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FULL TITLE OF THE TRIAL

Eye movement desensitisation and reprocessing for symptoms of post-traumatic stress disorder in adults with intellectual disabilities

SHORT TRIAL TITLE / ACRONYM: Trauma-AID

Version 3.0 dated 24 March 2022

This protocol has regard for the HRA guidance and order of content

Research Reference Numbers

Sponsor reference	**IRAS:260514**
IRAS reference	**260514**
REC reference	**19/WA/0173**
Funder	**NIHR HTA: 17/125/04**
ISRCTN	**35167485**

PROTOCOL HISTORY

Draft protocol versions were managed by electronic revision control.

Version control of all approved trial documents will be maintained using a version control log which will be held separately.

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
-	1	26 April 2019	-	-
1	1	26 Jun 2019	GHolland/PWillner	Update to DMC information following REC review
2	2	07 Oct 2021	S Hiles/P Willner/ P Langdon	Change of QoL instrument; Detail for schedule of activities Clarification of terms Findings of feasibility and preliminary studies Eligibility/diagnostic sources and timeframe Descriptive text for patient visits Integration of hybrid protocol COVID mitigation and remote working
10	3.0	24 March 2022	S Hiles/P Willner	Carer target update; Change to diagnostic assessment for intellectual disability

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Contents

Research Project Summary/Synopsis

Title	Eye movement desensitisation and reprocessing for symptoms of post-traumatic stress disorder in adults with intellectual disabilities
Short Title	Trauma-AID
Protocol Version Number and Date	Version 2: 07 October 2021
Methodology	Experienced ID specialist clinicians trained in using an adapted PES + EMDR protocol will treat adults with ID and PTSD/complex PTSD to an extended number of PES and EMDR sessions while considering multiple traumas and/or other comorbidities. A full outline of the manualised protocol is provided as Appendix 1.
Inclusion criteria	<u>PwID</u> • Aged ≥ 18 to ≤ 65 • Meeting criteria for a diagnosis of ID • Meeting ICD-11 diagnostic criteria for PTSD • Major identified trauma at least a year earlier • Able to communicate in English • Able to provide informed consent to both the referral and study participation <u>Carers</u> • Aged ≥ 18 and over • A family member or carer of a person with ID who has consented to participate in the trial • Able to communicate in English and to provide informed consent to study participation
Exclusion criteria	• Assessed by the clinical team as at high risk and/or requiring urgent treatment • Currently in therapy and unwilling to intermit • Previously completed a course of EMDR • Psychosis not well controlled by medication • Change of psychotropic medication or dosage within the last month • Unable to complete the assessments • Any medical condition or treatment, which, in the opinion of investigators, could affect the safety of the participant's participation or outcomes of the study.
Participants	Preliminary and feasibility study: 40 participants for ITQ validity assessment; with up to 6 qualitative interviews for acceptability of intervention plus 6 qualitative interviews of a hybrid model of remote and face to face working. Main trial: 144 participants; Carers; 144; NHS Therapists; 21. People with mild to moderate intellectual disabilities and PTSD or complex PTSD, and their carers. NHS

	therapists to discuss their experience of delivering the intervention.
Treatment Duration	Up to 20 weeks, (possibly more in exceptional circumstances).
Follow Up Duration	14 months
Project Duration	4 years
	Objectives
Primary	To determine whether EMDR is clinically and cost effective for symptoms of any PTSD presentation in adults with intellectual disabilities.
Secondary	Use of the ICD-11 to measure the complexity of PTSD presentation To determine effects of EMDR on other mental health problems and quality of life To establish the relative cost-effectiveness of EMDR compared with TAU in the study population.
Preliminary & Feasibility studies	The protocol makes multiple references to a preliminary study to validate the ITQ-ID and feasibility studies to assess the acceptability of the intervention. As of October 2021, these studies are now complete and the findings incorporated into the updated protocol.

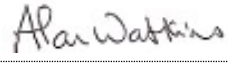
Protocol Approval

The undersigned confirm:

- that the research project as detailed within this protocol (Version 1 dated 26 June 2019), will be conducted in accordance with the UK policy framework for health and social care research (2017), the World Medical Association Declaration of Helsinki (2013), Good Clinical Practice (GCP) guidelines and the required Standard Operating Procedures (SOPs) and any subsequent amendments of the stated documents.

- that the findings of the research will be made publicly available through publication or other dissemination means without any unnecessary delay. An honest, accurate and transparent account of the trial will be given; and any discrepancies and serious breaches of GCP from the planned protocol will be explained.

Chief Investigator:	**Professor Paul Willner**
Signature:	
Date:	24 Mar 2022

Statistician:	**Professor Alan Watkins**
Signature:	
Date:	24 Mar 2022

Sponsor Representative:	**Dr Christine Burt**
Signature:	
Date:	24 Mar 2022

Abbreviations

ABAS	Adaptive Behaviour Assessment System
AE	Adverse Event
APR	Annual Progress Report
AR	Adverse Reaction
ASR	Annual Safety Report
BILD	British Institute of Learning Disabilities
BS	Bilateral Stimulation
CBT	Cognitive Behavioural Therapy
CI	Chief Investigator
CIPOS	Constant Installation of Positive Orientation and Safety
CORE-LD	Clinical Outcomes in Routine Evaluation – Learning Disability
CRF	Case Report Form
CRO	Contract Research Organisation
CSRI	Client Service Receipt Inventory
DM	Data Manager
DMC	Data Monitoring Committee
DSM	Diagnostic and Statistical Manual of Mental Disorders
ES	Effect Size
FC	Field Coordinator
GAS	Glasgow Anxiety Scale
GDS	Glasgow Depression Scale
HoD	Head of Department
HR	Health Related
EMDR	Eye Movement Desensitisation and Reprocessing
ICD	International Classification of Disease
ICF	Informed Consent Form
ID	Intellectual Disabilities
IES	Impact of Events Scale
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trial Number
ITQ	International Trauma Questionnaire
IQ	Intelligence Quotient
LANTS	Lancaster & Northgate Trauma Scales
MeLD	Men with Learning Disabilities
MRC	Medical Research Council
NHS ID	National Health Service Identification
NHS R&D	National Health Service Research & Development
NICE	National Institute of Clinical Excellence
MOSS-PAS	Previously known as PAS-ADD, Psychiatric Assessment Schedule for Adults with Developmental Disabilities
PES	Psychoeducation and emotional stabilisation
PI	Principle Investigator
PIS	Patient Information Sheet
PPI	Patient Public Involvement
PROM	Patient Reported Outcome Measure

PTSD	Post Traumatic Stress Disorder
PwID	People with Intellectual Disabilities
PWI-ID	Personal Wellbeing Index – Intellectual Disability
QA	Quality Assurance
QALY	Quality Adjusted Life Years
QC	Quality Control
QoL	Quality of Life
RA	Research Assistant
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SDV	Source Document Verification
SF-12	Short Form Health Survey
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
STU	Swansea Trials Unit
SUDs	Subjective Units of Distress
TAU	Treatment as usual
TF-CBT	Trauma-focussed cognitive behavioural therapy
TIDier	Template for Intervention Description and Replication
TIF	Trauma Information Form
TM	Trial Manager
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee
VAS	Visual Analogue Scale
VoC	Validity of Cognition
WASI	Wechsler Abbreviated Scale of Intelligence
WeLD	Women with Learning Disabilities
WEMWBS	Warwick-Edinburgh Mental Well-being Scale

1. Background and Rationale

1.1 Post-traumatic stress disorder in people with intellectual disabilities

Post-traumatic stress disorder (PTSD) is a common mental disorder that may develop following exposure to traumatic events. About 3% of the adult population in England suffer from current PTSD [1] and lower IQ is associated with increased rates of PTSD [2]. There is extensive evidence that people with intellectual disabilities (PwID) are more likely to suffer severe and prolonged bullying and/or sexual and other types of abuse [3,4,7]; and that adverse life events are traumatising in this population [8-10]. Exposure to trauma is known to impair executive functioning [11] and the impact of this loss of cognitive resources may be exacerbated, and risk heightened, for those with a developmental disability whose coping abilities are already impaired. It is no surprise that rates of PTSD are higher in PwID than in the general population [2].

PTSD has simple and complex presentations. Simple PTSD typically follows a single traumatizing event such as a road traffic accident; complex PTSD typically follows a history of chronic traumatisation such as prolonged abuse [3,14,15]. In addition to the characteristic symptoms of PTSD (re-experiencing, avoidance and hyperarousal), complex presentations of PTSD include further symptoms arising from a disturbance of self-regulatory capacities, and resembling aspects of borderline personality disorder (difficulty in regulating emotions; feelings of shame, guilt and worthlessness; difficulties in sustaining relationships and feeling close to others) [14]. Very recently, International Classification of Disease (ICD-11) has recognised Complex PTSD as a separate diagnosis [3].

A recent study of PwID presenting for treatment of PTSD reported that almost all had experienced multiple traumatic events in adulthood and around half (probably an under-estimate) reported that they had also experienced traumatic events in childhood [16]. PwID who have been traumatised typically show complex presentations of PTSD, and display self-harm or other challenging behaviours [4,12], particularly when the patient is on the autistic spectrum [13], as well as physical and psychiatric co-morbidity [4]. Frequently, PTSD is not diagnosed in this client group, and treatment focuses on the management of challenging behaviour. These patients are extremely complex and challenging, requiring highly specialist NHS intellectual disabilities (ID) services and considerable community support, and are at risk of admission to hospital. Their symptoms cause them and those around them significant distress.

1.2 Treatment of PTSD

On the basis of evidence from systematic reviews and meta-analyses, the UK National Institute of Clinical Excellence (NICE) and other clinical guidelines recommend trauma-focussed psychological therapies for PTSD [17,18], since therapies that do not require the patient to focus on traumatic memories are less effective [5]. The best-supported trauma-focussed interventions are trauma-focussed cognitive behavioural therapy (TF-CBT) and eye movement desensitisation and reprocessing (EMDR) [5]. EMDR includes an initial phase of psycho-education and emotional stabilisation (PES), before the main treatment phase in which the patient focusses on memories of past traumatic events while making controlled eye movements (or an alternative form of bilateral stimulation) that engage attention and enable the therapist to manage the intensity of the patient's distress.

While there is little to choose between TF-CBT and EMDR in terms of their effectiveness in PTSD, they differ in the experience offered to the patient. TF-CBT is a highly verbal intervention that aims to identify and modify over-interpretations of the

actual level of threat, and to modify beliefs and interpretations regarding the traumatic event. By contrast, EMDR is less reliant on verbal expression: during therapy the patient attends to emotionally disturbing material, in brief episodes, while simultaneously focusing on an external stimulus, typically, therapist-directed lateral eye movements [19]. EMDR is typically described as involving eight phases; 1: history taking and treatment planning; 2: preparation; 3: assessment; 4: desensitization; 5: reprocessing, which involves installing positive cognitions; 6: body scan 7: closure; and 8: reassessment. The actual EMDR procedure begins in phase 4.

There has been relatively little research on interventions for more complex presentations of PTSD, but what evidence there is suggests that phased approaches may be beneficial, in which the patient first undergoes psychoeducation and emotional stabilisation (PES) before undertaking any trauma-focussed intervention [14,20]. The PES phase targets problems such as affect dysregulation, interpersonal relationships, dissociation and somatic symptoms, so as to promote adaptive coping, a sense of safety, and emotional stabilisation. PES includes the first phase of the EMDR protocol (history taking and treatment planning) and aspects of phases 2 and 3 (preparation and assessment), and could lead on either to TF-CBT or to the later phases of EMDR.

1.3 Eye movement desensitisation and reprocessing (EMDR) for people with intellectual disabilities

It was thought for many years that PwID could not benefit from psychotherapy, leading to decades of benign neglect described as “the unoffered chair” [28]. Over the past twenty years [29] this assumption has been increasingly challenged, and it is now clearly evident that PwID can indeed benefit from adapted and accessible psychotherapeutic interventions for psychological disorders [30-32]. The present climate of austerity has profoundly weakened support services for PwID, who are increasingly thrown back on their own limited resources. This situation has heightened the importance of developing psychotherapies for PwID and mental health problems, to enable them to cope more effectively in an increasingly difficult world; and PwID with PTSD are a particularly needy group.

There have been no controlled trials of psychological therapies for PTSD in PwID. Current Government policy in the UK is committed to “transforming care for people with learning disabilities and/or autism and mental health problems or behaviour that challenges” by producing “a clearer model for health and care services”. The policy paper, “Transforming Care for People with Learning Disabilities: What next?”, acknowledges that “we have not made as much progress as we should have and instances of poor care remain too common” [27]. People with ID and PTSD, are among the most complex and challenging patients seen by services, and are among those receiving poor care: effective treatments are available for people with PTSD in the general population, but in the absence of clinical trials, they are only rarely available to PwID.

Because EMDR is a relatively simple procedure that is ostensibly less reliant than CBT on verbal expression, it could in principle, be considered more suitable for PwID. The standard EMDR protocol is difficult to use with PwID because the eye movement exercises (or alternative bilateral stimulation procedures) are unfamiliar, and their purpose is difficult to explain. However, the procedure can be made more accessible to PwID and acceptable to therapists by expanding the introductory PES phase and using some of the techniques developed for use with traumatised children (but adapted so as to be appropriate for adults [6]). Some case study reports suggest that adapted EMDR protocols can be used to treat PTSD in PwID [21,22]. However, in our

experience, therapists do not feel comfortable using the adult EMDR protocol with PwID, while clients find it difficult to understand the rationale and the terminology and to manage the desensitisation and reprocessing stages [23]. We also find that PwID need extensive preparation before commencing EMDR in order to increase engagement, to ensure that they have sufficient understanding of what they need to do, and why, and to militate against dropout from the EMDR phase.

This trial will therefore use a bespoke EMDR protocol that includes, as phase 1, a PES module that aims to install strengths and resources, stabilise emotional regulation, and build alliance and trust [14,24], and in phase 2 incorporates elements of the EMDR protocol as adapted for children [25], with minor changes to make it age appropriate for PwID. For phase 1 we have piloted a manualised 10-session PES protocol [26], adapted for PwID from a PES protocol used routinely with patients with PTSD in some adult mental health services. Both therapists and PwID in treatment find PES acceptable and helpful. Participants who completed the PES protocol showed a median 27% decrease in scores on the ID version of the Impact of Event Scale (IES) and provided positive feedback on their experiences [26]. Although piloted in a group format [26], the PES module can readily be delivered on an individual basis. For the purposes of this trial, a minor modification has been made to the PES module: the inclusion of an introduction to bilateral stimulation. We have also piloted a modified phase 2 EMDR protocol. The major adaptations [6] are (i) making the stages, language and outcomes more accessible; (ii) not preferring side-to-side finger movements over other forms of bilateral stimulation such as tapping; (iii) encouraging creative use of expression (such as techniques from art and narrative therapy/storytelling [e.g. 25]); and (iv) involvement of carers where appropriate to support the patient within and/or between therapy sessions. The intervention is described in greater detail below, and in Appendix 1.

1.4 Preclinical Data

NA

1.5 Clinical Data

EMDR is recommended by NICE as a first-line treatment of choice for PTSD in the general population [5,17,18]. There are a number of case study reports suggesting that adapted EMDR protocols can be used to treat PTSD in PwID [21,22], consistent with findings that psychotherapeutic approaches known to be effective in the general population appear also to be effective when adapted for people with mild to moderate ID [30-32].

1.6 Risks and Benefits

There are no significant risks to participants or society. There is a hypothetical risk that a client's condition could be worsened by participation in the therapy, but the likelihood of this happening is extremely small: it has not been identified as a significant issue in the relevant literature, albeit there may be temporary exacerbation of distress during sessions.

A potential benefit to participants is that they may learn to cope better with their traumatic memories, with a concomitant decrease in challenging behaviour, so increasing their opportunities for social inclusion, and decreasing the risk of placement breakdown, exclusion from services, and involvement with the criminal justice system.

A potential benefit to society is the avoidance of these outcomes, which are costly to services and impinge on other service users and members of the public. There are also potential benefits to carers and families, in relation to decreased occupational/family stress and improved social relationships.

1.7 Informing Potential Participants of Possible Benefits and Known Risks

Service users will typically have already discussed problems associated with poor mental health in individual care planning meetings. Potential participation in the trial, and the potential benefits of participating, as well as the potential risk of exacerbating symptoms in the short term, will be raised with the service user by carers or family members, and by the referrer, as would be the case for any referral to clinical support services.

1.8 Burden on participants

We were advised by one of our service user patient and public involvement (PPI) groups that while participants might gain a benefit from participation in therapy (in either arm of the trial), there is no such benefit to undertaking the assessments, which are relatively time consuming. They proposed, and we readily agreed, that service user participants should be paid a small honorarium (£10) for each of the five planned assessment sessions completed (two at baseline and three at follow-ups).

Informal (i.e. unpaid) carers will also receive a £10 honorarium to acknowledge the time given for completing questionnaires at four visits (baseline and three follow-ups).

1.9 Patient and Public Involvement

Our EMDR protocol was informed by interviews with treated patients [16,18]. In developing this proposal, we first conducted a focus group with patients with ID and PTSD in Shropshire, who, inter alia, endorsed the principle of conducting a randomised controlled trial (RCT) of psychological treatment for PTSD (i.e., including a control arm). We then engaged with the Research Advisory Group at the Tizard Centre (University of Kent), comprising people with mild ID who have experience of commenting on grant proposals. Their input led to several significant changes to the proposal (in particular: payment to participants for completing assessment sessions, and removal of ‘placement breakdown’ as an exclusion criterion). We also consulted the Chief Executive of the Challenging Behaviour Foundation, who joined the project as a co-investigator and project PPI lead, and will be a member of the Trial Steering Committee (TSC), along with independent service-user and carer PPI representatives.

We have also recruited two further PPI panels, additional to the Tizard Research Advisory Group:

- A group of service-users, drawn from established groups of Men and Women with Learning Disability (MeLD and WeLD) in Shropshire, the majority of whom have experienced, and been treated for, trauma.
- A group of carers of adults with intellectual disabilities and PTSD, recruited via the Challenging Behaviour Foundation.

Working closely with the project PPI lead, all three groups will continue to advise on all aspects of the study, in particular the quality of easy read materials, public engagement and dissemination. Their views will be sought on any non-routine issues arising during the conduct of the trial, and fed through to monthly TMG and biannual TSC meetings.

The budget for the project includes support to compensate members of the PPI panels for their time and for travel to face-to-face meetings.

The PPI network will be further expanded in relation to dissemination through engagement with Mencap, Respond, and the British Institute of Learning Disabilities (BILD). These contacts are already in place, and a senior manager within the BILD has been recruited to strengthen PPI input to the TSC.

1.10 COVID-19

The COVID-19 pandemic has caused severe disruption to the delivery of psychological services to people with intellectual disabilities (ID). While some inpatient services are working more or less normally, community services were prevented from offering face-to-face contact for several months, and in many NHS Trusts, clinical psychologists were redeployed from ID services into other therapeutic areas. While face-to-face working is slowly being restored, most Trusts still have very limited capacity for indoor contact, and redeployed staff are only slowly returning to their home bases. Remote working presents particular difficulties in ID services because some clients have limited access to suitable facilities, including both internet connectivity and private spaces, and many have limited ability to make use of such facilities. Nevertheless, some degree of remote working over video platforms may remain an acceptable alternative, or even the norm in some services, in the medium-to-long term.

In order to provide a safe and robust framework to allow the study to operate under COVID-19 restrictions, we explored the feasibility of a hybrid model in which therapy would always commence face-to-face, but therapists would be able to switch to a remote platform if it became necessary to discontinue face-to-face contact. Remote contact would not be needed for the majority of inpatients, who represent a minority of our likely trial participants, but could potentially be required for community-based patients depending on local conditions, or even by all outpatients in the event of a general lockdown. Based on current experience, we estimate that remote therapy might be feasible for upwards of two thirds of potential community-based participants.

2. Research Project Aims and Objectives

We aim to conduct a RCT to determine the clinical and cost-effectiveness of EMDR for symptoms of PTSD in adults with intellectual disabilities, compared with treatment as usual (TAU), which will be as defined by the therapist, and could include any non-trauma-focussed intervention. We aim to determine whether EMDR improves the mental health and quality of life of PwID who suffer PTSD; whether the EMDR protocol is cost-effective; and whether the outcomes are influenced by the complexity of the PTSD presentation.

The high prevalence among PwID of complex presentations of PTSD has influenced three aspects of this proposal:

1. Clinical trials of treatments for PTSD have typically used Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria. However, the official UK classification system, recognised and used by the NHS, is the International Classification of Disease (ICD). In relation to this project, ICD-11 has several advantages over DSM-5. In particular, ICD-11 treats PTSD and Complex PTSD as separate disorders, with additional criteria for Complex PTSD that can be used to estimate the degree of

complexity of the presentation [33, 34]. By contrast, DSM-5 does not distinguish PTSD and complex PTSD, creating uncertainty over the extent to which treatments are effective for one or other PTSD presentation. In DSM-5, a complex presentation is loosely indicated by the qualifier 'with dissociative features', but it is difficult, often impossible, to assess whether dissociative features are present in PwID. ICD-11, by contrast, focusses on disturbances in self-organization, including underlying emotional lability and distress, which can be readily assessed. There is also some evidence that ICD-11 provides a more valid diagnosis of PTSD than DSM-5 [35]. For all these reasons, we use ICD-11 criteria to diagnose PTSD, rather than DSM-5. The ICD-11 beta draft has been available online since 2015 [15]: the version for implementation was published in June 2018 [3].

2. EMDR protocols for PTSD and Complex PTSD start with a preparatory PES phase before commencing desensitization and reprocessing procedures [19]. For complex PTSD, both NICE and expert consensus guidelines recommend that the two phases of treatment are considered separately, with a common preparatory PES phase followed by a choice of approaches (EMDR or TF-CBT) thereafter [20,24]. Because we anticipate that a high proportion of patients will display complex presentations of PTSD, and because, in our experience, PwID require more extensive preparatory work, our treatment package begins with a free-standing PES module.

3. A secondary aim is to achieve a clearer understanding of whether the clinical efficacy of EMDR is related to the degree of complexity of patients' PTSD presentation. A picture is emerging from the general literature that EMDR may be less effective for chronic and complex presentations of PTSD [36-39]. The sparsity, methodological diversity and generally poor quality of the literature preclude any conclusion about whether this would apply to PwID with PTSD. Use of the ICD-11 diagnostic criteria, rather than DSM-5, enables measurement of the complexity of PTSD presentation [33,34], which therefore can be included as a factor in the analyses (alongside demographic variables such as age, gender and IQ).

4. A further aim is to establish the relative cost-effectiveness of EMDR compared with TAU in the study population. In addition to estimating the incremental cost per QALY gained for EMDR, using cost utility analysis, our study will also undertake cost effectiveness analysis to estimate the cost per successfully treated patient. This approach will make the study findings accessible to a wider range of stakeholders in providing and receiving treatment, as well as organisations such as the National Institute of Health and Care Excellence (NICE).

5. The aims are expanded to test the COVID-19 contingency practices from the feasibility study. They include

(i) Provision for delivery of a hybrid PES-EMDR intervention, through training of therapists and access to EMDR software that allows them to switch to remote delivery if it becomes impossible to continue face-to-face;
(ii) The participant information will be modified to include the possibility of remote contact should it become impossible to continue with face-to-face contact;
(iii) The potential of remote assessment, if indicated by participant preference or clinical need;
(iv) Re-evaluate the feasibility and acceptability of the hybrid procedure in a larger sample.

2.1 Research Project Objectives

2.1.1 Primary Objective

To determine whether EMDR is clinically and cost effective for symptoms of any PTSD presentation in adults with intellectual disabilities.

2.1.2 Secondary Objective(s)

Validation of the ICD-11 to measure the complexity of PTSD presentation.

To determine effects of EMDR on other mental health problems and quality of life.

To establish the relative cost-effectiveness of EMDR compared with TAU in the study population.

Other potentially useful efficacy parameters will include mental health and quality of life, and participant's and carer's satisfaction with the treatments received

2.2 Outcomes

2.2.1 Primary Outcome

The primary clinical outcome is the IES-ID score at the 8-month (post-treatment) follow-up assessment.

2.2.2 Secondary Outcome(s)

Secondary clinical outcomes are the other clinical measures at the same time point, and all clinical measures at 4 and 14 month follow-ups as per section 7.

3. Research Project Design

3.1 Research Project Overview

Participants:
Preliminary study: 40 patients;
Feasibility: up to 6 qualitative interviews with service users that have completed adapted EMDR therapy as a training case, this may be increased to by up to 6 more to assess delivery of remote therapy.
Main trial: 144 service user participants; 144 carers; 21 NHS therapists
Service user participants will be people with mild to moderate ID and PTSD or complex PTSD, diagnosed using ICD-11 criteria. Carers will be asked to complete questionnaires to provide their view of the trial participant while receiving the interventions. A sample of service user and carer participants will be interviewed regarding their experiences, and NHS therapists will discuss their experience of delivering the intervention to participants.

Intervention:
PwID will be treated using an adapted PES+EMDR protocol based on a combination of adult [19], child [25] and attachment-focused [40] EMDR. The PES phase of the protocol (Phase 1) comprises ten weekly sessions: this extended Phase 1 is intended to increase engagement and trust, so as to promote retention in the trial during EMDR. The EMDR phase (Phase 2) involves up to ten weekly sessions, typically fewer. However, in keeping with the NICE recommendation that the standard 8-12 sessions should be extended if multiple traumas and/or other comorbidities are present [18, 41], the treating clinician may if clinically necessary extend Phase 2 beyond 10 sessions, but should not exceed a further 5 sessions (Phase 2A) unless this is clinically essential. An outline of the protocol, which will be fully manualized during the set-up phase of the project, is provided as Appendix 1.

The protocol will be delivered by experienced ID specialist clinicians (typically clinical or consulting psychologists) who have undergone EMDR training. This is preferable to using EMDR therapists who are not ID specialist clinicians. Work with PwID requires specialist skills that are acquired slowly and not by everyone, and in a roll-out of the intervention, buying in therapy would often be impractical. Therapists recruited to participate in the project will be trained to administer the protocol by one of the co-investigators, who is an accredited EMDR trainer.

Comparator:
The comparator is TAU, which would typically include medication, behaviour support plans delivered through carers (intended to decrease challenging behaviour, e.g. by creating a less stressful environment); or non-trauma-focussed (such as anger/stress management) psychological interventions. For this trial, it does not include trauma-focused psychological interventions, and participants in the TAU arm of the trial will not be offered trauma-focussed therapy but could receive any of the other items on the menu of the clinical team supporting them. A process evaluation will include a description of the range, and distribution of the interventions provided as TAU as described in section 9.2.

Outcome:
We aim to determine the effectiveness and cost-effectiveness of our EMDR protocol relative to TAU. We will measure: symptoms of PTSD as the primary outcome; and secondary outcomes including health-related quality of life (HRQoL), mood, challenging behaviour, adverse effects, carer burden, treatment fidelity, quality adjusted life years (QALYs), and healthcare resource utilisation (see below, for

details). The cost effectiveness and cost utility analysis will be undertaken as a within-trial analysis [42].

3.2. Design and theoretical/conceptual framework

The study is designed as a RCT, with a nested qualitative study to assess fidelity, adherence and factors that influence outcome. Patients will be randomized to either PES+EMDR or TAU and followed up for 14 months post-randomization, with follow-up assessments at 4 (after PES), 8 (after EMDR) and 14 months. The study includes nested feasibility evaluation with a preliminary study and internal pilot phase (see below: Project Timetable). Health economic outcomes will be determined from data collected at baseline and 14-month assessments.

3.3. Sampling

All potential participants meeting inclusion/exclusion criteria and providing informed consent will be considered for inclusion, except where the local Principal Investigator (PI) and Trial Manager agree that to do so would overload the resources available for assessment of participants. Details of selection and analysis can be found in section 9.

3.4. Target population

The participants will be adults with mild to moderate ID and PTSD. Wherever feasible, for each participant, a carer will also be consented, who will complete some of the assessments (see section.7.2).

3.4.1. Diagnosis

- ID will be diagnosed using the Wechsler Abbreviated Scale of Intelligence (WASI-II) [44], completed by a participant, and the Adaptive Behavior Assessment System (ABAS-III) [45], completed by a carer. Results from previous diagnostic assessments using WASI-II or ABAS-III or other standardised IQ or adaptive behaviour scores will be accepted, if performed within the previous 5 years, prior to enrolment. The adaptive behaviour assessment will be waived for potential participants who have a diagnosis of ID or are in receipt of support from a NHS Learning Disability service, for whom impairment of adaptive behaviour can be assumed.

- PTSD will be diagnosed using a Trauma Information Form (TIF) [8] adapted to the ICD-11 criteria, and the International Trauma Questionnaire (ITQ) [34], with the diagnosis confirmed by a Consultant Psychiatrist. The ITQ is a novel instrument developed as a diagnostic instrument for ICD-11 PTSD and Complex PTSD, which inter alia provides a measure of the degree of complexity of the presentation.
- A validation study of an ID adaptation of the ITQ is included as a preliminary study (see section 3.6) [Complete, as of October 2021: the ITQ-ID was successfully validated as a diagnostic instrument for people with intellectual disabilities.]

3.5 Research Project Flowchart

A flowchart illustrating the trial can be found in Appendix 2.

3.6 Research Project Timeline

The overall duration of the project was originally 48 months. The timetable is extended as a consequence of the COVID-19 pandemic. Ethical and R&D permissions, a preliminary study, staff and therapist recruitment, and the early stages of therapist training, completed during the 6 months before the start of the main trial. A feasibility study will be undertaken in months 1-12 and the main study, including an internal pilot, will commence recruitment once the findings of the preliminary and feasibility study have been reviewed and incorporated.

The timetable of the main study is summarized in the following Gantt chart (Fig. 1.)

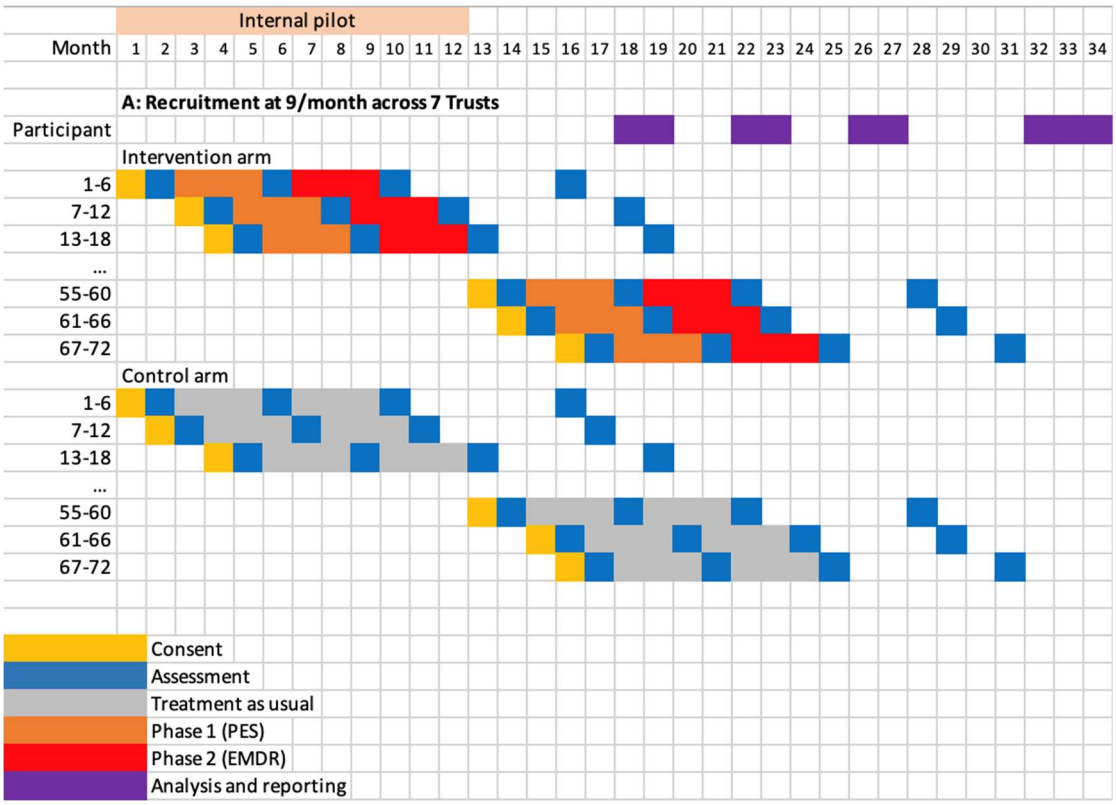


Figure 1: Timetable of internal pilot and main trial.

Feasibility study (Complete as of October 2021**)**

The aims of the feasibility study are to finalise the intervention and confirm its acceptability, incorporating provisions for the hybrid methodology. The objectives are:

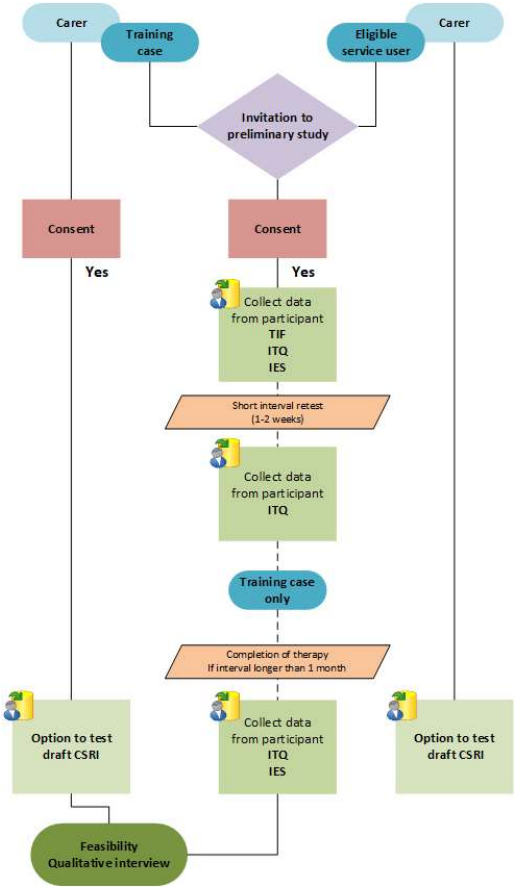
(i) completion of the manual for phase 2 of the protocol (EMDR), with sign-off for use in the trial, with part 3 to include logistical and clinical information for working remotely

(ii) training of research assistants, and supervised practice in data collection, both face to face and remotely, with sign-off by the assistant's supervisor;

(iii) completion of EMDR training by 12 therapists, with sign-off by their trainer;
(iv) administration of the complete PES+EMDR protocol to at least 6 patients, including hybrid procedure for at least 6 additional patients, with a satisfactory review of its acceptability to patients and carers, as assessed from interviews with patients and carers;
(v) Develop criteria to determine how to deal with the situation of participants who are unable to continue for technical reasons.
(vi) Estimate the proportion of patients who would be able to continue in therapy on a remote basis should that become necessary ;
(vii) Estimate the additional costs of remote delivery compared to face-to-face delivery.
(viii) progress will be reviewed by the Trial Steering Committee at regular intervals, to confirm or revise the progression criteria (i-iii);
(ix) patients included in the feasibility study will be drawn from the same population as the main study participants and will meet inclusion/exclusion criteria but will not be considered as participants in the main study.

Preliminary study (Complete as of October 2021)

The International Trauma Questionnaire (ITQ) is a novel instrument that was developed to support the new ICD-11 diagnosis of Complex Trauma (34). Because this is a new instrument, it has not yet been validated in a version adapted for use by PwID. In the period leading up to the start of the project, and during the feasibility phase, project staff and therapists recruited to the project will administer an adapted version of the ITQ to up to 40 participants (patients or volunteers) who meet study inclusion/exclusion criteria (Appendix 3). Participants will also be administered adapted versions of a Trauma Information Form (TIF) and the Impact of Event Scale (IES), to assess the concurrent validity of the adapted ITQ, and it will be administered on a second occasion to assess test-retest reliability. These data will be supplemented by data collected in the main trial to enable more detailed analysis of the psychometric properties of the adapted ITQ.



This study will include two cohorts of participants: patients treated by the therapists as their EMDR training case, prior to their being confirmed as trained to the standard required for the main trial, and volunteers meeting trial criteria recruited by the research staff. The patients (one per therapist) will be recruited at the convenience and according to the clinical judgment of the therapist, during the set-up phase of the project. Volunteers will be recruited at the convenience of the research team: the aim is to complete this part of the project during the set-up phase but it could take longer. For training-case patients included in this study who are undergoing EMDR, the ITQ and IES will also be administered at the end of the therapy to assess sensitivity to change.

Figure 2: Flowchart of preliminary and feasibility studies

Internal pilot study

The aim of the internal pilot is to test recruitment to the trial and retention through phases 1 and 2 of treatment.

The internal pilot has the following objectives:

(i) recruitment of at least 36 patients by 14 months

(ii) completion of interventions by at least 6 patients by 18 months, to test for retention through phases 1 and 2, and adherence to the planned timetable for delivery of the intervention.

(iii) recruitment of fewer than 36 patients by 14 months or completion by fewer than 6 patients at 18 months would trigger a referral to the Data Monitoring Committee and notification to the funder.
(iv) these figures will be monitored every 6 months by the Trial Steering Committee who will make a recommendation to the funder regarding trial continuation based on overall recruitment and recent recruitment trajectory. We aim to work collaboratively with the funder to flag up any concerns at an early stage to ensure that we can develop strategies to mitigate any risks to successful completion of the trial.

Recruitment timetable

Participant recruitment for the main study should commence following the results of the feasibility study and average 9 per month over 16 months, across the seven participating NHS Trusts. We consider this a realistic and achievable recruitment rate based on our clinical experience of working with this client group. (For example, in one team in Birmingham, trauma was the central issue in 20 of 57 referrals in 2017, of whom we would have been looking to recruit c. 1 in 3.)

4. Research Project Population

4.1 Number of Participants

A total of 144 participants will be recruited to the main study. The participants will be adults with mild to moderate ID and PTSD. Wherever feasible, for each participant, a carer (estimated 144) will also be consented, who will complete some of the assessments. A sample of NHS Therapists from our trained cohort (<40) will also be interviewed for their experiences in delivering the intervention as part of the feasibility study and at the qualitative evaluation at end of the trial.

4.2 Inclusion Criteria

PwID

- Aged ≥ 18 to ≤ 65
- Meeting criteria for a diagnosis of ID
- Meeting ICD-11 diagnostic criteria for PTSD
- Major identified trauma at least a year earlier
- Able to communicate in English and to provide informed consent to both the referral and study participation

Carers are defined as "the primary person who feels responsible for, and supports, the person with ID on a regular basis as judged by a clinician**"**. Patients should ideally have a carer who can participate, but those who have not will not be excluded. Carers will be invited to take part if they fulfil these inclusion criteria: In the situation where the carer attending subsequent assessment visits is different from previous, they will be asked to consent in an effort to avoid any gaps in data collection. A change in carer will be noted on the CRF.

- Aged 18 and over
- A family member or carer of a person with ID who has consented to participate in the trial
- Able to communicate in English and to provide informed consent to study participation

- Able to attend clinic visits, remote sessions or be present when a researcher performs the assessment visit.

4.3 Exclusion Criteria

PwID

- Assessed by the clinical team as at high risk and/or requiring urgent treatment
- Currently in therapy and unwilling to intermit
- Previously completed a course of EMDR
- Psychosis not well controlled by medication
- Change of psychotropic medication or dosage within the last month
- Unable to complete the assessments.
- Any medical condition or treatment which, in the opinion of investigators, could affect the safety of the participant's participation or outcomes of the study.

5. Participant Selection and Enrolment

5.1 Identifying Participants

Potential participants for the preliminary study will be identified on an opportunistic basis by NHS or care staff who are also research site staff who have received training on the preliminary study protocol.

Potential participants for the main trial will be identified by the clinical team to which they have been referred (see section 5.3), on the basis of an assessment of the patient's trauma history. Where a potential participant's trauma history suggests that s/he meets inclusion/exclusion criteria, the study will be discussed informally with them before making a referral to the research team including a discussion about their ability to take part in the study remotely. In order to protect the participant and considering local procedures, a detailed trauma history using formal assessment instruments will be taken only once, either by the research team, and fed back to the clinic, after the participant has consented, or in the clinic and later made available to the research team.

5.2 Consenting Participants

Written informed consent will be sought from service users and from their professional or home carers, as appropriate. As one of the inclusion criteria is "capacity to consent to both the intervention and the trial", the study falls outside the scope of the Mental Capacity Act.

No research procedures will be undertaken before consent has been given.

A standard research consent procedure will be used with service users, in which:

1. the trial is explained verbally in simple terms to the service user, checking frequently for understanding;
2. in addition to the full Participant Information Sheet, service users are also given a simplified information sheet to take home and read in their own time and at their own speed;
3. at least 3 days is given to consider and ask questions of researchers or carers;
4. the explanation is repeated in a second meeting;
5. consent is recorded by the researcher reading each paragraph of the consent form and the service user checking and initialling a set of tick boxes and signing the consent form;
6. in order to assure that the service user has been properly informed, the whole process may be witnessed and signed off by a third party (e.g. a carer) who is independent of the research team. This procedure has been used in many previous studies with people with mild to moderate ID [e.g. 46], and has never proved problematic.
7. A narrative account of the process along with relevant documents and files are added to the local clinical note system.

A similar consent procedure will follow for a service user's carer if they agree to participate.

If remote consent is required, then the following procedure (adapted from the hybrid protocol) will be implemented:

1 The therapist will ascertain from the patient if there is preference or need to work remotely.
2 The service user is introduced to the study by the therapist reading the Information Script during the course of a scheduled online meeting
3 If the service user expresses interest in participating, the therapist can pass relevant contact information (service user's mobile/telephone/email) to the RA.
4 The RA immediately mails out copies of the PIS, ICF (and easy read summaries) and confirms this to the therapist.
5 At the next session, the therapist goes through the PIS with the service user, inviting questions and checking understanding. The participant is encouraged to have another person present, for example a carer.
6 The therapist contacts the service user by phone or video and ascertains interest in the study. If the service user expresses interest the therapist passes relevant contact information (service user's mobile/telephone/email) to the RA, as well as any recommendations about how best to build rapport with the service user.
7 The RA contacts the participant by phone or video and introduces the study by using the Information Script.
8 If the service user is still interested in participating, the RA arranges a remote video or telephone appointment at least 2 days after the letter should arrive, and immediately mails or emails a confirmation along with copies of the PIS, easy-read summary and ICF.
9 At the appointment, the RA goes through the PIS with the participant, inviting questions and checking understanding. The participant is encouraged to have another person present, for example a carer.
10 The person taking consent goes through the ICF with the participant and either records a video of the participant signing it, or takes a photograph of the screen, ensuring that the recording or photograph includes a legible record of the signed form.
11 If the ICF has been video-recorded the recording is saved locally, where a member of the research team prints out the ICF, signs it, and records the name of the person who took consent.
12 If the ICF has been photographed, the person taking consent prints out the signed form, adds their own signature, files the form locally.
13 The signed form is securely filed, and the video of signing is securely stored on an access-controlled drive.
14 A narrative account of the process along with relevant documents and files are added to the local clinical note system.

A similar remote consent procedure will be used for carers.

5.3 Screening for Eligibility

The study will be located in NHS hospital and community services for people with intellectual disabilities. They are:

- Birmingham Community Healthcare NHS Foundation Trust
- Kent and Medway NHS and Social Care Partnership Trust
- Hertfordshire Partnership NHS Foundation Trust
- Midland Partnership NHS Foundation Trust
- Black Country Healthcare NHS Foundation Trust
- Norfolk Community Health and Care NHS Trust
- Coventry and Warwickshire Partnership NHS Trust

Clinicians to be trained as therapists delivering the intervention have been identified. Links to existing clinical pathways and access criteria, which differ between and, to some extent, within Trusts, and referral pathways will be developed in collaboration with the Trusts to meet the needs of the trial while respecting local working practices.

5.3.1 Therapist training and supervision

Within each Trust we will train therapists to deliver the EMDR intervention, and recruit participants from among their referrals. As a contingency arrangement in case of loss of trained therapists or difficulty in patient recruitment, further therapists will be included in the initial training schedule, located either in additional clinical teams in the same regional service (Norfolk and Suffolk Trusts, adjacent to Herts. & Essex) or in a neighbouring Trust (Black Country, adjacent to both South Staffs. & Shropshire and Birmingham). These three additional Trusts have also provided written agreement to participate. Training events will be run in London to cater to the south-east Trusts and in Birmingham to cater to the west-midlands Trusts. In order to manage the potential risk to the viability of the project of a greater than expected churn of trained therapists, a second set of training courses will be pencilled in and scheduled to produce additional trained therapists, if needed, around the mid-point of the recruitment phase.

Therapist training will comprise the standard 3-day EMDR Part 1 curriculum plus a fourth day on the EMDR-ID protocol, with a final training day following 4-6 months of supervised practice.

Remote delivery of EMDR for existing therapists and newly trained therapists will comprise a 1 day workshop and access to remotEMDR software (https://www.remotemdr.com/).

Refresher training will be available for sites that experience significant delays in starting due to Covid-19.

The therapists will subsequently receive supervision via skype in small groups, initially 2-weekly, falling to 3- and then 4-weekly over the course of the trial, with additional phone supervision available as needed.

5.4 Ineligible and Non-Recruited Participants

Brief details of all screened potential participants will be recorded. If not eligible, or eligible but declined to participate this will be noted.

5.5 Payment

A small value voucher (£10 per study visit) will be given to participants for each study visit (excluding therapy sessions) to encourage continue participation and follow up. This is being proposed following discussions with PPI representatives and will be a maximum of £50.

Carers will also be reimbursed for their time when completing questionnaires at visits. This will be a maximum of £50.

6. Randomisation and Blinding

6.1 Randomisation Details

A clinician will review the screening test results to assess whether the patient is eligible for randomisation. Potential participants and carers who fulfil all inclusion and meet no exclusion criteria will be informed of their screening results by local research staff and arrangements will be made for randomisation and treatment visits.

A web based randomisation and back-up systems will be provided by either REDCap clinical trial database or Sealed Envelope Ltd (https://sealedenvelope.com) based on a trial minimisation algorithm and randomisation list developed in consultation with a STU statistician.

6.2 Blinding

STU staff will review the randomisation allocations as they occur to ensure they follow the required specification.

Research Assistants will be blinded to the treatment allocation when completing outcome questionnaires.

Any adverse events (AEs) assessed as serious, unexpected and definitely, probably or possibly related to the intervention and the participant's (patient or carer) involvement in the trial will be reported to the TMG and the Sponsor. The DMC will receive unblinded Serious Adverse Events (SAEs). The TSC will receive blinded SAEs and a summary of AEs, as previously defined.

Unblinding of participants will take place on the basis of the trial statistical analysis plan.

6.3 Emergency Un-blinding

Emergency unblinding will be managed by RedCap or Sealed Envelope Ltd, dependent on the randomisation provider chosen in association with a nominated person(s) who will have access to the code break list.

The randomisation allocation will only be broken for a medical safety reason. All emergency unblinding of serious unexpected related events will be at the discretion of clinical site investigators or the CI when required to ensure participant safety. Further details are available in section 7.8.

All unblinding events must be automatically notified by email to the trial office. The trial office will notify the Research Ethics Committee (REC), local R&D offices and the DMC. Details of the unblinding must be documented using an Unblinding log and stored in a separate section of the Investigator Site File (ISF) retained by the local clinical PI and the Trial Master File (TMF).

6.4 Withdrawal Procedures

A participant or their carer may terminate their participant in the trial at any time without giving a reason and with no personal disadvantage.
A Principal Investigator or delegate may withdraw a participant due to:

- Patient or carer withdraws consent for treatment

- Unacceptable adverse events
- Intercurrent illness prevents further participation
- Development of serious disease preventing further treatment or any change in the participant's condition that justifies the discontinuation of treatment in the therapists/clinician's opinion.

The Sponsor has the right to terminate this trial at any time. In terminating the trial, the Sponsor and the Chief Investigator will ensure that adequate consideration is given to the protection of the participants' interests.

If the study is suspended or terminated for safety reasons, the Sponsor will promptly inform the Chief Investigator. The Sponsor will also promptly inform the relevant regulatory authorities of the suspension/termination and of the reasons for this action.

If participants withdraw or are withdrawn from treatment they will be encouraged to remain in the trial and to be followed up as per the trial schedule, or failing this, to obtain outcome data in accordance with the planned analysis.

7. Research Project Procedures

7.1 Schedule of Treatment for each visit

Participants in the intervention group will be treated according to the project treatment manual. Participants in the control group will receive whatever treatment the clinician treating them considers most appropriate, other than trauma-focused treatments. An overview of trial assessments can be found as Appendix 4.

7.2 Schedule of Assessment

The trial will involve the following procedures which may be conducted remotely where appropriate and necessary:

1 Baseline assessments will be standard care tools used in the diagnosis of ID and PTSD. An ID adaptation of the ITQ has been developed as described in section 3.6.

2 Primary outcome: PTSD symptoms, assessed using the self-report revised IES [8]. We use the IES rather than the Clinician Administered PTSD subscales [47] because the IES has been validated in a version adapted for PwID.

3 Secondary clinical measures (all validated for PwID):
   (i) PTSD symptoms: the self-report ITQ-ID [Appx. 3] and the informant-version Lancaster & Northgate Trauma Scales (LANTS) [9,48];
   (ii) Mood: the self-report Glasgow Depression and Anxiety Scales (GDS/GAS) [49,50] and Clinical Outcomes in Routine Evaluation – Learning Disability (CORE-LD) [51];
   (iii) Carer ratings of the participant's mental health (MPAS-ID [52]) and challenging behaviour the Aberrant Behavior Checklist (ABC) [53]

4 Heath-Related Quality of Life will be assessed by means of self-reported wellbeing using the Personal Wellbeing Index - Intellectual Disability (PWI-ID) [54]) and carer reports using the Short Form Health Survey (SF-12 [55]). The SF-12 is a standard, well-validated instrument. The PWI-ID is well-validated in general populations and as well as for PwID. We have included this measure

because we feel it important to attempt to evaluate QoL as experienced by the participants themselves.

5 Carer burden, assessed using the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) [56].

Pre-Screening/Referral
The initial contact will be during routine consultation from new or existing cases. The clinician will perform a clinical review to ascertain trauma history (Trauma Information Form (TIF) may be completed if part of the Healthcare Trust standard).
During this visit the study will be introduced to the patient and their carer. They will be given the appropriate patient information and consent form to take away and consider their participation.

Screening procedures
Following an open discussion with opportunity to ask questions, consent will be received by a delegated researcher if the patient and their carer agree to participate.

Eligibility will be confirmed by a clinician designated to do so on the delegation log, following confirmation of intellectual disability via administration of WASI-II, completed by a participant and ABAS-III*, completed by a carer or other standardised IQ or adaptive behaviour scores from the last 5 years. PTSD will be confirmed by the use of the TIF and ITQ-ID [appx. 3].

Baseline visit
If eligibility is confirmed, then the baseline assessment will conducted in the form of a semi-structured interview:

For the participant
- Medical history and current medication
- IES-ID, for assessment of PTSD symptoms
- GDS, for depression
- GAS, for anxiety
- CORE-LD, for mental health
- PWI-ID for quality of life

for the carer
- LANTS, for assessment of PTSD symptoms
- MPAS-ID, for mental health
- SF-12, for quality of life
- ABC, for challenging behaviour
- WEMWBS, for carer burden
- CSRI-ID for service and support costs

4, 8 & 14 Month follow-up visits
Each assessment timepoint will be conducted in the form of a semi-structured interview:

for the participant:
- Collection of AEs, assessed according to the protocol (section 7.8.2)
- A record of any changes to medication
- ITQ-ID
- IES-ID
- GDS
- GAS

- CORE-LD
- PWI-ID

for the carer the following instruments will be administered:

- LANTS
- MOSS-PAS
- SF-12
- ABC
- WEMWBS
- CSRI-ID

* ABAS waived for those participants who have a diagnosis of ID or are in receipt of support from a NHS Learning Disability service.

A complete summary of baseline (eligibility) and clinical outcome assessments can be found as appendix 4.

7.2.1 Outcome measures

7.2.1.1 Sessional outcome measure

Ratings of subjective distress [57], a standard measure used to track the course of recovery session-by-session during EMDR, will be taken by the therapist at the end of each EMDR session, and reported to the Trials Unit after the intervention is complete.

7.2.1.2 Fidelity of treatment delivery

Fidelity of treatment delivery will be monitored from audio-recordings (encrypted with 7-Zip) of PES and EMDR sessions. One session from each phase will be recorded – with patients' consent – with scoring using the EMDR Fidelity Rating Scale [58].

For the intervention arm, one patient, for each therapist will have audio recordings taken for both a PES and EMDR session. This will total 50 audio recordings in total.

All audio recordings will be saved as .wav files and stored on a secure server in Swansea University. The sound files will be transcribed verbatim by a competent member of the trial team, or sent to a SU approved supplier transcription service outside the University using appropriate encryption. The resulting transcripts will be saved as .doc files on a secure server in Swansea University.

7.2.1.3 Qualitative clinical outcome measures

Inadvertent unblinding, trial-related adverse effects and reasons for drop-out will be recorded.

A purposive sample of patients, therapists and carers will be interviewed about their experiences.

7.2.1.4 Health economic outcome measures

Resource use and related costs of developing and delivering the intervention, including therapist training, will be recorded and measured, where appropriate using standard costing templates (e.g. salary scales).

The costs (NHS, other health providers, social care) of supporting participants through the period of treatment will be collected using the Client Service Receipt Inventory - CSRI: ID version [59, 60] adapted for this study as is standard for this tool.

7.3 Follow up Procedures

Following randomisation to either PES+EMDR or TAU, participants will be followed up for 14 months post-randomisation. Follow up assessments will occur at 4 months (after PES), 8 months (after EMDR) and 14 months, as detailed in appendix 4.

7.4 Laboratory Assessments *(if applicable)*

None required for this research project.

7.5 Radiology Assessments *(if applicable)*

None required for this research project.

7.6 Annual Safety Reporting

An Annual Progress Report (APR) will be submitted by the CI to the HRA and REC using the current template available via the HRA website. Reports will be submitted within 30 days of the anniversary of the favourable opinion.

The report will include an update on the safety of participants as per the template.

7.7 Procedures for reporting blinded 'unexpected' and related' SAEs

In the unlikely event that unblinding is required, it will be at the discretion of the local investigators when clinically indicated for the participant. Details can be found in section 6.3.

7.8 Overview of the Safety Reporting Process/Pharmacovigilance responsibilities

All therapists will be trained in the use of the EMDR protocol. Therapists will need to show competency in EMDR before they can use it in practice.

All participants will be educated in skills and resources to build emotional regulation (to promote internal safety). This will include a raft of techniques tailored for each individual and their specific needs.

When seeking informed consent, the site researcher will explain to the participant and carer how to let the trial team know if they become unwell. Health and wellbeing will also be assessed at each trial visit.

7.8.1 Urgent Safety Measures

The CI and the site PIs may take immediate safety measure to protect trial participants' health and safety without authorisation from REC or sponsor. In the event of such actions, they must alert the sponsor as soon as possible. If a site PI takes this action, they must notify their local R&D department and the CI. The CI will notify the REC of the issue within five working days of the urgent safety measure, setting out the reasons for the measure and the plan for future action.

7.8.2 Adverse Events

In this trial we shall use standard definitions of adverse events:

Adverse Event (AE): Any untoward clinical occurrence experienced by a trial participant, which does not necessarily have a causal relationship with the intervention. An AE can therefore be any unfavourable or unintended sign, symptom or disease. Elective hospitalisations for pre-trial conditions are not AEs. The CI, the site PI or a delegate authorised in the site delegation log will assess each AE for seriousness, causality and expectedness.

This trial will record and report only AEs assessed as serious, unexpected and definitely, probably or possibly related to the intervention and the participant's (patient or carer) involvement in the trial.

Serious Adverse Event (SAE): An adverse event is serious if it:
- Results in death;
- Is life threatening;
- Requires hospitalisation or prolongation of an existing hospitalisation;
- Results in persistent or significant disability or incapacity; or
- Is otherwise considered medically significant by CI or site PI.

Clinical judgement should decide whether an AE is serious. Important medical events that are not life threatening or do not result in (prolonged) hospitalisation or disability, but jeopardise the participant's health or well-being or require intervention to prevent an SAE, should also be considered serious.

Causality: We shall classify the relationship of each SAE to the trial intervention as:
- Definitely causally related (with estimated probability > 90%);
- Probably causally related (with 50% < estimated probability < 90%);
- Possibly causally related (with 10% < estimated probability < 50%);
- Unlikely to be causally related (with 1% < estimated probability < 10%); or
- Not causally related (with estimated probability < 1%);

If in doubt about the causality of an SAE, the site PI should consult the CI. If there is still doubt, the CI will consult the chair of the DMC, who may consult the entire DMC.

Serious Adverse Reaction (SAR): A serious adverse event is a SAR if it is definitely, probably or possibly causally related to the trial intervention.

Expectedness: Expected AEs for trial participants fall into two main categories:
- Occurring more frequently in PwID, for example exacerbation of existing challenging behaviour including self harm;

- Occurring more frequently in those with PTSD, for example exacerbation of PTSD symptomatology; or

If in doubt about the expectedness of an SAR, the site PI should consult the CI. If there is still doubt, the CI will consult the chair of the DMC, who may consult the entire DMC.

7.8.3 Serious Adverse Event Recording and Reporting

This study will report only those adverse events assessed as serious, and unexpected and definitely, probably or possibly related to a participant's (patient's or carer's) involvement in the study. In order to make this judgement, all SAEs will be recorded in the electronic trial database, for review by the CI.

Within 24 hours of receiving notification of a SAE occurring following consent and up to 4 weeks after the end of the intervention, the site PI or delegate will: complete a trial SAE form; assess the events relatedness and expectedness; specify actions taken, including any follow-up required. The Trial Manager will notify the CI of the event. The TM/CI may request data clarification from the site as necessary.

If the SAE is assessed as related and unexpected, the CI will notify the REC and Sponsor within 24 hours of becoming aware of the event, even if that assessment is still provisional. The TM will report blinded cumulated SAEs to each meeting of the TSC. The DMC will receive unblinded reports and review all events.

8. Data Collection and Management

8.1 Data Collection

Clinical and health-economic assessments will be conducted by masked assessors, before randomisation, and with follow-up at 4 (post-PES), 8 (post-EMDR), and 14 months. The 4 and 8 month assessments may be delayed by up to a month (or exceptionally, 2 months for the 8-month assessment if the 4-month assessment was delayed) to enable completion of Phases 1 and 2 of treatment; the 14-month assessment will not be delayed. Data collection will require two sessions (of less than an hour)/participant at baseline, and typically one session at follow-ups, though some participants may need split sessions. Data will be entered directly into electronic templates on laptop computers; encrypted using 7-Zip; and downloaded remotely to STU, using a bespoke database designed on the REDCap data management system.

Participants will be anonymised by the use of individual study numbers. A copy of the study number code identifying participants will be kept securely within the ISF. Minimal identifiable data to link participants names, their study number and to send them relevant trial information will be stored separately from the ISF.

The Investigator Site File (ISF) containing original signed consent forms will be kept in secure premises. Access to the ISF will be restricted to researchers working on the trial. sponsor representatives and auditors authorised to access the file.

8.2 Data Management System

The trial electronic database will be managed and operated as required by GCP. The site investigator or delegate will record all study data using the trial specific electronic database provided by STU. Patients who were approached but not consented are to

be added to the trial screening log. The PIs are responsible for keeping a list of all consented patients. In addition, each PI will prepare a list of patients who were screened for participation of the trial but were not randomised and the reason for non-eligibility. The investigator will ensure accuracy, completeness, and timeliness of the data entered into the database.

Data will be checked according to a trial Data Management Plan and queries will be generated and sent to the site investigator for response using the electronic database. Corrections resulting from these queries will be confirmed and sent back to STU. The queries and their responses will be stored in the audit trail of the electronic database.

Data will be transferred to STU for analysis at the end of the trial once the database has been locked.

9. Data Analysis

9.1 Sample Size Considerations

A total of 144 PwID will be recruited to the main trial. We aim to detect a medium-to-large effect size (ES] of 0.65, with two-tailed significance at α=0.05 and power=0.90. This requires N=102 independent outcomes, equivalent to N=108 analysable outcomes from small clusters (average of 4 participants per therapist) with an intra-cluster correlation of 0.02. Our recruitment target thus pragmatically allows for both 25% loss to follow-up and (hitherto unreported) therapist effects in EMDR for PTSD.

A meta-analysis of studies of EMDR vs TAU in the general adult population reported a mean ES of 1.17 with 19% loss to follow-up [5]; a second meta-analysis, restricted to studies of survivors of childhood abuse, which many of our participants are expected to be, reported a smaller effect size (0.76 [37]: mean of the two studies = 0.97). For trials of CBT (the only intervention type for which there exists a corpus of information for PwID), effect sizes for PwID are generally similar to those reported in the general population [43]. The ES used here in sample size considerations is a conservative two thirds of the mean figure for the two meta-analyses cited.

All potential participants meeting inclusion/exclusion criteria and providing informed consent will be considered for randomisation, except where the local PI and Trial Manager agree that to do so would overload the resources available for assessment of participants.

9.2 Proposed Analysis

Quantitative outcomes
Quantitative outcome measures will be analysed by analysis of covariance, with baseline score as the covariate, using appropriate transformations where data depart from normality. Regression analysis will be used to identify factors that influence outcomes.

Process evaluation
A process evaluation will follow MRC guidelines [61] and will include:

- Completion of a Template for Intervention Description and Replication (TIDier) proforma to specify the intervention [62]
- A description of the procedures used as TAU
- Analysis of the fidelity of treatment delivery

- Recording of inadvertent unblinding, trial-related adverse events and reasons for drop-out.
- Interview transcripts of patients', therapists' and carers' views of the acceptability and efficacy of treatment will be subjected to a Thematic Analysis [63], and to Framework Analysis [64] for comparison.

9.3 Missing Data

Every attempt will be made to minimise missing data. Sites will be asked to follow up on missing participant data. Procedures will be in place for validating all data and imputation will be considered if required.

9.4 Transfer of Data

STU will be responsible for holding anonymised trial data in a secure electronic database which will have restricted access and be password protected. All data transferred from sites will be encrypted. All data held by STU will be regularly backed up on Swansea University servers.

10. Labs and Samples Analysis

None required for this research project.

11. Data Handling & Record Keeping

11.1 Confidentiality

At Swansea Trials Unit:
The electronic database will be stored and regularly backed up on a Swansea University server. All data files held at STU will be password protected.

Participant data will be anonymised by the use of study numbers. Analysis will be conducted by the study team on anonymised data.

At sites:
Paper records will be kept locked in secure premises. Access to the records will be restricted to researchers working on the study, Sponsor representatives and anyone authorised to audit the research project.

11.2 Research Project Documents

- A signed protocol and any subsequent amendments
- Current/Superseded Participant Information Sheets (as applicable)
- Current/Superseded Consent Forms (as applicable)
- Indemnity documentation from sponsor
- Ethics submissions/approvals/correspondence
- CVs of CI and site staff
- Delegation log
- Staff training log
- Site signature log
- Participant identification log
- Screening log
- Enrolment log
- Monitoring visit log
- Protocol training log
- Correspondence relating to the research project
- Communication Plan between the CI/PI and members of the research project team

11.3 Case Report Form

Electronic Case Report Forms (eCRFs) will be designed to collect data as required by the protocol. The eCRF will be the tool used to collect anonymised data from individual participant at each site. It will be designed to accurately represent the protocol and allow queries to be raised to identify missing or erroneous data. Paper versions of the CRF will be available for research staff to use, allowing for a blended approach to data collection.

11.4 Record Retention and Archiving

The CI will act as custodian of the trial data; however, this role will be delegated to STU. Personal data will be stored for 12 months with access restricted to site staff. The TMF will be archived for 5 years. Sites will be expected to archive their ISF locally for 5 years.

Destruction of the TMF and individual ISF's will require authorisation from the Sponsor.

11.5 Compliance

The CI will ensure that the research project is conducted in compliance with the principles of the Declaration of Helsinki. GCP, and the UK policy framework for health and social care research, STU standard operating procedures and policies.

Monitoring of the trial to ensure compliance with GCP will be conducted by STU via central and on-site monitoring and per data and trial monitoring plans.

11.6 Ethical Considerations

The research project will be conducted in accordance with the principles of GCP.

Prior to commencing the research, we will obtain Sponsorship approval, a favourable ethical opinion from an appropriate NHS REC, and local NHS R&D permission at each site.

All trial specific participant-facing documents and the protocol will be submitted for REC approval at all sites. Validated questionnaires will not be submitted to the REC for review unless requested.

Following approval from the funder, substantial amendments will not be implemented until they receive a favourable opinion from the HRA and REC. Non-substantial amendments will be sent to the HRA using the appropriate template. Sites will be notified of the outcome and implementation date of the amendment via the trial office.

In accordance with the favourable opinion, an Annual Progress Report (APR) will be sent by the CI to the REC within 30 days of the anniversary of the favourable opinion until the research ends. The CI will submit an end of study notification to the REC and R&D within 30 days of project close (or 15 days if terminated early).

Within 12 months of project close, the CI will submit a final report along with any publications or abstracts.

All correspondence and submission details will be filed in the TMF.

11.7 Quality Control and Quality Assurance

The CI, PIs and all institutions involved in the research project shall permit research project related monitoring, audits, and REC review. The CI agrees to allow the Sponsor or, representatives of the Sponsor, direct access to all research project records and source documentation.

11.8 Non-Compliance

The site PI is responsible for the overall conduct of the trial at the site and for compliance with the protocol or subsequent amendments.

In accordance with the principles of GCP, prospective planned deviations or waivers from the protocol are not permitted.

Accidental protocol deviations may occur. In the event that a site has deviated from the protocol, the event details will be recorded on a trial specific deviation form and reported to the CI via the trial office and to sponsor within 24 hours of awareness of the event.

Frequently recurring protocol deviations are not acceptable and will require immediate action when identified. All such instances will be investigated. Reporting of deviations and required protocol amendments will occur as required.

12. Research Project Management and Oversight Arrangements

12.1 Trial Management Group

The research project will be co-ordinated by a TMG, consisting of the grant holder (CI), PIs, the trial manager, statistician, STU representatives and a Sponsor representative. The TMG will oversee the day to day management of the trial and will meet in person or by teleconference monthly for the duration of the trial. The TMG will overview and provide guidance on all aspects of the trial. They will report at regular intervals to the TSC, DMC and the trial Sponsor.

12.2 Trial Steering Committee and Data Monitoring Committee

A TSC will be established and meet bi-annually to oversee the conduct and progress of the research project. The TSC will consist of, an independent psychologist (in the chair) and statistician, a sponsor representative, the Chief Executive of the Challenging Behaviour Foundation (as project PPI lead), along with independent service-user and carer PPI representatives and a representative of the British Institute of Learning Disabilities and the Chief Investigator (CI). The Trial/Data Manager and trial statistician will also attend.

A Data Monitoring Committee (DMC) will be established to oversee research project progress, comprising an independent statistician (in the chair), independent psychologist and an independent quality assessment specialist with experience of PwID. The funder and TSC will agree the final membership of the committee and stopping rules for the trial.

The DMC only will receive unblinded reports of any serious adverse events and will assess recruitment progress. The DMC will have responsibility for making recommendations to the Sponsor on whether to continue or terminate the trial if participant safety is considered to be at risk. Additional meetings will be convened if necessitated.

Terms of reference will be agreed for the committees.

13. Reporting, Publication and Notification of Results

13.1 Authorship Policy

Ownership of the data arising from this research project resides with the research project team and their respective employers. On completion of the research project, the research project data will be analysed, and a research project report will be prepared

13.2 Publication

The research project report will be used for publication and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the research project.

Summaries of results may also be made available to Investigators for dissemination within their clinical areas (where appropriate and according to their discretion).

13.3 Peer Review

The project has received an independent and expert peer review by NIHR HTA as the funders of the trial.

The sponsor has also conducted an appropriate governance and risk review prior to agreeing the sponsor role

14. Research Project Conduct Responsibilities

14.1 Protocol Amendments, Deviations and Breaches

The CI will seek approval for any amendments to the Protocol or other research project documents from the Sponsor, REC and NHS R&D Office(s). Amendments to the protocol or other research project docs will not be implemented without these approvals.

In the event that a CI needs to deviate from the protocol, the nature of and reasons for the deviation will be recorded in the CRF, documented and submitted to the Sponsor. If this necessitates a subsequent protocol amendment, this will be submitted to the Sponsor for approval and then to the appropriate REC and lead NHS R&D Office for review and approval.

In the event that a serious breach of GCP is suspected, this will be reported to the Sponsor immediately using the form “Breach Report Form”.

14.2 End of Research Project

The end of research project is defined as database lock. The Sponsor, CI and/or the TSC have the right at any time to terminate the research project for clinical or administrative reasons.

The end of the research project will be reported to the Sponsor and REC within 90 days, or 15 days if the research project is terminated prematurely. The CI will ensure that any appropriate follow up is arranged for all participants.

The funder will receive a draft final report submitted within 14 days of contract completion.

A summary report of the research project will be provided to the Sponsor and REC within 1 year of the end of the research project

15. References

1 McManus S, Meltzer H, Brugha T, Bebbington P, Jenkins R, editors (2008). Adult psychiatric morbidity in England, 2007: results of a household survey. Leeds: The NHS Information Centre.

2 Brewin, C. R., Andrews, B. & Valentine, J. D. (2000) Meta-analysis of risk factors for post-traumatic stress disorder in trauma-exposed adults. J. Consult. Clin. Psychol. 68, 748–766.

3 World Health Organization (2018) ICD-11 implementation version

4 Mevissen L & de Jongh A (2010) PTSD and its treatment in people with intellectual disabilities: A review of the literature. Clinical Psychol. Rev., 30, 308-316.

5 Bisson JI, Roberts NP, Andrew M, Cooper R, Lewis C (2013) Psychological therapies for chronic post-traumatic stress disorder (PTSD) in adults. Cochrane Database Syst Rev. 2013 Dec 13;(12):CD003388.

6 Barol BI , Seubert A (2010) Stepping stones: EMDR treatment of individuals with intellectual and developmental disabilities and challenging behaviour. J EMDR Prac. Res. 4, 156-169.

7 Beadle-Brown J, Mansell J, Cambridge P, Milne A, & Whelton B (2010). Adult protection of people with intellectual disabilities: Incidence, nature and responses. J. App. Res.Intellect. Disabil. 23, 573-584.

8 Hall JC, Jobson L. & Langdon PE (2014) Measuring symptoms of posttraumatic stress disorder in people with intellectual disabilities: The development and psychometric properties of the Impact of Event Scale-Intellectual Disabilities (IESIDs). British Journal of Clinical Psychology 53, 315-322.

9 Wigham S, Hatton C & Taylor J (2011) The effects of traumatizing life events on people with intellectual disabilities: a systematic review. J. Ment. Health Res. Intellect. Disabil. 4, 19–39.

10 Wigham S & Emerson E (2015) Trauma and life events in adults with intellectual disability. Current Developmental Disorders Reports 2, 93-99.

11 De Bellis MD & Zisk A (2014) The biological effects of childhood trauma. Child and Adolescent Clinics of North America 23, 185-222.

12 McCarthy J (2001) Post-traumatic stress disorder in people with learning disability. Advances in Psychiatric Treatment 7, 163-169.

13 Rumball F (2018) A systematic review of the assessment and treatment of posttraumatic stress disorder in individual with autism spectrum disorders. Rev. J . Autism Dev. Disord. doi.org/10/1007/s40489-018-0113-9.

14 The Complex Trauma Taskforce (2012) The ISTSS Expert Consensus Treatment Guidelines For Complex PTSD In Adults. http://www.istss.org/AM/Template.cfm?Section=ISTSS_Complex_PTSD_Treatment_Guidelines&Template=%2FCM%2FContentDisplay.cfm&ContentID=5185.

15 ICD-11 Beta Draft, Disorders specifically associated with stress. http://apps.who.int/classifications/icd11/browse/lm/en#/http%3a%2f%2fid.who.int%2ficd%2fentity%2f991786158

16 Mason-Roberts S, Bradley A, Karatzias T, Brown M, Paterson D, Walley R, Truesdale M, Taggart L, Sirisena C (2018) Multiple traumatisation and subsequent psychopathology in people with intellectual disabilities and DSM-5 PTSD: a preliminary study. J. Intellect. Disabil. Res. doi: 10.1111/jir.12505.

17 American Psychological Association (2004) Clinical practice guideline for the treatment of post-traumatic stress disorder. http://www.apa.org/ptsd-guideline/

18 National institute for Clinical Excellence (2005) Post-traumatic stress disorder: Management. www.nice.org.uk/Guidance/cg26

19 Shapiro F (1999) Eye movement desensitization and reprocessing (EMDR) and the anxiety disorders: Clinical and research implications of an integrated psychotherapy treatment. J Anxiety Disord13, 35–67.
20 Courtois C (2004) Complex trauma, complex reactions: Assessment and treatment. Psychotherapy: Theory, Research, Practice, Training 41, 412-425.
21 Gilderthorp RC (2015) Is EMDR an effective treatment for people diagnosed with both intellectual disability and post-traumatic stress disorder? J. Intellectual Disabilities 19, 58-68.
22 Jowett S, Karatzias T, Brown M, Grieve A, Paterson D & Walley R (2016) Eye movement desensitization and reprocessing (EMDR) for DSM-5 posttraumatic stress disorder (PTSD) in adults with intellectual disabilities: A case study review. Psychology of Trauma 8, 709-719.
23 Unwin G & Willott S. et al (submitted) Process issues in using eye movement desensitisation and reprocessing with adults with learning disabilities.
24 Herman JL (1997) Trauma and Recovery. New York: Basic Books.
25 Lovett J (1999) Small Wonders: Healing childhood trauma with EMDR. New York: Free Press
26 Stenfert Kroese B, Willott S, Thomas F & Willner P (2015) Trauma focussed cognitive-behaviour therapy for people with mild intellectual disabilities: Outcomes of a pilot study. Advances in Mental Health in Intellectual Disability 10, 299-310.
27 NHS England (2015) Transforming Care for People with Learning Disabilities: Next Steps. www.england.nhs.uk/wp-content/uploads/2015/01/transform-care-nxt-stps.pdf
28 Bender M (1993) The unoffered chair: the history of therapeutic disdain towards people with a learning difficulty. Clin Psychol Forum, 54: 7-12.
29 Stenfert Kroese B , Dagnan D, Loumidis K (1997) Cognitive Behaviour Therapy for People with Learning Disabilities. London: Routledge.
30 Vereenooghe L, Langdon PE (22013) Psychological therapies for people with intellectual disabilities: a systematic review and meta-analysis. Res Dev Disabil. 34, 4085-4102
31 *Taylor* J, *Lindsay* W, Hastings R & *Hatto*, C (Eds.) (*2013*). Psychological therapies for adults with intellectual disabilities. Chichester: Wiley-Blackwell.
32 Jahoda A, Stenfert Kroese B, Pert C (2017) Cognitive Behaviour Therapy for People with Intellectual Disabilities: Thinking creatively. London, Palgrave Macmillan.
33 Bisson JI, Cosgrove S, Lewis C, Robert NP (2015) Post-traumatic stress disorder. BMJ 351:h6161.
34 Hyland P, Shevlin M, Brewin CR, Cloitre M, … Bisson JI, Roberts NP 2017) Validation of post-traumatic stress disorder (PTSD) and complex PTSD using the International Trauma Questionnaire. Acta Psychiatrica Scandinavica 136, 313-322.
35 Hansen M, Hyland P, Armour C, Shevlin M & Elklit A (2015) Less is more? Assessing the validity of the ICD-11 model of PTSD across multiple trauma samples. European Journal of Psychotraumatology 6:28766.
36 McGuire TM, Lee CW & Drummond PD (2014) Potential of eye movement desensitization and reprocessing therapy in the treatment of post-traumatic stress disorder. Psychology Research and Behavior Management 7:273-83.
37 Bae H, Kim D & Park YC (2016) Dissociation predicts treatment response in eye-movement desensitization and reprocessing for posttraumatic stress disorder. J. Trauma Dissoc.17, 112-130
38 Ehring T, Welboren R, Morina N, Wicherts JM, Freitag J & Emmelkamp PM (2014) Meta-analysis of psychological treatments for posttraumatic stress disorder in adult survivors of childhood abuse. Clinical Psychology Review 34, 645-657.

39 Bae H, Kim D & Park YC. (2016) Dissociation predicts treatment response in eye-movement desensitization and reprocessing for posttraumatic stress disorder. J Trauma Dissoc. 17, 112-130
40 Parnell, L. (2013) Attachment-Focused EMDR: healing relational trauma. New York: Norton.
41 National institute for Clinical Excellence (2005) Post-traumatic stress disorder (Update). www.nice.org.uk/guidance/indevelopment/gid-ng10013
42 National Institute for Health and Care Excellence (NICE) (2013) Guide to the methods of technology appraisal. www.nice.org.uk/article/pmg9/resources/non-guidance-guide-to-the-methods-of-technology-appraisal-2013-pdf.
43 Willner P, Lindsay WR (2016) Cognitive behavioral therapy. In Singh NN (ed.) Handbook of Evidence-Based Practices in Intellectual and Developmental Disabilities, pp.283-310. New York, Springer.
44 Wechsler D (2011) Wechsler Abbreviated Scale of Intelligence, 2nd edition. Pearson
45 Harrison & Oakland (2015) Adaptive Behavior Assessment System, 3rd Edition. Pearson.
46 Willner P, Rose J, Jahoda A, Stenfert Kroese B, et al. (2013) A cluster randomised controlled trial of a manualised cognitive behavioural anger management intervention delivered by supervised lay therapists to people with intellectual disabilities. Health Technol Assess. 17(21):1-173
47 Blake DD, Weathers FW, Nagy LM, Kaloupek DG, Gusman FD, Charney DS, Keane TM. (1995) The development of a Clinician-Administered PTSD Scale. J Trauma Stress 8, 75-90.
48 Wigham S, Taylor JL & Hatton C (2014) A prospective study of the relationship between adverse life events and trauma in adults with mild to moderate intellectual disabilities. Journal of Intellectual Disability Research 58, 1131-1140.
49 Cuthill FM, Espie CA & Cooper S-A. (2003) Development and psychometric properties of the Glasgow Depression Scale for people with a learning disability: Individual and carer supplement versions. British Journal of Psychiatry 182, 347-353.
50 Mindham J & Espie CA. (2003) Glasgow Anxiety Scale for people with an Intellectual Disability (GAS-ID): development and psychometric properties of a new measure for use with people with mild intellectual disability. Journal of Intellectual Disability Research 47, 22-30.
51 Marshall K, Coiffait F-M & Willoughby-Booth S (2013) Assessing distress in people with intellectual disabilities. Learning Disability Practice 16, 26-30
52 Moss S, Prosser H, Costello H, Simpson N, Patel P, Rowe S, Turner S & Hatton C. (1998) Reliability and validity of the PAS-ADD Checklist for detecting psychiatric disorders in adults with intellectual disability. Journal of Intellectual Disability Research 42, 173-83.
53 Aman MG, Singh NN, Stewart AW & Field CJ. (1985) The Aberrant Behavior Checklist: a behavior rating scale for the assessment of treatment effects. Am. J. Ment. Deficiency 89, 85–91.
54 Cummins R. A. & Lau A. L. D. (2005) Personal Wellbeing Index – Intellectual Disability Manual, 3rd edn. School of Psychology, Deakin University, and Department of Rehabilitation Sciences, The Hong Kong Polytechnic University
55 Ware J Jr, Kosinski M & Keller SD (1996) A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Medical Care 34: 220–233, 1996
56 Stewart-Brown, S. L., Platt, S., Tennant, A., Maheswaran, H., Parkinson, J., Weich, S. & Clarke, A. (2011). The Warwick-Edinburgh Mental Well-being

Scale (WEMWBS): a valid and reliable tool for measuring mental well-being in diverse populations and projects. J. Epidemiol. Commun. Health, 65 (Suppl 2), A38-A39.
57 Kim D, Bae H & Park YC (2008). Validity of the subjective units of disturbance scale in EMDR. Journal of EMDR Practice and Research 2, 57-62.
58 Korn DL, Maxfield L, Smyth NJ, Stickgold R (2017) EMDR Fidelity Rating Scale. http://emdrresearchfoundation.org/research-grants/emdr-fidelity-rating-scale/
59 Beecham J & Knapp MRJ (1992) Costing psychiatric interventions. In: Measuring Mental Health Needs. In: Thornicroft GJ, Brewin CR, Wing JK (eds.), pp. 163-183, Gaskell, London.
60 Felce D, Cohen D, Willner P, et al. (2015) Cognitive behavioural anger management intervention for people with intellectual disabilities: costs and impact on health and social care resource use. Journal of Intellectual Disability Research 59, 68-81.
61 Moore GF, Barker M, Bonell C, Hardeman W, O'Cathain A, Wight D, Baird J (2015) Process evaluation of complex interventions: Medical Research Council guidance. BMJ 2015;350:h1258.
62 Hoffman TC (2014) template for intervention description and replication (TIDieR) *www.ncbi.nlm.nih.gov/pubmed/24609605*
63 Braun V, Clarke V (2006) Using thematic analysis in psychology. Qualitative Research in Psychology 3, 77-101.
64 Gale HK, Heath G, Cameron E, Rashid S, Redwood S (2013) Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Medical Research Methods 13:117.
65 Seubert A (2005). EMDR with clients with mental disability. In R Shapiro (Ed.), EMDR Solutions, Pathways to Healing. London: WW Norton & Company.
66 Knipe, J. (2015) EMDR Toolbox. New York: Springer
67 Knipe, J. (2010). Back of the head scale and the method of constant installation of present orientation and safety (CIPOS). In M. Luber (Ed.), Scripted protocols: Special populations (pp. 233–241). New York: NY: Norton
68 Eckers, D. (2010) The method of constant installation of present orientation and safety for children (CIPOS). In M. Luber (Ed) EMDR Scripted Protocols: Special populations (pp51-59). New York, Springer.
69 Fernandez I, Gallinari E. & Lorenzetti A (2004). A school- based EMDR intervention for children who witnessed the Pirelli building airplane crash in Milan, Italy. Journal of Brief Therapy, 2, 129-136.

16. Appendices

Appendix 1: Outline of the Psychoeducation and Emotional Stabilisation (PES) + adapted EMDR intervention

The adapted EMDR protocol has been developed from a combination of the standard adult protocol [19] and the child protocol [25], alongside guidance from attachment-focused EMDR [40] and publications from clinicians who have used EMDR for PwID [6,67]. Rather than the 8 phases in the standard protocol, we have 3 main phases for simplicity (with the first phase incorporated into the PES intervention). The primary adaptations revolve around reasonable adjustments alongside a set of guiding principles drawn from our work with PwID (including people who also have autism). The protocol will be manualised to facilitate consistent delivery.

The sessions may need to be shorter or broken up into sections with breaks (and therefore take longer overall), particularly for clients with attention difficulties. Conditional on the client's consent, carers are often involved, particularly in the earlier parts of the process (history taking and identifying targets).

Phase 1: PES (incorporates the first phase of the standard and adapted EMDR protocol)

a. The PES phase covers the standard EMDR protocol elements of history taking, preparation, formulation and risk assessment, but takes longer and includes additional skill-building components [26]. This addresses the often complex presentation of PTSD in PWID, particularly those who have survived multiple early traumas, and the consequent need to allow sufficient time to build a trusting therapeutic relationship and teach appropriate coping / emotional regulation skills that will allow individuals to obtain maximum benefit from EMDR [19]. The PES protocol [26] is already manualised, needing only minor modification.

b. Clients are educated in skills and resources to build emotional regulation (to promote internal safety), which include a raft of techniques tailored for each individual client. This will be tailored to their specific needs, including the Safe/Calm/Peaceful/Brave/Active Place or Safe Object (e.g. favourite possession from the Child Protocol if necessary) as standard, and additional EMDR resourcing, including Attachment-focussed EMDR [24] resourcing of Nurturing Figures, Protector Figures, Wise Figures, Inner Community, Team of Inner Resource (real or imagined, superheroes, etc.) to enhance self-soothing, self-care, protection and wisdom.

c. The skills and resources are often 'tapped in', (using whatever form of bilateral stimulation (BLS) is preferred by the client (eye movements, tactile or audio), in order to embed them more firmly and increase the familiarity of BLS prior to working through 'the bad stuff'.

d. The 1:1 PES sessions include the following components unless they are not relevant to the client's presenting problems:

- Staying Safe
- Understanding and managing emotions
- How our bodies remember – anxiety
- Disappearing and depression
- What is abuse and trauma and what are the effects on us?
- Triggers and how to avoid them
- Flashbacks, Nightmares, Dissociation, Flashbacks – how to deal with them

- Self Harm, lack of self-care, problems around eating – looking after ourselves
- How EMDR works on 'stuck' tricky feeling and can tap it out/move it on, with you being in control

Each session ends with a simple relaxation or mindfulness exercise. Most of our clients prefer the 'soles of the feet' mindfulnesss exercise but we introduce a number of alternatives from which they can choose.

Feedback from our clients indicates that practical exercises involving visual stimuli, drawing and other artwork, multiple choice questions, role-play, 'empty chair' exercises and movement are preferred over 'talk and chalk' sessions that involve lengthy periods of passive listening and sitting still. Personal preferences noted during PES will be carried forward into methods of expressions in the adapted EMDR protocol (further detail below).

'Booster' sessions or review sessions are introduced whenever the therapist and the client consider repetition to be useful (especially when clients have memory deficits).

Phase 2: Get ready (equivalent to phase 2 of the standard protocol)

a. If clients are unable to tell their trauma story and yet what happened is known (and with client consent), consider an accessible story-telling approach that is developmentally appropriate and takes language level into account [25]. The approach should be one which the person will like, provide a resolution to the trauma, and a belief that will help the person move forward with life. The length should be that of a 'bedtime story' with a beginning, a middle and an end, in the 3rd person, unnamed, but using the same gender and characteristics of client. The theme of the story is a trauma that can happen to people and proposes ways they can deal with such an event. It should be anchored enough in their real story, so that the client can see the story could be about them or someone very similar, e.g. by including features of their life. The trauma and lead up to it should be described in sufficient detail to access sensory phenomena (sights, sounds, smells tastes feelings). A link should be made to the client's current symptoms and describe EMDR as tapping out the tricky feeling (or alternative form of BS). The ending should be the description of realistic resolution of symptoms, return to activities, the body feeling fine and the positive beliefs/learning emerging from coming through the trauma and feeling safe/coping etc. (e.g. "he knew he was brave, loved, could call for help, could always feel better by thinking of his dog/aunt, etc."). The story should be repeated with updates and changes supplied by the individual (adapted from [25]).

b. Consider the tendency of PwID to acquiescence and to agree in order to please the therapist. The trust built up in phase 1 should mitigate against this but ways of saying 'no' or 'stop' should be agreed with the client. The client will be told in PES that it is important to remember "it is your own brain that will be doing the healing and you are the one in control".

c. Psycho-education, building on that delivered in PES, around why trauma memories can remain unprocessed ("stuck"): using accessible language and avoiding the use of metaphors where unhelpful. The metaphors either need to be re-thought (many standard metaphors, such as the factory image, may be inaccessible) or avoided (particularly when the client has ASD, as around 40% of PwID do). Concrete and tangible ways of explaining can be useful as can metaphors that the client can relate to from their everyday life, such as shoving a duvet into a small cupboard and/or use a model of a head/ brain. It can also help to use metaphors informed by the client's special interests, likes and hobbies.

d. Psycho-education around the EMDR model. Describe how trauma memories can get stuck in processing, how this approach could help with healing. Use similar guidance to above and use accessible leaflet (developed).

e. Top 10 bad memories and miracle question (or adapted version). The miracle question is a way of helping the client toward a goal by asking them to pretend that a miracle happened and the problem disappeared.

f. Scale subjective units of distress (SUDs), using an accessible scale agreed with client (this might not include numbers or words and might use a physical representation). A VAS using some area of interest of the client is ideal – likely not 10 points but a scaling to show size of feeling or the hand scale from the Child Protocol. (The therapist can observe distress if scaling is too difficult.)

g. Positive cognitions should be scaled for Validity of Cognition (VoC). These ratings can be difficult to obtain and focusing on abstract future cognitions could be too challenging. If this is the case, consider omitting VoC if too complex a concept.

h. Check stop sign and BLS preference.

i. Check consent now that the client is more fully informed.

Phase 3: Working through the bad stuff from the past (equivalent to phases 3-8 of the standard protocol)

At the beginning of each session, taking into account attention span and scaffolding the work as needed, check how things were in the week (following last session), ask for objective report where carer/family member involvement has been agreed by client, consider installing a positive self-belief resource at the beginning of each session if confidence is low, and then:

- Agree which memory to work on in that particular session
- Explore the picture that most captures this (may need to draw this out together)
- Work out what (bad stuff) this says about you (if possible)
- Where do you feel this in your body? Could focus on this if not possible to name the emotion.
- Scale the distress
- Decide what good stuff (positive/over now/brave/loved/coping feeling/I am a good person) to put in its place, and scale, if possible. (Similarly, multi-choice options, based on formulation, can be useful to scaffold the work.)
- Consider a short break at this point. Then, using the target memory agreed to work on:

a. SAFE - start from a safe place in the present and remind the client that what you are about to work through is past stuff. May need visual reminders and redirecting to the most helpful resources you developed in phase 1 to manage distress. Following the child protocol, ground in safe place and assemble ‘team’ of positive resources (as above).

b. FIRE UP the neural networks (visualise the memory picture identified above and link to thoughts, feelings, and body).

c. WORK THROUGH IT together, using the preferred form of BLS (consider scaling distress more frequently/checking what is coming up if notice non-verbal communication and titrate arousal level to keep within an appropriate

arousal window). Positive resources can be mobilised as required as cognitive interweaves.

d. BLOCKS/DISSOCIATION – Constant Installation of Positive Orientation (CIPOS [66,67], updated for children [68]) to be employed, using draw a picture and turn over. May use a four-field protocol [69].

e. WIRE UP the good stuff (i.e. that agreed to be put in place of the bad stuff) after tricky feelings are reported to be gone or as small as possible - at least 2 sets)

f. CHECK and body scan and process any remaining sensations

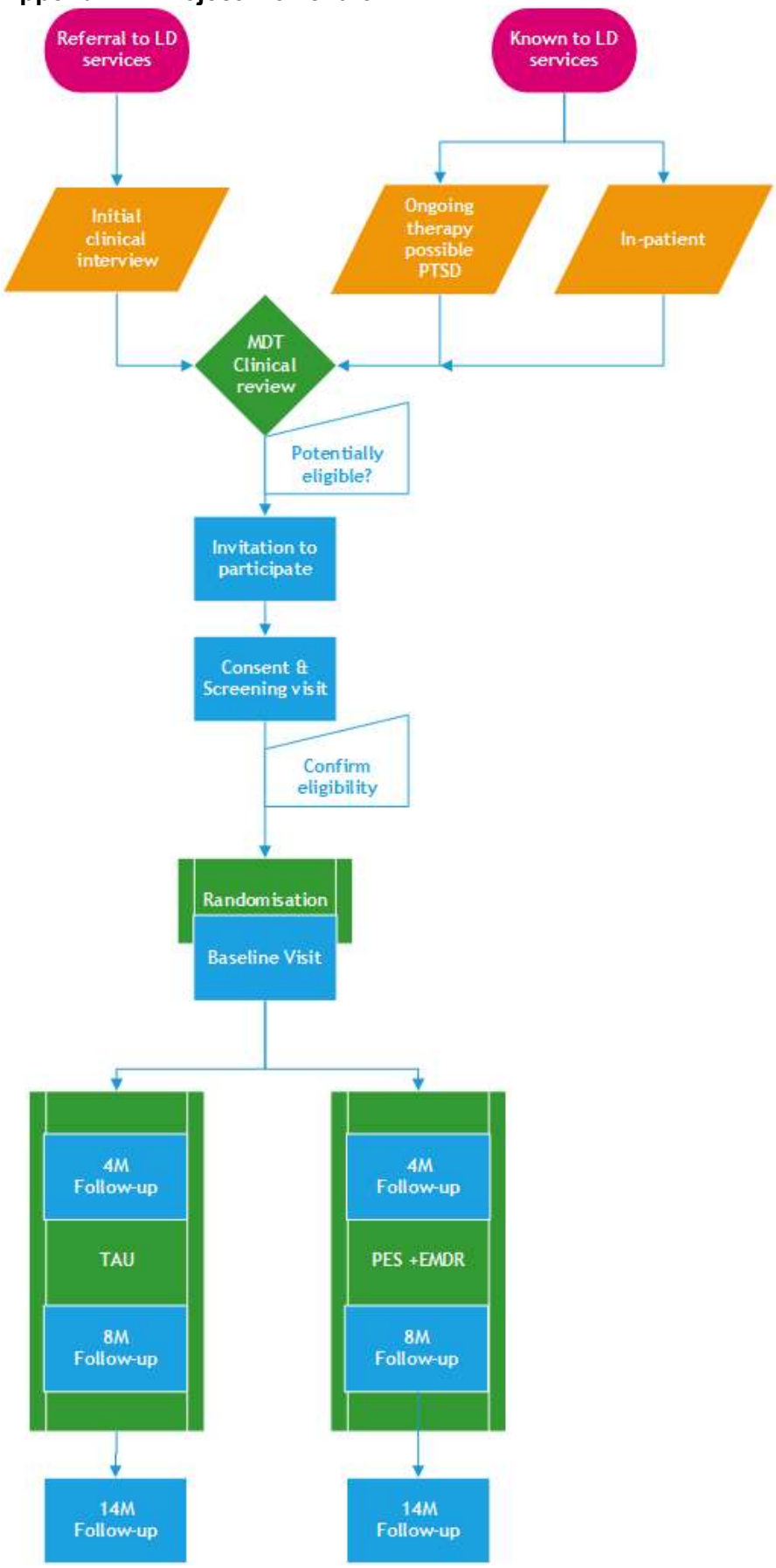
g. SAFE – return to safe place again (and de-brief). Consider involving carers at the end of the session to provide support between sessions and education about what to expect, such as further processing.

h. Future templates – slow sets once positive learning noted (may relate to original PC if identified, or reinforcing any positives emerging in processing, e.g. description of activities person now feeling wants to do, body feeling light/happy/free/safe/coping, etc. (e.g. “I know I can always tell dad”, “I know now I can always calm myself by thinking about the seaside”; whatever emerged for the individual).

The standard protocol starts with identifying the touchstone (earliest/primary) trauma memory, usually experienced in childhood, using a present concern or problem and ‘floating back’ in time. This might prove difficult for PwID, who have cognitive difficulties and may find it difficult to remember. If this is the case, consider processing a current problem that the therapist has linked in their formulation to the same emotion as in the touchstone. Barol and Seubert call this compassionate guesswork [6, 65]. The float-back can be asked about as a feeling which is often more accessible, e.g. “When you let your mind float back, when was the very first time that you felt like this?”.

Generally, more verbal direction will be needed for PwID than in the standard protocol in order to maintain focus and provide encouragement. The sets will be shorter and the whole process within a ‘sandwich’ of positive resource/safe place, after the Child Protocol [25].

Appendix 2: Project Flowchart



Appendix 3: International Trauma Questionnaire – Intellectual Disabilities (ITQ)

BACKGROUND:
An initial and preliminary 23-item version of the *International Trauma Questionnaire* (ITQ: Cloitre, Roberts, Bisson, & Brewin, 2015) operationalized the narrative descriptions of Posttraumatic Stress Disorder (PTSD) and Complex PTSD (CPTSD), as defined in the 11th version of the International Classification of Diseases (ICD-11).

This is an adapted version for people with intellectual and other developmental disabilities. It was developed with an advisory group of people with intellectual disabilities and autism. This version should be administered as a semi-structured interview.

Using samples of people without intellectual disabilities Item response theory (IRT) analysis was applied to data from a trauma-exposed community sample and a trauma-exposed clinical sample from the United Kingdom, and the results provided an empirical basis for the selection of a list of 12 indicators of PTSD and CPTSD symptoms. Confirmatory factor analytic results found that the latent structure of the ITQ was consistent with prior findings, and diagnostic rates of PTSD and CPTSD were in line with previous estimates based on the preliminary-stage version [1-3]. The resulting instrument is a brief, simply-worded measure, focusing only on the core features of PTSD and CPTSD, and employs straightforward diagnostic rules. The ITQ is therefore consistent with the organizing principles of the ICD-11, as set forth by the World Health Organization, to maximize clinical utility and ensure international applicability through a focus on the core symptoms of a given disorder. The ITQ is freely available in the public domain to all interested parties.

You should use the Trauma Information Form first with your respondent (Hall, Jobson and Langdon, 2014). This is to help ensure that they understand what we mean by the word "trauma", and the traumatic event that you are asking them about.

DIAGNOSTIC ALGORITHMS are as follows:
PTSD. A diagnosis of PTSD requires the endorsement of one of two symptoms from each of the three PTSD symptom clusters, plus endorsement of functional impairment associated with these symptoms. ***For the purposes of the Trauma-AID study we will also accept a diagnosis of "partial PTSD" defined as EITHER endorsement of one of two symptoms from each of the three PTSD symptom clusters, plus endorsement of functional impairment associated with these symptoms, OR endorsement of symptoms from each of the three PTSD symptom clusters, with no declared functional impairment.***

CPTSD. A diagnosis of CPTSD requires that the PTSD criteria are satisfied, and the endorsement of one of two symptoms from each of the three DSO symptom clusters, plus endorsement of functional impairment associated with these symptoms. ***For the purposes of the Trauma-AID study we will also accept a diagnosis of "partial DSO" as defined above, leading to a diagnosis of "partial CPTSD".***

REFERENCES:
1. Brewin, C. R., Cloitre, M., Hyland, P., Shevlin, M., Maercker, A., Bryant, R. A.,…Reed, G. M. (2017). A review of current evidence regarding the ICD-11 proposals for diagnosing PTSD and complex PTSD. *Clinical Psychology Review, 58,* 1-15. doi: 10.1016/j.cpr.2017.09.001.

2. Karatzias T., Shevlin M., Fyvie C., Hyland P., Efthymiadou E., Wilson D.,…Cloitre M. (2017). Evidence of distinct profiles of posttraumatic stress disorder (PTSD) and complex posttraumatic stress disorder (CPTSD) based on the new ICD-11 trauma questionnaire (ICD-TQ). *Journal of Affective Disorders,* 207, 181-187. http://dx.doi.org/10.1016/j.jad.2016.09.032

3. Hall, J.C., Jobson, L. and Langdon, P.E. (2014). Measuring symptoms of post-traumatic stress disorder in people with intellectual disabilities: The development and psychometric properties of the Impact of Events Scale – Intellectual Disabilities (IES-IDs). *British Journal of Clinical Psychology, 53*, 315-332. https://doi.org/10.1111/bjc.12048

4. Hyland, P., Shevlin M., Brewin C.R., Cloitre M., Downes A.J., Jumbe, S.,...Roberts, N.P. (2017). Validation of post- traumatic stress disorder (PTSD) and complex PTSD using the International Trauma Questionnaire. *Acta Psychiatrica Scandinavica*. *136,* 313-322. doi: 10.1111/acps.12771.

International Trauma Questionnaire – Intellectual Disabilities

Instructions: Please identify the experience that troubles the person most by using the Trauma Information Form, administered as a semi-structured interview. Refer to the pictorial prompt sheet as required.

Record the trauma here: _____

When did the experience occur? (circle one)

a. less than 6 months ago
b. 6 to 12 months ago
c. 1 to 5 years ago
d. 5 to 10 years ago
e. 10 to 20 years ago
f. more than 20 years ago

"I'm going to read some problems that people who have had trauma struggle with; can you tell me whether you have had any of these problems in the last month by saying yes, sometimes, or no when I ask the question?"	**No**	**Sometimes**	**Yes**
1. Are you having nightmares about the bad things that happened to you?	0	1	2
2. Are you having memories about the bad things which pop into your head and scare you?	0	1	2
3. Have you tried not to think about the bad things?	0	1	2

4. Have you tried not to go to places that remind you of the bad things that happened?	0	1	2
5. Have you felt really scared a lot of the time?	0	1	2
6. Have you felt really jumpy?	0	1	2

"In the last month, have the things we just talked about:"

7. Meant that you fell out with your friends?	0	1	2
8. Meant that you couldn't go to work or do your activities?	0	1	2
9. Meant that you couldn't do the things you normally do like school, hobbies or other things?	0	1	2

"I am going to read some more problems that people who have had trauma struggle with; can you tell me whether you generally feel this way by saying yes, sometimes or no when I ask the question?"

"How true is this of you?"

	No	**Sometimes**	**Yes**
1. When I am upset, it takes me a long time to calm down.	0	1	2
2. I feel sad	0	1	2
3. I feel like a failure	0	1	2
4. I feel worthless	0	1	2
5. I feel like I have no friends	0	1	2
6. I find it hard to be around people	0	1	2

"In the past month, have the bad feelings and thoughts we just talked about:"

	No	**Sometimes**	**Yes**

1. Meant that you fell out with your friends?	0	1	2
2. Meant that you couldn't do your work or your activities?	0	1	2
3. Meant that you couldn't do the things you normally do like school, hobbies, or other things?	0	1	2

Appendix 4: Project Schedule of Events including eligibility and outcome assessment.

	Referral/Clinic Pre-screening (completed assessments must be within 12 weeks of screening)	**Screening**	**Baseline†**		**Treatment Schedule*** (patients & carers)									
					Phase 1 (PES/TAU)				**Phase 2** (EMDR/TAU)				**Follow Up**	
Visit	V-2	V-1	V0		V1-V10		Assess		V11-V20		Assess		F/U	
Week	<-12	-4	0		5-15		16		17-27		28		60	
Window allowed§	NA	NA	NA		+4 wks		+4 wks		+4 wks		+4 wks		+4 wks	
Location	*All visits anticipated in Clinic/Community Setting although potential for other scenarios*													
	P-Participant C-Carer	**P**	**P**	**C**	**P**	**C**	**P**	**C**	**P**	**C**	**P**	**C**	**P**	**C**
Clinical History	X													
Patient Information	X													
Consent		X												
Diagnostic interview		X												
Diagnostic review		X												
Concomitant medication		X			X		X		X		X		X	
Confirm eligibility		X												
Randomisation			X											
Treatment (1-10 sessions for Phase 1 and 2)					X		X		X		X			
Adverse Events					X		X		X		X		X	
Distress Scale (SUDS)					X		X		X		X		X	

	Audio Recording	*With participants consent, one treatment session from phase 1 and phase 2 will be recorded with scoring using the EMDR Fidelity Rating Scale*														
	Interview	*In line with qualitative recruitment methods around 10 each of patients, carers and therapists will be interviewed about their experiences following completion of therapy.*														
Measure	**Instrument**		P	**C**	**P**	**C**	**P**	**C**	**P**	**C**	**P**	**C**	**P**	**C**	**P**	**C**
IQ	WASI-II[a]		X													
Adaptive behaviour	ABAS-III[a]			X[b]												
PTSD history	TIF[a]		X													
PTSD diagnosis/ Complexity	ITQ-ID[a]		X				X		X		X		X		X	
PTSD (primary)	IES-ID				X				X				X		X	
PTSD (secondary)	LANTS					X				X				X		X
Depression	GDS				X				X				X		X	
Anxiety	GAS				X				X				X		X	
Mental Health	CORE-LD				X				X				X		X	
Mental Health	MPAS-ID					X				X				X		X
QoL (primary)	SF-12					X				X				X		X
QoL (secondary)	PWI-ID				X				X				X		X	
Challenging behaviour	ABC					X				X				X		X
Carer burden	WEMWBS					X				X				X		X
Service/Support Costs	CSRI-ID					X				X				X		X

***** – Due to the nature of the treatment it may be necessary for either or both of the phase 1 and phase 2 treatment visits to extend beyond 10. It is anticipated this will be unlikely to exceed 15 for either.

† – TIF may be completed at pre-screening or screening subject to a Healthcare Trusts standard care procedure. The ITQ-ID will be completed at screening to confirm PTSD diagnosis.

a – Instruments to confirm ID diagnosis (WASI and ABAS) will be either completed as screening measures or results taken from the patient's clinical record, prior to consent, if standardised IQ or adaptive behaviour scores have been recorded within the past five years.

§ – Assessments should be completed within consecutive weeks. However, there may be a delay of up to 4 weeks within the assessment period.

[b] - ABAS waived for those participants who have a diagnosis of ID or are in receipt of support from a NHS Learning Disability service.