E-PAtS Feasibility Study

Early Positive Approaches to Support (E-PAtS) for families of young children with learning disability (sometimes referred to as developmental delay or intellectual disability): Feasibility study

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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 and will adhere to the principles outlined in the relevant study regulations, GCP guidelines, and Sponsor's SOPs.

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 clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publically 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.

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Name	**Signature**	**Date**
Chief Investigators :		
Name **Richard Hastings**	**Signature**	**Date**
Name **Nick Gore**	**Signature**	**Date**

General Information This protocol describes the E-PAtS Feasibility Study, and provides information about the procedures for entering participants into the study. The protocol should not be used as a guide, or as an aide-memoire for the treatment of other participants. Every care has been taken in drafting this protocol; however, corrections or amendments may be necessary. These will be circulated to the known Investigators in the study. Problems relating to the study should be referred, in the first instance, to CTR.

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This protocol has been developed by the E-PAtS Feasibility Study Management Group (SMG).

For **all queries** please contact the E-PAtS Feasibility Study team through the main study email address. Any clinical queries will be directed through the Study Manager to either the Chief Investigator or a Co-Investigator.

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Randomisation
To randomise a participant, call <<telephone number>> from <<day to day>> between <<time to time>> (See section 9.5 for more details).

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Table of Contents

1 Amendment History 9
2 Synopsis 10
3 Study summary & schema 13
3.1 Participant flow diagram 13
3.2 Study lay summary 13
4 Background 14
4.1 Rationale for current study 17
5 Study objectives/ endpoints and outcome measures 17
5.1 Primary objectives 17
5.2 Secondary objectives 17
5.3 Primary outcomes measure(s) 18
5.4 Secondary outcomes measure(s) 18
6 Study design and setting 20
6.1 Risk assessment 21
7 Site and Investigator selection 22
8 Participant selection 22
8.1 Inclusion criteria 22
8.2 Exclusion criteria 23
9 Screening and Recruitment 24
9.1 Participant identification 24
9.2 Screening logs 25
9.3 Recruitment rates 25
9.4 Recruitment/Informed consent 25
9.5 Randomisation 26
10 Withdrawal & lost to follow-up 26
10.1 Withdrawal 26
10.2 Lost to follow up 27
11 Study Intervention 27
11.1 Early Positive Approaches to Support (E-PAtS) 27
11.2 Compliance 32
12 Trial procedures 32
12.1 Baseline and follow-up assessments 32
12.2 Process Evaluation 33
13 Adverse Events 38
14 Statistical considerations 39
14.1 Randomisation 39
14.2 Blinding 39
14.3 Sample size 39
14.4 Missing, unused & spurious data 40
14.5 Procedures for reporting deviation(s) from the original SAP 40
14.6 Termination of the trial 40
14.7 Inclusion in analysis 40
15 Analysis 40
15.1 Statistical analysis 40
15.1.1 Sub-group & interim analysis 41
15.2 Analysis of Process Evaluation data 41
15.3 Cost effectiveness analysis 41
15.4 Progression criteria for a definitive trial 42
16 Data Management 43
16.1 Completion of CRFs 45
16.1.1 Paper CRFs 45
16.1.2 Electronic Database/Data Entry 45
17 Translational research or sub trial 46

18 Protocol/GCP non-compliance 46
19 End of Study definition 46
20 Archiving 46
21 Regulatory Considerations 46
21.1 Ethical and governance approval 46
21.2 Data Protection 47
21.3 Indemnity 47
21.4 Study sponsorship 47
21.5 Funding 47
22 Study management 47
22.1 SMG (Study Management Group) 47
22.2 SSC (Study Steering Committee) 47
22.3 DMEC (Data Monitoring and Ethics Committee) 48
22.4 Project Advisory Group (PAG) 48
23 Quality Control and Assurance 48
23.1 Monitoring 48
23.2 Audits & inspections 49
24 Publication policy 49
26 References 49
27 Appendices 0

Glossary of abbreviations

AE	Adverse Event
CBCL	Child Behaviour Checklist
CI	Chief Investigator
CRF	Case Report Form
CTR	Centre for Trials Research
CU	Cardiff University
E-PAtS	Early Positive Approaches to Support
GCP	Good Clinical Practice
IC	Informed consent
ICH	International Conference on Harmonization
ID	Intellectual Disability
IDMC	Independent Data Monitoring Committee
IQ	Intelligence Quotient
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trial Number
MRC	Medical Research Council
NHS	National Health Service
NICE	National Institute of Health and Care Excellence
NIHR	National Institute for Health Research
PAG	Patient Advisory Group
PHR	Public Health Research
PI	Principal Investigator
PID	Participant Identification
PIS	Participant Information Sheet
PPI	Public Patient Involvement
RA	Research Assistant
R&D	Research and Development
RCT	Randomised Controlled Trial
SAE	Serious Adverse Event
SDQ	Strengths and Difficulties Questionnaire
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
SMF	Study Master File
SMG	Study Management Group
SSC	Study Steering Committee
SMF	Study Master File
UK	United Kingdom
UP	Usual Practice
VABS	Vineland Adaptive Behaviour Scale

1 Amendment History

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version.

Amendment No.	Protocol version no.	Date issued	Summary of changes made since previous version
1 (minor)	V1.1	12/12/17	Changes to withdrawal criteria, following ethical review.
2 (substantial)	V1.2	31/01/18	Following QA review: • Update Participant flow diagram (Section 3.1). • Update Secondary Objectives (Section 2). • Small typographical errors corrected. Exclusion criteria changed to include families currently in crisis and unable to cope (9 or 10 on the Brief Family Distress Scale). Families that score an 8 will be eligible to take part. Clarified learning disability (sometimes referred to as developmental delay or intellectual disability). Randomisation process changed.

2 Synopsis

Short title	Early Positive Approaches to Support (E-PAtS) for families of young children with learning disability (sometimes referred to as developmental delay or intellectual disability): Feasibility study
Acronym	E-PAtS Feasibility Study
Internal ref. no.	
Funder and ref.	Public Health Research (PHR), National Institute for Health Research (NIHR) Ref: **15/126/11**
Study design	Feasibility study
Study participants	Families with at least one child with learning disability (ID) aged 18 months-5 years
Planned sample size	64 families

Inclusion criteria	• Family units with at least one child with an ID aged 18 months-5 years
	• The identified child with ID meets the following:
	  ○ an administrative label of ID (learning disability/learning difficulties in UK terminology)
	  AND
	  ○ has a standard score on the Vineland Adaptive Behaviour Scales composite score of <80
	• At least one parent/caregiver is available to attend the E-PAtS intervention
	• Parent/caregivers who are to participate in the study are ≥ 18 years old
	• Parent/caregivers who are to participate in the study have a level of English language enabling (verbal) completion of outcome measures

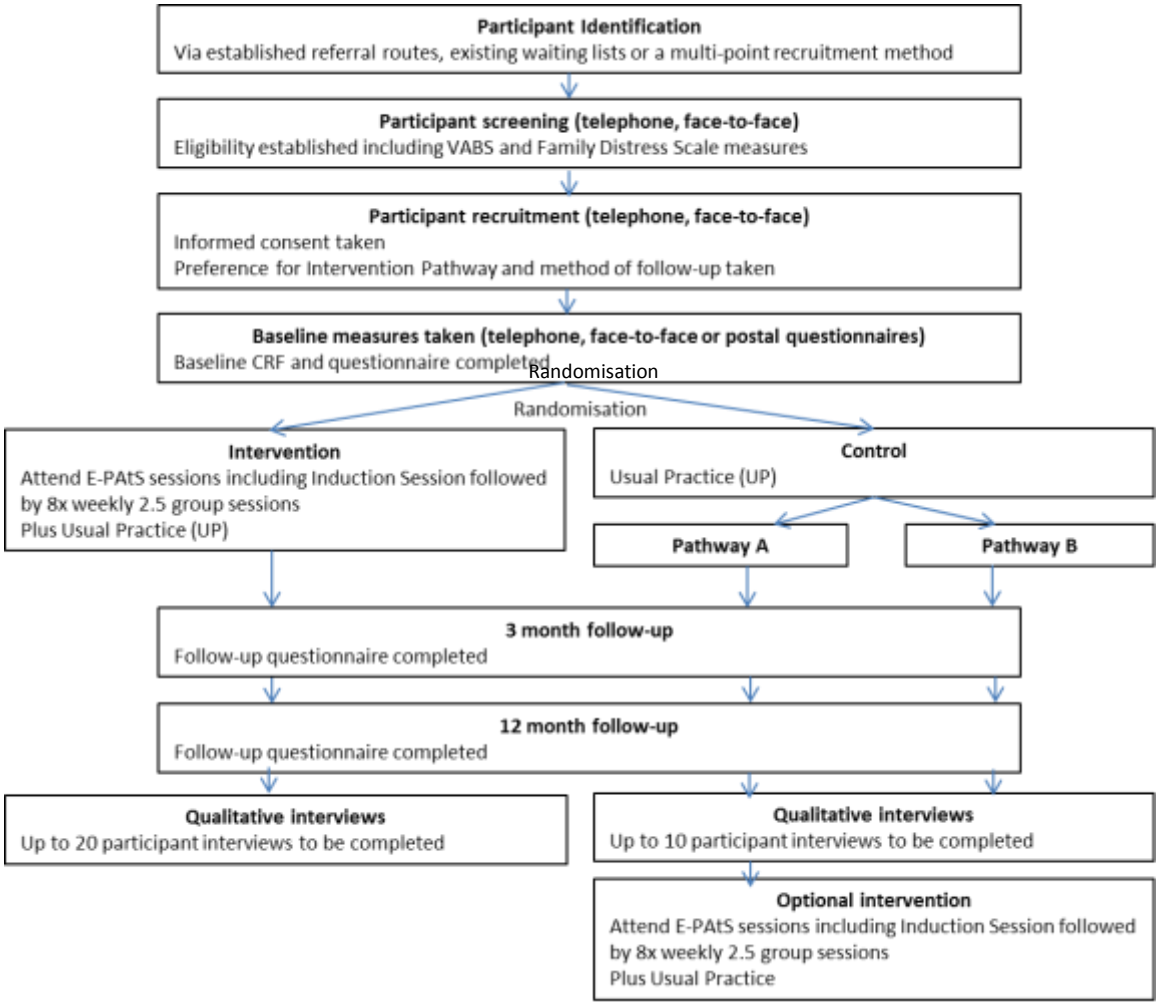
Exclusion criteria	• The identified child with ID is in a 24hr residential placement • The identified child with ID is in a foster placement due to end before the 12 month post-randomisation follow up data collection point • The primary caregiver is enrolled at baseline in a group or individually-delivered parenting programme outside of the study • The primary caregiver is enrolled in a programme of personal psychological therapeutic support at baseline • Any parent 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 9 or 10 on the 10-point Brief Family Distress Scale
Intervention duration	8 weeks
Follow-up duration	12 months post-randomisation
Planned study period	22 months
Primary objective	To assess the feasibility of delivering E-PAtS successfully to parents/caregivers of children (18 months-5 years) with ID by community parenting support provider organisations.
Secondary objectives	To assess: • The feasibility of recruiting eligible participants to the study and to determine the most effective recruitment pathways to identify families of young children with ID • The feasibility of recruiting suitable providers and facilitators to run E-PAtS parenting groups • Recruitment rates, adherence to the intervention and retention rates. • The views of providers and facilitators regarding delivering the intervention and study processes • The views of parents/caregivers regarding the intervention and study processes • The views of parents/caregivers regarding randomisation within the context of an RCT • Fidelity of implementation of the E-PAtS intervention through observation and participant/facilitator interviews • Usual practice in this setting and use of services/support in both groups • The feasibility of the outcome measures and whether there is preliminary evidence of differences on these measures between the intervention and control group • The feasibility of collecting resource use and health related quality of life data for parents and the child with ID in order to conduct health economic evaluation • The views of parents/caregivers regarding the acceptability of using their routinely collected data within the context of a RCT.
Primary outcomes	• Recruitment rates • Feasibility of, and preferences for randomisation • Study retention rates • Adherence rates to the E-PAtS intervention • Fidelity of the E-PAtS intervention • Measurement of usual practice (parenting programme including Triple P, Incredible Years or similar programme) • Provider willingness to participate in a definitive trial

	• Assessment of the barriers and facilitating factors for recruitment and engagement from the perspective of all stakeholders (process evaluation)
Secondary outcomes	• A range of established outcome measures, proposed to test the intervention in a main trial, will be measured: • The Warwick-Edinburgh Mental Well-Being Scale to measure parental psychological well-being. • Parental anxiety and depression-Hospital Anxiety and Depression scale. • Parent health-related quality of life- EQ-5D-5L • Parental situational coping approaches-the Brief COPE • Behavioural and emotional problems, and language development-the Child Behaviour Checklist (CBCL) • Adaptive skills and behaviour problems of the child with ID-Vineland Adaptive Behaviour Scales (VABS-3rd edition) • Child health-related quality of life-Paediatric Quality of Life Inventory TM Version 4.0 Generic Core Scales • Parent relationship with partner(if relevant)- Happiness of relationship scale • Perception of family functioning / quality of life-Family APGAR scale • Sibling behavioural and emotion problems- SDQ • Sibling relationship quality-Sibling Relationship Questionnaire (revised) • Social support available to the family-Family Support Scale • Criticism and warmth in the parent-child relationship from parents' perspectives-coded independently from the Five Minute Speech Sample • Parenting efficacy-7 items from the Parenting Sense of Competence Scale • Parental perceptions of the positive impact of their child- Positive Gains Scale • Parent relationship with partner and co-parenting (if relevant) - Disagreement over issues related to child, co-parenting • Parenting relationship and other family interactions - Child-parent relationship scale, and a Parent activities/involvement index • For intervention participants: 8 items from the Group Cohesion Scale measuring group members' perceived support from the group • Health economics: Client Service Receipt Inventory (modified)
Intervention	Early Positive Approaches to Support (E-PAtS) group intervention

3 Study summary & schema

3.1 Participant flow diagram



3.2 Study lay summary

Children with intellectual disability (ID) have a low level of intellectual ability and usually need help with everyday tasks (e.g., self-care, communication). Children with ID also are more likely to have challenging behaviour and parents are more likely to experience additional stress than parents of children without ID. We have developed a parenting programme for parents of young children (1½ to 5 years) with ID called Early Positive Approaches to Support (E-PAtS). In E-PAtS, parents are taught in a group to learn practical strategies over 8 weeks that help them to look after themselves, and help them with their child's development. A parent of a child with ID and a parenting professional co-deliver E-PAtS, after they receive training themselves. In this research, we plan to recruit 64 families of young children with ID to take part in a study where they will be assigned by chance to attend one of four E-PAtS groups or to only receive usual practice. If they are

assigned to receive usual supports, families will be given the option of receiving E-PAtS 12 months after recruitment. All families will also continue to receive usual practice in their local area. Mothers, fathers or other adult caregivers in the home will be invited to take part. All parents, whether they attend the E-PAtS groups or not, will be asked to answer questions about what may have changed for them during E-PAtS. The most important questions will be changes in parents' psychological well-being. Other measures include: the parents' mental health, positive perceptions, approaches to parenting, relationships with their partner (if they have one) and child with ID, the positive and problem behaviour of a brother or sister, sibling relationships, and how much the families access a variety of different services (especially social care, health services). This study is called a feasibility study – we will check out if the research works well so that a much bigger study can be planned in future. Amongst other things, we will find out if parents are willing to take part in the research, if they attend most of the E-PAtS course, whether they complete the research measures, and whether organisations who deliver parenting courses would be interested in taking part in a larger study. After the E-PAtS courses have been run, we will also interview mothers and fathers, the people who deliver E-PAtS, and people from the organisations providing E-PAtS. We will ask about what encouraged them to take part in the research, and what got in the way of this. We will also ask about their positive and difficult experiences in the E-PAtS groups. A family carer-led organisation, and a group of parent advisors, will be involved throughout the research including the design of the study. The findings from the research will be published in academic journals. We will communicate the findings to family carers, and parenting practitioners.

4 Background

Children with intellectual disability (ID) have an IQ <70, with associated deficits in adaptive skills, and their impairments emerge in the "developmental period" – typically considered to be before age 18 years. UK Learning Disability Observatory data show just over 2% of children in England have been identified by local authorities/schools as having intellectual disabilities (ID) [20]. Prevalence varies slightly with socio-economic factors but is broadly similar across the UK. Data from UK population-based research show that parents, especially mothers, of children with ID are 2-3 times more likely to report elevated or clinically concerning levels of mental health and other psychological problems when compared to parents who do not have a child with ID [1]. Population-based data for the UK and other countries suggest that rates of mental health problems at a level of clinical concern range from between approximately one third and one half of this population of parents [2]. Thus, parents of young children with ID represent a high-risk population in terms of parental psychosocial (ill) health.

Similar population-based data have shown that children with ID are 4-5 times more likely to have a diagnosable mental health disorder [3] compared to other UK children. In addition, high proportions (60-80%) of children with ID in population-based samples have clinically concerning levels of behaviour problems (including hyperactivity and conduct problems) [1]. These health inequalities for children with ID and their parents emerge early in life – by the time the child with ID is 3-5 years of age at the latest [4]. In addition, longitudinal studies suggest that increased behavioural and emotional problems in the child with ID leads to deterioration in parental well-being over time, and typically vice versa [5, 2]. Access to specialised supports is also a challenge for families of children with ID. For example, less than 30% of parents of children with ID who also had a diagnosable mental health problem had access to mental health services in the preceding 12 months [6]. Thus, children with ID and their parents face significant health inequalities and potential problems accessing appropriate support.

Moving beyond the dyadic association between the well-being of a child with ID and a parent, there are also ID family research studies applying family systems theory [7, 8] with findings that reflect similar data in other families. For example, the psychological problems of the child with ID can negatively affect parental well-being, and that of siblings [2]. In addition, parental relationship problems, parent-child relationships, sibling relationships, and overall family functioning may all be adversely affected in families of children with ID [2]. Parental well-being in families of children with ID may also be more strongly (or at least as strongly) associated with their partner's well-being than with their child's [2]. Given the research evidence, interventions are needed that target both parental well-being and child health outcomes, especially taking into account the very high levels of behaviour problems in young children with ID.

Furthermore, parenting behaviours, and parent-child relationship factors have been shown in longitudinal research studies to affect the short to medium term course and severity of behaviour problems in children with ID [2, 9]. Thus, interventions that also target parenting practices/strategies and parent-child relationships could have significant potential to support families of young children with ID.

The Early Positive Approaches to Support (E-PAtS) parenting programme is informed by existing research evidence about children with ID and their families [10] in addition to developmental systems approaches to early intervention [11]. E-PAtS is designed as a group parenting programme suitable for all families of young children with ID - addressing issues for parents and the child that may already be being experienced, or will be likely to emerge during the course of the child's development. E-PAtS is a bespoke ID parenting programme specifically informed by ID research and a conceptual model built to understand the situation of families of young children with ID. The primary focus is to enhance parental psychosocial well-being.

Recent systematic reviews of parenting interventions for parents of children with ID have been conducted by NICE to inform the Mental Health Problems in People with Learning Disabilities clinical guideline [12].

Although 15 RCTs of parenting programmes involving parents of children with ID were reviewed by NICE, parent well-being was not the focus of any of these programmes, the programmes were not developed for parents of children with ID (but were adapted from mainstream parenting programmes – e.g., Stepping Stones Triple P [13]), and the programmes were not targeted at families of *young* children with ID. The single exception was a RCT of an individual-family delivered Positive Behavioural Support intervention for young children with ID and severe behaviour problems [14] comparing the intervention alone to a version including a parent optimism component. Thus, NICE found no evidence relating to group parenting programmes designed specifically for parents of young children with ID, without a specific focus on a problem related to the child (e.g., severe behaviour problems), and with the explicit aim of improving parent psychosocial well-being. Therefore, there is a gap in both the availability of suitable group parenting programmes and in the evidence base. E-PAtS, and the current research proposal, directly addresses that gap.

Parenting programmes for families of children with ID are likely to remain a priority for UK services for several decades. For example, in England, learning (intellectual) disability services across the NHS, local authorities, and the for-profit and third sector are undergoing considerable change as a result of the government's Transforming Care programme. The new Service Model from the Transforming Care programme [15], identifies early intervention/early support, and support and skills training for parents as a part of a regional/ community response to better services for families of children with ID. In Scotland, parenting interventions are also a priority and are seen as a key way to improve the life chances of disadvantaged groups, including children with ID. The Scottish Government has proposed a coordinated parenting strategy across statutory and third sector organisations, with partners from the third sector taking a lead in delivering parenting interventions [16]. A feasibility study for E-PAtS, with the potential for a later large scale RCT evaluation, would therefore make a significant contribution in the UK providing evidence to inform on-going policy.

Apart from direct relevance to UK policy and practice, evidence from a robust programme of research on E-PAtS has the potential for substantial international scientific and policy impact. First, existing RCTs of group parenting programmes with parents of children with ID involve small samples only. Second, existing intervention studies have included, and thus measured outcomes typically for, only one parent in each family. Thus, effectiveness for fathers or for the non-included parent in the family remains unknown. Third, data analysis of existing group intervention RCTs has often failed to take account of the nested nature of the data (i.e., failing to account for parents clustered within the parenting groups that they attend). Fourth, only basic sub-group analyses of outcomes have been possible in existing ID parenting research due to small sample sizes. Although not all of these issues can be directly addressed in this feasibility study, this study may form the basis for a future large-scale trial of E-PAtS which would address these points and thus have significant scientific impact internationally in the ID field.

4.1 Rationale for current study

The current study aims to assess the feasibility of delivering E-PAtS to parents/ caregivers of children with ID by community parenting support provider organisations. The study will aim to contribute to the evidence base on improving outcomes for children with ID and their parents/ caregivers. Importantly, the study will aim to provide evidence to conduct a later, definitive RCT of the effectiveness and cost-effectiveness of E-PAtS.

5 Study objectives/ endpoints and outcome measures

5.1 Primary objectives

The primary objective of this study is to assess the feasibility of delivering E-PAtS successfully to parents/caregivers of children (18 months-5 years) with ID by community parenting support provider organisations.

5.2 Secondary objectives

To achieve the primary objective, the following will be assessed:

- The feasibility of recruiting eligible participants to the study and the most effective recruitment pathways to identify families of young children with ID.
- The feasibility of recruiting suitable providers and facilitators to run E-PAtS parenting groups.
- Recruitment rates, adherence to the intervention and retention rates.
- The views of providers and facilitators regarding delivering the intervention and study processes.
- The views of parents/caregivers regarding the intervention and study processes.
- The views of parents/caregivers regarding randomisation within the context of a RCT.
- Fidelity of implementation of the E-PAtS intervention through observation and participant/facilitator interviews.
- Usual practice in this setting and use of services/support in both groups.
- The feasibility of the outcome measures and whether there is preliminary evidence of differences on these measures between the intervention and control group.
- The feasibility of collecting resource use and health related quality of life data for parents and the child with ID to conduct health economic evaluation.
- The views of parents/caregivers regarding the acceptability of using their routinely collected data within the context of a RCT.

5.3 Primary outcomes measure(s)

The following primary outcomes will be measured and used to inform the decision to progress to a definitive trial

- Recruitment rates
- Feasibility of, and preferences for randomisation
- Study retention rates
- Adherence to the E-PAtS intervention
- Fidelity of E-PAtS intervention delivery
- Measurement of usual practice (parenting programme including Triple P, Incredible Years or similar programme)
- Provider willingness to participate in a definitive trial
- Assessment of the barriers and facilitating factors for recruitment and engagement from the perspective of all stakeholders (process evaluation)

5.4 Secondary outcomes measure(s)

- The feasibility of using a range of established outcome measures, proposed to test the intervention in a main trial, will be assessed. The outcome measures will assess outcomes for individual family members, sub-system relationships and overall family functioning. Secondary outcomes have been chosen based on: experience in research with families of young children with intellectual disabilities (ID) including the total measurement load parents have been willing to bear, brevity but with good psychometric properties, and potential comparisons with national datasets (e.g., Millennium Cohort Study) to provide context for the meaning of scores obtained. All outcome measures will be assessed at baseline, 3 months post randomisation and 12 months post randomisation, with the exception of VABS which will only be measured at baseline and 12 months post randomisation. The outcome measures include:
- Parent impact secondary outcomes (measures for both parents, irrespective of whether they attended the E-PAtS intervention):
    - Warwick-Edinburgh Mental Well-Being Scale to measure parental psychological well-being [21]
    - Parental anxiety and depression – Hospital Anxiety and Depression scale [22]
    - Parent health-related quality of life - EQ-5D-5L [23]
    - Parental situational coping approaches (i.e., coping strategies related to the care of their child with ID) – the Brief COPE [24]
- Secondary outcomes – child with ID:

- Behavioural and emotional problems, and language development – the Child Behavior Checklist (CBCL) [25] for children 1.5-5 years of age including the language development survey supplement
- Adaptive skills and behaviour problems of the child with ID measured via Vineland Adaptive Behaviour Scales (VABS – 3rd edition) [18]. The VABS has an overall standardised Adaptive Composite, and a further three standardised scores for key domains measured across the age range for this study: communication, socialisation, and daily living skills. Parents will also report on "maladaptive" behaviours in the VABS.
- Child health-related quality of life – measured using the Paediatric Quality of Life InventoryTM Version 4.0 Generic Core Scales [26]

- Secondary outcomes – family and family systems:
  - Parent relationship with partner (if relevant) - Happiness of relationship scale [27]
  - Perception of family functioning/quality of life - Family APGAR scale [28]
  - Sibling behavioural and emotion problems where there is at least one sibling in the family between the ages of two and 16 years of age – SDQ [29]
  - Sibling relationship quality - Sibling Relationship Questionnaire (revised) (where relevant) [30]
  - Social support available to the family – Family Support Scale [31]
  - Criticism and warmth in the parent-child relationship from parents' perspectives – coded independently from the Five Minute Speech Sample [32]
- Secondary outcomes assessing primary mechanisms of impact:
  - Parenting efficacy – 7 items from the Parenting Sense of Competence Scale [33]
  - Parental perceptions of the positive impact of their child – Positive Gains Scale [34]
  - Relationship with partner and co-parenting (if relevant) - Disagreement over issues related to child [27], co-parenting [35]
  - Parenting relationship and other family interactions - Child-parent relationship scale [36], and a Parent activities/involvement index
  - (For parents in families randomised to E-PAtS) 8 items from the Group Cohesion Scale measuring group members' perceived support from the group [37] evaluation)

Additional health economics outcomes:

- Client Service Receipt Inventory [38] modified (following piloting) to be suitable for families of children with ID. Primary caregivers will complete the full inventory at each timepoint, whilst secondary caregivers in the same family will be asked to complete a shorter version of the Client Service Receipt Inventory at each follow-up point, focused on their own receipt of services, because some of these caregivers may not live full-time with the child.

6 Study design and setting

The main study is a cluster randomised controlled trial. 64 families with a child (18 months- 5 years) with ID will be recruited in total from two research sites: from the University of Kent base; and the University of Warwick base. From each family, up to 2 parents/caregivers will be recruited, including mothers, fathers or adult family caregivers (e.g., siblings, grandparents). Participating families will be allocated to intervention or control on a 1:1 basis. From the intervention group, the 2 parents/caregivers will be invited to attend the E-PAtS intervention. Before randomisation, participants will be given the option of whether they would like to attend E-PAtS after 12 months if they are randomised to the control condition (Pathway A) or not and to continue to receive usual support only (Pathway B). All participants will have access to their usual services.

Between two and four training providers will deliver one or two E-PAtS courses during the feasibility study and be prepared to offer one or two additional E-PAtS courses after the 12-month follow-up, for parents in the control group who choose Pathway A. Four E-PAtS groups will be delivered to the intervention group, and up to four to the control group (depending on whether parents choose Pathway A prior to randomisation).

Families will be referred to the Study team by service providers in their local area following a flexible multi-point recruitment method. This will include parents in contact with local and national charitable support organisations, local authority services, special schools and nurseries, after school/weekend services for children with special educational needs and disabilities, parent/family support groups, social media, advertising in the media in local areas, and self-referral.

Research assistants will send study packs to potential participants including an information sheet and reply slip to return if they are interested in taking part. A short screening/recruitment telephone or face-to-face interview with a parent/caregiver will be conducted, the study will be explained and screening outcomes measures taken (with informed consent obtained). If eligible to take part, following scoring of the screening outcome measures, a recruitment/baseline visit will be arranged. During the recruitment/baseline interview the study will be explained in detail, consent will be obtained, preferences for method of completion of research measures obtained as well as preference of study pathway, if the family ends up being allocated to the control group after randomisation and baseline measures taken.

When consent and baseline measures have been collected for all participants within each family, the family will be randomised to intervention or control. Participants will be informed of their study allocation by telephone and provided with all details of attending the E-PAtS intervention, if applicable.

Data will be collected at 3 time-points: baseline, 3 months post-randomisation and 12 months post-randomisation. The method of data collection will be dependent on the preference of the participant at the screening/recruitment interview. Data will therefore be collected face-to-face, over the telephone or by

post. All data collection forms will be paper CRFs/questionnaires and data will be manually uploaded to a Clinical Database by Research Assistants at each site. Completed CRFs will be returned to the Study team at the Centre for Trials Research (CTR) by post.

The process evaluation will examine four key aspects of the feasibility of conducting a definitive trial of E-PAtS: 1) intervention recruitment, adherence, and reach; 2) intervention implementation; 3) intervention mechanisms, including receipt and acceptability; and 4) the feasibility of implementing E-PAtS within a definitive RCT. We will use recent MRC guidance [43] as a framework for the process evaluation to describe implementation processes, refine the intervention logic model through examining intervention mechanisms, and consider the role of context in shaping intervention implementation and mechanisms.

The process evaluation will employ a mixed methods approach. Quantitative methods will be used to assess recruitment rates/patterns and intervention fidelity. Qualitative interviews with intervention delivery staff, parent training providers and parents/carers will examine implementation processes, intervention mechanisms the role of contextual factors, and interrogate patterns in the quantitative data. The Project Advisory Group (PAG) of family carers will be asked to provide input on the content of the interviews held with parents, and advise on the relevance, acceptability, and framing of key questions.

The study will last 22 months in total and the end of the study will be considered the date that the last participant has completed follow-up.

Parents/caregivers and facilitators will not be blind to allocation. However, the statistician carrying out the main statistical analyses will remain blind to allocation up until the point the analysis is performed. Research Assistants (RAs) collecting follow-up data will aim to remain blind and will record if the participant has divulged their study allocation during follow-up data collection.

6.1 Risk assessment

A Risk Assessment has been completed to identify the potential hazards associated with the study and to assess the likelihood of those hazards occurring and resulting in harm. This risk assessment includes:

- The known and potential risks and benefits
- How the risk will be minimised/managed

This study has been categorised as low risk. A copy of the study risk assessment may be requested from the Study Manager. The Risk Assessment is used to determine the focus of monitoring activity (see section 25.1).

7 Site and Investigator selection

This trial will be carried out at 2 sites within the UK: the University of Warwick and the University of Kent. Before either site can begin recruitment a Principal Investigator at each site must be identified. The following documents must be in place and copies sent to the Study Manager (see contact details on page 4):

- Favourable opinion from the relevant Ethics committee
- A signed Study Agreement
- Current Curriculum Vitae and GCP training certificate of the Principal Investigator (PI)
- Completed Site Delegation Log and Roles and Responsibilities document
- Full contact details for all personnel involved
- A copy of the most recent approved version of the Participant Information Sheet(s) and Consent Form(s) on site headed paper

Upon receipt of all the above documents, the Study Manager will send written confirmation to the Principal Investigator detailing that the centre is now ready to recruit participants into the study. This letter/email must be filed in each site's Site File. Along with the written confirmation, the site should be provided with all documents required to recruit into the study.

Occasionally during the course of the study, amendments may be made to the study documentation listed above. The Study team in the CTR will issue the site with the latest version of the documents as soon as they become available. Site initiation will be by teleconference.

8 Participant selection

Participants are eligible for the study if they meet all of the following inclusion criteria and none of the exclusion criteria apply. All queries about participant eligibility should be directed to the Study Manager before randomisation/recruitment.

8.1 Inclusion criteria

- Family units with at least one child with a learning disability (ID) aged 18 months-5 years
- The identified child with ID meets the following criteria:
    - an administrative label of ID (learning disability/learning difficulties in UK terminology). An administrative label relates to identification of the child within the education, health or social care systems as having ID or as eligible for receipt of specialist ID services. Any severity (mild to profound) of ID is included, and also diagnoses indicating the presence of ID for younger children (e.g., "global developmental delay")

AND

has a standard score on the Vineland Adaptive Behaviour Scales [18] composite score of <80 (allowing for measurement error but still indicating significant developmental delay) at the time of the screening assessment.

- At least one parent/ caregiver is available to attend the E-PAtS intervention. This may be a biological, step, adoptive, or foster (if placement is currently planned to extend to 12m follow-up) parent or adult family caregiver including older siblings, grandparents or other family members who live in the family home and are recognised as caregivers.
- Parent/caregivers who are to participate in the study are ≥ 18 years old.
- Parent/caregivers who are to participate in the study have a level of English language enabling (verbal) completion of outcome measures. Note that reading skills are not required.

8.2 Exclusion criteria

- 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.
- The primary caregiver is enrolled at baseline in a group or individually-delivered parenting programme outside of the study – whether this is related to their role as a parent for the child with ID or for any other child in the family.
- The primary caregiver is enrolled in a programme of personal psychological therapeutic support at baseline.
- Any parent 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 9 or 10 on the 10-point Brief Family Distress Scale [19].

9 Screening and Recruitment

9.1 Participant identification

The strategy for recruiting families will be flexible and the study team will work collaboratively with the service providers to establish methods to identify potential families: either through established referral routes, existing waiting lists or in a multi-point recruitment method including via the following methods:

- local and national charitable support organisation
- special schools and nurseries
- after school/weekend services for children with special educational needs and disabilities
- parent/family support groups
- social media
- advertising in the media in local areas
- self-referral

Information will be gathered regarding the most effective participant identification processes.
Potential participants will be sent a study pack in the post, including a participant information sheet and a form to complete stating whether or not the participant is interested in taking part. Participants will be able to return the form in a prepaid envelope or via email/telephone/text.

Potential participants will be contacted by Research Assistants from the study team to arrange a short screening/recruitment interview, either by telephone or face-to-face. During the screening/recruitment telephone interview the following will be carried out:

- The study will be explained in detail, including the randomisation and consent process and participants will be sent/left with a copy of the information sheet to consider.
- Screening consent (either written if face-to-face or verbal if over the telephone) will be obtained to complete the screening outcome measures only.
- Screening measures will be taken to establish eligibility. This will require completion of the Vineland Adaptive Behaviour Scales (VABS) with the parent to determine eligibility in terms of the child's ID and the Brief Family Distress Scale to determine whether the family are currently in crisis and unable to cope.

Following the screening visit, the research assistant will score VABS and confirm eligibility with the PI. If eligible, the Research Assistant will arrange a recruitment/baseline visit. If any concerns are raised during the screening visit (i.e the family are in crisis), the PI will signpost the family to appropriate local support. Working guidelines for this will be established.

9.2 Screening logs

A screening log of all ineligible and eligible but not consented/not approached will be kept at each site by the Research Assistant so that any biases from differential recruitment will be detected. When at site, logs may contain identifiable information but this **must** be redacted prior to being sent to the CTR. The screening log should be sent to the E-PAtS Feasibility Study team every month.

9.3 Recruitment rates

A total of 64 families (up to 128 participants) will be recruited in two periods as identified in the project timeline.

9.4 Recruitment/Informed consent

- The participant will have been sent the Participant Information Sheet and consent form prior to the interview taking place and given sufficient time to read the information. The study will be explained in detail, including randomisation and consent for long-term follow-up using routinely collected data and appropriate data linkage. If happy to take part, informed consent will be obtained. If a face-to-face interview, written consent will be obtained. If a telephone interview, verbal consent will be obtained. The Research Assistant will read aloud each statement of the consent form and ask the participant to agree to each statement individually. The Research Assistant will then sign the consent form on behalf of the participant. A copy of the consent form will then be sent by post for signature by the participant.
- A contacts form will be completed for participants including multiple methods of contact (address, telephone, email address) to minimise loss to follow-up.
- Preferences for: a) follow-up data collection (face-to-face interview completion, telephone-based completion or postal questionnaires) and b) choice of study pathway will be obtained (participants

randomised to the control group who choose Pathway A will be invited to attend E-PAtS 12 months post-randomisation and participants who choose Pathway B will not be invited to an E-PAtS course).

- Baseline data collection completed (either at time of recruitment by telephone or at a suitable time for the participant by telephone, face-to-face or postal) including:
    - Baseline demographic CRF completed
    - Baseline outcome measures completed.

9.5 Randomisation

Families will be randomised following screening, selection of Study Path A or B and completion of baseline assessments. In this feasibility study, families will be randomised using an equal allocation 1:1 ratio to E-PAtS in addition to usual practice or Usual Practice alone (UP). The Research Assistant will inform participants of their allocation by telephone and will provide all details of starting the E-PAtS course to those allocated to the intervention arm.

10 Withdrawal & lost to follow-up

10.1 Withdrawal

Participants have the right to withdraw consent for participation in any aspect of the study at any time. The participants' care will not be affected at any time by declining to participate or withdrawing from the study. If a participant initially consents but subsequently withdraws from the study, clear distinction must be made as to what aspect of the study the participant is withdrawing from. These aspects could be:

1. Withdrawal from the intervention (attendance at the E-PAtS group) only
2. Withdrawal from future follow-up assessments
3. Withdrawal from previously collected data
4. Withdrawal of consent to all of the above

Participants who consent and subsequently withdraw should complete the study withdrawal form or the withdrawal form should be completed on the participant's behalf by the Research Assistant/ study team member based on information provided by the participant. This withdrawal form should be sent to the E-PAtS Feasibility Study email address. Any queries relating to potential withdrawal of a participant should be forwarded to The Study Manager.

10.2 Lost to follow up

Participants who do not complete the 12 month follow-up data collection interviews will be considered lost to follow-up.

11 Study Intervention

11.1 Early Positive Approaches to Support (E-PAtS)

The study intervention is the Early Positive Approaches to Support (E-PAtS) manualised group parenting programme for parents/caregiver of children with ID. The programme will be provided in addition to usual practice (UP). The programme has been developed specifically to support families of children with a range of needs relating to ID across diverse socio-economic contexts through engagement with both a primary and secondary caregiver. The programme focus has been developed for families of young children with ID rather than being adapted from a mainstream parenting programme and the context and assumptions of E-PAtS recognise that parents of children with ID often experience socio-economic disadvantage, unique parenting challenges, isolation and emotional difficulties and struggle to access services that meet their specific needs. The logic model for E-PAtS highlights a number of inputs and processes that facilitate increased engagement with this particular population of parents (See Appendix 1 for the E-PAtS Logic Diagram).

The E-PAtS programme has been co-produced with parents/family caregivers of children with ID, ensuring materials and methods of delivery are closely aligned to parents' needs and relevance and appropriateness is maximised to support engagement. It is co-delivered by a parent/family caregiver of a child with ID to model and facilitate peer-to-peer parent engagement and the programme content is designed for flexible use allowing for adaptation to the local needs of parents at a group level, and the individual needs of each parent within a group, to further increase personal relevance and subsequent engagement.

The E-PAtS intervention provides a socially and emotionally supportive group context and process, and provides an empowering approach that builds on parents' strengths. This recognises the emotional needs of parents and creates conditions that will maximise confidence, wellbeing, and positive interaction to promote further engagement. In addition, pilot studies have shown that E-PAtS is also assessable to parents who have children with a wide range of diagnoses relating to ID and to families who reflected socio-economic and ethnic diversity.

Programme facilitators are typically professionals employed by third-sector organisations, but have included a range of health and social care professionals (and could include education professionals). Each programme is also delivered with a parent/family caregiver co-facilitator employed by the organisation specifically to

deliver the E-PAtS programme. Facilitators deliver the programme in pairs (one professional and one parent/family caregiver facilitator) after completing a 5-day training programme and period of supervised practice (between 2 and 3 supervision meetings with the E-PAtS programme trainer during the first facilitation of a programme). Facilitators typically are required to have prior experience of supporting children with ID and/or their families, but are likely to have a variety of professional roles and qualifications. Family carer facilitators are the parent of a child with ID. E-PAtS programmes may be delivered in a range of community settings including child development centres, community centres and church halls.

The E-Pats intervention comprises an individual preparation interview with the facilitator followed by 8 sessions of 2.5 hours each. In pilot studies, this has been found to be feasible and acceptable for families. Finally, E-PAtS provides parents/family caregivers with a suite of resources and tools organised within a personalised workbook which allows information gained from sessions by one parent/family caregiver to be discussed, shared, and utilised with a secondary parent/caregiver.

The individual preparation interview with facilitators in order to 1) help the caregivers prepare for engaging in the group, 2) ensuring suitability of the programme in relation to the caregivers' current needs (e.g., families not in "crisis and unable to cope" currently), and identifying and 3) proactively resolving any potential barriers that relate to attendance and engagement (e.g., reading difficulties, cultural sensitivities, socio-economic factors).

The E-PAtS curriculum content provides a specific focus on supporting caregiver wellbeing and parenting behaviour in the context of raising a young child with ID. The content is, therefore, closely aligned to the particular needs of parents who have a young child with ID, increasing the potential for engagement. Further to this, the E-PAtS curriculum provides targeted support and resources to parents to support future engagement with other professional services and systems of social support.

The E-PAtS curriculum comprises eight 2.5-hour group sessions, delivered at times of day determined by the provider in accordance with the needs and preferences of participating families. The first two sessions of the E-PAtS curriculum focus predominantly on the emotional and wellbeing needs of parents/ family caregivers together with the development of a family system of support. Session 1 provides an introduction to the programme and establishes group process (see below) before providing advice and strategies to support access to professional services and financial supports for families and their children. The second session focuses on the emotional vulnerabilities and needs of parents/ family caregivers of children with ID, supports service access in relation to these and empowers parents/ family caregivers to develop self-management and social support systems to reduce these and build resilience over the long term. Further consideration and support in relation to both building systems of family support and safeguarding the emotional wellbeing of parents/ family caregivers is also included as a component of each subsequent session and are further

expanded upon in the final session of the programme (Session 8) that brings together all learning and supports for the continued use of the learning from the programme in the future.

Sessions 3,4,5,6 and 7 focus predominantly on supporting parent/ family caregiver knowledge and confidence in responding to child-focussed areas of difficulty that are also associated with poor outcomes for caregivers and families of young children with ID. Session 3 provides advice and support for caregivers to help their child sleep; Session 4 to help children acquire effective functional communication and Session 5 to help children develop a range of adaptive skills. Sessions 6 and 7 draw upon all previous sessions and provide additional curriculum to help caregivers prevent and address problem behaviour currently displayed by their child or that they may be at risk of developing in future.

Each programme session is based on evidence-based best practice developed through co-production with a range of professional experts and family caregivers (see earlier). Sessions provide an overview of each area with theoretical and practical considerations to empower caregivers and activate improved patterns of family interaction (following the Developmental Systems Model for early intervention [6]), with provision of further resources and signposting to support future advice and professional input for families who require this. E-PAtS is designed as a cohesive programme curriculum rather than a menu of choices with the expectation that parents/ family caregivers attend all sessions whether or not they or their child is currently displaying a difficulty in the topic area. This is based on a premise that families and their children who attend the programme are at increased risk of experiencing difficulties across all topic areas sometime in the child's development, but that this could be reduced through early intervention and proactive support. Second, it is considered that participating parents/ family caregivers will contribute towards the group process mechanisms, with the potential to support other group members in relation to one or more of the curriculum areas and that this may have potential benefits for both the caregiver in question and other group members. The definition of adherence is that at a minimum, it is expected that caregivers attend at least one of the parent/family caregiver focused sessions (session 1 or 2) and 3 of the child difficulty focused (sessions, 3,4,5,6 or 7), including sessions that relate specifically to current areas of difficulty for their own child, and the final integrative session (session 8).

Curriculum is delivered via a combination of oral and video presentations, group discussion and in-vivo exercises. The E-PAtS group process aims to create an emotionally and socially supportive setting that encourages engagement and addresses the wellbeing needs of caregivers. First, meeting and working with peers who are experiencing similar challenges and difficulties and being supported by a facilitator who is also a caregiver, provides emotional validation and inspiration to group members. Second, programme facilitators have received training and supervision to develop therapeutic competencies to be used in conjunction with delivery of all curriculum areas. These skills help ensure the emotional needs of caregivers are recognised

and responded to sensitively and constructively and that supportive relationships are fostered between group members.

Presentation of materials and exercises are also designed to support parent/ family caregiver engagement, identify their particular needs and strengths, and empower them to build upon these. Prior to delivery of each programme, facilitators are required to make localised adaptions to programme materials (e.g., information provided about current and local financial and service supports). Facilitators are also trained to respond to the specific needs of individual group members during delivery of each session (e.g., citing examples and strategies that are aligned with the presenting needs and circumstances of parents/ family caregivers who are in attendance, and their children).

Parents/ family caregivers are given opportunities to rehearse and develop strategies and skills within sessions but not assigned tasks to complete between sessions. This is based on the assumption that participants will likely present with a range of different needs and circumstances and are likely to need to develop family support systems and personal resource as a pre-requisite to implementing self-management and child-focused strategies. This may be possible for some participants within the time frame of programme delivery but more typically is predicted to occur following programme completion.

The structuring of the E-PAtS curriculum is also arranged to allow some flexibility in attendance to further increase engagement opportunities without parents having to feel awkward about missing sessions. Whilst parents/family caregivers are recommended to attend all sessions, programme completion is possible through attendance of one of the two parent/family caregiver focussed sessions (sessions 1 and 2) plus any three of the child-focussed sessions (sessions 3,4,5,6 or 7) and the final integrating session (session 8). To facilitate this, key themes (especially parent well-being) are repeated throughout all sessions. Thus, parents who do not attend all sessions are less likely to have a disjointed experience of the programme.

All parents/family caregivers are provided with a workbook that accompanies the programme. The workbook contains additional materials, tools and signposting resources in relation to each content area. The workbook is built around a 'person-centred profile' detailing the specific support needs for each family's child. By completing the workbook throughout the programme, families are empowered to create a resource based on their knowledge and experience, combined with evidence-based practices to inform broader systems of family and child support in the future. The workbook also allows information and learning from the programme to be shared with other family members who are unable to attend sessions directly, contributing towards engagement with fathers and other family caregivers and the development of a shared, collaborative approach for supporting children.

In addition to the programme manual (focused on the delivery of each session and the session content and materials), the implementation manual includes practical elements that the provider and facilitators need to

deliver E-PAtS (e.g., role profiles for facilitators, practical suggestions about location set-up, and all additional resources required to deliver E-PAtS). There is also a training programme and manual for training facilitators to deliver E-PAtS. The five days of training are guided by a manualised curriculum comprising 1.5 days of teaching in relation to the evidence base, theory and ways of working that underpin E-PAtS; 1.5 days teaching regarding the programme curriculum for E-PAtS, and 2 days of tutoring practice-based demonstration regarding curriculum delivery, group process, and co-production in the delivery of E-PAtS. Facilitators need to be able to demonstrate necessary skills and understanding of E-PAtS during the final training session, prior to implementation, and receive 2-3 supervision sessions from the trainer (in addition to any supervision with the host organisation) during their first delivery of the programme. To date, all training has been provided by Nick Gore (co-CI) but a second facilitator-trainer is in training.

Engaging with fathers is an important part of the E-PAtS intervention. Participation of fathers in group-based parent training occurs at low rates [17]. The E-PAtS programme aims to routinely engage with two parents or family caregivers. Single parents are able to invite a second adult family caregiver. The involvement of secondary caregivers (i.e., typically fathers) is, therefore, explicitly targeted in the programme and the collaborative facilitator stance of the E-PAtS group process also models the value and possibility of a supportive and shared/co-parenting approach to supporting children that is integral to E-PAtS, and is promoted to parents for adoption during and outside of sessions. In the E-PAtS pre-programme interview, careful consideration is given to how secondary caregivers can best engage with the programme, identifying potential barriers, and generating solutions to increase participation. Developers of E-Pats have also consulted with fathers of children with ID to develop and refine the programme content and fathers also serve as E-PAtS facilitators. The E-PAtS curriculum includes two sessions that focus predominantly on parent/family caregivers (with further consideration running through all subsequent sessions), and this includes recognition and support to non-primary caregivers (especially fathers) and other family members (e.g., siblings). The needs, roles and priorities of fathers are therefore addressed in session content directly. Flexibility concerning programme completion (whereby group members can select to attend one of the parent/ family caregiver-focussed sessions plus any three of the child-focussed sections and the final integrating session) also provides further possibilities for secondary caregivers to engage with at least some of the programme sessions (with primary caregivers potentially attending all sessions). Finally, secondary parents/caregivers are able to engage with the E-PAtS programme even if they are unable to attend the sessions through the workbook provided and are therefore able to experience and contribute towards positive outcomes for themselves and their family.

The comparator intervention will be Usual Practice (UP). UP includes any service (mainstream and specialised) provided to families and their children with intellectual disabilities (ID) as a part of an Education

Health and Care Plan (or equivalent outside of England) or via any other mechanism. Children with ID and their families could receive a wide variety of care and support from health, social and education sectors and the third sector depending on their needs. UP may vary by function (e.g., parent support, intervention for the child), and/or by the main recipient (the parent, the child with ID, the whole family). UP may include parenting support or psychological therapy for psychosocial health, but we will not recruit primary caregivers already receiving a recognisable parenting programme intervention, or a psychological therapy for mental health problems, at the time of baseline assessments (see Exclusion criteria). All other receipt of parenting support in both arms of the study will be recorded.

UP will be recorded by (both) parents in both arms of the study via monthly paper/electronic diary checklists to supplement and inform service receipt data gathered as a part of the economic evaluation. These data will enable us to describe UP for these families, which will inform a later definitive trial and other future research.

11.2 Compliance

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. Participant attendance at group sessions will be recorded by Facilitators on Session Adherence and Attendance forms. Observation of group sessions will measure adherence to the intervention.

12 Trial procedures

12.1 Baseline and follow-up assessments

Participants will be screened during a telephone/ face-to-face interview with research assistants (see Participant identification section above). As part of the eligibility check, a parental caregiver will be asked to complete the Vineland Adaptive Behaviour Scales (VABS) with the Research Assistant to determine eligibility in terms of the child's ID and the Brief Family Distress Scale to determine whether the family are currently in crisis and unable to cope. Both of these measures will then be scored by the research assistant.

If eligible and willing to take part, a recruitment/ baseline interview (either telephone interview or face-to-face) will be arranged and informed consent and baseline measures taken. Baseline data collection will include:

- Baseline demographic CRF completed including family living circumstances (including postal code, allowing coding of neighbourhood deprivation); gender, marital status, ethnic group, level of education, health/disability; parent health-related quality of life using the EQ-5D-5L; minimal

information on recent resource use; number of adults and children in household; household income and financial hardship; where the child with ID lives during a normal week and where they go to school/nursery; sibling gender and age.

- Baseline outcome measures completed (excluding Vineland Adaptive Behaviour Scales (VABS) and the Brief Family Distress Scale, which would have been taken for screening purposes) (See Outcome Measures section above).

Participants will be followed up at 3 months and 12 months post-randomisation for all outcome measures (except VABS which will not be completed at 3 month).

12.2 Process Evaluation

The process evaluation will examine four key aspects of the feasibility of conducting a definitive trial of E-PAtS: 1) intervention recruitment, adherence, and reach; 2) intervention implementation; 3) intervention mechanisms, including receipt and acceptability; and 4) the feasibility of implementing E-PAtS within a definitive RCT. MRC guidance [43] will be used as a framework for the process evaluation to describe implementation processes, refine the intervention logic model through examining intervention mechanisms, and consider the role of context in shaping intervention implementation and mechanisms. The process evaluation will employ a mixed methods approach. Quantitative methods will be used to assess recruitment rates/patterns and intervention fidelity. Qualitative interviews with intervention delivery staff, parent training providers and parents/carers will examine implementation processes, intervention mechanisms, the role of contextual factors, and interrogate patterns in the quantitative data. The Project Advisory Group (PAG) of family carers will be asked to provide input on the content of the interviews held with parents, and advise on the relevance, acceptability, and framing of key questions.

- Family recruitment and adherence, and intervention reach (feasibility issue 1):

E-PAtS attendance/engagement data for mothers and fathers will be recorded by facilitators for each group they run, including estimates of adherence. Qualitative interviews with facilitators (n=8, including at least three family carer co-facilitators) and representatives of intervention providers (up to 4) will be used to explore recruitment and engagement processes including barriers/facilitating factors for engaging mothers and fathers of young children with ID. Recruitment and engagement processes will also be explored through interviews with parents. Demographic information about recruited families will be examined to assess intervention reach among families with children with ID, and for fathers within these families.

- Intervention implementation (feasibility issue 2):

Fidelity of intervention implementation: All parenting practitioners (both professionals and family carer co-facilitators) will be trained in the delivery of E-PAtS through successful completion of a five-day training programme. We will also establish adherence to the E-PAtS manual for all parenting groups carried out in the feasibility study. Fidelity will be evaluated via standard E-PAtS facilitator self-rating of adherence forms for all sessions, to establish that both the session content has been delivered and that co-delivery has been provided with appropriate and balanced contributions from both professional and family caregiver facilitators. The E-PAtS programme manual contains a reflective practice and fidelity tool that will be used for this purpose. Three randomly chosen E-PAtS sessions (one from the first two sessions, two from the remaining six sessions) will also be video-recorded and independently rated by research assistants for adherence to the manual and balanced delivery of content and session involvement of the family carer co-facilitators. The fidelity to manual includes an average of 20 E-PAtS curriculum components per session that are rated as absent, partially present, or fully present. Additional components may be delivered relating to local adaptations and flexibility. These additional components are not formally assessed as a part of independent fidelity rating but will be recorded to aid understanding of how implementation processes and intervention mechanisms may vary according to the needs of different groups of parents. Involvement/balance of the family carer co-facilitators will be assessed with rating scales used in a current NIHR SSCR RCT of co-facilitated training [44]). Fidelity ratings at each of the two study sites (minimum of six recordings per site, plus three sessions for each delayed access E-PAtS course that may be delivered) will be carried out by the research assistant from the other site to ensure continued blinding.

Interviews with facilitators will be used to explore: the experience of engaging fathers in all sessions and/or in key aspects of the intervention (see Logic Model); adherence to the E-PAtS manual and key influences on implementation; any additions/adaptations made to the manualised content and the reasons for these; perceptions of the therapeutic relationship developed with parents; perceptions of group processes related to change and how these vary across sites/groups; perceptions of the mechanisms of change for parents, and whether they have used any elements of E-PAtS in their other work or their own family life. Data on local adaptations, and group processes and management will enable us to refine the intervention logic model, and to understand key influences on implementation fidelity, both at the level of the group, and delivery site level.

Recruitment of providers of parenting programmes and facilitators: Data will be collected on the demographic characteristics of facilitators delivering E-PAtS groups (e.g., professional training background, length of experience delivering parenting programmes), and the extent to which staffing requirements are achieved (e.g. the involvement of family carer co-facilitators). Qualitative interviews with facilitators and intervention provider representatives will explore factors that affect the fulfilment of staffing requirements.

- Intervention mechanisms, including receipt and acceptability (feasibility issue 3):

Between 3 and 12 months post-intervention, interviews will be conducted either face-to-face or over the telephone with: a) 10 mothers from families receiving the E-PAtS intervention, (b) 10 fathers from families receiving the E-PAtS intervention (5 fathers who took part in E-PAtS themselves, 5 where the mother of their ID child attended group sessions but the father did not), and (c) up to eight parents randomised to E-PAtS but who dropped out before intervention or attended only 1-2 sessions. Interviews with parents will address: recruitment to the intervention, including engagement and involvement of mothers and fathers; therapeutic relationships, group processes (e.g. peer support), and participants' perceptions of intervention mechanisms of change. Parents will also be asked about the acceptability of E-PAtS/fit with their family, perceptions of the research process, the impact of participating in E-PAtS on their daily life, sharing group learning with non-attending parents, and the outcomes from E-PAtS as they may have affected the daily life experience of the families (e.g., the E-PAtS strategies they used at home). In-depth discussions with sub-group (c) and fathers in sub-group (b) who did not fully participate in the E-PAtS group sessions will also focus on reasons for either not engaging or dropping out of the intervention and also, in the case of the partially-engaged fathers, their experience of the aspects of the intervention in which they did engage and/or were shared with them by their partner. Parent satisfaction questionnaires completed at the end of each E-PAtS group as a part of the intervention, supported (with attention to literacy needs of parents/family caregivers) and collated by the facilitators will be examined. Data from parents will be used to refine our understanding of key intervention mechanisms and identify optimal recruitment strategies for any future effectiveness RCT of E-PAtS. In all interviews with parents, participants will also be asked about whether and how socioeconomic status, age or ethnic identity might have had an impact upon uptake, adherence, experience or outcomes of the intervention. In addition, barriers and facilitators to the acceptability of consenting to the future trial if using routinely collected data will be investigated (i.e. if participants had been asked to consent to this, how would it have impacted on their decision to participate?)

- Feasibility of implementing E-PAtS within a definitive RCT (feasibility issue 4):

Data on recruitment (4.6.1), intervention fidelity and factors shaping implementation processes (4.6.2) and intervention mechanisms (4.6.3) will be used to help inform assessment of the feasibility of implementing E-PAtS within a definitive trial. Additionally we will carry out qualitative interviews with up to four representatives of the parent training provider teams involved with the study and up to 20 potential parent training provider organisations not involved in the feasibility study. These will examine the facilitating factors and barriers to the adoption of E-PAtS, willingness to take part in a later trial, and consider what systems and structures might be needed to maintain the intervention over time. A survey of up to a further 20 potential providers will also assess willingness to take part in a larger trial. Interviews and the survey will be carried

out within the two feasibility study regional sites and also in the central belt of Scotland and the far North of England (as potential additional regional sites for a later effectiveness trial). In interviews and surveys, data will be gathered on the providers' typical use of child-care to facilitate parents' involvement in parenting programmes.

We will also interview 8-10 parents who are randomised to the UP arm of the feasibility trial – to understand their experience of the UP arm, randomisation, and their choice of Study Path. All parent interviews will also include questions about their choice of Study Path.

Analysis of the data will then provide an over-arching synthesis of parents' experiences and perceptions related to the process evaluation aims and a triangulation exercise will provide an assessment of potential barriers and facilitating factors (gathered from all data sources) that may need to be taken into account in a future definitive trial, including recruitment strategies, implementation fidelity, intervention mechanisms and their interaction with local context.

- Other data for the process evaluation will include:

1. Services receipt questionnaires used as a part of the Health Economics evaluation (see Outcome Measures) that may identify the extent of any contamination through the receipt of other parenting programmes
2. Monthly diary usual practice checklists for all parents characterising Usual Practice (UP) and again identifying the extent of any contamination through participation in other parenting programmes. To help develop the checklist a focus group of 5-6 parents of young children with ID who are acting as parent advisors to the research (see PPI) will be asked to describe UP. They will also be asked to offer perspectives on how best to construct a diary checklist designed to capture UP on a monthly basis.
3. Reasons for drop out from the research recorded for all parents (if provided).

Figure 1. Schedule of enrolment, interventions and assessments[1]

Procedures		**Study timepoints**				
	Screening	**Baseline**	**Randomisation**	**Intervention period**	**3 month follow-up**	**12 month follow-up**
Consent for eligibility measures	X					

[1] Taken from the HRA CTIMP protocol template (2016).

Eligibility	X					
Vineland Adaptive Behaviour Scales (VABS)	X					X
Brief family Distress Scale	X					
Informed consent		X				
Contacts form		X				
Baseline CRF: Demographics EQ5D Resource use questions		X X X			X X	X X
Randomisation			X			
Intervention				X		
Warwick-Edinburgh Mental Well-Being Scale -parental psychological well-being		X			X	X
Parental anxiety and depression – Hospital Anxiety and Depression scale		X			X	X
Parent health-related quality of life - EQ-5D-5L		X			X	X
Parental situational coping approaches - the Brief COPE		X			X	X
Child Behavior Checklist (CBCL)		X			X	X
Pediatric Quality of Life InventoryTM		X			X	X
Happiness of relationship scale (if relevant)		X			X	X
Family APGAR scale		X			X	X
Sibling SDQ (if relevant)		X			X	X

Sibling Relationship Questionnaire (revised) (if relevant)		X			X	X
Family Support Scale		X			X	X
Five Minute Speech Sample		X			X	X
Parenting efficacy – 7 items from the Parenting Sense of Competence Scale		X			X	X
Positive Gains Scale		X			X	X
Parent relationship with partner and co-parenting questions (if relevant)		X			X	X
Child-parent relationship scale		X			X	X
Parent activities, involvement with child		X			X	X
Group Cohesion Scale (intervention only)		X			X	X
Demographics form (facilitators)			X			
Session adherence forms and attendance logs			X			
Video-recording observation of intervention session			X			
Observation rating forms			X			
Monthly diary usual care checklists				X	X	X
Participant qualitative interviews					X	
Qualitative interviews with facilitators					X	
Qualitative interviews with intervention providers					X	

13 Adverse Events

There are no expected adverse events related to the intervention or research procedures. The ethics committee will be asked to approve that adverse events should not be reported for this study.

However, should any member of the research team become concerned at any point about the well-being or safety of a participant or their child, study staff will follow a study-specific Standard Operating Procedure for dealing with harm which will be explained to participants during the consent process and highlighted explicitly in participant information sheets.

14 Statistical considerations

14.1 Randomisation

Families will be randomised using an equal allocation 1:1 ratio to E-PAtS or Usual Practice (UP). Randomisation will occur using randomly permuted blocks and will be developed by the study statistician The final randomisation list will be implemented by the senior statistician (in order to maintain the blind throughout the study of the statistician carrying out the main statistical analysis). Within this feasibility study, allocation will be stratified by a small number of key factors: study site, and whether families choose Study Path A or B. The Research Assistant will inform participants of their allocation by telephone.

14.2 Blinding

Parents and facilitators will not be blind to allocation. However, the statistician carrying out the main statistical analyses will remain blind to allocation up until the point the analysis is performed. In addition, outcome data will be collected by Research Assistants who will also remain blind to allocation, and will be trained to minimise the risk of participants revealing allocation in follow-up assessments (e.g., via use of standardised data collection script). If the Research Assistant is accidently made aware of the allocation of the participant, this will be recorded.

14.3 Sample size

A total of 64 families (32 families in the Usual Practice [UP] arm, 32 in the intervention arm) will be recruited. As this is a feasibility study, and the purpose is to provide estimates of key parameters for a future trial rather than to power the current study to detect statistically significant differences, a formal a priori power calculation will not be conducted [40]. However, recruiting 64 families will provide a certain level of precision around a 95% confidence interval (CI). For example, if 80% of families approached give consent for study participation, the 95% CI around the percentage can be estimated within +/- 9.8% (i.e., 70.2 to 89.8%). The widest the 95% CI would be, when the estimated percentage is 50%, is +/- 12.2%. Eight E-PAtS groups will be run in total: four as a part of the intervention arm for the study and up to a further four depending on the number of families who choose Study Path A (see Flow Diagram). While the sample size is based on families,

outcome data will be collected for individual parents. Parents within the same family will be randomised to the same arm, making this a cluster feasibility study with randomisation.

14.4 Missing, unused & spurious data

Detail of missing data will be described in the Statistical Analysis Plan (SAP).

14.5 Procedures for reporting deviation(s) from the original SAP

Any deviations from the original SAP will be submitted as substantial amendments where applicable and recorded in subsequent versions of the protocol and SAP.

14.6 Termination of the trial

There will be no formal 'stopping rules' or 'discontinuation criteria' for individual participants, parts of trial and entire trial. Any concerns with participant well-being will cross reference this section with those for the IDMC and TSC as these groups are likely to be involved with this decision making process.

14.7 Inclusion in analysis

All randomised participants' data will be included in analysis.

15 Analysis

15.1 Statistical analysis

As this is a feasibility study, the majority of the outcome analysis (recruitment, retention, adherence, fidelity to E-PAtS manual, parents' choice of Study Paths A/B, characterisation of Usual Practice) will be descriptive in nature. Continuous data will be reported as means and standard deviations, or medians and interquartile ranges, as appropriate. Categorical data will be reported as frequencies and proportions. Feasibility outcomes will be estimated with their associated 95% confidence intervals. Family characteristics at study entry will be described both overall and by parents' design choice (i.e., Study Path A or B).

No formal hypothesis testing will take place. The main preliminary analyses of outcomes will be Intention to Treat-based, accounting for clustering (groups in intervention arm, parents in families) using multilevel models. Single parent families will be included as a cluster of size 1. The primary analysis will examine mean WEMWBS scores between arms at 12 months post-randomisation, with baseline WEMWBS scores included as a covariate. The analysis will also adjust for randomisation factors. Secondary outcomes (including outcomes at three months post-randomisation) will be analysed similarly, with appropriate multilevel regression models. An exploratory complier average causal effect analysis will also be conducted, focused on parents who complete the E-PAtS programme (see earlier definitions of completion/adherence). Results from all regression models will be reported using point estimates and 95% confidence intervals.

A full statistical analysis plan will be written by the statistician and approved by the Study Management Group and Study Steering Committee prior to any analysis taking place.

15.1.1 Sub-group & interim analysis

No subgroup and interim analysis will take place.

15.2 Analysis of Process Evaluation data

With appropriate consent, all interviews will be audio-recorded, transcribed fully, and anonymised for analysis. Computer software (NVivo) will be used to manage the qualitative data and transcripts. Thematic analysis will be used to analyse each of the sub-sets of interviews (mothers, fathers, non-attenders, facilitators, provider organisations) separately and independently. We will then also use a thematic analysis approach for a qualitative synthesis across the interview sub-groups that all involve parents. This analysis will then provide an over-arching synthesis of parents' experiences and perceptions related to the process evaluation aims. Finally, a triangulation exercise will be conducted combining all of the qualitative results with the quantitative data analysis results including an assessment of potential barriers and facilitating factors (gathered from all data sources) that may need to be taken into account in a future definitive trial, including recruitment strategies, implementation fidelity, intervention mechanisms and their interaction with local context. Data collection across the feasibility study will be designed to maximise the potential for triangulation.

15.3 Cost effectiveness analysis

This study will include an assessment of the best possible ways of expressing the cost-effectiveness of the E-PAtS study for a larger subsequent trial.

The following will be evaluated:

(i) The performance of alternative client service receipt inventories (administered at baseline and at 3 months and 12 months post-randomisation) in collecting resource utilisation data.

(ii) The availability of routine health and social data sources that could be used to complement and validate self-reported resource utilisation data.

(iii) The appropriate sources of unit costs for potential resource consequences and an assessment of how much primary costing research will be required for the main study.

(iv) The best possible way of expressing the cost-effectiveness of the EPAtS programme using preference-based approaches. As part of the feasibility study, a discrete choice experiment will be designed with the potential to value the disparate outcomes observed by a subsequent definitive trial within a cost-benefit analysis framework. The qualitative research will be used as the basis for identifying potential attributes for this discrete choice experiment.

15.4 Progression criteria for a definitive trial

The following criteria will inform the decision to progress to a definitive trial:

- Recruitment of families - 50% of families approached, and who are eligible, consent to the study (and thus are willing to be randomised)
- Rate of recruitment – the target sample of 64 families is achieved within the study recruitment period
- Randomisation feasibility – 10-16 families are recruited in a local area of the E-PAtS provider to allow randomisation and a maximum of 8 families per E-PAtS group
- Study retention – 75% of primary caregivers are retained for follow-up at 12 month data collection point
- Adherence – 70% of primary caregivers and 40% of recruited secondary caregivers adhere to the E-PAtS programme (one of first two sessions, three from the remaining six sessions, and the final integrative session)
- Fidelity – 70% of E-PAtS curriculum components are rated as partially or fully present in all recorded group sessions available for analysis
- Usual practice – between baseline and 12 month follow-up, no more than 30% of primary caregivers in the UP arm of the study receive a parenting programme (a Triple P, Incredible Years, or similar programme)

- Provider willingness to participate in a definitive trial – a sufficient number of training providers indicate a willingness to take part in a new trial and to provide the number of E-PAtS groups needed for the definitive trial (numbers needed to be informed by a sample size calculation for the definitive trial protocol)
- Study Steering Committee consensus – considering all progression criteria, feasibility study findings, and evidence of whether progression criteria not met can be mitigated, a clear majority of the SSC independent members recommend progression to a definitive trial

  The following information will be used to inform the protocol for a definitive trial
- The recruitment pathways leading to the largest numbers of families recruited and highest levels of consent, while not introducing important bias, will be identified and used to inform the protocol
- Primary outcome – will be confirmed as the WEMWBS if 90% of the collected measure are usable (data completeness)
- Secondary outcomes – any secondary outcome will be re-considered if <70% of collected data are usable for any measure
- Usual practice trial arm – if 70% or more of parents choose one of the Study Paths A or B, this Study Path will be used in the definitive trial
- The process evaluation will also be used to understand the barriers and facilitating factors for recruitment and engagement from the perspective of all stakeholders (parents, parenting providers, facilitators), including potential consent for data linkage of routinely collected data. Recommendations for enhancements or additions will be incorporated into the protocol.

16 Data Management

Source data will be paper versions of the CRFs/questionnaires. If CRFs/questionnaires are completed by the Research Assistant face-to face or over the telephone, the Research Assistant will return CRFs/ questionnaires to the study site immediately. If CRFs/questionnaires are posted to the participants, they will be returned in free-post envelopes to the study sites. CRFs/questionnaires will only contain a unique identifier (PID) per participant, initials and date of birth. No other identifiable information will be recorded on the CRFs/questionnaires.

The Research Assistants at each site will enter CRF/questionnaire data on to a secure bespoke Microsoft SQL Server database. Access to the database will be via username and password and restricted to appropriately-

trained personnel only. The database will be housed on local servers managed by Cardiff University staff in accordance with all appropriate legislation.

Identifiable data will be encrypted and stored separately from non-identifiable data.

Wherever possible data will be validated at point of entry, thereby reducing the opportunity for missing or unexpected data. All changes made to the data will be recorded and visible via an audit log within the database.

The planning, development, testing and maintenance of the database will be performed in line with CTR SOPs, as will the data management function.

Copies of CRFs/questionnaires will be returned to the CTR/Study Manager by courier. Qualitative interview / observation recordings will be will be recorded on encrypted audio-recorders / video-recorders and stored on password protected computers at site. Recordings will be securely transferred to the study team at the Centre for Trials Research by Fastfile. All files will be encrypted. Any transcripts will be fully pseudonymised. A data management plan will be developed to outline the details of how data will be collected, transferred stored and accessed by the team.

The following source data will be collected:

Study data	Source Data									
	Contacts form	Screening form	Baseline CRF	Questionnaires	Demographics form (facilitator)	Video-recording observation	Observation rating form	Session adherence forms/attendance logs	Monthly diary usual care checklists	Qualitative interview recordings
Contacts information	X									
Screening information		X								
Demographics / baseline measures			X							
Study outcomes				X						
Demographics (facilitators)					X					
Fidelity of session content								X		
Attendance data								X		

Observation data for intervention sessions						X	X			
Qualitative interview data										X
Usual care data									X	

16.1 Completion of CRFs

16.1.1 Paper CRFs

The original versions of the CRFs/questionnaires/diaries are to be retained at the local site. Research Assistants at each site will be responsible for data entry from CRFs/questionnaires/diaries onto the online study database. A copy of the CRFs/questionnaires/dairies will be returned to the CTR for data checking/ querying within approximately four weeks of completion. In accordance with the principles of GCP, the PI is responsible for ensuring accuracy, completeness, legibility and timeliness of the data reported to the CTR in the CRFs.

CRF pages and data received by the CTR from participating sites will be checked for missing, illegible or unusual values (range checks) and consistency over time.

If missing or questionable data are identified, a data query will be raised on a data clarification form. The data clarification form will be sent to the relevant participating site. The site shall be requested to respond to the data query on the data clarification form. The original CRF pages should not be altered.

All answered data queries and corrections should be signed off and dated by a delegated member of staff at the relevant participating site. The completed data clarification form should be returned to the CTU and a copy retained at the site along with the participants' CRFs.

The CTR will send reminders for any overdue data. It is the site's responsibility to submit complete and accurate data in a timely manner.

16.1.2 Electronic Database/Data Entry

It is intended to develop data recording for this study as a web-based system. Research Assistants at each site will enter all data onto the study electronic database. This is a secure encrypted system accessed by an institutional password, and complies with Data Protection Act standards. The system can be accessed on:

<Web address to be confirmed>

All data on the online database will be subject to data check for data quality, as per the data management plan. Due to the low-risk of this feasibility study and based on participant numbers, this QC check is set as 10%.

17 Translational research or sub trial

N/A

18 Protocol/GCP non-compliance

The Principal Investigator should report any non-compliance to the study protocol or the conditions and principles of Good Clinical Practice to the CTR in writing as soon as they become aware of it.

19 End of Study definition

The end of the study is defined as the date of final data capture to meet the study endpoints. In this case end of study is defined as the date of the last follow-up data collection.

The sponsor must notify the Ethics Committee of the end of a clinical study within 90 days of its completion or within 15 days if the study is terminated early.

20 Archiving

The Study Master File (SMF) containing essential documents will be archived at an approved external storage facility for a minimum of 15 years. The CTR will archive the SMF on behalf of the Sponsor. The Principal Investigator at each site is responsible for archival of the Site file on approval from the Sponsor. Essential documents pertaining to the study shall not be destroyed without permission from the Sponsor.

21 Regulatory Considerations

21.1 Ethical and governance approval

This protocol will receive approval from a University of Warwick ethics committee.

Approval will be obtained from the host care organisation who will consider local governance requirements and site feasibility. The Research Governance approval of the host care organisation must be obtained before recruitment of participants within that host care organisation.

21.2 Data Protection

The CTR will act to preserve participant confidentiality and will not disclose or reproduce any information by which participants could be identified, except where specific consent is obtained. Data will be stored in a secure manner and will be registered in accordance with the Data Protection Act 1998. Participants will always be identified using a unique Participant identification number (PID) and additional identifiers. All other identifiable information will not be stored with collected data.

21.3 Indemnity

The University of Warwick has in force a Public and Products liability policy, a Clinical Trials insurance policy and a professional Indemnity policy which provides cover for "negligent harm" and the activities here are included with in that coverage subject to the terms, conditions and exceptions of the policy. The University of Warwick does not provide compensation for non-negligent harm.

21.4 Study sponsorship

The University of Warwick will act as Sponsor for study. Delegated responsibilities will be assigned to the sites taking part in this study (see Delegation Logs).

21.5 Funding

The study is funded by National Institute for Health Research (NIHR) Public Health Research (PHR) programme. Host organisations will meet the costs of programme delivery that relate to the training of facilitators, employment of facilitators, use of facilities, and reproduction of materials.

22 Study management

22.1 SMG (Study Management Group)

The SMG will normally meet bimonthly during the study. SMG members will consist of all Co-investigators, collaborators and the study team and will oversee all aspects of the E-PAtS Feasibility Study. The role of the SMG will be to help set up the study by providing specialist advice, input to and comment on study procedures and documents (information sheets, Protocol, etc.). They will also advise on the promotion and running of the study and deal with any issues that arise. SMG members will be required to sign up to the remit and conditions as set out in the SMG Charter.

22.2 SSC (Study Steering Committee)

A Study Steering Committee (SSC), consisting of an independent chair with expertise in ID research and trials research, and at least two other independent members including a lay representative and Statistician, will

meet at least annually and will oversee all aspects of the E-PAtS Feasibility Study. Non-independent members will include the joint CI. The joint CI, statistician, Study Manager and other members of the study management team may attend in an observer capacity at the request of the Chair.

The first meeting will be as soon as possible, and ideally before the study commences, to review the Protocol and arrange the timelines for the subsequent meetings. If necessary, additional/more frequent meetings may occur. The SSC will provide overall supervision for the study and provide advice through its independent chair. The ultimate decision for the continuation of the study lies with the SSC.

SSC members will be required to sign up to the remit and conditions as set out in the SSC Charter which will be filed in the TMF.

The SSC will determine whether an independent Data Monitoring and Ethics Committee is required for the study at their first meeting or whether the SSC will take on data monitoring function. As this is a low risk study, it is expected that an iDMEC will not be required.

22.3 DMEC (Data Monitoring and Ethics Committee)

See above. If applicable, this section will be completed following decision by the SSC.

22.4 Project Advisory Group (PAG)

We will also establish a Project Advisory Group (PAG) of parents of young children with ID, supported by Shurlock and our PPI partner organisation. This group will not have a formal governance role, but will offer strategic advice on engaging families, and will contribute to the interpretation of the feasibility study findings. The PAG will also advise on information sheets and other ethics matters, and on co-production of dissemination outputs for parents, act as ambassadors for the research project, and creating communication pathways with parents of young children with ID and parent networks. PAG members will also work with the research team to develop a parent monthly diary checklist to assist with recording information about Usual Practice.

23 Quality Control and Assurance

23.1 Monitoring

The clinical trial risk assessment has been used to determine the intensity and focus of central and on-site monitoring activity in the E-PAtS Feasibility study. Low monitoring levels will be employed and are fully documented in the study monitoring plan.

Investigators should agree to allow study related monitoring, including audits and regulatory inspections, by providing direct access to source data/documents as required. Participant consent for this will be obtained.

Findings generated from on-site and central monitoring will be shared with the Sponsor, CI, and PIs.

23.2 Audits & inspections

This study may be participant to inspection and audit by the University of Warwick under their remit as Sponsor. The sites/ host organisations will permit study-related monitoring, audits and REC review, providing direct access to source data/documents.

24 Publication policy

Outputs from the E-PAtS Feasibility Study will include open access peer reviewed journal articles in international academic journals, at national and international academic conferences and at University public engagement events. All publications and presentations relating to the study will be authorised by the SMG.

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27 Appendices

- Appendix 1 Logic diagram of the E-PAtS

CONTEXT AND ASSUMPTIONS:

- Parents of children with ID are at risk of isolation, experiencing problems with ***psychological wellbeing*** and report difficulties accessing services. Young children with ID are at risk of developmental and behavioural/emotional problems, associated with poor wellbeing, reduced quality of life and high long-term support costs.
- Parent wellbeing is a major ***family characteristic stressor,*** known to reduce the quality of ***family patterns of interaction (Guralnick, 2001b)*** which further impact upon child outcomes. The relationship between child behaviour and parental wellbeing is bidirectional (as predicted by ***couple and parent-child sub-systems*** in ***Family Systems*** theory).
- A parent-focused programme that targets ***family and material resources,*** to improve ***family patterns of interaction*** in ways consistent with the ***Developmental Systems Model principles of early intervention (Guralnick, 2001b),*** alongside an analysis of the ID specific context ***(Gore et al., 2014)*** is needed.

AIMS AND MECHANISMS

- E-PAtS is underpinned by ***DSM principles of early intervention***. It is informed by a ***developmental framework*** and ***systems perspective*** (directly informed by a review of key variables in the ID context , Gore et al., [2014]), maximises ***early detection, integration and co-ordination of supports*** and utilises ***evidence based*** practices in ***co-production partnership*** with parents
- E-PAtS builds ***family and material resources*** by fostering ***parental psychological wellbeing***, knowledge and skills of parents of children with ID in the early years and increasing access to social and professional support.
- This provides a basis for improving ***family patterns of interaction*** especially ***parent/caregiver-child and other family relationships/transactions,*** supporting positive change for children.
- Improved child development further supports improved parental wellbeing and reduces support costs longer term.

INPUTS

E-PAtS Co-production (*co-production partnership*):

- Programme developed through on-going co-production with families and professional stakeholders
- Programme routinely delivered by parent/ family caregiver facilitator and professional facilitator working in partnership
- Programme materials adapted for each delivery to reflect characteristics of local resources, services and facilitators
- Flexibility and within-session tailoring of programme materials and delivery to meet individual needs of parents/families in each group

E-PAtS Setting and Context (*early detection, integration and co-ordination*):

- Delivered in Early Years settings for families with children in critical period (under 5 years)
- Recruitment process to support access by families of children with a wide range of intellectual and developmental disabilities, and those awaiting diagnosis
- Deliverable in range of services by facilitators with a range of professional backgrounds and family caregiver facilitator
- Programme and session length that is acceptable to and feasible for families, and fits with typical service delivery
- Procedure for identifying, training and ensuring competence of programme facilitators. Facilitators gain confidence and knowledge through training and programme delivery

E-PAtS Group Process (*systems perspective*):

- Group preparation interview to support engagement for 2+ parents/caregivers (i.e. Mother and father)
- Emotionally supportive group context and family-to-family peer networking
- Empowering approach building on group member's strengths
- Engagement with ***couple sub-system***. At least 2 caregivers (i.e., mother and father) from each family through programme attendance and other engagement mechanisms such as sharing of session materials and workbook and resources with other family members

E-PAtS Programme Curriculum (*developmental framework, evidence-based practices*):

- Grounded in evidence-based approaches specific to children with ID and ***parent-child subsystem***
- 2 x primary sessions on empowering families and supporting caregiver resilience and wellbeing (with further coverage of both areas in all additional sessions)
- 5 x sessions on supporting development and reducing emotional and behavioural problems for children and increasing the skills / capacity of family caregivers
- One final integration session including planning beyond the group programme
- Curriculum structure supports flexible attendance for primary and second caregiver (completion requires attendance of at least 1 parent/caregiver session plus 3 child-focussed sessions and final integrative session)
- Work book, resources and tools given to each group member to support family patterns of interaction outside of sessions and over the longer term

PROCESSES

Building Family Resource

Social and emotional peer support to build confidence, increase resilience and support wellbeing for family caregivers.

Increased caregiver skills and strategies to support own emotional wellbeing and resilience.

Collaboration for ***couple sub-system*** of 2+ caregivers (i.e., mother and father) to develop shared knowledge and approach for supporting child.

Individualisation that responds to the varied needs and circumstances of children and families.

Increased caregiver skills and knowledge to support development, emotional and behavioural difficulties for children with ID via ***parent-child sub-system.***

Building Material Resource

Strategies and Knowledge to support proactive engagement with local services and professionals.

Facilitation of a socially and emotionally supportive peer group context.

OUTCOMES

SHORT TERM (Post-intervention)	MEDIUM TERM (approx. 6-months)	LONG TERM (12 months+)
Group process and knowledge acquired from programme curriculum leads to:	*Implementation of skills acquired from programme, building on prior outcomes leads to:*	*Further implementation of skills and interaction of prior outcomes leads to:*
Parents / family caregivers: Increased ***parental psychological wellbeing***, confidence, and resilience Increased partnership working between ***couple sub-system*** and other family members Increased knowledge/skills in child development, emotional and behavioural problems	**Parents / family caregivers:** Further increased ***parental psychological wellbeing,*** confidence, and resilience; increased partnership working between ***couple sub-system***/ family members ***Improved patterns of family interaction*** (caregiver-child and other family relationships transactions)	**Parents / Family caregivers:** Maintained/further ***parental psychological wellbeing,*** confidence, and resilience; increased partnership working between ***couple sub-system family members*** Continued ***positive patterns of family interaction*** Improved family quality of life
Family Support System: Increased knowledge and engagement regarding professional /financial support services	**Family Support System:** Increased access to appropriate professional support services Enhanced system of social support	**Family Support System:** Reduced need for specialist professional/service utilisation Maintained system of social support
Child: Improved ***parent-child sub-system*** relationship / positive perception of child	**Child:** Improved ***parent-child sub-system*** relationship / positive perception of child Improved development and adaptive skill acquisition Initial reductions in emotional and behavioural problems	**Child:** Maintained ***parent-child sub-system*** relationship / positive perception of child Further improved development and adaptive skill acquisition for child Further reduced emotional and behavioural problems

EXTERNAL FACTORS

- Availability of local services and supports for families to access following the programme
- Competing demands on time and availability of family caregivers to attend programme

NOTE - *Bold italics* are used to highlight key concepts or references that relate to the theoretical grounding of the E-PAtS intervention and the outcomes