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FULL TITLE OF PROJECT

Helping Families: The Systematic Development and Pilot Randomised Controlled Trial of a Psychoeducational Intervention for Parents with Personality Disorders

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BACKGROUND

Child mental health and parental personality disorder

One in ten children in the UK experience significant emotional or behavioural difficulties that interfere with developmental progress, family life and school achievement, while increasing long-term risks for poor adult mental health, unemployment and crime [59-61]. The likelihood of severe and persistent problems is increased when a parent has a personality disorder [62, 63]. This diagnostic category applies to 4.4% of the general population and 40% of adult mental health service users [34, 35], of whom about 25% are parents [26]. People with personality disorder are highly sensitive to stress and prone to dysregulated mood, self-harm, substance use and interpersonal challenges that can affect their capacity to offer the stable, responsive care and nurture required for healthy child development [64]. As a consequence, their children may be more likely to come into contact with child protection services and develop enduring mental health problems of their own [65]. Moreover, having a child with emotional and/or behavioural difficulties is stressful in itself, and may worsen a vulnerable parent's own mental health [37].

Standard parenting psychoeducation

Interventions that target maladaptive parenting can lead to significant benefits in child mental health and developmental outcomes. The strongest effects are obtained for psychoeducational "parent training" programmes, especially when used to treat disruptive child behaviour problems [27, 28]. Typical content incorporates social learning principles and methods such as skills rehearsal, video modelling and role-play of effective discipline and relationship-enhancing strategies. Unfortunately, standard parent training curricula achieve higher dropout rates and poorer outcomes for families with co-occurring child and parental psychopathology [50, 66].

Specialised psychoeducational interventions

Although more specialised parenting interventions have been developed for complex families, these are not currently designed to meet the specific needs of parents with personality disorders and their children [36]. One promising health technology relevant to this population is the Helping Families Programme (HFP) [17, 22-25], which was originally developed for use with complex, multi-problem families. The content combines parenting psychoeducation with cognitive, behavioural and interpersonal strategies from five clinical modules, selected according to the needs of individual families. The aims are to (i) improve parent-child relationships and interpersonal conflicts, (ii) promote effective coping with daily stress, (iii) implement effective mood regulation strategies, (iv) minimise harm from substance misuse, and (v) build social support. HFP also includes manualised techniques for developing personalised action plans and collaborative relationships with parents. Results from real-world cohort studies demonstrate good service user acceptability and significant impacts on a range of child and parent outcomes [23-25].

The flexible, modular structure and goal-directed approach of HFP have strong potential for adaptation and integration with the content and methods of Psycho-Education with Problem-Solving (PEPS) [16, 19-21]. PEPS uses a structured clinical assessment and psychoeducation to explore the meaning of a personality disorder diagnosis, and link this to current difficulties in social functioning and relationships. Personal goals in these domains are then addressed in a focused problem-solving intervention. In recognition that people with personality disorders often have difficulties maintaining participation in treatment [67], PEPS has well defined theory and methods to optimise motivation and therapeutic rapport [68, 69]. Previous evaluations, including a pragmatic randomised controlled trial, show good retention and significant clinical impact [19, 20].

Relevance to current NHS policy and practice

Costs of child mental health problems and adult personality disorders. The UK has 10.5 million children, one million of whom have mental health problems [43]. Although effective child mental health interventions exist, relatively few studies have looked at cost-effectiveness [44]. The strongest evidence relates to parent training for severe child disruptive behaviour [27]. These interventions cost about £1,200 per participant and can produce savings to society of £16,435 per family over a 25-year period [45]. Further estimates suggest that parenting interventions for high-risk families could cost £210 million to provide but may save £5.2 billion over the longer term [46]. At the same time, annual direct treatment costs in the UK for adults with personality disorder exceed £70 million, with wider societal costs estimated at £8 billion per year in England [47]. This reflects the considerable demands placed on a range of services, including emergency departments, social services and the criminal justice system. Even small reductions in personality-related problems and child behaviour problems could lead to substantial savings.

Current practice challenges. The interrelationship between child and parental psychopathology remains a serious challenge to current services. Policy initiatives advocate integration but much mental health provision offers fragmented care that focuses on the needs of *either* the adult *or* the child [38]. Furthermore, many parents are reluctant to disclose their own mental health difficulties to practitioners in children's services, or discuss parenting difficulties within adult mental health services, due to stigma and fear of safeguarding procedures [39]. Parents diagnosed with a personality disorder may be especially aware of enduring negative attitudes among some clinical staff [70, 71]. This may hinder help-seeking and consequently increase the likelihood of a mental health crisis [40].

Potential benefits for patients and the NHS. Successful early intervention through effective parenting support is a major policy and service priority [27, 41]. The proposed research will advance scientific and clinical knowledge in a population where specialised early intervention is strongly indicated but rarely tested [42]. It will help to establish a differentiated conceptual model of parenting for adults affected by personality disorder, building upon and refining the generalised models of developmental psychopathology that currently exist. Our pilot work will be used to inform a subsequent large-scale trial in which theoretical mechanisms of change can be elaborated and verified.

We will incorporate in-depth service user and clinician consultations, interviews, and systematic descriptions of usual care in order to better understand and overcome barriers to integrated care for targeted families. This will generate new contextualised knowledge about the design and delivery of accessible, acceptable and effective support for parents who are often marginalised by conventional parenting programmes. The resulting intervention has the potential to improve parenting and family functioning while attending to safeguarding needs. Patient and NHS benefits may include improved child and parental mental health with reduced need for crisis services. There is longer-term potential to reduce the entrenched burden of psychosocial adversity and intergenerational transmission of mental disorders within families.

Our team has wide experience of implementing training and supervision programmes in manualised parenting interventions across the UK and internationally. This has shown that there is significant demand among practitioners, managers and commissioners for more targeted and effective ways of helping vulnerable, high-need families. Demonstrating such intent, two NHS trusts in addition to our confirmed research sites have already expressed interest in the proposed health technology and willingness to participate in future evaluations.

AIMS & OBJECTIVES

Aims

The following study aims will be achieved through a three-phase study design.

Phase 1: To develop a manualised screening process and psychoeducational intervention for parents with personality disorders who have children with emotional or behavioural disorders.

Phase 2: To assess the acceptability of the screening process and intervention to clinicians and service users, and the feasibility of implementation in candidate service settings.

Phase 3: To test the intervention in a pilot RCT designed to (i) demonstrate the feasibility of trial procedures; (ii) obtain preliminary evidence about the intervention's effects on parent, child and family outcomes and cost-effectiveness; and (iii) generate process data and obtain variance estimates necessary to design and power a full trial.

Objectives

Phase 1: (i) establish a Manualisation Working Group comprised of co-applicants who are authors of established psychoeducational manuals for parenting and personality disorders; (ii) produce novel clinical manuals through an iterative process of distillation and integration of existing theory-based and empirically-supported psychoeducational intervention methods; and (iii) establish consultation groups of service users and clinicians to consider emergent findings from the literature reviews and successive drafts of the new manuals.

Phase 2: (i) implement the new manuals and support their final iterative development through a series of clinical case studies involving assessment of clinicians' and users' experiences, perceived impacts and rapid feedback of emergent findings; (ii) establish feasible referral and recruitment pathways in candidate mental health and social care services; (iii) continue clinician and service user focus groups that will review and comment on data and ethical issues emerging from case studies; (iv) obtain a detailed description of usual care to inform definition of the pilot trial comparator arm; (v) obtain independent ethical scrutiny of the issues raised in the case studies and descriptive study of usual care; and (vi) develop a research protocol for the pilot trial, with defined intervention and control conditions and acceptable and feasible methods for identifying and selecting eligible participants.

Phase 3: (i) conduct a pilot trial with a parallel process evaluation to investigate the influence of contextual factors on implementation and outcome generation for the intervention; (ii) assess trial feasibility with respect to predefined parameters; (iii) obtain variance estimates for parent and child outcomes; (iv) measure intervention costs and make preliminary estimates of cost-effectiveness; and (v) produce a full-scale trial protocol.

DESIGN

Research framework

The research brief calls for the development and manualisation of a complex screening process and psychoeducational intervention. The MRC framework for complex interventions [33] has been used to formulate a phased research design that includes (i) use of evidence and theory from existing manualised interventions and systematic reviews; (ii) feasibility testing and preliminary outcome generation derived from a case series and pilot RCT; and (iii) concurrent process evaluation to examine subjective experience and contextual factors.

Our pragmatic, mixed-methods approach [75] is intended to produce generalisable research findings and detailed understanding of the new health technology that will be used to inform a definitive trial. Research findings will be concurrently and sequentially combined to inform the development and refinement of the new health technology. The use of child and adult services across two NHS Trusts will provide initial understanding of the technology's performance under varied circumstances. The involvement of a service user researcher is intended to facilitate understanding of service user perspectives, which can complement, contest and add value

to data derived from other sources and methods.

Empirical methods will test *a priori* hypotheses across primary outcomes and secondary outcomes. Follow-up data will determine the extent to which short-term changes persist. Randomisation is intended to reduce selection bias and other threats to internal validity. Qualitative methods using multiple informants are intended to identify and examine key process themes related to service user experience, the use and implementation of the technology, and associated contextual characteristics.

Research plan

Phase 1: Screening and intervention development. Development of the new health technology will be undertaken by the Manualisation Working Group (MWG) led by authors of PEPS (McMurran) and HFP (Day & Ellis). Distillation and integration of existing clinical materials will be informed by supplementary evidence from updated systematic reviews and iterative feedback from clinician and service user consultation groups. Each group will contain N=10 participants and meet at least three times. The draft screening manual will set out systematic procedures for identifying and selecting eligible participants. The psychoeducational manual will aim to (i) build rapport and motivation; (ii) share knowledge about personality disorders and parenting; (iii) develop effective parenting skills; (iv) reduce parenting stress; and (v) improve child, parent and family outcomes.

Phase 2: Pre-pilot feasibility study. Two research therapists will be trained and supervised to deliver the new health technology to a purposive sample of N=12 parents representing predefined demographic, case-mix and service variables. After treatment, key informant interviews will assess clinicians' experiences of case identification procedures and parents' experiences of screening and psychoeducation (up to N=24 total interviews). Preliminary outcomes will be investigated on standardised parent-report measures of child, parent and family functioning, and therapeutic alliance. Concurrent collection and analysis of process and outcome data will enable rapid feedback of emergent findings to the MWG and the rest of the research team. An independent expert in biomedical ethics will scrutinise the content and initial use of the new health technology against relevant frameworks.

Descriptive data on usual care will be obtained through documentary sources (operational policies, activity data) and thematic analysis of key informant qualitative interviews (N=10), with service representation in each research site from CAMHS (n=2), adult mental health (n=2) and social services (n=1). This will define usual care pathways and case co-ordination arrangements. Thematic analysis will support drafting of final clinical manuals and the pilot trial protocol, which will define (i) the comparator arm (usual care), (ii) an acceptable and feasible methodology for establishing eligibility for the intervention, and (iii) efficient trial recruitment pathways.

Phase 3: Pilot RCT. A two-arm, parallel RCT will randomly allocate N=70 consenting parents in a 1:1 ratio to the psychoeducational intervention (plus usual care) or usual care alone. Primary outcomes will be child and parental mental health. Secondary outcomes will be parenting satisfaction, parenting behaviour and therapeutic alliance. Measures will be collected at baseline, post-treatment and 6-month follow-up by a research worker blind to group allocation. Regular newsletter briefings and telephone contact at 3 months post-intervention will be used to promote retention. Multi-level models will be used to estimate treatment effects. Population variances for future power calculations will be determined using the upper 80th percentile of confidence intervals around the estimated population variance [15]. Feasibility of trial procedures will be examined using proportions and 95% CIs for rates of (i) initial identification, (ii) consent and availability to be approached by a research therapist, (iii) consent and availability for screening, (iv) trial eligibility, (v) availability for baseline assessment, (vi) randomisation, (vii) treatment retention, and (viii) availability for follow-up. A parallel process evaluation will undertake up to N=30 key informant interviews with NHS clinicians, local authority social service staff and parent participants in order to explore (i) acceptability of, and adherence to, identification, screening and intervention procedures; and (ii) contextual factors that shape implementation of the new health technology and explain outcome variability. Interviewees will be purposively sampled using service characteristics and outcome. Health service costs will be viewed alongside the outcome measures in a cost-consequences analysis. A cost-utility analysis will be performed by combining data on costs with QALYs. Uncertainty around economic results will be assessed by cost-effectiveness planes and acceptability curves.

SETTING

A coordinated, multi-site approach will enable the new health technology to be thoroughly piloted across different service contexts. We will conduct the research in two NHS Mental Health Foundation Trusts in

London that serve large and diverse populations with high rates of adult and child mental health problems. This will be augmented by additional fieldwork in children's social service teams operating within the same catchment areas. Relevant services within the two NHS Trusts are outlined below.

South London and Maudsley (SLaM) NHS Foundation Trust

SLaM covers four London boroughs (Southwark, Lambeth, Lewisham and Croydon) with a total catchment population of approximately 1.2 million, as well as providing a number of specialist regional and national services. Adult mental health services are configured into Clinical Academic Groups (CAGs) centred on distinct disorder clusters, including eight community Mood, Anxiety and Personality (MAP) teams that treat adults aged 18-65 years with a range of emotional and personality problems. The MAP CAG includes three specialist outpatient services and a service-user led support network for people with personality disorder. These services offer a range of individual and group therapies. Community MAP teams typically provide case management, and fewer psychological therapies. The CAMHS CAG has four borough community services that work with a range of mental health presentations in children and adolescents aged 0-18 years. Specialist regional and national teams have more narrowly defined referral pathways centred on specific treatment modalities and/or clinical criteria.

Central and North West London (CNWL) NHS Foundation Trust

CNWL provides services to a catchment area of 1.45 million across five London boroughs (Brent, Harrow, Hillingdon, Kensington & Chelsea, Westminster) and Milton Keynes. Adults with personality disorders primarily receive care from seven community recovery teams. A specialist personality disorder service based at the Waterview Centre provides an 18-month group-based treatment programme for service users from Kensington & Chelsea and Westminster. Community CAMHS teams are located in each of the CNWL boroughs, providing multidisciplinary assessment and treatment to children and adolescents (0-18 years). There is also a specialist parental mental health service operated jointly with the NSPCC through CAMHS at Parkside Clinic (Kensington & Chelsea).

HEALTH TECHNOLOGY

Psychoeducation

Psychoeducation is an evidence-based psychotherapeutic modality used across a wide range of health conditions, including child emotional and behavioural disorders and adult personality disorders. Psychoeducation enables service users and their families to learn about the nature of a defined health problem or illness, its treatment, effective coping and management strategies, and skills needed to avoid relapse [72]. The aims are to increase knowledge and insight, promote emotional and behavioural change, and mobilise coping resources.

"Parent training" is a very well established psychoeducational approach for child mental health problems. It is delivered in individual or multi-family group formats and aims to teach parents the knowledge and skills needed for identifying, understanding and responding to the emotional and behavioural problems of their children. NICE [27] recommends parent training for children with (or at risk of developing) disruptive behaviour disorders. Psychoeducational parenting programmes are also available for children with anxiety and other internalising difficulties [28].

Typically programmes are structured and manualised to aid implementation and replication. The focus is usually on the parents only, though some include children and/or teachers. Standard parenting programmes are delivered over 10-12 weeks with 1-2-hour weekly sessions. Those designed for families with more complex difficulties are more likely to use an individual format and have a longer duration [73, 74].

Components of the new health technology

PEPS and HFP provide the platform for our proposed health technology. These established programmes are both underpinned by explicit theoretical models and supported by evidence of impact and acceptability from feasibility and pilot studies. PEPS and HFP possess concordant aims and manualised treatment methods that (a) successfully engage and retain service users; (b) deliver specialised psychoeducation about personality disorders and parenting; (c) develop service user goals, action plans, adaptive coping and problem-solving skills; (d) reduce distress; and (e) improve relationships.

PEPS is particularly applicable because it includes specific collaborative procedures for building rapport, broaching the diagnosis of personality disorder, and relating it sympathetically to everyday social and

interpersonal difficulties. Psychoeducation about personality disorder leads to the formulation of personalised goals that are addressed through structured social problem-solving techniques.

Psychoeducation in HFP includes well validated parenting content combined with specialised modules that use cognitive, behavioural and interpersonal strategies to promote change in five key risk domains for maladaptive parenting. The module topics are highly relevant to parents with personality disorders, as they focus on interpersonal conflict, emotional dysregulation, poor coping, substance misuse and social isolation.

The Manualisation Working Group will lead the development of the new health technology including specification of theory, aims, content, methods, duration and format. The MWG will oversee the synthesis of HFP and PEPS into a single approach, augmented by a manualised screening process to identify and select eligible families. The iterative work of the MWG will be informed by emergent findings from literature reviews and the Phase 2 case series, as well as repeated feedback from clinician and service user consultation groups.

We envisage that the intervention will be delivered to individual parents, including partners where appropriate, over a 12-16 session duration. Provisional screening procedures (see Section 12.4) will include use of brief keyworker-rated assessment measures of personality disorder and child mental health, followed by in-depth diagnostic assessment (based on a parent interview) and debriefing. The new health technology is planned as an additional screening and intervention procedure alongside routine child and adult mental health care. It will be assessed at the end of each research phase against Elements 1 and 2 of the Parenting Programme Evaluation Tool, a nationally recognised system to determine the quality of parenting interventions [57].

Comparator

The new intervention will be compared with usual care as there is no clearly established integrated care pathway or health technology for target families. The content and variations in usual care will be examined in Phase 2. Routine CAMHS assessment should ordinarily include enquiry about parental mental health, but rarely involves systematic examination of the range of possible difficulties. If parental mental disorder (including personality disorder) is identified, there may be attempts to liaise with adult services. However, links in either direction are typically weak, notwithstanding some examples of good practice [26]. Parenting interventions often involve some degree of psychoeducation but typically without a specific component exploring parental mental health and its influence on parenting or child mental health. NICE [29, 30] has issued guidance on borderline and antisocial personality disorders recommending that community mental health services should be responsible for the routine care. The welfare of dependent children should be considered as part of routine risk assessment. However, there is little to guide routine adult mental health assessments of parenting and children's needs beyond general safeguarding and child welfare protocols [31, 32].

Target population

Parents. The new health technology will target one primary caregiver ("parent") who lives with and has direct parenting responsibilities for their index child. This ensures that the parent is in a position to implement content of the psychoeducational intervention. Where a family has more than one child who potentially meets eligibility criteria, the parent will be asked to nominate an index child with whom they experience greatest difficulty in parenting. Parental personality disorder will be assessed on the Structured Clinical Interview for DSM-IV Axis II (SCID-II) [1]. All personality disorder types (and combinations thereof) will be eligible as the disorders typically co-occur [77, 78] and there is scant evidence that parenting difficulties are specific to any single personality disorder. Psychosis will be ruled out using the SCID-I Psychotic Screen [79]. On advice from clinical experts and service user representatives, parents who are engaged in individual or group psychotherapy focused on personality disorder will be excluded because of concerns that adding psychoeducation would complicate therapeutic process and outcome. Participants may continue with other interventions (e.g. substance misuse interventions, employment support) not directly related to personality disorder or parenting. We will not exclude families on the basis of any direct intervention involving the child, since we are developing a specialised parenting intervention that should complement other types of CAMHS support. Moreover, a number of families may be in contact with social services, and will not be screened out. Inclusion and exclusion criteria are operationalised as below.

Inclusion: (i) primary parental caregiver for index child; (ii) aged 18-65 years; (iii) presence of any personality disorder; (iv) proficient in written and spoken English; and (v) capacity to provide informed consent to participate.

Exclusion: (i) presence of psychosis; (ii) engaged in individual or group psychotherapy directly related to personality disorder; (iii) engaged in another structured parenting intervention; (iv) receiving inpatient care; or (v) insufficient language or cognitive abilities to participate fully in trial procedures.

Children. Children will have severe emotional and/or behavioural difficulties, signified by primary DSM-IV Axis 1 diagnoses of oppositional defiant disorder, conduct disorder, attention deficit (hyperactivity) disorder, mood disorder, anxiety disorder (including separation anxiety) or attachment disorder. We will exclude psychotic or neurodevelopmental disorders because of the significant personal needs of the children and adolescents concerned. Children who are being actively considered for or are subject to an application for care or supervision proceedings by social services will be excluded. This is because such action may lead to the removal of the child and subsequent withdrawal of the parent from the study. Child inclusion and exclusion diagnoses will be assessed by parent interviews using one of two well validated, standardised instruments: the Development and Well-Being Assessment (DAWBA) [2] (parents of 5-16-year-olds), or the Preschool Age Psychiatric Assessment (PAPA) [76] (parents of 3-4-year-olds). Inclusion and exclusion criteria are operationalised as below.

Inclusion: (i) living at home with index parent; (ii) aged 3-16 years; (iii) presence of an emotional or behavioural disorder; and (iv) attending, or being considered for, CAMHS.

Exclusion: (i) presence of neurodevelopmental or psychotic disorder; (ii) not residing with index parent; or (iii) considered for or subject to an application for care or supervision proceedings.

Sample sizes

Descriptive study of usual care (Phase 2). N=10 key informant interviews will be completed in order to describe pre-trial usual care arrangements in candidate recruitment sites. Participants will be purposively sampled to represent key agencies (i.e. CAMHS, adult mental health, social services), and on the basis of their case responsibility for the target population and/or line management of such clinical staff.

Case series (Phase 2). We will target N=12 eligible families for the pre-pilot intervention, recruited at a rate of N=3 families per month per Trust over two months. Participants will be purposively sampled from a range of referring CAMHS and adult teams and will include index children of varying ages and diagnoses. We will attempt qualitative interviews with each parent participant and referring keyworker (N=24).

Pilot RCT (Phase 3). A confidence interval approach [14] has been used to calculate a sample size of N=70 based on key feasibility objectives for the pilot RCT. It was decided a priori that the single most important feasibility criterion would be a treatment retention rate of at least 65%. This benchmark was informed by a recent systematic review that identified a median non-completion rate of 37% for personality disorder treatments [67]. Using a 95% CI for the proportion of parents who complete treatment and an expected completion rate of 80% based on previous evaluations of HFP [23] and PEPS [20], we have determined that a sample size of N=35 in the intervention group will enable a sufficiently precise estimate of this feasibility objective (95% CI .67-.93). We expect further attrition to occur over the subsequent follow-up period. With a sample size of N=70 across both groups, we can be 95% confident that the anticipated 6-month follow-up rate of 70% will be estimated to within ±10.7 percentage points. A sample size of N=70 will also be sufficient to obtain stable estimates of population variances for future power calculations [15].

Recruitment is expected to be more efficient than in the case series (see above), due to embedding and refinements of participant identification procedures over time. Our recruitment target will be N=5 families per Trust area per month over 7 months (i.e. N=35 families to be recruited and randomised in each Trust). To achieve the required sample size, we estimate that we will need to approach approximately three times as many families (i.e. N=105 in each Trust and a total N=210). This is based on cautious projections using recruitment data from relevant studies. A previous PEPS trial showed that 68% of adult service users with suspected personality disorders were willing to be contacted about research [20]. Somewhat lower voluntary response rates (43%-46%) have been found in intervention trials targeting high-risk parents [80, 81]. However, our target population may be relatively more open to parenting support since candidate parents will already have a child attending (or being considered for) CAMHS. The major unknown concerns the willingness of parents who have not previously sought a mental health diagnosis to take part in a study targeting parental personality disorder. Although some studies have found that non-referred parents are very willing to undertake assessments of their own mental health [82], this tendency may not generalise to personality disorder screening.

Taking all of the above into account, we have made a conservative estimate that 65% of N=210 parents approached will consent to being contacted by the research team. Allowing 10% loss (out of 210) for those who decline to participate, do not meet basic eligibility criteria or cannot be contacted, N=116 candidates are expected to complete full diagnostic screening. Allowing 15% loss (out of 210) for diagnostic ineligibility, we anticipate that 40% of those approached will be confirmed as eligible for the trial. We expect further attrition of approximately 7% between confirming eligibility and randomisation, which leaves one-third of the original total expected to complete all baseline assessments and randomisation procedures (see uploaded flow diagram).

The process evaluation will involve qualitative interviews with samples of parent and clinician participants. Clinicians will be selected on the basis of their involvement in identification and/or case management of eligible participants. Parents will be purposively selected to ensure range and diversity in terms of treatment allocation, clinical characteristics and outcome. The precise number of participants will be determined by data saturation (and may therefore be inflated), but we anticipate this will be achieved with N=30 informants.

Sampling frame estimates

Prevalence of eligible families in contact with adult mental health services. Reviewing all electronic patient records in the SLaM MAP CAG, we identified 556 out of 3527 open cases (16%) with a diagnosis of personality disorder (as of August 2013). This compares with approximately 900 recorded personality disorder cases in CNWL. Another recent audit showed that a quarter of cases in CNWL's specialist personality disorder service are parents with dependent children. Extrapolating across both Trusts gives an estimate of 350 current service users who are parents with a recorded diagnosis of personality disorder; many of whom, especially in community teams, will not be engaged in psychotherapy [83]. True prevalence of personality disorder in these services is expected to be around 2500 cases, based on (i) a combined catchment population of 2.6 million, (ii) community prevalence of personality disorder at 4% [34], (iii) 10% of people with personality disorder having current contact with services [84], and (iv) 25% living with dependent children. A large proportion of these parents would be expected to have children with mental health problems. Precise figures are unavailable, but rates of mental disorder in offspring of parents with Axis I diagnoses are in the region of 30-50% [85, 86] and may be even higher where a parent has personality disorder [87].

Prevalence of eligible families in contact with CAMHS. We reviewed all electronic patient records in the SLaM CAMHS CAG, and identified 1650 out of 6913 open cases (24%) with parental mental health needs recorded in brief risk screens (as of August 2013). Assuming that 40% of these parents meet criteria for personality disorder [35], we expect over 600 CAMHS cases to have a parent with personality disorder. About half of these cases have child diagnoses that are also consistent with our eligibility criteria. Similar rates are expected to apply in CNWL, where the total caseload of London-based CAMHS teams is around 4200.

Specific recruitment sites. Following from the above, we broadly estimate there will be 1000-2000 eligible families across all candidate NHS services. Within this large sampling frame, recruitment efforts will concentrate on teams where we have (i) already established relatively high numbers of potentially eligible cases, and (ii) obtained greatest enthusiasm and support from senior clinicians and service managers. In SLaM CAMHS, we will initially include community teams from Lewisham (1491 total cases; 294 with identified parental mental health needs) and Lambeth (926 total cases; 266 with identified parental mental health needs). In CNWL we will focus on the specialist parental mental health service (approximately 90 intakes per year) and other CAMHS in Kensington & Chelsea and Westminster. In adult services, we will prioritise the four specialist personality disorder services in SLaM (total caseload 211) and Waterview Centre in CNWL (caseload 45). Even though many adults attending these specialist services will be engaged in psychotherapy and therefore ineligible for the research, we will work with staff to identify potential participants from among those who are assessed but not taken on for specialist treatment. This amounts to almost 100 people per year in the Waterview Centre alone, suggesting a rich source of potential participants**.**

We will also collaborate with a SLaM MAP team, Croydon East, serving a broader case-mix with the largest concentration of personality disorder cases among the MAP locality teams (671 total cases; 85 with personality disorder). In CNWL, we will focus on two community recovery teams in Kensington & Chelsea and Westminster (over 500 total cases with more than 50 having a personality disorder diagnosis).

Estimated NHS prevalence rates suggest that these services will be sufficient to meet Phase 1, 2 and 3 recruitment targets. NHS recruitmentwill be augmented by additional recruitment through pathways established with local authority teams. We will continuously monitor rates of identification, approach, consent, screening, eligibility and treatment uptake within individual teams. This information will be triangulated with qualitative feedback from clinicians and parent participants to assess strengths and weaknesses of proposed recruitment procedures. If necessary, changes will be made and additional services may be involved in the pilot RCT.

PROCEDURES

Phases 1 and 2 consultation

Service user and clinician focus groups will have a consultative function to support the development of the new health technology. Each group will contain up to 10 members and will meet at least twice in Phase 1 and once in Phase 2. The purpose will be to review and comment on (i) drafts of the new clinical manuals, (ii) evidence obtained from literature reviews on relevant treatment and case identification strategies, and (iii) emergent findings from clinical case studies. Selection for group membership will be based on expertise, perspective and experience. Recruitment of clinicians and service users will be achieved through the networks of study investigators and collaborators. Clinicians and service managers working with the target population will be identified and invited to participate.

Service user groups will be facilitated using semi-structured topic guides. Discussions will be recorded and professionally transcribed. An auditable transcript of the process will be produced and be circulated to group members, providing a mechanism for content checking and informing discussion at subsequent group meetings. A service user researcher will work with the Trial Manager to complete a thematic analysis of each focus group, providing an efficient report of findings for the MWG. The thematic analysis will describe strength of support for proposed clinical methods and materials, and suggested amendments. The findings will be fed back to, and between, user and clinician groups, thereby permitting cross-fertilisation of opinions between service user and clinician groups.

Prof. Richard Ashcroft (Professor of Bioethics, Queen Mary, University of London) will independently review the new health technology, proposed research procedures and emergent findings.

Phases 2 and 3 recruitment (clinical case series & pilot RCT)

Identification. Keyworkers in candidate services will review caseloads against specified research eligibility criteria. They will be guided by (i) a structured identification algorithm that sets out clear procedures and decision rules, and (ii) ongoing liaison and consultation with the research team. Provision has also been made for keyworkers across services to use an eight-item clinician-rated personality disorder screen as an optional decision support tool. A score of $\geq$3 on the Standardised Assessment of Personality-Abbreviated Scale for Informants (SAPAS-INF) [18] has acceptable sensitivity (>75%) in community mental health settings [88]. This will improve efficiency and avoid approaching ineligible parents unnecessarily. We will log the accuracy of referrals and take corrective action if necessary.

Adult mental health and social care staff may require additional resources to identify child mental health needs if a CAMHS referral is not in place. Our draft participant identification algorithm incorporates the informant-rated SDQ Impact Supplement (SDQ-IS) for this purpose [89]. The SDQ-IS assesses the impact of one or more identified child difficulties across five areas of functioning: emotional well-being, home life, friendships, school and leisure activities (each scored 0-2). A total impact score of $\geq$2 suggests clinical caseness. The use of SAPAS-INF and SDQ-IS will assist initial identification of potential participants but will not be a prerequisite for diagnosis or eligibility.

In some circumstances parents may not have sought personality disorder diagnosis but may be considered eligible for the research by their keyworker. Prior to raising the research study, the keyworker will carefully consider the interests of the parent in knowing or not knowing about their potential diagnostic status and the relative benefits and risks of participating in the research screening procedures. Where considered in the parent's interests, the keyworker will initiate an exploratory discussion about the parent's known emotional and interpersonal difficulties and their effects on parenting capacity. Only when sufficient rapport and common understanding has been established will the keyworker then introduce the broad aims and purpose of the research project including discussion of the eligibility criteria and the screening procedures involved.

Consent. After initial identification, the keyworker will determine whether or not a parent is agreeable to being contacted by a member of the research team. Training will be provided to enable keyworkers to accurately convey the basic aims of the research and sensitively broach the topic of personality disorder. This will be based on previous staff workshops developed by our team to support personality disorder trials [56].

A clinically experienced research therapist will carry out formal consent procedures since people with personality disorder may require additional time and therapeutic skills to secure trust. The research therapist will offer a face-to-face meeting to discuss the study and provide a Participant Information Sheet. The meeting will also be used to confirm basic eligibility criteria. The research therapist will encourage potential participants to

spend as much time as they need (at least one week) before deciding on participation. If agreeable, the parent will then be asked to sign a consent form.

Selection and debriefing. Eligibility will be formally assessed by research therapists using the SCID-II and DAWBA/PAPA. Research therapists will be fully trained in the use of these instruments. A separate parent debriefing session will be scheduled with the parent to review the diagnostic assessment outcome. Regardless of eligibility, parents will be able to discuss usual care options in local adult mental health services and CAMHS.

Baseline assessment and randomisation. Parents who are selected as being eligible will be invited to complete baselines measures prior to (i) starting the intervention (for participants in the pre-pilot case series), or (ii) random allocation into either the experimental or usual care arm of the pilot trial. As with the initial approach and selection/debriefing, randomisation will be sensitively managed by a research therapist. Randomisation will occur shortly after baseline assessment using an independently monitored computer system set up by the accredited Clinical Trials Unit at KCL.

Phases 2 and 3 data collection

Participant demographics (Phases 2 & 3). A specially designed proforma will be used to collect descriptive data from participating families about parent/child age, sex and ethnicity; family household composition; and family socioeconomic status. We will also collect basic information (professional background, service type) about clinicians who participate in key informant interviews.

Description of usual care (Phase 2). This will define usual care pathways for the target population, including routine mechanisms for establishing and sharing care plans across CAMHS, adult mental health and children's social care services in the research sites. Data will be obtained through documentary sources (operational policies, activity data) and N=10 key informant interviews representing staff with clinical and/or managerial responsibility in relevant mental health teams and local social services. Interviews will be audio-recorded and transcribed verbatim.

Clinical case series (Phase 2). Individual semi-structured interviews will be used to assess clinicians' and parents' experiences of screening, intervention and clinic-based research procedures. Pre-post outcome measures will be collected to explore preliminary clinical benefits (and risks) on a case-by-case basis. The purpose will be to inform modifications of clinical manuals, and methodological refinements required to produce a feasible protocol for the pilot trial.

All parents who receive the intervention (up to N=12) will be eligible for the interviews, which will be conducted by a research worker at the conclusion of the intervention. Questions will be developed iteratively, but the topic guide is expected to focus on perceptions regarding: (i) applicability of the health technology to personal, child and family needs; (ii) areas of impact; (iii) factors affecting engagement and retention; (iv) effects of participation on use of other services; (v) scope for further development of screening/intervention procedures (e.g. in content, methods, duration, intensity or format); and (vi) ease of completion and relevance of outcome measures. Interviews will also be completed with clinicians who identified this initial cohort of parent participants. Questions will explore (i) ease of use for eligibility algorithms and associated screening tools; (ii) factors affecting decisions to approach potential participants; (iii) training and support needs related to participant identification; and (iv) potential influence of the health technology on usual care for parent participants and/or their children. All interviews will be audio-recorded and transcribed verbatim.

Clinical outcomes (Phases 2 & 3). Validated parent-report measures with well established psychometric properties will assess primary and secondary outcomes. These measures have been reviewed by service user representatives to ensure relevance and comparative ease-of-use. Outcomes will be measured pre- and post-intervention in the clinical case series, and at three time points in the pilot trial: T1, pre-randomisation baseline;, T2, post-intervention follow-up (12-16 weeks from baseline); and T3, 6-month follow-up (9-10 months from baseline). Measures will be collected by a research worker blind to group allocation.

Primary outcomes. These will be child and parental mental health, as required by the research brief. The following measures will be used. (i) Strengths and Difficulties Questionnaire (SDQ) [3] is a 25-item questionnaire that assesses emotional and behavioural problems in 3-16 year-olds. It will be used to obtain a broad measure of child psychopathology. (ii) Eyberg Child Behavior Inventory (ECBI) [4] is a 36-item questionnaire that assesses intensity and number of disruptive behaviour problems in 2-16 year-olds. It will provide a comprehensive measure of child behaviour difficulties. (iii) Child Behavior Checklist-Internalising Scale (CBCL-Int) [5] is a 32-item questionnaire that assesses internalising problems in 6-18 year-olds (school-

age version) with an alternate 28-item version available for children aged 1 ½ to 5 years (preschool version). Standardised T-scores will be used to combine results from both versions and provide a comprehensive measure of child emotional difficulties. (iv) Concerns About My Child (CAMC) [6] is a visual analogue scale that requires parents to nominate, prioritise and rate up to three key concerns about their child. The same concerns that are nominated at baseline will be re-rated at follow-up, providing a sensitive, individualised index of change. (v) Symptom Checklist-27 (SCL-27) [7] is a 27-item questionnaire that assesses psychological symptoms in adults. It will provide a broad measure of parental mental health.

Secondary outcomes. These will also be assessed at all three time points, except for the WAI-SR (T2 only). (i) Kansas Parental Satisfaction Scale (KPSS) [8] is a 3-item scale that provides a brief measure of stress and dissatisfaction in the parenting role. (ii) Arnold-O'Leary Parenting Scale [9] is a 30-item questionnaire that assesses dysfunctional discipline styles in parents of children aged from 2-16 years. It correlates significantly with more time-consuming observational ratings of parenting behaviour (r= .84), and scores have been shown to differentiate between clinic and non-referred groups of children. (iii) Working Alliance Inventory-Short Revised (WAI-SR) [11] is a 12-item questionnaire that assesses therapeutic alliance. It will be used to assess and compare the quality of therapeutic relationships developed by research therapists and usual care clinicians.

Feasibility parameters (Phase 3). Data on key feasibility parameters will be routinely gathered by research therapists. Cumulative data will be obtained on rates of (i) initial participant identification by keyworkers, (ii) verbal consent for approach, (iii) availability for approach, (iv) informed consent to participate, (v) availability for diagnostic screening, (vi) eligibility to participate in the trial, (vii) availability for T1 assessment, (viii) randomisation into the trial, (ix) treatment retention, and (x) availability for T2 and T3 assessments in each arm of the trial.

Process evaluation (Phase 3). Building on Phase 2 methods and findings, a process evaluation in Phase 3 will investigate implementation of trial procedures, intervention process, and relationships between contextual factors and observed outcomes. Data will be collected from structured observations and up to N=30 qualitative interviews with referring clinicians and parent participants (see Section 12.1). In the observational work, research therapists will record case observations in relation to (i) the recruitment of each participating family; (ii) applications of and deviations from manualised screening and intervention procedures; and if so, (iii) associated factors. Interviews will be conducted at T3 by a research worker using semi-structured topic guides drafted on the basis of Phase 2 findings. These will be employed flexibly and subject to iterative development in order to reflect and explore emergent themes from observations and early interviews. Respondents will be asked questions that explore all topics set out in the pre-defined topic list. However, the researcher will be responsive to issues emerging from respondents' accounts. All interviews will be audio-recorded and transcribed verbatim.

Economic evaluation (Phase 3). Economic evaluation will be conducted from (i) an NHS/Personal Social Services perspective and (ii) a societal perspective. Intervention costs will be estimated by combining data on number of screening and intervention sessions provided, with unit costs derived from local data on service expenditure and activity. Costs will include therapist time, on-costs, overheads and capital. Estimates of staff training and supervision costs will also be included. Other resource use information for parents and children will be collected for the six months prior to baseline and follow-up using a modified version of the Client Service Receipt Inventory (CSRI) [13]. Versions of this schedule have been used in over 300 research studies in the UK and internationally with adults and children. Services will include primary and secondary health care, social care, school-related services (e.g. educational psychologists and other educational support), early years help, and youth and criminal justice services. We will also record (i) time spent by parents accompanying their children to use services, (ii) days off work due to health problems, and (iii) days out of school for children. Resource use data will be combined with appropriate national unit costs [90] to calculate the total service costs. Parental time lost from work will be valued using average wage rates. Time lost from school is complex to value and a range of estimates will be used in sensitivity analyses. These will include the cost of providing a day's schooling and an estimate of the future returns from education. For the cost-utility analysis, cost data will be combined with quality adjusted life years (QALYs) derived from the EQ-5D [11] and ED-5D-Y [12]. The EQ-5D-Y is designed for use with youth but in absence of a more appropriate measure it will used for all children in this study.

DATA ANALYSIS

Phase 2 analysis

Description of usual care. Data from documentary sources and interviews will be synthesised in tables and process diagrams. These will be shared with informants to establish accuracy, and used to compare and contrast routine practice between sites. The information will be used to inform (i) participant interviews in the Phase 2

case series, (ii) the collection of interviews and structured observational data in the Phase 3 process evaluation (see 14.6 above), and (iii) definition of the comparator condition in the pilot trial.

Clinical case series. Transcripts will be downloaded to NVivo, a computer package for the management, classification and analysis of text-based data. Thematic coding frameworks will be constructed to allocate codes to emergent themes and issues within the data, facilitating their identification and organisation. The coding frameworks will be developed by the research worker, supported by Weaver. After initial coding by the research worker, a sample of transcripts will be independently re-coded by Weaver and the service user researcher, both blind to original coding. This will enable discrepancies to be identified and consensus reached about the interpretation and application of the coding framework. Data that do not fit the initial coding framework will lead to the generation of new themes and framework revision. Data will then be consistently classified, indexed and subject to thematic analyses using the refined coding framework. Validation will be undertake with a sample of participants. Emergent themes from the interviews will be shared within the research team, and findings will provide context for interpreting individual case outcomes.

Phase 3 Analysis

Statistical analysis. As this is a pilot study, the statistical analysis will be mainly descriptive in nature, aiming to provide estimates of key trial parameters and to inform power calculations for a future definitive trial. A description of the sample will be presented using means and standard deviations for continuous data, or medians and interquartile range if data are skewed. Frequencies and proportions will be used to analyse categorical variables. Feasibility of trial procedures will be assessed using proportions of predetermined parameters and their estimated 95% CIs. We will analyse primary clinical outcomes using multi-level models [91] to estimate the likely range of the treatment effect (by assessing 95% CI) at post-treatment and 6-month follow-up (with pre-randomization values as a covariate). Population variances for future power calculations will be determined using the upper 80th percentile of confidence intervals around the estimated population variance, as recommended by Browne [15].

Process evaluation. Drawing on observational and interview data, the primary aims of the process evaluation analysis will be to (i) assess the acceptability of, and adherence to, recruitment procedures in NHS and local authority services; (ii) assess treatment fidelity; and (iii) investigate whether any contextual factors impact either positively or negatively upon implementation of the intervention or the generation of outcomes. Interview data will be transcribed, coded and loaded to NVivo for analysis as described in 15.1 above. The analysis will be focused on understanding clinicians' and parent participants' experiences of the new health technology and trial participation. Case-based observational data relating to recruitment and treatment fidelity will be subject to a descriptive analysis designed to generate process variables used in secondary quantitative analysis.

Economic evaluation. The main economic evaluation will take the NHS/Personal Social Services perspective preferred by NICE with secondary analyses incorporating all other costs. Differences in mean total costs between experimental and comparator groups will be compared using ordinary least squares regression adjusting for baseline costs and with bootstrapped confidence intervals generated due to the likely skewed regression residuals [92]. Costs will be viewed alongside all outcomes (but not formally linked) in a cost-consequences analysis. A cost-utility analysis will subsequently be conducted by linking the cost data with QALYs. QALY gains will be calculated using area under the curve methods, controlling for baseline utility. The point estimates of cost and QALYs will indicate whether the new health technology is dominant (resulting in better outcomes at lower cost) or whether each extra QALY produced by the intervention (or indeed usual care) is at an increased cost. Uncertainty around cost-effectiveness estimates will be addressed using cost-effectiveness planes (produced by generating 1000 cost-QALY combinations using bootstrapping). This will allow us to determine the probability that the intervention results in (i) lower costs and more QALYs, (ii) lower costs and fewer QALYs, (iii) increased costs and fewer QALYs, or (iv) increased costs and more QALYs than usual care. Cost-effectiveness results will be further interpreted using cost-effectiveness acceptability curves (CEACs) generated using the net benefit approach where the monetary value of an individual's QALY gain minus their service cost is calculated [93]. A range of threshold QALY values will be used to include the £20-30,000 value used by NICE.

From this pilot evaluation we will be able to generate indicative cost-effectiveness estimates. We do not propose to model beyond the pilot study period but that will be desirable in a future study. However, we will need to address the expected uncertainty around specific cost variables in the analysis and this will inform future data collection methods. In particular, we will explore the impact on the results of varying the cost of the intervention, the cost of parental time and the cost of lost school days.

PLAN OF INVESTIGATION & TIMETABLE

Phase 1 (Months 0-9)

Months 0-3: establish PMG, MWG, PSC, Adult Service User and Youth Advisory Panels; recruit service user and clinician focus groups; identify and update relevant systematic reviews.

Months 4-7: conduct and analyse focus groups; produce draft health technology manuals; submit Phase 2 REC/R&D and audit applications.

Months 8-9: prepare Phase 2 recruitment; appoint research therapists; undertake independent ethical review; complete Phase 2 REC/R&D and audit approvals; report Phase 1 findings.

Phase 2 (Months 10-18)

Months 10-11: train research therapists; train service staff in participant identification procedures; begin data collection for usual care study.

Months 12-16: recruit N=12 parent participants and deliver health technology in clinical case series; collect and analyse T1 and T2 outcomes; conduct and analyse N=24 key informant interviews; collect and analyse data for usual care study; synthesise Phase 2 findings; undertake independent ethical review; complete pilot RCT protocol; submit Phase 3 REC/R&D applications.

Months 17-18: conduct and analyse additional focus groups; complete revision and production of manuals; complete Phase 3 REC/R&D approvals; produce and disseminate project findings and reports; prepare Phase 3 recruitment.

Phase 3 (Months 19-37)

Months 19-28: recruit and randomise trial participants (N=70; 5 participants/Trust/month) and collect T1 data up to Month 25; deliver 3-month intervention and collect T2 data (N=35) up to Month 28.

Months 28-34: collect T3 data, including process evaluation observations and interviews (N=30); analyse and disseminate interim findings.

Months 35-37: produce and integrate final impact, process and economic findings; produce final health technology manual and definitive trial protocol; produce and disseminate project findings and final reports.

RISK AND ETHICAL ISSUES

Safe and effective care

The wellbeing and safety of participating parents and their children will be paramount. Eligible parents will have complex mental health difficulties that may be associated with known or emergent concerns about child maltreatment. Usual care is likely to involve a number of practitioners working across several teams and agencies. The newly developed screening and intervention procedures will be an additional component to usual care. Primary case management responsibility will remain with local services. A standard case co-ordination protocol based on best practice and local guidelines [32, 58] will be developed in concert with services to describe: (i) research staff roles and responsibilities; (ii) co-ordination and continuity of care for participating parents and their children; (iii) effective management of safeguarding concerns; and (iv) information-sharing procedures between the researchers and other professionals and agencies. Research therapists will be trained and supervised to ensure adherence to the protocol.

Ethical review

An independent expert will review and report on ethical issues raised by emergent findings and research protocols. A number of other robust systems will be in place for handling potential ethical issues, as outlined below.

Research participation. Research will only commence once full NHS REC and local governance approvals are obtained, based on thorough assessments of all protocols, participant information sheets and consent forms. Clinicians will be trained to accurately identify potential participants and introduce the research with sensitivity and transparency so that parents' needs, interests and choices are respected. Participants will be fully informed, verbally and in writing, of study procedures. Informed written consent will be required prior to full diagnostic

screening. Parents will have the opportunity to consider and seek further advice about implications of participation for themselves and their children prior to consent, with a minimum of seven days to make a decision. The use of gold standard assessment instruments will limit risk of misdiagnosis. Systematic debriefing will be offered for parents to explore screening results. Participants may withdraw from the study at any time with no consequences for their care.

Adverse reactions to experimental condition. These are not anticipated but will be continuously monitored by research therapists. All adverse events will be reported to the Chief Investigator and reviewed by the independent PSC. Actions may include modification or suspension of research procedures.

Continuity of usual care. Usual care will remain available to all participants in conjunction with the new health technology. Eligible parents who not wish to participate in the research and parents who are screened but ineligible will receive clear, accessible information about options within local services

FLOW DIAGRAMS

Fig. 1. Flow diagram of sequential research design

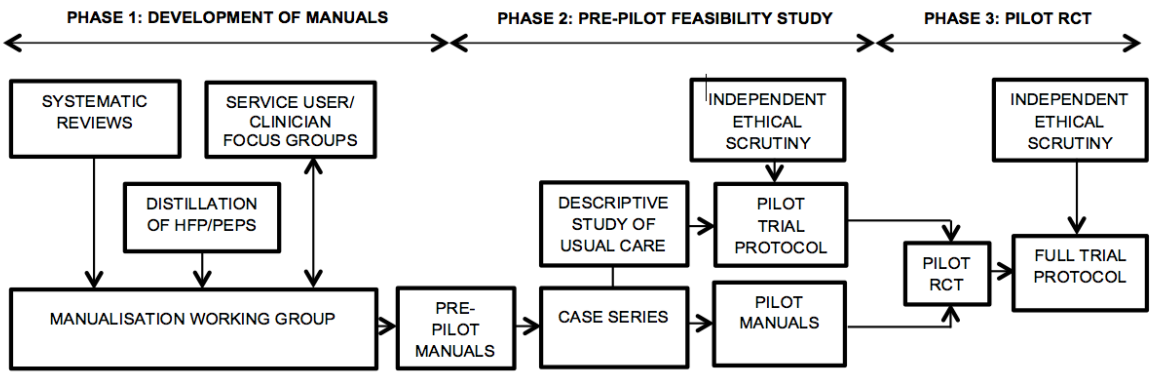
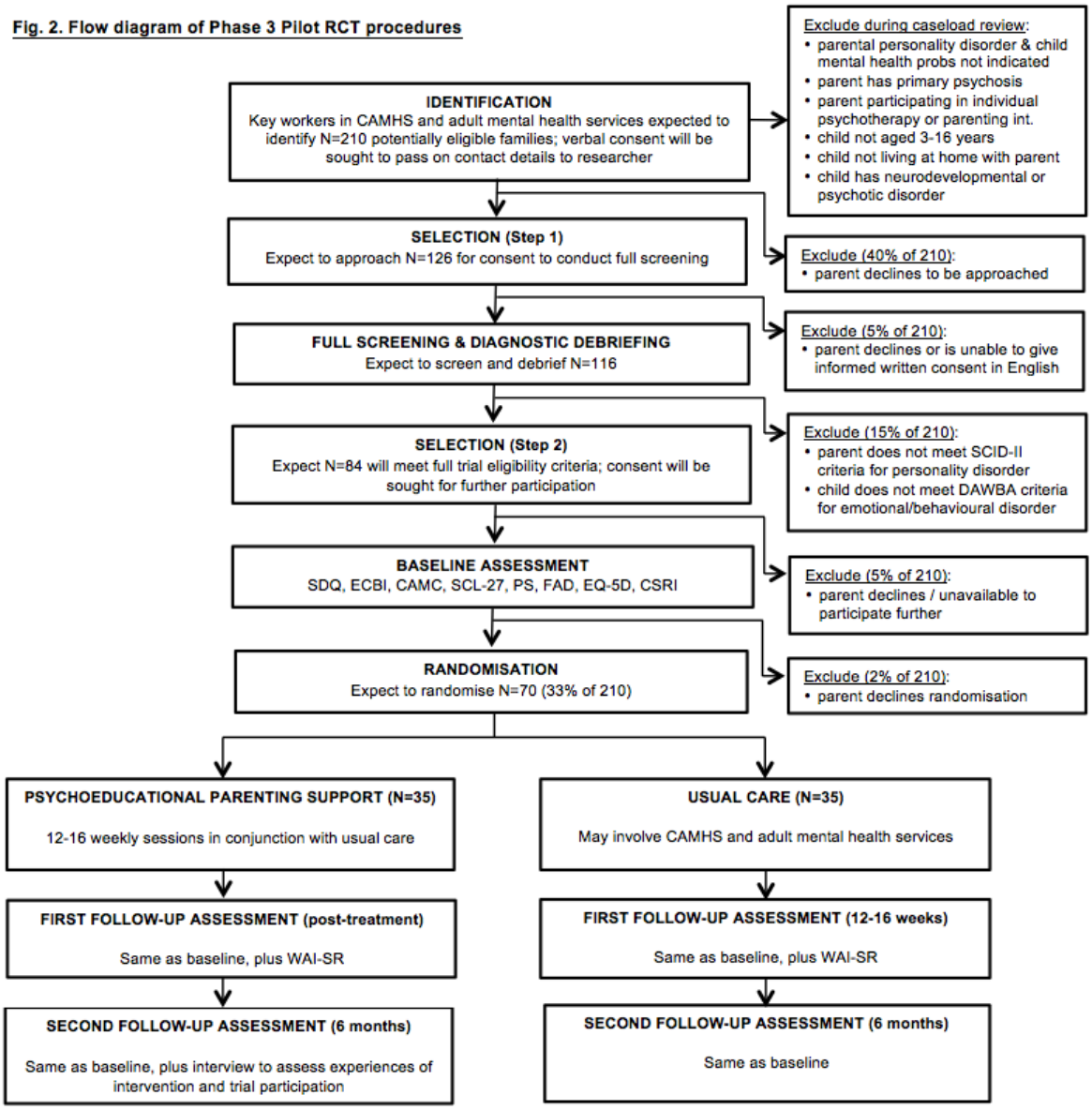


Fig. 2. Flow diagram of Phase 3 Pilot RCT procedures



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