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Early Positive Approaches to Support (E-PAtS) for families of young children with intellectual disability: a randomised controlled trial

Submission date
03/08/2023

Recruitment status
Recruiting

Registration date
10/08/2023

Overall study status
Ongoing

Last Edited
22/01/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Children with intellectual disability (ID) find learning and developing everyday skills hard. They can also have more behavioural and emotional problems than other children. Parents/caregivers of children with ID also often have emotional problems. Parents/caregivers of children with ID may need support to look after their wellbeing and help their child. Early Positive Approaches to Support (E-PAtS) is an 8-session group programme. It was developed by parents/caregivers and professionals working together. A parent/caregiver and a professional run each session. It helps parents/caregivers learn things to support their own wellbeing and support their child with ID. We want to test if E-PAtS improves wellbeing for parents/caregivers who have a child (0 months to <7 years) with Intellectual Disability (ID). We also want to test if E-PAtS is good value for money and is delivered as planned. We also want to explore the experiences of families and facilitators.

Who can participate?
A parent/caregiver can participate if they have at least one child with an ID (a child with additional developmental needs) who is no younger than 18 months, and no older than 6 years of age. The parent/caregiver needs to be ≥ 18 years old, needs to have a sufficient level of English language enabling (verbal) completion of outcome measures and is able to provide informed consent.
A parent/caregiver is unable to participate if:
· The identified child with ID is in a 24hr residential placement
· The identified child with ID is in a foster placement due to end before the 12-month post-randomisation follow up data collection point
· Parent/caregiver is enrolled at baseline in a group or individually-delivered parenting programme outside of the study
· Parent/caregiver is enrolled in a programme of personal psychological therapeutic support at baseline
· Parent/caregiver in the family has already participated in an E-PAtS group
· There are current child protection concerns relating to the identified child with ID that have been identified by professionals/services and indicated to programme facilitators or their host

organisation at the point of recruitment
· The family are recognised to be in a state of current crisis and unable to cope/a score of 8-10 on the 10-point Brief Family Distress Scale

What does the study involve?
Potential participants will be informed about the study initially by the service providers and provided with a study summary information sheet. Potential participants will be screened to check if they are eligible to take part in the study. This involves a telephone conversation with a researcher who will ask questions to ensure the eligibility of the potential participant. If eligible, the potential participant will provide their consent to take part in the study. The participant will be asked to complete some questionnaires at baseline. The participant will be randomised to receive either the E-PAtS programme (plus usual practice) or receive usual practice (with the option to enrol on the E-PAtS programme after 12 months of being in the study). All participants will complete questionnaires again at 4 and 12-months post randomisation. Participants are also given the choice to take part in interviews to ask about their experience of taking part in the research, and their experience of E-PAtS (if they have attended a group).

What are the possible benefits and risks of participating?
The E-PAtS programme has been designed in collaboration with family carers, practitioners, and researchers from across the UK. The programme is designed to provide useful information, support, and strategies for families who have children with additional needs and may therefore be useful for you if you are selected to attend the sessions (or decide to attend these at a later point).
Because E-PAtS is a new programme, we do not know yet if it will benefit participants. By taking part in this study, participants will be helping answer whether the E-PAtS group sessions are beneficial to parent/caregivers of children with additional developmental needs. The results of this study may benefit parent/caregivers of children with additional developmental needs in the future.
Whether or not participants take part in an E-PAtS group, they will be asked to spare some time to fill out questionnaires. The questionnaires and E-PAtS group sessions include positive things but will also ask participants to reflect on challenges they may face with their child. However, it is not thought that taking part in the study will pose any risk to parents/caregivers or their children.

Where is the study run from?
The study is being led/sponsored by researchers at the University of Kent and is being conducted with the Centre for Trials Research at Cardiff University (UK).

When is the study starting and how long is it expected to run for?
April 2023 to November 2026

Who is funding the study?
The study is being funded by the Public Health Research (PHR) programme of the National Institute for Health Research (NIHR) (UK).

Who is the main contact?
The trial manager at the Centre for Trials Research: E-PAtStrial@cardiff.ac.uk

Contact information

Type(s)

Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

National Institute for Health and Care Research (NIHR)
150724

Study information

Scientific Title
A cluster randomised controlled trial of Early Positive Approaches to Support (E-PAtS) for families of young children with intellectual disability (E-PAtS RCT)

Acronym
E-PAtS

Study objectives
The Early Positive Approaches to Support (E-PAtS) group programme was designed for and with families of children with ID to improve psychosocial outcomes for parents/caregivers and developmental outcomes for children and to directly address gaps in research and services. A NIHR-PHR funded feasibility trial of E-PAtS (1), satisfied progression criteria, found E-PAtS was received favourably by parents and was associated with improvements in parent wellbeing. The current study will determine whether E-PAtS can be used as a low-cost public health intervention across the UK to improve health and social outcomes for parents/caregivers and their children with ID.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/08/2023, Tizards Ethics Committee (The Registry, University of Kent, Canterbury, CT2 7NZ, United Kingdom; +44 (0)1227 764000; lssjethics@kent.ac.uk), ref: 0897

Study design
Multi-centre two-arm cluster randomized wait-list control trial with embedded process and economic evaluations

Primary study design
Interventional

Study type(s)
Other

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

Interventions
When consent and baseline measures have been collected for all participants within each family, the family will be randomised to E-PAtS and UP or UP and waitlist control. Participating families will be allocated to intervention or control on a 1:1 basis. Families will be randomised in batches of 6 to 16 two weeks before the planned E-PAtS program starts at each service provider, using randomly-permuted blocks of varying sizes to reduce imbalance within each service provider.

The E-PAtS course consists of 8 x 2.5-hour sessions. The E-PAtS intervention is a manualised programme, and all facilitators will be trained in the programme content and all sessions must contain course content, detailed in the manual.

Intervention Type
Behavioural

Primary outcome(s)
Warwick-Edinburgh Mental Well-Being Scale to measure parental/caregivers mental wellbeing (38) at 12 months post-randomisation. Measured at baseline, months 4 and 12 post randomisation.

Key secondary outcome(s))
Parents/Caregivers:
1. Perceptions of parenting: 7 efficacy subscale items from the Parenting Sense of Competence Scale; Measured at baseline, months 4 and 12 post randomisation
2. Parental/caregiver anxiety and depression: Hospital Anxiety and Depression scale; Measured at baseline, months 4 and 12 post randomisation

Children:
1. Adaptive development: The GO4KIDDS Brief Adaptive Scale adapted to include an additional communication item; Measured at baseline, months 4 and 12 post randomisation
2. The Strengths and Difficulties Questionnaire (completed by parents/caregivers of children 2 years and above); Measured at baseline, months 4 and 12 post randomisation
3. Single Sleep question from Millennium Cohort Survey Measured at baseline, months 4 and 12 post randomisation

Families:
1. Family functioning: Family APGAR scale; Measured at baseline, months 4 and 12 post randomisation

Support:
1. Support for family: Family Support Scale. Measured at baseline, months 4 and 12 post randomisation

The health economics evaluation will utilise:
1. Parent health-related quality of life (EQ-5D-5L; Measured at baseline, months 4 and 12 post randomisation
2. Client Service Receipt Inventory (CSRI) [Feasibility study] modified. Measured at baseline, months 4 and 12 post randomisation

Completion date
30/11/2026

Eligibility

Key inclusion criteria
First parent/caregiver:
1. With at least one child with an ID aged 18 months to 6 years
2. The identified child with ID meets the following:
3.1. Has a diagnosis or in process of exploring a diagnosis or presentation related to intellectual and/or developmental disability – including but not restricted to Learning Disability, Global Developmental Delay, Autism, Pervasive Developmental Delay or Special Educational Needs
AND
3.2. Has a standard composite score on the Domain-level version of the Vineland Adaptive Behaviour Scales III Domain Version of <80
4. Available to attend the E-PAtS intervention
5. ≥18 years old
6. Has sufficient level of English language enabling (verbal) completion of outcome measures
7. Able to provide informed consent

Second parent/caregiver:
1. ≥18 years old
2. Have sufficient level of English language enabling (verbal) completion of outcome measures
3. Has at least weekly contact with the identified child with ID
4. Able to provide informed consent

Participant type(s)
Carer, Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
18 months

Upper age limit
6 years

Sex
All

Total final enrolment
0

Key exclusion criteria
First parent/caregiver:
1. The identified child with ID is in a 24hr residential placement

2. The identified child with ID is in a foster placement due to end before the 12-month post-randomisation follow-up data collection point
3. Parent/caregiver enrolled at baseline in a group or individually-delivered parenting programme outside of the study
4. Parent/caregiver enrolled in a programme of personal psychological therapeutic support at baseline
5. Parent/caregiver in the family has already participated in an E-PAtS group
6. There are current child protection concerns relating to the identified child with ID that have been identified by professionals/services and indicated to programme facilitators or their host organisation at the point of recruitment
7. The family are recognised to be in a state of current crisis and unable to cope/a score of 8-10 on the 10-point Brief Family Distress Scale

Second parent/caregiver:
1. Enrolled at baseline in a group or individually delivered parenting programme outside of the study
2. Enrolled in a programme of personal psychological therapeutic support at baseline
3. Has already participated in an E-PAtS group

Date of first enrolment
01/09/2023

Date of final enrolment
30/11/2026

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Wales

Study participating centre
University College London
Wing B
Maple House
Tottenham Court Road
London
England
W1T 7NF

Study participating centre

University of South Wales
Faculty of Life Sciences and Education
University of South Wales
Pontypridd
Wales
CF371DL

Study participating centre
Ulster University
2-24 York Street
Belfast
Northern Ireland
BT15 1AP

Sponsor information

Organisation
University of Kent

ROR
https://ror.org/00xkeyj56

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research NIHR150724

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 available upon request from E-PAtSTrial@cardiff.ac.uk.
-The name of the investigator/body who should be contacted for access to the datasets: University of Kent
-The type of data that will be shared: pseudonymised participant level data
-Dates of availability: From July 2027
-Whether consent from participants was required and obtained: yes required and obtained
-Comments on data anonymization: pseudonymised
-Any ethical or legal restrictions: none known

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes