Title: Trauma-focused therapy in early psychosis: Results of a feasibility randomised controlled trial of EMDR for Psychosis (EMDRp) in Early Intervention settings

Short title: EMDR for psychosis

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ACKNOWLEDGEMENTS

The EASE Feasibility trial team thanks the Early Intervention staff at Lancashire and South Cumbria NHS Foundation Trust who referred to and supported the delivery of the study, and the service users who took part in this trial. We are grateful for the support of the independent

chair of our Trial Steering Committee (TSC), Professor Andrew Gumley, and the other members of the TSC. We also thank the members of the Lived Experience Advisory Panel (LEAP) of the Manchester Complex Trauma and Resilience Research Unit for their advice and guidance, and Dr Kate Allsopp, Dr Kim Cartwright and Ms Alice Newton for the coordination of the Patient and Public Involvement consultations conducted with LEAP over the course of the study.

FUNDING STATEMENT
This project is funded by the National Institute for Health and Care Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number PB-PG-0317-20037). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

CONFLICTS OF INTEREST STATEMENT
Co-authors Logie, Keane, and Malkin are involved in the delivery of EMDR training workshops and events. All other co-authors have no conflicts of interest to declare.

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 vs TAU only was conducted. Participants completed baseline, 6-month and 12-month post-randomisation 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

60 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 8 therapy sessions and 97% rated therapy sessions demonstrated good treatment fidelity. At 6-month, there were signals of promise of efficacy of EMDRp+TAU vs 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-centre trial of EMDRp is feasible and warranted.

KEY WORDS: Randomised controlled trial; Eye Movement Desensitization and Reprocessing; Psychosis; Trauma; Psychological Therapies

1. INTRODUCTION

Psychosis affects 0.7% of the population, causing significant personal and societal burden and poor recovery outcomes (e.g. Finberg *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 *et al*., 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., Varese *et al.*, 2012; Pastore *et al.,* 2022) 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 *et al*., 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 (van den Berg *et al*., 2015; de Bont *et al*., 2016), stimulating efforts to adapt it for clients with psychosis (Phillips *et al*., 2021). As existing randomised 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 *et al*., 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.

2. METHODS

The trial protocol and feasibility criteria were pre-specified (ISRCTN16262847; Varese *et al.* 2020). 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).

2.1 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) versus TAU alone. Participants in both arms were assessed at baseline, 6- and 12-months post-randomization.

2.2 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 *et al*., 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 ≥ 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.

2.3 Randomisation

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 randomisation service (www.sealedenvelope.com). The allocation sequence was concealed from the research team, and RAs conducting the follow-up assessments were blind to treatment allocation.

2.4 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.* (2020). The manualised 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 *et al.,* 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.

2.5 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.

2.6 Assessments and outcomes

2.6.1 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 operationalised 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 jeopardise 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 randomised per month; (b) at least 70% of participant were retained at post-randomisation 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.

2.6.2 Rater-blinded and self-report measures: We gathered descriptive clinical and demographic information alongside the Trauma and Life Events checklist (TALE; Carr *et al*, 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-randomisation 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, excitative symptoms, affective symptoms and symptoms of cognitive disorganisation (Shafer *et al.*, 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 *et al.,* 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 (Woodword et al., 2014) can in be found in *Supplementary Material 3.*

The Personal and Social Performance Scale (PSP; Morosini et al., 2000), an interviewer-rated measure of functioning across four domains: socially useful activities, personal and social relationships, self-care and disturbing/aggressive behaviour. 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.,* 2007) 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 (6 items measuring PTSD symptoms) and a dimensional 'disturbances in self-organisation' (DSO) score, reflecting the additional symptoms that characterise 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 analogue 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 judgement.

The General Anxiety Disorder scale (GAD-7; Spitzer *et al,* 2006), a frequently used self-report measure of anxiety, comprises 7 items rated on a 4-point scale (0 = not at all; 3 = nearly every day).

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

2.6.3 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 hospitalisations; 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.

2.7 Data analysis

Descriptive statistics were used to summarise 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.,* 2020). 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 *et al.,* 2014), we calculated unadjusted mean differences and their associated 80% CI at 6 months and 12 months as well as their corresponding standardised mean difference (Cohen's d).

3. RESULTS

The CONSORT diagram is shown in Figure 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, randomising 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.

[Insert Figure 1 approximately here]

3.1 Feasibility outcomes

Recruitment and retention. We recruited 100% of our target sample of 60, averaging 3 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-randomisation assessment in the EMDRp+TAU and TAU groups respectively. Retention in the two arms was similar at the 6-month (80.6% vs 69.0%; $\chi_2 = 1.09$, $p = .296$) and 12-month follow-ups (71.0% vs 69.0%; $\chi_2 = 0.02$, p = .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. 23 EMDRp+TAU participants (74.2%) received eight or more sessions of EMDRp (green progression zone); 4 did not attend any. The remainder dropped out before session 8 due to withdrawal from the trial (2 participants), engagement difficulties with both EI services and the trial (4) and deciding to prioritise 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, 8 entirely remotely, and 9 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).

3.2 Rater-blinded and self-report measures

Baseline characteristics are summarised 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, SD = 1.55 out of a possible highest score of 10).

[Insert Table 1 approximately here]

[Insert Table 2 approximately here]

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 summarised in Table 3, with summary statistics for each measure tabulated by trial arm for each time point.

[Insert Table 3 approximately here]

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 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.

3.3 Adverse events

We recorded 60 AEs; 13 were rated as SAEs (4 in the EMDRp+TAU arm, 8 in TAU and 1 pre- randomisation). 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 vs 14), mostly consisting in expected adverse reactions (i.e., transient and mild exacerbations of symptoms coinciding with the onset of trauma memory reprocessing work).

3.4 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 (2 participants) and Dialectical Behaviour Therapy (1 participant). The access to psychological treatments by the TAU only group should be considered when interpreting the differences in clinical outcomes above.

4. DISCUSSION

This is the first randomised 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., Vila-Badia *et al.,* 2021; Buswell *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 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 *et al.* 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.

The findings from this study indicate the feasibility and desirability of conducting a multi-centre 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-centre 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-centre study, and therefore findings may not generalise 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 *et al.,* 2018) and the neural and psychological mechanisms of action of EMDR in other patient groups (e.g., Landin-Romero *et al.,*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 maximise the effectiveness of this treatment approach for early psychosis.

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