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Effects of a novel, brief psychological therapy (Managing Unusual Sensory Experiences) for hallucinations in first episode psychosis (MUSE FEP): Findings from an exploratory randomised controlled trial

Robert Dudley [a,b,*], Guy Dodgson [a], Stephanie Common [c], Emmanuel Ogundimu [d], James Liley [d], Lucy O'Grady [a], Florence Watson [c], Christopher Gibbs [a], Bronia Arnott [e], Charles Fernyhough [d], Ben Alderson-Day [d], Charlotte Aynsworth [a]

[a] Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust, St. Nicholas Hospital, Jubilee Road, Gosforth, Newcastle Upon Tyne, NE3 3XT, United Kingdom
[b] Department of Psychology, University of York, YO10 5DD, United Kingdom
[c] Tees, Esk & Wear Valley NHS Trust, Wessex House, Falcon Court, Stockton on Tees, TS18 3TX, United Kingdom
[d] University of Durham, Stockton Road, Durham, DH1 3LE, United Kingdom
[e] Newcastle University, Population Health Sciences Institute, Baddiley-Clark, NE2 4AX, Newcastle Upon Tyne, United Kingdom

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ABSTRACT

Hallucinations are a common feature of psychosis, yet access to effective psychological treatment is limited. The Managing Unusual Sensory Experiences for First-Episode-Psychosis (MUSE-FEP) trial aimed to establish the feasibility and acceptability of a brief, hallucination-specific, digitally provided treatment, delivered by a non-specialist workforce for people with psychosis. MUSE uses psychoeducation about the causal mechanisms of hallucinations and tailored interventions to help a person understand and manage their experiences. We undertook a two-site, single-blind (rater) Randomised Controlled Trial and recruited 82 participants who were allocated 1:1 to MUSE and treatment as usual (TAU) (n = 40) or TAU alone (n = 42). Participants completed assessments before and after treatment (2 months), and at follow up (3–4 months). Information on recruitment rates, adherence, and completion of outcome assessments was collected. Analyses focussed on feasibility outcomes and initial estimates of intervention effects to inform a future trial. The trial is registered with the ISRCTN registry 16793301. Criteria for the feasibility of trial methodology and intervention delivery were met. The trial exceeded the recruitment target, had high retention rates (87.8%) at end of treatment, and at follow up (86.6%), with good acceptability of treatment. There were 3 serious adverse events in the therapy group, and 5 in the TAU group. Improvements were evident in both groups at the end of treatment and follow up, with a particular benefit in perceived recovery in the MUSE group. We showed it was feasible to increase access to psychological intervention but a definitive trial requires further changes to the trial design or treatment.

1. Introduction

Hallucinations are a common feature of Psychosis, with many reporting hearing (Australian Schizophrenia Research Bank, 2017) or seeing things others do not (Dudley et al., 2023a,b). For some, these experiences can be extremely distressing, and can contribute to higher rates of admission and relapse (Waters et al., 2018). Cognitive Behavioural Therapy for Psychosis (CBTp) has been recommended for some time (National Institute of Clinical Excellence NICE, 2002) but access to psychological therapy remains limited. This is owing to a lack of trained therapists, the time taken to train them, and CBTp usually entailing 6 or more months of weekly appointments (Morrison, 2017)

Owing to these rate limiting factors a number of approaches have been used to increase access. One solution is to use briefer treatments for psychosis (Hazell et al., 2018). Another is to broaden the provision by training non-specialist staff to deliver therapy as part of routine clinical practice (Garety et al., 2018; Turkington et al., 2002). However, CBT for psychosis encompasses a wide range of treatment targets (Morrison, 2017) which can cause challenges in training and delivery of a complex intervention by a less trained workforce. One method to overcome this

* Corresponding author. Department of Psychology, University of York, York, YO10 5DD, United Kingdom.
E-mail address: rob.dudley@york.ac.uk (R. Dudley).

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issue of complexity is to focus on targeting specific symptoms such as auditory hallucinations (Hayward, 2018; Hazell et al., 2018) or a limited number of key causal mechanisms (Foster et al., 2010; Myers et al., 2011) with the aim of achieving meaningful results more efficiently. An additional strategy is to reduce complexity by standardising the treatment using digital technologies; an area where there has been a rapid growth in digital innovations to augment mental health care, as recommended in the NHS Long-Term Plan (Hollis et al., 2018; NHS Long term plan, 2019). Accordingly, treatments for psychosis are increasingly delivered using novel digital approaches (Freeman et al., 2022; Garety et al., 2021; Craig et al., 2018; Yiend et al., 2022) which provide treatment in an accessible and engaging way.

This present study combines these approaches by offering a brief, targeted therapy focussed solely on helping hallucinations, using a widely available workforce with a treatment that is delivered using a digital platform. The approach used, called Managing Unusual Sensory Experiences (MUSE), focusses on causal mechanisms that lead people to hear and see things others do not. It uses engaging technology such as videos, and animations over 4 to 6 sessions to explain how the mind works to make sense of the world around; how processes like inner speech (Fernyhough, 2004); vigilance (Dodgson and Gordon, 2009; Dudley et al., 2014); and the consequences of trauma (Dudley et al., 2023a; Stevens et al., 2019) can lead to hallucinatory experiences. These explanations link to key interventions and coping strategies that target these causal processes, such as interrupting the phonological loop as a way of affecting inner speech. This process draws on psychoeducation to help a person change their understanding of their experiences as well as to manage their experiences better and cope more effectively. A full description of the rationale for this approach, as well an illustration of the modules and examples of the interventions offered is provided in the trial protocol (Dudley et al., 2022).

Two uncontrolled studies with people with Psychosis (MUSE PSYCHOSIS; Dodgson et al., 2021a) and those at risk of transition to Psychosis (MUSE ARMS; Dodgson et al., 2021b) provided preliminary evidence of acceptability and impact when treatment was offered by trained psychological therapists, particularly for those service users in the earlier stages of their psychosis. However, there is a clear need to refine such results before MUSE can be considered a viable treatment option. As such, the aim of the current study was to inform the design of a definitive clinical and cost-effectiveness trial by evaluating the feasibility, safety and acceptability of MUSE therapy compared to treatment as usual (TAU) amongst people with hallucinations in the early stages of psychosis. Moreover, given the need to increase access, the aim was to train a more widely available frontline workforce (rather than psychological therapists), to deliver MUSE in routine community services. In the UK, this workforce typically comprises of psychiatric nurses, occupational therapists, and social workers who provide care coordination which is a clinical case and crisis management function. Past attempts have noted the challenges in training staff to deliver psychological treatments in busy clinical services (Garety et al., 2018) but Early Intervention in Psychosis (EIP) teams have lower case-loads encouraging greater opportunity for provision of evidence-based treatments (Bird et al., 2010; Brabban and Dodgson, 2010). Also, as MUSE is highly standardised it both reduces the complexity of delivery, and increases consistency of delivery.

The present study is a feasibility randomised controlled trial of the MUSE intervention. The primary aim was to establish the clinical feasibility of the intervention, in terms of participant recruitment, uptake, safety and satisfaction with treatment, retention in the trial, and uptake of training and delivery of therapy by the non-specialist workforce. An additional aim was to estimate the parameters to calculate the effect size on key outcomes to inform a future definitive trial.

2. Material and methods

2.1. Design

This was a single blind, pragmatic randomised controlled trial (ISRCTN registry: 16793301; registered December 7, 2021) comparing MUSE plus treatment as usual (TAU) with TAU alone. Assessment occurred pre-randomisation, two months post-randomisation (post-treatment) and three-four months post-randomisation (follow-up).

Full consideration of sample size requirements, randomisation, blinding, measures, data monitoring and assessment of safety were described in the trial protocol published before completion of data collection (Dudley et al., 2022). No significant changes were made to the methods after trial commencement. Qualitative interviews captured service-users' experience of therapy and clinicians' experiences of the training and supervision in MUSE. Clinicians were asked about factors affecting uptake, adherence, and facilitators/barriers to implementation. Thematic analysis of the qualitative interviews will assess the acceptability of the training, intervention, and trial procedures (in preparation) further informing any future definitive study.

2.2. Participants

Eligible participants were recruited from two UK mental health Trusts (CNTW and TEWV NHS Trusts). The participants were; aged 16 years and over; met ICD-11 criteria for schizophrenia, schizoaffective disorder or entry criteria for an EIP service; current hallucinations for at least four weeks; considered these an important issue to work on; had a care coordinator; were able to provide written, informed consent; and judged to be clinically stable at the time of the assessments and for the past month (for example had no medication changes or reported increase in self-harm ideation or incidents within the past month). Exclusion criteria were: known organic illness; primary diagnosis of substance misuse non-English speaking; currently (or in the past 6 months) engaged in CBTp.

2.3. Randomisation and blinding

Participants were randomly allocated in a 1:1 ratio to receive either MUSE and TAU, or TAU alone. Stratified block randomisation was completed using an online randomisation service (Sealedenvelope.com). It was stratified by site and employed randomised-permuted blocks of 4–6. All post-randomisation assessments were completed by research assistants who were blind to participant allocation. There were 5 full blind breaks with 2 in TAU and 3 in MUSE. When breaks in blinding were reported, assessments were completed by another research assistant ensuring the assessor remained blind to allocation.

2.4. Procedure

Eligible participants were identified by members of the clinical team and asked for verbal permission to be contacted by a research team member. Research assistants provided information sheets, obtained written informed consent, and administered baseline measures. Recruitment began in June 2021 and was completed in May 2022. Follow-up assessments ran from August 2021 to September 2022.

Participants were allocated to receive either treatment as usual (TAU), or up to 8 1-h sessions of MUSE plus TAU over a two-month (8 week) period. In the UK, TAU for service-users with psychosis is based on the principles of the Care Programme Approach and comprises a range of interventions, including psychiatric medication, care coordination, social or vocational support, family interventions, outpatient follow-up care, and access to CBTp. The MUSE intervention was delivered by care coordinators who acted as research therapists having completed three days of training on MUSE prior to taking on cases. Therapy was conducted in participants' homes or at clinical bases. The

initial sessions generally focused on engagement, psycho-education about how the mind works and on normalising the experience of hallucinations. Subsequent sessions focussed on identification of key causal processes and the use of coping strategies. Optional sessions were available for understanding and managing visions and sleep. Adherence checklists were utilised to maximize fidelity, with any protocol divergences monitored during therapist supervision. Supervision sessions occurred fortnightly using a group supervision format and were facilitated by psychological therapists with clinical experience of MUSE.

2.5. Outcomes

The primary purpose of the study was to consider the feasibility of a future definitive trial. Consequently, there was a focus on recruitment and retention rates, adherence to allocation, trial and treatment acceptability (assessed through discontinuation rates and a qualitative study).

Progression criteria based on ADEPT guidelines (Bugge et al., 2013) were developed based on discussion with the Patient Public Involvement group (PPI), trial steering and management groups in advance of the final data collection. The progression criteria were divided into three categories (green, amber and red).

2.5.1. Measures

Auditory hallucinations were assessed using the Psychotic Symptom Rating Scales (PSYRATS (Haddock et al., 1999)) which is an 11 item semi-structured interview assessing frequency, duration, loudness, distress intensity and control of hallucinations. The delusions subscale was also completed. In addition, the self-report voice-impact subscale on the Hamilton Program for Schizophrenia Voices Questionnaire (HPSVQ; Van Lieshout and Goldberg, 2007) was used. Additional items asking about hallucinations in non-auditory modalities (visual, somatic, olfactory and tactile) were assessed as well (Dudley et al., 2023b).

Levels of anxiety and depression (Depression, Anxiety and Stress Scales (DASS) Lovibond and Lovibond, 1995), as well as perceived recovery (QPR process of recovery questionnaire; Neil et al., 2009) were assessed. The perceived impact of the intervention (The CHoice of Outcome In Cbt for psychosEs (CHOICE) Greenwood et al., 2010) was used to assess progress towards therapy-related goals. To determine therapy acceptability and alliance, the Satisfaction with Therapy and Therapist Scale (Oei and Green, 2008) and Working Alliance inventory were used (Horvath, 1986). In addition, at each session, a short self-assessment form comprising items adapted from the main measure of hallucinations monitored variations in voice frequency and distress. Therapists completed a therapy adherence checklist each session reporting on what modules of the MUSE package had been used. To help establish the feasibility of collecting information on health economics, self-report measures of service use and quality of life (Short Form-36; Ware and Sherbourne, 1992), EQ-5D (EuroQol Research Foundation, 2019), perceived capability (Investigating Choice Experiments Capability Measure for Adults (ICECAP-A; Flynn et al., 2015) were collected as well as case record review using a tool developed for the study.

2.6. Adverse events

Serious adverse events (SAEs) and adverse events (AEs) were recorded via participant self-report to therapists and/or research assistants during the trial. Screening of electronic medical records was also conducted at follow-up. All SAEs were reported to the Chair of the Trial Steering Committee and trial Sponsor for independent monitoring.

2.7. Statistical analysis

A target sample of 80 participants was deemed sufficient to both demonstrate feasibility and to obtain reliable parameter estimates for sample size in a definitive trial. Guidance on external pilot studies indicates that samples of 35 per arm or more give a reliable estimate of the standard deviation of the outcome measure (Teare et al., 2014). An estimated attrition of 12.5% was based on past research of psychological therapy with people with psychosis (Morrison et al., 2018) and similar brief interventions (Freeman et al., 2022) meaning 70 people were expected to complete the study.

When considering outcomes, the focus was placed on descriptive statistics, point estimates, and associated 95% confidence intervals rather than tests of statistical significance. Effect sizes are reported based on Cohen's d (Cohen's d = mean difference/(pooled standard deviation)). Descriptive baseline and follow-up data were summarised as mean (*sd*) for continuous variables and frequencies/percentages for categorical variables. Analyses followed a pre-specified plan approved by the chief investigator, the trial statistician, and the trial steering committee (available to view online at ISRCTN registry) and was based on intention-to-treat principles at the participant level. A linear mixed model was used to estimate the effect of MUSE on the outcome at end of treatment and follow up while controlling for study site. The analysis was repeated adjusting for baseline variables (age, sex, number of hallucinations, duration of hallucinations, length of time engaged in the service, site, and PSYRATS delusions score). All available data was used from each timepoint, with missing data imputed with pro-rating. The main analyses were all conducted in R (version 4.1.2) using the 'lme4' package (version 1.1–30).

In line with the recent CONSORT - Social and Psychological Interventions (CONSORT-SPI; Grant et al., 2018) guidance, which recommends minimising the distinction between primary and secondary outcomes for psychological therapies trials, all outcomes are reported at all assessment time points.

2.8. Ethical considerations

The investigation was carried out in accordance with the Declaration of Helsinki. Ethical approval was provided by the NHS Yorkshire and the Humber-Sheffield Research Ethics Committee (21/YH/0090), Health Research Authority (HRA/HCRW) approval (IRAS 292150). Informed consent of the participants was obtained after the nature of the procedures had been fully explained. The trial was funded by National Institute of Health Research (NIHR201078).

2.9. Patient and public involvement

As detailed in the trial protocol (Dudley et al., 2022) people with lived experience of hallucinations were involved all aspects of the MUSE treatment development as well as in the trial set up, delivery of the study and in the interpretation and dissemination its findings. We held monthly PPI meetings and had PPI representation on the Trial steering committee.

3. Results

3.1. Feasibility considerations

3.1.1. Recruitment and retention

132 individuals were referred to the trial, with 94 people consented and 82 recruited and randomised with 40 allocated to MUSE and 42 to TAU. 11 participants of the 132 referred declined to participate from referral to baseline assessment. Others were excluded owing to not meeting entry criteria or not being contactable. Recruitment into the trial exceeded the target (green zone). In terms of retention, 72 (87.8% green) completed end of treatment and 71 completed follow up assessments (86.6% amber). Of the treatment group three withdrew owing to experiencing bereavements and one was lost to follow up. (Fig. 1)

Baseline characteristics are reported in Table 1. The groups were similar in age, sex, and ethnicity. Participants reported high levels of distress and negative consequences from their hallucinations

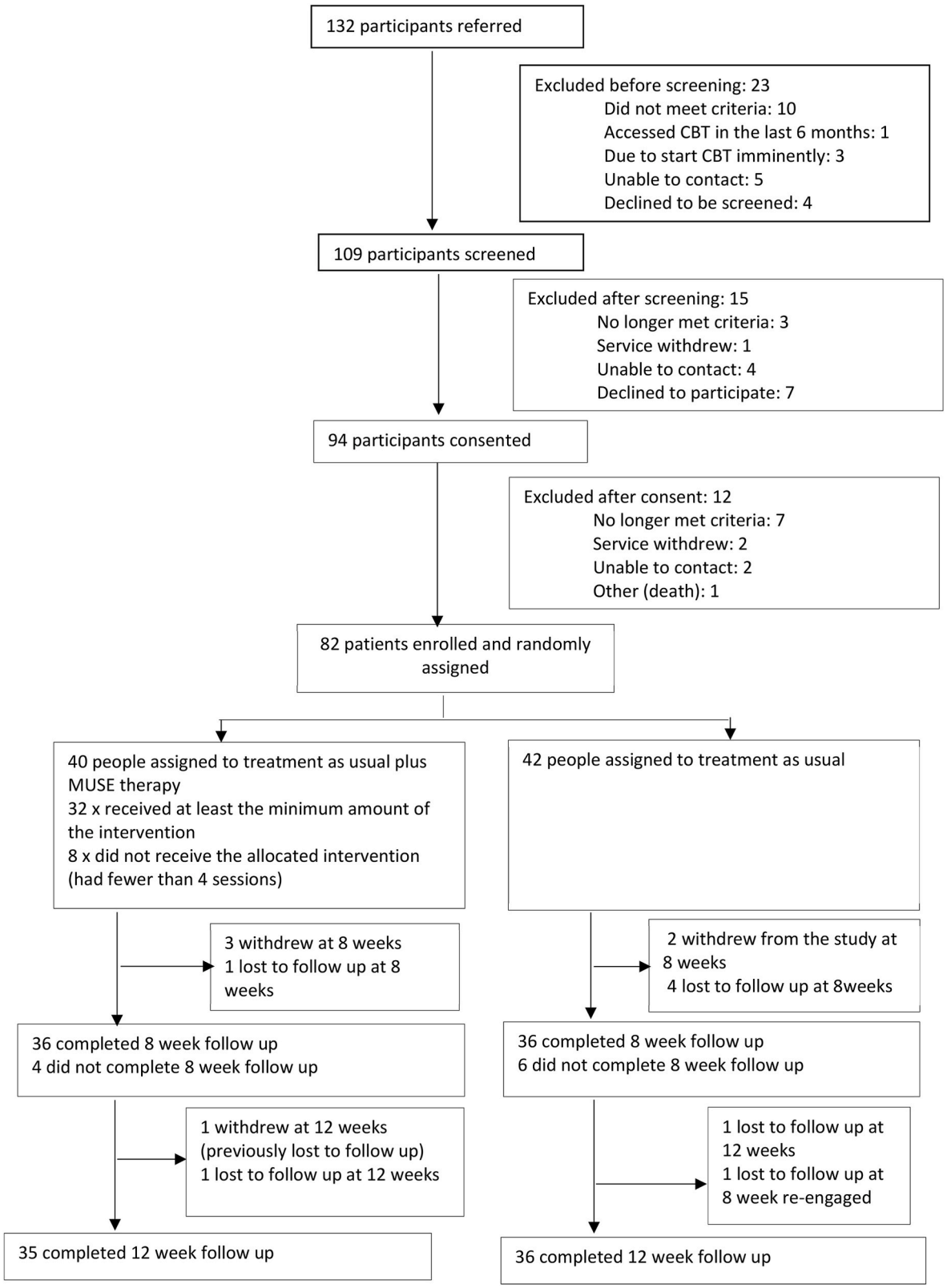

Fig. 1. CONSORT diagram for flow of participants.

comparable to that seen in other psychological therapy trials for hallucinations (Craig et al., 2018). The MUSE group reported somewhat higher levels of unemployment, and psychiatric admission but lower levels of current antipsychotic medication use. The MUSE group reported hearing voice for longer as well.

3.1.2. Staff training

25 care coordinators from 15 EIP teams attended a three-day training course on MUSE. Most had little or no previous therapy experience. Of the 25 trained, 16 went on to work with one or more supervised therapy cases. The training was run on three occasions owing to attrition of the

Table 1
Demographic characteristics of participants at baseline.

	Total sample (N = 82)	TAU n = 42	MUSE n = 40
	Mean SD or N (%)	Mean SD or N (%)	Mean SD or N (%)
Age	30.4 (10.34)	29.21 (10.27)	31.65 (10.4)
Sex			
Female	38 (46%)	20 (48%)	18 (45%)
Male	44 (54%)	22 (52%)	22 (55%)
Ethnicity			
White	78 (95.5%)	39 (93%)	39 (97.5%)
Asian	2 (2.5%)	1 (2%)	1 (2.5%)
Black	1 (1%)	1 (2%)	
Mixed	1 (1%)	1 (2%)	
Employment status			
Unemployed	41 (51%)	16 (39%)	25 (64%)
Working full or part time	23 (29%)	12 (29%)	11 (28%)
Student	11 (14%)	9 (22%)	2 (5%)
Health related benefits	5 (6%)	4 (10%)	1 (3%)
Highest educational level			
No qualification	4 (6%)	2 (5%)	2 (6%)
GCSE	33 (47%)	16 (43%)	17 (52%)
A levels (or sixth form equivalent)	26 (37%)	15 (41%)	11 (33%)
Undergraduate	7 (10%)	4 (11%)	3 (9%)
Past Psychiatric admission			
Yes	19 (24%)	6 (15%)	13 (33%)
No	61 (76%)	34 (85%)	27 (67%)
Current antipsychotic medication			
Yes	59 (79%)	34 (87%)	25 (69%)
No	16 (21%)	5 (13%)	11 (31%)
Duration of time in EIP in months	10.54 (9.50)	10.57 (9.99)	10.5 (9.1)
Duration of voice hearing in months	86.23 (110.59)	70.32 (103.6)	102.1 (117.4)
Number of hallucination modalities	2	2	2

workforce resulting from changes in roles with a number leaving for new posts or advanced training opportunities. Also, 7 of the 15 recruiting sites withdrew from the study following a resurgence in Covid 19 midway through the trial. Owing to this three people were treated by a clinical psychologist rather than a care coordinator, and this protocol deviation was recorded and reported to the sponsor and Trial Steering Committee. Hence, the mean number of cases per MUSE therapist was 2.35 (range 1–6).

3.1.3. Treatment adherence and fidelity

36 (90%) participants attended at least one session of MUSE with the mean being 5.4 sessions ($sd = 1.13$, range = 0–8). Therapy was classed as 'insufficient' if participants had completed less than 4 sessions meaning 32 (80% green) had a satisfactory dose of treatment. Session by session recording of content covered in MUSE sessions indicated good adherence to the protocol with participants completing an average of 4.5 of the 7 modules in the sessions available. All participants who had a satisfactory "dose of treatment" (32/32; 100%) completed the module on: understanding voices; 97% completed how the mind works; 87.5% the module on inner speech; 53% the trauma and memory module, and 66% the module on hypervigilance. The modules on visions (31%) and sleep (19%) were the least used.

Supervision attendance was variable as it tended to occur when working with a case. Planned audio recordings to independently assess adherence were not undertaken owing to an inability to resolve information governance issues.

3.1.4. Participant satisfaction

The participants all reported they agreed or strongly agreed that they were satisfied with MUSE therapy and that they would recommend it to someone with a similar problem (Oei and Green, 2008).

3.1.5. Adverse events

There were 14 adverse events documented across the study period reported by 11 individuals randomised into the trial. 8 were classed as serious adverse events and there were 5 in the TAU group and 3 in the MUSE + TAU group, and all were assessed as unrelated to the intervention by the independent TSC Chair. In addition, a person sadly died after they had consented, but before any assessments were undertaken. Details are provided in Table 2.

3.2. Outcomes by trial arm and assessment time point

Outcome at each time point is shown in Table 3 as well as the intention to treat analysis. There was considerable improvement in both groups over a relatively short period of three months (within subject effect sizes of Cohen's $d = 0.8–0.9$ on PSYRATS AH at 12 weeks for example). The reduction in scores on the PSYRATS in both arms at 12 weeks was greater than that reported in successful treatment studies for distressing hallucinations (Craig et al., 2018) delivered over similar timescales. The same pattern was evident on all the outcome measures meaning that at the end of treatment and at follow up there were negligible differences between groups (effect sizes all trivial to small as reported on Table 3), with a possible exception of the improvements in perceived recovery but even this was a small effect. Analyses run controlling for baseline variables (age, sex, number of hallucinations, duration of hallucinations, length of time engaged in the service, site, and PSYRATS delusions score) made no difference to the findings. Health economics data (EQ5D, ICECAP and SF-36) were collected to establish feasibility of data collection and are not reported here but the full data is available as outlined in the data availability statement.

3.3. Impact of covid

Midway through the trial a resurgence of Covid 19 led to 7 of the 15 teams withdrawing citing staffing pressures. The impact of Covid on trial delivery was assessed by considering the number of sessions provided before the resurgence (mean = 5.57 sd = 0.53) in comparison to after (mean = 5.3, $sd = 1.24$) with no significant difference found ($W = 109$, $p = 0.53$). Similarly, there was no difference in any baseline assessment

Table 2
Incidence of adverse events across groups.

	MUSE n = 40	TAU n = 42
Serious Adverse Event **(SAE)**		
Participants with an SAE	3	4
Number of SAEs	3	5
Types of SAE		
Death[a]	0	0
Hospital admission – mental health	2	1
Overdose/self-injury requiring treatment in general hospital	0	1
Hospital admission – physical health	0	3
Pregnancy loss	1	0
Adverse event (AE)		
Participants with AE	1	3
Number of AEs	1	5
Types of AE		
Overdose/Self-injury – no treatment sought	0	2
Physical injury – unrelated to mental health – no treatment sought	0	1
Attended A&E – mental health – no treatment required	0	1
Attended A&E – physical health – no treatment required	0	0
Police incident	1	1

A&E Accident and Emergency room.

[a] One person died after consenting to the trial, but was not contactable for many months, and no baseline assessments were undertaken, and person was not randomised.

Table 3
Baseline, end of treatment and follow up scores on outcome measures.

	TAU	MUSE	Coefficient[a]	95% CI	Cohen's *d*
PSYRATS AH total					
Baseline	29.81 (4.45)	29.3 (5.55)			
8 weeks	23.53 (12.89)	24.56 (10.2)	1.63	−2.00–5.26	0.06
12 weeks	22.39 (11.65)	21.91 (12.05)	−0.05	−3.71–3.59	−0.03
PSYRATS Distress					
Baseline	15.71 (2.75)	15.38 (3.44)			
8 weeks	12.47 (6.98)	12.61 (5.85)	0.50	−1.65–2.65	0.02
12 weeks	11.86 (6.67)	11.2 (7.41)	−0.43	−2.59–1.74	−0.07
Hamilton total					
Baseline	23.64 (5.64)	23.62 (6.04)			
8 weeks	20.49 (9.43)	20.85 (7.82)	0.34	−2.41–3.09	0.03
12 weeks	17.94 (10.06)	18.12 (8.71)	−0.06	−2.81–2.69	0.01
PSYRATS Delusions					
Baseline	13.45 (7.37)	14.5 (7.02)			
8 weeks	11.5 (8.75)	10.42 (8.39)	−1.65	−4.89–1.61	−0.09
12 weeks	9.19 (8.32)	8.6 (7.97)	−0.93	−4.2–2.34	−0.05
DASS Stress					
Baseline	14.1 (4.18)	14.4 (3.83)			
8 weeks	12.46 (6.08)	11.94 (5.01)	−0.47	−2.39–1.45	−0.07
12 weeks	11.43 (6.32)	11 (5.47)	−0.43	−2.37–1.52	−0.05
DASS Anxiety					
Baseline	11.4 (4.42)	11.75 (4.20)			
8 weeks	9.83 (5.02)	9.91 (5.29)	0.04	−1.63–1.71	0.01
12 weeks	8.571 (4.45)	8.5 (5.09)	−0.2	−1.90–1.48	−0.01
DASS Depression					
Baseline	13.4 (5.75)	14.42 (4.23)			
8 weeks	11.97 (5.98)	11.65 (5.67)	−0.40	−2.33–1.54	−0.04
12 weeks	10.83 (6.39)	10 (5.67)	−1.27	−3.23–0.69	−0.10
QPR					
Baseline	26.88 (12.39)	27.4 (9.47)			
8 weeks	31 (11.76)	35.15 (9.35)	2.30	−1.99–6.61	0.28
12 weeks	31.29 (13.05)	33.94 (11.78)	1.22	−3.07–5.53	0.15
CHOICE					
Baseline	71.15 (19.84)	71.55 (19.77)			
8 weeks	65.93 (23.46)	59.85 (23.54	−4.65	−12.85–3.54	−0.18
12 weeks	64 (25.25)	59.77 (23.81	−4.74	−13.10–3.61	−0.12

[a] The coefficient is the estimated effect on the outcome (in points) from MUSE vs TAU, and could be interpreted as an adjusted mean difference.

scores before and after the resurgence (full analysis available on request).

4. Discussion

The MUSE FEP trial established the feasibility of delivering a brief, digitally delivered treatment for distressing hallucinations, by a less specialist workforce. The trial recruited to target, and retained a sufficient number of participants (86% at follow up). Withdrawals were mainly owing to suffering significant bereavements. There was good uptake (90%) and compliance (80% received 4 or more sessions) with the MUSE treatment. Satisfaction with the treatment was high. Adverse and serious adverse events were similar across conditions and not obviously attributable to treatment.

The study also demonstrated it was possible, but not easy owing to high rates of therapist attrition, to train a wider workforce and for them to deliver treatment. Despite most therapists treating a small number of participants there was evidence of good adherence to the treatment with most participants receiving more than the minimum number of sessions, and content being recorded as covering the core modules. This would imply that standardised treatment delivered on a digital platform helps with adherence (Killikelly et al., 2017).

A future definitive trial would appear to be feasible but negligible differences between the groups at both end of treatment and follow up requires further consideration. The impact on perceived recovery, but not on measures of hallucinations was also reported in another hallucination focussed treatment (Longden et al., 2022). In this context of general improvement any additional intervention would have to have a very powerful effect in order to demonstrate impact. Reasons for this general improvement may be owing to the participants being in the early stage of psychosis where improvement is common (Lewis et al., 2002). We did not ask about Duration of Untreated Psychosis which has been associated with recovery, but instead asked about duration of voice hearing and length of time in service. These baseline variables were included as covariates but made no difference. Hence, it is unclear if duration of hallucinations or psychosis impacted on our findings. It is notable that EIP services have smaller case-loads help improve quality of relationships developed by staff with service users which aids recovery (Goldsmith et al., 2015; Turkington et al., 2017). It is possible that the care coordinators trained in MUSE could have used the ideas more widely leading to contamination of TAU. However, a review of notes revealed no evidence of MUSE being used in TAU. In fact, the notes review produced little evidence of any hallucination focussed work being undertaken in TAU. At most, only one or two care coordinators in each team were trained in MUSE, meaning most staff had not had the training, reducing the risk of contamination.

The short duration of the intervention and the follow up may well have reduced the capacity to deliver a sufficient number of treatment sessions, or for any effect to be clearly revealed against the general improvement seen in both groups. If a demonstrable benefit of MUSE is to be established to warrant a definitive trial, then future studies could introduce a baseline period to the design to ensure stability of the experiences before treatment is offered. Another strategy may be to increase the number of sessions and extend the follow up period to enable larger differences to emerge between the groups owing to a greater dose of treatment and a longer time period to consolidate the gains. Of course, it would also be important to consider the value of an active comparison group that controls for any digital placebo effect (Firth and Torous, 2015).

The present study was ambitious in combining targeted, brief, digitally delivered treatment by a non-specialist workforce. Future dismantling studies could try to consider these factors and isolate the active ingredients of digital interventions (in this case the modules and interventions that people found helpful) which may assist in refining the features which yield maximum benefits, whilst improving our understanding of the mechanisms which drive them (Michie et al., 2017). Finally, it is important to note that the group were representative of the local population (ONS, 2021) but was not very diverse. There are different outcomes for people with Black or Asian backgrounds (Griffiths et al., 2023) involved in EIP services, and the impact of MUSE for these groups, and its cultural relevance/acceptability is not tested here. Future trials may consider recruiting from teams with a greater diversity in the

population.

5. Conclusions

Overall, MUSE as a treatment appears to be safe and acceptable. Our approach of focussing on one experience (hallucinations), targeting key causal mechanisms, providing treatment from a more available workforce, using a digital platform has promise for increasing access to psychological therapies.

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CRediT authorship contribution statement

Robert Dudley: Writing – review & editing, Writing – original draft, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Guy Dodgson:** Writing – review & editing, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization. **Stephanie Common:** Writing – review & editing, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Emmanuel Ogundimu:** Writing – review & editing, Formal analysis, Data curation. **James Liley:** Writing – review & editing, Formal analysis, Data curation. **Lucy O'Grady:** Writing – review & editing, Project administration, Data curation. **Florence Watson:** Writing – review & editing, Project administration, Data curation. **Christopher Gibbs:** Writing – review & editing, Validation, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Bronia Arnott:** Writing – review & editing, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Charles Fernyhough:** Writing – review & editing, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Ben Alderson-Day:** Writing – review & editing, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Charlotte Aynsworth:** Writing – review & editing, Supervision, Project administration, Methodology, Investigation.

Declaration of competing interest

RD receives payment for workshops in treating hallucinations and GD, SC and RD declare they are involved in running treatment studies investigating psychological therapies for psychosis. All other authors declare no competing interest. MUSE is not licensed and will be made freely available if proven to be beneficial.

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