

## Original Article

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# Trauma-focused therapy in early psychosis: results of a feasibility randomized controlled trial of EMDR for psychosis (EMDRp) in early intervention settings

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## Abstract

**Background.** Trauma is prevalent amongst early psychosis patients and associated with adverse outcomes. Past trials of trauma-focused therapy have focused on chronic patients with psychosis/schizophrenia and comorbid Post-Traumatic Stress Disorder (PTSD). We aimed to determine the feasibility of a large-scale randomized controlled trial (RCT) of an Eye Movement Desensitization and Reprocessing for psychosis (EMDRp) intervention for early psychosis service users.

**Methods.** A single-blind RCT comparing 16 sessions of EMDRp + TAU *v.* TAU only was conducted. Participants completed baseline, 6-month and 12-month post-randomization assessments. EMDRp and trial assessments were delivered both in-person and remotely due to COVID-19 restrictions. Feasibility outcomes were recruitment and retention, therapy attendance/engagement, adherence to EMDRp treatment protocol, and the ‘promise of efficacy’ of EMDRp on relevant clinical outcomes.

**Results.** Sixty participants (100% of the recruitment target) received TAU or EMDR + TAU. 83% completed at least one follow-up assessment, with 74% at 6-month and 70% at 12-month. 74% of EMDRp + TAU participants received at least eight therapy sessions and 97% rated therapy sessions demonstrated good treatment fidelity. At 6-month, there were signals of promise of efficacy of EMDRp + TAU *v.* TAU for total psychotic symptoms (PANSS), subjective recovery from psychosis, PTSD symptoms, depression, anxiety, and general health status. Signals of efficacy at 12-month were less pronounced but remained robust for PTSD symptoms and general health status.

**Conclusions.** The trial feasibility criteria were fully met, and EMDRp was associated with promising signals of efficacy on a range of valuable clinical outcomes. A larger-scale, multi-center trial of EMDRp is feasible and warranted.

## Introduction

Psychosis affects 0.7% of the population, causing significant personal and societal burden and poor recovery outcomes (e.g. Fineberg *et al.* 2013; Jääskeläinen *et al.* 2013). Current guidelines (e.g. NICE, 2014) recommend pharmacological and psychological interventions, but treatment effects are often modest and variable (Bighelli *et al.*, 2018; Cramer & Rosenheck, 2006; Jauhar *et al.*, 2014; Wykes, Steel, Everitt, & Tarrier, 2008). It is imperative that these outcomes are improved, particularly in relation to ‘early’ or ‘first episode psychosis’ – a crucial period when targeted support might heighten chances of recovery, prevent adverse outcomes and reduce the patient burden that may be brought about by adverse reactions to currently recommended treatments e.g. antipsychotic medication side effects.

Meta-analyses have demonstrated a robust association between trauma exposure and risk of psychosis (e.g. Pastore, de Girolamo, Tafuri, Tomasicchio, & Margari, 2022; Varese *et al.*, 2012)

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as well as associations with more severe symptom profiles, adverse prognoses, and severe comorbidities (e.g. Alameda et al. 2021; Bailey et al. 2018). Trauma and its psychological sequelae are particularly prevalent in people with early psychosis (Rodrigues & Anderson, 2017). However, most trauma-focused intervention trials exclude people with psychotic symptoms (e.g. Ronconi, Shiner, & Watts, 2014). Eye Movement Desensitization and Reprocessing (EMDR) is a recommended treatment for trauma (e.g. NICE, 2018) that has been receiving growing empirical scrutiny in clients with complex mental health presentations beyond PTSD (e.g. Perlini et al., 2020). Clinical trials focusing on people with life-time diagnoses of psychosis with comorbid PTSD have found that EMDR can improve PTSD and paranoid symptoms (de Bont et al., 2016; van den Berg et al., 2015), stimulating efforts to adapt it for clients with psychosis (Phillips, Maguire, McSherry, & Pinto, 2021). As existing randomized controlled trials as so far only focused on patients with comorbid PTSD diagnoses, research is therefore needed to establish whether EMDR is effective at ameliorating symptoms in patients with early psychosis who have significant lifetime trauma and active or ongoing psychotic symptoms, whether or not they present with comorbid PTSD.

Building on work by others (e.g. van den Berg, van der Vleugel, Staring, De Bont, & De Jongh, 2013), we conducted a feasibility trial of an 'EMDR for psychosis' (EMDRp) intervention developed by clinicians in Lancashire (UK) to address the needs of clients with early psychosis, focusing on uncertainties that must be addressed ahead of large-scale trials to evaluate the efficacy and cost effectiveness of this intervention.

## Methods

The Trial protocol and feasibility criteria were pre-specified (ISRCTN 16262847; Varese et al., 2021). The study received approval from a National Health Service (NHS) Ethics committee and the NHS Health Research Authority (HRA). Research and treatment delivery procedures were adapted over the course of the trial in response to issues brought about by the COVID-19 pandemic as briefly described below, and in more detail in Supplementary Material 1 in accordance with the CONSERVE (CONSORT and SPIRIT Extension for RCTs Revised in Extenuating Circumstances) framework (Orkin et al., 2021).

## Design

A single-blind, parallel group RCT design with random allocation to two arms: 16 sessions of EMDRp over 6 months alongside Treatment As Usual (EMDRp + TAU) *v.* TAU alone. Participants in both arms were assessed at baseline, 6- and 12-months post-randomization.

## Procedure and participants

Participants were recruited from four Early Intervention (EI) services in Lancashire and South Cumbria (UK). Staff identified and approached prospective participants, and the research team obtained informed consent from those interested. Participants were screened using the Positive and Negative Syndrome Scale (PANSS; Kay, Fiszbein, & Opler, 1987) and a modified version of the Trauma Screening Questionnaire (TSQ), a brief 10-item screener for trauma and post-traumatic symptoms used in previous trials of trauma-focused therapy for people with psychosis (de Bont et al., 2015). Follow-up assessments were conducted by

research assistants (RAs) blind to treatment allocation. Early in the trial, assessments took place in person either at the participant's home or at local NHS facilities but during restrictions due to the COVID-19 pandemic, were conducted over the telephone or via video calls. When restrictions eased, participants were given a choice of remote or face-to-face assessments.

*Inclusion criteria* were: (a) aged at least 16 years; (b) capacity and willingness to provide informed consent; (c) ICD-10 diagnosis of schizophrenia-spectrum disorders or meeting local EI psychosis support criteria, operationally defined using the PANSS and/or the psychosis transition criteria of the Comprehensive Assessment of At-Risk Mental States (Yung et al., 2005); (d) having recent contact with EI services and an assigned care-coordinator; (e) being within 3 years from psychosis onset; judged by their responsible clinician as being clinically stable (i.e. no antipsychotic treatment change in the previous month, not actively suicidal in the previous 2 months); (f) reporting at least 1 traumatic event on the TSQ and at least subsyndromal post-traumatic symptom in the previous week (scores >0 on TSQ items 3.1 to 3.5); (g) meeting criterion level of positive symptoms severity (score  $\geq 3$  on PANSS P1, P3, P5, or P6)

*Exclusion criteria* included: (a) primary diagnosis of substance/alcohol dependence or evidence of severe intellectual disability or cognitive dysfunction (as provided by the clinical team); (b) requiring an interpreter; (c) receipt of EMDR from a qualified psychological therapist in accordance with NICE guidance (NICE, 2018) in the previous 12 months.

## Randomization

Participants Were randomly allocated on a 1:1 ratio to receive either TAU or EMDRp + TAU using a pseudo-random list with random permuted blocks of varying sizes hosted at an online randomization service ([www.sealedenvelope.com](http://www.sealedenvelope.com)). The allocation sequence was concealed from the research team, and RAs conducting the follow-up assessments were blind to treatment allocation.

## EMDRp

The Emdrp intervention was consistent with the standard EMDR protocol (Shapiro, 2001), with phases adapted or expanded to address the needs of clients with psychosis, based on previous work by others (van den Berg et al., 2013) and pilot work by the research team (Ward-Brown et al., 2018). For further details of the protocol and adaptations, see Varese et al. (2021). The manualized intervention allowed up to 16 sessions over 6 months and was delivered by three accredited EMDR therapists who received an initial 3-day training workshop on the protocol and attended fortnightly group supervision led by two EMDR consultants. Sessions were recorded for supervision purposes. Treatment fidelity was evaluated in a subsample of recordings using the EMDR Fidelity Rating Scale (EFRS; Korn, Maxfield, Smyth, & Stickgold, 2017), rated by two EMDR consultants who developed the study intervention. EMDRp sessions were initially delivered in person at local NHS facilities. Following the onset of the pandemic, treatment was delivered remotely via video calls. When restrictions eased, participants were given a choice on whether to attend therapy in person or remotely.

## TAU

Participants Allocated to the TAU arm received treatment in line with national clinical guidelines (NICE, 2014) from their EI care

team. Case notes reviews were conducted to monitor the care received by these participants and recorded what proportion of TAU participants received EMDR or other individually prescribed psychological interventions during the trial.

## Assessments and outcomes

### Feasibility outcomes

There were four feasibility outcomes: (a) recruitment of EI participants into a trial of EMDRp; (b) levels of trial retention; (c) the therapists' ability to deliver EMDRp in EI settings with sufficient fidelity to the treatment protocol; and (c) levels of engagement of EI clients in EMDRp. These were operationalized a priori using a three-level 'traffic light' approach (Avery et al., 2017) with thresholds to indicate, for each outcome, whether a future larger-scale trial would be feasible using the current design ('green'), whether the trial would be feasible if modifications were applied ('amber'), or whether there are unresolvable issues that would jeopardize a future trial ('red'). The outcomes and thresholds were approved by an independent trial steering committee, and are reported in full in Supplementary Material 2. In brief, a future larger-scale trial was regarded as feasible ('green') if: (a) three or more participants were recruited and randomized per month; (b) at least 70% of participant were retained at post-randomization assessments; (c) at least 70% of EMDRp + TAU participants attended 8 out of 16 planned EMDRp sessions; and (d) over 80% of rated therapy recordings received at least acceptable EFRS ratings.

### Rater-blinded and self-report measures

We gathered descriptive clinical and demographic information alongside the Trauma and Life Events checklist (TALE; Carr, Hardy, & Fornells-Ambrojo, 2018), a 20-item tool to screen for exposure to potentially traumatic events. To examine the 'promise of efficacy' of EMDRp, several interview and self-report measures were administered at both baseline and post-randomization assessments. All assessors received training and ongoing supervision in the administration and scoring of all rater-blind clinical interviews and demonstrated excellent reliability against ratings produced by expert raters. Data collected at the three assessment points included:

*The PANSS*, a widely used scale for rating semi-structured interviews assessing the presence and severity of 30 psychotic and other symptoms of psychopathology, each scored on a 7-point rating scale (1 = symptoms absent; 7 = extreme symptom severity). While the PANSS total score is most frequently reported in RCTs, recent factor analytic studies have uncovered a more complex latent structure corresponding to positive symptoms, negative symptoms, excitatory symptoms, affective symptoms, and symptoms of cognitive disorganization (Shafer & Dazzi, 2019). Here, we report analyses focused on PANSS total scores; a more detailed breakdown of PANSS subscales can in be found in Supplementary Material 3.

*The Psychotic Symptom Rating Scales* (PSYRATS; Haddock, McCarron, Tarrier, & Faragher, 1999), a widely used semi-structured interview comprising 17 items assessing dimensional features of auditory hallucinations (PSYRATS-AH; 11 items) and delusions (PSYRATS-D; 6 items). Items are scored on a five-point ordinal scale (0 = least severe; 4 = most severe). Here we report analyses based on PSYRATS-AH and PSYRATS-D total scores. A more detailed breakdown of PSYRATS-AH and PSYRATS-D scores informed by recent factor analytic studies (Woodward et al., 2014) can in be found in Supplementary Material 3.

*The Personal and Social Performance Scale* (PSP; Morosini, Magliano, Brambilla, Ugolini, & Pioli, 2000), an interviewer-rated measure of functioning across four domains: socially useful activities, personal and social relationships, self-care and disturbing/aggressive behavior. Each domain is rated on a six-point scale measuring the level of functioning (absent = 1; very severe = 6) and the scores are then pooled on a 10-point interval scale to provide an overall score out of 100.

*The Questionnaire about the Process of Recovery* (QPR; Neil et al., 2009) is a 22-item self-report measure assessing intrapersonal and interpersonal features of personal recovery, developed in collaboration with people with lived experience of psychosis. Items are scored on a 5-point scale (0 = disagree strongly; 4 = strongly agree), with higher scores being indicative of greater perceived personal recovery. Used as an outcome measure in several RCTs of psychological therapies for psychosis, the QPR has also been endorsed as a routine outcome measure in EI services in England (NHSE, 2016).

*The Green et al., Paranoid Thoughts Scale* (GPTS; Green et al., 2008), a 32-item self-report measure assessing paranoid thinking. Each GPTS item is scored on a 5-point Likert scale (1 = not at all; 5 = totally).

*The PTSD Checklist for DSM-5* (PCL-5; Weathers et al., 2013) is a 20-item self-report questionnaire based on the DSM-5 criteria for PTSD. Items are scored using a 5-point scale (0 = not at all; 4 = extremely). In addition to providing a total PTSD severity score (range 0–80), the PCL-5 can be used to identify participants presenting clinically significant post-traumatic symptoms i.e. PTSD severity scores >31, which are indicative of possible PTSD 'caseness'.

*The International Trauma Questionnaire* (ITQ; Cloitre et al., 2018), an 18-item self-report measure assessing post-traumatic symptoms over the previous month consistent with ICD-11 diagnostic criteria for PTSD and Complex PTSD (CPTSD). Items are scored on 5-point scales (0 = not at all; 4 = extremely). The questionnaire provides a dimensional PTSD score (six items measuring PTSD symptoms) and a dimensional 'disturbances in self-organization' (DSO) score, reflecting the additional symptoms that characterize CPTSD. A diagnostic algorithm can be applied to ITQ scores to identify individuals with probable ICD-11 diagnosis of PTSD or CPTSD (Cloitre et al., 2018).

*The Dissociative Experiences Scale-II* (DES-II; Carlson & Putnam, 1993), a widely used self-report measure of dissociation symptoms and experiences. Each item is rated on a 0–100% scale, reflecting the estimated amount of time a participant experiences a dissociative event(s) in their daily life. As one of the DES-II items reflects experiences that are common in people with psychosis (hearing voices), the mean DES-II score used in the present analyses was estimated using the remaining 27 items.

*The EQ-5D-5L* (Janssen et al., 2013) is a self-report measure of overall health across five dimensions: physical mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The scale also includes a visual analog scale (EQ-VAS) where participants rate their perceived overall health from 0 (the worst health imaginable) to 100 (the best health imaginable). While the EQ-5D-5L is used predominantly for health economics analyses and was administered in this trial to evaluate the viability of collecting this information alongside service use data in a future larger-scale trial, the EQ-VAS was used as a quantitative health outcome measure reflecting the respondent's own judgment.

*The General Anxiety Disorder scale* (GAD-7; Spitzer, Kroenke, Williams, & Löwe, 2006), a frequently used self-report measure of

anxiety, comprises seven items rated on a 4-point scale (0 = not at all; 3 = nearly every day).

*The Patient Health Questionnaire* (PHQ-9; Kroenke, Spitzer, & Williams, 2001), a nine-item self-report measures of low mood and depression frequently used alongside the GAD-7 and each item is scored similarly.

### Adverse events

In line with Good Clinical Practice and the UK Policy Framework for Health and Social Care Research (HRA, 2023), we monitored all adverse events (AEs) experienced by participants over the course of the trial. HRA guidance was followed to classify and report serious adverse events (SAEs; i.e. resulting in death; life-threatening; requiring new or prolonged hospitalizations; resulting in persistent or significant disability/incapacity). All AEs and SAEs were assessed for relatedness to the trial by a clinically qualified senior researcher and the chair of the independent trial steering committee.

### Data analysis

Descriptive statistics were used to summarize the flow of participants across the trial, in accordance with CONSORT fields for feasibility trials (Eldridge et al., 2016) and to compare observed data against a-priori feasibility thresholds (Varese et al., 2021). As per protocol, no formal hypothesis testing was carried out to compare the two trial arms for clinical effectiveness. Summary statistics (Mean, SD, % of missing data) were tabulated for each measure by trial arm for each time point (baseline, 6-month follow-up and 12-month-follow up). In line with methodological/statistical proposals for reconciling recommendations to refrain from conventional inferential testing (via estimation of treatment effects with 95% CIs) and the benefits of providing evidence in support of the 'promise of efficacy' of novel interventions to inform future larger-scale evaluations (Lee, Whitehead, Jacques, & Julious, 2014), we calculated unadjusted mean differences and their associated 80% CI at 6 months and 12 months as well as their corresponding standardized mean difference (Cohen's *d*).

## Results

The Consort diagram is shown in Fig. 1. Between June 2019 and April 2021 (with a suspension of recruitment between March and July 2020 because of COVID-19 restrictions), 108 service users were referred. We assessed for eligibility 69 individuals, randomizing 60 to either receiving EMDRp + TAU ( $n = 31$ ) or TAU only ( $n = 29$ ). Six-month follow-ups were completed between January 2020 and January 2022, and the 12-month follow-up assessments between July 2020 and May 2022.

### Feasibility outcomes

#### Recruitment and retention

We recruited 100% of our target sample of 60, averaging three randomizations in each month of active recruitment (green progression zone). Fifty participants (83%) completed at least one assessment follow-up (green); 45 (75%) completed 6-month assessments (green) and 42 (70.0%) completed 12-month assessments (green). Trial retention was comparable across arms, with 83.9 and 82.7% of participants completing at least one post-randomization assessment in the EMDRp + TAU and TAU groups respectively. Retention in the two arms was similar at the 6-month (80.6% *v.* 69.0%;  $\chi^2 = 1.09$ ,  $p = 0.296$ ) and

12-month follow-ups (71.0% *v.* 69.0%;  $\chi^2 = 0.02$ ,  $p = 0.865$ ) but noticeably lower for the 34 participants recruited prior to the onset of the COVID-19 pandemic (69.7% at 6-month and 63.6% at 12-month) compared to 27 recruited following the implementation of COVID-related procedural adaptations (81.5% at 6-months and 77.8% at 12-months).

### Therapy engagement

Following the onset of the pandemic, treatment had to be suspended until procedures could be adapted to enable the remote delivery of the intervention, and until the necessary research governance approvals to re-initiate the trial had been obtained. Ten participants in the EMDRp + TAU arm receiving treatment in March 2020, had their treatment suspended until July 2020. Eight subsequently resumed therapy remotely, and we extended the therapy window for affected participants to enable the delivery of up to 16 sessions of EMDRp as per protocol and in light of ethical concerns related to the sudden withdrawal of therapy. Twenty-three EMDRp + TAU participants (74.2%) received eight or more sessions of EMDRp (green progression zone); four did not attend any. The remainder dropped out before session 8 due to withdrawal from the trial (two participants), engagement difficulties with both EI services and the trial (4) and deciding to prioritize other psychological therapies offered by EI services as per TAU (2). Participants received on average 10.8 EMDRp sessions (range 0–16; median = 12), with those attending at least 1 session receiving a mean of 12.4 sessions (range 2–16; median = 16). Ten participants attended therapy sessions entirely face-to-face, eight entirely remotely, and nine a combination of remote and face-to-face sessions.

### EMDR fidelity

All therapists demonstrated adequate or very good EFRS scores across all 37 sessions (11% of 334 sessions delivered); 96.7% of rated sessions had adequate ratings or higher (green progression zone).

### Rater-blinded and self-report measures

Baseline characteristics are summarized in Table 1. Further detail on participants' trauma history are provided in Table 2, indicating that virtually every participant in the trial reported repeated (98% of the sample) and multiple (100%) exposures to the traumatic events assessed by the TALE, with high levels of perceived impact of these events on their ongoing difficulties ( $M = 8.10$ , *s.d.* = 1.55 out of a possible highest score of 10).

There were 15 blind breaks (randomization assignments revealed to assessors) over the follow-up period. Except for one case, it was possible to re-allocate participants to a different blind assessor for the completion of the assessments. When this was not possible, the PANSS, PSYRATS, and PSP were rated by a blind assessor based on a recording of the assessment interview. Descriptive statistics of the measures collected at the three assessment points are summarized in Table 3, with summary statistics for each measure tabulated by trial arm for each time point.

Based on the 80% CIs, at the 6-month follow-up assessment there was potential indication of treatment effect in favour of the EMDRp + TAU arm on measures of total psychotic symptom severity (PANSS total score), subjective recovery from psychosis (QPR), post-traumatic symptoms (PCL-5 total score and the ITQ PTSD) symptoms of anxiety and depression (GAD-7 and PHQ-9) and self-reported general health status (EQ-VAS). At

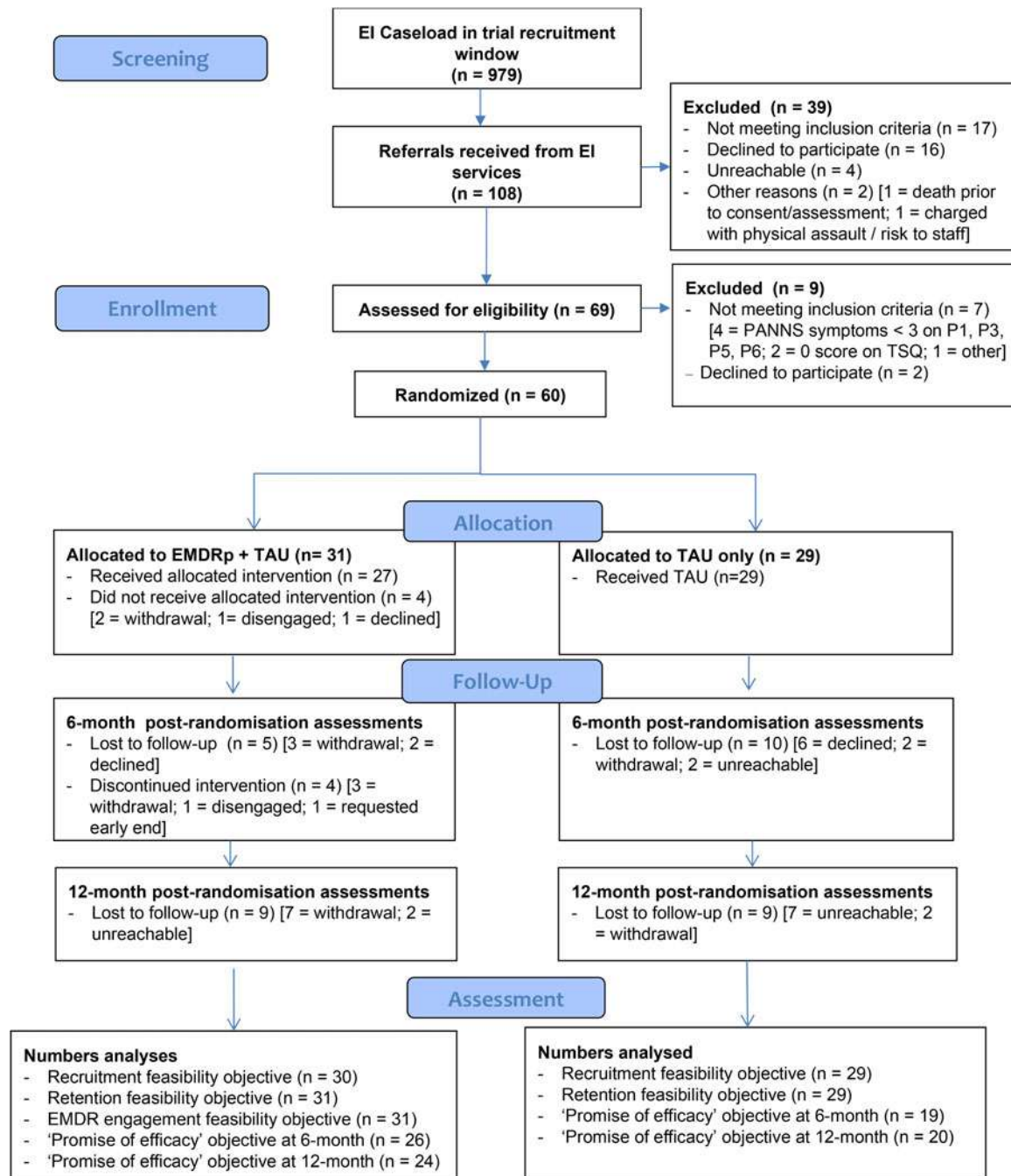


Figure 1. CONSORT diagram.

12-months, evidence of promise of the intervention remained for both PTSD symptoms and general health status, whereas signals of efficacy for other outcomes were more modest compared to 6-month follow-up. Inspection of scores indicates that this was likely not due to exacerbation of symptoms in the EMDRp + TAU arm (i.e. treatment gains were maintained) but rather improvements in the TAU group between the 6- and 12-month follow-up assessment. We calculated odds ratios with 80% CIs reflecting the odds of presenting clinically significant post-traumatic symptoms on the PCL-5 (scores >31, indicative of possible DSM-5 PTSD diagnosis) and the ITQ (meeting the ICD-11 diagnostic criteria for PTSD and CPTSD) in the intervention arm

compared to TAU (see Table 4). Being allocated to the EMDRp + TAU arm was related to lower odds of meeting criteria for PTSD on the ITQ and PCL-5 at both 6-months and 12-months and with lower odds of meeting criteria for CPTSD at the 12-months.

#### Adverse events

We recorded 60 AEs; 13 were rated as SAEs (4 in the EMDRp + TAU arm, 8 in TAU and 1 pre-randomization). No SAEs were related to the trial procedures or intervention. More non-serious events were recorded in the EMDRp + TAU arm compared to TAU (33 v. 14), mostly consisting in expected adverse reactions

**Table 1.** Baseline demographic and clinical characteristics of the trial sample

Participant characteristics	Total <i>N</i> = 60		EMDRp + TAU <i>n</i> = 31		TAU only <i>n</i> = 29	
	<i>n</i> (%)	M (s.d.)	<i>n</i> (%)	M (s.d.)	<i>n</i> (%)	M (s.d.)
<b>Gender</b>						
Female	36 (60%)		20 (65%)		16 (55%)	
Male	24 (40%)		11 (35%)		13 (45%)	
<b>Age</b>						
Range (years)	17–62	36.01 (13.15)	17–62	36.25 (13.86)	18–61	35.75 (12.58)
<b>Ethnicity</b>						
White	52 (87%)		29 (94%)		23 (79%)	
Asian	4 (7%)		2 (6%)		2 (7%)	
Mixed race	2 (3%)		0 (0%)		2 (7%)	
Black	2 (3%)		0 (0%)		2 (7%)	
<b>Marital status</b>						
Single	35 (58%)		16 (52%)		19 (66%)	
Married/living together	13 (22%)		9 (29%)		4 (14%)	
In a relationship	5 (8%)		3 (10%)		2 (7%)	
Separated	1 (2%)		1 (3%)		0 (0%)	
Divorced	6 (10%)		2 (7%)		4 (14%)	
<b>Employment status</b>						
Paid/self-employed	11 (18%)		8 (26%)		3 (10%)	
Voluntary	2 (3%)		1 (3%)		1 (3%)	
Unemployed	37 (62%)		14 (45%)		23 (79%)	
Student	4 (7%)		4 (13%)		0 (0%)	
Housewife/husband	1 (2%)		0 (0%)		1 (3%)	
Retired	1 (2%)		1 (3%)		0 (0%)	
Exempted	1 (2%)		1 (3%)		0 (0%)	
Other (sick leave)	3 (5%)		2 (7%)		1 (3%)	
<b>Psychiatric features</b>						
Past admission to psychiatric unit	19 (32%)		11 (36%)		8 (28%)	
Past psychiatric section	16 (27%)		9 (29%)		7 (24%)	
Taking antipsychotic medication	57 (96%)		29 (94%)		28 (97%)	
Dose equivalence to Haloperidol (in mg) <sup>a</sup>	6.32 (5.24)		6.16 (5.50)		6.50 (5.04)	

<sup>a</sup>Calculated using the Defined Daily Dose (DDD) method (Leucht, Samara, Heres, & Davis, 2016).

(i.e. transient and mild exacerbations of symptoms coinciding with the onset of trauma memory reprocessing work).

### TAU Psychological interventions

Case note reviews indicated that many TAU participants accessed a range of psychological therapies over the trial follow-up period. By the 12-month follow-up assessment, 66% of TAU participants had accessed or already completed a psychological therapy offered by EI or other NHS services, including CBT (16 participants), EMDR (two participants) and Dialectical Behavior Therapy (one participant). The access to psychological treatments by the TAU only group should be considered when interpreting the differences in clinical outcomes above.

### Discussion

This is the first randomized controlled trial to evaluate the feasibility of a trial of trauma-focused therapy for early psychosis clients. We found it is possible to recruit and retain a sufficient number of service users in UK EI settings to enable a larger scale evaluation of EMDRp. Consistent with previous research with people with first episode psychosis (e.g. Buswell, Haime, Lloyd-Evans, & Billings, 2021; Vila-Badia et al., 2021), all participants reported multiple and repeated exposures to traumatic events, with particularly high levels of perceived impact on ongoing difficulties of trial participants. Although our inclusion criteria were purposely broad to include participants with subsyndromal post-traumatic symptoms, many met the criteria for probable PTSD and/or Complex PTSD, which is again congruent with

**Table 2.** TALE data for the 60 randomized participants

Trauma category		Overall (N = 60)		TAU (n = 29)		EMDRp & TAU (n = 31)	
		n	%	n	%	n	%
Trauma type (TALE item number)	War exposure (item 1)	1	1.7	0	0.0	1	3.2
	Attachment related (2–4)	54	90.0	26	89.7	28	90.3
	Witnessed verbal or physical abuse at home (9)	40	66.7	19	65.5	21	67.7
	Any interpersonal (any of below items)	–	–	–	–	–	–
	• Bullying & discrimination (5 & 6)	47	78.3	21	72.4	26	83.9
	– Sexual abuse (13 & 14)	39	65.0	19	65.5	20	64.5
	– Emotional abuse (7)	49	81.7	23	79.3	26	83.9
	– Physical abuse (8 & 10)	53	88.3	25	86.2	28	90.3
	– Emotional neglect (11)	42	70.0	19	65.5	23	74.2
	– Physical neglect (12)	13	21.7	5	17.2	8	25.8
	Psychosis-related (15–17)	60	100	29	100	31	100
	Criminal justice (18)	26	43.3	11	37.9	15	48.4
	Non-interpersonal (19)	35	58.3	15	51.7	20	64.5
	Other trauma (20)	26	43.3	9	31.0	17	54.8
Perceived impact (TALE item 21.c)	Mean impact of index traumas on current difficulties (range, s.d.)	8.10 (3–10, 1.88)		7.96 (3–10, 1.92)		8.23 (5–10, 1.87)	
Multiple exposure	Repeated events (at least 1 item answered ‘yes’ to ‘more than once’)	59	98	29	100.0	30	96.8
	Multiple trauma types (more than 1 of above types reported)	60	100.0	29	100.0	31	100.0
Trauma types	Mean number of trauma types (range and s.d.)	8.06 (2–12, 2.34)		7.55 (2–12, 2.26)		8.54 (3–12, 2.35)	
Trauma timing	Child (any item < age 16 years)	59	98.3	28	96.6	31	100
	Adult (any item > age 16 years)	55	91.7	26	89.7	29	93.5
	Both (any item < age 16 AND > age 16 years)	54	90.0	26	89.7	28	90.3

past research (e.g. Panayi et al., 2022; Rodrigues & Anderson, 2017). Future evaluations of trauma therapies in patients with psychosis may benefit from using similarly broad inclusion criteria.

We found that the EMDRp intervention can be delivered with high levels of fidelity, and that it is possible to engage EI clients in this intervention using both remote and face-to-face means. Although some clients struggled to engage, this was expected given that avoidance is a common response to trauma, and given that the intervention involved exposure to trauma-related memories and images. Our levels of treatment drop-out were similar to past trials of trauma-focused therapies (Lewis, Roberts, Gibson, & Bisson, 2020), suggesting that clients with early psychosis may not find this treatment any less tolerable than other patient groups.

While the safety of the therapy can only be established via a larger-scale trial, our data suggest that EMDRp has a promising safety profile, as no SAEs were related to the intervention or trial procedures. The higher number of non-serious AEs observed in the EMDRp + TAU group may be a by-product of the more intensive scrutiny of participant allocated to this trial arm who had regular contact with EMDR therapists. As in previous trials

(e.g. Lewis et al., 2020), transient and mild exacerbations of distress in response to trauma memory reprocessing work typically did not require a change in care provision and were usually resolved by the next therapy session. Future trials of trauma-focused therapies in this client group may nonetheless benefit from more sensitive assessments of potential symptom exacerbation during therapy, e.g., via analysis of brief questionnaires collected at each therapy session (Burger et al., 2023).

The findings also support the ‘promise of efficacy’ of EMDRp as a potentially valuable intervention for EI service users with a trauma history. At the end of treatment, EMDRp showed promise of benefit on a range of outcomes frequently considered in trials of psychological therapy for early psychosis, including overall psychotic symptom severity and subjective recovery from psychosis. Whilst other psychosis-related outcomes showed no robust promise of efficacy in this small trial, promising findings were observed in relation to improved affective symptoms, general health status and post-traumatic symptoms. As often seen in psychotherapy trials, between-group differences at the 12-month follow-up were less pronounced but continued to show potential benefit on post-traumatic symptoms and general health status.

**Table 3.** Mental health outcome data at baseline and follow-up assessments

	EMDRp + TAU			TAU			M diff.	80% CI	Cohen's d
	M	s.d.	Missing	M	s.d.	Missing			
<b>PANSS</b>									
Baseline	66.8	11.3	0	67.9	14.4	0			
6 Month	56.4	13.3	1	64.1	10.9	0	-7.7	(-12.5 to -2.8)	-0.6
12 Month	50.7	14.8	1	54.4	9.6	1	-3.7	(-9.0 to 1.5)	-0.3
<b>PSYRATS-AH</b>									
Baseline	18.5	15.0	0	16.1	16.7	0			
6 Month	13.5	15.5	1	17.0	14.5	1	-3.5	(-9.6 to 2.5)	-0.2
12 Month	16.0	15.2	1	13.2	14.5	2	2.7	(-3.5 to 9.0)	0.2
<b>PSYRATS-D</b>									
Baseline	15.8	4.6	0	13.6	6.7	0			
6 Month	10.3	7.3	1	10.9	7.7	0	-0.6	(-3.5 to 2.4)	-0.1
12 Month	7.0	8.4	2	7.8	8.1	1	-0.8	(-4.3 to 2.6)	-0.1
<b>GPTS</b>									
Baseline	91.0	34.2	0	83.9	39.6	0			
6 Month	65.0	27.8	4	71.2	22.5	2	-6.3	(-16.9 to 4.4)	-0.2
12 Month	61.4	30.6	2	60.4	24.1	0	1.1	(-10.3 to 12.4)	0.0
<b>QPR</b>									
Baseline	32.1	8.3	1	28.6	9.8	0			
6 Month	37.3	11.1	4	31.2	9.1	3	6.1	(1.7 to 10.5)	0.6
12 Month	39.2	11.9	2	37.1	8.6	0	2.1	(-2.2 to 6.3)	0.2
<b>GAD-7</b>									
Baseline	15.7	3.9	0	15.0	4.4	0			
6 Month	10.5	5.9	4	14.2	5.1	3	-3.7	(-6.0 to -1.3)	-0.7
12 Month	10.2	6.6	2	12.4	5.3	0	-2.2	(-4.7 to 0.3)	-0.4
<b>PHQ-9</b>									
Baseline	18.1	4.1	0	18.3	4.6	0			
6 Month	13.3	6.8	5	16.5	6.1	3	-3.3	(-6.1 to -0.5)	-0.5
12 Month	12.2	6.8	2	12.6	5.5	0	-0.5	(-3.0 to 2.1)	-0.1
<b>PCL-5</b>									
Baseline	54.3	12.8	1	50.9	18.0	0			
6 Month	35.8	21.2	4	48.1	19.2	3	-12.2	(-20.9 to -3.6)	-0.6
12 Month	31.5	21.6	3	40.7	16.3	0	-9.2	(-17.2 to -1.3)	-0.5
<b>ITQ PTSD</b>									
Baseline	16.8	5.2	2	14.6	7.8	0			
6 Month	10.6	8.1	5	13.8	6.0	4	-3.2	(-6.3 to 0.0)	-0.4
12 Month	10.1	7.3	4	13.8	6.9	2	-3.8	(-6.9 to -0.7)	-0.5
<b>ITQ DSO</b>									
Baseline	22.8	6.0	2	22.8	7.6	0			
6 Month	17.3	10.0	5	21.1	8.4	4	-3.8	(-7.9 to 0.2)	-0.4
12 Month	13.9	8.7	4	17.6	10.0	2	-3.6	(-7.7 to 0.5)	-0.4

(Continued)

**Table 3.** (Continued.)

	EMDRp + TAU			TAU			M diff.	80% CI	Cohen's d
	M	s.d.	Missing	M	s.d.	Missing			
DES-II									
Baseline	34.6	18.0	2	29.3	18.6	0			
6 Month	25.6	16.5	4	28.9	21.5	3	-3.3	(-11.4 to 4.8)	-0.2
12 Month	26.8	20.7	3	25.4	17.3	0	1.4	(-6.6 to 9.4)	0.1
PSP									
Baseline	57.4	15.4	0	51.4	14.0	0			
6 Month	61.2	14.1	1	56.6	10.2	0	4.6	(-0.3 to 9.5)	0.4
12 Month	64.8	13.1	2	61.5	9.2	1	3.3	(-1.5 to 8.0)	0.3
EQ-5D VAS									
Baseline	50.2	18.2	1	50.4	25.2	0			
6 Month	65.1	19.3	4	49.1	21.5	3	16.0	(7.3-24.6)	0.8
12 Month	68.7	14.7	3	59.8	22.7	0	8.9	(0.9-17.0)	0.5

**Table 4.** Probable presence of DSM-5 and ICD-11 post-traumatic stress diagnoses at the three assessment points

		EMDRp + TAU		TAU		OR	80% CI
		n	%	n	%		
PCL-5							
Probable PTSD (>31)							
Baseline	Yes	28	90.3	26	89.7		
	Missing	1	3.2	0	0		
6 Month	Yes	12	48.0	14	70.0	0.3	(0.1-0.8)
	Missing	4	16.0	3	15.0		
12 Month	Yes	9	40.9	16	80.0	0.2	(0.1-0.6)
	Missing	3	13.6	0	0		
ITQ							
CPTSD criteria met							
Baseline	Yes	19	61.3	15	51.7		
	Missing	3	9.7	0	0		
6 Month	Yes	7	28.0	8	40.0	0.5	(0.2-1.3)
	Missing	5	20.0	4	20.0		
12 Month	Yes	5	22.7	12	60.0	0.2	(0.1-0.5)
	Missing	4	18.2	2	10.0		
PTSD criteria met							
Baseline	Yes	24	77.4	15	51.7		
	Missing	3	9.7	0	0		
6 Month	Yes	7	20.0	11	55.0	0.2	(0.1-0.6)
	Missing	5	20.0	4	20.0		
12 Month	Yes	7	31.8	14	70.0	0.2	(0.1-0.5)
	Missing	4	18.2	2	10.0		

The findings from this study indicate the feasibility and desirability of conducting a multi-center trial to evaluate the efficacy of EMDRp for patients suffering from early psychosis. Whilst this feasibility study reports preliminary evidence that EMDRp can be a valuable addition to usual care provided by EI services, our findings should be interpreted with caution. The trial followed a pre-registered protocol and prespecified thresholds to evaluate the feasibility of a future multi-center evaluation of EMDRp. However, the delivery of the trial was severely affected by the COVID-19 pandemic, resulting in several procedural adaptations which are here reported transparently in line with CONSERVE guidelines. Of note, the unexpected circumstances of the COVID-19 pandemic allowed us to demonstrate that it is possible to safely deliver trauma-focused therapy in clients with complex/severe mental health problems using remote means, therefore adding to emerging evidence base on the acceptability and efficacy of 'teletherapy' for severe mental health problems and survivors of complex trauma. The trial was single-center study, and therefore findings may not generalize to other EI settings in the UK or other countries. As there was no active treatment control arm, the study cannot clarify the relative effectiveness of EMDRp compared to other psychosocial intervention for psychosis. The signals of efficacy observed across varied mental health outcomes are nonetheless encouraging, especially considering the high levels of uptake of psychological therapies in participants allocated to the TAU arm. Future trials evaluating the efficacy of EMDRp may therefore benefit from procedural and analytic strategies to account for the high levels of uptake of psychological interventions in TAU provided by EI services. Furthermore, mechanistic research informed by the growing evidence on the potential mediators of the trauma-psychosis relationship (Williams, Bucci, Berry, & Varese, 2018) and the neural and psychological mechanisms of action of EMDR in other patient groups (e.g. Landin-Romero, Moreno-Alcazar, Pagani, & Amann, 2018) may be integrated in future efficacy trials to clarify how EMRPP may bring about benefit on valued outcomes for early psychosis clients, and inform subsequent measures to maximize the effectiveness of this treatment approach for early psychosis.

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