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Personalised treatment packages for adults with a learning disability

Submission date
15/08/2022

Recruitment status
No longer recruiting

Registration date
16/11/2022

Overall study status
Completed

Last Edited
30/06/2026

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
The PETAL programme is designed to help adults with a learning disability who display aggression and those who support them work together to better understand and meet the person's individual needs. Although there are some issues that are commonly experienced, everyone is different, so a personalised approach is needed. 10-25% of adults with mild to severe learning disabilities display aggression. This behaviour affects their quality of life, leading to exclusion from social networks and community facilities including access to healthcare, placement breakdown, inability to stay in the family home, seclusion, overmedication etc.

A better understanding of the causes of an individual's aggressive behaviour and coproducing a personalised treatment package could make a significant difference to their quality of life. We work with adults with a learning disability and their families and paid carers to develop the PETAL therapy to address aggression and test if it works better than the current approaches available.

Who can participate?
Adults with learning disabilities and their carers (family or paid)

What does the study involve?
The PETAL therapy has four phases which are presented below:
1. Review the evidence about which psychosocial treatments for aggression work for adults with learning disabilities and for other client groups. We reviewed the manuals and how they are delivered.
2. Talk to adults with a learning disability who have good outcomes, and those with poorer outcomes, their family or paid carers and professionals. With those who reported things went well, we asked why they thought that was so. Where it did not go so well and explored what might have been more helpful.
3. Use routinely collected NHS data to assess how adults with a learning disability who display aggression respond to treatments. This enabled us to better understand what influences patient outcomes and to inform the design of PETAL therapy.
4. Use the findings from 1, 2 and 3, and worked with adults with learning disabilities, carers and professionals, to develop a personalised treatment package called PETAL therapy. We

developed a manual. We will train NHS staff in how to deliver the personalised treatment package and will test whether it is practical and acceptable, making changes if needed.
5. Find out, in a large trial, whether the personalised treatment package makes a positive difference to the health and quality of life of adults with a learning disability and how cost-effective it is.

What are the possible benefits and risks of participating?
There are a number of potential benefits to this study. At the moment, there is not a consistent approach to the management of aggression in adults with intellectual disabilities across the UK. If the PETAL therapy is effective, then it could be rolled out in all NHS services for adults with intellectual disabilities. Without evidence, we cannot convince health and social care services to change their usual practices. In addition, professionals, family, and paid carers would have gained special skills to better support adults with intellectual disabilities with aggressive challenging behaviour. There are no identified disadvantages to taking part in this research. Nonetheless, there is a time commitment to attend the PETAL therapy sessions over a period of 14 weeks. In addition, each research visit and interview might last for about 1 hour. If you find the PETAL therapy sessions, the research visits, or the interview too long, you may request a break.

Where is the study run from?
North London NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2021 to October 2026

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

Who is the main contact?
Prof. Angela Hassiotis, a.hassiotis@ucl.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
316749

Central Portfolio Management System (CPMS)
53581

Study information

Scientific Title

Personalised treatment packages for adults with learning disabilities who display aggression in community settings: A cluster randomised controlled trial (PETAL therapy)

Acronym
PETAL therapy

Study objectives
The PETAL therapy alongside usual care significantly reduces aggressive challenging behaviour in adults with intellectual disability compared to usual care alone at 9 months post-randomisation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/10/2022, Health and Care Research Wales (Castlebridge 4, Cardiff, CF11 9AB, Wales, UK; +44 (0)2920 230457; HCRW.approvals@wales.nhs.uk, Wales.REC7@wales.nhs.uk), ref: 22/WA/0267

Primary study design
Interventional

Study design
Cluster randomized controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Intellectual disability

Interventions
Current interventions as of 03/01/2024:
We will randomise clusters (i.e., community learning disability services) to one of the two intervention arms. Intervention arms: The PETAL therapy alongside usual care. The PETAL therapy for aggressive challenging behaviour is a manualised personalised multicomponent package. It has been developed following a realist review of the evidence, qualitative interviews with people who had received an intervention for aggressive challenging behaviour, previous work by the co-applicant group and consultation with experts and experts by experience (i.e., family carers and people with intellectual disability). The PETAL therapy includes 7 modules and 2 review sessions that need to be completed within 14 weeks. The duration of each module can last up to 2 hours. The duration may differ depending on the person and their needs (i.e., some people may only be able to manage 40-minute sessions) and some people may need several breaks during the session. Sessions will be dyadic (the person with a learning disability and a family or paid carer). Control arm: Usual care alone. That means any care that is available within services across the UK.

Previous interventions:
We will randomise clusters (i.e., community learning disability services) to one of the two intervention arms. Intervention arms: The PETAL therapy alongside usual care. The PETAL

therapy for aggressive challenging behaviour is a manualised personalised multicomponent package. It has been developed following a realist review of the evidence, qualitative interviews with people who had received an intervention for aggressive challenging behaviour, previous work by the co-applicant group and consultation with experts and experts by experience (i.e., family carers and people with intellectual disability). The PETAL therapy includes 7 modules and 2 review sessions that need to be completed within 14 weeks. The duration of each module can last up to 2 hours. The duration may differ depending on the person and their needs (i.e., some people may only be able to manage 40-minute sessions) and some people may need several breaks during the session. Sessions will be dyadic or triadic (with or without a carer or the adult with the intellectual disability). Control arm: Usual care alone. That means any care that is available within services across the UK.

Intervention Type
Behavioural

Primary outcome(s)
Aggressive challenging behaviour measured using the Aberrant Behaviour Checklist irritability scale (ABC-I) at baseline, and 4 and 9 months follow up

Key secondary outcome(s)
Current secondary outcome measures as of 09/06/2023:

1. Episodes of physical aggression measured using the Behaviour Problems Inventory-short (BPI-S) at baseline, and 4 and 9 months follow up
2. Risk measured using the Threshold Assessment Grid (TAG) at baseline, and 4 and 9 months follow up
3. Family carer and paid carer confidence in managing aggression measured using the Difficult Behaviour Self-Efficacy scale at baseline, and 4 and 9 months follow up
4. Family carer wellbeing measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at baseline, and 4 and 9 months follow up
5. Family carer Social Care Related Quality of Life measured using the Adult Social Care Outcomes Toolkit (ASCOT) at baseline, and 4 and 9 months follow up
6. Service use and medications measured using the Client Service Receipt Inventory (CSRI) at baseline, and 4 and 9 months follow up
7. Adult with intellectual disability health-related quality of life measured using the EuroQoL five Dimensions Scale (EQ-5D-3L) proxy and EuroQoL EQ-5D Learning disability (EQ-5D-LD) at baseline, and 4 and 9 months follow up

Other measures
1. Demographic data collected at baseline only
2. Clinical characteristics, including general ability of the person with an intellectual disability measured using the Adaptive Behaviour Scale-Short Version (ABS-S) at baseline only
3. Mental health status measured using the Moss Psychiatric Assessment Schedules (Moss-PAS (ID); formerly known as mini PAS-ADD), at baseline only
4. Adverse Events will be collected at 4 and 9 months follow up
5. Other therapies received by participant will be collected at baseline only
6. Staffing per team will be collected at baseline only

Previous secondary outcome measures:

1. Episodes of physical aggression measured using the Behaviour Problems Inventory-short (BPI-S) at baseline, and 4 and 9 months follow up
2. Mental health status measured using the Moss Psychiatric Assessment Schedules (Moss-PAS (ID); formerly known as mini PAS-ADD), at baseline, and 4 and 9 months follow up
3. Risk measured using the Threshold Assessment Grid (TAG) at baseline, and 4 and 9 months follow up
4. Family carer and paid carer confidence in managing aggression measured using the Difficult Behaviour Self-Efficacy scale at baseline, and 4 and 9 months follow up
5. Family carer wellbeing measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at baseline, and 4 and 9 months follow up
6. Family carer Social Care Related Quality of Life measured using the Adult Social Care Outcomes Toolkit (ASCOT) at baseline, and 4 and 9 months follow up
7. Paid and family carer distress measured using the Kessler Psychological Distress Scale (K6) at baseline, and 4 and 9 months follow up
8. Service use and medications measured using the Client Service Receipt Inventory (CSRI) at baseline, and 4 and 9 months follow up
9. Adult with intellectual disability health-related quality of life measured using the EuroQoL five Dimensions Scale (EQ-5D) proxy at baseline, and 4 and 9 months follow up
10. Demographic data collected at baseline only
11. Clinical characteristics, including general ability of the person with an intellectual disability measured using the Adaptive Behaviour Scale-Short Version (ABS-S) at baseline, and 4 and 9 months follow up
12. Adverse Events measured using data recorded in the study log at baseline, 4 and 9 months follow up

Completion date
31/05/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 09/06/2023:

1. Aged 18 years or over
2. Living in the community (e.g., residential care home, supported living, family home)
3. Registered with and/or eligible to receive support from community learning disabilities services
4. Incidents of physical aggression to people or property for at least 3 months. It is likely that people will have several additional comorbid behaviours such as verbal aggression, mental health problems, self-injury, stereotypies etc.
5. Consent to participate provided in keeping with UK capacity legislation or assent from family /nominated consultees for those lacking capacity
6. Family carer/other member able to understand English

Previous inclusion criteria:

1. Aged 18 years old and over living in the community
2. Being under the care of a community intellectual disability service
3. Having a diagnosis of intellectual disability diagnosis by community intellectual disability

service
4. Weekly incidents of physical aggression to people or property over 3 months
5. Consent to participate provided in keeping with UK capacity legislation or assent from their family/nominated consultees for those lacking capacity
6. Family carer able to understand English or questionnaire version available in the participant's language.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
204

Key exclusion criteria
Current exclusion criteria as of 09/06/2023:

1. Currently being an inpatient
2. Alcohol or drug dependent
3. Current enrolment in another clinical trial

_____

Previous exclusion criteria:

1. Not having an intellectual disability diagnosis
2. Alcohol or drug dependent
3. Current enrolment in another clinical trial

Date of first enrolment
26/01/2024

Date of final enrolment
31/07/2025

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
North London NHS Foundation Trust
4th Floor, East Wing
St. Pancras Hospital
4 St. Pancras Way
London
England
NW1 0PE

Study participating centre
Devon Partnership NHS Trust
Wonford House Hospital
Dryden Road
Exeter
England
EX2 5AF

Study participating centre
Norfolk Community Health and Care NHS Trust
Norwich Community Hospital
Bowthorpe Road
Norwich
England
NR2 3TU

Study participating centre
South Eastern Health and Social Care Trust
Trust Headquarters Ulster Hospital
Upper Newtownards Road
Dundonald

Belfast
Northern Ireland
BT16 1RH

Study participating centre
Western Health and Social Care Trust
Mdec Building
Altnagelvin Area Hospital Site
Glenshane Road
Londonderry
Northern Ireland
BT47 6SB

Study participating centre
Southern Health and Social Care Trust
Southern Area College of Nursing
Craigavon Area Hospital
68 Lurgan Road, Portadown
Craigavon
Northern Ireland
BT63 5QQ

Study participating centre
Hounslow and Richmond Community Healthcare NHS Trust
Thames House
180-194 High Street
Teddington
England
TW11 8HU

Study participating centre
Lincolnshire Partnership NHS Foundation Trust
St George's
Long Leys Road
Lincoln
England
LN1 1FS

Study participating centre
East London NHS Foundation Trust
Robert Dolan House

9 Alie Street
London
England
E1 8DE

Study participating centre
Leicestershire Partnership NHS Trust
Room 100/110 Pen Lloyd Building
County Hall
Leicester Road
Leicester
England
LE3 8RA

Study participating centre
Oxford Health NHS Foundation Trust
Littlemore Mental Health Centre
Sandford Road
Littlemore
Oxford
England
OX4 4XN

Study participating centre
Bradford District Care Trust
Lynfield Mount Hospital
Heights Lane
Bradford
England
BD9 6DP

Study participating centre
Yourhealthcare Community Interest Company
Hollyfield House
22 Hollyfield Road
Surbiton
England
KT5 9AL

Study participating centre

North East London NHS Foundation Trust
West Wing
C E M E Centre
Marsh Way
Rainham
England
RM13 8GQ

Study participating centre
Tees, Esk and Wear Valleys NHS Foundation Trust
Trust Headquarters
West Park Hospital
Edward Pease Way
Darlington
England
DL2 2TS

Study participating centre
Berkshire Healthcare NHS Trust Headquarters
Skimped Hill Lane
Bracknell
England
RG12 1LH

Study participating centre
Norfolk and Suffolk NHS Foundation Trust
County Hall
Martineau Lane
Norwich
England
NR1 2DH

Study participating centre
Hertfordshire Partnership University NHS Foundation Trust
The Colonnades
Beaconsfield Close
Hatfield
England
AL10 8YE

Study participating centre

Cambridgeshire and Peterborough NHS Foundation Trust
Elizabeth House,
Fulbourn Hospital
Fulbourn
Cambridge
England
CB21 5EF

Study participating centre
Pennine Care NHS Foundation Trust
225 Old Street
Ashton-under-lyne
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OL6 7SR

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

Study participating centre
Northamptonshire Healthcare NHS Foundation Trust
St Marys Hospital
77 London Road
Kettering
England
NN15 7PW

Study participating centre
NHS South East London Icb - 72q
160 Tooley Street
London
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SE1 2TZ

Sponsor information

Organisation
North London NHS Foundation Trust

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research (NIHR) Programme Grant for Applied Research (PGfAR)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		08/11/2025	30/06/2026	Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes