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Personalised interventions for parents who have children with behaviour problems

Submission date
01/11/2021

Recruitment status
No longer recruiting

Registration date
07/02/2023

Overall study status
Ongoing

Last Edited
11/07/2025

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 aim of this study is to test two new interventions which are designed to help parents who are having difficulty in managing their child's behaviour. Persistent disruptive behaviour is a common problem in childhood and is associated with poor outcomes into adulthood. Parenting programmes have been shown to be effective in helping some families manage difficult behaviour but a significant number of families cannot engage with group training for a number of reasons, or do not show meaningful improvements despite attending. Our previous work has shown that many families would prefer a more personalised approach to treatment that better reflects their child's problems and their family circumstances. This study aims to explore two new approaches which are conducted on a one-to-one basis and therefore offer far more personalised help. A randomized controlled trial will test the effectiveness of Personalised Programmes for Children (PPCP) compared to a waiting-list condition, prior to implementation of the Parent-Led Education and Support (PLES) intervention. Following this, the effectiveness of the PLES intervention will also be assessed.

Who can participate?
We will be recruiting parents or carers who have children aged between 4 and 9, who have previously tried parent training courses but not found them to be helpful for their child's behaviour problems, or parents who were offered group training but did not want to join a group for whatever reason. Recruitment will be from North and South London.

What does the study involve?
Potential participants will be recruited from Child and Adolescent Mental Health Services, or Local Authorities or other community services managed by or working with publicly funded organisations. They will be identified as parents or carers who are still in need of help despite having considered other options. Parents who agree to take part will be asked some questions about their child to determine whether their problems are still current, and that they are therefore eligible to take part in the trial.

All the families in the study will receive a detailed assessment of their child's behaviour and of various aspects of parent and family functioning. They will then be randomly allocated to one of the two treatments.

Those allocated to Parent-Led Education and Support (PLES) will be provided with a range of information and materials that they can refer to as well as an online parenting programme. They will also be supported by a CAMHS (Child & Adolescent Mental Health Service) practitioner who will answer any questions they might have, who will meet with them every 2 to 3 weeks.

Families allocated to The Personalised Programme for Children and Parents (PPCP) will be contacted by one of our therapists and will meet with them over a period of 16 weeks.

Towards the end of the trial, the assessments will be done again with both groups to see how effective the treatments have been.

What are the possible benefits and risks of participating?
There are many potential benefits to taking part in this study. Firstly, it is hoped and anticipated that families will benefit from both interventions, in terms of a decrease in behaviour problems among their children, and an increase in their confidence and ability to manage stressful situations when they arise, and enhancement of their parenting skills. A decrease in the incidence of stressful behaviour is also likely to have beneficial effects on the parents' own mental health.

It is possible that some participants might feel upset while discussing topics related to parental and child mental health, but therapists will be trained to provide appropriate practical and emotional support.

Where is the study run from?
The study is being run from the Tavistock and Portman NHS Foundation Trust, London, UK.

When is the study starting and how long is it expected to run for?
October 2021 to August 2025

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
268597

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 268597, CPMS 51636

Study information

Scientific Title
Randomised controlled trial testing two personalised assessment and intervention packages for children with conduct problems aged 4 - 9 years in child mental health services

Acronym
PPC RCT

Study objectives

Will a personalised package of treatment (PPCP) for children with conduct and oppositional problems and their parents and carers who have declined or not responded to or for whatever reason cannot engage in a group approach, lead to improved clinical and cost benefit outcomes when compared to no treatment (16 week waiting list group)?
Will PPCP be better than parent-led education and support (PLES)?
Is PLES itself an effective intervention?
How cost-effective are either of the proposed interventions?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/03/2022, HRA and Health and Care Research Wales (HCRW) (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2545; hra.approval@nhs.net), ref: 22/NW/0005

Study design
Multi-centre waiting list randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Conduct disorder and/or oppositional disorder in children aged 4 to 9 years

Interventions
The Personalised Programme for Children and Parents (PPCP) is a manualised programme based on evidence-based theories, including social learning and attachment theory which is delivered over 16 weeks and which is adjusted and tailored according to parental feedback. Detailed assessment of child problems and related family issues provide the basis for developing the intervention.

The Parent-Led Education and Support (PLES) intervention commences after a waiting-list period of 16 weeks. It provides parents with a range of self-administered formats and information with additional advice being provided by a CAMHS practitioner. They are also given access to an online parenting programme covering key skills that have been shown to be effective in reducing child behaviour problems.

Randomisation
Each participant will be allocated a unique, anonymised ID number generated by an independently monitored computer system set up by the accredited Clinical Trials Unit at King's College (KCTU), London. This number will be passed on to the Randomisation Team at the KCTU, who will inform the Trial Co-ordinator of the outcome of allocation. This will be communicated to the trial's senior clinical supervisor, who will then arrange for either a PPCP therapist (intervention arm) or PLES therapist (comparison arm) to make contact with the allocated participant in order to communicate the next steps. Other members of the research team (including the Chief Investigator, statistician and research workers) will remain blind to participant allocation status. Intervention delivery for the PPCP arm of the trial will begin as soon as possible after allocation and continue for 16 weeks. Delivery of the PLES intervention will take place after participants have been on a 16 week waiting list. Participants will continue to receive usual services.

Intervention Type
Behavioural

Primary outcome measure
Child mental health measured using The Parent Account of Child Symptoms (PACS) interview with parent at baseline and at 16 weeks post-randomisation for both arms of the trial. This comparison will inform the primary efficacy objective (PPCP arm versus Waiting List). The PACS will also be employed at 32 weeks (end of treatment for the PPCP arm and start of treatment for the PLES arm), and again at 48 weeks post randomisation for the PLES arm. This design allows for longer-term follow-up of the active treatments (PPCP and PLES).

Secondary outcome measures
Baseline Assessment = T1
16 weeks following randomisation = T2
32 weeks following randomisation = T3
48 weeks following randomisation = T4 (N.B. PLES arm only)

Child mental health & behaviour:
1. Visual Analogue Scale (VAS) parent interview T1, T2, T3, T4
2. Strengths & Difficulties Questionnaire (SDQ) parent questionnaire at T1, T2, T3, T4
3. Strengths & Difficulties Questionnaire (SDQ) teacher questionnaire at T1 only for both PLES and PPCP
4. Eyberg Child Behaviour Inventory (ECBI) parent questionnaireat T1, T2, T3, & T4
5. Affective Reactivity Index (ARI-P) parent questionnaire at T1, T2, T3, T4
6. Child quality of Life assessment (CHU9D) parent questionnaire at T1, T2, T3, T4
7. York Assessment of Reading for Comprehension (YARC) at T1, T3, T4

Parental mental health:
8. Generalised Anxiety Disorder Assessment (GAD-7) parent questionnaireat T1, T2, T3 & T4
9. Patient Health Questionnaire (PHQ-9) parent questionnaireat T1, T2, T3 & T4

Parenting and relationships:
10. Quality of Attachment Relationships Questionnaire (QUARQ) parent questionnaire at T1, T2, T3 & T4
11. Short Alabama Parenting Questionnaire (APQ) parent questionnaire at T 1, T2, T3 & T4
12. Self-efficacy Parenting Scale (SEPS) parent questionnaire at T1, T2, T3 & T412. You and Your Partner (Moffitt) parent questionnaireat T1, T2, T3 & T4

13. Attachment and Parenting: Observation of parent-child interaction directed by researcherat T1 & T4 for the PLES arm, and T1 & T3 for the PPCP arm
14. Child and Adolescent Services Use Schedule (CA-SUS) at T1, T2, T3 & T4
15. Confusion, Hubbub and Order Scale (CHAOS) parent questionnaireat T1 & T3 for the PPCP arm, and T1 & T for the PLES arm

Overall study start date
01/10/2021

Completion date
31/08/2025

Eligibility

Key inclusion criteria
Families who have a child (aged between 4 and 9 years) with behavioural difficulties, who have either attended a parenting group and not found it helpful, or who were offered a group but were unable to attend for whatever reason.

Participant type(s)
Other

Age group
Child

Lower age limit
4 Years

Upper age limit
9 Years

Sex
Both

Target number of participants
246

Key exclusion criteria
1. Child has significant developmental delay.
2. Parents have marked difficulty in understanding of spoken and written English so that assessment with standard research instruments is not possible.
3. Parents lack the capacity to give informed consent to participate.
4. Child has a confirmed diagnosis of autism spectrum disorder.
5. Child is the subject of a Child Protection Plan

Date of first enrolment
07/02/2023

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Tavistock and Portman NHS Foundation Trust
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Study participating centre
Kings College London
Institute of Psychology, Psychiatry and Neuroscience
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SE5 8AF

Sponsor information

Organisation
The Tavistock and Portman NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website

https://www.noclor.nhs.uk

ROR
https://ror.org/04fx4cs28

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

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

Publication and dissemination plan
Planned publications in high-impact peer-reviewed journals.

Intention to publish date
30/04/2025

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

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 file	version 3.0	20/12/2022	06/02/2023	No	No
HRA research summary			28/06/2023	No	No