APPENDIX 2

HRA PROTOCOL COMPLIANCE DECLARATION:

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

FULL/LONG TITLE OF THE STUDY

COMPARISON OF TWO PERSONALISED ASSESSMENT AND INTERVENTION PACKAGES FOR CHILDREN WITH CONDUCT PROBLEMS AGED 4-9 IN CHILD MENTAL HEALTH SERVICES

SHORT STUDY TITLE / ACRONYM

THE PPC Study

PERSONALISED PROGRAMMES FOR CHILDREN

PROTOCOL VERSION NUMBER AND DATE

VERSION 6.0 12.02.25

RESEARCH REFERENCE NUMBERS

IRAS ID Number: 268597

SPONSORS Number: S-434-1793

FUNDERS Number: LTC-RP PG 0814-20001

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol, Good Clinical Practice, The UK Data Protection Act 2018 and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's Standard Operating Procedures (SOPs) and King's College London Clinical Trials Unit SOPs, and other regulatory requirements.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:
Signature:

Date:
Priscilla Essuman..... 15/08/2024

Name (please print):

Priscilla Essuman
.....

Position:

Sponsorship Manager (Noclor on behalf of Tavistock and Portman NHS Foundation Trust)

Chief Investigator:

Signature: Date:

Rob Senior 15/08/2024
.....

Name: (please print):

Dr Rob Senior
.....

KEY STUDY CONTACTS

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Joint-sponsor(s)/co-sponsor(s)	N/A
Funder(s)	NIHR (PGfAR)
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Committees	The Study Steering Committee will be comprised of a UK based independent chair, independent statistician, health economist and clinician, and a PPI representative. This committee will meet 4-6 monthly.

STUDY SUMMARY

Study Title	Personalised assessment and intervention packages for children with conduct problems in Child Mental Health Services.
Internal ref. no. (or short title)	PPC
Research Questions/Aims	1. Conduct an RCT to evaluate the efficacy of a new intensive home-based intervention for children with conduct problems, called the *Personalised Programme for Children and Parents* (PPCP) which is an individual family approach which is adapted, or personalised, to the specific needs and circumstances of each family in comparison to a waiting list control group. 2. As a secondary analysis, to compare a less intensive intervention, the *Parent-led Education and Support* (PLES) which is a package of resources and support, against the waiting list. 3. A further secondary analysis is to compare the PPCP with the PLES. The specific research questions to be assessed are: – Primary research question: (i) Is PPCP an effective intervention for persistent conduct problems? Secondary research questions: (ii) Is the intensive

	PPCP intervention more effective than the low-level PLES intervention? (iii) Is the low-level intervention, PLES, effective? (iv) Are either of the two interventions cost-effective?
Study Participants	Parents of children aged 4 to 9 with significant conduct or oppositional difficulties who have been referred to structured parenting groups but have declined, dropped out or whose children have not responded and those who for whatever reason cannot engage in a group approach.
Planned Size of Sample (if applicable)	248 parent-child dyads
Follow up duration (if applicable)	Follow-up will be16 weeks and 32 weeks following the commencement of the intervention in each trial arm.
Planned Study Period	1 October 2022 – 31 August 2025 (delayed start due to Covid)

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIAL SUPPORT GIVEN**
NIHR Programme Grants for Applied Research	

ROLE OF STUDY SPONSOR

The sponsor is responsible for confirming that the study design has integrity, the resources required for initiation are secured, all applicable regulatory approvals have been received before commencement, and that arrangements are in place for monitoring and reporting to ensure research conduct is in compliance with Good Clinical Practice (GCP) and all applicable laws and regulations. The sponsor will also confirm that there is a clear dissemination and data retention plan once the study has closed.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS/FUNDER

Study Steering Group/Funder

The Study Steering Committee (SSC) will provide overall supervision for the project on behalf of the Project Sponsor and Funder to ensure that the project is conducted to the rigorous standards set out

in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice. It will include an independent chair, PPI representatives, and independent clinicians and academics who will meet every 4-6 months. These will report to NIHR and the sponsor as required. Due to the very low probability of adverse events, we have confirmed with NIHR that no Data Monitoring and Ethics Committee (DMEC) is required.

There will also be ongoing communication every 6-8 months with 'internal' PPI advisory groups consisting of children and young people and their parents, and an 'external' Stakeholder advisory group composed of external user organisations.

PROTOCOL CONTRIBUTORS

Dr Rob Senior: study design and overall management, manual writing, training and dissemination.
Professor Stephen Scott: study design, manual writing, data analysis, training and dissemination.
Professor Jonathan Hill: study design, data analysis and dissemination.
Dr Eilis Kennedy: study design, manual writing and dissemination.
Professor Sabine Landau: study design and statistical input.
Jackie Briskman: study co-ordination, training, data management and dissemination

KEY WORDS:

Conduct disorder
Oppositional Defiant Disorder
Parent training
Personalisation
Randomised Controlled Trial

PERSONALISED PROGRAMMES FOR CHILDREN

STUDY PROTOCOL

PERSONALISED PROGRAMMES FOR CHILDREN

1 BACKGROUND

There is substantial evidence that conduct problems developing early in life commonly persist, and lead to adolescent violence, personality disorders, psychiatric disorders and substance misuse (1). Parent[1] training delivered in groups is effective, and can make a substantial difference for many children with these problems (2). However parent training may be undermined by a particularly challenging combination of circumstances, namely, a treatment that requires commitment and organisation from parents, combined with high levels of disorganisation in the families associated with multiple vulnerabilities. Problems with uptake are evidenced by 30–68 % of families with children with conduct problems declining to take part in available programmes (3, 4); out of 60% of families interested in Parent Training Programmes in the UK, only 4–18 % are estimated to have taken them up (5): even where families take up the offer of a programme, dropout rates are estimated at up to 40% (6, 7). A recent meta-analytic synthesis of published qualitative studies examining barriers to and facilitators of parenting programmes has identified a number of explanations for non-participation ranging from parents' frustrations about the time constraints and practical difficulties of committing to lengthy group based programmes to requests that programmes are more flexible and individually tailored (8). Addressing the problem of limitations in the reach of parent training has been identified as a key research priority in the recent NICE guideline on conduct disorders (9).

Conduct problems are associated with poor economic circumstances, marital discord, parental mental health problems, and parental hostility (10). While these associations do not demonstrate causality, there is evidence that each is associated with poorer outcome from parenting programmes for conduct problems (11). In a systematic review of predictors of poor outcome for parent training low socioeconomic status had a large effect size. The role of low socioeconomic status in relation to parent training is poorly understood. To some extent it may simply be an easily measured proxy for other family vulnerabilities that contribute to difficulties in making use of the training, but theories also postulate effects of economic pressure on parental well-being and coping. Practically, inadequate finances may make getting to parent training groups more difficult.

The same review also identified maternal mental health to be a particularly salient environmental factor associated with treatment failure (11). The importance of parental mental health in the development and maintenance of conduct problems is recognised in the recent NICE guidelines which recommends as a key research priority evaluating whether combined interventions also targeting parental mental health improve child outcomes (9). Inter-parental conflict and parental criticism of the child are also well established factors predicting poor outcome (12).

[1] For the purpose of this protocol, the use of 'parent' will encompass parents, caregivers, and guardians that reside with the child.

In addition to the problems related to the acceptability of parent training, it is increasingly clear that a 'one size fits all' model of intervention fails to take into account individual differences and that sub-groups of children may require different treatment approaches tailored to their particular needs. Updating Parent Training Programmes to take account of this evidence is another major focus of this programme of research. Current Parent Training Programmes despite their widespread implementation in the NHS have remained largely unchanged since they were initially developed in the 1980's. Examples of this clinical heterogeneity in children with conduct problems identified in recent research, much of it undertaken by the applicants, includes:

1. There is now extensive support for the subtyping of conduct problems based on the presence of high versus low levels of Callous-Unemotional (CU) traits (13) and the emerging pattern of distinct neurocognitive vulnerability to anti-social behaviour in children with high vs. low levels of CU traits indicates that interventions can be tailored to suit the specific profile of atypical affective processing that characterises each group of children (14).Children with high CU traits appear genetically vulnerable to anti-social behaviour and are relatively insensitive to punishment, threat and others' distress. There is some evidence that parent training is less effective for children with high CU traits and this may be because of an insensitivity to certain critical components of traditional behavioural approaches. Although CU traits have recently been introduced as a specifier for children who meet the diagnostic criteria for conduct disorder in DSM-5 it is clear that CU traits represent a risk for poor treatment outcomes for children with milder conduct problems (ODD) as well as more severe Conduct Disorder (15).Despite the association with poorer treatment outcomes recent systematic reviews have concluded that there is evidence of durable change in CU traits in response to Parent Training Programmes particularly when delivered in early childhood (16) and that approaches which are flexible and personalised are likely to work best (16). RCT evidence suggests that modifying current Parent Training Programmes to introduce adjunctive components that explicitly target deficits related to CU traits can significantly enhance parent training outcomes (17).

2. In contrast, children with low CU Traits are more commonly exposed to harsh and inadequate parenting (10), so interventions focusing on systemic factors such as social adversity are more likely to be beneficial and such children are likely to be sensitive to traditional disciplinary strategies employed in parenting programmes (12).

In view of the many reasons for poor outcomes from parent training there is a strong case for using ideographic approaches to understanding the processes, and for seeking to establish approaches to treatment that take account of the diversity of needs. Hence we conducted a programme to make personalised treatment. Recent evidence supports the value of a personalised approach. A randomised evaluation in the US found personalised approaches to depression, anxiety and conduct problems in youth to be substantially more effective and cost effective than either usual care or standard evidence-based programmes (18). Personalised approaches improved outcomes despite length of treatment being substantially shorter than usual care (children in usual care were in treatment a mean 75 days longer than personalised treatment) (18).

2 RATIONALE

As described above, we undertook the first three years of the programme grant because we were very concerned that children with conduct problems were a poorly served group who did particularly badly in terms of current functioning and longer term outlook for mental health and well-being, with particularly high rates of criminality, domestic violence, drug misuse, failure to get any educational qualifications, and unemployment with dependence on state benefits. Such individuals cost society in many ways, not only financially (estimated at £260,000 each, and over £1m in severe cases) but also in the damage they cause, recently highlighted for example in the rise of knife crime. Conduct

problems have the highest social gradient of all mental health problems in childhood, so to create a fairer, socially equitable society, they are particularly deserving of effective treatments.

Our systematic review of personalised treatments confirms that there is currently no existing personalised programme for children with conduct disorders that could be used to work with this group of children.

Our longitudinal study successfully collected pre-post data on a larger number of families than set out in the original proposal, with 150 paired sets of data. A number of key findings have emerged, which underline the need for a personalised programme for children with conduct problems.

As expected, despite enrolment in probably the best group-based parenting programme, over one third failed to make minimally useful treatment gains, so are at particularly high risk of continuing problems and a poor long-term prognosis. There is therefore a pressing need to develop a new intervention for these cases. Currently there is nothing available.

The overall treatment effect in everyday practice was somewhat modest and smaller than that which is found when well-trained and regularly supervised staff are deployed, so our new intervention will make use of experienced CAMHS personnel, train them well in the new intervention, and give them regular supervision to drive up standards, and their level of skill will be measured to ensure this.

We found that some family characteristics associated with poor outcomes in observational studies, such as depression, harsh parenting, interparental discord and socio-economic deprivation, did not predict response to treatment. This suggests that these factors do not impinge on outcomes in a linear way, but rather in a personal way, so that for example some depressed parents managed to relate to their children adequately, whereas others do not. This underlines the need to assess these risk factors individually for each family and address the risk factor if it is affecting their ability to bring up their children. Our findings are consistent with a recently published meta-analysis (Leijten et al., 2018).

The follow-up 3 months after the post-treatment assessment was illuminating. Whilst the overall mean scores were the same as at post-treatment, which could lead to the view that people improve and then stay improved, inspection of the individual scores revealed that there was considerable heterogeneity, with 35% of cases who had originally done well then declining significantly in their scores at the follow-up period. Therefore, standard treatment fails to address the needs of this group, so our new personalised programme will continue to work with families after the end of the programme for a further 3 months, checking whether they have consolidated their initial gains, and if not, offering booster sessions. This is not a characteristic of any current parenting programme for conduct problems, although such a conceptual approach is used in CBT for depression, where after initial treatment there is often a relapse prevention phase.

The qualitative research came across with a strong message that parents wanted their predicament to be understood individually. (McKay et al., 2020). In particular, they wanted their child properly assessed, feeling that they were different from other children (including their siblings) but that this had not been addressed in current practice where for the vast majority, when their children were showing behaviour problems, they were allocated directly to a parenting group. A number of the children had characteristics such as ADHD, autistic traits, and callous unemotional traits. Parents wanted to have their children directly seen by professional, and the assessment shared with them; they also wanted to feel understood about what they had tried already, what has worked and what had not worked, rather than simply being dropped into a parenting group. Children with different subtypes of antisocial behaviour with the characteristics described above require a somewhat different approach to treatment which will be incorporated in our new programme, but is not addressed by current programmes.

Another finding from the qualitative research was that some people found that either they knew what was being covered (some were being made to go on the same programme repeatedly, since the

children hadn't progressed), or that the group went too slowly for them or they had missed a session so fell behind. They wanted to go at their own pace. This is one of the reasons why our new intervention is based individually so that each family can go at their own pace; a 2nd characteristic of the new programme is that the next skill will only be taught once parents feel they have mastered the current one and been able to demonstrate this. Further, this will be measured by routine outcome measurement of each therapeutic session, so that parents immediately feedback whether they feel they have benefited, and this is documented. Then if there is failure to progress, this can be spotted quickly and addressed.

A third finding from qualitative research was that parents felt the school did not understand and that their children's difficulties at school were not being properly addressed. The new programme will therefore have a strong element of liaison with school to help parents to work more collaboratively and effectively with school by sharing elements of the assessment and considering management strategies.

A fourth finding from the qualitative research was that parents wanted to be able to communicate directly with others in the same predicament, so in a new programme we propose to set up on-line opportunities for parents to support each other.

A repeated theme from referrers to our groups was that there is a sizeable population of families who have not engaged with conventional services and were unable to get to groups. These are often the most needy families. Common reasons included being too busy to come to groups (typically, a lone parent with a number of young children to handle); shyness and suspicion of the unknown aspects of turning to a group of other people; shame on meeting them that they will be labelled as being poor parents; lack of transport to get to appointments including groups; acute financial stress meaning there was not mental headspace to think about going out to get treatment for their child; unpredictable personal stresses at home, such as a violent partner, depressive episodes, and drug misuse that made turning up to regular appointments impracticable. We believe that this group is an important one who are currently unserved by current agencies yet are some of the most disadvantaged in society. They above all need a personalised service addressing their particular problems, which will engage them by understanding the difficulties and see them at home. This was an unexpected finding but is a sizeable group so our new intervention proposes to recruit them to see if we can help, and as for all cases in the new intervention, offer home-based service with the child present, so that the quality of relationship can be directly observed and addressed, alongside helping the difficult life circumstances.

3 RESEARCH QUESTION/AIM(S)

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 (i.e. compared to end of 16 week Waiting List). 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?

3.1 Objectives

Train NHS mental health professionals to deliver the personalized approach.

Conduct a full RCT to establish whether the personalized approach is superior to parent-led education and support for those for whom group parent training did not work and those who, for whatever reason, cannot engage in a group approach.

Assess the clinical efficacy of PPCP compared to no treatment (waiting list) and as a secondary comparison its relative efficacy when compared with the low-level intervention PLES, and the efficacy of PLES compared to no treatment (waiting list).

The cost-effectiveness of both interventions will be assessed using the child and adolescent service use schedule (CA-SUS).

3.2 Study Impact

The quantitative and qualitative findings, informed by the systematic review in phases 1 and 2, provided a rationale for the personalised approach to intervention for those parents and their children who did not respond to or did not access standardised parent training. The main purpose of this next phase will be the evaluation of efficacy and cost effectiveness of our new personalised approach to intervention (PPCP) for this group of children. The primary outcome measure will be the Parent Account of Child Symptoms (PACS) semi-structured interview of conduct symptoms assessed at the end of treatment (16 weeks after randomisation). Secondary clinical outcomes about the child comprise the Eyberg Child Behavior Inventory (ECBI) for conduct problems, and the Strengths and Difficulties Questionnaire (SDQ) for general wellbeing. Parenting will be measured by the Alabama Parenting Questionnaire (APQ) and by direct observation – this the proximal target of the intervention. .If PPCP is found to be efficacious, we will seek the opportunity to roll it out in CAMHS.

In addition, this study will address the secondary objectives of assessing the relative efficacy of PPCP compares to the active control PLES, and will also use the opportunity to assess the efficacy of PLES. The same clinical outcome measures will be used for these additional purposes.

4 STUDY DESIGN

The study is a waitlist randomised controlled trial of personalised assessment and intervention for children with conduct and oppositional problems who have not benefitted from parent training, or those who for whatever reason cannot engage in a group approach, compared with no treatment (waiting list). It is a two-centre study conducted from the Tavistock Clinic and the South London and Maudsley NHS Foundation Trust.

4.1 Statistical design

The study uses a waitlist design. Participants are randomised to two trial arms: (i) 16 weeks waitlist followed by 16 weeks PLES treatment or (ii) 16 weeks PPCP treatment. The 16-week comparison between the two trial arms will inform the primary efficacy objective (PPCP vs waitlist). The design includes PLES treatment after waitlist, to enable assessment of the secondary relative efficacy objectives (PPCP vs PLES; PLES vs waitlist). Outcome assessments take place before randomisation (baseline), after 16 weeks intervention in either trial arms, and at 32 weeks after PLES intervention in the waitlist/PLES arm. Note that the 16 week assessment in the waitlist arm measures the outcome after waitlist treatment as well as providing the starting value for the PLES outcome assessment at 32 weeks.

The design allows for longer-term follow-up of the active treatments (PPCP and PLES) at 32 weeks and 48 weeks respectively. However, these extra assessments are not for the purposes of the current

trial evaluation. They are described here, but are not included in the analysis plan and will not be reported in the main trial paper.

The health economic evaluation will be a within-trial cost-consequences analysis from a societal perspective of PPCP versus a waitlist control comparator. Secondary objectives: to undertake an assessment of the potential impact of PPCP on long-term costs to the public sector arising from conduct disorder in childhood and adolescence; to undertake a within-trial cost-utility analysis of PPCP versus waitlist control from an NHS/social care services perspective.

4.2 Revised Study Plan

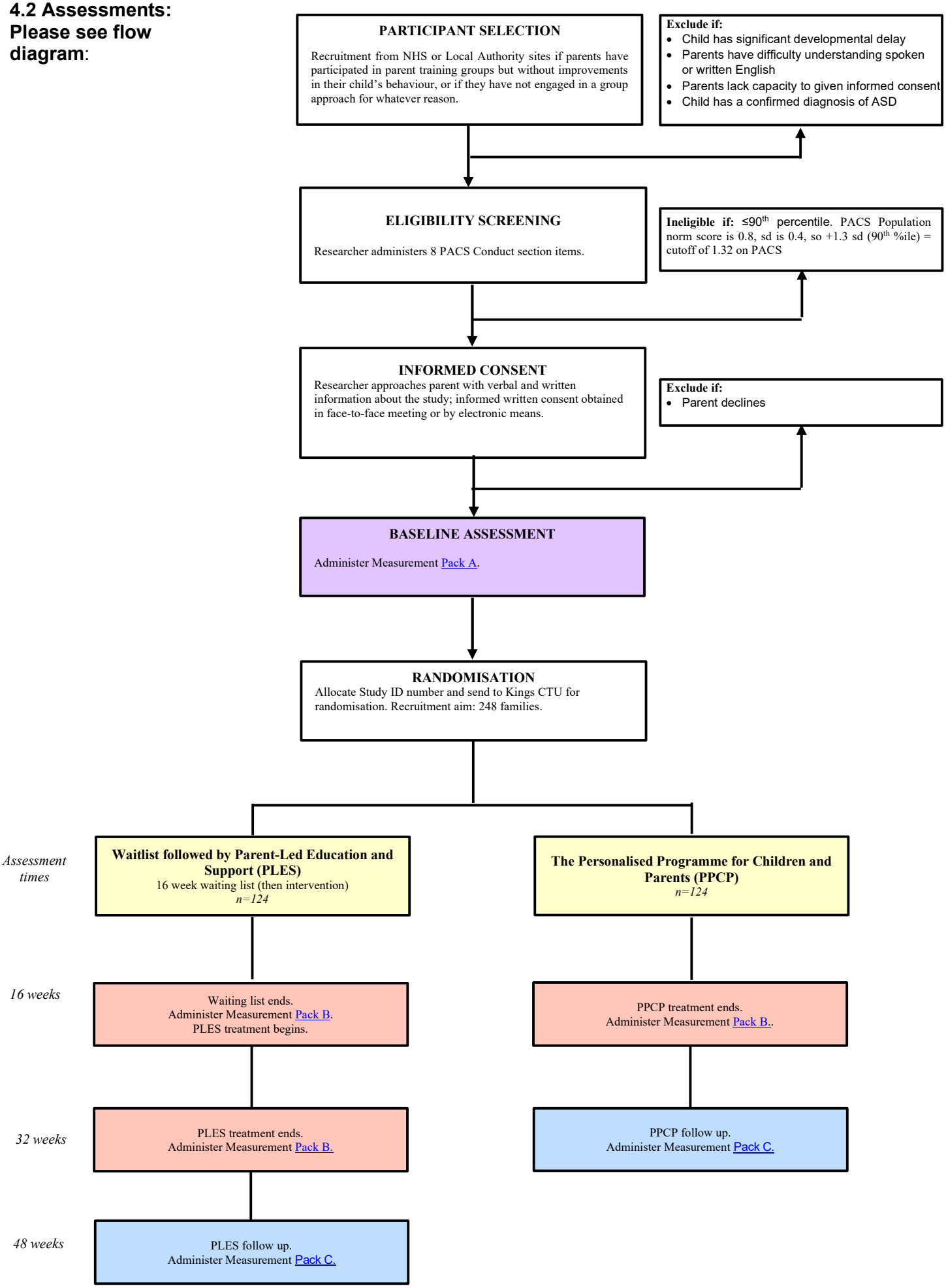
In discussion with the funder it was decided to stop recruitment on 31st August 2024 despite not reaching the intended sample size. It was agreed to follow up participants to 16 weeks and then lock these data and analyse only the 16 week outcomes as part of the NIHR funder report. We will formally report on outcome differences between PPCP and waitlist arms at 16 weeks. 32 week outcomes will be collected beyond the end of the original funding period which was 31st April 2025; data will now be collected until 31st August 2025. By necessity future analyses of differences with PLES will not be blind. Depending on attrition rates it might also be only possible to provide descriptive analyses involving the PLES arm. However, the team is committed to ultimately publishing all outcome data collected as part of this study.

By the end of December 2024, we had recorded the outcomes of 80 trial participants at the 16-week-from-randomisation stage. This means that comparisons will be made between 40 participants who have completed the PPCP intervention and 40 participants who have been on the waiting list, which is the primary outcome objective.

However, in view of the revised sample size (numbers of participants being around 30-40% of those predicted) the study may be better described as a Pilot and Feasibility Study, rather than a full RCT.

NIHR has agreed a proposal to conduct two additional qualitative interviews exploring the experience of study participants and that of the practitioners in order to optimise learning for the NHS. These will be conducted and analysed as described in Section 7.3 Process Evaluation.

4.2 Assessments: Please see flow diagram:



Measurement packages in PPC study (to be read in conjunction with trial design flowchart)		
Time (weeks)	**PLES** *Randomised to Waiting List (then PLES treatment)*	**PPCP** *Randomised to PPCP Treatment immediately*
Baseline	*A*	*A*
16 weeks	B	B
32 weeks	B	C
48 weeks	C	
A = Demographics, Economics, Baseline Outcome Variables, Putative Moderators B = Full outcomes including primary C = Full outcomes + Economics		

Measures	Focus; Child, Parent or Family	Outcome, Demographic, Clinical or Economic
<u>Questionnaires:</u>		
DSM-5 Personality Disorders (UBQ – DSM-V VERSION)	Parent	C
Adapted Affective Reactivity Index (ARI-P)	Child	C
Alcohol Use Disorders Identification (AUDIT)	Parent	C
Brief Self Efficacy Scale (BPSES)	Parent	C
Child Quality of Life Assessment (CHU9D)	Child	O
Drug Use Disorders Identification (DUDIT)	Parent	C
Parent Quality of Life (EQ-5D-3L)	Parent	E
Eyberg Child Behaviour Inventory (ECBI)	Child	O
Generalised Anxiety Disorder Assessment (GAD-7)	Parent	C
Inventory of Callous-Unemotional traits (ICU) (Parent report)	Child	O
Patient Health Questionnaire (PHQ9)	Parent	O
Quality of Attachment Relationships	Child	O
Short Alabama Parenting Questionnaire (APQ)	Parent	O
Social Communication Questionnaire (SCQ)	Child	C
Parent Strengths & Difficulties Questionnaire (SDQ)	Child	C
Teacher Strengths & Difficulties Questionnaire (SDQ)	Child	C
You and Your Partner (Moffitt) (YYP)	Parents	C
Confusion, Hubbub and Order Scale (CHAOS)	Family	C
<u>Interviews:</u>		
Child and Adolescent Services Use Schedule (CA-SUS)	Family	E
Demographic interview	Family	D
Parent Account of Child Symptoms Conduct problems section (PACS CP) PRIMARY OUTCOME MEASURE	Child	O
Parent Account of Child Symptoms Oppositional Defiance Disorder section (PACS ODD)	Child	O

Parent Account of Child Symptoms ADHD section (PACS ADHD)	Child	O
Parent Account of Child Symptoms global assessment of Expressed Emotion (EE)	Parent	O
Visual Analogue Scale of Parent Defined Problems (VAS)	Child	O
Observations:		
Observation of Parent-Child Interaction (OBS)	Family	C
York Assessment of Reading for Comprehension (YARC)	Child	O

Measures Pack A – Baseline Assessment prior to Randomisation

Adapted Affective Reactivity Index (ARI-P)
Alcohol Use Disorders Identification (AUDIT)
Child Quality of Life Assessment (CHU9D)
Child and Adolescent Service Use Schedule (CA-SUS)
Confusion, Hubbub and Order Scale (CHAOS)
Demographic interview
Drug Use Disorders Identification (DUDIT)
Eyberg Child Behaviour Inventory (ECBI)
Generalised Anxiety Disorder Assessment (GAD-7)
Inventory of Callous-Unemotional traits (ICU)
Observation of Parent-Child Interaction (OBS)
Parent Account of Child Symptoms Conduct Problems (PACS CP)
Parent Account of Child Symptoms Oppositional Defiance Disorder section (PACS ODD)
Parent Account of Child Symptoms ADHD (PACS ADHD)
Parent Account of Child Symptoms Expressed Emotion (PACS EE)
Parent Quality of Life (EQ-5D-3L)
DSM-5 Personality Disorders (UBQ – DSM-V VERSION)
Patient Health Questionnaire (PHQ9)
Quality of Attachment Relationships (QUARQ)
Brief Self Efficacy Scale (BPSES)
Short Alabama Parenting Questionnaire (APQ)
Social Communication Questionnaire (SCQ)
Parent Strengths & Difficulties Questionnaire (SDQ)
Teacher Strengths & Difficulties Questionnaire (SDQ)
Visual Analogue Scale (VAS)
York Assessment of Reading for Comprehension (YARC)
You and Your Partner (Moffitt) (YYP)

Measures Pack B: 16 weeks post randomisation both arms, repeated 32 weeks Post randomisation PLES arm only (=16 weeks after starting treatment)

Adapted Affective Reactivity Index (ARI-P)
Child Quality of Life Assessment (CHU9D)
Child and Adolescent Service Use Schedule (CA-SUS)
Eyberg Child Behaviour Inventory (ECBI)
Generalised Anxiety Disorder Assessment (GAD-7)
Inventory of Callous-Unemotional traits (ICU)
Parent Account of Child Symptoms Conduct Problems (PACS CP)

Parent Account of Child Symptoms Oppositional Defiance Disorder section (PACS ODD)
Parent Account of Child Symptoms ADHD (PACS ADHD)
Parent Account of Child Symptoms Expressed Emotion (PACS EE)
Parent Quality of Life (EQ -5D-3L)
Patient Health Questionnaire (PHQ9)
Quality of Attachment Relationships (QUARQ)
Brief Self Efficacy Scale (BPSES)
Short Alabama Parenting Questionnaire (APQ)
Parent Strengths & Difficulties Questionnaire (SDQ)
Visual Analogue Scale (VAS)
You and Your Partner (Moffitt) (YYP)

Measures Pack C: Follow Up 32 weeks after randomisation in PPCP arm, 48 weeks after randomisation in PLES arm (so for both, 16 weeks after treatment ends)

Adapted Affective Reactivity Index (ARI-P)
Child Quality of Life Assessment (CHU9D)
Child and Adolescent Service Use Schedule (CA-SUS)
Eyberg Child Behaviour Inventory (ECBI)
Generalised Anxiety Disorder Assessment (GAD-7)
Inventory of Callous-Unemotional traits (ICU)
Observation of Parent-Child Interaction (OBS)
Parent Account of Child Symptoms Conduct Problems (PACS CP)
Parent Account of Child Symptoms Oppositional Defiance Disorder section (PACS ODD)
Parent Account of Child Symptoms ADHD (PACS ADHD)
Parent Account of Child Symptoms Expressed Emotion rating (EE)
Parent Quality of Life (EQ-5D-3L)
Patient Health Questionnaire (PHQ9)
Quality of Attachment Relationships (QUARQ)
Brief Self Efficacy Scale (BPSES)
Short Alabama Parenting Questionnaire (APQ)
Parent Strengths & Difficulties Questionnaire (SDQ)
Visual Analogue Scale (VAS)
York Assessment of Reading for Comprehension (YARC)
You and Your Partner (Moffitt) (YYP)

Notes:

Measures

The PACS semi-structured interview of conduct problems is the primary outcome measure and is a more precise instrument than questionnaires. However, we have included the Eyberg Child Behaviour Inventory since it is widely used in studies across the world, particularly in the USA. The Strengths and Difficulties Questionnaire gives a more broad measure of well-being but is not a formal outcome. The Visual Analogue Scale is important since the parents define the problem so this is more personalised than the symptom count.

The Short Alabama parenting questionnaire measures the proximal target of the intervention, namely parenting style.

The measures marked C for Clinical are to help characterise the clinical nature of the sample.

Timing

The 32/48 week time points are principally for the economic evaluation and do not form part of the main study which is to compare outcomes 16 weeks after treatment.

5 METHODS of DATA COLLECTION

Assessments will be conducted on each of the two sites by two Research Assistants. Supervision and assistance will be provided by the Research Coordinator based at the Tavistock Clinic. Assessments will be completed at baseline prior to randomisation and then at 16 and 32 weeks for PPCP and 16, 32 and 48 weeks for PLES. Parents will be sent a link to an online survey (or a paper pack of questionnaires if they prefer) prior to their first meeting with the research assistants and the assistants will support their completion as required. Assessment time points are shown in the flow diagram (see section 4.2 Assessments). The primary end point is 16 weeks after the baseline assessment.

The screen will be the conduct problem sections of the Parent Account of Child symptoms interview, administered by a researcher.

Baseline assessments will include measures on: Demographics, Medical history, Child behaviour including the Primary Outcome Measure (PACS Conduct Section), and Eyberg and SDQ, Co-morbid diagnoses (PACS and SCQ), Child characteristics (ICU and YARC), Parental well-being and parental relationship (GAD-7, PHQ-9), Parenting (Alabama and Self Efficacy). Parents will be asked for their consent for researchers to make an audiovisual recording of parents and children during the Parent/Child observation interaction, and to make an audio recording of the PACS parent interview.

To compensate parents for the time they spend completing questionnaires and being interviewed, we will give them £40 of vouchers for the initial and final assessments, and £10 for completing the interim assessment. We will also refund any travel expenses they might incur as part of the study.

Subject to passing the brief eligibility screen (for which research consent is not necessary), Parents will be asked for their consent for the research project, including making contact with their child's teacher. If the parent is in agreement, we will ask teachers to complete the Strengths and Difficulties Questionnaire (SDQ) to provide a brief snapshot of any behavioural difficulties at school. If parents are reluctant for us to contact their child's teacher, then we will not make contact with the child's school. Similarly, we will give teachers the option to complete the SDQ, but there will be no pressure on them to do so. Information from the SDQ is helpful in providing additional details about the child's behaviour whilst at school, but it is not essential to the overall assessment. Information from the SDQ will also be shared with the CAMHS clinicians who will be working with families in both intervention and usual care groups.

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Assessments
QUESTIONNAIRES FILLED IN BY PARENT PRIOR TO HOME VISIT BY RESEARCHER:
a) CONCERNING CHILD (Parent report)
Strengths and Difficulties Questionnaire (Goodman 1997)
Eyberg Child Behaviour Inventory (ECBI)

Social Communication Questionnaire (SCQ) (Rutter et al, 2009)
Inventory of Callous-Unemotional Traits (ICU) (Frick, 2014)
Quality of attachment relationships questionnaire (QUARQ) (Briskman et al, 2012)
Adapted Affective Reactivity Index (Stringaris et al 2012)
Child Health Utility 9D quality of life measure (CHU9D)
b) CONCERNING PARENTS/ FAMILY
Confusion, Hubbub and Order Scale (CHAOS) (Matheny, Wachs, Ludwig, & Phillips, 1995)
Short Alabama Parenting Questionnaire (APQ) (Scott et al, 2011)
Brief Self-Efficacy Parenting Scale (Woolgar, 2015)
Generalised Anxiety Disorder Assessment (GAD-7)
Patient Health Questionnaire (PHQ-9)
Relationship with Partner (Moffitt)
Parent Personality SCID-II
Parent alcohol use (AUDIT)
Parent drug use (DUDIT)
TOTAL PARENT QUESTIONNAIRE TIME 80 minutes
QUESTIONNAIRE FILLED IN BY TEACHER
Strengths and Difficulties Questionnaire (Goodman 1997)
INTERVIEW WITH PARENT BY RESEARCHER
Parent Account of Child Symptoms Interview (PACS) include EE rating **Primary Outcome Measure** (Taylor et al., 1997)
Child and Adolescent Service Use Schedule (CA-SUS)
Visual analogue scale of 3 main concerns about child (Scott, 2001)
TOTAL INTERVIEW TIME 80 minutes
ASSESSMENT OF CHILD BY RESEARCHER 2 DURING HOME VISIT
York Assessment of Reading Comprehension (YARC)
TOTAL CHILD ALONE ASSESSMENT TIME 50 minutes
ASSESSMENT OF PARENT WITH CHILD BY RESEARCHER 2 DURING HOME VISIT
Observation of parent-child interaction (Matias et al 2014)
TOTAL PARENT-CHILD INTERACTION TIME 25 minutes

6. INTERVENTIONS

Participants will be randomly allocated to one of two groups:

Group 1: Waiting list followed by ***Parent-Led Education and support*** (PLES) designed to provide parents with support in parenting a child with persistent conduct problems. Research into parents' preferences for how to receive help indicate that many prefer self-administered formats (Metzler, Sanders et al., 2012). Following initial assessment, families randomised to this arm of the trial will wait 16 weeks and then be re-assessed before receiving the treatment. Inclusion of this waitlist period will enable the study to answer the question whether 1) the more intensive treatment is superior to no treatment (the primary aim of the trial) and also, as a secondary analysis, 2) whether the PLES intervention is superior to no treatment (waitlist). The study team will maintain close and frequent contact with the families while they are awaiting treatment and provide a contact number should they wish to speak to one of the researchers. NIHR and the programme steering committee have approved this change. Currently this population receive no treatment at all so it is felt that this is ethical. The PLES condition in this study will provide parents with a range of self-administered formats (see below) with additional advice being provided weekly by a CAMHS practitioner, in response to parents' own questions. Parents will have access to an online parenting programme which covers key aspects of parenting skills which have been shown to be effective in reducing child behaviour problems. The practitioner will be familiar with the online programme and will be available to talk over parents' questions about it. Parents will also be provided with other sources of information regarding children and their parents, such as books, and specifically prepared reading, which cover topics which are additional to the online programme and provide alternative approaches. These include reflecting on children's thoughts and feelings, and how parents decide when to listen, when to comfort, and when to ensure they behave as expected. The practitioner will be available to talk over all the written and online materials. It is also designed to be an informative and cheaper alternative to the intensive personalised programme, PPCP, so that a finding of no difference between the intervention arms will have service implications. A trained practitioner will be assigned to the parents over a 16 week period, so that they can meet, where possible online, every week.

Group 2: ***The Personalised Programme for Children and Parents*** (PPCP) is a manualised programme based on evidence-based theories, including social learning theory and attachment theory. It is a strength based, active outreach approach. The starting point is parent defined concerns and goals. Detailed assessment of child problems and related family issues will provide an informed basis for developing the intervention. The programme is adjusted and tailored throughout, based on parental feedback and routine monitoring, using standardised measures. It employs key interventions that have been shown to reduce child conduct problems including collaborative working, active rehearsal and coaching.

The programme is separated into modules which will be selected and ordered in line with parental priorities and concerns. It is anticipated that the programme will normally include sections from the joint parent and child module. The modules are:

1. Individual parent: Focusing on parent wellbeing and emotional regulation

2. Parents working together: Joint couple sessions focusing on couple communication, problem solving and working together on child nurture and behaviour management

3. Joint parent(s) and child. Parent(s) and child sessions, using active rehearsal and coaching in play sessions. Sections will be chosen according to need and include:

a) Nurture and mutuality to strengthen parental sensitivity and parent-child mutuality
b) Praise and reward
c) Limit setting and compliance
d) Using consequences effectively

e) Problem solving with children

4. Parent(s) and School: Helping parents to improve communication and establish joint goals and plans for their child with school.

The programme will have 12-24 sessions, according to family needs and preference. Sessions will be clinic-based or home-based, according to parent(s) wishes. If additional services are needed, PPCP therapists will help the family access those services and work collaboratively with them. The primary endpoint is after 16 weeks.

The practitioners who administer the interventions will be recruited separately from the research team. They will be qualified CAMHS practitioners, recruited through the standard NHS recruitment services. On appointment, they will undergo initial intensive training for 3 days, followed by weekly supervision by the Trial Clinicians in accordance with a detailed manual.

7. METHODS of DATA ANALYSIS

7.1 Quantitative Analysis

7.1.1 Primary Analysis

The original plan based on meeting the recruitment target and having access to a locked database containing relevant baseline, 16 week and 32 week variables was as follows:

All analysis will be according to the intention-to-treat principle. Characteristics of the treatment groups will be described at baseline. Preliminary analysis will investigate the pattern of missing outcome data. The statistical analyses of the primary outcome measure (PACS) and the secondary measures will estimate three treatment effects to address the primary and secondary objectives of this study. Briefly, we use linear mixed models to estimate relevant contrasts. Continuous outcome variables such as PACS will be analysed in long format, for example the PACS variable will consist of stacked measures of (i) PACS recorded at baseline in either arm, (ii) PACS recorded at 16 weeks in either arm, and (iii) PACS recorded at 32 weeks in the waitlist/PLES arm only. The models will contain a dummy variable for PPCP trial arm (PPCP), a dummy variable for the 16 week assessment time point (W16), the product of these two dummy variables (PPCP x W16), and a dummy variable indicating the 32 week assessment time point in the waitlist/PLES arm (W32), binary participant sex and continuous age as known predictors of outcomes, dummy variables for delivering PLES or PPCP interventions and randomisation stratifiers. With this parameterisation the regression coefficient of PPCP x W16 represents the treatment effect of PPCP vs waitlist at 16 weeks; and the other treatment effects can be estimated by estimating relevant contrasts of the regression coefficients. To account for the correlation between the two or three repeated measures on the same participant (and to acknowledge that the contrast between waitlist and PLES is a within-trial arm comparison) a subject-varying random intercept will be included.

The analyses will remain valid in the presence of missing values in the outcome variables, provided the variables that predict missingness are included in the respective linear mixed model (missing at random, MAR, assumption).

After it was agreed with the funder to stop recruitment and only formally report on the PPCP vs waitlist comparisons at 16 weeks as part of this study, the SAP had to be amended. Specifically, the proposed analyses were simplified so that they could be carried out after the 16 week data was locked (i.e. not requiring access to any 32 week data:

All analysis will be according to the intention-to-treat principle. Characteristics of the treatment groups will be described at baseline. Preliminary analysis will investigate the pattern of missing outcome

data. The statistical analysis of the primary outcome measure (PACS) and the secondary measures (ECBI etc) will estimate the effect of PPCP relative to waitlist at 16 weeks post randomisation. Briefly, we will use an ANCOVA approach to estimate relevant trial arm differences. The models will contain a dummy variable for the PPCP trial arm and include covariates for binary participant sex and continuous age as known predictors of outcomes and for the randomisation stratifier.

These simplified analyses will remain valid in the presence of missing values in the outcome variables, provided the variables that predict missingness are included in the respective linear mixed model (missing at random, MAR, assumption).

A full statistical analysis plan (SAP) will be developed by the trial statisticians and agreed with the principal investigators and TSC before any post randomisation data is seen by either party.

7.1.2 Secondary Analyses

Comparison of PLES versus PLES Waiting List: Appropriate statistical methods will be used to make within-person comparisons using the same measures as above.

Comparison of PPCP versus PLES at 32 weeks.

Outcomes after commencing each of the two interventions (16 weeks post randomisation for PPCP, and 32 weeks post-randomisation for PLES) will be compared using similar statistical methods as described in the updated primary analysis.

7.2 Health Economic Analysis

Resource use will be measured using the Child and Adolescent Service Use Schedule (CA-SUS) (Beecham & Knapp, 1992, 2001). The measure is self-reported by parents in interview and has been successfully applied in many previous economic evaluations. Health and social care resource use will be costed using nationally applicable unit costs from standard sources (e.g. NHS reference costs for hospital episodes, British National Formulary for medication and PSSRU Unit Costs of Health and Social Care for community services). In addition, our group has access to a wide range of education sector unit costs from a variety of sources, including directly calculated as well as publicly available costs. The cost of the new personalised intervention will be directly calculated, using a micro-costing approach, based on data collected from therapists and clinical records.

The economic evaluation will be carried out from an NHS/Personal social services perspective as recommended by NICE, and a cost-consequences analysis will also be undertaken from a societal perspective and will focus on costs and parental and child quality of life outcomes measured within the period of study (up to 16 weeks). The economic analysis will be conducted within a cost-utility and cost-consequences framework with the former estimating the programme incremental cost per quality adjusted years of life (QALYs) gained for both parents and children over the trial follow-up period. Parental QALYs will be estimated through administration of the self-complete EQ5D measure and for children using the recently developed CHU-9 instrument.

The economic analysis will also evaluate the within-trial resource impacts from a wider societal perspective (e.g. inclusive of costs to the education system) and will also seek to translate any observed improvement in behavioural outcomes over trial follow-up into estimates of long-term resource savings to public sector organisations. An existing decision analytic model published by Bonin et al (2011) will be used as a basis for exploring the long-term public sector resource impacts linked to any improved behavioural outcomes observed within the trial. This secondary economic analysis will be used to assess the sensitivity of the estimated difference in overall cost of service use between intervention and controls to inclusion of wider and longer-term resource impacts.

We will employ standard methods of statistical analysis to evaluate programme cost-effectiveness, including multiple imputation for missing data (dependent on the nature and extent of the missing data) and parametric tests for differences in costs, with covariates for pre-specified baseline factors and the robustness of the parametric tests confirmed using bias-corrected, nonparametric bootstrapping. Conclusions regarding intervention cost-effectiveness will be assessed using varying assumptions regarding the maximum incremental cost per QALY threshold for determining programme value for money (using the existing cost-effectiveness threshold adopted by NICE as the "base-case"). We will also evaluate statistical uncertainty around the estimated mean programme incremental cost per QALY by evaluating the probability that the intervention will be cost-effective across varying assumed threshold values.

7.3 PROCESS EVALUATION

Qualitative process evaluation analysis

The primary aims of the process evaluation analysis are to understand the parents' experiences of the Parent-led Education and Support (PLES) intervention and the Personalised Programme for Children and Parents (PPCP) intervention, assess the feasibility of delivering both interventions, and to examine the real-life processes of intervention fidelity.

Parent Interviews

Semi-structured interviews will be conducted with 15 to 20 subjects from each arm of the trial or at data saturation if sooner, when the intervention and follow-up assessments have been completed. Additional signed consent is not required as participants have already consented to being interviewed and recorded when first recruited to the study. Interviews will be conducted using a topic guide, but the researcher will be responsive to issues emerging from parents' accounts. Interviews will be conducted in-person or via zoom, whichever is most convenient for the parent, audio-recorded and transcribed verbatim.

Participants will receive a new information sheet to inform them of the additional interview, and to invite them to take part. They will also be informed that if they do decide to participate in the qualitative interview, they will receive an additional payment in the form of vouchers to the value of £50.

The Qualitative Research Associate will provide training, supervision and support to the Researchers engaged in delivering and coding the interviews.

Trial Therapist Interviews

The five clinicians in the PPC study – three PPCP and two PLES – will be interviewed by the Qualitative Research Associate to examine their experiences of the process of both interventions from development to implementation. (The interview guide has been added to the study checklist). Interviews will be conducted over zoom at a time most convenient for the clinician, audio-recorded and transcribed verbatim. The Qualitative Research Associate will undertake a reflexive thematic analysis and the Researchers will be involved in checking the transcripts as an additional way to increase their skillset across the project.

8. STUDY SETTING

Potential participants will be identified from the parents or carers of children referred to Parent Training Groups funded and/or delivered by a local authority or NHS at participating sites in North London, South London and Berkshire. Recruitment and data collection will take place at all three sites. Parents who have participated in parent training groups but their children still show high levels of behaviour problems, or those who for whatever reason cannot engage in a group approach will be invited to

take part in the RCT. All CAMHS sites are fully equipped with staff experienced in treating and researching child conduct problems and possess the necessary facilities to conduct this research. For example, all sites have the appropriate rooms for consultations, meetings, individual and group treatment, and suitable toys and books for children.

9. SAMPLE AND RECRUITMENT

9.1 Eligibility Criteria

9.1.1 Inclusion criteria

a) Aged 4 – 9 years
b) With a minimum score on Parental Account of Children's Symptoms (PACS) scale of +1.3SD (i.e. top 10%) with a raw score greater than or equal to 1.32.
c) (i) Having previously been referred to a Parent Training group using evidence based principles and either participated, dropped out or declined to attend or (ii) Known to Child and Adolescent Mental Health Services or Local Authorities or other community services managed by or working with public funded organisations who for whatever reason cannot engage in a group approach.

9.1.2 Exclusion criteria

a) Child has significant developmental delay.
b) Parents have marked difficulty in understanding of spoken and written English so that assessment with standard research instruments is not possible.
c) Parents lack the capacity to give informed consent to participate.
d) Child has a confirmed diagnosis of autism spectrum disorder.
e) Child is the subject of a Child Protection Plan.

9.2 Recruitment

The primary pathway into the trial will be to identify families who have been offered, have attended, or are attending, Parent Training groups being delivered in North London, South London and Oxford for child behaviour problems. Parents who report that their child continues to show challenging behaviour will be targeted. Group facilitators will ask these parents if they would be interested to hear about a research project which is aiming to find out whether a new, individualised approach to child behaviour problems can be more helpful than a group-based approach. Parents will be given a brief introduction to the study and, if they express interest, the facilitator will ask for their permission to pass their contact details on to the study team. Parents who agree to hear more about the study will be contacted by the research team.

Researchers will ask parents to complete a screening questionnaire to determine whether their child's behaviour problems warrant inclusion in the trial. Researchers will also determine that both parent and child fulfil criteria for inclusion into the study, and that there are no criteria that exclude them from taking part. They will establish that the parent has capacity to consent on behalf of both themselves and the child. These parents and children will be invited to take part in the RCT.

A secondary pathway into the trial will be parents of children with significant behaviour problems who are currently in contact with local authorities, the voluntary sector, or CAMHS, who for whatever reason cannot engage in a group approach. They will be invited by their clinician/referrer in the same way as described above.

A poster/flyer targeting parents of children with behaviour problems will be distributed to those parents who wish to learn more about participating in the PPC RCT. Through a QR code on the poster, parents will be directed to a web-page hosted by the Tavistock & Portman NHS Trust, from which they can make their own decision about whether or not they wish the study to contact them. The web page will be easily accessible from their mobile phone. The poster will be sent to SENDCOs in schools, to clinicians in CAMHS NHS clinics and to practitioners of parenting groups. They can then circulate the flyers to parents they feel might benefit from participation in the trial. Parents can access the trial email and/or telephone number if they wish to make initial enquiries or if they are unable to use the QR code, without having to commit to taking part in the study. It is likely that many parents will prefer the opportunity to look at a website before committing themselves to participation, resulting in a more informed choice by parents. The onus on the clinician to "sign them up" is removed, making it easier to refer a larger number of families.

The flyer will also be posted on social media platforms such as Twitter, Facebook, and parenting forums. This will be a way of making the study available to the greatest number of parents who might benefit from the interventions that are offered.

9.2.1 Size of trial sample

The trial aims to recruit and randomise 248 parent/child dyads. Half of the total number recruited (estimate 124) will be randomised to each arm of the trial. This sample size has been calculated on the basis of a PACS 16 week difference between the mean scores of the PPCP and waitlist groups of 0.4 standard deviations, based on an independent samples t-test with 80% power and alpha=0.05 (sample size required = 198), and is inflated for an anticipated 20% attrition rate (Scott et al 2001; Scott et al 2010). This is a conservative estimate, our previous trial with a clinical population got an effect size of 1.06 standard deviations compared to a wait list control (Scott et al 2001). A standardised effect size of 0.4 amounts to a PACS difference of 0.16 points. We consider such a difference clinically significant because any numerous studies it has been associated with clinically significant reduction in child aggressive and antisocial behaviour, improved school attendance and a happier family atmosphere. Also these improvements have been retained at longer term follow-up over several years (Scott et al 2014).

9.2.2 Randomisation procedures and blinding arrangements

Randomisation of parent/child dyads to waitlist/PLES or PPCP trial arms will be at the individual dyad level with 50% of dyads randomised to either arm. Within parent subpopulation (“decliners” or “non-responders to group approaches”) we will use randomly varying block sizes to ensure that the times when dyads start on their allocated groups also balances across trial arms. Randomisation will be provided online vis an independently monitored computer system set up by the accredited Clinical Trials Unit at King's College (KCTU).

The procedure is as follows: Each participant will be allocated a unique, anonymised ID number King’s College London Clinical Trials Unit. Details will be entered into the KCLTU randomisation system. The outcome of allocation will be communicated to the trial's senior clinical supervisor, Dr Doolan, 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, senior statistician and research assistants) will remain blind to participant allocation status throughout the trial. As a result of the change in study design and the analyses of 16-week outcome data before locking the 32 week data collection blinding it is now only possible for the 16-week outcome collection and analyses to remain blind, but not for any 32-week outcome data.

9.3 Consent

It is the responsibility of the Chief Investigator, or person delegated by the Investigator to obtain written informed consent from each parent (or person(s) with parental responsibility) prior to participation in the trial. The informed consent process will be conducted by a member of the research team, who will be GCP trained, suitably qualified and experienced in assessing capacity and will have been delegated this duty by the CI or PI on the delegation log. Participants will be given adequate time to consider the study and given the opportunity to ask any questions. It will be explained to the participant that they are under no obligation to participate in the trial and that they can withdraw at any time during the trial without having to give a reason. They will also be informed that any routine care they are receiving will not impacted by withdrawing from the trial. A copy of the signed informed consent form will be given to the participant. The original signed form will be retained in the trial file at the site and a copy in the medical/case notes/source documents. If the PIS and consent form is amended during the trial, participants will be informed of the changes and will be re-consented as appropriate.

We will require children to participate in brief videotaped assessments and psychometric testing. These assessments and tests will be explained to them by researchers; parents may also contribute to the explanation. Researchers will obtain the verbal and/or written consent of each child.

10 ETHICAL AND REGULATORY CONSIDERATIONS

This research is subject to review by the Health Research Authority for HRA Approval and the NHS Research Ethics Committee for REC Favourable Opinion.

10.1 Assessment and management of risk

10.1.1 Safeguarding

It is entirely possible that disclosures may occur during the course of the study that require safeguarding action to be taken. At the point of agreeing to take part, the limits of confidentiality will be shared. If there are any indications that a child is currently suffering or at risk of suffering significant harm i.e. neglect, physical abuse, sexual abuse and emotional abuse, Researchers will be instructed as follows:

1. Stop the procedures

2. Use clinical judgement to decide whether to express concern and investigate level of risk further with the parent i.e. if this won't put the child at further risk.

- If possible, ask for more details about the situation.
- Indicate to the parent the need to share what they have heard with others.
- If possible, inform the parent that a safeguarding alert will be raised and this information will be shared with the relevant agencies.

They will then discuss this urgently with the Project Coordinator (Jackie Briskman) or with the Principal Investigators (Rob Senior or Stephen Scott) in her absence. This procedure is to help clarify the nature of the concerns and to determine whether the information available constitutes evidence that a child is being abused or is at risk of abuse and to agree a way forward. Having shared their concerns it is then the Local Authority's decision to investigate and decide on the next course of action.

It will be the responsibility of the designated safeguarding lead officer (Project Coordinator), in conjunction with the Principal Investigator, to make the decision about making contact with relevant services, for a discussion or to make a referral. The designated safeguarding lead officer will oversee and follow up the referral which should be made within 24 hours of becoming aware of the concern and immediately if the risk is imminent.

Clinicians experienced in managing safeguarding issues will provide supervision and training to all research assistants, and NHS procedures regarding safeguarding will be followed at all times. Disclosures will be treated as adverse events and will be documented and reported to the REC. Leadership of the programme at each site will come from senior consultant child and adolescent psychiatrists very experienced in addressing safeguarding issues for clinicians and researchers. Where information needs to be shared in the interests of the child this will be shared with the study participant involved unless it is considered that this places the child at greater risk.

In addition, researchers will be mindful that participants may themselves be experiencing mental health difficulties, and that there is a risk that they may experience participating in the study as stressful and/or distressing. For those participants who have been identified as having been diagnosed with a mental health difficulty, research assistants and clinicians will be particularly mindful of this; any concerns research assistants have about the wellbeing of participants who are not known to be experiencing mental health problems will be communicated to supervisors. Supervisors will then take on responsibility for any follow-up actions.

Some participants may struggle at times during the study with the perceived stigma surrounding child conduct problems and other comorbid factors, such as parental mental health difficulties. Consideration will be given to this at all times by clinicians and research assistants in their interactions with participants. Research assistants who are recruited to the study will have demonstrated strong empathy skills, as well as a good understanding of the factors and theories of processes underlying the development of child conduct problems. In addition, research assistants will receive ongoing supervision regarding their interactions with participants, which will incorporate any feedback received by the team about the conduct of research assistants from participants themselves. As part of the treatment, parents will also receive psychoeducational support regarding child conduct problems in order to reduce self-stigmatisation.

Participants may at times become distressed during the course of the study. All assessments will take place in confidential settings. Research assistants will remain sensitive to participants' distress at all times; Participants will be able to take breaks, should they need to, and may stop the assessment if they wish. Parents will also be given the option of being interviewed individually or with the other parent in order to minimise any stress or discomfort.

The research team are mindful of the importance of participant confidentiality and steps to minimise any risks to data confidentiality will be taken, including the use of pseudocodes to anonymise data, and the secure storage of all personal information and linking data in either locked cabinets, in the case of hard copy data, or on secure password-protected NHS computer networks. Full details regarding the steps taken to ensure participant confidentiality are noted in section 10.7 of this protocol.

Additionally, the research team will continue to consult with the parent reference group to ensure that potential risks to participants are identified, and efforts taken to minimise them where possible.

10.1.2 Minimising risks posed by coronavirus

Study procedures will be adapted to the changes required to protect both research staff and participants from exposure to coronavirus, and will follow the Trust policy with regard to minimising this risk. While the recommendation to minimise unnecessary contacts remains in place, staff will

be encouraged to conduct as much of the research as possible without face-to-face contact. Researchers will be trained to use alternative procedures for obtaining informed consent i.e. via video or phone contact and home visits will only be undertaken if absolutely necessary. All home visits must be discussed with the trial coordinator in advance and agreed by them. When attending someone's home researchers will be reminded of essential precautions i.e. to wear a mask and maintain social distancing as much as is possible under the circumstances within the home.

Prior to a visit, the family will receive an information sheet on how to protect themselves and the researcher and will be given the opportunity to decline a visit if they are not entirely happy with the arrangements. They will be asked to sign a separate consent form which relates only to the home visit. Visits will be cancelled if there is any possibility that the researcher, or anyone living within the household, has symptoms of coronavirus. All procedures regarding home visits and family visits to the NHS site are contained within the Trust's policy on coronavirus and will be clearly stated in the Standard Operating Procedures for staff.

10.2 Research Ethics Committee (REC) and other Regulatory review & reports

Regulatory Review & Compliance

10.3 Peer review

The study was submitted and successfully received NIHR funding. As part of this screening process, it has undergone extensive peer-review by external peer-reviewers.

10.4 Patient & Public Involvement

The conceptualisation and design of the PPC study as a whole has been driven by feedback from patients and clinicians regarding their experiences of parent training. In addition, a recent qualitative synthesis of studies looking at parents' and professionals' perceptions of the barriers to and facilitators of parent training identified a number of issues which will be examined in depth in the proposed research.

Feedback from parents involved in the qualitative component of the PPC study informed the development of the current phase of the study. Meetings with parents highlighted the importance of balancing what is asked for when participating in a research study while acknowledging the difficulties many families were still facing. This vital feedback regarding the measures employed, language used in interactions and interviews, and the timing of data collection appointments have informed the current study. Additional advice regarding acceptability will be continually sought from the Patient Reference Group.

Patients (parents of children attending CAMHS) have been involved in the design of the study. In order to ensure continued co-production as the study moves into the next phase, we will continue to use a Patient Reference Group to inform the study progress.

The Patient Reference Group will be/have already been consulted on:
- The design of the study
- Methods of data collection, including timings and the design of written material
- Analysis of data collected including supporting the interpretation of qualitative and quantitative data
- The writing up of data, including the development of lay summaries of the findings to feedback to the research participants

The reference group would not have access to patient identifiable material and would receive support and training where appropriate in order to undertake any analysis.

10.5 Protocol compliance

If an amendment to the protocol is necessary, the Chief Investigator will consult with the sponsor's representative (NOCLOR) for an opinion on whether it should be considered a minor or a substantial amendment for the purposes of the REC. The necessary paperwork and supporting documents will be passed to NOCLOR. Amendments will be submitted to the REC for consideration by the sponsor, and to our funding body, NIHR. If ethical approval for the amendment is granted, the R&D department will be notified of the change(s) by the research team overseen by the Chief Investigator.

All amendments to the protocol shall be tracked in a log at the end of the protocol; a copy of this log will be stored with the current and superseded protocols in the appropriate folder in the Trial Management File.

10.6 Data protection and patient confidentiality

Information provided in confidence during assessments will be pseudonymised and not be used or disclosed in any form that might identify the participant. Pseudonyms will be held in a password protected database on an encrypted NHS server at the Tavistock and Portman NHS Foundation Trust, accessible solely to the chief investigator and immediate research team.

The online database used for quantitative assessments will be prepared for electronic use by the King's College London Clinical Trials Unit. All access will be via encrypted channels and limited to the research teams.

A Data Protection Impact Assessment will be carried out on the study assessing identified risks, likelihood of harm, severity of harm, mitigation and overall risk. Information with regards to the study participants will be kept confidential and managed in accordance with the GDPR, NHS Caldicott Guardians, Research Governance Framework for Health and Social Care and the Research Ethics Committee approval.

A Data Processing Agreement will be set up between the Tavistock and Portman and the research partners. Trial data will be stored and processed in a way that is compliant with The Data Protection Act 2018 and UK General Data Protection Regulation (GDOPR)

Data will be stored for up to 5 years beyond the end of the study date so that it is available for writing up the results of the study in peer-reviewed publications. The custodian of this data is Dr Rob Senior, Chief Investigator.

10.7 Indemnity

As the Tavistock and Portman NHS Foundation Trust will act as sponsors, indemnity for the research elements is provided through NHS schemes under Clinical Negligence Scheme for Trusts (CNST). Insurance or indemnity for the design of the protocol will be provided through NHS schemes (CNST). Indemnity for the clinical interventions provided by participating sites will be via the NHS Trust involved.

The NHS indemnity scheme will cover the potential legal liability of the sponsor arising from the design, conduct and management of the study.

10.8 Access to the final study dataset

The Chief Investigator and researchers will have access to the final full dataset. Any other person wishing to have access to the full dataset must submit a formal request to the Chief Investigator for approval.

11. DISSEMINIATION POLICY

11.1 Dissemination policy

Intellectual property rights relating to the data arising from the study shall be held by the Tavistock & Portman NHS Foundation Trust.

Following the completion of the studies, data will be meticulously analysed. Findings will be tabulated and detailed in publications.

Consent to publish study data may be granted to co-investigators by the Tavistock & Portman NHS Foundation Trust.

All dissemination arising from the study must contain details of NIHR as the funder of the study, along with the standard disclaimer.

Participants who consent to receive the study findings will be sent an electronic or hard copy interim report and a final lay summary of the findings, depending on their preferred method of communication. They will also be provided with the details of where to access the online publication of the full study report.

11.2 Authorship eligibility guidelines and any intended use of professional writers

In partnership with the core study team of co-applicants, the Chief Investigator will make the decision regarding authorship for any peer-reviewed articles. All authors will be individually named.

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