Psychiatry Research 351 (2025) 116564

Contents lists available at ScienceDirect

Psychiatry Research

journal homepage: www.elsevier.com/locate/psychres

Managing unusual sensory experiences in at-risk mental state for psychosis in England: A parallel group, single-blind, randomised controlled feasibility trial

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ARTICLE INFO

Keywords:
At-risk mental state for psychosis
Unusual sensory experiences
Psychoeducation
Feasibility study
Randomised control trial

ABSTRACT

Young people at risk of psychosis often present to services with unusual sensory experiences (USE). Managing Unusual Sensory Experiences (MUSE) is a digital intervention that therapists can use with clients to support better understanding of these experiences and how to manage them. This study aimed to test the feasibility of delivering MUSE within a RCT design. We conducted a randomised, single-blind, feasibility study of MUSE + Treatment as Usual (TAU), compared to TAU, for individuals experiencing USE in At-Risk Mental State (ARMS) services across two mental health trusts in England. Assessments were conducted at baseline, 12 weeks (post-treatment), and 20 weeks (follow-up). Ninety-three people were randomised (47 to TAU and 46 to MUSE+TAU). 79 % of participants completed the primary outcome measures at the primary timepoint (post-treatment). For the primary outcomes, the functioning (SOFAS) score at 12 weeks favoured MUSE+TAU (SOFAS adjusted mean difference 4·19 [95 % CI:10·22 to 1·85] with a Cohen's d of -0·28 [95 % CI:0·68 to 0·12]) and further improved at 20 weeks (adjusted mean difference -5·33 [95 % CI:11·65 to 1·0]; Cohen's d -0·35 [95 % CI:0·77 to 0·07]). The other primary outcome measure (PSYRATS-AH) explored impact on USE and found no difference at 12 weeks (mean adjusted difference 0·01 [95 % CI:4·88 to 4·87], Cohen's d 0·00 [95 % CI:0·48 to 0·48]), but slightly favoured TAU at 20 weeks (adjusted mean difference -1·43 [95 % CI:6·53 to 3·66], Cohen's d -0·14 [95 % CI:0·64 to 0·36]). MUSE is a promising intervention for therapists to use in support of individuals at risk of psychosis.

1. Introduction

The term At-Risk Mental State (ARMS) was established by Yung and McGorry (1996) to describe those at increased risk of developing psychosis. Early intervention with individuals at risk is argued to offer a unique opportunity to prevent the development of full psychosis and other enduring mental health problems (NHS England, 2023; Yung et al., 2021) with benefits for the individual, their family and society (McGorry et al., 2024).

In ARMS presentations, Cognitive Behavioural Therapy (CBT) has been recommended as a first line of treatment (NICE, 2014); however, the evidence from trials remains inconclusive (Kuharic et al., 2019; Fusar-Poli et al., 2019), particularly within shorter timescales (Mei et al., 2021). Treatments for ARMS may be advanced by attempts to improve

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https://doi.org/10.1016/j.psychres.2025.116564
Received 13 March 2025; Received in revised form 21 May 2025; Accepted 23 May 2025
Available online 24 May 2025

the efficacy of interventions in CBT for psychosis (CBTp). Treatments have focused both on maintenance mechanisms (Freeman et al., 2016) and proposed causal mechanisms (Garety et al., 2017), or have used technology to make treatment more engaging and effective (Garety et al., 2017). Clinical recommendations for ARMS encourage stepped-care interventions, whereby CBT and low-intensity, needs-based interventions are used prior to consideration of pharmacology (NICE, 2014; Addington et al., 2017; Schmidt et al., 2015). Newman-Taylor and Bentall (2024) argue that more precision in matching service users to specific treatments, and focusing on key mechanisms that maintain symptoms, could increase the effectiveness of treatment. CBT interventions that have specifically focused on hallucinations or delusions have shown positive results in shorter timescales (Wilson et al., 2020). Briefer, psychoeducation-based approaches have shown favour amongst patients (Welsh and Tiffin, 2014); however, findings from a systematic review indicate a need for more clinical trials of psychoeducation-based approaches in this field, with explicit explanations of content required (Herrera et al., 2023). Unusual Sensory Experiences (USE) are a frequent presenting symptom for individuals accessing ARMS services (Strelchuk et al., 2023), and patients indicate a strong desire to better understand the causes of USE and how to manage them (Hamilton et al., 2025). Therapeutic approaches should accordingly provide research-based explanatory understanding of the mechanisms behind USE.

A novel psychological intervention named Managing Unusual Sensory Experiences (MUSE) directly addresses some of the issues raised, providing an alternative explanation for USE before experiences become entrenched and unhelpful explanations are established. MUSE was developed in partnership with people with lived experience (PWLE), clinicians in Early Intervention in Psychosis (EIP) and ARMS teams, and researchers from the Hearing the Voice project, an interdisciplinary research collaboration (Fernyhough, 2014). MUSE is a brief intervention (6–8 sessions), which provides psychoeducation on the proposed causal mechanisms of USE, drawing on different psychological mechanisms to provide normalising explanations. Changing an individual's attribution away from unhelpful explanations (such as persecution) towards a view that everyone's brain is prone to errors when under strain can be powerfully normalising and reduce distress.

MUSE highlights how cognitive processes can lead to USE, particularly when people feel under threat, which can result in source monitoring errors about inner speech or memory intrusions and overreliance on predictions. MUSE has two initial modules, one providing psychoeducation about USE and the other promoting curiosity about how the mind works. The remaining modules are linked to proposed subtypes of hallucinations, with the clinician and service user identifying which modules to complete. The Inner Speech module describes how inner speech develops and how it takes on a dialogic character, and how it is possible to hear other people's voices in inner speech (Fernyhough, 2004). Neural networks and intrusive thoughts are used to explain how individuals are prone to have unwanted thoughts which can be experienced as voices. The Memory module focuses on the role of trauma and how intrusive trauma memories can be experienced as USE. The Hypervigilance and Visions module provides psychoeducation on how human perception is driven by predictions (Clark, 2013) and has a goal of avoiding the non-detection of signals of danger (Haselton and Nettle, 2006), which can result in people holding such strong predictions of what they expect to see or hear that incoming sensory information does not override the prediction (Dodgson and Gordon, 2009). Illusions are used to engage service users and demonstrate key concepts; for example, the hollow mask illusion demonstrates how our predictions correct what we see and how this operates at a preconscious level. MUSE also introduces coping techniques which target these mechanisms, promoting control over symptoms and reducing distress. MUSE sessions are led by a clinician and involve discussing and displaying concepts which the clinician can then link to the service user's experiences. Sessions can be conducted remotely using software like Microsoft Teams, and service users can be given access to MUSE to promote learning between sessions.

The acceptability of MUSE has been investigated within the ARMS population in a non-randomised study (Dodgson et al., 2021), delivered by CBTp therapists, with good participant satisfaction. The objective of the present study was to establish whether a definitive trial of MUSE is feasible and warranted. The research questions were 1) to answer key feasibility uncertainties and 2) to identify whether there was a signal of efficacy for MUSE+TAU in comparison to Treatment as Usual (TAU).

2. Methods

2.1. Study design

MUSE ARMS was a parallel group, single-blind, randomised controlled feasibility trial conducted at two NHS mental health trusts in NE England (Cumbria, Northumberland, Tyne and Wear NHS FT; Tees, Esk and Wear Valley NHS FT). Participants were randomised either to MUSE+TAU or TAU, where TAU could include CBT. Ethical approval was provided by the NHS Northeast – Newcastle and North Tyneside Research Ethics Committee (NE/23/0032), Health Research Authority (HRA/HCRW) approval (IRAS323903). The trial was conducted in accordance with CONSORT guidelines (Grant et al., 2018) and prospectively registered with ISRCTN (58,558,617). The trial protocol (Hamilton et al., 2023) was published two months after recruitment started. Our Lived Experience Advisory Panel completed accredited training in research methods at Northumbria University. PPI was involved in all aspects of the trial including advising on and trialling measures, co-producing semi-structured interviews, co-facilitating interviews, qualitative analyses, and membership of the Trial Steering Committee (TSC).

2.2. Participants

Participants were identified as suitable by clinical teams, with inclusion criteria of having been accepted onto ARMS pathways or services (age range: 14–35), with a Comprehensive Assessment of At-Risk Mental State – Perceptual Abnormalities Subscale (CAARMS-PA; Yung et al., 2005) score of 3 or above within the last four weeks, a desire to focus on USE within their treatment, and judged to be clinically stable for the previous two weeks. Exclusion criteria included intellectual disability or severe cognitive dysfunction affecting ability to engage with research material or lacking capacity to give informed consent. Participants were given the options of male, female, or other to report their gender. All participants received written information about the study, prior to consent procedure. All participants gave written informed consent or guardian-written consent for younger participants, who also provided written assent.

2.3. Randomisation

An independent web-based randomisation service (sealedenvelope.com) was used. Randomisation was in the ratio 1:1 to the two groups: MUSE+TAU (intervention) or TAU (control). Randomisation was stratified by site, gender (M/F/Other), and age (14–17 years/18–35 years inclusive). Randomisation allocation was independent and dynamically generated using a randomised modified minimisation method (Kuznetsova and Tymofyeyev, 2012) to assure allocation concealment along with preservation of allocation ratio. Trial assessors were masked to allocation. Unblinded researchers informed all participants of the randomisation outcome. There was one unblinding event and the assessor was replaced.

2.4. Procedures

MUSE is typically a 6–8 session intervention, with four sessions considered an adequate dose, and was delivered by clinicians

(Community Psychiatric Nurses or Clinical Psychologists, Agenda for Change band 6–8a) who had been on a 3-day training course and were experienced in using MUSE. The main intervention offered in TAU was CBT, but limited case management and medication reviews were available. MUSE and CBT were delivered by accredited CBT therapists or clinicians working towards accreditation. CBT in the TAU condition was delivered by therapists who had not used MUSE. Capacity pressures meant that not all teams could deliver CBT and, in some services, supportive psychotherapy (including needs-based emotional support, psychoeducation, normalisation, and stress management) was delivered by therapists not trained in CBT or by case managers.

Treatment fidelity was maintained through group supervision of MUSE therapists and adherence assessments of randomly selected therapy recordings. Therapists delivering MUSE completed a checklist after each session identifying which sections of MUSE had been completed. With consent, MUSE sessions were recorded and a random selection of the recordings were rated by either the Principal Investigators (NB, JS) or Chief Investigator (GD) on whether that content had been covered correctly and was compliant with the MUSE model. CBT and case management supervision was provided within the services.

2.5. Outcomes

The progression criteria were prespecified with our PPI group and agreed with the combined TSC/Data Monitoring and Ethical Committee (DMEC) before data collection. Progression criteria were monitored using a traffic light system: Green (proceed), Amber (amend), Red (stop). Key uncertainties were identified as *recruitment rate* of participants randomised into the trial and *therapy engagement*, defined as receiving a minimum of 4 sessions of MUSE. Participants were requested to give consent for sessions to be recorded and a random sample were checked for *therapy fidelity*. *Assessment retention* was defined as 70 % of participants completing the primary outcome measures at the primary timepoint (post-treatment). Monitoring of related SAEs was used to define the *safety* of MUSE. AEs were identified by therapist or researcher report or from the electronic patient record, and rated for relatedness. SAEs were reported to the chair of the TSC.

Assessments were conducted at baseline, 12 weeks post-randomisation (post-treatment), and 20 weeks post-randomisation (follow-up). All assessment timepoints consisted of the first primary outcome measure of auditory hallucinations, assessed using the Psychotic Symptom Rating Scales (PSYRATS-AH; Haddock et al., 1999), an 11-item semi-structured interview assessing frequency, duration, loudness, distress intensity, and control of hallucinations, with subscales for attribution (PSRATS-ATT), distress (PSYRATS-DIS), and delusions (PSYRATS-DS; Woodward et al., 2014). Global functioning, assessed using the Social and Occupational Functional Assessment Scale (SOFAS; Goldman et al., 1992), was the second primary outcome measure. Secondary outcomes included measures of distress from USE (assessed by the CAARMS-PA; Yung et al., 2005), anxiety (General Anxiety Disorder-7; Spitzer et al., 2006), low mood (Patient Health Questionnaire-9; Kroenke et al., 2001), and quality of life (Recovering Quality of Life; Keetharuth et al., 2018). The assessment battery also included two moderators measuring sleep and past trauma. We included measures and cognitive tasks tracking the mechanisms which may underlie USE, such as source monitoring (Brookwell et al., 2013), which will be reported separately. Post-therapy satisfaction was obtained using the revised version of the Satisfaction with Therapy and Therapist Scale (STTS-R; Oei and Shuttlewood, 1999; Oei and Green, 2008).

Monitoring transition to psychosis was beyond the scope of this study. However, consent was requested from participants to access electronic patient records and the national Mental Health Service Data Base (MHSDS) to check for transition to psychosis three years after the final follow-up appointment.

2.6. Statistical analysis

The sample size of 70 completed assessments (35 per arm) provides a standard deviation estimate precise enough that, if used in the definitive trial's sample size calculation, the future trial will have at least 80 % power with approximately 90 % assurance (Teare et al., 2014). This meant that this trial was not powered to detect a significant difference between treatment groups; hence no *p*-values will be reported. In line with the recent CONSORT Social and Psychological Interventions guidance (Grant et al., 2018), which recommends minimising the distinction between primary and secondary outcomes for psychological therapy trials, all treatment effect outcomes are reported at all assessment timepoints. Descriptive analysis was conducted to summarise demographic and trial-related variables and primary and secondary outcomes using means, standard deviations, frequencies, and percentages. Longitudinal data for baseline, 12-week, and 20-week outcomes were analysed using generalised linear mixed effect models and generalised estimating equations. Treatment allocation, site, and gender were used as covariates in the models. The treatment effect was estimated by adding an interaction for time and treatment in the model. We report the treatment effect estimate as the adjusted mean difference between groups, with 95 % CIs and Cohen's *d* effect sizes.

Statistical analyses used R (R: The R Project for Statistical Computing). The statistical analysis plan (appendix 1) was approved by the TSC and posted on ISRCTN before data analyses. We have verified through cross-tabulation of missingness rates and treatment allocation that missingness was at random. Further adjustment for missingness was not undertaken. The Analysis Report is presented in appendix 2.

3. Results

The first participant consented on 5 May 2023 and the final participant on 22 February 2024; see CONSORT diagram (Fig. 1) for details. Ninety-three participants were randomised, with a mean age of 19.4 years (see Table 1). Baseline data analysis by demographic and socioeconomic characteristics shows that participants were evenly split between adolescent (14–17 years) and adult (18–35 years) age groups. Most participants self-identified as female (58 %) and lived with their parents (72 %). Ninety-one percent of participants were from a White British ethnic background, suggesting the cohort was representative of the catchment area. In the MUSE+TAU group, around 63 % of the participants were currently in education, compared to 42.6 % in the TAU control group. One-third of participants were receiving state benefits. Most participants were not on medication for depression or anxiety. Two participants had been prescribed antipsychotic medication before referral to the ARMS service, one had their antipsychotic medication discontinued following assessment by the ARMS psychiatrist (see supplementary Table 1). The other individual was assessed as ARMS by the service, but this was disputed by the CAMHS psychiatrist who continued to prescribe and was therefore counted as a transition to psychosis, as per our protocol. There were significant baseline differences between the two recruitment sites, where Site 2 participants were older and had lower scores on the PSYRATS AH, indicating less severe symptoms compared to Site 1 (see supplementary Table 2).

The first research question was to answer research uncertainties to ascertain whether a definitive study was feasible. *Recruitment* was planned to be 9.8 randomisations per month; a rate of 9.6 was achieved (green). *Therapy engagement* was set at 4 sessions of MUSE being considered an adequate dose, as agreed by PWLE; 82 % of MUSE participants achieved this, above the 80 % threshold for green. *Assessment retention* had a threshold of 70 % for green at the primary timepoint, reflecting some of the engagement issues with this client group. A retention rate of 79 % was achieved (green). *Therapy fidelity* was assessed by rating a random selection of MUSE therapy tapes ($n = 18$), with 100 % rated as showing fidelity. *Safety* was assessed by the number of SAEs that were related to delivering MUSE. There were no related

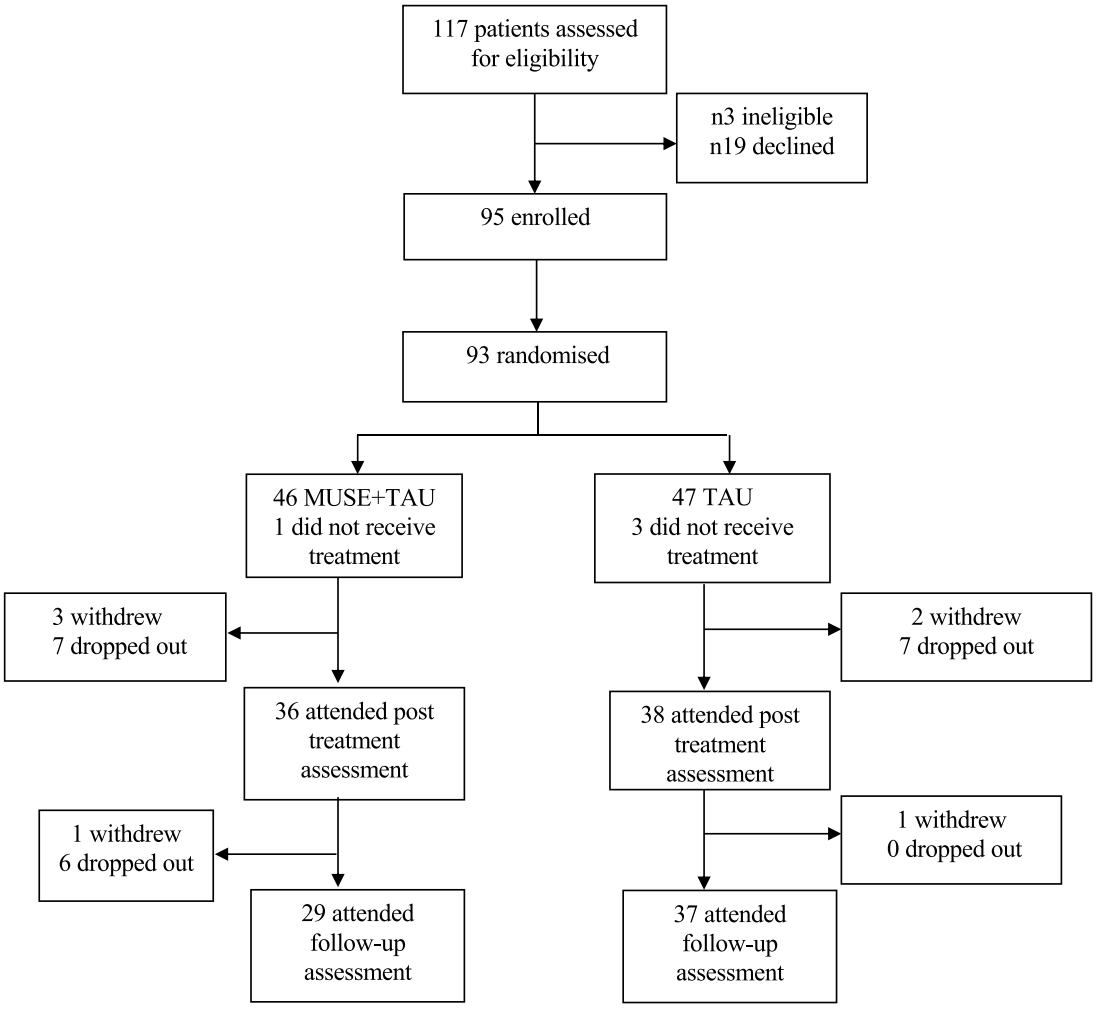

Fig. 1. Trial structure.

SAEs, so the progression criterion was green; however, there were two related AEs, where participants stated that discussing their voices caused increased distress. In our protocol only SAE were to be escalated to the TSC chair. Relatedness decisions were recommended by the Principal Investigators (NB and JS) and checked by the CI (GD). Overall, there were 15 AEs in the MUSE+TAU group and 21 AEs in the TAU group. A further component of feasibility was to interview participants and staff about the acceptability of the research processes and treatment; this will be described in a forthcoming qualitative paper.

Table 2 shows the mean scores, adjusted mean differences, and Cohen's *d* effect sizes between the two treatment groups (MUSE+TAU and TAU) over a 12- and 20-week period. The study was not powered to find significant differences, so these are not reported. For the primary outcomes, there is a small to moderate effect favouring MUSE+TAU on the SOFAS; at 12 weeks there is a beta estimate of −4.19 (95 % CI: −10.22 to 1.85) and a Cohen's *d* of −0.28 (95 % CI: −0.68 to 0.12); at 20 weeks the beta estimate is −5.33 (95 % CI: −11.65 to 1.00) and Cohen's *d* −0.35 (95 % CI −0.77 to 0.07). PSYRATS Auditory Hallucinations (AH) at 12 weeks has a beta estimate of −0.01 (95 % CI: −4.876 to 4.866) and a Cohen's *d* of 0.00 (95 % CI: −0.48 to 0.48), indicating no difference between MUSE+TAU and TAU groups. At 20 weeks, the beta estimate is −1.43 (95 % CI: −6.53 to 3.66) and Cohen's *d* −0.14 (95 % CI: −0.64 to 0.36), favouring TAU. For the PSYRATS subscales, the distress scale slightly favoured TAU at 12 weeks (Cohen's *d*: −0.05; 95 % CI: −0.53 to 0.44) and 20 weeks (Cohen's *d*: −0.18; 95 % CI: −0.69 to 0.33), but the attribution scale slightly favoured MUSE+TAU at 12 weeks (Cohen's *d*: 0.09; 95 % CI: −0.41 to 0.59) and 20 weeks (Cohen's *d* 0.24; 95 % CI −0.29 to 0.76). However, these effect sizes are very small as per Cohen's *d* effect size categorisation.

For secondary outcome measures, anxiety (GAD-7) showed a moderate Cohen's *d* of 0.55 at 12 weeks favouring MUSE+TAU, which reduced at 20 weeks to a small to moderate Cohen's *d* of 0.34. Small to moderate Cohen's *d* figures favouring MUSE+TAU at 12 and 20 weeks were found for the PSYRATS delusions subscale (12 weeks only), a second measure of distress from USE (CAARMS-PA) (20 weeks only), depression (PHQ9), and quality of life (ReQoL); see Fig. 2.

The MUSE+TAU treatment group had a mean of 5.66 sessions with a standard deviation of 2.21 by 20 weeks, with 83.3 % occurring by the post-treatment assessment. MUSE+TAU participants also received an additional 1.61 CBT sessions (SD=2.44), with 23.9 % occurring by the post-treatment assessment. For the TAU group, participants had an average 5.87 CBT sessions with a larger variability (SD = 5.4), with 60.6 % of the sessions delivered before the post-treatment assessment (see supplementary Table 3 for more information). Satisfaction with therapy was measured by the STTS-R (Oei and Shuttlewood, 1999; Oei and Green, 2008), and there were no significant differences between the conditions (see supplementary Table 4). A full description of USE experienced by our participants is presented in another paper (under review, reference omitted).

4. Discussion

The prespecified progression criteria were green (proceed) for all five areas, and a signal of efficacy was identified on one of the primary

Table 1
Baseline participant characteristics.

	MUSE (*N* = 46)	TAU (*N* = 47)	Total (*N* = 93)
Age, years			
Mean (SD, range)	19·0 (4·6;14–32)	19·9 (5·5; 14–35)	19·4 (5·2; 14–35)
Age group			
14–17	23 (50·0 %)	23 (48·9 %)	46 (49·5 %)
18–35	23 (50·0 %)	24 (51·1 %)	47 (50·5 %)
Gender			
Female	29 (63·0 %)	25 (53·2 %)	54 (58·1 %)
Male	16 (34·8 %)	21 (44·7 %)	37 (39·8 %)
Other	1 (2·2 %)	1 (2·1 %)	2 (2·2 %)
Ethnicity			
Asian/Asian British - Bangladeshi	1 (2·2 %)	0 (0·0 %)	1 (1·1 %)
Asian/Asian British - Indian	0 (0·0 %)	1 (2·1 %)	1 (1·1 %)
Asian/Asian British - Pakistani	0 (0·0 %)	1 (2·1 %)	1 (1·1 %)
Black/African/Caribbean/ Black British - African	1 (2·2 %)	0 (0·0 %)	1 (1·1 %)
Other	1 (2·2 %)	0 (0·0 %)	1 (1·1 %)
White - Any other White background	1 (2·2 %)	1 (2·1 %)	2 (2·2 %)
White - British	42 (91·3 %)	43 (91·5 %)	85 (91·4 %)
White - Irish	0 (0·0 %)	1 (2·1 %)	1 (1·1 %)
Currently in education (Yes %)	29 (63·0 %)	20 (42·6 %)	49 (52·7 %)
Highest education			
Primary education or less	15 (32·6 %)	9 (19·1 %)	24 (25·8 %)
Secondary education	20 (43·5 %)	28 (59·6 %)	48 (51·6 %)
Tertiary / further education	11 (23·9 %)	10 (21·3 %)	21 (22·6 %)
Usual living status			
Living alone (+/- children)	3 (6·5 %)	6 (12·8 %)	9 (9·7 %)
Living together as a couple	5 (10·9 %)	2 (4·3 %)	7 (7·5 %)
Living with husband/wife (+/- children)	0 (0·0 %)	3 (6·4 %)	3 (3·2 %)
Living with other relatives	0 (0·0 %)	1 (2·1 %)	1 (1·1 %)
Living with others	3 (6·5 %)	3 (6·4 %)	6 (6·5 %)
Living with parents	35 (76·1 %)	32 (68·1 %)	67 (72·0 %)
Estranged from family	5 (10·9 %)	5 (10·6 %)	10 (10·8 %)
Education and employment status			
Student/in education	26 (56·5 %)	19 (40·4 %)	45 (48·4 %)
Both Student/in education and employed	3 (6·5 %)	2 (4·3 %)	5 (5·4 %)
Paid or self-employment	5 (10·9 %)	10 (21·3 %)	15 (16·1 %)
Unemployed	12 (26·1 %)	16 (34·0 %)	28 (30·1 %)
Currently not prescribed psychotropic medication	25 (54·3 %)	32 (68·1 %)	57 (61·3 %)
Types of psychotropic medication prescribed			
Antipsychotic Medication	2 (4·3 %)	0 (0 %)	2 (2·2 %)
Antidepressant Medication	18 (39·1 %)	13 (27·7 %)	31 (33·3 %)
Anxiolytic Medication	4 (8·7 %)	1 (2·1 %)	5 (5·4 %)
Hypnotic Medication	1 (2·2 %)	2 (4·3 %)	3 (3·2 %)

outcomes and several of the secondary outcomes. Our first research question was to resolve feasibility uncertainties; we demonstrated that it was possible to recruit, randomise, and retain participants in the study. A high number of participants had at least 4 sessions of MUSE, which was delivered by clinicians with good treatment fidelity. There were no related SAEs.

The second research question focused on a signal of efficacy, which needs to be placed in context with the comparator arm. TAU included care management, medication, supportive psychotherapy and CBT. The MUSE+TAU group had an average of 5.66 MUSE sessions and 1.61 CBT sessions (total 7.27 psychotherapy sessions) compared to 5.87 CBT sessions in the TAU group, suggesting that MUSE reduced the number of CBT sessions required. This is consistent with the clinical report from teams that regularly use MUSE, where delivery may be either by non-therapists or therapists, depending on the complexity of the presentation, and where MUSE is seen as a stepped-care intervention reducing demand for CBT (see supplementary Table 3). Compared to guidance recommendations (NICE, 2014), the interventions offered were brief, but this was constrained by the 20-week follow-up period, which was in turn a function of the available funding envelope. Overall, there was little difference between the groups in overall access to psychological therapy sessions, and most teams were able to provide the recommended treatment of CBT in TAU, with supportive psychotherapy rarely delivered in practice.

Two measures of hallucinations were included. PSYRATS-AH was the primary outcome measure, with CAARMS-PA distress a secondary outcome measure. Participants improved on both measures in both conditions; however, PSYRATS-AH total score was similar at 12 weeks but slightly favoured TAU at 20 weeks. The subscales were mixed, with PSYRATS-DS slightly favouring TAU, while the attribution subscale slightly favoured MUSE+TAU. The CAARMS-PA distress score slightly favoured MUSE+TAU. The CAARMS is a rating scale that covers other modalities of USE beyond the auditory; eight participants entered the trial with only visual hallucinations, thus scoring 0 at baseline on the PSYRATS-AH. This was an unexpected finding, as previous research (Dudley et al., 2023b) suggests that visions are usually reported in combination with voices.

The second primary outcome measure, SOFAS, showed more improvement in the MUSE+TAU group (Cohen's *d* of 0.27 increasing to 0.35 at 20 weeks). Other studies (Spiteri-Staines et al., 2024) have suggested that there are long-term problems in functioning in the ARMS population. The secondary outcome measures of PSYRATS-DS, anxiety, depression, and quality of life also indicated more improvement in the MUSE+TAU group at post-treatment assessments, with Cohen's *d* ranging from 0.27 to 0.54. This is a promising signal of efficacy, with MUSE+TAU showing benefits on domains that are often the direct target of CBT interventions (functioning, anxiety, and depression). The reattribution of USE to psychological mechanism-based explanations, as suggested by the PSYRATS-Attribution and qualitative interviews (which will be reported in a forthcoming article), appears to confer generalisable benefits to these other domains. In a future definitive trial, global functioning and quality of life would be the primary outcome measures, having been emphasised by our PPI group as the outcomes that are most meaningful to service users. The participant interviews reported increased understanding and control leading to improvements in relationships. MUSE shows promise in improving the outcomes that matter most to patients: quality of life and functioning (Anthony, 1993). However, the TAU group received 1.4 fewer sessions of psychotherapy, suggesting the findings should be interpreted with caution.

As this was a feasibility study it was not powered to find a significant difference between conditions, and a larger study is thus required to investigate the efficacy of MUSE. Another limitation is that transition to psychosis was not the primary outcome (Fusar-Poli et al., 2017). Feasibility trials in the United Kingdom do not attract sufficient funding to enable an extended follow-up period. Transition to psychosis information will be sought from electronic patient records and the NHS England MHSDS database three years after closure of the main trial. Data on whether participants are seen by EIP services will be presented in due course. The participants were representative of the recruitment area and services. The North East of England is not an ethnically diverse area, and thus different backgrounds are not strongly represented. This is a limitation, and any future trial needs to ensure both that MUSE can be successfully delivered through the use of an interpreter and that the scientific content is acceptable to people from different backgrounds.

There were two related AEs in which participants said that discussing their USE increased their distress. These participants' responses on the STTS-R also suggested that MUSE made things somewhat or a lot worse. One other participant also suggested that MUSE made things somewhat worse. Two of these participants had high scores on the PSYRATS-DS; previous work on MUSE has indicated that the treatment is more effective before people have formed delusional beliefs (Dodgson et al., 2021). The lower rates of assessment retention in the MUSE condition (see Table 2) could be a further sign that some people found MUSE challenging; however, these participants had similar levels of reduction

Table 2
Effects of TAU versus MUSE+TAU for continuous primary and secondary outcomes.

	TAU		MUSE+TAU			Effect size
Outcome	**Mean (SD)**	**N**	**Mean (SD)**	**N**	**Adjusted mean difference (TAU – MUSE+TAU)(95 %CI)**	**Cohens d (95 %CI)**
SOFAS Score						
Baseline	60·68 (15·13)	47	55·94 (13·92)	46	..	..
12 weeks	61·05 (15·09)	38	61·39 (16·12)	36	−4·19 (−10·22 to 1·85)	−0·28 (−0·68 to 0·12)
20 weeks	64·73 (14·69)	37	66·69 (15·46)	29	−5·33 (−11·65 to 1·00)	−0·35 (−0·77 to 0·07)
PSYRATS AH						
Baseline	23·45 (9·60)	47	22·30 (9·49)	46		
12 weeks	19·24 (10·60)	38	17·81 (11·28)	36	−0·01 (−4·88 to 4·87)	0·00 (−0·48 to 0·48)
20 weeks	17·84 (9·23)	37	18·38 (11·04)	29	−1·43 (−6·53 to 3·66)	−0·14 (−0·64 to 0·36)
PSYRATS Attribution						
Baseline	3·49 (1·57)	47	3·78 (1·84)	46	..	..
12 weeks	3·26 (1·78)	38	3·42 (2·13)	36	0·17 (−0·77 to 1·11)	0·09 (−0·41 to 0·59)
20 weeks	3·54 (2·04)	37	3·41 (1·88)	29	0·44 (−0·55 to 1·43)	0.24 (−0·29 to 0·76)
PSYRATS Distress						
Baseline	12·19 (6·40)	47	11·46 (6·17)	46		
12 weeks	9·53 (6·57)	38	8·78 (6·89)	36	−0·30 (−3·38 to 2·79)	−0·05 (−0·53 to 0·44)
20 weeks	8·76 (5·98)	37	9·28 (6·80)	29	−1·16 (−4·38 to 2·07)	−0·18 (−0·69 to 0·33)
PSYRATS Delusions						
Baseline	6·49 (7·43)	47	8·24 (7·62)	46	..	..
12 weeks	5·11 (6·37)	38	4·75 (7·33)	36	1·70 (−1·37 to 4·78)	0·27 (−0·22 to 0·76)
20 weeks	2·03 (4·44)	37	3·21 (6·34)	29	0·07 (−3·15 to 3·28)	0·01 (−0·50 to 0·52)
CAARMS.PA.Global_1						
Baseline	4·55 (0·78)	47	4·46 (0·69)	46	..	..
12 weeks	3·95 (1·37)	38	3·94 (1·24)	36	−0·12 (−0·73 to 0·50)	−0·10 (−0·63 to 0·43)
20 weeks	3·81 (1·39)	37	3·90 (1·35)	29	−0·20 (−0·84 to 0·44)	−0·18 (−0·73 to 0·38)
CAARMS.PA. Frequency Duration						
Baseline	4·21 (1·12)	47	4·46 (0·98)	46	..	..
12 weeks	3·71 (1·47)	38	3·75 (1·68)	36	0·19 (−0·52 to 0·91)	0·14 (−0·38 to 0·66)
20 weeks	3·51 (1·54)	37	3·52 (1·64)	29	0·25 (−0·50 to 0·99)	0·18 (−0·36 to 0·72)
CAARMS PA Distress Score						
Baseline	66·09 (24·17)	46	74·20 (15·61)	46	..	..
12 weeks	51·05 (28·10)	38	53·86 (28·74)	36	3·84 (−8·73 to 16·40)	0·15 (−0·35 to 0·65)
20 weeks	41·22 (27·12)	37	41·38 (29·55)	29	7·38 (−5·78 to 20·53)	0·29 (−0·23 to 0·82)
GAD7						
Baseline	14·50 (4·94)	45	15·78 (4·49)	46	..	..
12 weeks	13·53 (4·97)	38	11·58 (6·37)	33	2·88 (0·22 to 5·53)	0·55 (0·04 to 1·05)
20 weeks	11·69 (6·01)	32	10·73 (6·98)	26	1·79 (−1·07 to 4·65)	0·34 (−0·20 to 0·89)
PHQ9						
Baseline	17·37 (6·20)	45	18·24 (5·59)	46	..	..
12 weeks	14·84 (6·07)	38	13·88 (7·93)	33	1·70 (−1·20 to 4·59)	0·27 (−0·19 to 0·74)
20 weeks	13·53 (6·58)	32	13·27 (9·35)	26	1·38 (−1·74 to 4·50)	0·22 (−0·28 to 0·72)
ReQOL						
Baseline	31·15 (14·17)	45	27·27 (10·91)	46	..	..
12 weeks	33·76 (13·48)	37	35·74 (16·83)	33	−5·28 (−11·68 to 1·13)	−0·36 (−0·79 to 0·08)
20 weeks	38·06 (16·76)	32	40·15 (18·79)	26	−5·39 (−12·27 to 1·50)	−0·36 (−0·83 to 0·10)

on primary outcome measures at post-treatment assessment compared to those who remained in the study at 20 weeks. Further research needs to monitor engagement and identify whether there are patients for whom MUSE is not suitable. PSYRATS attribution data hint that MUSE may have its effect through changing people's understanding of their experiences, in part through helping individuals to frame their unusual experiences in a more positive way (Dodgson et al., 2021). For some this may be challenging, but for others it appears reassuring and empowering. Further work needs to investigate the mechanism of change in MUSE and help to identify which individuals may not benefit from the treatment.

A key inclusion criterion was acceptance into an ARMS service or onto an ARMS pathway. CAARMS rates a Perceptual Abnormalities score of 3 or 4 as moderate, with the person able to dismiss the experiences and not find them particularly distressing, and categorises this score as consistent with an ARMS presentation. A PA score of 5 or 6 is viewed as a true hallucination, which can only be questioned with effort and may generate distress, indicating the presence of psychosis. At baseline, 49 participants had a PA score of 5 or 6 but had been allocated to the ARMS pathway by clinical teams. This suggests a discrepancy between CAARMS scores and service allocation across the eight clinical teams. CAARMS training and reliability checks for scores were routine practice for all the ARMS services. This discrepancy could be caused by systematic overscoring on the PA domain, or a difference in how clinical teams define ARMS in relation to the CAARMS criteria. This creates a research challenge about the definition of ARMS and whether it should be based on CAARMS scores or the CAARMS-informed judgement of clinicians. Interestingly, there was only one transition to psychosis through the study; this individual entered the study on antipsychotic medication, prescribed by a CAMHS psychiatrist, and was the only participant on antipsychotic medication at the 12-week assessment. The introduction of CAARMS 23 (Yung et al., 2023) may contribute to resolving this issue.

In conclusion, the results of this study have resolved key uncertainties and suggest that MUSE is a promising intervention for this client group. Other work has suggested that non-therapists can be briefly trained to deliver MUSE with high satisfaction with the intervention (Dudley et al., 2024). The digital format makes it easy for clinicians to use and promotes adherence to the treatment model. MUSE has the potential to be scaled up at pace. A definitive trial of MUSE in this population is recommended.

MUSE lived experience advisory group

Cheryl Blake, Helen Errington, Wendy Fleming-Smith, Pat Higgins, Gayl McCain, Nina Ni, Katie Rumney, Jack Singh

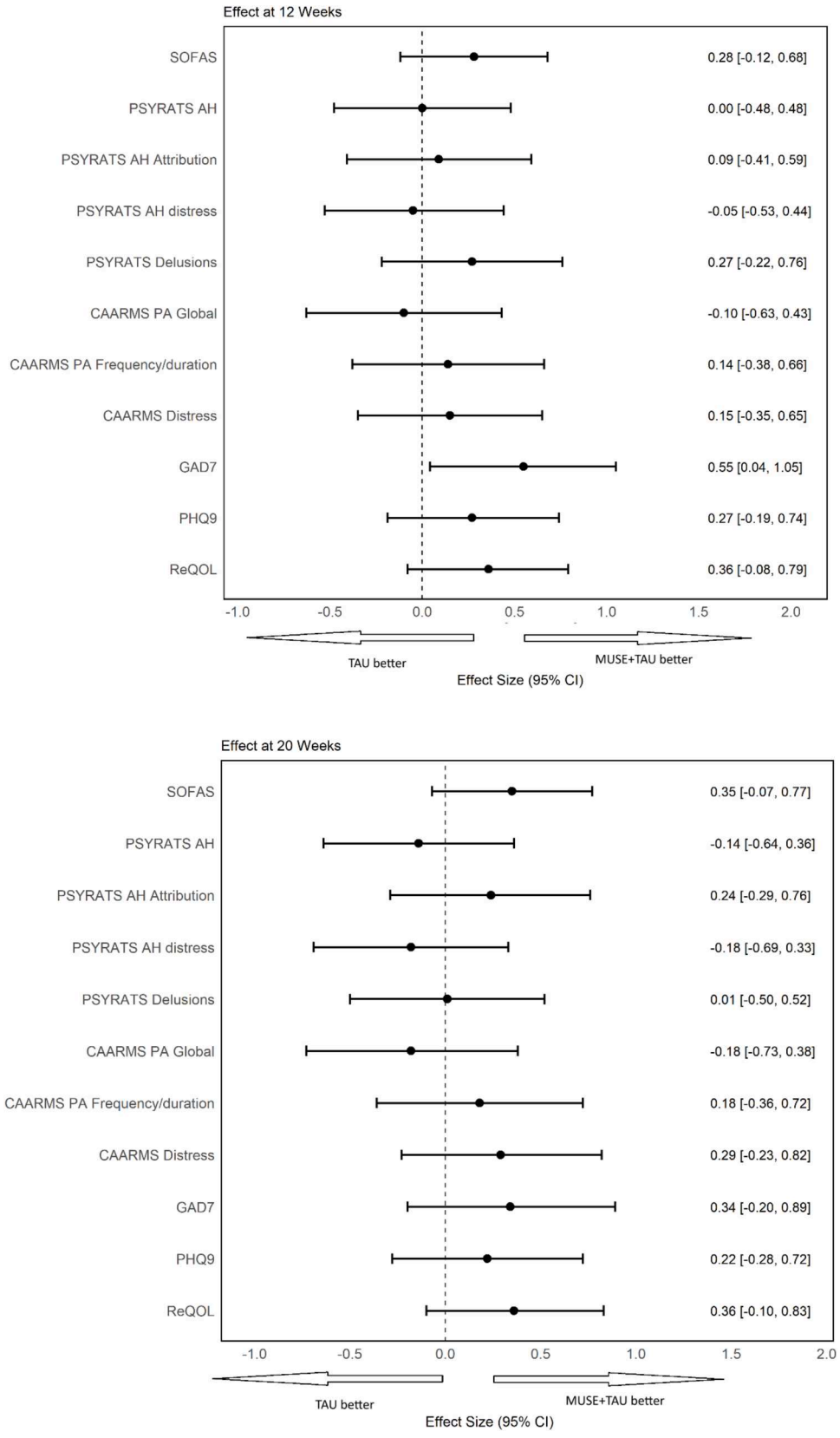

Fig. 2. Effect sizes for MUSE+TAU compared to TAU at 12 and 20 weeks.

Data sharing

The MUSE ARMS dataset is publicly available at: http://doi.org/10.15128/r2nv9352901

Statement of ethics

The trial was conducted ethically following the World Medical Association Declaration of Helsinki.

Consent to participate statement

All participants gave written informed consent before any research procedures. Potential participants aged 14–15 years old were given an age-appropriate brief summary of the research and what their involvement would be if they chose to take part. Parents or guardians gave informed consent, in addition to child assent, for all children/young people who were aged under 16 years old, and on occasion for those who were aged under 18 years old, where they/their parent or guardian or clinical care team suggested this would be helpful.

Study approval statement

Ethical approval was provided by the NHS North East: Newcastle and North Tyneside Research Ethics Committee (NE/23/0032), Health Research Authority (HRA/ HCRW) approval (IRAS323903).

CRediT authorship contribution statement

Guy Dodgson: Writing – review & editing, Writing – original draft, Supervision, Investigation, Funding acquisition, Conceptualization. **Akansha Singh:** Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Data curation. **Nicola Barclay:** Writing – review & editing, Writing – original draft, Supervision, Investigation, Funding acquisition. **Lauren Birkett:** Writing – review & editing, Writing – original draft, Project administration, Investigation, Data curation. **Charleen Boyle:** Writing – review & editing, Writing – original draft, Supervision, Investigation, Data curation. **Toby Brandon:** Writing – review & editing, Writing – original draft, Supervision, Investigation, Formal analysis, Conceptualization. **Robert Dudley:** Writing – review & editing, Writing – original draft, Supervision, Investigation, Funding acquisition, Conceptualization. **Jochen Einbeck:** Writing – review & editing, Writing – original draft, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Chris Gibbs:** Writing – review & editing, Writing – original draft, Supervision, Investigation, Funding acquisition, Conceptualization. **Jahnese Hamilton:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Data curation. **Vickie Larry:** Writing – review & editing, Writing – original draft, Supervision, Investigation, Data curation. **Jenny Simpson:** Writing – review & editing, Writing – original draft, Supervision, Investigation, Data curation. **Charles Fernyhough:** Writing – review & editing, Writing – original draft, Investigation, Funding acquisition, Conceptualization.

Declaration of competing interest

We declare no competing interests.

Acknowledgements

This project was funded by the National Institute for Health and Care Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant reference NIHR204125). The views expressed are those of the authors and not necessarily those of NIHR or the Department of Health and Social Care. We would like to thank the participants in the study and the family members who also contributed to the qualitative interviews. Unblinded research tasks and some additional blinded assessments were supported by local research departments, including Sarah Bentley, Emily Clare, Sarah Garner, Mike Kelly, Michelle Odgers, Bethan Senior, Abbey Underwood, and Vicky Wilson. Dr David Smailes and Dr Peter Moseley supported the mechanisms tasks. We thank the independent members of the TSC, Professor Richard Bentall, Dr Alison Brabban, and Dr Valentina Short. The enthusiasm and support of the clinical teams across both trusts was greatly appreciated, but particular thanks to the trial therapists in TEWV (Natalie Brophy, Mark Dawson, Natalie Eastwood, Nicola Elliot, Louise Leach, Sam O'Connor, Jane Pratt, Richard Swann, Luke Vine, Paul Williams) and in CNTW (Hayley Connor, Carina Ewels, Toyah Lebert, Claire Mason, Joyce Obnial, Lynn Orr, Louise Ross Eloise Tod, Andrew Weightman).

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.psychres.2025.116564.

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