ISRCTN35167485 https://doi.org/10.1186/ISRCTN35167485

A therapist-led treatment for symptoms of post-traumatic stress disorder (PTSD) in adults with intellectual disabilities (ID) using eye movement desensitisation and reprocessing (EMDR)

Submission date
24/06/2019

Recruitment status
No longer recruiting

Registration date
22/07/2019

Overall study status
Ongoing

Last Edited
02/01/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
People with intellectual disabilities (PwID) are at increased risk of all types of abuse. PwID exposed to traumatic events show typical symptoms of post-traumatic stress disorder (PTSD) anxiety, flashbacks, recurring nightmares, and more complex presentations e.g. difficulty in regulating emotions; shame, guilt, worthlessness; difficulties in sustaining relationships and feeling close to others, as well as challenging behaviours. PwID require highly specialist NHS intellectual disability (ID) services, and are at risk of admission to hospital. The aim of the study is to assess if general populations treatments would be effective or provide value for money when used with PwID.
Eye movement desensitization and reprogramming (EMDR) is an effective treatment in the general adult population. The first stages of treatment psychoeducation and stabilisation (PES) and EMDR help PwID develop strategies to calm their turbulent emotions; the later EMDR stages involve focusing attention on past traumatic events while making controlled eye movements. Standard EMDR is difficult to use with PwID because the eye movement exercises are unfamiliar and difficult to explain. However, the procedure can be adapted to PwID by expanding the introductory PES phase and adapting some of the techniques used in the treatment of traumatised children. We will investigate how well an adapted EMDR protocol works in PwID, compared with treatment as usual (TAU), as defined by the therapist.

Who can participate?
PwID aged 18 - 65 and their carers

What does the study involve?
Patients with ID referred for treatment and confirmed as having PTSD will be allocated randomly to receive either PES+EMDR or TAU. PTSD, mental health problems and challenging behaviour will be assessed before treatment, after PES, after EMDR, and 6 months later. Reasons for dropping out will be recorded and we will measure how well the treatment is delivered. We will also collect data about the costs of providing treatment, whether treatment

improves patients' and their carers' quality of life, and if it decreases the costs of supporting patients in the community. At the end of the study we will interview a sample of patients, therapists and carers to find out their views of the treatment, and the impact.

What are the possible benefits and risks of participating?
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. A potential benefit to participants in the intervention group 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.

Where is the study run from?
1. University of Birmingham
2. Swansea Clinical Trials Unit

When is the study starting and how long is it expected to run for?
November 2019 to April 2025

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof. Paul Willner, p.willner@swansea.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Peter Langdon

ORCID ID
https://orcid.org/0000-0002-7745-1825

Contact details
University of Birmingham, Edgbaston
Birmingham
United Kingdom
B15 2TT
-
p.langdon@bham.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Central Portfolio Management System (CPMS)
42218

Study information

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

Acronym
Trauma-AID

Study objectives
EMDR provides value for money, improves the mental health and quality of life for PwID who suffer PTSD when compared to standard available treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/07/2019, Wales Research Ethics Committee 3 (The Caerphilly Suite, Holiday Inn Cardiff North M4/J32, Merthyr Road, Coryton, Cardiff CF15 7LH; 02920785736; Wales. REC3@wales.nhs.uk), ref: 19/WA/0173

Study design
Randomized; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Complex Intervention

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post-traumatic stress disorder in adults with intellectual disabilities

Interventions
Intervention:
Patients will be treated using an adapted PES+EMDR protocol based on a combination of adult, child and attachment-focused 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, 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.
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 treatment-as-usual (TAU). TAUh would typically include medication, behaviour support plans delivered through carers (intended to decrease challenging behaviour, e.g. by creating a less stressful environment); and/or trauma-focused or non-trauma-focussed (such as anger/stress management) psychological interventions.
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 (further described in section 9.2 of the protocol).
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.

Design:
The study is designed as a randomized controlled trial (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 and internal pilot phases (further detail in the Project Timetable). Health economic outcomes will be determined from data collected at baseline and 14-month assessments.

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 of the protocol.

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.

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-II) [45], completed by a carer.
• 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 pre-pilot study (see below)

Setting/context:
The study will be located in NHS hospital and community services for people with intellectual disabilities. We have written agreement to participate from four large NHS Trusts, located in the west midlands (Birmingham, South Staffs. & Shropshire) and the south-east of England (Herts. & Essex, Kent & Medway), and clinicians to be trained as therapists have been identified. Agreements will be negotiated as to how the trial intersects with 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 that meet the needs of the trial while respecting local working practices.

Therapist training and supervision:
Within each Trust we will train therapists in at least three clinical teams 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. 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.

Data collection:
Clinical and health-economic assessments will be conducted by masked assessors, before randomization, and with follow-up at 4 (post-PES), 8 (post-EMDR), and 14 months. Quantitative clinical outcomes measures will be recorded at all four time points; health economic outcome measures will be recorded at baseline and the 4-, 8 and 14-month time points. 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 Swansea Trials Unit, using their
bespoke REDCap data management system.

Pre-pilot study:
The International Trauma Questionnaire 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 (including patients undergoing treatment for PTSD and volunteers who have experienced trauma). Participants will also be administered adapted

versions of a Trauma
Information Form and the Impact of Event Scale, 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. For 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.

Feasibility study (months 1-12):
The aims of the feasibility study are to finalize the intervention and confirm its acceptability. The objectives are:
1. Completion of the manual for phase 2 of the protocol (EMDR), with sign-off for use in the trial;
2. Training of research assistants, and supervised practice in data collection, with sign-off by the assistant's supervisor;
3. Administration of the complete PES+EMDR protocol to at least 6 patients, with a satisfactory review of its acceptability to patients and carers, as assessed from interviews with patients and carers.
4. Progress will be reviewed by the Trial Steering Committee at 6 months, to confirm or revise the progression criteria
5. This timetable is less constrained than it might appear: therapists will be in a position to commence treating patients well before the completion of their EMDR training because, as specialist ID clinicians, they will already possess the skills to implement phase 1 of the intervention (PES), which we already know from earlier work is acceptable to patients. (vi) Progress will be reviewed by the Trial Steering Committee at 6 months, to confirm or revise the progression criteria (i-iii). (vii) 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.

Recruitment timetable:
Patient recruitment for the main study should commence at month 7 and average 1.5 per month over 24 months, in each of the four participating NHS Trusts (1.25/m in 3 Trusts and 2/m in the fourth). (Drawing on three to five teams in each Trust, we will aim to recruit an average of 1 patient per team every 2 months. 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.)

Internal pilot study (months 7-18):
The aim of the internal pilot is to test recruitment to the trial and retention through phases 1 and 2 of treatment. (The feasibility study will be complete by the time the first patients in the internal pilot commence phase 2 of treatment(EMDR) in m onth 13.) The internal pilot has the following objectives:
1. Recruitment of at least 36 patients by 14 months
2. 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.
3. 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.
4. 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 so as to ensure that we can develop strategies to mitigate any risks to successful completion of the

Intervention Type
Behavioural

Primary outcome(s)
Score at the 8 month (post-treatment) follow up assessment using the Impact of Events Scale-revised for people with intellectual disabiltiies (IES-ID).

Key secondary outcome(s))
Current secondary outcome measures as of 14/11/2025:
1. PTSD symptoms measured using the Impact of Events Scale – Intellectual Disabilities (IES-ID) at 4 months and 14 months
2. PTSD symptoms measured using Lancaster & Northgate Trauma Scales (LANTS) at 4 months, 8 months and 14 months
3. Depression symptoms measured using the Glasgow Depression Scale (GDS) at 4 months, 8 months and 14 months
4. Anxiety symptoms measured using the Glasgow Anxiety Scale (GAS) at 4 months, 8 months and 14 months
5. Mental health measured using Clinical Outcomes in Routine Evaluation – Learning Disability (CORE-LD) at 4 months, 8 months and 14 months
6. Mental health measured using the Moss Psychiatric Assessment Schedules (MPAS-ID) at 4 months, 8 months and 14 months
7. Quality of life measured using the Short Form Health Survey - 12 (SF-12) at 4 months, 8 months and 14 months
8. Quality of life measured using the Personal Wellbeing Index (PWI) at 4 months, 8 months and 14 months
9. Challenging behaviour measured using the Aberrant Behavior Checklist (ABC) at 4 months, 8 months and 14 months
10. Carer burden measured using the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) at 4 months, 8 months and 14 months
11. Economic impact measured using the Client Service Receipt Inventory - Intellectual Disabilities (CSRI-ID) at 4 months, 8 months and 14 months

Previous secondary outcome measures:
1. PTSD symptoms measured using the Impact of Events Scale – Intellectual Disabilities (IES-ID) at 4 months and 14 months
2. PTSD symptoms measured using Lancaster & Northgate Trauma Scales (LANTS) at 4 months, 8 months and 14 months
3. Depression symptoms measured using the Glasgow Depression Scale (GDS) at 4 months, 8 months and 14 months
4. Anxiety symptoms measured using the Glasgow Anxiety Scale (GAS) at 4 months, 8 months and 14 months
5. Mental health measured using Clinical Outcomes in Routine Evaluation – Learning Disability (CORE-LD) at 4 months, 8 months and 14 months
6. Mental health measured using Psychiatric Assessment Schedule for Adults with Developmental Disabilities (PAS-ADD) at 4 months, 8 months and 14 months
7. Quality of life measured using the Short Form Health Survey - 12 (SF-12) at 4 months, 8 months and 14 months

8. Quality of life measured using the Personal Wellbeing Index (PWI) at 4 months, 8 months and 14 months
9. Challenging behaviour measured using the Aberrant Behavior Checklist (ABC) at 4 months, 8 months and 14 months
10. Carer burden measured using the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) at 4 months, 8 months and 14 months
11. Economic impact measured using the Client Service Receipt Inventory - Intellectual Disabilities (CSRI-ID) at 4 months, 8 months and 14 months

Completion date
31/07/2026

Eligibility

Key inclusion criteria
Patients with intellectual disabilities (PwID)
1. Aged > = 18 to < = 65
2. Meeting criteria for a diagnosis of ID
3. Meeting ICD-11 diagnostic criteria for PTSD
4. Major identified trauma at least a year earlier
5. Able to communicate in English and to provide informed consent to both the referral and study participation

Carers
1. Aged > = 18 and over
2. A family member or carer of a person with ID who has consented to participate in the trial
3. Able to communicate in English and to provide informed consent to study participation

Added 14/11/2025:
4. Able to attend clinic visits (or remote sessions if offered) or be present when a researcher performs the assessment visit

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment

Key exclusion criteria
1. Assessed by the clinical team as at high risk and/or requiring urgent treatment
2. Currently in therapy and unwilling to intermit
3. Previously completed a course of EMDR
4. Psychosis not well controlled by medication
5. Change of psychotropic medication or dosage within the last month
6. Unable to complete the assessments.
7. 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.

Date of first enrolment
01/11/2019

Date of final enrolment
30/06/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Birmingham Community Healthcare NHS Foundation Trust
3, Priestley Wharf
Holt Street
Birmingham Science Park
Aston
Birmingham
England
B7 4BN

Study participating centre
Black Country Partnership NHS Foundation Trust
Delta Point
Greets Green Road
West Bromwich
England
B70 9PL

Study participating centre

St Georges Hospital
Corporation Street
Stafford
England
ST16 3SR

Study participating centre
Kent And Medway NHS and Social Care Partnership Trust
Farm Villa
Hermitage Lane
Maidstone
England
ME16 9PH

Study participating centre
Hertfordshire Partnership University NHS Foundation Trust
99 Waverley Road
St Albans
England
AL3 5TL

Study participating centre
Hellesdon Hospital
Drayton High Road
Norwich
England
NR6 5BE

Study participating centre
Norwich Community Hospital
Bowthorpe Road
Norwich
England
NR2 3TU

Sponsor information

Organisation
Birmingham Community Healthcare NHS Foundation Trust

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 17/125/04

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		17/12/2025	02/01/2026	Yes	No
HRA research summary			28/06/2023	No	No
Protocol (other)			09/04/2025	No	No
Study website		11/11/2025	11/11/2025	No	Yes