

Title

A mixed methods, randomised controlled feasibility trial of Eye Movement Desensitisation and Reprocessing (EMDR) plus Standard Care (SC) vs. SC alone for DSM-5 Posttraumatic Stress Disorder (PTSD) in adults with intellectual disabilities (IDs)

Short Title

EMDR for DSM-5 PTSD in adults with IDs

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ABSTRACT

Objective: To report the results of the first randomised feasibility trial of Eye Movement Desensitisation and Reprocessing (EMDR) plus Standard Care (SC) vs. SC alone for DSM-5 Posttraumatic Stress Disorder (PTSD) in adults with intellectual disabilities (IDs). **Method:** A total of 29 participants were randomised to either to EMDR + SC (n= 15) or SC (n= 14). Participants completed measures on traumatic stress (PCL-C) and comorbid distress at baseline, 1-week post-treatment and 3-month follow-up. **Results:** In the EMDR + SC group, 9 (60%) participants at post-treatment and 7 (47%) participants at 3-month follow-up were diagnosis free. In SC, 4 (27%) at post-treatment and follow-up were diagnosis free. At post-treatment 3 participants (20%) dropped out from the EMDR + SC group, and 1 (7%) dropped out from the SC group. **Conclusions:** It is feasible, acceptable and potentially effective to deliver EMDR in this population group.

Keywords: intellectual disability, PTSD, EMDR, randomised feasibility study

INTRODUCTION

There is international growing interest in understanding the psychological sequelae of traumatic life events in people with intellectual disabilities (IDs) (Byrne, 2017), although information regarding the prevalence of life events exposure in this population is scarce. A review of the literature across four studies reported incidence rates for negative life events exposure between 2.5% and 60% (Mevisen & de Jongh, 2010). More recently, it has been suggested that 79% of individuals with ID were exposed to at least one potentially traumatic event, with most individuals being exposed to, on average, 2.8 events (Scotti et al., 2012). There is also evidence to suggest that people with ID were more likely than people without ID to have experienced certain traumatic life events. For example, people with ID were between 3 and 6 times more likely to be physically, emotionally and/or sexually abused (Soylu, et al., 2013; Hulbert-Williams et al., 2014). Institutionalization, dependency on caregivers and being physically restrained, were also more likely reported by adults with ID (Hulbert-Williams et al., 2014; Wigham, Taylor, Hatton, 2013)

Posttraumatic stress disorder (PTSD) is a common condition following exposure to traumatic events and results from an inability to integrate one's emotional response to the experience due to the overwhelming nature of an event or condition (van der Kolk, McFarlane, & Weisaeth, 2007), with enduring biological, psychological and social sequelae (Brown, Baker, & Wilcox, 2012). Individuals with ID might be at an increased risk for developing PTSD due to a reduced ability to process traumatic memories after the event(s) (Breslau, Lucia, & Alvarado, 2006), having fewer experiences in managing general life events, less social support, and more communication difficulties, compared to the non ID population (Tomasulo & Razza, 2007; Hershkowitz, Lamb & Horowitz, 2007; Mevisen, Didden, Korzilius & de Jongh, 2016). Considering the high risk of exposure to life events,

and subsequent psychopathology, research into the treatment of trauma pathology in this population group is paramount.

The National Institute of Clinical Excellence (NICE, 2005) in the UK currently recommends two evidence-based treatments for PTSD in the general population; Trauma-Focused Cognitive Behavioural Therapy (TfCBT) and Eye Movement Desensitisation and Reprocessing (EMDR). EMDR is a psychotherapeutic approach, grounded in the adaptive information processing model, which hypothesizes that pathology is a consequence of unprocessed, distressing past experiences. Exposure to the traumatic memories combined with bilateral stimulation, usually in the form of eye movements, enables processing of traumatic memories (Shapiro 2001, 2002). TfCBT combines elements of psychoeducation, cognitive restructuring, anxiety management and exposure (Follette and Ruzek, 2006). By definition, TfCBT requires more advanced cognitive abilities and communication skills whereas access to thoughts and feelings to enable trauma processing is assumed. For that reason, EMDR might be a more appropriate intervention for people with ID. Unfortunately, there has been no trial on the clinical and cost-effectiveness of either TfCBT or EMDR for PTSD in people with ID. Nevertheless, there have been numerous published positive case studies on EMDR for psychological trauma in people with ID (Jowett et al., 2016). In their case studies review, Jowett et al. (2016) concluded that overall EMDR is an acceptable and potentially efficacious treatment for people with ID and psychological trauma. A range of forms of bilateral stimulation was used across case studies, with visual stimulation being the preferred method and others such as auditory, tactile, and tapping being used to meet the needs of different participants. The number of treatment sessions of EMDR for each case showed great variation (6 to 13) with session length being tolerated between 20 and 90 mins, depending on the severity of disability.

The present study reports on the first ever randomised-feasibility trial on EMDR + Standard Care (SC) vs. SC alone for people with ID and DSM-5 PTSD. Qualitative interviews with participants were also used to further assess the acceptability and usefulness of EMDR.

METHODS

Trial design

This study is a phase II, multi-site, parallel arm, blinded, feasibility-randomised controlled trial with a qualitative sub-study (MRC, 2008) and is registered at The Integrated Research Application System (IRAS ID 127358). The trial design was approved by the appropriate NHS and University Ethics Committees.

Participants and Setting

Participants with a mild to moderate ID were selected from six ID NHS outpatient clinics across Scotland and Northern Ireland. Inclusion criteria were: 1) a diagnosis of a mild to moderate ID, 2) aged between 18 – 65 years old, 3) exposed to childhood or adulthood traumatic life events as defined by the The Childhood Trauma Questionnaire (CTQ; Bernstein & Fink, 1998) and The Life Events Checklist (LEC-5; Gray, Litz, Hsu, & Lombardo, 2004), 4) experiencing subsequent traumatic symptomatology as defined by The Post-Traumatic Stress Disorder Checklist (PCL-5; Weathers et al., 2013) and 5) being able to cope with the demands of interviews and therapy as determined by the referring clinician. Exclusion criteria were 1) unwilling to participate or unable to give consent, 2) did not meet the cut off (< 38) for PTSD on the PCL-5; 3) severe challenging behaviour, 4) a history of psychotic illness, 5) current substance use disorder, 5) presence of suicidal ideation or intent as assessed at a clinical interview and 6) unable to cope with the demands of the interview and therapy because of the disability.

Eligible participants were identified and they were referred onto the study by the local community ID teams if they had history of exposure to traumatic life events. Potential participants were invited by their community team referrer to take part in the study. This was then followed-up with a phone call one week later by a researcher. The researcher then visited interested participants in the presence of a carer to discuss the study. All participants received easy-read information sheets and consent forms with pictures or symbols to explain text. Following confirmation of inclusion and exclusion criteria, participants were randomly allocated to one of the groups; EMDR + SC or SC alone using a computer-generated schedule unbeknown to the assessor, therapists or patients. Participants were then assessed blindly by a research assistant on three occasions; before treatment, 1-week post-treatment and 3-months follow-up. Each participant was seen throughout their treatment by the same therapist. All participants continued their usual psychological, psychiatric and medical care during the study.

Sample size

Since this is a feasibility study, a formal sample size calculation was not required. It was considered at least 50 participants should be sufficient to address the feasibility questions and inform the sample size for a future definitive RCT. Previous studies of EMDR for adults with PTSD in non-ID populations recruited between 22 to 50 participants (Cusack et al., 2016).

Intervention

The EMDR treatment was conducted by four experienced psychotherapists (2 psychiatrists, 1 clinical psychologist, 1 social worker) trained to deliver EMDR to adults with ID. The treatment sessions were conducted individually. Up to eight sessions were offered as part of the study in line with the NICE (2005) guidelines for the treatment of PTSD. Each

therapy session lasted up to approximately 1 hour. The treatment protocol is described briefly as follows.

EMDR is a psychotherapeutic approach, grounded in the adaptive information processing model, which hypothesises that pathology is a consequence of unprocessed, distressing past experiences (Shapiro 2001, 2002). It has an eight-phase protocol that addresses past, present, and future contributors to current distress (Shapiro, 2002). The eight-phase treatment includes phase 1, history taking; phase 2, preparation, including affect management and psychoeducation; and phase 3, assessing the components of the distressing memory, including an image, a self-referencing negative belief associated with the memory, a desired positive belief, and the current emotional and physiological components of the image and belief. The desired positive belief is rated on a Validity of Cognition Scale (VOCS; Shapiro, 1989) and the emotion reported is rated on a Subjective Unit of Discomfort Scale (SUDS; Wolpe, 1990). Phases 4 to 6 involve utilising a form of bilateral stimulation while the client's attention is directed toward the components of the assessment phase with the desired outcome of a SUDS score of 0 and a VOCS score of 7. Phase 7 is the closure phase, and phase 8 is the re-evaluation phase. The targets for processing include the initial sensitising event and the present triggers and "templates" for appropriate future functioning. Bilateral stimulation included a standard light bar, tactile and auditory stimulus to accommodate participants' disabilities. Supervision and support to all therapists was provided by the same consultant psychiatrist to ensure treatment fidelity.

Study Outcomes

All participants completed the same battery of self-report measures at pre-treatment, post-treatment, and three-months following completion of treatment. Basic demographics included gender, age, and ethnicity, and employment, marital and living arrangements. Minor

language adaptations were made to LEC; CTQ and PCL-5 to ease comprehension for adults with ID. Answering scales were also presented as visual coloured number stairs (e.g. PCL-5) to enable understanding. Questions were administered orally to all participants by one of the researchers on the project.

Members of the research team were vigilant for signs of distress or discomfort during the completion of self-report measures. A member of the research team was present during the completion of the assessments to address any distress as a result of the interview and provide support. When seeking informed consent to take part in the study, it was made clear to the participants that their responses would be kept confidential and anonymous, unless any participant response indicated that either themselves or others were at risk of harm. If confidentiality needed to be breached, a member of the participant direct community ID team was informed immediately to provide necessary help and support.

Traumatic life events

The Life Events Checklist (LEC-5; Gray, Litz, Hsu, & Lombardo, 2004) is a 17-item, self-report measure that screens for potentially traumatic events in the respondent's lifetime and was used to assess adulthood trauma. Participants rated each item by indicating if the events: (1) happened to them; (2) if they witnessed it; and (3) if they learned about it. The measure demonstrated good test-retest reliability and convergent validity in non-ID population (Gray et al., 2004) but has not been tested in the ID population.

The Childhood Trauma Questionnaire (CTQ; Bernstien & Fink, 1998) is a 28-item self-report questionnaire that assesses history of childhood emotional, sexual and physical abuse and emotional and physical neglect on a 5-point Likert scale (1 = never true - 5 = very often true). The measure demonstrated good internal consistency, test-retest reliability, and

convergent validity in non-ID populations (Bernstein & Fink, 1998) but has not been tested in the ID population.

Primary outcome

Post-Traumatic Stress Disorder Checklist (PCL-5; Weathers et al., 2013) is a 20-item self-report questionnaire. It can be divided into four subscales corresponding to the PTSD symptom clusters as per DSM-5: Intrusion (five items), Avoidance (two items), Negative alterations in cognitions and mood (seven items), and Alterations in arousal and reactivity (six items). Participants respond on a 5-point Likert scale (0 = not at all, 4 = extremely). Individuals rate how much they have been bothered by a problem in the past month (e.g. intrusive memories). A cut-off score of 38 is paired with DSM-V criteria for diagnosis is indicative of probable PTSD (Weathers et al., 2013). The measure has good reliability and validity across a range of non-ID populations (e.g. Bovin et al., 2016) but has not been tested in the ID population .

Secondary outcomes

The Glasgow Anxiety Scale for people with a Learning Disability Scale (GAS-ID; Mindham & Espie, 2003) is a 27-item self-report scale that comprises the ‘three systems’ of cognitive, behavioural and somatic symptoms which co-present in anxiety disorders. The measure has demonstrated excellent test-retest reliability and validity in people with ID (Mindham & Espie, 2003).

The Glasgow Depression Scale for people with a Learning Disability Scale (GDS-LD; Cuthill, Espie & Cooper, 2003) is a 20 item self-report scale to measure depression symptoms in individuals with learning disabilities ID. The measure has demonstrated excellent test-retest reliability and validity in this population (Cuthill et al., 2003).

The Clinical Outcomes in Routine Evaluation – Learning Disability (CORE – LD; Marshall et al. 2013) is a 30-item generic measure of psychological distress comprising of five domains: functioning (6 items), problems (11 items), social/cognitive (6 items) well-being (3 items), and risk (4 items). The measure has shown good test-retest reliability and validity in people with ID (Marshall & Willoughby-Booth, 2007; Brooks, Davies & Twigg, 2013).

Qualitative data

At post-treatment, all participants and their carers were invited to participate in a brief one-off semi-structured interview with a researcher on the team. The interview started with an open-ended question about access to psychological services within NHS or voluntary sector services. This was followed by further open-ended questions guided by a list of broad topics (see Table 1) which allowed interviewees to direct discussion on participating in the trial. Probing and summarising techniques were used to clarify the links interviewees made between topics discussed and to gain a deeper understanding of issues discussed. Interviews were carried out in the participants' homes or any other suitable place of their choice by a research assistant, who had experience in working with adults with ID and their carers.

TABLE 1 ABOUT HERE

Statistical methods

All statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) 23. Means (SDs) were calculated for continuous variables and frequencies (%) for categorical variables (Tables 2 and 3). Comparisons between treatment groups in demographic characteristics, trauma characteristics and pre-treatment scores were made by means of t-tests and chi-square analyses (Likelihood Ratio Chi-Square reported for values

less than 5). A series of two-way repeated measures (within subjects) 3 x 2 analyses of variance (ANOVA), Time (pre-intervention, 1-week post-intervention and 3-month follow-up) x Group (EMDR, SC), with time as the repeated measure, were conducted for all outcome measures to compare the two study arms across all outcomes (Table 4). An intention-to-treat analysis using last-observation-carried-forward (LOCF) approach was performed. At post-treatment, missing values were replaced for 3 participants in the EMDR group and 2 in the SC group, with pre-treatment scores across all outcomes measures. At follow-up, missing values were replaced for 3 participants in the EMDR group and 1 in the SC group with pre-treatment scores and 3 participants in EMDR group and 2 in the SC group with post-treatment scores. Proportions of people with ID who were diagnosis free were also calculated at post-treatment and follow-up for both groups.

Qualitative data analysis

The qualitative data were analysed using a thematic analysis framework ‘a method for identifying, analysing and reporting patterns (themes) within data’ (Braun & Clarke 2006; p. 79). The transcribed interviews were read and analysed by two researchers independently (SRM, AB). Transcripts were then entered into NVIVO 10. Emerging themes were compared and the final codes and themes were discussed and verified by the first author. The research team reached an agreement on the final thematic framework.

RESULTS

This study recruited between January 2014 to December 2016.

Recruitment Feasibility

Figure 1 shows participant flow through the study. Fifty one participants were approached to take part and 33 individuals with ID consented (a 64.7% response). Twenty-nine participants were randomised to either groups. The sample were primarily female (62 %) with a mean of 42.10 years (SD=11.52, range =20-63). The characteristics of the participants allocated to EMDR + SC and SC alone are summarized in Table 2. As illustrated in Table 2, there were no differences between EMDR + SC and SC alone groups by age, gender, education, living arrangements, severity of ID, or co-morbidity. All participants reported having experienced at least one traumatic life event. A significant proportion of the overall sample (n = 22, 75.8%) reported that they had experienced traumatic events in both childhood and adulthood, and just under a quarter of the sample reported only experiencing trauma during adulthood (n =7, 24.1%). No participants reported exposure to traumatic events only in childhood. Twelve participants attended four or more of the eight EMDR sessions (mean 6.8 SD=1.4; range 4-8). The mean number of sessions was 3.1 (SD=2.15); range 1-8.

FIGURE 1 ABOUT HERE

TABLE 2 ABOUT HERE

Primary and secondary outcomes

Table 3 illustrates the means and standard deviations for each group at pre-treatment, post-treatment and follow-up for all outcome measures. Two-way repeated-measures ANOVA's with post hoc comparisons test using Bonferroni corrections were used to analyse the scores of pre, post and follow-up of three months. The results are presented in Table 4 with three levels of time with two groups (EMDR + SC and SC alone). Total GAD as the outcome variable revealed a significant interaction between time x group [$F(2, 26) = 3.67, p < .05, \eta^2 = .22$]. Those in EMDR + SC group showed significant improvement in general

anxiety as measured by GAD compared to SC alone. No statistically significant interactions were found on any of the other outcomes measures.

TABLE 3 ABOUT HERE

TABLE 4 ABOUT HERE

Clinically significant change was measured by determining if participants still met the criteria for PTSD at post-treatment and follow-up PCL scores. In EMDR + SC group, a proportion of 9 (60%) participants at post-treatment and 7 (47%) participants at 3-month follow-up were diagnosis free. In the SC alone group, 4 participants (27%) at post-treatment and follow-up were diagnosis free.

Post-treatment qualitative findings

A sample of 9 participants who participated in the EMDR sessions took part in the semi-structured interviews post therapy. Two participants' interviews were terminated prematurely due to overwhelming distress and inability to engage in an interview setting. Overall seven interviews were included in the data analysis (57 % male). Interviews lasted for 3–18 minutes (mean length= 8 minutes).

Thematic analysis revealed three core themes; PTSD symptoms, therapeutic process, and recommending EMDR and improving access to ID services. Nine sub-themes were identified within three core themes (see Table 5). A main theme emerged through the in-depth exploration of these themes: EMDR treatment for PTSD and ID experiences. Identification codes were applied to preserve confidentiality and anonymity of the participants. Each subtheme is described and illustrated with relevant quotations as follows.

TABLE 5 ABOUT HERE

Theme 1: PTSD symptoms

This theme provides evidence on how PTSD clinically presents in adults with ID. Participants with more severe traumatic distress were able to recognise and describe their PTSD symptoms of intrusion, avoidance and negative alterations in cognitions and mood.

Intrusion

Intrusion symptoms were reported in forms of intrusive memories and traumatic nightmares. All participants who reported intrusion symptoms were able to recognise after treatment these symptoms had reduced significantly.

'My dream, my nightmare aren't as bad as they used to be.... but I'd still have the nightmares.' (Participant 4)

'It broke some of my memories away. Some of them's faded away, it's calming down a bit, so that's what's helped.' (Participant 2)

Avoidance

Avoidance was observed through the avoidance of trauma-related thoughts/feelings.

'....really, that I would never, ever talk about ...' (Participant 1)

'In my head I was saying oh my god I'm going to have to talk about this.... Because there's, just, telling them some stuff that I've never even eh spoke to, to anyone about and, in years so.' (Participant 4).

Negative alterations in cognitions and mood

Negative alterations in cognitions and mood symptoms were identified through an inability to experience positive emotions and persistent distorted blame of self or others. Only

two participants could reflect on these symptoms since the beginning of treatment and were able to identify improvements after treatment.

'I just felt that, depressed, and low.....I just wanted to, drink, and end my life..... Oh, yeah. It's just been good that it's made such a difference, I'm really happy.' (Participant 1)

'I still feel it was my fault....and I felt like I wasn't loved by anyone...I blamed God for it all, as well. ... Since the traumatic class started, honestly, that's really helped me out... I haven't thought about that I was in the wrong, or I was the bad one, or I wasn't loved or it was my fault.' (Participant 3)

Theme 2: Therapeutic process

This theme described the views and experiences of adults with ID in therapy. The following topics were discussed; therapeutic relationship, components of therapy, emotions and installation of positive cognitions.

Therapeutic relationship

The majority of the participants commented on their experiences of their therapeutic relationship. Two participants illustrated great importance on the involvement of one continuous clinician throughout the treatment and described feeling safe in the presence of their therapist.

'It was just between me and [therapist] and it was lovely.' (Participant 3)

'And enjoying seeing the person all the time. It's like getting close to someone special, that's what it's like.' (Participant 2)

Another participant described his therapeutic relationship as a supportive one. This participant commented how his therapist supported him in developing a therapeutic relationship and throughout the therapy process: *'every time I wanted to give up, they [partner + therapist] would talk me out of it and eh, I continued with it'* (Participant 4). Some participants expressed difficulties in establishing a therapeutic bond as well as talking through their traumatic event/s.

'It's hard when it's somebody you don't know..... Yeah, probably better with people that you know.' (Participant 5)

'I think it was talking about, it was difficult talking about...when I didn't really know [therapist], and that...' (Participant 6)

Components of therapy

This sub-theme represents all the participants' experiences of the usefulness and difficulties of EMDR intervention. Three participants expressed that talking about trauma experiences with their therapist was helpful as it provided symptom relief and an opportunity to open-up.

'Really, kind of like, [therapist] really got me to open up about stuff.' (Participant 1)

'I thought it was, what was also helpful was, when you said something, like, when we talked about something.' (Participant 5)

'Well it's helpful, like, discussing, like, my problems, and that.... It helped me, when I got it out, all in the open.' (Participant 6)

One participant suggested writing down feelings could have helped as part of the therapy. *'It could have been a bit better because if I'd written down how I feel.'* (Participant 7). The form of bilateral stimulation techniques and the comfort level of each person was also discussed. Two participants described these techniques enhanced feelings of calm and wellbeing.

'I had to keep following with the fingers.... So that was really good, and interesting to see, and to know to do that ... she asked me to close my eyes, and then, she just tapped my leg, and that was really lovely, it was a lovely feeling, and I could feel it all in my body, to make me feel calm and relaxed....' (Participant 3)

'Like, the hand machines.... And the ones on the head as well..... Aye, my muscles were less tense.' (Participant 7)

Another participant displayed unrest through the standard light bar; visual bilateral stimulation technique.

'What I didn't find helpful was the red dot [therapist] used to use. It was just the way, you had to sit and watch this red dot.... And then, think of stuff, and then, when you thought about it, [therapist] was like, no, you've got to look at the red dot again. And I was like, but the red dot's annoying.' (Participant 5)

Timing was also raised as problematic with two participants expressing their frustration that sessions overrun. This experience demonstrated adults with ID may have lacked the understanding and importance of the therapists' role of returning them to a comfortable and safe level of emotional functioning prior to ending a session.

'Make sure, when you do it again, that you make sure you check the time, because [therapist] went over the time.' (Participant 5)

'[therapist] forgot the appointment went on too late and [therapist] didn't eh shut down (Participant 4).

Location of therapeutic environment was raised by two participants. One participant found the clinic room to be a safe and calm environment *'It's relaxing and it's a nice environment where you are'* (Participant 2), although the other participant preferred if the treatment was delivered in a home setting due to his poor attendance; *'I'd probably have preferred it if it was at home because I'd probably be able to do a lot more sessions and not being able to miss a few'* (Participant 4).

Emotions

The majority of participants reported experiencing a mixture of emotions from initial contact with a member of the research team to the end of treatment. A few participants expressed pre-therapy anxiety by reporting feelings of being worried and nervous due to different reasons such as:

'I thought it was a group session with other people.' (Participant 3)

'I wasn't on the waiting list and it was like, after seeing you, two weeks later, its. I just felt like I jumped in at the deep end.' (Participant 4)

Disclosing information about their trauma events led to feelings of embarrassment, being afraid and distressed. After revealing their traumatic history to their therapist, three participants were overwhelmed with emotions and admitted to being tearful in the sessions.

Installation of positive cognitions

Participants produced self-empowering and self-referencing statements throughout the interviews. Several participants commented on achieving this success on their own without involvement from others (e.g. health care professionals to support them). *'I've done it, instead of somebody else done it'* (Participant 5).

Two participants were able to move to alternative outlooks beyond their traumatic experience.

'I've just realised that I'm better without him, because look at me today, this is who I am. So, it's his own problem, so I'm not gonna get upset about it anymore, because I'm worth every, better than him.' (Participant 3)

'Well, I was thinking about keeping things in the past and going to the future.'
(Participant 7).

Theme 3: Recommending EMDR and improving access to ID services

This theme provided participants viewpoints' of EMDR as an acceptable treatment for PTSD, and their experiences and knowledge of accessing psychological services.

EMDR as an acceptable treatment?

Participants did identify positive changes after receiving therapy. Many commented on feeling relaxed and at ease with themselves.

'I felt relaxed and happier..... I feel much better now than I was before I went to therapy.' (Participant 7)

'Yes, I did find it helpful. I was more relaxed, I felt more at ease.' (Participant 2)

'I could put my mind at ease about what's happened, in my lifetime.' (Participant 5)

Access to psychological services

Participants openly voiced several suggestions on improving access to psychological therapies for adults with ID. Many expressed wanting to gain access to extra health practitioners, such as psychologists, who specialise in working for people with disabilities. One participant commented on consulting with too many practitioners at the same stage. *'and not too many people to speak to in one shot. I'd rather have one to one, I feel more comfortable that way'* (Participant 1).

Adults with ID are less likely to self-refer and often rely on healthcare professionals to direct them to the appropriate service/s. This was evident through their experiences. Two

participants expressed their knowledge and understanding of going to their GP for their first contact of gaining access to psychological therapies. Another participant had no understanding where to go for help “*I don't know what you could do*’ (Participant 6) while another suggested that more information on variety of psychological therapies for ID should be available.

‘It would have helped eh, if my GP had mentioned something like this eh.... but eh, they, they never mention anything like this to me. I think they should advertise EMDR a bit more.’(Participant 4).

Two participants expressed their appreciation about being given the opportunity to access EMDR therapy. One participant commented how she would recommend it to her peers. *‘So it was lovely, just to get an experience, to go through that..... Because it's really different to before..... I would probably tell them this, and tell them the good news about this, it's brilliant, you should go for it’* (Participant 3).

DISCUSSION

We reported the results of the first ever randomised-feasibility trial on the effectiveness of EMDR + SC versus SC alone for DSM-5 PTSD in people with ID. Overall, results indicate that EMDR can be a useful intervention for people with ID and traumatic stress, particularly so for symptoms of general anxiety. With regard to PTSD symptoms, at 1-week post-treatment and three-month follow-up, a higher number of participants in the EMDR + SC group were diagnosis free compared to participants in the SC alone group. Qualitative findings supported the quantitative findings and reiterated that PTSD is a debilitating condition for people with ID. Qualitative findings also highlighted that although

the therapeutic process of EMDR can be challenging at times, this is an acceptable intervention for people with ID. However, it is also important to highlight that a level of abreaction is expected with ease of such emotions as therapy progresses. Unfortunately, these qualitative findings were not supported by the quantitative results where, although not statistically significant, a higher drop-out rate was observed in the EMDR group (20%) compared to the control group (7%). Nevertheless, it is important to note that higher drop-out rates were observed in EMDR effectiveness studies in the general population. For example, drop-out rates were observed for the EMDR group (43.5%) in a study comparing EMDR versus another intervention for PTSD (Karatzias et al., 2011), as well as a study comparing EMDR versus TfCBT versus WL (e.g. 43% (Power et al., 2001)). Others such as Bradley, Greene, Russ, Dutra, Westen, (2005) and similarly with the present study have reported a mean drop-out rate of 21.1% across studies on psychological interventions for PTSD.

Unfortunately, we failed to collect information regarding treatment discontinuation but several mechanisms can be put in a place for a future trial to ensure successful recruitment and retention. For example, a range of patient information options can be available, such as symbolised information, easy read versions and audio options, or a short video demonstrating the delivery of EMDR and highlighting the range of options for undertaking the bilateral stimulation, such as alternating flashing lights, gentle tapping and sensory hearing bilateral stimulation. Prior to consent of potential participants, discussion with families and support workers at an early stage should be initiated in the recruitment process to ensure that issues such as transport to attend clinic appointments are addressed, allowing full participation in therapy. It might also be important to allow a family member or supporter to be present during therapy if required and with the consent of the participant to minimise distress associated with participation and to ensure that appropriate support is in

place for participants during the therapeutic process. During therapy, It is also worthwhile to develop participant and carer information materials to cover the possibility of ‘memory tracks’ to help cope with recurring memories related to the trauma under treatment, and provide details on local support between therapy sessions. Finally, individual adjustments should also be made to allow those adults with intellectual disabilities who also present with physical health conditions, such as cerebral palsy and visual and hearing problems, to fully access the clinic area. In relation to retention in a subsequent randomised trial, it will be important to maintain period check-ins with participants groups to maximise retention at follow up.

Although not adequately powered, EMDR produced less favourable results than those reported in previous research on the effectiveness of EMDR for PTSD in the general population (e.g. Bisson & Andrew, 2005; Bisson et al., 2007; Bradley et al., 2005; Benish, Imel, Wampold, 2007) in the repeated measures analysis. Although, many results approximate significance (e.g. intrusion and reactivity), it was surprising that EMDR had no significant effects on traumatic stress over time compared to SC alone. This may be due to the large drop-out rates in the present study, which have also resulted in a number of missing data. This coupled with the use of Last-Observation-Carried-Forward (LOCF) method employed for data imputation might have led to less favourable outcomes in the present study, and at the same time might have compromised the validity of our results. These results can also be explained by the nature of the instruments used to assess outcomes in the present study. Jowett et al. (2016) have discussed that there is a paucity of suitable and validated instruments to assess traumatic stress in this ID population group. In the present study LEC, CTQ and PCL-5, although well tolerated by the participants, have not been validated in the ID population. It might also be the case that considering that our sample was multiply traumatised, symptoms of ICD-11 Complex PTSD (CPTSD) (Karatzias et al., 2017) might

have been present. There has been a debate in the literature whether exposure therapies like EMDR are suitable for people with CPTSD (Cloitre, 2015). Future research should explore the presence of CPTSD in people with IDs.

Further methodological weaknesses can be observed in the present study. Cell sizes were rather small in both groups although adequate measures of control (i.e. randomisation, blind assessments) were exercised. With regard to methodological limitations, the present study also lacked the inclusion of another intervention to compare EMDR against. In treatment outcome studies it is important to demonstrate that an intervention is better than no intervention (Stevens, Hynan & Allen, 2000), especially in PTSD which demonstrates high rates of natural recovery (Kessler, Sonnega, Bromet, Hughes & Nelson, 1995).

Notwithstanding its limitations, this is the first ever randomised-feasibility trial on the effectiveness of EMDR for PTSD in people with ID. Considering that the present study confirms that it is possible to identify and recruit adults with ID and PTSD, that the outcome measures are acceptable to the participants, that it is feasible and acceptable to deliver EMDR in this population group, and that EMDR is potentially effective especially for symptoms of anxiety, we strongly recommend a definitive and adequately powered trial on the effectiveness of EMDR in people with IDs.

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Table 1. Key questions and examples of prompting questions from interviews.

Topic	Example Questions
Access to psychological services	How do you think people who have been through difficult life events should be best helped in psychological services within NHS or voluntary sector services?
Positive and negative aspects of participating in the programme.	Did you find the treatment helpful? In what way? Why? Why not? •How was EMDR/the treatment explained to you by Dr...? •How would you have felt if you had been put on a waiting list? •What do you remember about the first appointment/meeting Dr...?
Perceived changes / improvements in symptoms and day-to-day function and general outlook resulting from participating in the programme. Factors that enabled / inhibited positive change.	Was anything difficult about having the treatment sessions?
Suggestions for improving the layout and format of the sessions.	Can you think of anything good about having the treatment sessions? What?
Further information and support needs.	What do you think could be done to make the treatment programme better?

Table 2. Demographic and Trauma Characteristics by Group

	Level/Units	EMDR + SC (n=15) Mean (SD) or n (%)	SC (n=14) Mean (SD) or n (%)	Comparison χ^2 (df), <i>p</i>
Age		42 (11.3)	42 (12.1)	t=221 (27),.827
Gender	Male	6(40.0)	5 (35.7)	.000 (1), 1.000
	Female	9 (60.0)	9 (64.3)	
Living Arrangements	Independent	4 (26.7)	3 (21.4)	.843 (2), .656
	Supported living	11 (73.3)	11 (78.6)	
Education	Secondary	11 (73.3)	11 (78.6)	.000 (1), 1.000
	FE College	4 (26.7)	3 (21.4)	
Psychotropic Medication	Yes	13 (86.7)	12 (85.7)	.000 (1), 1.000
	No	2 (13.3)	2 (13.3)	
ID Level	Mild	13 (86.7)	11 (78.6)	.000 (1), 1.000
	Moderate	2 (13.3)	3 (21.4)	
Co-morbidity	Yes	12 (80.0)	7 (50.0)	1.71 (1), .191
	No	3 (20.0)	7 (50.0)	

Table 3. Pre-treatment, Post-treatment and Follow-Up Means (SDs) of Outcome Measures.

Measure	Group	Pre – treatment	Post - treatment	Follow-up
CORE-LD				
Functioning	EMDR + SC	4.57 (2.50)	4.36 (2.98)	3.93(3.22)
	SC	5.07 (2.43)	4.07 (2.27)	4.43 (2.68)
Problems	EMDR + SC	11.36 (4.72)	8.86 (4.11)	9.36 (5.23)
	SC	12.29 (3.45)	10.14 (4.57)	8.93 (4.27)
Risk	EMDR + SC	2.15(2.10)	1.69 (2.21)	1.77 (2.10)
	SC	1.31 (1.44)	0.85 (1.14)	0.54 (0.78)
Social	EMDR + SC	6.50 (2.47)	4.79(2.42)	4.50 (3.11)
	SC	6.43 (1.99)	5.86 (2.69)	5.00 (2.75)
Wellbeing	EMDR + SC	3.14 (1.23)	2.36 (2.02)	2.79 (1.76)
	SC	3.64 (1.15)	3.00 (1.57)	2.50 (1.45)
Total	EMDR + SC	27.79 (10.50)	22.00 (11.86)	22.43 (13.89)
	SC	28.71 (8.14)	24.07 (10.51)	21.50 (10.55)
PCL-5				
Intrusion	EMDR + SC	15.07 (3.97)	8.36 (6.22)	9.36 (5.71)
	SC	12.36 (5.05)	9.93 (5.16)	10.50 (5.36)
Avoidance	EMDR + SC	4.57 (1.10)	2.93 (2.40)	3.00 (1.76)
	SC	5.36 (1.60)	4.71 (1.94)	4.21 (2.23)
Cognitive and mood change	EMDR + SC	16.00 (6.16)	9.29 (6.86)	10.14 (7.14)
	SC	14.71 (6.44)	9.29 (4.80)	10.21 (4.25)
Arousal and reactivity	EMDR + SC	13.64 (5.12)	7.93 (5.72)	8.86 (4.88)
	SC	12.71 (4.92)	10.64 (5.05)	11.00 (4.46)
Total	EMDR + SC	49.29 (12.66)	28.50 (18.77)	31.14 (16.38)
	SC	45.14 (13.31)	35.14 (13.00)	36.43 (13.83)
GAS				
Behavioural (specific fear)	EMDR + SC	8.36 (2.90)	7.29 (3.07)	7.50 (3.03)
	SC	6.64 (3.65)	6.57 (2.77)	6.57 (2.82)
Somatic (physiological symptoms)	EMDR + SC	10.50 (3.41)	8.14 (4.01)	8.57(3.50)
	SC	9.71 (3.41)	8.93 (2.24)	8.86 (1.79)
Cognitive (worries)	EMDR + SC	13.43 (3.13)	11.36 (4.43)	11.07 (5.00)
	SC	12.50 (3.67)	11.57 (3.39)	12.36 (3.91)
Total	EMDR + SC	32.29 (6.84)	26.93 (9.40)	26.00 (10.62)
	SC	28.86 (9.01)	26.93 (7.24)	27.79 (7.10)
GDS				
	EMDR + SC	17.86 (7.61)	13.50 (8.51)	15.50 (8.65)
	SC	18.14 (5.19)	16.21 (7.17)	15.21 (6.78)

Note: EMDR: eye movement desensitization and reprocessing; SC: standard care, PCL-5: Post-Traumatic Stress Disorder Checklist; CORE – LD: Clinical Outcomes in Routine Evaluation – Learning Disability GAS-ID: The Glasgow Anxiety Scale for people with a Learning Disability Scale; GDS-LD :The Glasgow Depression Scale for people with a Learning Disability Scale

Table 4. Two way-repeated measures analyses of variance of Time (pre-treatment, post treatment, follow up) x Group (EMDR + SC, SC) for outcome measures.

	Time				Group				Time x Group			
	(df,df error)	F	p	η^2	(df,df error)	F	p	η^2	(df,df error)	F	p	η^2
CORE-LD												
Functioning	(2,26)	2.94	.071	.18	(1,13)	0.14	.713	.01	(2,26)	0.92	.412	.06
Problems	(2,26)	7.58	.003	.37	(1,13)	0.25	.628	.02	(1,18)	1.01	.356	.07
Risk	(2,24)	3.84	.036	.24	(1,12)	5.19	.042	.30	(2,24)	0.48	.625	.04
Social	(2,26)	7.24	.003	.36	(1,13)	1.01	.333	.07	(2,26)	0.80	.459	.06
Wellbeing	(2,26)	4.21	.026	.24	(1,13)	0.47	.507	.04	(2,26)	3.07	.064	.19
Total	(2,26)	9.64	.001	.43	(1,13)	0.07	.800	.01	(1,17)	0.98	.389	.07
PCL-5												
Intrusion	(1,17)	15.83	.000	.55	(1,13)	0.00	1.00	.00	(1,18)	3.68	.059	.22
Avoidance	(2,26)	5.55	.010	.30	(1,13)	7.40	.017	.36	(2,26)	0.46	.634	.03
Cognitive and mood change	(1,16)	26.86	.000	.67	(1,13)	0.05	.823	.00	(1,17)	0.26	.687	.02
Arousal and reactivity	(2,26)	17.11	.000	.57	(1,13)	0.64	.437	.05	(2,26)	2.86	.075	.18
Total	(1,18)	32.10	.000	.71	(1,13)	0.31	.589	.02	(1,18)	2.67	.110	.17
GAS-ID												
Behavioural (specific fears)	(2,26)	1.75	.195	.12	(1,13)	1.14	.306	.08	(2,26)	1.21	.315	.09
Somatic (physiological symptoms)	(2,26)	5.49	.010	.30	(1,13)	0.10	.928	.00	(2,26)	1.14	.334	.08
Cognitive (worries)	(2,26)	2.27	.124	.15	(1,13)	0.03	.870	.00	(2,26)	1.40	.265	.10
Total	(2,26)	6.10	.007	.32	(1,13)	0.04	.839	.00	(2,26)	3.67	.039	.22
GDS												
	(2,26)	4.61	.019	.26	(1,13)	0.18	.681	.01	(2,26)	2.24	.127	.15

Note: PCL-5: Post Traumatic Stress Disorder Checklist; CORE – LD: Clinical Outcomes in Routine Evaluation – Learning Disability GAS-LD: The Glasgow Anxiety Scale for people with a Learning Disability Scale; GDS-LD: The Glasgow Depression Scale for people with a Learning Disability Scale. η^2 Cohen (1988) provides the following guidelines for interpreting the η^2 values: 0.01 to 0.059, small effect size; 0.06 to 0.139, medium effect size; 0.14, large effect size.

Table 5. Summary of the thematic analysis. (N=7)

Main Theme	Codes	Sub-themes
EMDR treatment for PTSD and ID experiences	PTSD symptoms Therapeutic process Recommending EMDR and improving access to ID services	Intrusions Avoidance Negative alterations in cognitions and mood Therapeutic relationship Components of therapy Emotions Positive cognitions EMDR as an acceptable treatment? Access to psychological services

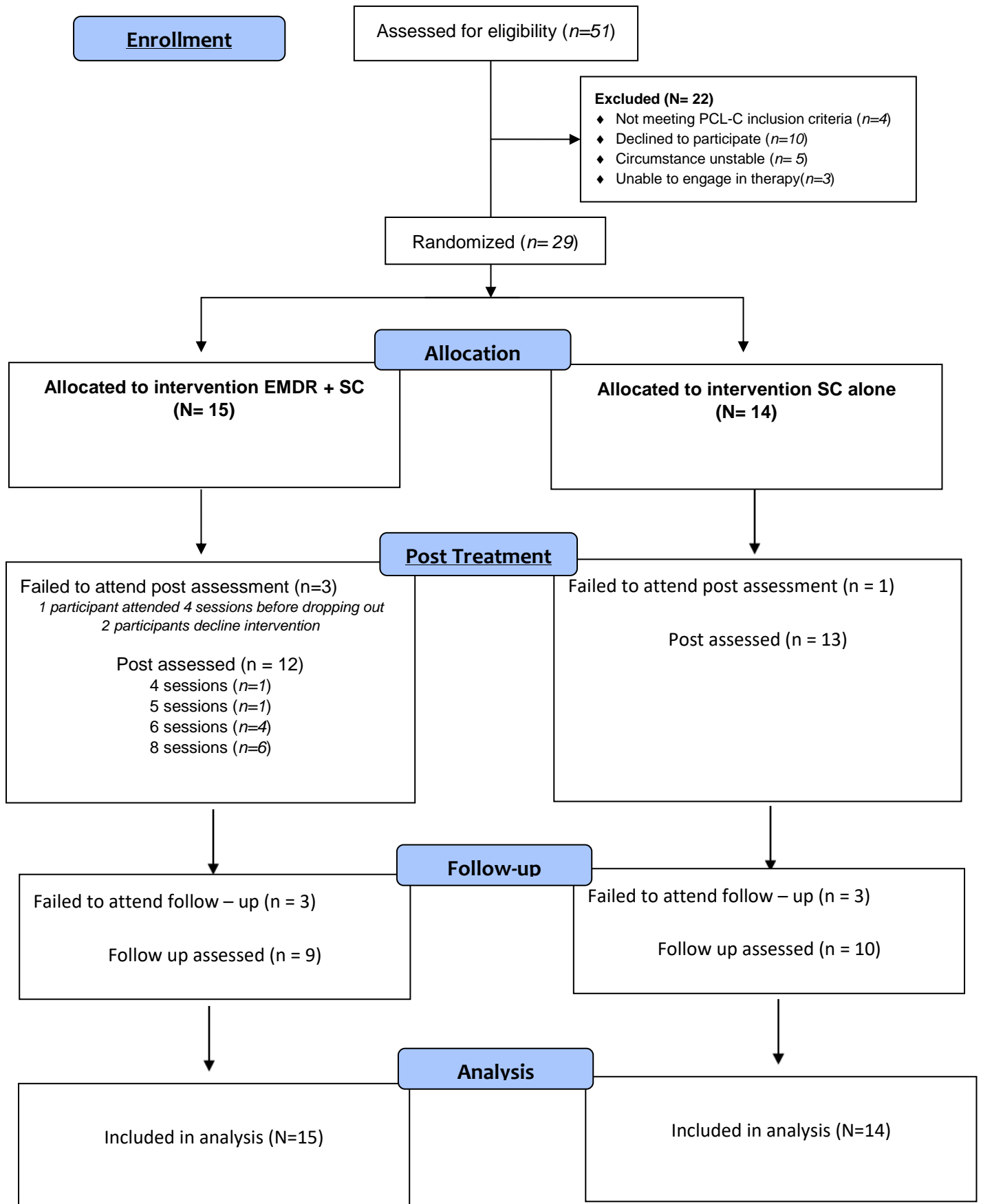


Figure 1. Flow of participants through the trial. CONSORT flow chart