to mitigate the lower than expected

prevalence of low self-esteem in this population.

3. Results

3.1. Sample

Recruitment commenced on February 22, 2020, but was then paused on March 15, 2020, due to the COVID-19 pandemic. Sponsor approval to restart was provided on December 3, 2020, and the first participant was randomised to treatment or control on January 28, 2021. Recruitment closed on October 7, 2022. Throughout the lifetime of the trial, 478 (58 %) of 828 patients passed our initial eligibility screening checks and were contacted by their clinical team (Fig. 1). Of this group, 57 (12 %) were confirmed as eligible, consented to take part, completed the baseline assessment and were randomised to treatment or control. Three participants took part in two trials, leading to 60 randomisations in total; 25 (12 treatment, 13 control), 23 (11 treatment, 12 control) and 12 (6 treatment, 6 control) participants took part in the self-stigma, JTC and self-esteem trials, respectively.

Most[3] participants were men ($n = 41$; 72 %) and most were white ($n = 53$; 93 %). Three participants, all in England, were assessed as lacking the capacity to consent to research. The average age of participants was 39.8 (SD 11.5), and 27 (47 %) were receiving inpatient care (Table 1). Most were diagnosed with schizophrenia ($n = 43$; 75 %) or schizoaffective disorder ($n = 8$; 14 %), with an average time since first diagnosis of 12.2 years (SD 9.3). Their average PANSS total score was 82.8 (n = 53; SD 18.3), indicating moderate symptom severity (Leucht et al., 2005). All were assessed by their clinical team as lacking the capacity to decide whether or not to take antipsychotic medication; oral antipsychotics in 30 (53 %) cases, and long-acting injectable 'depot' medication in 24 (42 %). Twenty-five participants (44 %) were also deemed to lack capacity to decide whether or not to receive inpatient psychiatric care. Of the 53 unique participants with a full baseline mechanism assessment, 7 (13 %) presented with all 3 target mechanisms, 24 (45 %) presented with 2 and 22 (42 %) presented with only one. Forty-one (77 %), 35 (66 %) and 15 (28 %) presented with high self-stigma, the JTC bias and/or low self-esteem, respectively.[4]

3.2. Primary outcomes

We achieved our goal of gathering post-treatment MacCAT-T data from at least 75 % of those randomised to treatment or control; 82 % (95 % CI 77 % to 87 %; $n = 49$) provided MacCAT-T data at post-treatment, and 88 % (95 % CI 83 % to 93 %; $n = 37$) provided it at follow-up (see Table 2). Measures of the targeted psychological mechanisms were completed by 80 % of participants at post-treatment (95 % CI 75 % to 85 %; $n = 48$), and 88 % at follow-up (95 % CI 83 % to 93 %; n = 37). Most of our secondary efficacy outcomes were completed by at least 75 % of participants, with the exception of the PANSS at post-treatment, which was completed by 73 % (95 % CI 68 % to 79 %; $n = 44$). Completion rates for the individual trials are provided in Table 2 (MacCAT-T and mechanisms) and supplementary file (secondary efficacy outcomes). No blind-breaks were reported, meaning no assessors needed to be replaced. Masking was maintained for all of the 86 post-treatment or follow-up assessments.

Fifty participants (83 %) rceived the predefined minimal 'dose' of at least 3 h (see Fig. 1). Self-stigma, JTC and self-esteem trial participants received an average of 5.2 (SD 2.9) (treatment 5.6, SD 3.5; control 4.7 SD 2.2), 4.5 (SD 2.0) (treatment 4.7, SD 1.8; control 4.3, SD 2.2) and 4.4 (SD 2.3) (treatment 3.8, SD 2.2; control 5.0, SD 2.4) hours of contact, respectively. Supervision, tape-rating of randomly selected recordings, and analysis of therapist reflective reports all indicated satisfactory adherence to the specific clinical protocols. Key components of therapy were delivered and disallowed components were. The self-stigma protocol appeared to be the most challenging one to implement; several participants found it difficult to relate to the self-stigma concept, since they did not believe they were ill or had a need for care. Control participants were engaged with, listened to and assessed, but no formulation was offered prior to competion of their final research assessment.

Table 3 provides ITT effect sizes for each of the interventions on the MacCAT-T subscales. The direction of effects in the self-stigma trial largely favoured the control condition, particularly at follow-up. The direction of effects in the JTC and self-esteem trials largely favoured the interventions. However, all estimates had wide confidence intervals, and many included large benefits and large harms. A similar pattern of effects emerged from the PP analysis (supplementary file).

3.3. Secondary outcomes

Table 3 also provides effect sizes for change in the target mechanisms. There was no indication that self-stigma or self-esteem was reduced in those receiving the self-stigma or self-esteem interventions, but confidence intervals were again very wide. For data-gathering in the JTC trial, the direction of effect favoured the intervention, particularly at post-treatment, but confidence intervals were also wide. The PP analysis produced a similar set of estimates (supplementary file). Estimates for all other secondary efficacy outcomes are provided in the supplementary file.

3.4. Adverse events

Three SAEs involving 3 participants (two instances of self-harm and one suicide attempt) were detected during baseline assessment, prior to randomisation. None were attributed to study procedures. However, a further SAE detected after randomisation (early withdrawal of a self-esteem control participant) was assessed as having been caused by the baseline research assessment; it appeared to have caused this person to become more distressed by their symptoms. A further 10 SAEs involving an additional 5 participants were also detected between randomisation and post-treatment assessment, but none were attributed to study procedures (see supplementary file). All 11 SAEs occurred in either the self-stigma (4 events in 3 participants) or self-esteem (7 events in 4 participants) trials. Five new SAEs were detected in 4 of the 42 participants assessed at follow-up. Each was detected by masked researchers, and each occurred between post-treatment and follow-up. None were attributed to study procedures.

Fourteen participants reported at least 1 mild-moderate adverse event at post-treatment (supplementary file). The most frequent, reported by 7 participants (3, 2 and 2 in the self-stigma, JTC and self-esteem trials, respectively), involved thinking too much about past negative events. Eight participants reported at least 1 mild to moderate adverse event at follow-up. The most frequent, reported by 5 participants, again involved thinking too much about past negative events.

Further information on adverse events, acceptability and perceived need for care are provided in the supplementary file. No significant differences between treatment and control were detected.

4. Discussion

This is the first umbrella trial to be conducted in a mental health context (Meyer et al., 2020; Wagner et al., 2024). It has produced, within a short time, the first three single-blind randomised controlled

[3] Descriptive statistics for the overall study refer to the 57 unique participants at first baseline assessment, where possible (i.e., unless there are missing data) and unless otherwise stated. Descriptive statistics at the trial level refer to the full randomised sample for that trial, where possible.

[4] We recruited an additional 4 participants with low self-esteem, bringing the total proportion with low self-esteem to 33 %, however they did not receive a full mechanism assessment, in part because only the self-esteem trial was recruiting at the point they entered the study.

Table 1
Participant characteristics: intention-to-treat sample (abbreviated).

	All (n = 57)	Self-stigma therapy plus usual care group (n = 12)	Assessment plus usual care group (n = 13)	JTC plus usual care group (n = 11)	Assessment plus usual care group (n = 12)	Self-esteem plus usual care group (n = 6)	Assessment plus usual care group (n = 6)
Age (years)	39.8 (11.5)	46.6 (11.6)	38.3 (8.4)	33.6 (9.0)	42.5 (14.6)	35.2 (10.1)	44.4 (7.5)
Gender							
Women	16 (28.1)	3 (25.0)	2 (15.4)	2 (18.2)	5 (41.7)	2 (33.3)	2 (33.3)
Men	41 (71.9)	9 (75.0)	11 (84.6)	9 (81.8)	7 (58.3)	4 (66.7)	4 (66.7)
Education (years)	14.4 (3.0)	15.5 (3.4)	13.5 (2.9)	14.2 (3.7)	14.0 (1.8)	14.8 (3.4)	13.5 (1.3)
Employment status							
Employed, paid	3 (5.3)	0	1 (7.7)	1 (9.1)	0	1 (16.7)	0
Employed, voluntary	3 (5.3)	0	0	0	3 (25.0)	0	0
Unemployed	46 (80.7)	11 (91.7)	11 (84.6)	10 (90.9)	8 (66.7)	5 (83.3)	4 (66.7)
Student	2 (3.5)	1 (8.3)	0	0	1 (8.3)	0	0
Marital status							
Single	46 (80.1)	11 (91.7)	9 (69.2)	10 (90.9)	8 (66.7)	5 (83.3)	5 (83.3)
Married or civil partnership	4 (7.0)	1 (8.3)	1 (7.7)	0	1 (8.3)	0	1 (16.7)
In a relationship	2 (3.5)	0	1 (7.7)	1 (9.1)	1 (8.3)	0	0
Divorced	2 (3.5)	0	0	0	1 (8.3)	1 (16.7)	0
Widowed	1 (1.8)	0	0	0	1 (8.3)	0	0
Other	0	0	1 (7.7)	0	0	0	0
Service type							
Outpatient	30 (52.6)	8 (66.7)	8 (61.5)	6 (54.5)	7 (58.3)	2 (33.3)	1 (16.7)
Community mental health team	28 (49.1)	8 (66.7)	8 (61.5)	6 (54.5)	5 (41.7)	2 (33.3)	1 (16.7)
Community rehabilitation team	1 (1.8)	0	0	0	1 (8.3)	0	0
Early intervention service	1 (1.8)	0	0	0	1 (8.3)	0	0
Inpatient	27 (47.4)	4 (33.3)	5 (38.5)	5 (45.5)	5 (41.7)	4 (66.7)	5 (83.3)
Acute ward	22 (38.6)	2 (16.7)	4 (30.8)	4 (36.4)	4 (33.3)	3 (50.0)	5 (83.3)
Rehabilitation ward	3 (5.3)	2 (16.7)	1 (7.7)	0	1 (8.3)	0	0
Intensive psychiatric care ward	2 (3.5)	0	0	1 (9.1)	0	1 (16.7)	0
Ethnicity							
White British	51 (89.5)	11 (91.7)	13 (100.0)	10 (90.9)	11 (91.7)	5 (83.3)	4 (66.7)
White Other	2 (3.5)	0	0	0	1 (8.3)	0	1 (16.7)
Black British	0	0	0	0	0	0	0
Black Other	2 (3.5)	0	0	1 (9.1)	0	0	1 (16.7)
Asian British	1 (1.8)	1 (8.3)	0	0	0	0	0
Asian Other	1 (1.8)	0	0	0	0	1 (16.7)	0
Chart diagnosis (ICD-11)							
Schizophrenia	43 (75.4)	9 (75.0)	11 (84.6)	8 (72.7)	10 (83.3)	4 (66.7)	4 (66.7)
Schizoaffective disorder	8 (14.0)	3 (25.0)	2 (15.4)	1 (9.1)	0	2 (33.3)	0
Delusional disorder	3 (5.3)	0	0	0	1 (8.3)	0	2 (33.3)
Schizophreniform disorder	0	0	0	0	0	0	0
Unspecified (non-affective) psychosis – non-FEP	1 (1.8)	0	0	1 (9.1)	0	0	0
Unspecified (non-affective) psychosis – FEP	2 (3.5)	0	0	1 (9.1)	1 (8.3)	0	0
Time since first diagnosis (years)	12.2 (9.3)	16.7 (10.3)	12.7 (6.5)	12.7 (10.6)	10.8 (11.3)	8.7 (9.6)	14.9 (10.2)
Duration of untreated psychosis (years)	1.6 (2.5)	1.0 (1.5)	1.9 (2.9)	0.7 (1.2)	1.5 (2.1)	3.4 (4.5)	0.7 (0.6)
Prescribed antipsychotic							
Yes, atypical, oral	29 (50.9)[a]	5 (41.7)	6 (46.2)	5 (45.5)	5 (41.7)	4 (66.7)	5 (83.3)
Yes, atypical, LAI	11 (19.3)	4 (33.3)	2 (15.4)	2 (18.2)	2 (16.7)	0	0
Yes, typical, oral	1 (1.8)	0	0	0	1 (8.3)	0	0
Yes, typical, LAI	13 (22.8)	3 (25.0)	4 (30.8)	4 (36.4)	4 (33.3)	2 (33.3)	0
No	0	0	0	0	0	0	0
Average chlorpromazine equivalents, (excluding antipsychotic-free)	439.6 (238.6)	396.4 (284.3)	524.0 (269.8)	488.5 (278.1)	385.3 (122.5)	351.5 (141.5)	390.2 (227.7)

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Table 1 (*continued*)

	All (n = 57)	Self-stigma therapy plus usual care group (n = 12)	Assessment plus usual care group (n = 13)	JTC plus usual care group (n = 11)	Assessment plus usual care group (n = 12)	Self-esteem plus usual care group (n = 6)	Assessment plus usual care group (n = 6)
Receipt of past psychological therapy							
Yes	27 (47.0)	5 (41.7)	8 (61.5)	4 (36.4)	2 (16.7)	4 (66.7)	2 (33.4)
No	27 (47.4)	4 (33.3)	4 (30.1)	6 (54.5)	10 (83.3)	2 (33.3)	2 (33.3)
Legal status							
Voluntary/informal (S&E)	20 (35.1)	4 (33.3)	6 (46.2)	4 (36.4)	2 (16.7)	4 (66.7)	2 (33.3)
Emergency treatment order (S)	0	0	0	0	0	0	0
Emergency detention certificate (S)	0	0	0	0	0	0	0
Compulsory treatment order (S)	12 (21.1)	3 (25.0)	3 (23.1)	3 (27.3)	3 (25.0)	1 (16.7)	0
Short term detention (S)	3 (5.3)	1 (8.3)	0	0	2 (16.7)	0	0
Community compulsory treatment order (S)	12 (21.1)	4 (33.3)	2 (15.4)	2 (18.2)	4 (33.3)	0	0
Guardianship (E)	0	0	0	0	0	0	0
Community treatment order (E)	1 (1.8)	0	1 (7.7)	0	0	0	0
Section 2 (E)	1 (1.8)	0	0	0	0	0	1 (16.7)
Section 3 (E)	6 (10.5)	0	0	2 (18.2)	1 (8.3)	1 (16.7)	2 (33.3)
Section 5 [2] (E)	0	0	0	0	0	0	0
Section 5 [4] (E)	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0
Offending history							
Yes, any	21 (36.8)	3 (25.0)	7 (53.8)	3 (27.3)	5 (41.7)	2 (33.3)	3 (50.0)
No	29 (50.9)	8 (66.7)	5 (38.5)	6 (54.5)	7 (58.3)	3 (50.0)	1 (16.7)
Drug misuse							
Score of ≥6 on DAST	28 (49.1)	4 (33.3)	9 (69.2)	7 (63.6)	6 (50.0)	2 (33.3)	3 (50.0)
Score of <6 on DAST	25 (43.9)	8 (66.7)	3 (23.1)	3 (27.3)	5 (41.7)	4 (66.7)	2 (33.3)
Alcohol misuse							
Score of ≥8 on AUDIT	16 (28.1)	5 (41.7)	4 (30.8)	2 (18.2)	5 (41.7)	0	1 (16.7)
Score of <8 on AUDIT	39 (68.4)	7 (58.3)	8 (61.5)	9 (81.8)	6 (50.0)	6 (100)	5 (83.3)
Lacking capacity to consent to research							
Yes	3 (5.3)	1 (8.3)	1 (7.7)	0	0	1 (16.7)	0
No	54 (94.7)	11 (91.7)	12 (92.3)	11 (100)	12 (100)	5 (83.3)	6 (100)
Type of treatment decision(s) participants lacked capacity to make							
Whether to take antipsychotic medication	57 (100)	12 (100)	13 (100)	11 (100)	12 (100)	6 (100)	6 (100)
Whether to receive psychiatric inpatient care	25 (43.9)	4 (33.3)	5 (38.5)	5 (45.5)	5 41.7)	2 (33.3)	5 (83.3)
Both	25 (43.9)	4 (33.3)	5 (38.5)	5 (45.5)	5 41.7)	2 (33.3)	5 (83.3)
MacCAT-T domain(s) with impairment							
Understanding	29 (50.9)	6 (50.0)	6 (46.2)	4 (36.4)	7 (58.3)	3 (50.0)	4 (66.7)
Reasoning	30 (52.6)	5 (41.7)	7 (53.8)	4 (36.4)	7 (58.3)	4 (66.7)	4 (66.7)
Appreciation	39 (68.4)	6 (50.0)	8 (61.5)	9 (81.8)	11 (91.7)	3 (50.0)	5 (83.3)
Communication	3 (5.3)	0	1 (7.7)	0	1 (8.3)	1 (16.7)	0
Number of MacCAT domains with impairment							
1	27 (47.4)	8 (66.7)	6 (46.2)	7 (63.6)	4 (33.3)	3 (50.0)	1 (16.7)
2	18 (31.6)	3 (25.0)	5 (38.5)	2 (18.2)	3 (25.0)	2 (33.3)	3 (50.0)
3	10 (17.5)	1 (8.3)	2 (15.4)	2 (18.2)	4 (33.3)	0	2 (33.3)
4	2 (3.5)	0	0	0	1 (8.3)	1 (16.7)	0
Low self-esteem (<15 on RSES)							

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Table 1 (*continued*)

	All (n = 57)	Self-stigma therapy plus usual care group (n = 12)	Assessment plus usual care group (n = 13)	JTC plus usual care group (n = 11)	Assessment plus usual care group (n = 12)	Self-esteem plus usual care group (n = 6)	Assessment plus usual care group (n = 6)
Yes	19 (33.3)	3 (25.0)	1 (7.7)	1 (9.1)	2 (16.7)	6 (100.0)	6 (100.0)
No	38 (66.7)	9 (75.0)	12 (92.3)	10 (90.9)	10 (83.3)	0	0
High self-stigma (>59 on ISMI)							
Yes	45 (78.9)	12 (100.0)	13 (100.0)	7 (63.6)	6 (50.0)	6 (100.0)	4 (66.7)
No	11 (19.3)	0	0	4 (36.4)	6 (50.0)	0	1 (16.7)
ISMI total							
Baseline	67.12 (12.87)	73.15 (10.52)	72.08 (5.96)	56.56 (12.93)	65.53 (12.89)	73.31 (5.90)	64.40 (19.73)
JTC bias (≤2 beads)							
Yes	34 (59.6)	5 (41.7)	5 (38.5)	11 (100.0)	12 (100.0)	2 (33.3)	2 (33.3)
No	19 (33.3)	7 (58.3)	8 (61.5)	0	0	2 (33.3)	2 (33.3)
Clinician-rated incapacity severity							
Not at all impaired	2 (3.5)	0	0	1 (9.1)	0	0	1 (16.7)
Borderline impaired	3 (5.3)	1 (8.3)	1 (7.7)	0	0	0	1 (16.7)
Mildly impaired	16 (28.1)	3 (25.0)	5 (38.5)	4 (36.4)	1 (8.3)	3 (50.0)	1 (16.7)
Moderately impaired	21 (36.8)	6 (50.0)	4 (30.8)	3 (27.3)	5 (41.7)	1 (16.7)	3 (50.0)
Markedly impaired	9 (15.8)	2 (16.7)	1 (7.7)	2 (18.2)	5 (41.7)	0	0
Severely impaired	3 (5.3)	0	1 (7.7)	1 (9.1)	0	1 (16.7)	0
Amongst the most extremely impaired patients	0	0	0	0	0	0	0
PANSS-rated symptom severity							
Minimal or absent illness	1 (1.8)	0	0	1 (9.1)	0	0	0
Mildly ill	21 (36.8)	6 (50.0)	8 (61.5)	1 (9.1)	6 (50.0)	0	1 (16.7)
Moderately ill	19 (33.3)	6 (50.0)	3 (23.1)	6 (54.5)	3 (25.0)	2 (33.3)	1 (16.7)
Markedly ill	8 (14.0)	0	0	3 (27.3)	1 (8.3)	2 (33.3)	2 (33.3)
Severely ill	4 (7.0)	0	1 (7.7)	0	1 (8.3)	1 (16.7)	1 (16.7)
BNA-rated cognitive impairment (z-score category)[b]							
At least moderate impairment ($z \leq -0.5$)	17 (29.8)	6 (50.0)	3 (23.1)	2 (18.2)	3 (25.0)	3 (50.0)	–
Less than moderate impairment ($z \geq -0.5$)	13 (22.8)	2 (16.7)	5 (38.5)	3 (27.3)	5 (41.7)	0	–

Note: Data are mean (SD) or n (%). Percentages might not sum to 100 % due to rounding.

[a] 15 of these participants were being prescribed clozapine.

[b] BNA data was missing for 12 participants in the English sites due to incorrect administration of the digit-symbol task and can therefore be considered missing completely at random (MCAR). MCAR missing data increases imprecision (i.e., due to reduced statistical power), but is otherwise ignorable. The denominator n for each group excluding this MCAR data is as follows; all $n = 45$; self-stigma treatment n = 11; self-stigma control n = 11; JTC treatment n = 8; JTC control $n = 10$; self-esteem treatment n = 5; self-esteem control $n = 3$.

trials of interventions designed to improve the treatment decision-making capacity of people diagnosed with schizophrenia-spectrum disorders. Wider adoption of the umbrella paradigm could greatly shorten the time and cost involved in developing more effective interventions for a range of different mental health conditions.

Our screening and referral to randomisation rates were 7 % and 62 %, respectively, and we successfully gathered post-treatment MacCAT-T data from 82 % of people who took part, surpassing our target of 75 % (Xia et al., 2009). On these metrics, our trial performed well in comparison to conventional trials of complex interventions for psychosis (Szymczynska et al., 2017). Our sample appeared to be representative of our target population. Participants were moderately unwell on average, had lower MacCAT-T understanding, reasoning and appreciation compared to clinical samples involving a mixture of patients with and without capacity, (Grisso et al., 1997; Palmer et al., 2002) and had similar MacCAT-T scores to those receiving involuntary inpatient care (Mandarelli et al., 2018).

Although we needed more time and resource to achieve our randomisation target than originally planned, this was necessary to address the effects of the COVID-19 pandemic, when inpatient wards were closed for long periods, and face-to-face contact with potential participants was often prohibited. Extensive COVID-19 risk assessment and management procedures needed to be designed and implemented before the trial was allowed to restart. Although demonstrating feasibility in this adverse context provides some reassurance about implementation in less difficult circumstances, it is important to carefully consider the impact of this 'history effect'. Mara and Peugh (2020) provide a full discussion of this in the context of randomised behavioural clinical trials (Mara and Peugh, 2020).

There were no reported blind-breaks, meaning no assessors needed to be replaced. We think this is partly because both treatment and control involved equivalent therapist contact (i.e., unlike in trials involving a usual care control condition, participants could mention their therapist's name to their assessor without fear of breaking the blind), and partly because the pandemic minimised interactions between therapists and assessors.

At first glance, the direction of post-treatment effect sizes on the MacCAT-T appears to favour the interventions for JTC and self-esteem,

Table 2
Means, standard deviations and data completion rates for primary efficacy outcomes and mechanisms at baseline, post-treatment and follow-up: intention-to-treat sample.

	Self-stigma trial				JTC trial				Self-esteem trial			
	Therapy plus usual care (n = 12; 10 at FU)		Assessment plus usual care (n = 13; 10 at FU)		Therapy plus usual care (n = 11; 8 at FU)		Assessment plus usual care (n = 12; 8 at FU)		Therapy plus usual care (n = 6; 3 at FU)		Assessment plus usual care (n = 6; 3 at FU)	
	Mean (SD) or N (%)	95 % CI for mean or %	Mean (SD) or N (%)	95 % CI for mean or %	Mean (SD) or N (%)	95 % CI for mean or %	Mean (SD) or N (%)	95 % CI for mean or %	Mean (SD) or N (%)	95 % CI for mean or %	Mean (SD) or N (%)	95 % CI for mean or %
MacCAT-T Understanding (0–6)												
Baseline	3.68 (1.18)	2.93, 4.43	3.38 (1.01)	2.77, 3.99	3.26 (1.49)	2.26, 4.26	2.68 (1.52)	1.71, 3.65	3.24 (1.30)	1.88, 4.60	2.72 (0.84)	1.84, 3.60
Data completion	12 (100)	–	13 (100)	–	11 (100)	–	12 (100)	–	6 (100)	–	6 (100)	–
8 weeks	3.80 (0.88)	3.21, 4.39	3.44 (0.44)	3.14, 3.74	3.76 (0.99)	3.00, 4.52	2.93 (1.16)	2.04, 3.82	3.94 (0.92)	2.80, 5.08	2.53 (1.11)	0.76, 4.30
Data completion	11 (91.7)	83.8, 99.5	11 (84.6)	74.8, 94.4	9 (81.8)	70.4, 93.2	9 (75.0)	62.8, 87.3	5 (83.3)	68.4, 98.2	4 (66.7)	47.8, 85.5
24 weeks	4.22 (0.83)	3.63, 4.81	4.65 (0.83)	4.06, 5.24	3.85 (1.15)	2.64, 5.07	3.36 (1.40)	2.07, 4.65	4.28 (1.45)	0.00, 6.00[a]	2.58 (1.66)	0.00, 6.00[a]
Data completion	10 (100)	–	10 (100)	–	6 (75.0)	60.0, 90.0	7 (87.5)	76.0, 99.0	2 (66.7)	40.0, 93.3	2 (66.7)	40.0, 93.3
MacCAT-T Reasoning (0–8)												
Baseline	4.17 (1.75)	3.06, 5.28	4.46 (2.40)	3.01, 5.91	4.18 (1.47)	3.19, 5.17	3.33 (1.83)	2.67, 4.99	3.33 (2.07)	1.16, 5.50	3.83 (1.72)	2.02, 5.64
Data completion	12 (100)	–	13 (100)	–	11 (100)	–	12 (100)	–	6 (100)	–	6 (100)	–
8 weeks	4.36 (1.96)	3.04, 4.68	4.73 (1.79)	3.53. 5.93	4.89 (1.90)	3.83, 6.35	3.11 (2.03)	1.55, 4.67	3.80 (1.64)	1.76, 5.84	2.00 (2.16)	0.00[c], 5.44
Data completion	11 (90.9)	83.3, 99.5	11 (84.6)	74.8, 94.4	9 (81.8)	70.4, 93.2	9 (75.0)	62.8, 87.3	5 (83.3)	68.4, 98.2	4 (66.7)	47.8, 85.5
24 weeks	4.90 (0.74)	4.37, 5.43	5.90 (1.79)	4.62, 7.18	6.00 (1.26)	4.68, 7.32	4.86 (2.19)	2.83, 6.89	6.50 (2.12)	0.00, 8.00[a]	3.00 (2.83)	0.00, 8.00[a]
Data completion	10 (100)	–	10 (100)	–	6 (75.0)	60.0, 90.0	7 (87.5)	76.0, 99.0	2 (66.7)	40.0, 93.3	2 (66.7)	40.0, 93.3
MacCAT-T Appreciation (0–4)												
Baseline	2.58 (1.00)	1.94, 3.22	2.46 (1.13)	1.78, 3.14	1.81 (1.08)	1.08, 2.54	1.00 (0.74)	0.53, 1.47	2.50 (1.38)	1.05, 3.95	1.83 (0.98)	0.80, 2.86
Data completion	12 (100)	–	13 (100)	–	11 (100)	–	12 (100)	–	6 (100)	–	6 (100)	–
8 weeks	2.45 (1.37)	1.53 3.37	3.00 (1.00)	2.33, 3.67	2.56 (1.01)	1.78, 3.34	1.11 (1.05)	0.30, 1.92	2.40 (0.89)	1.29, 3.51	1.50 (1.91)	0.00, 4.00[a]
Data completion	11 (90.9)	83.3, 99.5	11 (84.6)	74.8, 94.4	9 (81.8)	70.4, 93.2	9 (75.0)	62.8, 87.3	5 (83.3)	68.4, 98.2	4 (66.7)	47.8, 85.5
24 weeks	2.40 (0.70)	1.90, 2.90	2.90 (0.88)	2.27, 3.53	2.33 (1.03)	1.25, 3.41	1.43 (1.27)	0.26, 2.60	2.50 (2.12)	0.00, 4.00[a]	2.50 (2.12)	0.00, 4.00[a]
Data completion	10 (100)	–	10 (100)	–	6 (75.0)	60.0, 90.0	7 (87.5)	76.0, 99.0	2 (66.7)	40.0, 93.3	2 (66.7)	40.0, 93.3
MacCAT-T Communication (0–2)												
Baseline	1.75 (0.45)	1.46, 2.00[b]	1.77 (0.44)	1.50, 2.00[b]	1.64 (0.50)	1.30, 1.98	1.75 (0.45)	1.46, 2.00[b]	1.50 (0.55)	0.92, 2.00[b]	2.00 (0.00)	–
Data completion	12 (100)	–	13 (100)	–	11 (100)	–	12 (100)	–	6 (100)	–	6 (100)	–
8 weeks	1.55 (0.69)	1.09, 2.00[b]	1.55 (0.69)	1.09, 2.00[b]	1.56 (0.53)	1.15, 1.97	1.67 (0.50)	1.29, 2.00[b]	1.80 (0.45)	1.24, 2.00[b]	2.00 (0.00)	–
Data completion	11 (90.9)	83.3, 99.5	11 (84.6)	74.8, 94.4	9 (81.8)	70.4, 93.2	9 (75.0)	62.8, 87.3	5 (83.3)	68.4, 98.2	4 (66.7)	47.8, 85.5
24 weeks	1.90 (0.32)	1.67, 2.00[b]	1.80 (0.42)	1.50, 2.00[b]	1.83 (0.41)	1.40, 2.00[b]	1.71 (0.49)	1.26, 2.00	2.00 (0.00)	–	2.00 (0.00)	–
Data completion	10 (100)	–	10 (100)	–	6 (75.0)	60.0, 90.0	7 (87.5)	76.0, 99.0	2 (66.7)	40.0, 93.3	2 (66.7)	40.0, 93.3
MacCAT-T Total (0−20)												
Baseline	12.18 (1.96)	10.93, 13.43	12.08 (3.37)	10.04, 14.12	10.90 (3.19)	8.76, 13.04	8.77 (3.47)	6.57, 10.97	10.58 (3.68)	6.72, 14.44	10.38 (1.93)	8.35, 12.41
Data completion	12 (100)	–	13 (100)	–	11 (100)	–	12 (100)	–	6 (100)	–	6 (100)	–
8 weeks	12.16 (3.98)	9.49, 14.83	12.71 (3.00)	10.69, 14.73	12.76 (3.34)	10.19, 15.33	8.82 (2.90)	6.59, 11.05	11.94 (1.00)	10.70, 13.80	8.02 (4.32)	1.15, 14.89
Data completion	11 (90.9)	83.3, 99.5	11 (84.6)	74.8, 94.4	9 (81.8)	70.4, 93.2	9 (75.0)	62.8, 87.3	5 (83.3)	68.4, 98.2	4 (66.7)	47.8, 85.5
24 weeks	13.42 (1.56)	12.30, 14.54	15.25 (2.79)	13.25, 17.25	14.02 (2.98)	10.89, 17.15	11.36 (3.74)	7.90, 14.82	15.28 (5.69)	0.00, 20.00[a]	10.08 (6.61)	0.00, 20.00[a]
Data completion	10 (100)	–	10 (100)	–	6 (75.0)	60.0, 90.0	7 (87.5)	76.0, 99.0	2 (66.7)	40.0, 93.3	2 (66.7)	40.0, 93.3

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Table 2 (*continued*)

	Self-stigma trial				JTC trial				Self-esteem trial			
	Therapy plus usual care (n = 12; 10 at FU)		Assessment plus usual care (n = 13; 10 at FU)		Therapy plus usual care (n = 11; 8 at FU)		Assessment plus usual care (n = 12; 8 at FU)		Therapy plus usual care (n = 6; 3 at FU)		Assessment plus usual care (n = 6; 3 at FU)	
	Mean (SD) or N (%)	95 % CI for mean or %	Mean (SD) or N (%)	95 % CI for mean or %	Mean (SD) or N (%)	95 % CI for mean or %	Mean (SD) or N (%)	95 % CI for mean or %	Mean (SD) or N (%)	95 % CI for mean or %	Mean (SD) or N (%)	95 % CI for mean or %
Draws to decision (beads task) (1+)												
Baseline	5.25 (5.45)	1.79, 8.71	3.46 (2.60)	1.89, 5.03	1.18 (0.40)	1.00[c], 1.45	1.17 (0.39)	1.00[c], 1.42	2.50 (0.58)	1.58, 3.42	2.00 (1.15)	1.00[c], 3.83
Data completion	12 (100)	–	13 (100)	–	11 (100)	–	12 (100)	–	4 (66.7)	47.8, 85.5	4 (66.7)	47.8, 85.5
8 weeks	–	–	–	–	1.56 (1.33)	1.00[c], 2.58	1.11 (0.33)	1.00[c], 1.36	–	–	–	–
Data completion	–	–	–	–	9 (82)	70.4, 93.2	9 (75)	62.8, 87.3	–	–	–	–
24 weeks	–	–	–	–	2.17 (1.60)	1.00[c], 3.85	1.71 (0.76)	1.01, 2.41	–	–	–	–
Data completion	–	–	–	–	6 (75)	60.0, 90.0	7 (88)	76.0, 99.0	–	–	–	–
N (%) extreme responders (≤2 beads on beads task)												
Baseline	5 (41.7)	27.7, 55.6	5 (38.5)	25.2, 51.7	11 (100)	–	12 (100)	–	2 (33.3)	14.5, 52.2	2 (33.3)	14.5, 52.2
Data completion	12 (100)	–	13 (100)	–	11 (100)	–	12 (100)	–	4 (66.7)	47.8, 85.5	4 (66.7)	47.8, 85.5
8 weeks	–	–	–	–	8 (73)	59.6, 85.9	9 (75)	62.8, 87.3	–	–	–	–
Data completion	–	–	–	–	9 (82)	70.4, 93.2	9 (75)	62.8, 87.3	–	–	–	–
24 weeks	–	–	–	–	4 (50)	32.7, 67.3	6 (75)	60.0, 90.0	–	–	–	–
Data completion	–	–	–	–	6 (75)	60.0, 90.0	7 (88)	76.0, 99.0	–	–	–	–
SIMS total (0–40)												
Baseline	20.03 (6.1)	16.15, 23.91	18.56 (6.12)	14.67, 22.45	15.10 (7.61)	9.66, 20.54	10.00 (7.55)	4.93, 15.07	8.05 (7.01)	0.00[c], 16.75	18.50 (2.08)	15.19, 21.81
Data completion	12 (100)	–	12 (92.3)	85.1, 99.6	10 (90.9)	82.4, 99.4	11 (91.7)	83.8, 99.5	5 (83.3)	68.4, 98.2	4 (66.7)	47.8, 85.5
8 weeks	15.33 (8.31)	9.39, 21.27	12.27 (7.47)	7.25, 17.29	–	–	–	–	–	–	–	–
Data completion	10 (83.3)	72.7, 93.9	11 (84.6)	74.8, 94.4	–	–	–	–	–	–	–	–
24 weeks	14.50 (6.35)	9.96, 19.04	12.30 (7.20)	7.15, 17.45	–	–	–	–	–	–	–	–
Data completion	10 (100)	–	10 (100)	–	–	–	–	–	–	–	–	–
RSES total (0–30)												
Baseline	17.19 (6.44)	13.10, 21.28	16.92 (2.47)	15.43, 18.41	17.73 (5.57)	13.99, 21.47	19.50 (6.57)	15.33, 23.67	8.50 (4.97)	3.28, 13.72	9.17 (4.92)	4.01, 14.33
Data completion	12 (100)	–	13 (100)	–	11 (100)	–	12 (100)	–	6 (100)	–	6 (100)	–
8 weeks	–	–	–	–	–	–	–	–	12.00 (9.82)	0.00[c], 24.19	14.25 (2.63)	10.07, 18.43
Data completion	–	–	–	–	–	–	–	–	5 (83.3)	68.4, 98.2	4 (66.7)	47.8, 85.5
24 weeks	–	–	–	–	–	–	–	–	9.50 (13.44)	0.00, 30.00[a]	16.50 (6.36)	0.00, 30.00[a]
Data completion	–	–	–	–	–	–	–	–	2 (66.7)	40.0, 93.3	2 (66.7)	40.0, 93.3

Note: Where confidence intervals exceeded the minimum and/or maximum possible score for the measure, the minimum and/or maximum possible score has been provided instead.

[a] Confidence intervals exceeded minimum and maximum possible scores.

[b] Confidence interval exceeded maximum possible score.

[c] Confidence interval exceeded minimum possible score.

but not self-stigma. Although effect sizes derived from small trials are likely to be too prone to sampling error to be informative (Leon et al., 2011), we also note the size and direction of effects favouring the JTC intervention were very similar to those we observed in a previous open trial (Turner et al., 2019). Between randomisation and post-treatment, we recorded 11 serious adverse events (SAEs) involving 10 % (6/60) of participants. Overall, SAEs do not appear to have occurred more frequently in our study, when compared to conventional trials using a similar SAE protocol [e.g., (Morrison et al., 2018)].

4.1. Limitations & recommendations

Most (93 %) of our participants were white. Although this is broadly representative of the Scottish population (National Records of Scotland,

Table 3
Between-group effect sizes for primary efficacy outcomes and mechanisms at post-treatment and follow-up: intention-to-treat sample.

	Self-stigma intervention plus usual care vs. assessment plus usual care	JTC intervention plus usual care vs. assessment plus usual care	Self-esteem intervention plus usual care vs. assessment plus usual care
MacCAT-T Understanding, 8 weeks			
N analysed (N missing)	11 (1) vs. 11 (2)	9 (2) vs 9 (3)	5 (1) vs 4 (2)
Unstandardised difference in means (95 % CI)	0.36 (−0.27, 0.98)	0.62 (−0.53, 1.78)	0.70 (−0.53, 1.92)
Hedges' g (95 % CI)	0.35 (−0.51, 1.22)	0.41 (−0.55, 1.38)	0.74 (−0.73, 2.21)
MacCAT-T Understanding, 24 weeks			
N analysed (N missing)	10 (0) vs. (10 (0)	6 (2) vs. 7 (1)	2 (1) vs. 2 (1)
Unstandardised difference in means (95 % CI)	−0.44 (−1.20, 0.32)	0.26 (−1.58, 2.10)	Not estimable (N < 8)
Hedges' g (95 % CI)	−0.42 (−1.33, 0.49)	0.18 (−0.96, 1.32)	Not estimable (*N* < 8)
MacCAT-T Reasoning, 8 weeks			
N analysed (N missing)	11 (1) vs. 11 (2)	9 (2) vs 9 (3)	5 (1) vs 4 (2)
Unstandardised difference in means (95 % CI)	−0.41 (−2.17, 1.35)	1.44 (−0.67, 3.55)	1.90 (−0.24, 4.04)
Hedges' g (95 % CI)	−0.20 (−1.05, 0.66)	0.79 (−0.20, 1.79)	0.79 (−0.69, 2.27)
MacCAT-T Reasoning, 24 weeks			
N analysed (N missing)	10 (0) vs. 10 (0)	6 (2) vs. 7 (1)	2 (1) vs. 2 (1)
Unstandardised difference in means (95 % CI)	−0.74 (−1.98, 0.50)	0.84 (−1.56, 3.24)	Not estimable (N < 8)
Hedges' g (95 % CI)	−0.40 (−1.31, 0.51)	0.54 (−0.62, 1.70)	Not estimable (*N* < 8)
MacCAT-T Appreciation, 8 weeks			
N analysed (N missing)	11 (1) vs. 11 (2)	9 (2) vs 9 (3)	5 (1) vs 4 (2)
Unstandardised difference in means (95 % CI)	−0.39 (−1.38, 0.59)	1.66 (0.47, 2.84)	1.08 (−1.44, 3.60)
Hedges' g (95 % CI)	−0.39 (−1.25, 0.48)	1.76 (0.62, 2.90)	0.57 (−0.87, 2.02)
MacCAT-T Appreciation, 24 weeks			
N analysed (N missing)	10 (0) vs. 10 (0)	6 (2) vs. 7 (1)	2 (1) vs. 2 (1)
Unstandardised difference in means (95 % CI)	−0.52 (−1.29, 0.25)	1.00 (−0.93, 2.93)	Not estimable (N < 8)
Hedges' g (95 % CI)	−0.47 (−1.38, 0.44)	1.01 (−0.21, 2.23)	Not estimable (*N* < 8)
MacCAT-T Communication, 8 weeks			
N analysed (N missing)	11 (1) vs. 11 (2)	9 (2) vs 9 (3)	5 (1) vs 4 (2)
Unstandardised difference in means (95 % CI)	0.00 (−0.63, 0.63)	−0.11 (−0.64, 0.42)	0.00 (−0.54, 0.54)
Hedges' g (95 % CI)	0.00 (−0.86, 0.86)	−0.21 (−1.17, 0.74)	0.00 (−1.41, 1.41)
MacCAT-T Communication, 24 weeks			
N analysed (N missing)	10 (0) vs. 10 (0)	6 (2) vs. 7 (1)	2 (1) vs. 2 (1)
Unstandardised difference in means (95 % CI)	0.10 (−0.26, 0.46)	0.15 (−0.44, 0.75)	Not estimable (N < 8)
Hedges' g (95 % CI)	0.20 (−0.70, 1.10)	0.32 (−0.83, 1.46)	Not estimable (N < 8)
MacCAT-T Total, 8 weeks			
N analysed (N missing)	11 (1) vs. 11 (2)	9 (2) vs. 9 (3)	5 (1) vs. 4 (2)
Unstandardised difference in means (95 % CI)	−0.04 (−3.24, 3.16)	3.46 (−0.11, 7.03)	3.62 (−1.30, 8.53)
Hedges' g (95 % CI)	−0.02 (−0.87, 0.84)	1.00 (−0.02, 2.01)	1.23 (−0.34, 2.80)
MacCAT-T Total, 24 weeks			
N analysed (N missing)	10 (0) vs. 10 (0)	6 (2) vs 7 (1)	2 (1) vs. 2 (1)
Unstandardised difference in means (95 % CI)	−1.53 (−3.71, 0.66)	1.77 (−3.45, 6.99)	Not estimable (N < 8)
Hedges' g (95 % CI)	−0.70 (−1.63, 0.23)	0.63 (−0.55, 1.80)	Not estimable (N < 8)
Draws to decision (beads task), 8 weeks			
N analysed (N missing)	–	9 (2) vs. 9 (3)	–
Unstandardised difference in means (95 % CI)	–	0.44 (−0.29, 1.18)	–
Hedges' g (95 % CI)	–	0.96 (−0.05, 1.97)	–
Draws to decision (beads task), 24 weeks			–
N analysed (N missing)	–	6 (2) vs. 7 (1)	–
Unstandardised difference in means (95 % CI)	–	0.43 (−1.13, 1.99)	–
Hedges' g (95 % CI)	–	0.80 (−0.39, 1.99)	–
Extreme responders (beads task), 8 weeks			
N analysed (N imputed)		11 (2) vs. 12 (3)	
Relative risk of event (95 % CI)	–	0.97 (0.60, 1.58)	–
Absolute risk of event (95 % CI)	–	−0.02 (−0.38, 0.34)	–
NNT for benefit (B) or harm (H) (95 % CI)	–	50B (3B, 3H)	–
Extreme responders (beads task), 24 weeks			
N analysed (N imputed)		8 (2) vs. 8 (1)	
Relative risk of event (95 % CI)	–	0.67 (0.30, 1.48)	–
Absolute risk of event (95 % CI)	–	−0.25 (−0.71, 0.21)	–

(*continued on next page*)

Table 3 (*continued*)

	Self-stigma intervention plus usual care vs. assessment plus usual care	JTC intervention plus usual care vs. assessment plus usual care	Self-esteem intervention plus usual care vs. assessment plus usual care
NNT for benefit (B) or harm (H) (95 % CI)	–	4B (1B, 5H)	–
SIMS total, 8 weeks			
N analysed (N missing)	10 (2) vs 11 (2)	–	–
Unstandardised difference in means (95 % CI)	0.64 (−5.75, 7.03)	–	–
Hedges' g (95 % CI)	0.10 (−0.78, 0.98)	–	
SIMS total, 24 weeks			
N analysed (N missing)	10 (0) vs 10 (0)	–	–
Unstandardised difference in means (95 % CI)	−0.05 (−5.58, 5.48)	–	–
Hedges' g (95 % CI)	−0.01 (−0.91, 0.89)	–	–
RSES total, 8 weeks			
N analysed (N missing)	–	–	5 (1) vs. 4 (2)
Unstandardised difference in means (95 % CI)	–	–	−0.69 (−10.60, 9.21)
Hedges' g (95 % CI)	–	–	−0.11 (−1.52, 1.30)
RSES total, 24 weeks			
N analysed (N missing)	–	–	2 (1) vs. 2 (1)
Unstandardised difference in means (95 % CI)	–	–	Not estimable (N < 8)
Hedges' g (95 % CI)	–	–	Not estimable (N < 8)

2024), a number of urban centres in the UK have greater ethnic diversity. A definitive trial may require adaptations to ensure it produces culturally generalisable findings (Waheed et al., 2015).

A number of studies have used total MacCAT-T scores as an indicator of overall capacity (Killey et al., 2022; Kolva et al., 2014; Naughton et al., 2012; Velázquez-Navarrete and Gutiérrez-Rojas, 2019; Vrouenraets et al., 2021). We also chose to report this data, primarily because measuring capacity as a single continuous variable preserves statistical power (Altman and Royston, 2006). However there are several problems with this approach. Firstly, the MacCAT-T assesses four key overlapping but distinct components of decision-making, and impairment on only one of these can be sufficient for a judgement of incapacity. For this reason, the developers of the MacCAT-T discourage calculation of a total score (Grisso et al., 1997). Secondly, summing the individual component scores to create a total score causes some (e.g., reasoning; scored 0–8) to erroneously have greater weight than others (e.g., communication; scored 0–2). Thirdly, capacity is conceptualised as a dichotomous variable in clinical practice and law. Although categories and continua are not necessarily mutually exclusive, it is important that trials produce data which can be directly translated to practice. All of this has important implications for the choice of primary outcome in a future trial and, in turn, its design. One option is to use a binary determination of capacity, informed by the MacCAT-T as well as clinical interview and case-note review (Owen et al., 2008). Although this might provide a simple and direct estimate of efficacy, a significantly larger sample size would be required to maintain statistical power to detect group differences (Altman and Royston, 2006). Conceptually, dichotomising naturally continuous variables ignores and obscures the similarity which exists between individuals close to but on opposite sides of the borderline (Altman and Royston, 2006).

We included both inpatients and outpatients in our study. Although inpatients might be expected to demonstrate larger changes in mental state over the timeframe of the study, exploratory subgroup analyses of pilot studies such as ours are not recommended (Eldridge et al., 2016). A future definitive trial should consider selecting this or other potentially moderating variables for further examination, via pre-planned subgroup or moderator analyses.

'Adaptivity' is an important feature of umbrella and other platform trials. It refers to the ability of a trial to alter aspects of its design as new information arises (e.g., relating to safety, efficacy, feasibility) (Pallmann et al., 2018). Normally this involves the adding or dropping of arms or trials, but can include other design elements, such as trial allocation ratio (Pallmann et al., 2018). Although we plan to introduce adaptivity into a future trial, we decided against this for the pilot phase, partly because we were not testing efficacy, and partly because funding models for pilot studies are largely geared towards supporting conventional trials, not open-ended adaptive ones. However, an adaptive trial allocation algorithm could have allowed us to respond much more quickly to the emerging evidence that fewer patients had low self-esteem than we expected. More generally, there is likely to be significant value in demonstrating the feasibility and potential benefits of adaptive procedures, prior to implementing them in a definitive trial.

Our interventions were designed to be brief, partly to increase their chances of implementation within busy services, should they prove effective, and partly because we eventually plan to combine the effective ones into a longer, modularised intervention. However, studies focused on identifying the required duration and intensity of supported decision-making interventions for this group are recommended.

4.2. Implications

Overall, our study has three key implications. First, it demonstrates that a significant proportion of patients with psychosis and impaired capacity are willing and able to collaborate with professionals to try to regain their capacity and/or understand what factors help or hinder it. This represents an important advance, not least because of evidence suggesting psychiatrists are less likely to use shared treatment decision-making with people with psychosis who lack capacity (Hamann et al., 2009). DEC:IDES suggests that providing them with supported treatment decision-making may be a feasible alternative. Second, it shows that ambitious new methodologies, implemented across multiple sites, can be used to accelerate the development of new interventions in psychiatry and mental healthcare. Third, it suggests an adequately powered version of DEC:IDES is now required to investigate efficacy.

CRediT authorship contribution statement

Paul Hutton: Resources, Investigation, Validation, Methodology, Formal analysis, Conceptualization, Writing – original draft, Supervision, Project administration, Data curation, Writing – review & editing, Funding acquisition. **Christopher D.J. Taylor:** Resources, Investigation, Conceptualization, Data curation, Supervision, Project administration, Funding acquisition, Writing – review & editing, Methodology. **James Kelly:** Supervision, Investigation, Conceptualization, Writing – review & editing, Funding acquisition, Project administration, Resources, Methodology, Data curation. **Richard Emsley:** Methodology, Writing – review & editing, Funding acquisition, Conceptualization. **Anvita Vikram:** Resources, Writing – review & editing, Project administration, Investigation, Methodology. **Candy Ho Alexander:** Resources, Investigation, Supervision, Project administration, Writing – review & editing, Methodology. **Andrea McCann:** Methodology, Project administration, Resources, Investigation, Writing – review & editing. **David Saddington:** Writing – review & editing, Project administration, Resources, Investigation, Supervision, Methodology. **Emma Eliasson:** Resources, Investigation, Project administration, Writing – review &

editing, Methodology. **Joseph Burke:** Project administration, Investigation, Writing – review & editing, Methodology, Resources. **Sean Harper:** Resources, Supervision, Project administration, Investigation, Methodology, Funding acquisition, Writing – review & editing, Conceptualization. **Thanos Karatzias:** Resources, Investigation, Conceptualization, Methodology, Writing – review & editing, Funding acquisition. **Peter J. Taylor:** Writing – review & editing, Investigation, Conceptualization, Methodology, Formal analysis, Funding acquisition. **Andrew Watson:** Investigation, Writing – review & editing, Funding acquisition, Resources, Conceptualization, Methodology. **Nadine Dougall:** Writing – review & editing, Investigation, Conceptualization, Funding acquisition, Formal analysis, Methodology. **Jill Stavert:** Investigation, Methodology, Conceptualization, Writing – review & editing, Funding acquisition. **Suzanne O'Rourke:** Funding acquisition, Writing – review & editing, Methodology, Conceptualization, Investigation. **Angela Glasgow:** Methodology, Writing – review & editing, Project administration, Investigation. **Regina Murphy:** Writing – review & editing, Methodology, Project administration, Investigation. **Karen Palmer:** Resources, Methodology, Supervision, Project administration, Writing – review & editing, Investigation. **Nosheen Zaidi:** Project administration, Resources, Writing – review & editing, Methodology. **Polly Bidwell:** Writing – review & editing, Investigation, Project administration, Resources, Methodology. **Jemma Pritchard:** Writing – review & editing, Investigation, Methodology, Project administration. **Lucy Carr:** Project administration, Methodology, Writing – review & editing, Investigation. **Amanda Woodrow:** Project administration, Investigation, Writing – review & editing, Resources, Data curation, Software, Methodology, Supervision, Conceptualization.

Consent for publication

Not applicable.

Ethics approval and consent to participate

The trial received a favourable ethical opinion from the NHS Scotland A Research Ethics Committee (REC reference: 19/SS/0069) and Wales Research Ethics Committee 5 (REC reference: 19/WA/0155). Informed written or audio-recorded consent was obtained from all research participants with capacity to consent. For participants lacking capacity to consent, we followed Consultee procedures as laid out in the Mental Capacity (England & Wales) Act (2005) and proxy consent procedures as laid out in the Adults with Incapacity (Scotland) Act (2001).

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Paul Hutton reports financial support was provided by Chief Scientist Office. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.schres.2025.06.018.

Data availability

Data collected in this study will be stored for 10 years and made available for audit by ENU or NHS approved staff. We made an a priori decision that, because the small sample size increases the risk of participant identification, it would not be available to other researchers.

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