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The Impact of Trauma-Focused Cognitive Behavior Therapy for Psychosis on Post-Traumatic Stress Symptoms in Daily Life: Experience Sampling Methodology Outcomes of the STAR Trial

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Keywords
Post-traumatic stress disorder · Schizophrenia spectrum disorder · Ecological momentary assessment · Experience sampling methodology · Psychological therapy

Abstract
Introduction: People with psychosis have high rates of post-traumatic stress disorder (PTSD). The Study of Trauma And Recovery (STAR) randomized controlled trial found that a trauma-focused cognitive behavior therapy for psychosis (TF-CBTp) added to treatment-as-usual (TAU) reduced PTSD symptoms in people with psychosis compared to TAU only. We hypothesized that TF-CBTp would also reduce PTSD symptoms in daily life, using experience sampling methodology (ESM), which would be associated with improvements on a clinical measure of PTSD. ***Methods:*** Participants were adults with PTSD and schizophrenia

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spectrum diagnoses, a subsample of the STAR trial ($N = 153$; TF-CBTp+TAU = 73, TAU = 80). Participants completed ESM assessments of intrusive memories, hyperarousal, dissociation, avoidance, and negative trauma-related cognitions through a smartphone app multiple times daily over 6 days, at baseline and 9 months post-randomization (end of therapy). ***Results:*** No between-group differences were found in ESM measures of momentary PTSD symptoms at 9 months. Significant timepoint × therapy interactions indicated greater decrease over time in hyperarousal, negative cognitions, and avoidance, and in variability of intrusive memories, in TF-CBTp+TAU compared to TAU. ESM measures at 9 months were significantly associated with improvements on the Clinician-Administered PTSD Scale for DSM-5. ***Conclusion:*** While findings are tentatively in favor of TF-CBTp, the robust reductions in PTSD symptoms found in the STAR trial using retrospective outcome measures were not fully replicated with ESM, suggesting these methodologies may be capturing different features of symptom expression and processes of therapeutic change. Including both approaches in future research could provide a fuller picture of therapy effects on "in-the-moment" versus reflective reports of experiences.
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Plain Language Summary

Many people with psychosis (which can include hearing voices or having beliefs not shared by others) have also experienced trauma and develop post-traumatic stress disorder (PTSD). Symptoms include intrusive memories, feeling on edge (hyperarousal), avoiding reminders of the event, and holding negative beliefs about oneself or others. A talking therapy called trauma-focused cognitive behavior therapy for psychosis (TF-CBTp) was tested in a large trial, the Study of Trauma And Recovery. It found this therapy, combined with usual care, reduced PTSD symptoms more than usual care alone, based on questionnaires and clinician interviews. In this study, we wanted to find out whether the therapy also changed how people experienced PTSD symptoms day-to-day. We used a smartphone app to ask 153 participants about their symptoms several times a day, over 6 days, before therapy started and again 9 months later, once it had finished. We found no difference between the therapy group and the usual care group in day-to-day symptom levels at 9 months. However, the therapy group improved more over time in feeling on edge, avoidance, negative beliefs, and how much intrusive memories varied moment to moment. People whose day-to-day symptoms improved also tended to improve on the clinician-completed measure. These results offer some support for the benefits of TF-CBTp, but the clear improvements seen in the original trial were not fully matched by the smartphone data. This suggests the two methods may capture different aspects of people's experiences; using both together could give a more complete picture of how therapy affects symptoms.
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Introduction

Experiencing trauma is a well-established risk factor for psychosis, linked to its onset, severity, and persistence in a dose-response relationship [1–4]. People with psychosis frequently report extensive trauma histories across their lifespan, often involving multiple forms of adversity, and in particular interpersonal victimization [5]. Rates of post-traumatic stress disorder (PTSD) in this population are markedly elevated – up to five times those observed in the general population – and are associated with worse clinical outcomes [6, 7]. It is therefore vital to develop effective interventions that target PTSD symptoms and associated psychological processes in individuals with psychosis.

Psychosis has historically been a criterion for exclusion from PTSD therapy trials and services [8], often due to concerns about potential iatrogenic harm [9]. However, there is now emerging evidence that trauma-focused therapies can be both safe and effective in this population [10–12]. The largest study of this kind to date is the Study of Trauma And Recovery (STAR) trial [13], a randomized controlled trial comparing the effectiveness of a trauma-focused cognitive behavior therapy for psychosis (TF-CBTp) in addition to treatment-as-usual (TAU) compared to TAU alone in addressing post-traumatic stress symptoms in people with psychosis. TF-CBTp is an integrated therapy that targets trauma memories and related beliefs, while also addressing psychosis-related experiences, appraisals, and their consequences. The primary outcome in the STAR trial was total PTSD symptom severity within the past month, as measured by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) [14], a semi-structured interview assessing the severity of symptoms, as specified by DSM-5 [15]. At 9-month follow-up, which corresponds to the end of therapy, there were significantly lower PTSD symptoms in TF-CBTp group participants compared to controls, with a medium-to-large effect size. The same was true for all CAPS-5-related secondary outcomes

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(symptom clusters, dissociative subtype, loss of diagnosis, and clinically significant change), and for self-report measures of post-traumatic cognitions, complex PTSD (cPTSD), and two out of three dissociation subscales [16].

Retrospective measurement is used routinely to evaluate outcomes in clinical trials, using standardized assessments of relevant therapy targets. Nevertheless, there is a potential for recall bias [17] and such measures may not capture dynamic moment-to-moment fluctuations in symptomatology, which may be particularly present in PTSD [18, 19]. Experience sampling methodology (ESM) [20] involves brief assessments administered multiple times a day over several days, in a real-world setting. This methodology can therefore enhance our understanding of intervention effects, in addition to traditional retrospective measurement of outcomes.

ESM has been used successfully to capture PTSD symptoms in daily life in psychosis patients with trauma histories [21, 22] and has recently begun to be incorporated into clinical trials of psychological interventions in psychosis [23–25], offering novel insights into underlying mechanisms and changes in daily life functioning, distinct from retrospective measures. ESM was incorporated into the STAR trial design with the aim of measuring the extent to which specific PTSD symptoms change in response to TF-CBTp in the flow of daily life, and the extent to which these changes are related to reductions in clinically assessed PTSD symptoms. It is, to the best of our knowledge, the largest ESM study to date in people with distressing psychosis and PTSD symptoms. It was hypothesized that the severity and variability of momentary intrusive trauma memories and related psychopathology, i.e., negative trauma-related cognitions, avoidance, dissociation, and hyperarousal, would be lower at the end of therapy (9 months post-randomization) in the TF-CBTp+TAU group compared to TAU alone. A secondary hypothesis was that experience sampling outcomes at the post-therapy timepoint would be associated with changes from baseline to end of therapy in the CAPS-5 retrospective measure of PTSD symptoms across groups.

Methods

Study Design

This study is an adjunct intensive longitudinal ESM study of a subsample of participants ($N = 153$) recruited into the STAR trial (ISRCTN93382525), a multisite, rater-blind, parallel arm randomized controlled trial comparing an integrated therapy addressing PTSD and psychosis symptoms (TF-CBTp) in addition to TAU, to TAU alone. The protocol and full results of the trial are reported elsewhere [13, 16].

Randomization followed completion of baseline assessments, including the ESM study, via a web-based service hosted by King's Clinical Trials Unit (KCTU). Allocation was in 1:1 ratio, stratified by center, and used randomly varying sized blocks. Research assessors, who also supported the ESM component of the assessments, were blind to group allocation.

Participants

Trial participants were recruited from secondary mental health services in five National Health Service (NHS) organizations across England. Participants met ICD-10 criteria for schizophrenia spectrum diagnoses (F20–29) ascertained from the ICD-10 checklist by the research team following clinical note review and consultation with the care team, as appropriate, and scored ≥2 ("moderate" intensity) on the distress item of the hallucinations (including multisensory hallucinations; Peters et al., *under review*) or delusion subscales of the Psychotic Symptom Rating Scales (PSYRATS) [26].

Participants also endorsed at least one traumatic life event occurring >1 month before assessment, which still currently affected them as rated on the Trauma And Life Events checklist [27]. They met diagnostic criteria for PTSD on the CAPS-5, a standardized interview of PTSD symptom severity [14].

Participants were excluded if they were <18, had psychosis or PTSD symptoms that were primarily organic in etiology, had a primary substance misuse diagnosis, required an interpreter to engage with the trial procedures, were currently experiencing an acute mental health crisis, or (within the previous 3 months) had major medication changes (started/stopped an antipsychotic, or switched to/from clozapine) or received a trauma-focused therapy. Every participant who consented to take part in the STAR trial was invited to provide additional consent to take part in the current ESM study. If this was declined, their participation in the rest of the trial was not affected.

Measures

Full details of the measures collected at each timepoint can be found in the STAR trial protocol [13]. Those relevant to the current study include the ESM questionnaire and the CAPS-5 [14], an instrument assessing PTSD symptom severity within the previous month.

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Table 1. ESM items and corresponding variables in analyses

Trauma-related symptom construct	ESM item(s)	Response options
Intrusive memories	Since the last beep, unwanted memories about the experience popped into my mind	1 (not at all)–7 (very much so)
Hyperarousal	Since the last beep, I felt super-alert, watchful, or on guard Since the last beep, I felt jumpy or easily startled	1 (not at all)–7 (very much so)
Avoidance	Since the last beep, I avoided thoughts, feelings, or physical sensations that remind me of the experience Since the last beep, I avoided places, people, or situations that remind me of the experience	1 (not at all)–7 (very much so)
Dissociation	Since the last beep, I felt spaced out, numb, or emotionally shut down. Since the last beep, I felt like my body was not real or did not belong to me Since the last beep, I felt like the world around me was not real	1 (not at all)–7 (very much so)
Negative trauma-related cognitions	Right now, I believe people can be trusted[a] Right now, I believe the world is a dangerous place Right now, I believe I am a good person[a]	1 (not at all)–7 (very much so)

[a]Reverse-scored.

Specifically, the CAPS-5 rates the severity of four PTSD symptoms consistent with DSM-5 diagnostic criteria for PTSD: intrusion, avoidance, cognitions and mood, and arousal and reactivity symptoms, across 20 items on a 5-point scale ("absent" to "extreme"), yielding a total score ranging from 0 to 80, with higher scores indicating greater symptom severity.

The ESM questionnaire consisted of 29 questions assessing affective states, contextual information, and severity of psychosis and PTSD symptoms rated on Likert scales of 1 ("not at all") to 7 ("very much so"). Items were based on previous ESM studies with similar populations [28, 29] and informed by the International Trauma Questionnaire (ITQ, which also includes items on complex PTSD [30]) and Posttraumatic Cognitions Inventory (PTCI [31]). Although dissociation refers to a diverse range of phenomena, here it is operationalized as including experiences encompassing various forms of "psychological detachment" such as depersonalization and derealization [32]. Items were further refined in collaboration with consultants with lived experience of trauma and psychosis. Consultation focused on the wording and presentation of ESM items to ensure appropriateness and acceptability for the target population.

Some items were phrased to capture the current moment (Right now. . ., i.e., "momentary" items), whereas others referred to the timeframe between moments (Since the last beep. . ., i.e., "interval" items). The latter timeframe allowed us to capture phenomena of interest that might have occurred in the time interval between the previous and current ESM beep (up to 180 min) and which may have been too infrequent to enable sampling using only momentary items.

Multi-item constructs were calculated as the mean of the items, with a single item score or mean of the remaining 2 items used if one item was missing. The present study utilizes data from 11 items, shown in Table 1. A multilevel confirmatory factor analysis was conducted to verify the factor structure of the multi-item ESM constructs while accounting for the hierarchical nature of the data, showing good fit (RMSEA = 0.029). Between- and within-person ω-type reliability coefficients [33] estimated from the multilevel confirmatory factor analysis model using Lai's method [34] were as follows: dissociation $\omega_B = 0.93$, $\omega_W = 0.73$; hyperarousal $\omega_B = 0.88$, $\omega_W = 0.77$; avoidance $\omega_B = 0.93$; avoidance $\omega_W = 0.62$; negative cognitions $\omega_B = 0.59$, $\omega_W = 0.53$.

Procedure

There were two independent periods of six ESM assessment days: at baseline (prior to randomization) and 9 months post-randomization (corresponding to the end of therapy in the therapy group). The ESM periods began after completion of the STAR assessment questionnaire and interview measures.

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We used a mobile app, m-Path, to deliver the ESM questionnaires [35], either on participants' personal mobile or study-provided smartphones. During onboarding meetings ahead of each ESM period, participants completed a practice ESM questionnaire with a research worker to clarify understanding of the items.

Notifications were delivered on a quasi-random signal-contingent sampling scheme: participants received up to 10 notifications a day delivered at random times within time windows of 90 min, with one notification per window. The 90-min windows were scheduled to the participants' waking hours. If their waking hours were less than 15 h (i.e., 10 × 90 min), they received a reduced number of notifications. Following the initial notification, the ESM questionnaire was available to the participant for 15 min.

Participants with an atypical schedule (e.g., an upcoming holiday or invasive medical procedure) were not onboarded to the study until after these event(s) had passed, to ensure study responses reflected a typical week. Participants received a check-in call 2 days into the procedure to prompt compliance. Following completion, participants were debriefed and received GBP 30 honorarium for the baseline ESM assessment, and an additional GBP 45 for completing the follow-up ESM assessment.

Intervention: TF-CBTp

TF-CBTp is a manualized therapy integrating standard psychological therapy for PTSD and for psychosis, consisting of approximately weekly individual 60- to 90-min sessions lasting 9 months, delivered by experienced therapists. Therapy adhered to PTSD model-based interventions, but psychosis-focused interventions were embedded throughout to address relevant experiences, appraisals, and behaviors as they arose. Full details on TF-CBTp and its delivery in the trial are described in the STAR paper [16] and the therapy guide (Keen, Hardy et al., *under review*).

Statistical Analysis

The ESM dataset has a multilevel structure, such that multiple observations (level 1) are nested within days (level 2) and participants (level 3), at two assessment timepoints. Due to the complexity of sample size estimation for three-level models (which require an unfeasibly large number of unknown parameters to input), the sample size calculation was based on a simple (two-level) multilevel model with random intercepts at the participant level and autocorrelated residuals with an autoregressive structure of the first order at the ESM beep level. A target sample size of 151 participants, accounting for 25% attrition, provided 79% power to detect a mean difference of 0.4 between the therapy and control groups (on a 1–7 Likert scale), at the 0.05 level of significance.

Multilevel linear regression models were used to control for within-participant clustering of multiple observations and to accommodate missing data [36, 37], using the "mixed" command in Stata 18 [38]. Models were fitted using restricted maximum likelihood estimation, allowing for the use of all available data under the assumption that data are missing at random and that all variables associated with missing values are included in the model. To test for the latter, we fitted models to examine if baseline characteristics (e.g., gender, ethnicity, age, and CAPS-5 total score) were associated with the probability of missing a beep in the baseline ESM period.

To test the effect of TF-CBTp+TAU compared to TAU only, we fitted separate linear multilevel regression models on each ESM outcome, as well as for outcome variability, calculated as the squared successive difference (SSD) between adjacent beeps within each day. Each model included timepoint, therapy group, site, and a timepoint × therapy group interaction as the independent variables, and we included random intercepts at the day and person level to account for the within-participant clustering of the repeated measures. Timepoint is centered at the 9-month assessment, and as such, the coefficient of the treatment variable estimates the difference in the mean level of the outcome between therapy groups at 9 months. The variance of the within-person errors is assumed to be the same across timepoints.

To examine the relationship between ESM outcomes at 9 month with change in CAPS-5 scores across groups, a change score was calculated as the difference between the CAPS-5 total score at baseline and at 9 months for each participant. We similarly fitted separate three-level linear mixed effect models for each ESM construct, with the latter as the dependent variable and CAPS-5 change score, therapy group, and site as the independent variables, including random intercepts at the participant and day levels. To examine the association between CAPS-5 change and ESM outcome variability at 9 months, the same models were fitted with each ESM outcome's SSD as the dependent variable.

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Table 2. Demographics of the ESM sample (N = 153) by arm

	TAU	Therapy	Total ESM	Test statistic (p)
N (%)	80 (52.3)	73 (47.7)	153	
Age, years				
Mean (SD)	39.3 (±12.1)	34.5 (±11.7)	37 (±12.1)	**t(151) = 2.51 (0.013)**
Gender identity, *n* (%)				
Men	30 (37.5)	30 (41.1)	60 (39.2)	Fisher's exact (0.430)
Women	47 (58.8)	40 (54.8)	87 (56.9)	
Nonbinary	1 (1.3)	3 (4.1)	4 (2.6)	
Prefer not to say	2 (2.5)	0 (0.0)	2 (1.3)	
Relationship status, *n* (%)				
Not currently in a relationship	44 (55.0)	45 (61.6)	89 (58.2)	Fisher's exact (0.791)
Cohabiting/married/civil partnership	26 (32.5)	20 (27.4)	46 (30.1)	
Separated/divorced/widowed	9 (11.3)	8 (11.0)	17 (11.1)	
Missing	1 (1.3)	0 (0.0)	1 (0.7)	
Normal living situation, *n* (%)				
Supported accommodation	6 (7.5)	4 (5.5)	10 (6.5)	Fisher's exact (0.206)
Temporary accommodation/no fixed	2 (2.5)	6 (8.2)	8 (5.2)	
Rented (council/private)	45 (56.3)	44 (60.3)	89 (58.2)	
Own property	11 (13.8)	4 (5.5)	15 (9.8)	
In family home	14 (17.5)	15 (20.6)	29 (19.0)	
Missing	2 (2.5)	0 (0.0)	2 (1.3)	
Ethnicity, *n* (%)				
Black African	5 (6.3)	6 (8.2)	11 (7.2)	Fisher's exact (0.811)
Black Caribbean	3 (3.8)	4 (5.5)	7 (4.6)	
Mixed ethnicity	6 (7.5)	3 (4.1)	9 (5.9)	
South Asian	1 (1.3)	3 (4.1)	4 (2.6)	
White British	60 (75.0)	53 (72.6)	113 (73.9)	
Other	5 (6.3)	4 (5.5)	9 (5.9)	
Highest level of schooling, *n* (%)				
Primary school	1 (1.3)	3 (4.1)	4 (2.6)	Fisher's exact (0.774)
Secondary (no exam qualifications)	7 (8.8)	7 (9.6)	14 (9.2)	
Secondary GCSE (or equiv. O/CSE)	17 (21.3)	16 (21.9)	33 (21.6)	
Secondary A levels (or equivalent)	12 (15.0)	14 (19.2)	26 (17.0)	
Vocational education/college	20 (25.0)	14 (19.2)	34 (22.2)	
University (undergraduate)	12 (15.0)	13 (17.8)	25 (16.3)	
University (postgraduate)	6 (7.5)	4 (5.5)	10 (6.5)	
Other	2 (2.5)	2 (2.7)	4 (2.6)	
Missing	3 (3.8)	0 (0.0)	3 (2.0)	
Employment, *n* (%)				
Paid employment (part/full time)	15 (18.8)	12 (16.4)	27 (17.7)	Fisher's exact (0.189)
Studying	2 (2.5)	5 (6.9)	7 (4.6)	
Volunteering	2 (2.5)	5 (6.9)	7 (4.6)	
Retired	3 (3.8)	0 (0.0)	3 (2.0)	
Not currently working	56 (70.0)	51 (69.9)	107 (69.9)	
Missing	2 (2.5)	0 (0.0)	2 (1.3)	
Diagnosis, *n* (%)				
F20 (schizophrenia)	13 (16.3)	12 (16.4)	25 (16.3)	Fisher's exact (0.967)
F22 (persistent delusional disorders)	1 (1.3)	1 (1.4)	2 (1.3)	
F25 (schizoaffective disorders)	9 (11.3)	6 (8.2)	15 (9.8)	
F28 (other nonorganic psychotic disorders)	23 (28.8)	23 (31.5)	46 (30.1)	
F29 (unspecified nonorganic psychosis)	34 (42.5)	31 (42.5)	65 (42.5)	

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Table 2 (continued)

	TAU	Therapy	Total ESM	Test statistic (*p*)
Psychosis symptom presentation, *n* (%)				
Delusions	66 (82.5)	61 (83.6)	127 (82.0)	$\chi^2(1) = 0.03$ (0.861)
Voices	66 (82.5)	59 (80.8)	125 (81.7)	$\chi^2(1) = 0.40$ (0.525)
Hallucinations in other modalities (HOMS)	67 (83.8)	61 (83.6)	128 (83.7)	$\chi^2(1) = 0.001$ (0.975)
Psychosis measures (mean [SD])				
PSYRATS-Voices (n = 123)	30.63 (±6.3)	31.02 (±5.4)	30.81 (±5.9)	t(121) = −0.363 (0.717)
PSYRATS-Delusions (n = 127)	16.61(±3.3)	17 (±2.5)	16.80 (±2.9)	t(120) = −0.763 (0.447)[b]
PSYRATS-HOMS (n = 127)	29.66 (±7.1)	30.18 (±5.9)	29.91 (±6.6)	$z = -0.302$, $p = 0.762$
GPTS (n = 147)	38.29 (±18.2)	43.52 (±18.6)	40.82 (±18.5)	t(145) = −1.724 (0.087)
Meeting cPTSD criteria on ITQ (n = 152), *n* (%)	65 (81.3)	61 (84.7)	126 (82.9)	$\chi^2(1) = 0.14$ (0.708)
Other diagnoses, *n* (%)				
Any comorbid diagnosis	51 (63.8)	56 (76.7)	107 (70.0)	$\chi^2(1) = 3.05$ (0.081)
Anxiety disorders	9 (11.3)	16 (21.9)	25 (16.3)	$\chi^2(1) = 3.18$ (0.075)
Autism	5 (6.3)	7 (9.6)	12 (7.8)	$\chi^2(1) = 0.59$ (0.443)
Bipolar disorder	5 (6.3)	5 (6.8)	10 (6.5)	
Depression (with and without psychotic features)	22 (27.5)	30 (41.1)	52 (34.0)	$\chi^2(1) = 3.15$ (0.076)
Personality disorders	21 (26.3)	24 (32.9)	45 (29.4)	$\chi^2(1) = 0.81$ (0.369)
Substance use disorders	3 (3.8)	7 (9.6)	10 (6.5)	Fisher's exact (0.195)
Other (e.g., ADHD; eating disorders; severe stress and adjustment disorders)	6 (7.5)	4 (5.5)	10 (6.5)	Fisher's exact (0.748)
On antipsychotic medication, *n* (%)	66 (82.5)	58 (79.5)	124 (81.0)	$\chi^2(1) = 0.23$ (0.631)
Dosage (olanzapine equivalent) (n = 113)	13.36 mg	10.30 mg	11.93 mg	**t(111) = 2.376 (0.019)**
Multiple trauma exposure[a], *n* (%)				
Repeated events (at least 1 TALE item endorsed "more than once")	80 (100)	73 (100)	153 (100)	
Mean number of trauma items endorsed (1–20)	11.61 (±3.3)	11.63 (±3.2)	11.62 (±3.2)	t(151) = −0.034 (0.973)
Trauma timing, *n* (%)				
Multiple (>1) trauma types	80 (100)	73 (100)	153 (100)	
Child (endorsed any TALE item <16)	75 (93.8)	67 (91.8)	142 (92.8)	$\chi^2(1) = 0.22$, (0.638)
Adult (endorsed any TALE item 16 or over)	78 (97.5)	68 (93.2)	146 (95.4)	$\chi^2(1) = 1.65$ (0.198)
Both (endorsed any TALE item <16 and 16 or over)	73 (91.3)	62 (84.9)	135 (88.2)	$\chi^2(1) = 1.47$ (0.226)
Trauma measures (mean [SD])				
CAPS-5	49.97 (±10.8)	49.62 (±11.7)	49.80 (±11.2)	t(151) = 0.192 (0.848)
ITQ-PTSD	17.59 (±4.2)	18.35 (±4.0)	17.95 (±4.1)	t(150) = −1.128 (0.261)
ITQ-DSO	18.26 (±5.0)	19.06 (±3.9)	18.64 (±4.5)	$z = -0.60$ (0.546)
PTCI	4.85 (±1.1)	4.92 (±1.0)	4.88 (±1.0)	t(151) = −0.414 (0.680)

SD, standard deviation; PTSD, post-traumatic stress disorder; DSO, disturbances of self-organization; ITQ, International Trauma Questionnaire [30]; TALE, Trauma And Life Events checklist [27]; CAPS-5, Clinician-Administered PTSD Scale for DSM [14]; PSYRATS, Psychotic Symptom Rating Scales [26]; PTCI, Posttraumatic Cognitions Inventory [31]. Significant findings in bold. [a]Based on baseline TALE data; participants were selected on 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. [b]Equal variance not assumed.

Registration

All analyses of the current study were registered on the Open Science Framework using the template for registration of ESM studies [39]. Registration happened after data collection, but prior to data access [40], in line with what has been referred to as post-registration [41]. Deviations from the registration are reported in the online supplementary material 1 and Table S1 (for all online suppl. material, see https://doi.org/10.1159/pps/aemag010).

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Results

Sample

Of the 305 participants recruited to the STAR trial, 153 (50.2%) participants took part in the ESM study, of whom 73 were allocated to TF-CBTp+TAU and 80 allocated to TAU (47.4% and 53.0% of the STAR group allocations, respectively). Demographic and clinical information about the sample is provided in Table 2. In the ESM subsample, those allocated to TAU were significantly older ($t(151) = 2.51$, $p = 0.013$) and had higher antipsychotic medication dose (olanzapine equivalent) ($t(111) = 2.38$, $p = 0.019$) than those in TF-CBTp. There were no other significant differences between the arms. Here, 111 (72.5%) participants completed the follow-up ESM assessment; attrition did not differ significantly between TF-CBTp (19/73, 26.0%) and TAU (23/80, 28.8%; $\chi^2 = 0.14$, $p = 0.71$).

When compared with the 152 people who did not consent to the ESM study, the sample in the ESM study was significantly younger (mean in ESM = 37, mean in non-ESM = 40.73, $t(303) = 2.64$, $p < 0.01$) and had contact with mental health services at a younger age (mean in ESM = 22.53, mean in non-ESM = 25.48, $t(289) = 2.31$, $p = 0.02$). A Fisher's exact test revealed a significant association between ICD-10 diagnosis and ESM participation ($p = 0.027$), driven by higher rates of F28 diagnoses and lower rates of F20 diagnoses in the ESM subsample. Similarly, there was a significant association between current working situation and ESM participation ($p = 0.024$), with higher rates of paid employment in the ESM subsample. There were no other significant differences in demographics or in PTSD symptom severity at baseline. When comparing the ESM subsample who completed both ESM timepoints ($n = 111$; TAU = 57, TF-CBTp = 54) to the non-ESM sample, only differences in employment and age at first contact with mental health services remained significant.

Data Availability

The mean number of beeps scheduled over each 6-day ESM period was 54.4 (standard deviation [SD] = 6.4) out of a possible 60. Mean compliance, i.e., mean number of completed ESM questionnaires out of the total scheduled, was 32.6 (59.4%, SD = 14.5) at baseline and 29.1 (54.1%, SD: 14.2) at 9 months. The total data (number of questionnaires/beeps completed) available at each timepoint were 2,547 for TAU and 2,301 for TF-CBTp at baseline, and 1,691 for TAU and 1,476 for TF-CBTp at 9 months. None of the demographic variables specified (age, gender, or ethnicity) predicted missingness at baseline, and neither did CAPS-5 total symptom severity.

Analysis of Outcomes

Hypothesis 1

Severity and variability of momentary post-traumatic stress symptoms would be lower at the end of therapy (9 months post-randomization) in the TF-CBTp+TAU group compared to TAU alone.

Hypothesis 1 was not supported: we found no significant differences between the TF-CBTp+TAU and TAU groups at 9 months (post-therapy) in ESM outcomes of intrusive memories, dissociation, avoidance, hyperarousal, and negative trauma-related cognitions. There was, however, evidence of a greater reduction from baseline to 9 months in the therapy group compared to TAU in ESM scores, as indicated by significant interaction effects between timepoint and therapy arm, for hyperarousal ($\beta = 0.26$, standard error [SE] = 0.11, $p = 0.015$), negative cognitions ($\beta = 0.39$, SE = 0.09, $p < 0.001$), and avoidance ($\beta = 0.23$, SE = 0.11, $p = 0.034$) (see Fig. 1). Although no significant baseline differences were found between arms on ESM outcomes (see online suppl. Table 2), the TF-CBTp+TAU group started at marginally higher levels on two out of the three domains showing significant interactions (see Fig. 1), which may explain at least some of the discrepancies between interaction and main effects at 9 months.

Similarly, we found no significant differences in variability (as measured by SSD) between the TF-CBTp+TAU and TAU groups at the 9-month follow-up. There was, however, evidence of a greater reduction in the variability of momentary intrusive memories from baseline to 9 months in the therapy group compared to TAU ($\beta = 1.08$, SE = 0.46, $p = 0.019$). See Table 3 for full test statistics.

Hypothesis 2Experience sampling outcomes at the post-therapy timepoint would be associated with changes from baseline to end of therapy in the CAPS-5 retrospective measure of PTSD symptoms.

Mean change in CAPS-5 score between baseline and 9 months across both groups in the ESM subsample who completed both ESM timepoints was 13.86 (SD = 16.67; range = 67 to −15). In line with our hypothesis, there was a significant negative association between CAPS-5 change scores and all momentary items (hyperarousal [$\beta = -0.44$, SE = 0.08, $p < 0.001$];

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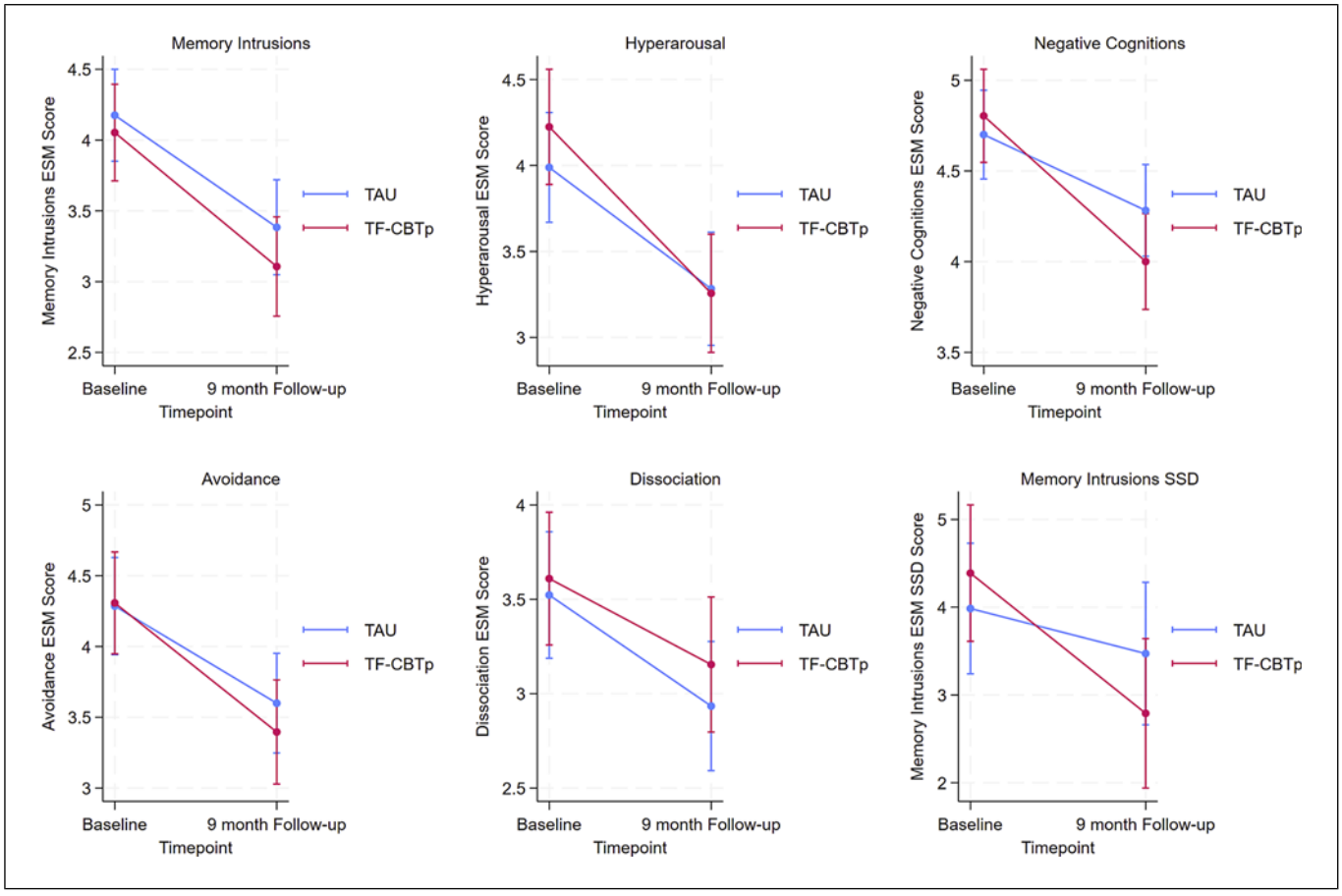


Fig. 1. Graphs showing estimated marginal means of ESM outcomes over time by therapy group.

intrusive memories [β = −0.42, SE = 0.07, $p < 0.001$]; negative trauma-related cognitions [β = −0.50, SE = 0.08, $p < 0.001$]; dissociation [β = −0.47, SE = 0.08, p = $p < 0.001$]; avoidance [β = −0.39, SE = 0.08, $p < 0.001$]) at 9 months, indicating that participants who showed greater overall clinical improvement in PTSD symptoms, as measured by the CAPS-5, experienced reduced levels of PTSD symptoms in daily life at 9 months.

There was a significant negative association between CAPS-5 change scores and variability (SSD) of hyperarousal (β = −0.11, SE = 0.06, $p = 0.05$) and dissociation (β = −0.15, SE = 0.06, $p = 0.009$) measured at 9 months, indicating greater overall clinical improvement in PTSD symptoms was related to reduced levels of moment-to-moment variability in hyperarousal and dissociation. There was no significant association with SSD of avoidance, intrusive memories, and negative trauma-related cognitions (see Table 4).

Discussion

This study is the largest to date to utilize ESM to test the impact of a trauma-focused psychological intervention for people with distressing symptoms of psychosis and PTSD in the flow of daily life. Our primary hypotheses were tested for between-group differences in momentary PTSD symptoms, namely, intrusive memories, hyperarousal, dissociation, avoidance, and negative trauma-related cognitions, at the 9-month (i.e., post-therapy) follow-up assessment of the STAR trial [16]. Unlike the trial findings, no significant differences between the therapy and control groups were found on any of the ESM PTSD items post-therapy. However, significant timepoint × therapy interaction effects were identified for hyperarousal, negative cognitions, and avoidance symptoms. These effects indicate that participants in the therapy group experienced greater reductions in these specific symptom domains over time compared to controls, but these were not sufficiently

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Table 3. Main effects of treatment and interaction with timepoint on ESM outcomes and SSD

Outcome	Adjusted mean difference, β (SE)	95% CI	*p* value
Intrusive Memories			
Main effect of treatment[a]	−0.27 (0.25)	−0.76, 0.21	0.263
Timepoint × treatment arm	0.16 (0.11)	−0.07, 0.38	0.170
Hyperarousal			
Main effect of treatment	−0.03 (0.24)	−0.50, 0.45	0.913
Timepoint × treatment arm	**0.26 (011)**	**0.05, 0.47**	**0.015**
Negative trauma-related cognitions			
Main effect of treatment	−0.28 (0.19)	0.30, 0.08	0.131
Timepoint × treatment arm	**0.39 (0.09)**	**0.22, 0.55**	**<0.001**
Dissociation			
Main effect of treatment	0.22 (0.25)	−0.27, 0.71	0.383
Timepoint × treatment arm	−0.13 (0.09)	−0.31, 0.05	0.146
Avoidance			
Main effect of treatment	−0.20 (0.26)	−0.71, 0.31	0.433
Timepoint × treatment arm	**0.23 (0.11)**	**0.02, 0.44**	**0.034**
Intrusive memory SSD			
Main effect of treatment[a]	−0.68 (0.60)	−1.86, 0.49	0.256
Timepoint × treatment arm	**1.08 (0.46)**	**0.18, 1.99**	**0.019**
Hyperarousal SSD			
Main effect of treatment	−0.03 (0.38)	−0.78, 0.71	0.932
Timepoint × treatment arm	0.13 (0.30)	−0.45, 0.72	0.657
Negative trauma-related cognition SSD			
Main effect of treatment	−0.06 (0.17)	−0.39, 0.27	0.721
Timepoint × treatment arm	0.20 (0.12)	−0.04, 0.44	0.105
Dissociation SSD			
Main effect of treatment	−0.15 (0.36)	−0.86, 0.57	0.688
Timepoint × treatment arm	−0.03 (0.26)	−0.55, 0.49	0.905
Avoidance SSD			
Main effect of treatment	0.02 (0.42)	−0.80, 0.84	0.957
Timepoint × treatment arm	0.05 (0.32)	−0.57, 0.68	0.873

CI, confidence interval; SE, standard error. Significant differences highlighted in bold. [a]Difference between treatment groups at 9 months.

large to result in a significant group difference at the follow-up timepoint. Furthermore, there were no between-group differences at the post-therapy timepoint in symptom variability on any ESM outcome, although a significant interaction effect was found for intrusive memories, again with the therapy group showing a greater reduction in fluctuations over time compared to the control group.

The therapy group showed steeper reductions over the 9 months in mean levels of momentary avoidance, negative trauma-related cognitions and hyperarousal, and variability in intrusive memories compared to the control group (as illustrated in Fig. 1). This provides tentative support for the effectiveness of TF-CBTp and potentially suggests that these specific psychological processes, as they unfold moment to moment in daily life, may be particularly responsive to therapy. Reduced variability in intrusive memories indicates greater stability in the experience of intrusive symptoms, which is relevant in the context of evidence linking higher symptom variability with increased relapse risk in other psychiatric populations [42].

Nevertheless, the lack of significant differences between groups at the 9-month timepoint diverges from the findings of the main STAR trial, which showed a moderate-to-large reductions in PTSD symptom severity in the TF-CBTp+TAU group compared to TAU [16]. The effects on PTSD were

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Table 4. Standardized regression coefficients for the relationship between change in CAPS-5 and ESM outcomes at 9 months

ESM outcome	Standardized β (SE)	95% CI	*p* value
Intrusive memories	**−0.42 (0.07)**	**−0.56, −0.28**	**<0.001**
Hyperarousal	**−0.44 (0.08)**	**−0.59, −0.28**	**<0.001**
Negative trauma-related cognitions	**−0.50 (0.08)**	**−0.65, −0.35**	**<0.001**
Dissociation	**−0.47 (0.08)**	**−0.62, −0.31**	**<0.001**
Avoidance	**−0.39 (0.08)**	**−0.54, −0.23**	**<0.001**
Intrusive memory SSD	−0.05 (0.05)	−0.15, 0.04	0.273
Hyperarousal SSD	**−0.11 (0.06)**	**−0.22, 0**	**0.050**
Negative trauma-related cognition SSD	0 (0.05)	−0.10, 0.10	0.988
Dissociation SSD	**−0.15 (0.06)**	**−0.26, −0.04**	**0.009**
Avoidance SSD	−0.05 (0.07)	−0.16, 0.05	0.313

CI, confidence interval; SE, standard error. Significant associations highlighted in bold.

consistent across both observer-rated and self-report measures, and on all PTSD outcomes (i.e., total score, symptom clusters, post-traumatic cognitions, remission from PTSD diagnosis [including cPTSD and dissociative subtype of PTSD], and clinically significant change). Given these robust findings, the equivocal results using ESM were unexpected. There are several potential reasons for the lack of support for our hypotheses and the discrepancies with the trial results, relating to differences in the samples, constructs measured, and the context and timing in which symptom data are collected.

The participants with ESM data at both timepoints in the current study contain only a subsample (41.6%) of STAR trial participants with CAPS-5 follow-up data and thus could be open to potential selection bias. Although there were no differences in PTSD or psychosis symptom severity between the current sample and those who did not participate in ESM, they were younger and had higher rates of employment, which may reflect characteristics of individuals who are more likely to take part in an ESM study. While these demographic differences are unlikely to have had a substantial impact on the discrepancies in findings, subtle effects cannot be entirely ruled out. There were no differences between the therapy and control groups within the ESM sample, apart from lower antipsychotic dosage in the former compared to the latter, which could potentially have attenuated therapy effects.

In terms of the constructs measured, we found a significant association between changes in clinician-rated PTSD symptoms (CAPS-5 change scores from baseline to follow-up) and ESM-assessed PTSD symptoms at follow-up. Participants who showed larger reductions in CAPS-5 scores reported lower levels of PTSD symptoms in daily life across all five symptom domains captured via ESM at follow-up. Additionally, CAPS-5 change scores were significantly negatively associated with symptom variability in hyperarousal and dissociation. These associations demonstrate that individuals with more clinical improvement, as measured by the CAPS-5, tended to experience less persistent symptoms, and in some cases less moment-to-moment symptom fluctuations, in their daily lives. Consistent with other studies showing alignment between "past-month" ratings and day-to-day symptom experience in PTSD [43, 44], these associations suggest we should not conclude any discrepancy in trial outcomes is due to a complete lack of overlap in the CAPS-5 and ESM measurements. Further alignment emerged in the pattern of therapy effects: the post-traumatic cognitions cluster from the CAPS-5 questionnaire, and the ESM negative trauma-related cognition variable both showed the largest effect size of TF-CBTp in their respective models, which is in line with research highlighting post-traumatic cognitions as a key target of change in TF-CBT for PTSD [45, 46]. We did not find any change over time between therapy arms in momentary dissociation (the corresponding items specifically probing depersonalization and derealization), aligning with the main STAR trial findings in which all PTSD outcomes except the depersonalization/derealization subscale of a dissociation measure (DSPS) [47] significantly favored STAR therapy.

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The discrepancies between the ESM outcomes in this sub-study and the retrospective standardized interview assessment in the STAR trial may be attributable to more subtle measurement differences. The CAPS-5 is a retrospective, clinician-rated, multidimensional measure of trauma symptom severity over several domains, integrating intensity and frequency of experiences and with a broader range of difficulties for each cluster, assessed over the past month in the STAR trial. The ESM variables contain either single item or 2–3 item constructs assessing the experience in the current moment or since the last beep, on a scale of 1–7. Examination of the distribution of ESM measures indicated that participants did make full use of the Likert scale. However, for items assessing intrusive memories, avoidance, hyperarousal, and dissociation, the distribution tended to be bimodal, with increased frequency at the extreme ends of the scale (i.e., responses of 1 and 7), suggesting that either participants were more likely to be scoring the item based on whether the experience had happened or not since the last beep, or experiences of moderate intensity may not have been captured in the moment. Nevertheless, it would be premature to draw definitive conclusions about differences in sensitivity to change across the two measures.

The distinction between ESM as a self-report measure and the CAPS-5 as interviewer-rated could also have contributed to differences in findings. However, this explanation appears less plausible given that other self-report instruments used in the STAR trial (e.g., ITQ [30]; PTCI [31]) demonstrated similar or even larger therapy effects to the CAPS-5. Thus, it is more likely that the divergence reflects differences between retrospective and momentary assessment methods in terms of timeframe captured, rather than mode of administration. It is possible that participants' experience of PTSD symptoms is reported differently across assessment types, resulting in distinct but complementary findings. It may be that when reporting on symptoms in daily life, individuals endorse higher symptom severity due to the acute intensity of the experience in that moment. However, retrospective assessments offer the opportunity to reflect on their experience over a longer period (e.g., the past month), integrating not only the frequency and intensity of symptoms but also the degree to which they feel manageable in a broader context. In this way, a person may still experience intense symptoms at times, while still reporting overall improvement when reflecting over longer periods, due to changes in coping, appraisal, or perceived trajectory of symptoms, reducing their overall perceived impact (Edwards et al., *under review*).

For instance, post-therapy, someone could experience an unwanted trauma memory as highly intrusive in the moment, thereby scoring high on the ESM item, but instead of making a threatening appraisal (e.g., "This means I am losing control"), they now have a more helpful interpretation (e.g., "This is an understandable and common consequence of my past") and therefore respond in a more adaptive way (e.g., use coping statements and grounding instead of suppression), resulting in reduced distress. None of these contextual factors (i.e., changes in appraisal, coping, and impact on distress) would be captured by the specific ESM items we used in this study, but they would be in an interview such as the CAPS where the individual is asked to reflect more broadly on their experience of their symptoms, including the impact they have had, in the last month.

Thus, while the momentary presence of symptoms remains, their retrospective impact may be judged to be lower, which could in part explain diverging results from the CAPS-5 and ESM assessments. Indeed, it has been proposed that forgetting or underreporting the severity of previously experienced symptoms may serve as an adaptive mechanism that comes as part of a recovery process [43, 48, 49]. PTSD has a well-established fluctuating course in which periods of relative stability may alternate with acute symptom exacerbation in response to triggers or stressors [50, 51]. Overall clinical improvement, as captured retrospectively by the CAPS-5, may therefore coexist with intermittent symptom challenges in daily life. These findings suggest that PTSD recovery can still occur with changes in the overall burden and perceived impact of symptoms over time, without a complete remission in the momentary occurrence of symptoms in daily life. Therefore, potentially the combination of ESM and retrospective assessments can provide important information on what changes occur in response to therapy.

Although use of ESM as an outcome measure in clinical therapy trials is still relatively novel, recent studies that have utilized it all report some amount of divergence in ESM findings vs. traditional clinical measures [23–25]. Myin-Germeys et al. [24] found no therapy effect on psychosis distress on the Comprehensive Assessment of At-Risk Mental States (CAARMS [52]), a retrospective interview, but showed significant effects on ESM momentary distress associated with

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psychotic experiences, arguing that ESM captured more subtle, fine-grained changes in daily life not detected by traditional measures (although this may partly reflect measure-specific properties; i.e., CAARMS is typically anchored to peak symptom severity over several months, and thus not that sensitive to change). Similarly, Burger et al. [25] found reductions in voice-hearing captured by ESM that were not reflected in retrospective PSYRATS scores, attributing this to ESM's greater ecological validity. In contrast, Edwards et al. [23] found a pattern more consistent with the present study: retrospective interview measures showed significant reductions in distress across both forms of AVATAR therapy, whereas ESM measures showed significant reductions only for the extended form, with the authors concluding that different aspects of distress were represented across the complementary methodologies. Taken together, these findings suggest divergence between ESM and retrospective measures is common and can operate in either direction. This is consistent with the proposition that ESM and retrospective measures may be capturing distinct yet meaningful facets of symptom experience, whereby the latter may reflect the integrated appraisal of symptom burden and perceived impact over time, whereas ESM captures moment-to-moment symptom expression and variability in daily life. Rather than providing a more or less sensitive or valid estimate of therapy efficacy, it may be better understood as providing complementary information to retrospective reports about how symptoms are experienced in daily life and change following therapy. Continued research incorporating both methodologies is needed to explore how these different assessment modes relate to one another. Future trials may benefit from using ESM more selectively, for example, where the aim is to examine symptom variability, in-the-moment coping responses, the relationship between environmental triggers, associated psychological mechanisms and symptom expression, and the degree to which symptoms interfere with daily functioning. Specifically in relation to the impact of TF-CBTp, future work could examine its impact on ESM measures of momentary appraisals and coping responses following intrusive or distressing trauma symptoms, alongside distress or daily life functioning, as well as context-dependent variation in symptom expression.

The present study has some limitations. The average ESM questionnaire completion rate was 57.2%, resulting in a relatively large amount of missing data. Nevertheless, this is in range of average ESM compliance scores from psychosis populations [53], although slightly lower than another, albeit smaller, study in a psychosis-PTSD sample [25]. No demographic or clinical predictors of missingness were identified, although nonrandom missingness remains a possibility. Although the factor structure of the multi-item ESM PTSD symptom constructs was confirmed, the entire ESM questionnaire has not been fully validated, and the reliability of the negative trauma-related cognition construct was lower than expected, which should be noted when interpreting the findings. ESM was assessed at two timepoints only (baseline and end of therapy), a pragmatic decision given the burden of repeated ESM assessments in this complex clinical population. We were therefore unable to examine the temporal unfolding of symptom change during therapy, or to establish whether shifts in ESM symptoms preceded changes in clinician-rated PTSD severity.

Conclusion

To conclude, our hypotheses that the TF-CBTp group would have significantly lower severity scores than the TAU group on daily-life PTSD symptoms 9 months post-randomization were not supported. Nevertheless, the therapy group showed greater reductions than the control group from baseline to follow-up in momentary avoidance, hyperarousal, and negative trauma-related cognitions, as well as in fluctuations in intrusive memories. Overall, these findings provide tentative support for the effectiveness of TF-CBTp on PTSD in daily life, but are somewhat discrepant with the main STAR trial, which showed robust effects on all clinical measures of PTSD. CAPS-5 clinical improvement and momentary symptom severity and variability showed significant associations, suggesting the differences in findings cannot be explained by a lack of validity of the ESM items. We suggest that the variations in strength of effects between ESM and traditional clinical, retrospective measures may be related to the measurement of different, but equally meaningful features of PTSD symptom expression, with therapeutic change in TF-CBTp potentially occurring at the contextual level of appraisal, coping, and impact on functioning, despite the continued occurrence of PTSD symptoms in daily life.

Appendix

STAR group nonauthor collaborators are as follows (in alphabetical order): affiliated with South London and Maudsley NHS Foundation Trust – Michael Arhin-Acquaah, Kavita Bains,

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Statement of Ethics

This study was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. Ethical approval was provided by the London-Camberwell St Giles Research Ethics Committee (20/LO/0853 – amendment 1). Written informed consent was obtained from each participant prior to assessment and randomization.

Conflict of Interest Statement

E.P., A.H., F.V., and R.U. provide psychological therapies for individuals with psychosis and/or PTSD in NHS settings, and E.P. is the Director of a psychological therapies specialist service for psychosis (PICuP). E.P., A.H., F.V., R.D., and C.S. are employed to provide training and/or receive fees (or generate fees for their clinics or research units) for workshops and presentations on psychological therapies for psychosis and/or PTSD; E.P., A.H., F.V., R.D., and R.E. hold or have held grants to carry out trials of psychological therapy for individuals. The remaining authors have no conflicts of interest to declare.

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Author Contributions

M.R.: investigation, data curation, formal analysis, visualization, and writing – original draft. P.P.: investigation, data curation, and writing – review and editing. A.H. and R.B.: funding acquisition, conceptualization, and writing – review and editing. R.E.: funding acquisition, conceptualization, and methodology. C.S. and R.D.: investigation and writing – review and editing. R.U.: project administration, investigation, and writing – review and editing. G.L., C.J.E., and I.M.-G.: methodology, and writing – review and editing. E.P.: funding acquisition, conceptualization, project administration, and writing – review and editing. F.V.: funding acquisition, conceptualization, investigation, and writing – review and editing.

Data Availability Statement

The data that support the findings of this study are not publicly available until the publication of the main trial results but are available from the corresponding author upon request following review by the STAR Trial Management Team.

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