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Trauma-focused therapy integrated with cognitive behavioural therapy for psychosis for people with post-traumatic stress disorder and psychosis (the STAR trial): a multicentre, pragmatic, randomised trial in the UK

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Summary

Background People with psychosis have high rates of post-traumatic stress disorder (PTSD), which is associated with a poor prognosis. We aimed to investigate the effectiveness of a trauma-focused therapy integrated with cognitive behavioural therapy for psychosis (CBTp) in people with psychosis.

Methods STAR was a rater-blind, parallel-group, pragmatic randomised controlled trial conducted across five UK sites. We randomly assigned (1:1) adults with co-occurring PTSD and psychosis in secondary care to trauma-focused CBTp plus treatment as usual or treatment as usual only, using randomly varying block size, stratified by site. Trauma-focused CBTp is a flexible, individualised, formulation-based therapy integrating trauma-focused therapeutic components with CBTp, lasting 9 months. The primary outcome was PTSD symptom severity, assessed using clinician-administered PTSD scale for DSM-5 (CAPS-5), at 4 months (mid-therapy) and 9 months (primary endpoint). Secondary outcomes were (1) percentage of participants showing PTSD remission from diagnosis and clinically significant change, individual symptom clusters, post-traumatic cognitions, and dissociation; (2) psychosis symptoms; (3) mood disorders; (4) psychological recovery; and (5) social functioning, assessed at the same timepoints. We used linear mixed models in the intention-to-treat population at 9 months, incorporating all outcome data including at 4 months. Lived experience experts were integral throughout the research. This study was registered prospectively with ISRCTN, ISRCTN93382525.

Findings Between Oct 1, 2020, and March 20, 2023, we randomly assigned 305 participants (151 [49·5%] to treatment as usual and 154 [50·5%] to trauma-focused CBTp plus treatment as usual). The mean age of participants was 38·9 years (SD 12·4). 127 (42%) participants were men, 171 (56%) were women and seven (2%) were non-binary or preferred not to say; 232 (76%) were White. All reported repeated and multiple traumas. Of 154 in the trauma-focused CBTp plus treatment-as-usual group, 144 (94%) engaged with therapy and 146 (95%) received a minimal therapeutic dose. 267 (88%) of 305 participants attended a follow-up assessment (4 months, 9 months, or both); at 9 months, 241 (79%) participants provided primary outcome data and 169–248 (55–81%) provided secondary outcome data. There were significant effects on CAPS-5 scores (adjusted mean difference in PTSD symptom severity –8·67 [95% CI –13·41 to –3·94]; p=0·0003; Cohen's *d* –0·73) and on 22 (81%) of 27 secondary outcomes, unadjusted for multiple testing (Cohen's *d* ranging from –0·26 to –0·82), including all PTSD outcomes (except derealisation and depersonalisation); delusions, paranoia, and hallucinations in other modalities; suicidal ideation, depression, anxiety, and stress; and psychological recovery. There were no effects on voices, referential beliefs, substance use, or social functioning (Cohen's *d* ranging from –0·05 to –0·28). 62 (50%) of 125 participants in the therapy group showed PTSD remission compared with 25 (22%) of 116 in the treatment-as-usual group (odds ratio [OR; PTSD present] 0·11, 95% CI 0·03–0·32; p=0·0001) and 56 (45%) participants in the therapy group compared with 31 (27%) in the treatment-as-usual group had clinically significant change in CAPS-5 score (OR 4·45, 95% CI 1·59–12·44; p=0·0044; number needed to treat for PTSD remission was 4). No serious adverse event was unexpected and related to trial procedures (78 reported in each group), with the most common being physical illness or injury.

Interpretation Trauma-focused CBTp is safe, highly acceptable, and effective in people with co-occurring psychosis and PTSD. This underserved population should no longer be denied access to psychological interventions to treat their trauma sequelae.

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See Online for appendix

Research in context

Evidence before this study

Evidence suggests post-traumatic stress disorder (PTSD) and psychosis may exist on a continuum of trauma responses. PTSD is characterised by intrusive trauma memories such as flashbacks and other types of re-experiencing, negative appraisals, hyperarousal, and avoidance of trauma reminders. In people with psychosis, these post-traumatic symptoms are frequently intertwined with psychosis symptoms, such as delusions and hallucinations, with traumatic events often shaping the psychosis phenomenology.

Three systematic reviews, including a Cochrane review and one from our group, had evaluated psychological interventions for PTSD in people with psychosis or severe mental illness before our protocol paper. These studies reported emerging evidence from open and pilot randomised controlled trials (RCTs) and case-series studies that treating PTSD can be safe and efficacious in patients with psychosis. The 2017 Cochrane review concluded that despite low-to-medium risk of bias in the four published RCTs, large-scale trials were needed to provide high-quality evidence.

We searched PsychInfo for articles published from database inception up to Dec 31, 2022, with search terms related to PTSD, psychosis, and trauma-focused therapies and no language restrictions (appendix p 3). Two other systematic reviews and meta-analyses were published following completion of the STAR trial, corroborating previous conclusions. The two RCTs in people with psychosis specifically, in the Netherlands and the UK, both showed that trauma-focused therapies were safe and feasible in this population. However, only the Dutch trial found significant, medium-to-large effects on PTSD symptoms, with both the control and therapy groups improving in the UK trial; the different findings are potentially related to sample and therapy protocol differences.

The evidence for the effect on psychosis symptoms is more equivocal. Although several case-series studies have shown promising results, the Dutch RCT found effects on paranoid thoughts but not voices. None of the psychosis secondary outcomes were significant in the UK trial.

Added value of this study

STAR is the largest RCT to date showing the effectiveness of a trauma-focused therapy integrated with cognitive behavioural therapy for psychosis (CBTp) in people with psychosis and PTSD. Our study differed from previous trials by ensuring the participants met full PTSD diagnostic criteria and presented with current, distressing psychosis symptoms, including hallucinations in a range of sensory domains, and that the intervention included trauma memory work. Importantly, although trauma-focused CBTp is longer than interventions in previous trials, engagement with therapy and delivery of minimal therapeutic dose were exceptionally high.

Implications of all the available evidence

Trauma-focused therapies can be delivered safely and effectively for people with PTSD and psychosis in different clinical settings. Trauma-focused CBTp, with an integrated PTSD and psychosis therapy protocol that included trauma memory reprocessing, a focus on engagement, and a flexible approach to stabilisation is safe, highly acceptable, and effective on a range of PTSD, psychosis, and mood disorder outcomes.

Long-term effectiveness and cost-effectiveness, to be reported in future papers, need to be established to determine whether clinical guidelines should be updated to recommend trauma-focused CBTp for implementation in clinical services.

Introduction

Traumatic events, particularly childhood victimisation, are related to the occurrence, severity, and persistence of psychosis, with a dose–response relationship.[1,2] People with psychosis report high rates of adversity and trauma, particularly interpersonal victimisation, with most experiencing multiple traumas.[3] The prevalence of post-traumatic stress disorder (PTSD) in this population is up to 5 times that in the general population,[4] with post-traumatic and psychosis symptoms frequently intertwined.[5,6] Psychosis symptoms in such individuals have a poorer response to medication,[7] and functional and clinical outcomes are worse than in those with psychosis alone.[3,8] Developing effective psychological interventions that improve outcomes is a priority.

Despite the need, therapists can be reluctant to address PTSD symptoms in people with psychosis because of concerns that the memory reprocessing techniques included in trauma-focused therapies might exacerbate psychosis symptoms.[9] These concerns had, up to a decade go, excluded individuals with psychosis from all prominent PTSD trials.[10] However, emerging evidence shows that trauma-focused therapies can be safe and efficacious in treating PTSD in people with psychosis.[11,12]

The two randomised controlled trials (RCTs) conducted in individuals with PTSD and psychosis, in the Netherlands[13] and the UK,[14] both showed that trauma-focused therapies were safe and feasible in this population, but only the Dutch trial found significant group effects on PTSD symptoms, with both control and therapy groups improving in the UK trial. There are two potential reasons for these discrepant results. First, the therapy protocol in the UK trial involved cognitive restructuring only, without the trauma memory reprocessing or exposure element, with some evidence that the level of emotional processing in the therapy group was not sufficient to facilitate adaptation to trauma memories.[15] Second, participants did not meet full PTSD diagnostic criteria. As a result, participants presented with less severe, and possibly less stable, PTSD

symptoms, potentially leading to some degree of spontaneous recovery occurring in both groups.

Findings regarding the secondary benefits of trauma-focused therapies for psychosis symptoms are more equivocal.[11,12] However, the presence of psychosis symptoms was not a prerequisite for entry into the Dutch and UK trials, which only required a current or historical psychosis diagnosis. No study so far has looked at hallucinations in modalities other than auditory, despite the prominence of visual, somatic, and other sensory hallucinations in people with psychosis.[16]

The evidence to date derives from diverse small trials in different health settings, and a large, pragmatic effectiveness trial is now needed.[11,12] The STAR trial differed from previous trials by participants meeting PTSD DSM-5 diagnostic criteria and presenting with at least one current distressing psychosis symptom, and including the assessment of hallucinations in modalities other than voices. The trauma-focused component of our intervention incorporated trauma memory reprocessing techniques and was integrated with cognitive behavioural therapy for psychosis (CBTp), taking into account the frequently interlinked nature of psychosis and PTSD symptoms, according to our previous theoretical models,[5,6,17] practice recommendations,[18] and case-series studies.[19–21] Generally, integration of memory reprocessing procedures within standard therapies is preferable for populations with complex needs and comorbidity,[22,23] potentially mitigating against disengagement for those who might find trauma-focused procedures difficult to tolerate.[24] The longer duration of our therapy (9 months) allowed for a wider range of putative trauma-related mechanisms that may maintain or exacerbate psychosis symptoms, such as negative appraisals, emotional regulation, and interpersonal difficulties, to be included as individualised treatment targets, as well as ensuring sufficient time and focus is given to the development of a collaborative and safe therapeutic relationship, particularly for people with complex trauma histories.

The primary hypothesis was that a trauma-focused therapy integrated with CBTp, in addition to treatment as usual, would reduce post-traumatic stress symptom severity in people with co-occurring PTSD and psychosis (9 months after randomisation [end of therapy]), compared with treatment as usual alone. Secondary hypotheses were that beneficial effects would also be found on psychosis symptoms, mood disorders, and functioning. Two further secondary aims, the sustainability of therapy effects 2 years after randomisation and cost-effectiveness, will be reported in separate papers once analyses are completed, as prespecified in our statistical analysis plan.

Methods

Study design and participants

The Study of Trauma And Recovery (STAR) trial is a rater-blind, parallel-group RCT comparing an integrated therapy targeting PTSD and psychosis symptoms (trauma-focused CBTp) plus treatment as usual with treatment as usual alone. The study setting was secondary care mental health services, which in the UK treats almost exclusively people with severe mental illness. Participants were recruited from adult services in five National Health Service (NHS) mental health trusts across England (South London, Manchester, Newcastle, Oxford, and Sussex), serving an ethnically diverse population through various services including adult community mental health teams, early intervention for psychosis (EIP) services, inpatient wards, residential and rehabilitation services, and outpatient clinics. Study procedures were delivered either in person in community or university settings, or by video link or telephone, depending on COVID-19-related restrictions and participant preference thereafter.

The trial was registered prospectively (ISRCTN93382525) and the protocol was published at the start of the trial[25] (also available on the STAR website). We followed CONSORT guidelines for social and psychological interventions (CONSORT-SPI).[26] The London–Camberwell St Giles Research Ethics Committee (20/Lo/0853) provided ethics approval and a trial steering committee and data monitoring and ethics committee provided oversight and monitoring. People with lived experience of trauma, psychosis, or both were consulted on the need for the trial and shaped the research questions, were included as co-applicants on the funding application, were members of the trial steering committee, advised on the choice of outcome measures, co-produced and co-delivered the research workers' training, and dissemination and writing up of results.

Participants were identified through referrals from clinical teams, from research registers, or by screening clinical notes, in concordance with local NHS trust procedures. Participants were eligible if they met ICD-10 checklist[27] criteria for schizophrenia-spectrum diagnoses (F20–29), ascertained by the research team, following clinical notes review and consultation with the care team as appropriate, and scored 2 or above (moderate intensity) over the past month on the distress item of at least one positive symptom, including non-auditory hallucinations, of the Psychotic Symptom Rating Scales (PSYRATS).[28]

Participants needed to have experienced at least one trauma, including those related to psychosis or its treatment,[29] on the Trauma and Life Events (TALE) checklist[30] and to meet PTSD criteria on the clinician-administered PTSD scale for DSM-5 (CAPS-5).[31] Participants were excluded if they were younger than 18 years; their psychosis or PTSD symptoms had an organic cause; they had a primary substance use disorder, such that psychosis symptoms were secondary to the substance use; required an interpreter; were experiencing an acute mental health crisis; had major medication changes (started or stopped an antipsychotic medication

For the **STAR website** see https://static1.squarespace.com/static/68d6b9bda3f56445286bf124/t/6903ccef8e39d46fb7660178/1761856751899/STAR_PROTOCOL_3.06+15.05.25+%28CLEAN%29.pdf

For the **statistical analysis plan** see https://static1.squarespace.com/static/68d6b9bda3f56445286bf124/t/6903cf000917451f78be16ca/1761857280894/STAR+Statistical+Analysis+Plan+V3.0_signed.pdf

or switched to or from clozapine) or were currently receiving or had received trauma-focused therapy, within the previous 3 months.

Gender and ethnicity were self-reported. Participants provided informed consent before the eligibility assessment.

Randomisation and masking

Randomisation (1:1) followed completion of baseline assessment via a web-based service hosted by King's Clinical Trials Unit. Allocation was stratified by site and used randomly varying sized blocks. Referring clinicians, therapists, and participants were not masked, as is customary in psychological therapy trials. The senior statistician (RE) was unmasked only after the final database checks, but the analyses were done unmasked since therapist effects needed to be accounted for in the trauma-focused-CBTp group only.

The research workers who did the assessments remained masked to group allocation throughout the study. Allocation was unmasked in 30 (6%) of 477 follow-up assessments completed; 15 (50%) were due to participants revealing group allocation to the research worker, seven (23%) to participants' clinical team revealing allocation, four (13%) to the research team accidentally revealing allocation, and four (13%) to other reasons. These assessments were either allocated to (17 [57%]) or scored by (13 [43%]) another research worker without the unmasking information.

Procedures

Trauma-focused CBTp[18,19,32] is an individualised, formulation-based therapy integrating standard psychological therapies for PTSD and for psychosis, lasting 9 months (appendix pp 4–5). The therapy is a manualised but flexible approach, consisting of four phases that guide the therapy process from assessment to consolidation, with key therapeutic components for PTSD and psychosis symptoms delivered in phase 3 (model-based interventions). There are general milestones for progress from one phase to another, but it is expected this process will not happen in a linear way. Engagement and therapeutic alliance are prioritised throughout; management of risk and practical issues are addressed if and when they arise. Unlike highly protocolised PTSD treatments delivered in previous trials,[13] our protocol did not specify a defined number of sessions for treatment completion, but aimed to offer as many sessions as possible, including booster sessions, within the therapeutic window: we anticipated that approximately 26 weekly or twice-weekly individual 60–90 min sessions would be offered in the first 6 months, followed by monthly booster sessions over the next 3 months, to consolidate therapeutic gains (appendix p 6). Therapists were doctoral-level clinical psychologists or CBT therapists with a minimum of 2 years' experience of working with patients with severe mental health problems.

The comparator was treatment as usual only, delivered by mental health services. Treatment as usual consisted of multidisciplinary care, including medication and outpatient psychiatric appointments, psychologically informed case management, and potential access to various psychotherapies, including CBTp. Clinicians involved in participants' treatment received a manual summarising best practice and evidence-based treatment guidelines for psychosis and for PTSD to promote standardisation of good quality treatment as usual. Treatment decisions about medication, additional psychosocial interventions, or discharge to primary care or other care pathways remained the clinical team's responsibility. Interventions (medication and psychological) provided by clinical teams throughout trial participation were recorded through case-note review.

Full details of screening stages (appendix p 9) and assessment procedures are published elsewhere.[25] Assessments were done at baseline, 4 months (mid-therapy), and 9 months (post-therapy; primary endpoint) after randomisation. The 4-month assessment was included to minimise trial attrition and provide data for the intention-to-treat analysis for those who were lost to follow-up at the primary endpoint. Participants received £20 reimbursement for completing assessments at each timepoint, plus travel expenses.

Outcomes

The primary outcome was PTSD symptom severity on the CAPS-5 (past-month version),[31] a semi-structured interview assessing the severity of symptoms delineated in DSM-5. Secondary outcomes were also assessed in relation to the past month unless otherwise specified. All outcome scales have shown reliability, validity, and acceptability for psychosis.

For PTSD, we analysed (1) the percentage of participants achieving remission of PTSD and dissociative subtype of PTSD diagnoses on the CAPS-5, and complex PTSD diagnosis on the International Trauma Questionnaire (ITQ);[33] (2) the percentage of participants with clinically significant change on CAPS-5 (15-point decrease); (3) CAPS-5 individual symptom clusters (severity scores for criteria B–E); (4) dimensional scales of self-reported PTSD and disturbances in self-organisation symptoms (six items each) on the ITQ; (5) Brief Version of the Posttraumatic Cognitions Inventory (nine items) score,[34] which assesses cognitive appraisals of the trauma and its aftermath; (6) three Dissociative Subtype of PTSD Scale (15 items)[35] subscale scores (derealisation and depersonalisation, seven items; loss of awareness, six items; and psychogenic amnesia, two items), assessing lifetime occurrence and current frequency and intensity of dissociative symptoms.

For psychosis, we analysed PSYRATS scores,[28] a multidimensional, clinician-administered, semi-structured interview of delusions (six items) and voices

(11 items) assessing dimensions such as distress, preoccupation, and conviction. The PSYRATS (11 items) was also administered for hallucinations in other modalities, covering visual, olfactory, somatic, sexual, felt presence, gustatory, and non-verbal auditory modalities (PSYRATS-Hallucinations in Other Modalities Subscale[36]). If more than one modality was present, the most prominent hallucination was rated, or if the hallucination occurred simultaneously in several senses, the multimodal hallucination was rated, allowing us to capture the most salient experience for the person. Because of limitations in the original PSYRATS interviewer-rated scale, each PSYRATS item was also self-rated by participants using a thermometer (0–10) rating scale (PSYRATS-Continuous[36]) in addition to the standard interviewer ratings (0–4; appendix pp 9–10). We analysed self-reported paranoia using the Green et al Paranoid Thoughts Scale–Revised[37] (reference subscale, eight items, and persecution subscale ten items).

For mood disorders, we analysed Depression Anxiety Stress Scale[38] scores, which include seven items for each of the three domains assessed. Scores of 21 or greater on the depression subscale represent severe depression, and scores of 15 or greater on the anxiety subscale represent severe anxiety. We analysed Paykel Suicidal Feelings Scale[39] scores (five items). Scores of 1 or greater indicate some suicidal ideation. We analysed Brief Version of the Alcohol, Smoking and Substance Involvement Screening Test[40,41] scores (ten items pertaining to recent use [past 3 months] of substances scored 0–6 on frequency).

For psychological recovery, we analysed Short Version (11 items plus one personal goal, each scored 0–10) of the Choice of Outcome In CBT for Psychoses (CHOICE) scale.[42] The CHOICE scale was developed by our group in collaboration with experts-by-experience, reflecting themes they considered important psychological therapy outcomes.

For social and occupational functioning, we analysed Personal and Social Performance Scale (PSP)[43] scores. PSP is a 100-point single-item rating scale based on the assessment of functioning in four areas (socially useful activities, personal and social relationships, self-care, and disturbing and aggressive behaviour). For an impairment to be rated, it must relate to psychological problems rather than lack of opportunity. Scores of 60 or lower indicate low functioning.

There was excellent inter-rater reliability for the three PSYRATS subscales (intra-class correlation [ICC] 0·997; 75 tapes). All other secondary measures were participant rated.

Choice of primary outcome

CAPS-5 is the recommended gold-standard measure in PTSD research, including in psychosis populations. The scale is freely available from the US Department of Veterans Affairs' National Center for PTSD website, which also provides online training for its administration. With our population, CAPS-5 took between 45 min and 2 h to administer, depending on complexity of the trauma, clinical presentation, and functioning of the participant, and was carried out over more than one session, if required.

CAPS-5 consists of seven criteria (criteria A–G). Scores are anchored to an index event, which was elicited using the TALE checklist.[30] The index event could be a single trauma or multiple incidents. Meeting criterion A (ie, only events including objective actual or threatened death, serious injury, or sexual violence) was not a requirement in this study, with events related to psychosis and its consequences[29] (eg, hearing a threatening voice, involuntary admission, or forced restraint), emotional and physical neglect, and discrimination and attachment-disrupting experiences being included as possible index events. PTSD diagnostic status is determined by an algorithm of minimum scores on specific items from criteria B to E, and meeting criteria F and G, according to DSM-5 diagnostic rules.

Severity of symptoms is scored on a five-point scale (absent to extreme) on four criteria: re-experiencing symptoms (criterion B), avoidance symptoms (criterion C), cognitions and mood symptoms (criterion D), and arousal and reactivity symptoms (criterion E). Criteria F and G are scored dichotomously (yes or no) on whether the duration of the experience is more than 1 month, and whether it has caused subjective distress and impairment in functioning.

The total symptom severity score (total of 20 item scores on criteria B–E) was the primary outcome. There was excellent inter-rater reliability for total severity scores in this study (ICC 0·989; conducted on 47 randomly selected tapes).

Statistical analysis

The sample size accounted for 1:1 allocation, partial nested design owing to therapist clustering in the therapy group (ICC 0·01), 0·05 significance level, and 20% attrition. A target of 300 participants (150 per group and 60 per site) had 80% power to detect an effect size of 0·33 on the primary outcome.

Analyses were done in Stata (version 18) in the intention-to-treat population at the 9-month primary endpoint, incorporating all outcome data, including the 4-month timepoint. All outcomes are reported, in line with CONSORT-SPI[26] guidance, which recommends minimising the distinction between primary and secondary outcomes for psychological therapies trials.

Analyses used linear mixed models with maximum likelihood estimation, accounting for missing outcome data under the missing-at-random assumption. Fixed effects were site, baseline value of the outcome, group, time, and group-by-time interaction. Participants and therapists were included as random intercepts, accounting for repeated measures and clustering due to the partial nested design.

For the **National Center for PTSD** see https://www.ptsd.va.gov/professional/continuing_ed/caps5_clinician_training.asp

Marginal treatment effects were estimated as between-groups adjusted mean differences with 95% CIs and two-sided p values. For binary secondary outcomes, the same approach was applied using logistic mixed models, with effects reported as odds ratios (ORs). The percentage reductions in number of participants meeting criteria for the Dissociative subtype of PTSD and complex PTSD between baseline and 9 months after randomisation were calculated as 1–(percentage 9–months/percentage baseline)*100 in each group. In line with CONSORT guidance,[44] secondary outcomes were considered exploratory and therefore not adjusted for multiple testing.

Effect sizes (Cohen's *d*) were calculated as the adjusted mean difference of the outcome divided by the pooled sample SD at baseline and presented in a forest plot.

Scale scores were prorated at the participant level when item-level data were missing. To ensure the missing-at-random assumption was supported, differential predictors of missing outcomes were checked by comparing participants with and without missing data on key baseline variables. As none predicted missingness significantly, no covariates were included for this purpose.

A dose–response model was considered to estimate the linear effect of therapy dose, using randomisation as an instrumental variable for the number of sessions attended. Complier-average causal effects were estimated using instrumental variable methods on the basis of prespecified definitions of compliance and fidelity in the trauma-focused-CBTp group.

Further information on analyses is specified in the statistical analysis plan, which was approved by the data monitoring and ethics committee before analyses were done.

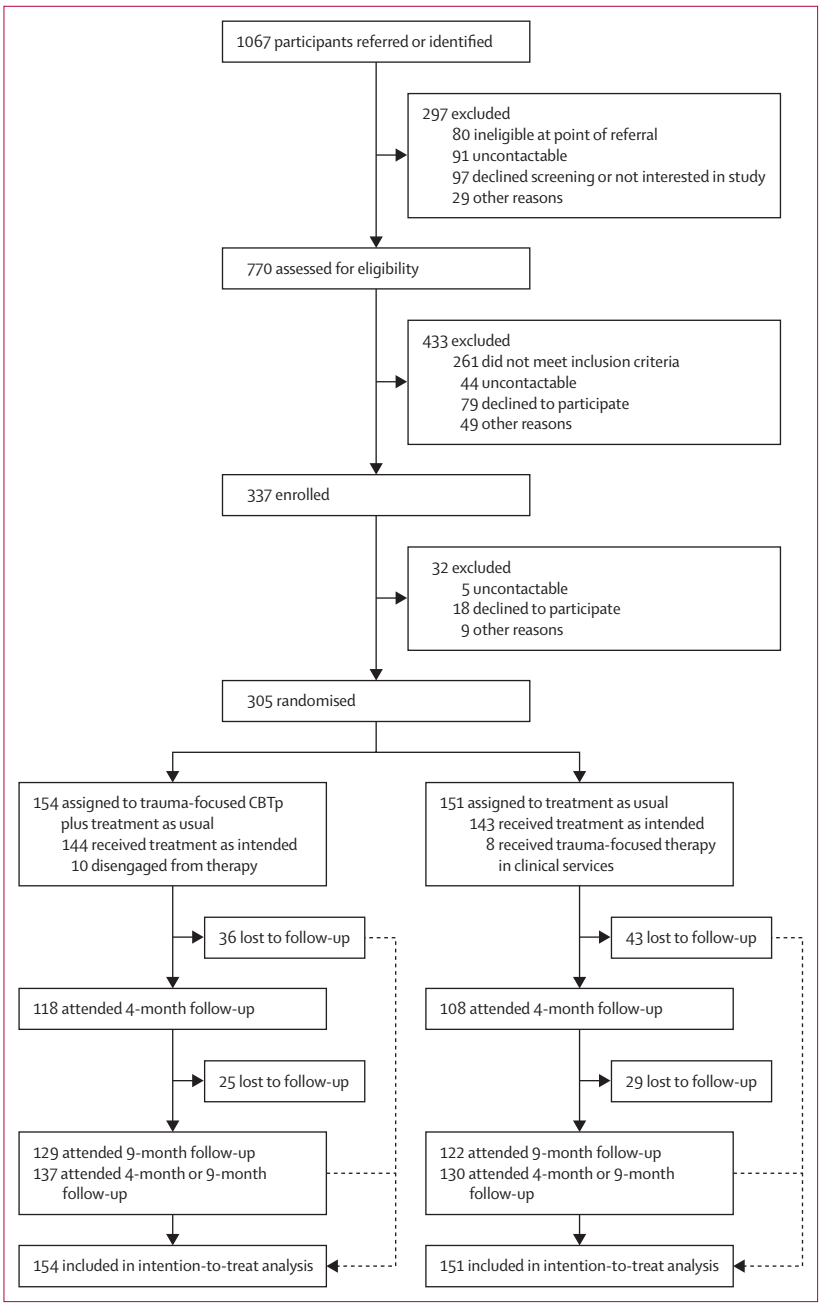

Figure 1: **Trial profile**
CBTp=cognitive behavioural therapy for psychosis.

Role of the funding source

The funder reviewed and approved the protocol, but had no role in the choice of measures, data collection, data analysis, data interpretation, or writing of the report.

Results

Recruitment took place between Oct 1, 2020, and March 20, 2023, with the final 9-month follow-up completed on Feb 28, 2024. 1067 potential participants were referred or identified through research registers or case-note review; 770 (72%) were assessed for eligibility, with 337 (44%) eligible and 433 (56%) excluded (figure 1). Among those referred or identified, 194 (18%) declined to participate or give consent. The most common exclusion reason was no psychosis symptoms or scoring below threshold on psychosis symptom distress (152 people; 45% of ineligible referrals and identification; appendix p 12). We randomly assigned 305 participants (154 [50·5%] to trauma-focused CBTp plus treatment as usual and 151 [49·5%] to treatment as usual).

267 (88%) of 305 participants completed at least one measure at the 4-month or 9-month assessments, with 251 (82%) attending the 9-month assessment. The mean time at which 9-month assessments took place was 291 days after randomisation (SD 31; range 242–476).

Our a-priori definition for engagement with therapy was based on previous UK CBTp trials, which specify attending at least six sessions; we added attendance of at least one phase 3 (model-based interventions) session as an extra criterion (appendix p 7). Only ten (6%) of the 154 participants randomly assigned to the therapy group disengaged from therapy, two (1%) of whom never started

	Treatment as usual (n=151)	Trauma-focused CBTp plus treatment as usual (n=154)	Total (n=305)
Age, years			
Mean (SD)	39·5 (11·9)	38·2 (12·9)	38·9 (12·4)
Median (range)	38·0 (18·0–61·0)	37·5 (18·0–65·0)	38·0 (18·0–65·0)
Gender identity			
Men	65 (43%)	62 (40%)	127 (42%)
Women	83 (55%)	88 (57%)	171 (56%)
Non-binary	1 (1%)	3 (2%)	4 (1%)
Prefer not to say	2 (1%)	1 (1%)	3 (1%)
Same gender assigned at birth			
No	2 (1%)	2 (1%)	4 (1%)
Yes	147 (97%)	149 (97%)	296 (97%)
Prefer not to say	2 (1%)	3 (2%)	5 (2%)
Relationship status			
Not currently in a relationship	93 (62%)	95 (62%)	188 (62%)
Cohabiting, married, or civil partnership	43 (29%)	36 (23%)	79 (26%)
Separated, divorced, or widowed	14 (9%)	22 (14%)	36 (12%)
Missing data	1 (1%)	1 (1%)	2 (1%)
Normal living situation			
Supported accommodation	11 (7%)	13 (8%)	24 (8%)
Temporary accommodation or no fixed accommodation	3 (2%)	9 (6%)	12 (4%)
Rented (council or private)	90 (60%)	99 (64%)	189 (62%)
Own property	18 (12%)	8 (5%)	26 (9%)
In family home	27 (18%)	24 (16%)	51 (17%)
Missing data	2 (1%)	1 (1%)	3 (1%)
Living with, as best described			
Live alone	59 (39%)	57 (37%)	116 (38%)
Live with partner or spouse without children	23 (15%)	20 (13%)	43 (14%)
Live with partner or spouse with children	14 (9%)	14 (9%)	28 (9%)
Live with children only	14 (9%)	16 (10%)	30 (10%)
Live with parents or other family members	25 (17%)	26 (17%)	51 (17%)
Live with one or several friends	5 (3%)	6 (4%)	11 (4%)
Live with housemates, lodgers, or tenants (not friends)	8 (5%)	11 (7%)	19 (6%)
Other	1 (1%)	4 (3%)	5 (2%)
Missing data	2 (1%)	0	2 (1%)

(Table 1 continues in next column)

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	Treatment as usual (n=151)	Trauma-focused CBTp plus treatment as usual (n=154)	Total (n=305)
Self-defined ethnicity			
Black African	9 (6%)	10 (7%)	19 (6%)
Black Caribbean	6 (4%)	7 (5%)	13 (4%)
Mixed ethnicity	11 (7%)	8 (5%)	19 (6%)
South Asian (Bangladeshi, Indian, or Pakistani)	6 (4%)	4 (3%)	10 (3%)
White British	108 (72%)	116 (75%)	224 (73%)
White Other (includes Irish, German, or unspecified)	5 (3%)	3 (2%)	8 (3%)
Other (includes Chinese, Vietnamese, Filipino, Arab Algerian, Turkish, former USSR, Egyptian, Iraqi, Greek, Jewish, or Romany)	6 (4%)	6 (4%)	12 (4%)
English as first language			
No	14 (9%)	13 (8%)	27 (9%)
Yes	136 (90%)	141 (92%)	277 (91%)
Missing data	1 (1%)	0	1 (<1%)
Migrated to the UK			
No	127 (84%)	132 (86%)	259 (85%)
Yes	23 (15%)	21 (14%)	44 (14%)
Missing data	1 (1%)	1 (1%)	2 (1%)
Sought asylum in the UK			
No	145 (96%)	145 (94%)	290 (95%)
Yes	5 (3%)	7 (5%)	12 (4%)
Missing data	1 (1%)	2 (1%)	3 (1%)
Highest level of schooling completed			
Primary school	1 (1%)	7 (5%)	8 (3%)
Secondary (no qualifications)	20 (13%)	22 (14%)	42 (14%)
Secondary GCSE (or equivalent)	37 (25%)	33 (21%)	70 (23%)
Secondary A levels (or equivalent)	23 (15%)	26 (17%)	49 (16%)
Vocational education or college	30 (20%)	26 (17%)	56 (18%)
University (undergraduate)	24 (16%)	23 (15%)	47 (15%)
University (postgraduate)	11 (7%)	8 (5%)	19 (6%)
Other	2 (1%)	3 (2%)	5 (2%)
Missing data	3 (2%)	6 (4%)	9 (3%)
Current working situation, as best described			
Paid employment (part-time or full-time)	21 (14%)	18 (12%)	39 (13%)
Studying	4 (3%)	12 (8%)	16 (5%)
Volunteering	6 (4%)	5 (3%)	11 (4%)
Caregiver	1 (1%)	1 (1%)	2 (1%)
Retired	3 (2%)	0	3 (1%)
Not currently working	114 (76%)	117 (76%)	231 (76%)
Missing data	2 (1%)	1 (1%)	3 (1%)

(Table 1 continues in next column)

(one because of being offered an alternative psychological treatment as part of treatment-as-usual and one because of being diagnosed with a brain tumour). The mean

	Treatment as usual (n=151)	Trauma-focused CBTp plus treatment as usual (n=154)	Total (n=305)
(Continued from previous column)			
Diagnosis, ascertained by research team, ICD-10 code			
Schizophrenia, F20	27 (18%)	34 (22%)	61 (20%)
Persistent delusional disorders, F22	2 (1%)	2 (1%)	4 (1%)
Schizoaffective disorders, F25	24 (16%)	16 (10%)	40 (13%)
Other non-organic psychotic disorders, F28	35 (23%)	38 (25%)	73 (24%)
Unspecified non-organic psychosis, F29	63 (42%)	64 (42%)	127 (42%)
Psychosis symptoms presentation			
Delusions	122 (81%)	128 (83%)	250 (82%)
Voices	120 (80%)	124 (81%)	244 (80%)
Hallucinations in other modalities	121 (80%)	134 (87%)	255 (84%)
Types of other hallucinations			
Visions	86 (57%)	93 (60%)	179 (59%)
Olfactory	58 (39%)	62 (40%)	120 (39%)
Somatic	72 (48%)	71 (46%)	143 (47%)
Sexual somatic	18 (12%)	25 (16%)	43 (14%)
Felt presence	90 (60%)	102 (66%)	192 (63%)
Gustatory*	13/87 (15%)	14/95 (15%)	27/182 (15%)
Non-verbal auditory*	38/86 (44%)	39/97 (40%)	77/183 (42%)
Meeting complex PTSD criteria on ITQ	119/151 (79%)	122/150 (81%)	241/301 (80%)
Other diagnoses			
Anxiety disorders	25 (17%)	30 (20%)	55 (18%)
Autism	6 (4%)	10 (7%)	16 (5%)
Bipolar disorder	15 (10%)	10 (7%)	25 (8%)
Depression (with and without psychotic features)	44 (29%)	55 (36%)	99 (33%)
Personality disorders	37 (25%)	43 (28%)	80 (26%)
Substance use disorders	9 (6%)	15 (10%)	24 (8%)
Other (eg, ADHD, eating disorders, or severe stress and adjustment disorders)	11 (7%)	9 (6%)	20 (7%)
Number of other diagnoses			
None	57 (38%)	49 (32%)	106 (35%)
One	51 (34%)	61 (40%)	112 (37%)
Two or more	43 (29%)	44 (29%)	87 (29%)
(Table 1 continues in next column)			

	Treatment as usual (n=151)	Trauma-focused CBTp plus treatment as usual (n=154)	Total (n=305)
(Continued from previous column)			
Medication (ascertained through case-note review)			
Any antipsychotic and dose (olanzapine equivalent)	124 (82%); 12·57 mg	131 (85%); 11·61 mg	255 (84%); 12·08 mg
Typical	24 (16%)	19 (12%)	43 (14%)
Atypical	103 (68%)	113 (73%)	216 (70%)
Clozapine	10 (7%)	14 (9%)	24 (8%)
Polypharmacy (>1 antipsychotic)	16 (11%)	21 (14%)	37 (12%)
Antidepressant	103 (68%)	91 (59%)	194 (64%)
Mood stabiliser	19 (13%)	13 (8%)	32 (11%)
Anxiolytic	42 (28%)	41 (27%)	83 (27%)
Age psychosis symptoms first started	22·8 (12·3)	22·2 (11·6)	22·5 (11·9)
Age at first contact with mental health services	24·1 (10·7)	23·8 (11·3)	24·0 (11·0)
Number of past psychiatric admissions	2·44 (5·2)	2·95 (9·2)	2·70 (7·5)

Data are n (%), n/N (%), or mean (SD). All demographic information was elicited from participants directly apart from medication and diagnoses. CBTp=cognitive behavioural therapy for psychosis. PTSD=post-traumatic stress disorder. ITQ=International Trauma Questionnaire. *These categories were added after commencement of the trial, hence valid data were fewer than other categories.

Table 1: **Baseline characteristics**

number of sessions attended by participants who disengaged was 2·7 (SD 1·8), compared with 25·0 (9·3) for those who engaged in therapy. A further 13 (8%) of 154 participants had a therapist-defined unplanned ending but, unlike in previous shorter trials (eight sessions over 10 weeks),[13] were not included in our disengagement definition, since over a 9-month window premature endings are often due to reasons other than disengagement with therapy (eg, one participant stopped at 8 months after 17 attended sessions because of getting a job, another at 4 months after nine sessions because of dental treatment; another declined reallocation after ten sessions when their therapist left 4 months into therapy). Mean sessions attended by those 13 participants were 9·5 (SD 1·7) over a mean period of 4·6 months ranging from 2·7 months to 8·0 months (appendix pp 7–8).

Minimal therapy dose was operationalised separately as the delivery of either therapy-informed or trauma-focused procedures, classified according to the therapy checklist completed by therapists after each session (appendix p 11). Of 154 participants, therapists were able to deliver a minimal therapy dose to 146 (95%): trauma-focused strategies to 124 (81%) and trauma-informed interventions only to 22 (14%). Eight (5%) of 154 participants did not receive a sufficient dose of either (all of whom were disengagers). Of the 144 (94%) of 154 participants who engaged in therapy, therapists delivered trauma-focused procedures to 123 (85%) and trauma-informed interventions only to 21 (15%). Of the 13 participants who had therapist-defined unplanned endings, five (38%) received trauma-focused and eight (62%) trauma-informed interventions only (appendix p 8).

Eight (5%) of 151 participants in the treatment-as-usual only group received a trauma-focused intervention. A further 48 (32%) participants received another individual psychological therapy, with 33 (22%) receiving a trauma-informed psychological therapy (of which 13 [9%] received National Institute for Health and Care Excellence [NICE]-compliant CBTp), consistent with standard treatment-as-usual delivery (appendix pp 13–14).

Participant characteristics were typical of populations with complex mental health needs, with the majority not working (231 [76%]), not in a relationship (188 [62%]), and living alone or with family members (167 [55%]; table 1; appendix pp 15–18).

89 (29%) participants were recruited from EIP services, where UK good practice guidelines[45] recommend embracing diagnostic uncertainty for those experiencing a first episode of psychosis, resulting in a preponderance of F28 and F29 diagnoses (other and unspecified non-organic psychotic disorder). 199 (65%) participants had at least one other diagnosis, alongside psychosis and PTSD, with depression being the most common. 255 (84%) participants were prescribed antipsychotic medication and 194 (64%) were prescribed antidepressant medication.

Participants' trauma histories and index events are provided in table 2. All participants reported repeated and multiple exposure to the traumas assessed by the TALE[30] (mean number of trauma types 8·6 [SD 2·0]; range 3–12, out of a possible 13), with 261 (86%) participants experiencing traumas both in childhood and adulthood. Perceived current impact of index event was high (mean 8·7 [SD 1·2]), with 106 (37%) participants scoring 10 (maximum score). Almost all (303 [99%]) participants reported interpersonal traumas, with sexual abuse being the most common index event (144 [48%]).

	Treatment as usual		Trauma-focused CBTp plus treatment as usual		Total	
	Overall	Index event(s)	Overall	Index event(s)	Overall	Index event(s)
Trauma type (TALE item number)						
War exposure (item 1)	7/151 (5%)	2/151 (1%)	11/154 (7%)	4/154 (3%)	18/305 (6%)	6/305 (2%)
Attachment related (items 2–4)	135/151 (89%)	21/151 (14%)	144/154 (94%)	29/154 (19%)	279/305 (92%)	50/305 (16%)
Witnessing verbal or physical abuse at home (item 9)	106/151 (70%)	17/151 (11%)	122/154 (79%)	14/154 (9%)	228/305 (75%)	31/305 (10%)
Any interpersonal	150/151 (99%)	115/151 (76%)	153/154 (99%)	127/154 (83%)	303/305 (99%)	242/305 (79%)
Bullying and discrimination (items 5 and 6)	132/151 (87%)	17/151 (11%)	141/154 (92%)	17/154 (11%)	273/305 (90%)	34/305 (11%)
Sexual abuse (items 13 and 14)	115/150 (77%)	69/150 (46%)	109/153 (71%)	75/153 (49%)	224/303 (74%)	144/303 (48%)
Emotional abuse (item 7)	136/151 (90%)	33/151 (22%)	130/154 (84%)	34/154 (22%)	266/305 (87%)	67/305 (22%)
Physical abuse (items 8 and 10)	139/151 (92%)	52/151 (34%)	141/154 (92%)	69/154 (45%)	280/305 (92%)	121/305 (40%)
Emotional neglect (item 11)	128/149 (86%)	21/149 (14%)	121/154 (79%)	27/154 (18%)	249/303 (82%)	48/303 (16%)
Physical neglect (item 12)	54/150 (36%)	6/150 (4%)	66/153 (43%)	6/153 (4%)	120/303 (40%)	12/303 (4%)
Psychosis related (items 15–17)*	125/151 (83%)*	24/151 (16%)	131/154 (85%)*	22/154 (14%)	256/305 (84%)*	46/305 (15%)
Criminal justice (item 18)	76/151 (50%)	10/151 (7%)	87/154 (57%)	5/154 (3%)	163/305 (53%)	15/305 (5%)
Non-interpersonal (item 19)	67/150 (45%)	8/150 (5%)	60/154 (39%)	2/154 (1%)	127/304 (42%)	10/304 (3%)
Other (item 20)	59/148 (40%)	29/148 (20%)	65/150 (43%)	17/150 (11%)	124/298 (42%)	46/298 (15%)
Perceived impact (TALE item 21c)						
How much are you affected currently by index event or events?	..	8·7 (1·2; 6·0–10·0); n=142	..	8·7 (1·2; 5·0–10·0); n=146	..	8·7 (1·2; 5·0–10·0); n=288
Multiple exposure						
Repeated events* (≥1 item answered yes to "more than once")	151/151 (100%)	132/150 (88%)	154/154 (100%)	138/154 (90%)	305/305 (100%)	270/304 (89%)
Multiple trauma types* (>1 of the 13 types reported)	151/151 (100%)	85/151 (56%)	154/154 (100%)	84/154 (55%)	305/305 (100%)	169/305 (55%)
Number of trauma types*	8·5 (1·9; 3·0–12·0); n=151	2·1 (1·6; 1·0–10·0); n=151	8·6 (2·2; 3·0–12·0); n=154	2·2 (1·7; 1·0–12·0); n=154	8·6 (2·0; 3·0–12·0); n=305	2·1 (1·6; 1·0–12·0); n=305
Trauma timing						
Child* (any item at age <16 years)	142/151 (94%)	75/151 (50%)	145/154 (94%)	80/154 (52%)	287/305 (94%)	155/305 (51%)
Adult* (any item at age ≥16 years)	144/151 (95%)	90/151 (60%)	140/154 (91%)	86/154 (56%)	284/305 (93%)	176/305 (58%)
Both* (any item at age <16 years and ≥16 years)	134/151 (89%)	64/151 (42%)	127/154 (83%)	64/154 (42%)	261/305 (86%)	128/305 (42%)
Index events that meet criterion A (exposure to actual or threatened death, serious injury, or sexual violence) on CAPS-5	..	137/146 (94%)	..	140/151 (93%)	..	277/297 (93%)

Data are n/N (%) or mean (SD; range). CAPS-5=clinician-administered PTSD scale for DSM-5. CBTp=cognitive behavioural therapy for psychosis. TALE=Trauma and Life Events. *Participants were selected on the basis of the presence of distressing psychotic experiences (item 15), so this item has been removed as it will, by definition, be endorsed by 100% of the sample. This item has been kept for index events to assess the number of participants whose index events were related to their psychotic experiences.

Table 2: **Trauma experiences (from TALE checklist)**

Participants scored highly on PTSD, psychosis, and mood disorders measures (tables 1, 3). 241 (80%) of 301 participants met complex PTSD criteria on the ITQ. Of 305 participants, 250 (82%) presented with delusions, 280 (92%) experienced at least one type of hallucination, and 248 (81%) reported more than one modality. All seven types of hallucination modalities assessed were represented, with the most common being a sense of felt presence and visual hallucinations (table 1). The mean self-reported duration of illness (current age minus age when psychosis symptoms first started) was 16·2 years (SD 13·7).

239 (81%) of 296 participants met criteria for severe depression and 236 (80%) of 295 for severe anxiety; 230 (82%) of 282 reported suicidal ideation. Functioning was low, with 218 (78%) of 278 reporting marked difficulties in at least one area of functioning.

There were no marked differences between groups on any demographic or clinical variables at baseline (table 1).

Primary outcome scores (total symptom severity on CAPS-5) were available for 241 (79%) of 305 participants at 9 months. Data availability for secondary outcomes varied across measures (table 3).

	Treatment as usual	Trauma-focused CBTp plus treatment as usual	Adjusted mean difference (SE; 95% CI)	p value	Cohen's *d* effect size
Primary outcome					
Total PTSD symptom severity score on CAPS-5 (items 1–20; range 0–80)					
Baseline	49·11 (11·72); n=151*	49·39 (12·02); n=154	..	..	..
Month 4	41·94 (16·22); n=106	41·01 (14·18); n=115	−1·35 (1·5; −4·26 to 1·57)	0·36	−0·11
Month 9	40·64 (17·17); n=116	32·02 (18·94); n=125	−8·67 (2·42; −13·41 to −3·94)	0·0003	−0·73
Secondary outcomes					
PTSD					
CAPS-5 criterion B (intrusion symptoms; items 1–5; range 0–20)					
Baseline	13·01 (4·18); n=150	13·30 (4·25); n=154	..	..	..
Month 4	10·42 (4·94); n=107	11·07 (4·45); n=116	0·48 (0·50; −0·51 to 1·46)	0·34	0·11
Month 9	10·42 (5·38); n=119	8·33 (5·81); n=129	−2·29 (0·75; −3·76 to −0·82)	0·0023	−0·54
CAPS-5 criterion C (avoidance symptoms; items 6–7; range 0–8)					
Baseline	6·07 (1·74); n=150	5·78 (1·80); n=154	..	..	..
Month 4	5·12 (2·39); n=107	4·80 (2·16); n=115	−0·13 (0·28; −0·69 to 0·42)	0·64	−0·08
Month 9	4·77 (2·59); n=119	3·63 (2·68); n=128	−0·98 (0·35; −1·66 to −0·29)	0·0052	−0·55
CAPS-5 criterion D (cognition and mood symptoms; items 8–14; range 0–28)					
Baseline	17·75 (5·30); n=150	17·87 (5·11); n=154	..	..	..
Month 4	15·63 (6·64); n=107	15·02 (5·97); n=115	−0·94 (0·64; −2·20 to 0·32)	0·14	−0·18
Month 9	15·30 (7·10); n=117	11·81 (7·12); n=126	−3·47 (0·86; −5·15 to −1·80)	<0·0001	−0·67
CAPS-5 criterion E (arousal and reactivity symptoms; items 15–20; range 0–24)					
Baseline	12·31 (3·84); n=150	12·44 (4·12); n=154	..	..	..
Month 4	10·71 (4·83); n=106	10·20 (4·69); n=115	−0·64 (0·49; −1·59 to 0·31)	0·19	−0·16
Month 9	10·03 (4·97); n=117	8·59 (6·04); n=125	−1·59 (0·71; −2·95 to −0·17)	0·028	−0·39
ITQ: PTSD severity (range 0–24)					
Baseline	17·38 (4·53); n=151	17·89 (4·15); n=150	..	..	..
Month 4	15·31 (5·72); n=65	14·14 (5·10); n=63	−1·43 (0·60; −2·62 to −0·25)	0·018	−0·33
Month 9	14·15 (6·44); n=98	11·10 (6·96); n=105	−3·55 (0·82; −5·16 to −1·95)	<0·0001	−0·82
ITQ: DSO severity (range 0–24)					
Baseline	18·14 (4·80); n=151	18·63 (4·52); n=150	..	..	..
Month 4	16·22 (5·31); n=65	15·83 (5·69); n=63	−0·84 (0·73; −2·27 to 0·59)	0·25	−0·18
Month 9	15·05 (6·50); n=98	11·86 (7·10); n=105	−3·33 (0·82; −4·94 to −1·72)	0·0001	−0·71
PTCI-9 (range 1–7)					
Baseline	4·83 (1·11); n=151	4·79 (1·10); n=151	..	..	..
Month 4	4·54 (1·39); n=61	4·28 (1·22); n=59	−0·23 (0·16; −0·54 to 0·09)	0·17	−0·20
Month 9	4·32 (1·45); n=99	3·63 (1·46); n=104	−0·62 (0·15; −0·92 to −0·32)	0·0001	−0·56
DSPS: derealisation and depersonalisation (range 0–7)					
Baseline	2·47 (2·40); n=145	2·48 (2·39); n=148	..	..	..
Month 4	1·86 (2·11); n=59	1·62 (2·09); n=55	−0·07 (0·32; −0·70 to 0·56)	0·82	−0·03
Month 9	1·92 (2·27); n=93	1·50 (2·15); n=101	−0·33 (0·22; −0·77 to 0·11)	0·15	−0·14

(Table 3 continues on next page)

	Treatment as usual	Trauma-focused CBTp plus treatment as usual	Adjusted mean difference (SE; 95% CI)	p value	Cohen's *d* effect size
(Continued from previous page)					
DSPS: loss of awareness (range 0-6)					
Baseline	2·48 (1·99); n=146	2·41 (1·95); n=148	..	..	..
Month 4	1·92 (1·94); n=59	1·60 (1·74); n=55	−0·15 (0·28; −0·69 to 0·39)	0·58	−0·08
Month 9	2·01 (1·87); n=93	1·37 (1·76); n=102	−0·51 (0·20; −0·90 to −0·12)	0·0098	−0·26
DSPS: psychogenic amnesia (range 0–2)					
Baseline	0·84 (0·92); n=143	0·87 (0·91); n=142	..	..	..
Month 4	0·64 (0·88); n=56	0·67 (0·90); n=55	0·02 (0·14; −0·24 to 0·29)	0·86	0·03
Month 9	0·72 (0·89); n=92	0·55 (0·85); n=97	−0·24 (0·09; −0·42 to −0·06)	0·0093	−0·26
Psychosis†					
PSYRATS: delusions (range 0–24)					
Baseline	16·83 (3·24); n=122	17·32 (2·88); n=128	..	..	..
Month 4	13·90 (6·37); n=79	14·28 (5·10); n=85	0·08 (0·72; −1·34 to 1·50)	0·91	0·03
Month 9	13·34 (6·60); n=88	12·34 (6·75); n=106	−1·40 (0·71; −2·79 to −0·01)	0·048	−0·46
PSYRATS: voices (range 0–44)					
Baseline	31·09 (5·60); n=119	31·72 (4·96); n=121	..	..	..
Month 4	26·30 (11·04); n=77	26·02 (11·32); n=89	−1·24 (1·34; −3·86 to 1·38)	0·36	−0·23
Month 9	24·94 (12·02); n=83	24·32 (12·61); n=99	−1·46 (1·30; −4·01 to 1·09)	0·26	−0·28
PSYRATS: other modalities (range 0–44)					
Baseline	30·30 (6·70); n=117	30·48 (5·93); n=125	..	..	..
Month 4	20·43 (14·22); n=74	23·37 (13·03); n=83	3·16 (1·72; −0·21 to 6·52)	0·07	0·50
Month 9	23·68 (12·76); n=79	19·33 (13·81); n=100	−4·51 (1·51; −7·46 to −1·55)	0·0028	−0·72
GPTS-R part A (reference; range 0–32)					
Baseline	16·56 (8·57); n=142	19·33 (9·09); n=141	..	..	..
Month 4	13·87 (9·16); n=46	15·13 (8·90); n=38	−0·51 (1·41; −3·27 to 2·26)	0·72	−0·06
Month 9	13·03 (9·57); n=90	12·54 (9·49); n=96	−1·43 (1·16; −3·70 to 0·83)	0·22	−0·16
GPTS-R part B (persecution; range 0–40)					
Baseline	21·38 (11·77); n=141	25·21 (11·49); n=141	..	..	..
Month 4	17·02 (13·21); n=45	20·84 (12·26); n=38	0·05 (1·72; -3·32 to 3·42)	0·98	0·00
Month 9	17·27 (12·66); n=90	15·44 (12·28); n=96	−4·58 (1·47; −7·46 to −1·69)	0·0019	−0·39
Mood disorders					
DASS-21: depression (range 0–42)					
Baseline	29·07 (9·96); n=149	30·73 (9·79); n=147	..	..	..
Month 4	25·64 (12·58); n=61	25·26 (11·64); n=57	−2·25 (1·50; −5·20 to 0·70)	0·14	−0·23
Month 9	24·26 (12·69); n=99	20·45 (13·26); n=102	−4·33 (1·72; −7·69 to −0·96)	0·012	−0·44
DASS-21: anxiety (range 0–42)					
Baseline	24·43 (10·87); n=149	26·23 (10·41); n=146	..	..	..
Month 4	20·89 (10·64); n=61	21·16 (11·18); n=57	−0·74 (1·26; −3·22 to 1·74)	0·56	−0·07
Month 9	21·68 (11·84); n=99	18·57 (11·18); n=101	−3·47 (1·43; −6·27 to −0·67)	0·015	−0·33
DASS-21: stress (range 0–42)					
Baseline	28·35 (9·79); n=149	30·54 (8·55); n=147	..	..	..
Month 4	23·61 (11·36); n=61	25·40 (10·43); n=57	0·97 (1·31; −1·60 to 3·53)	0·46	0·10
Month 9	23·80 (11·29); n=99	21·84 (11·47); n=102	−3·21 (1·49; −6·13 to −0·28)	0·032	−0·35
Adapted Paykel Suicidal Feelings Scale (range 0–5)					
Baseline	2·41 (1·44); n=143	2·55 (1·55); n=139	..	..	..
Month 4	2·33 (1·49); n=58	1·79 (1·66); n=52	−0·41 (0·23; −0·86 to 0·03)	0·07	−0·28
Month 9	2·02 (1·67); n=94	1·50 (1·64); n=103	−0·53 (0·21; −0·94 to −0·13)	0·011	−0·36
Brief ASSIST composite (range 0–60)					
Baseline	5·99 (5·62); n=143	6·17 (5·24); n=140	..	..	..
Month 4	5·11 (5·24); n=47	8·26 (5·79); n=43	0·88 (0·64; −0·38 to 2·14)	0·17	0·16
Month 9	5·66 (5·05); n=93	5·79 (5·03); n=94	−0·25 (0·37; −0·98 to 0·48)	0·50	−0·05

(Table 3 continues on next page)

	Treatment as usual	Trauma-focused CBTp plus treatment as usual	Adjusted mean difference (SE; 95% CI)	p value	Cohen's *d* effect size
(Continued from previous page)					
Psychological recovery					
CHOICE (range 0–10; higher scores indicate better outcomes)‡					
Baseline	3·55 (1·70); n=141	3·73 (1·80); n=140	..	..	..
Month 4	4·18 (2·00); n=44	4·75 (1·89); n=39	0·52 (0·28; –0·04 to 1·08)	0·067	0·30
Month 9	4·53 (1·81); n=87	5·66 (2·19); n=92	0·91 (0·26; 0·40 to 1·42)	0·0005	0·52
Social and occupational functioning					
Personal and Social Performance Scale (range 0–100; higher scores indicate higher functioning)‡					
Baseline	45·42 (17·53); n=136	47·63 (16·72); n=142	..	..	..
Month 4	51·06 (16·33); n=54	51·11 (17·15); n=46	0·36 (3·27; –6·04 to 6·76)	0·91	0·02
Month 9	53·73 (20·62); n=88	59·42 (19·52); n=81	3·70 (2·80; –1·79 to 9·19)	0·19	0·22

Data are mean (SD), unless otherwise indicated. Higher scores indicate greater severity of symptoms, unless otherwise specified. CBTp=cognitive behavioural therapy for psychosis. CAPS-5=clinician-administered PTSD scale for DSM-5. PTSD=post-traumatic stress disorder. DSO=disturbances in self-organisation. DSPS=Dissociative Subtype of Post-traumatic Stress Scale. PTCI-9=Brief version of the Posttraumatic Cognitions Inventory. PSYRATS=Psychotic Symptom Rating Scales. GPTS-R=Green et al Paranoid Thoughts Scale–Revised. DASS-21=Depression Anxiety Stress Scale. ASSIST=Alcohol, Smoking and Substance Involvement Screening Test. CHOICE=Choice of Outcome in CBT for Psychoses. *One participant's baseline CAPS-5 score was missing (data file was corrupted) and the missing value was imputed for the primary outcome measure by replacing with the mean. †The PSYRATS was only administered to those who reported presence of that symptom (delusions present n=250, voices present n=244; and hallucinations in other modalities present n=255). Differences with numbers reported in cells include missing data. PSYRATS-Continuous version scores and analyses are provided in the appendix (p 19), as they followed the same pattern as the standard version. ‡These variables have been reversed in figure 2.

Table 3: **Summary statistics of outcomes by group and timepoint and estimated treatment effects**

Total CAPS-5 scores were significantly more reduced in the trauma-focused-CBTp group compared with treatment as usual after therapy, with a moderate-to-large effect size (Cohen's *d* –0·73, 95% CI –1·13 to –0·33; figure 2). Both groups showed improvements at the 4-month timepoint, but only the therapy group continued to improve, while scores in the treatment-as-usual group plateaued (figure 3). Secondary outcome analyses consistently favoured the therapy group, showing a similar trajectory to the primary outcome (appendix pp 20–24). Overall, 22 (81%) of 27 outcomes were significantly different between groups at p<0·05 (effect size range for significant effects –0·26 to –0·82; figure 2).

All PTSD secondary outcomes except for depersonalisation and derealisation showed significantly greater reductions in the trauma-focused CBTp group compared with treatment as usual, with small to large effect sizes (Cohen's *d* –0·40 to –0·67 for CAPS-5 symptom clusters, –0·71 [95% CI –1·06 to –0·37] for disturbances of self-organisation [ITQ subscale], –0·82 [95% CI –1·19 to –0·45] for PTSD [ITQ subscale], –0·32 [95% CI –0·84 to –0·29] for post-traumatic cognitions, –0·26 [95% CI –0·46 to –0·06] for loss of awareness, and –0·26 [95% CI –0·46 to –0·06] for psychogenic amnesia).

All PTSD binary outcomes showed highly significant treatment effects (table 4). 62 (50%) of 125 participants in the trauma-focused CBTp group no longer met PTSD criteria following therapy, compared with 25 (22%) of 116 in the treatment-as-usual group (OR 0·11 [95% CI 0·03 to 0·32]; number needed to treat 4; absolute risk reduction 28%). 56 (45%) of 125 participants showed a clinically significant change (≥15 reduction in CAPS-5 scores) in therapy compared with 31 (27%) of 116 in treatment as usual. There were reductions of 50% and 56% between baseline and 9 months in the number of participants in the therapy group meeting criteria for the dissociative subtype of PTSD (on CAPS-5) and complex PTSD criteria (on the ITQ), respectively, compared with 18% and 28% reductions in the treatment-as-usual group.

Two of the three PSYRATS subscales showed significantly greater reductions in the trauma-focused CBTp group compared with treatment as usual (Cohen's *d* for delusions –0·46 [95% CI –0·91 to 0·00] and –0·72 [95% CI –1·18 to –0·25] for hallucinations in other modalities). The scores for hearing voices were reduced in both groups, with no significant group effect (Cohen's *d* –0·28, 95% CI –0·76 to 0·21). Scores for persecutory (Cohen's *d* –0·39, 95% CI –0·63 to –0·14) but not referential beliefs (–0·16, 95% CI –0·41 to 0·09) showed significantly greater reductions in the therapy group compared with treatment as usual (table 3).

All mood disorders and psychological recovery treatment effects were significant (Cohen's *d* –0·33 to –0·52), apart from substance use (–0·05, 95% CI –0·18 to 0·09) and social and occupational functioning (–0·22, 95% CI –0·54 to 0·10; table 3).

306 adverse events were reported in 164 (54%) participants (72 [57%] of 127 men in the trial, 88 [52%] of 171 women, and four [57%] of seven non-binary or prefer not to say; appendix pp 25–29). 165 of these events were serious adverse events, reported across 105 (34%) participants (40 [32%] of 127 men, 61 [36%] of 171 women, and four [57%] of seven non-binary or prefer not to say). The most common serious adverse event type was

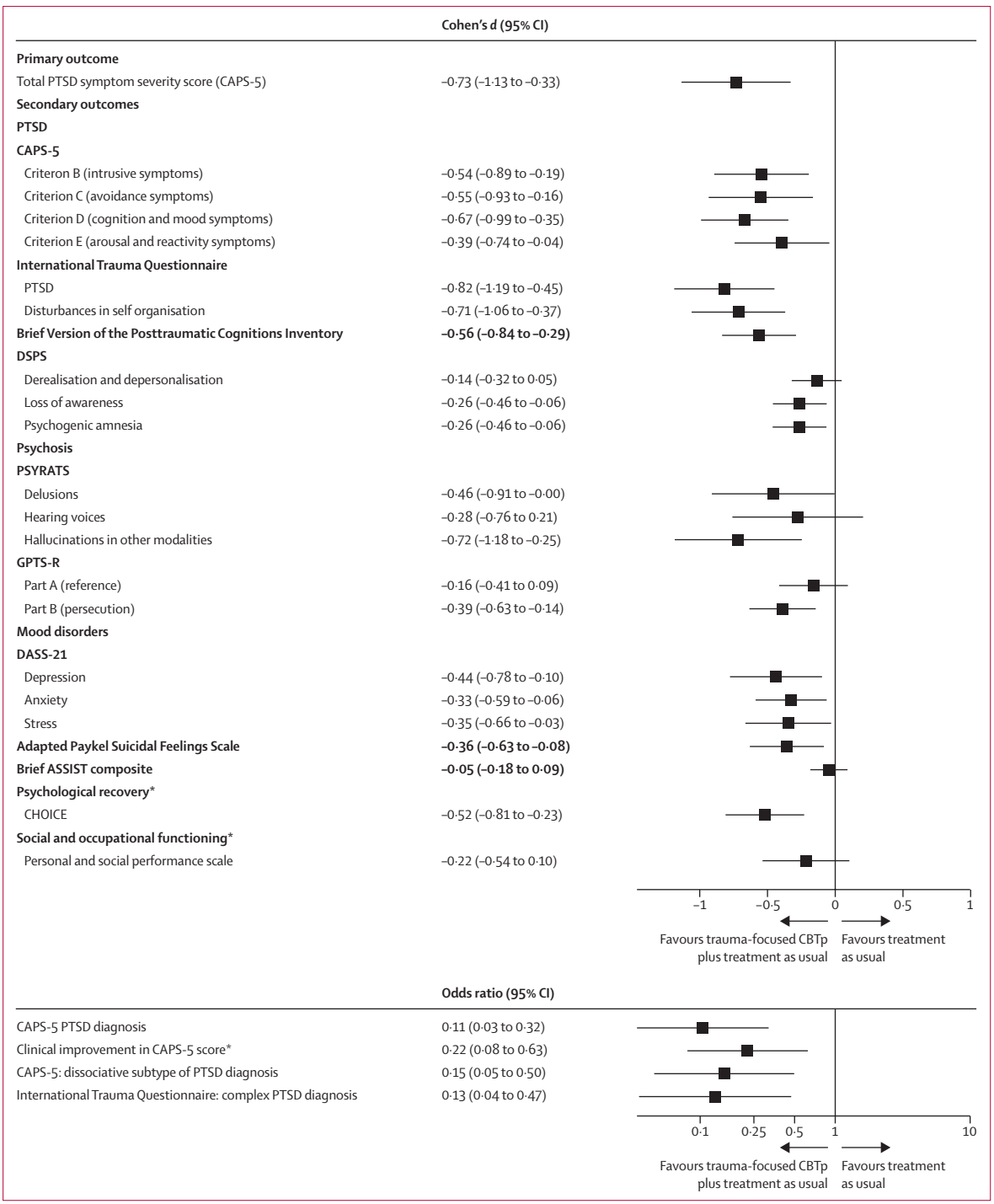

***Figure 2*: Forest plot of primary and secondary outcomes**
ASSIST=Alcohol, Smoking and Substance Involvement Screening Test. CAPS-5=clinician-administered PTSD scale for DSM-5. CBTp=cognitive behavioural therapy for psychosis. CHOICE=Choice of Outcome in CBT for Psychoses. DASS-21=Depression Anxiety Stress Scale. DSPS=Dissociative Subtype of Post-traumatic Stress Scale. GPTS-R=Green et al Paranoid Thoughts Scale–Revised. PTSD=post-traumatic stress disorder. PSYRATS=Psychotic Symptom Rating Scales. *These variables have been reversed.

physical illness or injury (60 [36%]). There were equal numbers of serious adverse events in each group: 78 in 52 (34%) participants in the trauma-focused CBTp group and 78 in 47 (31%) participants in treatment as usual. Logistic regression analysis showed no effects of gender (men and women only due to small number in binary or prefer not

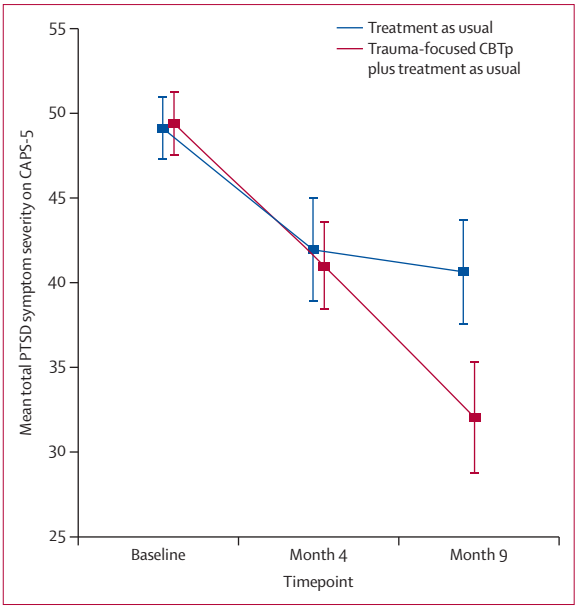

Figure 3: **Observed trajectory for primary outcome (CAPS-5 score) at 4 months and 9 months in both groups**
Error bars represent 95% CIs. CAPS-5=clinician-administered PTSD scale for DSM-5. CBTp=cognitive behavioural therapy for psychosis. PTSD=post-traumatic stress disorder.

	Treatment as usual	Trauma-focused CBTp plus treatment as usual	Odds ratio (95% CI)	p value
CAPS-5: PTSD diagnosis				
Baseline	151/151 (100%)	154/154 (100%)	..	..
Month 4	85/107 (79%)	89/115 (77%)	0·81 (0·50–2·17)	0·68
Month 9	91/116 (78%)	63/125 (50%)	0·11 (0·03–0·32)	0·0001
Clinical improvement in the CAPS-5*				
Baseline	..	..	..	..
Month 4	27/106 (26%)	29/115 (25%)	0·99 (0·34–2·87)	0·98
Month 9	31/116 (27%)	56/125 (45%)	4·45 (1·59– 12·44)	0·0044
CAPS-5: dissociative subtype of PTSD diagnosis				
Baseline	101/150 (67%)	101/154 (66%)	..	..
Month 4	56/106 (53%)	56/113 (50%)	0·72(0·27–1·94)	0·52
Month 9	63/114 (55%)	41/123 (33%)	0·15 (0·05–0·50)	0·0019
International Trauma Questionnaire: complex PTSD diagnosis				
Baseline	119/151 (79%)	122/150 (81%)	..	..
Month 4	40/65 (62%)	34/63 (54%)	0·56 (0·14–2·31)	0·42
Month 9	55/97 (57%)	38/105 (36%)	0·13 (0·04–0·47)	0·0020

Data are n/N (%), unless otherwise specified. CAPS-5=clinician-administered PTSD scale for DSM-5. CBTp=cognitive behavioural therapy for psychosis. PTSD=post-traumatic stress disorder. *This variable is reversed in figure 2.

Table 4: **Summary statistics of binary outcomes by group and timepoint and estimated treatment effects**

to say group; OR 1·33 [95% CI 0·66–2·70]; p=0·42) or treatment group (1·57 [0·82–2·99]; p=0·17), and no significant gender–treatment interaction (0·47 [0·17–1·28]; p=0·14) in predicting serious adverse events. The remaining nine serious adverse events (nine [3%] participants) occurred between consent and randomisation (three of these participants had additional serious adverse events after randomisation, hence total number of participants reporting a serious adverse event being less than the sum of the two groups plus pre-randomisation). None were rated as both unexpected and related to trial procedures.

Prespecified secondary analyses using instrumental-variable methods to account for non-adherence and control group contamination corroborated the primary intention-to-treat findings, as did a mean score approach allowing for missing-not-at-random outcome data using RCTMISS in Stata (appendix pp 30–32).

Post-hoc analyses comparing the trauma-focused CBTp group with treatment-as-usual subgroups receiving different types of psychological therapies would be invalid as receipt of concomitant therapies is a non-random, post-randomisation variable. Descriptive data for each subgroup, compared with the full treatment-as-usual sample, are provided in the appendix (p 33), showing that CAPS-5 means of all treatment-as-usual subgroups (receiving CBTp, trauma-informed therapies, any therapy apart from trauma-focused therapy, or no therapy) were similar to the full treatment-as-usual sample, with the exception of those who received trauma-focused therapy, whose scores were closer to those of the trauma-focused-CBTp group.

Discussion

STAR is the largest RCT to date to investigate a trauma-focused therapy integrated with CBTp (trauma-focused CBTp) in people with distressing psychosis and PTSD symptoms. The primary hypothesis was supported, with a greater reduction in PTSD symptom severity in trauma-focused CBTp plus treatment as usual compared with treatment as usual at 9 months (moderate-to-large effect size of –0·73). There were significant treatment effects for all PTSD symptom clusters, post-traumatic cognitions, two of three dissociation measures, remission from PTSD diagnosis (including dissociative subtype and complex PTSD), and clinically significant change, similar to findings from studies of military veterans without psychosis.[46] These findings were robust, with significant effects on both the primary observer-rated clinical assessment of PTSD (CAPS-5) and the secondary self-reported measure (ITQ) of core PTSD (large effect size) and complex PTSD (moderate-to-large effect size). Importantly, the therapy was safe and highly acceptable, with no iatrogenic effects, evidenced by high therapy adherence, low disengagement rate, and no unexpected and related serious adverse events.

Small to moderate-to-large effects were found for most secondary outcomes, including psychosis symptoms (delusions, paranoia, and hallucinations in other modalities), mood disorders (depression, anxiety, stress, and suicidal ideation), and psychological recovery. The trajectory for most secondary outcomes was similar to that of PTSD symptoms, with the therapy group showing

greater improvement compared with the treatment-as-usual group from 4 months onwards, potentially coinciding with the delivery of phase 3 model-based interventions (appendix pp 4–5). The secondary outcomes that did not show a difference (voices, ideas of reference, and social functioning) improved in both groups, except substance use, which showed no reduction in either group.

The sample was representative of people with complex mental health presentations who are help-seeking for distressing psychosis, PTSD, and other comorbid symptoms, with scores on PTSD and psychosis measures similar to or worse than comparable trials,[47–49] suggesting that the findings are generalisable to clinical populations in front-line mental health services. However, the results need to be interpreted within the context of several study limitations. There was no active control condition, since STAR was a pragmatic, effectiveness trial aiming to investigate the real-world, comparative benefits of trauma-focused CBTp over standard care in routine practice. No long-term follow-up data are reported, since the primary research question was to assess the effects of trauma-focused CBTp at the end of therapy. Psychosis diagnoses may have been unreliable since formal diagnostic interviews were not used. Variability in how psychosis diagnoses were confirmed may have increased the diagnostic heterogeneity of the sample which, although reflecting the range of schizophrenia-spectrum disorders, had fewer participants with schizophrenia (F20) diagnoses than previous trials.[13,14] The therapy was delivered by experienced therapists trained to competence who had access to expert clinical supervision, which does not necessarily reflect general mental health services.

The 9-month duration of trauma-focused CBTp could be problematic for implementation, although NICE recommend more than 12 sessions for PTSD related to complex or multiple trauma exposure,[50] and more than 16 sessions for CBTp,[51] so integrating the two therapies reduces therapy duration. Nevertheless, trauma-focused CBTp is considerably longer than the highly protocolised PTSD therapies used in the Dutch trial[13] (prolonged exposure and eye movement desensitisation and reprocessing [EMDR]), which consisted of eight weekly 90-min sessions over 10 weeks, with similar effect sizes to trauma-focused CBTp on PTSD symptom severity (–0·78 and –0·65). However, effect sizes are not intrinsic to an intervention but reflect the intervention's interaction with the context in which it is delivered.[52] The relevant contextual parameters here are the population, comparison group, and service setting. The psychosis inclusion criterion in the Dutch trial was a lifetime psychosis diagnosis, without requiring the presence of psychosis symptoms, and the trial had a wait-list control group rather than treatment as usual. Crucially, the Dutch study's mental health system was reported to be well resourced, with substantive access to multi-disciplinary support, facilitating the feasibility of a brief, targeted intervention. By contrast, STAR participants often had limited multidisciplinary support, as evidenced by the minimal number of sessions delivered with a care coordinator (13 [0·4%] of 3613 attended sessions), resulting in unmet needs that had to be addressed as part of the therapy. Lastly, the longer therapy duration enabled therapists to deliver a minimal therapy dose to 95% of the full therapy sample and trauma-focused interventions to 85% of those who engaged in therapy (94% of the full therapy sample). Based on our adherence data showing only 58% (83 of 144 engagers) received a booster session, mostly because of therapy lasting longer than the planned 6 months (appendix p 7), we would actually recommend the therapy window be increased to 12 months, to allow the inclusion of 3-monthly booster sessions to consolidate therapeutic gains, in addition to 9 months of trauma-focused CBTp.

The effect of trauma-focused CBTp across several meaningful clinical and functional outcomes is in line with our integrated therapy approach,[18,19] which draws on cognitive-behavioural models of psychosis and PTSD to assess, formulate, and intervene collaboratively with a range of potential therapy targets and their interaction.[32] The results are also consistent with theoretical accounts[5] and empirical studies showing a link between trauma sequelae and psychosis symptoms.[53,54]

The lack of effect on voices was unexpected, given the large effects shown previously with imagery rescripting, a trauma-focused strategy,[55] but was consistent with a meta-analysis reporting significant effects for delusions but not voices.[11] Although trauma sequelae are hypothesised to interact with voice hearing, potentially the therapeutic strategies did not focus enough on their maintaining mechanisms or therapists did not provide a sufficient dose, or participants' voices did not show the hypothesised links with their index trauma, unlike hallucinations in other modalities where underlying shared mechanisms may have been more prominent. However, voice severity improved in both groups in the present study, so the non-significant effect could have been due to a treatment focus on voices in psychosis services, which may not apply to hallucinations in other modalities, which tend to be neglected.[16]

The reduction in suicidality, alongside mood disorders, added to the safety profile of the therapy, even in the presence of severe psychosis symptoms. This finding is important because clinician and patient avoidance of emotionally demanding trauma-focused work and concerns about iatrogenic harm have been barriers to addressing trauma sequelae in this population. Notably, disengagement rates, even if adding those who had a therapist-defined unplanned ending (23 [15%] of 154 participants) were lower than the anticipated 25% based on previous similar trials,[13,46] likely due to the integration of therapeutic strategies to support management of psychosis symptoms, as well as a focus on engagement throughout.[18,19,32] Furthermore, we

adopted a flexible approach to stabilisation (ie, as much as needed, as little as necessary), by contrast with other trauma-focused approaches for complex populations where stabilisation is either omitted[13] or included as a distinct phase.[46] Our approach of tailoring the dose of coping strategies on the basis of collaborative formulation and shared decision making, interwoven with trauma-focused work on memories and beliefs, may have supported individuals' sustained engagement. This finding suggests personalised, flexible protocol delivery is required to optimise engagement in trauma therapies for severe mental health conditions.

Whether therapeutic gains are maintained (assessed 24 months after randomisation) is a secondary research question, to be reported separately. Although additional, shorter follow-up intervals might have offered some benefits, these were outweighed by associated assessment burden and potential detrimental effects to the 24-month follow-up rates. Further work to identify potential moderators of outcome, understand mechanisms of change, stakeholder perspectives, and cost-effectiveness will also be reported in adjunct studies. Only a superiority RCT, matching levels of therapist expertise and supervision across groups, can reveal whether trauma-focused CBTp is more effective than already available trauma-informed therapies (such as CBTp) or other trauma-focused interventions. Further work is required to develop and evaluate scalable implementation models of trauma-focused CBTp.

In conclusion, the robust findings of this large, multisite RCT of trauma-focused CBTp for people with distressing psychosis and PTSD symptoms show that the intervention is safe, highly acceptable, and effective on a range of PTSD, psychosis, and mood disorders outcomes. The integrated PTSD and psychosis therapy protocol, focus on engagement, and flexible approach to stabilisation may have facilitated adherence to therapy, with very low disengagement rates. These findings challenge the exclusion of people with psychosis symptoms from trauma services and clinical trials, who should no longer be denied access to psychological interventions to treat their trauma sequelae.

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Contributors

EP, RE, and HJ had full access to the study data and take responsibility for the integrity of the data and the accuracy of the analyses. EP, AH, FV, RD, KG, CS, AM, NK, and RE contributed to study conception and design. EP, HJ, SS, RU, RE, FV, RD, CS, KG, AH, and AM contributed to acquisition, analysis, or interpretation of data. EP took responsibility for the main drafting of the paper, apart from the Discussion, which was drafted by AH; HJ took responsibility for the Results section. All authors contributed to critical revision of the manuscript for important intellectual content and had final responsibility for the decision to submit for publication. HJ and RE contributed to the statistical analysis. EP, AH, FV, RD, KG, CS, AM, RE, SB, and NK obtained funding. SS, RU, and all STAR group members contributed to administrative, technical, or material support. AH, NK, SB, RD, and CS contributed to clinical supervision.

Declaration of interests

EP, SS, RU, FV, CS, RD, KG, NK, SB, AH, and AM provide psychological therapies for individuals with psychosis or PTSD in NHS settings. EP is the director, NK the coordinator, and AH the Trauma Informed Care lead of a psychological therapies specialist service for psychosis (Psychological Interventions Clinic for outpatients with Psychosis [PICuP]). CS, AM, NK, RD, and KG have written manuals for psychological therapies for psychosis and psychological formulation for which they receive book royalties (from APPI, Guildford Press, Wiley, Routledge, and New Harbinger). EP, AH, RD, FV, KG, CS, SB, NK, and AM are employed to provide training or receive fees (or generate fees for their clinics or research units) for workshops and presentations on psychological therapies for psychosis or PTSD. EP, AH, RD, FV, KG, CS, RE, and AM hold or have held grants to carry out trials of psychological therapy for individuals with psychosis. HJ declares no competing interests.

Data sharing

An anonymised version of the main outcome data and the corresponding statistical code are available from the trial team after publication of the main results paper, following review of appropriateness of request by the trial team.

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References

1 Flinn A, Hefferman-Clarke R, Parker S, et al. Cumulative exposure to childhood adversity and risk of adult psychosis: a dose-response meta-analysis. *Psychol Med* 2025; **55:** e162.

2 Zhou L, Sommer IEC, Yang P, et al. What do four decades of research tell us about the association between childhood adversity and psychosis: an updated and extended multi-level meta-analysis. *Am J Psychiatry* 2025; **182:** 360–72.

3 Grubaugh AL, Zinzow HM, Paul L, Egede LE, Frueh BC. Trauma exposure and posttraumatic stress disorder in adults with severe mental illness: a critical review. *Clin Psychol Rev* 2011; **31:** 883–99.

4 de Bont PA, van den Berg DP, van der Vleugel BM, et al. Predictive validity of the Trauma Screening Questionnaire in detecting post-traumatic stress disorder in patients with psychotic disorders. *Br J Psychiatry* 2015; **206:** 408–16.

5 Hardy A. Pathways from trauma to psychotic experiences: a theoretically informed model of posttraumatic stress in psychosis. *Front Psychol* 2017; **8:** 697.

6 Steel C, Fowler D, Holmes EA. Trauma-related intrusions and psychosis: an information processing account. *Behav Cogn Psychother* 2005; **33:** 139–52.

7 Hassan AN, De Luca V. The effect of lifetime adversities on resistance to antipsychotic treatment in schizophrenia patients. *Schizophr Res* 2015; **161:** 496–500.

8 Seow LSE, Ong C, Mahesh MV, et al. A systematic review on comorbid post-traumatic stress disorder in schizophrenia. *Schizophr Res* 2016; **176:** 441–51.

9 Gairns S, Alvarez-Jimenez M, Hulbert C, McGorry P, Bendall S. Perceptions of clinicians treating young people with first-episode psychosis for post-traumatic stress disorder. *Early Interv Psychiatry* 2015; **9:** 12–20.

10 Ronconi JM, Shiner B, Watts BV. Inclusion and exclusion criteria in randomized controlled trials of psychotherapy for PTSD. *J Psychiatr Pract* 2014; **20:** 25–37.

11 Toutountzidis D, Ricketts E, Laws KR. Trauma-focused psychological interventions for psychosis: meta-analytic evidence of differential effects on delusions and hallucinations. *Psychol Med* 2026; **56:** e11.

12 Niemeyer H, Opper F, Sabé M, Holmes EA, Böge K. Psychological interventions for persons with co-occurring psychotic and traumatic-stress symptoms: a systematic review and meta-analysis. *Schizophr Bull* 2026; **52:** sbaf185.

13 van den Berg DP, de Bont PA, van der Vleugel BM, et al. Prolonged exposure *vs* eye movement desensitization and reprocessing vs waiting list for posttraumatic stress disorder in patients with a psychotic disorder: a randomized clinical trial. *JAMA Psychiatry* 2015; **72:** 259–67.

14 Steel C, Hardy A, Smith B, et al. Cognitive-behaviour therapy for post-traumatic stress in schizophrenia. A randomized controlled trial. *Psychol Med* 2017; **47:** 43–51.

15 O'Driscoll C, Mason O, Brady F, Smith B, Steel C. Process analysis of trauma-focused cognitive behavioural therapy for individuals with schizophrenia. *Psychol Psychother* 2016; **89:** 117–32.

16 Toh WL, McCarthy-Jones S, Copolov D, Rossell SL. Have we overlooked the significance of multinodal hallucinations in schizophrenia? *Psychiatry Res* 2019; **279:** 358–60.

17 Morrison AP, Frame L, Larkin W. Relationships between trauma and psychosis: a review and integration. *Br J Clin Psychol* 2003; **42:** 331–53.

18 Hardy A, Good S, Dix J, Longden E. "It hurt but it helped": a mixed methods audit of the implementation of trauma- focused cognitive-behavioral therapy for psychosis. *Front Psychiatry* 2022; **13:** 946615.

19 Keen N, Hunter ECM, Peters E. Integrated trauma-focused cognitive-behavioural therapy for post-traumatic stress and psychotic symptoms: a case-series study using imaginal reprocessing strategies. *Front Psychiatry* 2017; **8:** 92.

20 Clarke R, Kelly R, Hardy A. A randomised multiple baseline case series of a novel imagery rescripting protocol for intrusive trauma memories in people with psychosis. *J Behav Ther Exp Psychiatry* 2022; **75:** 101699.

21 Varese F, Douglas M, Dudley R, et al. Targeting dissociation using cognitive behavioural therapy in voice hearers with psychosis and a history of interpersonal trauma: a case series. *Psychol Psychother* 2021; **94:** 247–65.

22 Harned MS, Korslund KE, Foa EB, Linehan MM. Treating PTSD in suicidal and self-injuring women with borderline personality disorder: development and preliminary evaluation of a dialectical behavior therapy prolonged exposure protocol. *Behav Res Ther* 2012; **50:** 381–86.

23 Mills KL, Teesson M, Back SE, et al. Integrated exposure-based therapy for co-occurring posttraumatic stress disorder and substance dependence: a randomized controlled trial. *JAMA* 2012; **308:** 690–99.

24 Brand RM, Bendall S, Hardy A, Rossell SL, Thomas N. Trauma-focused imaginal exposure for auditory hallucinations: a case series. *Psychol Psychother* 2021; **94** (suppl 2)**:** 408–25.

25 Peters E, Hardy A, Dudley R, et al. Multisite randomised controlled trial of trauma-focused cognitive behaviour therapy for psychosis to reduce post-traumatic stress symptoms in people with co-morbid post-traumatic stress disorder and psychosis, compared to treatment as usual: study protocol for the STAR (Study of Trauma And Recovery) trial. *Trials* 2022; **23:** 429.

26 Grant S, Mayo-Wilson E, Montgomery P, et al. CONSORT-SPI 2018 explanation and elaboration: guidance for reporting social and psychological intervention trials. *Trials* 2018; **19:** 406.

27 Janca A, Hiller W. ICD-10 checklists--a tool for clinicians' use of the ICD-10 classification of mental and behavioral disorders. *Compr Psychiatry* 1996; **37:** 180–87.

28 Haddock G, McCarron J, Tarrier N, Faragher EB. Scales to measure dimensions of hallucinations and delusions: the psychotic symptom rating scales (PSYRATS). *Psychol Med* 1999; **29:** 879–89.

29 Rodrigues R, Anderson KK. The traumatic experience of first-episode psychosis: a systematic review and meta-analysis. *Schizophr Res* 2017; **189:** 27–36.

30 Carr S, Hardy A, Fornells-Ambrojo M. The Trauma and Life Events (TALE) checklist: development of a tool for improving routine screening in people with psychosis. *Eur J Psychotraumatol* 2018; **9:** 1512265.

31 Weathers FWBD, Schnjurr PP, Kaloupek DG, Marx BP, Keane TM. The clinician-administered PTSD scale for DSM-5 (CAPS-5). National Center for PTSD, 2013.

32 Hardy A, Keen N, van den Berg D, et al. Trauma therapies for psychosis: a state-of-the-art review. *Psychol Psychother* 2024; **97:** 74–90.

33 Cloitre M, Shevlin M, Brewin CR, et al. The International Trauma Questionnaire: development of a self-report measure of ICD-11 PTSD and complex PTSD. *Acta Psychiatr Scand* 2018; **138:** 536–46.

34 Wells SY, Morland LA, Torres EM, Kloezeman K, Mackintosh M-A, Aarons GA. The development of a brief version of the Posttraumatic Cognitions Inventory (PTCI-9). *Assessment* 2019; **26:** 193–208.

35 Wolf EJ, Mitchell KS, Sadeh N, et al. The dissociative subtype of PTSD scale: initial evaluation in a national sample of trauma-exposed veterans. *Assessment* 2017; **24:** 503–16.

36 Tsang W. Psychometric validation of an adapted self-rated version of the PSYRATS. King's College London, 2023.

37 Freeman D, Loe BS, Kingdon D, et al. The revised Green et al Paranoid Thoughts Scale (R-GPTS): psychometric properties, severity ranges, and clinical cut-offs. *Psychol Med* 2021; **51:** 244–53.

38 Lovibond PF, Lovibond SH. The structure of negative emotional states: comparison of the Depression Anxiety Stress Scales (DASS) with the Beck Depression and Anxiety Inventories. *Behav Res Ther* 1995; **33:** 335–43.

39 Paykel ES, Myers JK, Lindenthal JJ, Tanner J. Suicidal feelings in the general population: a prevalence study. *Br J Psychiatry* 1974; **124:** 460–69.

40 WHO ASSIST Working Group. The alcohol, smoking and substance involvement screening test (ASSIST): development, reliability and feasibility. *Addiction* 2002; **97:** 1183–94.

41 Hides L, Cotton SM, Berger G, et al. The reliability and validity of the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) in first-episode psychosis. *Addict Behav* 2009; **34:** 821–25.

42 Webb R, Bartl G, James B, et al. Exploring the development, validity, and utility of the short-form version of the Choice of Outcome In CBT for Psychoses: a patient-reported outcome measure of psychological recovery. *Schizophr Bull* 2021; **47:** 653–61.

43 Patrick DL, Burns T, Morosini P, et al. Reliability, validity and ability to detect change of the clinician-rated Personal and Social Performance scale in patients with acute symptoms of schizophrenia. *Curr Med Res Opin* 2009; **25:** 325–38.

44 Hopewell S, Chan A-W, Collins GS, et al. CONSORT 2025 explanation and elaboration: updated guideline for reporting randomised trials. *BMJ* 2025; 389.

45 NHS England. Implementing the early intervention in psychosis access and waiting time standard: guidance. London: NHS England, 2016.

46 Milligan T, Smolenski D, Lara-Ruiz J, Kelber MS. Loss of PTSD diagnosis in response to evidence-based treatments: a systematic review and meta-analysis. *JAMA Psychiatry* 2025; **82:** 718–27.

47 Oprel DAC, Hoeboer CM, Schoorl M, et al. Effect of prolonged exposure, intensified prolonged exposure and STAIR+prolonged exposure in patients with PTSD related to childhood abuse: a randomized controlled trial. *Eur J Psychotraumatol* 2021; **12:** 1851511.

48 Freeman D, Emsley R, Diamond R, et al. Comparison of a theoretically driven cognitive therapy (the Feeling Safe Programme) with befriending for the treatment of persistent persecutory delusions: a parallel, single-blind, randomised controlled trial. *Lancet Psychiatry* 2021; **8:** 696–707.

49 Garety PA, Edwards CJ, Jafari H, et al. Digital AVATAR therapy for distressing voices in psychosis: the phase 2/3 AVATAR2 trial. *Nat Med* 2024; **30:** 3658–68.

50 NICE. Post-traumatic stress disorder (PTSD): the management of PTSD in adults and children in primary and secondary care. London: Gaskell Press, 2005.

51 NICE. Psychosis and schizophrenia in adults: treatment and managment. London: National Institute for Health and Care Excellence, 2014.

52 McGinty EE, Alegria M, Beidas RS, et al. The *Lancet Psychiatry* Commission: transforming mental health implementation research. *Lancet Psychiatry* 2024; **11:** 368–96.

53 Bentall RP, Wickham S, Shevlin M, Varese F. Do specific early-life adversities lead to specific symptoms of psychosis? A study from the 2007 the Adult Psychiatric Morbidity Survey. *Schizophr Bull* 2012; **38:** 734–40.

54 Wearne D, Ayalde J, Curtis G, et al. Visual phenomenology in schizophrenia and post-traumatic stress disorder: an exploratory study. *BJPsych Open* 2022; **8:** e143.

55 Strachan L, McEvoy P, Arntz A, Steel C, Paulik G. Effectiveness of imagery rescripting for trauma-affected voice hearers: an open trial. *Clin Psychol Psychother* 2024; **31:** e3052.