TITLE

Feasibility study of a psychoeducational parenting intervention for families with parental personality disorders and child mental health needs

RESEARCH TEAM

Principal Investigator

Dr Crispin Day, King's College London & South London and Maudsley NHS Foundation Trust

Trial Manager & Co-investigator

Dr Daniel Michelson, King's College London & South London and Maudsley NHS Foundation Trust

Co-investigators

Prof. Mike Crawford, Imperial College & Central and North West London NHS Foundation Trust
Ms Megan Ellis, South London and Maudsley NHS Foundation Trust
Prof. Mary McMurran, University of Nottingham
Dr Paul Moran, King's College London & South London and Maudsley NHS Foundation Trust
Ms Lou Morgan, Emergence
Dr Paul Ramchandani, Imperial College & Central and North West London NHS Foundation Trust
Prof. Stephen Scott, King's College London & South London and Maudsley NHS Foundation Trust
Dr Daniel Stahl, King's College London
Dr Tim Weaver, Imperial College

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 criminality [1-3]. The likelihood of severe and persistent problems is increased when a parent has a personality disorder [4-5]. This diagnostic category applies to 4.4% of the general population and 40% of adult mental health service users [6-7], of whom about 25% are parents [8]. 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 [9]. 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 [10]. Moreover, having a child with emotional and/or behavioural difficulties is stressful in itself, and may worsen a vulnerable parent's own mental health [11, 12].

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 [13-14]. Typical content incorporates social learning principles and methods such as skills rehearsal, video modelling and role-play of effective discipline and relationship-enhancing strategies. However, evidence suggests that standard parent training curricula achieve lower retention rates and poorer outcomes for families with co-occurring child and parental psychopathology [12, 15-16].

Specialised psychoeducational interventions

A variety of specialised parenting interventions have been developed for complex families, but these are not currently designed to meet the specific needs of parents with personality disorders and their children [17]. One promising health technology relevant to this population is the Helping Families Programme (HFP) [12, 18-22], 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 [20-22].

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) [23-26]. 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 [26], PEPS has well defined theory and methods to optimise motivation and therapeutic rapport [28-29]. Previous evaluations, including a pragmatic randomised controlled trial, show good retention and significant clinical impact [24-25].

A manualisation working group, comprised of co-applicants who are authors of HFP and PEPS, was established in June 2014 to develop and manualise a systematic screening procedure and psychoeducational intervention for parents with personality disorders who have children with emotional or behavioural disorders. Developmental work has involved (a) distillation and integration of theory-based and empirically-supported psychoeducational methods from HRP and PEPS; (b) scoping literature reviews; (c) consultation with focus groups of clinicians (potential intervention providers) and service users (potential participants). Formative research is now required to assess the feasibility of the newly developed manuals, prior to further development and evaluation.

Relevance to current NHS policy and practice

Costs of child mental health problems and adult personality disorders. UK 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 [30]. 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 [31].

Current practice challenges. Policy initiatives advocate integration but much mental health provision offers fragmented care that focuses on the needs of *either* the adult *or* the child [32]. 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 [33-35]. This may hinder help-seeking and consequently increase the likelihood of a mental health crisis [36].

Potential benefits for patients and the NHS. The proposed research will advance scientific and clinical knowledge in a population where specialised early intervention is strongly indicated but rarely tested [37]. 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.

AIMS & OBJECTIVES

This research aims to assess the feasibility, acceptability and outcomes of a new health technology for parents with personality disorders whose children have emotional or behavioural disorders.

The specific objectives are to:

(i) Implement the new health technology (comprised of a manualised screening process and psychoeducational parenting intervention) and support its final iterative development through a series of clinical case studies involving assessment of clinicians' and service users' experiences and perceived impacts

(ii) Establish feasible recruitment pathways in candidate mental health services

(iii) Develop a protocol for subsequent pilot randomised controlled trial, with defined intervention and control conditions and feasible methods for identifying and selecting eligible participants

DESIGN

A mixed-method case series design will assess feasibility, acceptability and outcomes in a purposive sample of N=12 cases, using qualitative and quantitative data collected from (i) service users who participate in a new parenting intervention; and (ii) referring clinicians.

SETTING

Target organisations

A coordinated, multi-site approach will enable the new health technology to be 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.

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. The Child and Adolescent Mental Health Services (CAMHS) CAG has four borough community services that work with a range of mental health presentations in children and adolescents aged 0-18 years.

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).

Target staff

Case identification procedures will be used by multidisciplinary staff from CAMHS and adult mental health services, including psychiatrists, psychologists, psychiatric nurses, psychiatric social workers and occupational therapists. Formal case selection procedures (using standardised diagnostic interviews) and treatment of eligible and consenting participants will be carried out by appropriately trained and supervised research therapists (AfC Band 7).

PARTICIPANTS

Target population

The target population is parents with personality disorders whose children (aged 3-11 years) have emotional and/or behavioural disorders.

Specific inclusion criteria

Parent: (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. Child: (i) living at home with index parent; (ii) aged 3-11 years; (iii) presence of an emotional or behavioural disorder; and (iv) attending, or being considered for, CAMHS.

Specific exclusion criteria

Parent: (i) presence of psychosis; (ii) engaged in another structured parenting intervention; (iii) receiving inpatient care; or (iv) insufficient language or cognitive abilities to participate fully in trial procedures. Child: (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.

SAMPLING

Size and rate

We will target N=12 eligible families who participate in the new parenting intervention. We will attempt qualitative interviews with each parent participant and referring keyworker (N=24). 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 anticipate a recruitment rate of N=3 families per month per Trust over two months.

Recruitment sites

Based on recent audits of relevant electronic patient records, 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 SLaM MAP community teams serving a broader case-mix (e.g Croydon East; 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).

We will continuously monitor rates of identification, approach, consent, 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 screening procedures.

HEALTH TECHNOLOGY: Outline

A new health technology will provide additional screening and intervention procedures alongside routine child and adult mental health care. PEPS and HFP will provide the main intervention content. 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 (i) successfully engage and retain service users; (ii) deliver specialised psychoeducation about personality disorders and parenting; (iii) develop service user goals, action plans, adaptive coping and problem-solving skills; (iv) reduce distress; and (v) 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.

A Manualisation Working Group has overseen the synthesis of HFP and PEPS into a single approach, informed by literature reviews and service user and staff consultation groups. The new intervention will be delivered to individual parents, including partners where appropriate, over 16 weekly sessions. As explained in greater detail below, the associated screening procedure 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.

SCREENING PROCEDURES

Identification

Keyworkers in collaborating services will review their caselists against specified study eligibility criteria. Keyworkers 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) [38] has acceptable sensitivity (>75%) in community mental health settings [39]. This will improve efficiency and avoid approaching ineligible parents unnecessarily.

Adult mental health staff may require additional resources to identify child mental health needs if a CAMHS referral is not in place. Our participant identification algorithm incorporates the informant-rated SDQ Impact Supplement (SDQ-IS) for this purpose [40]. 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.

Training and ongoing consultation will be offered to support staff with the tasks outlined above. The format and content will be based on previous staff workshops developed by our team to support personality disorder trials [41].

Consent

After initial identification, the keyworker will determine whether or not a parent is agreeable to being approached by a member of the research team. If so, a clinically experienced 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

Parental personality disorder will be formally assessed by research therapists using the Structured Clinical Interview for DSM-IV Axis II (SCID-II) [42]. All personality disorder types (and combinations thereof) will be eligible as the disorders typically co-occur [43-44] and there is scant evidence that parenting difficulties are specific to any single personality disorder. 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) [45] (parents of 5-11-year-olds), or the Preschool Age Psychiatric Assessment (PAPA) [46] (parents of 3-4-year-olds). 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.

INTERVENTION PROCEDURES

The programme will be delivered by specially trained and supervised research clinicians according to a detailed manual. It will involve 16 weekly sessions (lasting 60 to 90 minutes) with the primary parental caregiver, although other caregivers may also be involved when appropriate. The index child and other siblings will not be direct recipients of the intervention. However, parent participants will be encouraged to practice techniques with their child(ren) in between sessions. Sessions will take place in the family home, and/or local clinics if preferred by the parent. The programme will help participants to (i) identify the ways in which their personality traits affect their parenting and impact on children's development; (ii) identify mutually agreed goals for change; and (iii) understand and use a range of evidence-based parenting and self-care strategies.

MEASURES AND DATA COLLECTION PROCEDURES

Participant demographics

A specially designed proforma will be used to collect descriptive baseline 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 interviews.

Feasibility parameters

Rates of participant identification, approach, consent and eligibility will be routinely collected from key-worker logs. We will also collect data from therapist logs on rates of session attendance, treatment dropout and fidelity.

Primary clinical outcomes

The following validated, parent-report measures will be used pre- and post-intervention (16 weeks from baseline).

Strengths and Difficulties Questionnaire (SDQ) [47]. 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.

Eyberg Child Behavior Inventory (ECBI) [48]. 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.

Child Behavior Checklist-Internalising Scale (CBCL-Int) [49]. 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.

Concerns About My Child (CAMC) [50]. 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.

Symptom Checklist-27 (SCL-27) [51]. A 27-item questionnaire that assesses psychological symptoms in adults. It will provide a broad measure of parental mental health.

Secondary clinical outcomes

These will also be collected pre- and post-intervention, except for the WAI-SR (post-intervention only).

Kansas Parental Satisfaction Scale (KPSS) [52]. A 3-item scale that provides a brief measure of stress and dissatisfaction in the parenting role.

Arnold-O'Leary Parenting Scale [53]. 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.

Working Alliance Inventory-Short Revised (WAI-SR) [54]. A 12-item questionnaire that assesses therapeutic alliance. It will be used to assess the quality of therapeutic relationships developed by research therapists.

Qualitative interviews

Individual semi-structured interviews will be used to assess clinicians' and parents' experiences of screening and intervention procedures. All parents who receive the intervention (up to N=12) will be eligible for the interviews, which will be conducted by a researcher at the conclusion of the intervention. Questions will be developed iteratively, but a semi-structured 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

DATA ANALYSIS

Feasibility data

Descriptive statistics will be used to assess quantitative feasibility parameters across different services and user profiles.

Acceptability data

Qualitative interview 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. Transcripts will be independently coded by at least two researchers (including a service user researcher) to 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 undertaken with a sample of participants.

Outcome data

Individual case outcomes and indicators of reliable clinical change [55] will be presented descriptively. Context for interpreting individual case outcomes will be obtained from qualitative themes, as described above.

TIMETABLE

Months 1-2. Train research therapists; train service staff in participant identification procedures.

Months 3-7. Recruit N=12 parent participants and deliver health technology in clinical case series; collect and analyse outcome measures; conduct and analyse N=24 key informant interviews; synthesise findings.

Months 8-9. Produce and disseminate project findings and reports; complete revision of manuals; complete protocol for further research.

RISK AND ETHICAL ISSUES

Safe and effective care

Case co-ordination. 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 [56-57] 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.

Potential adverse events. Each research and clinical contact will incorporate a brief review of potential adverse reactions, including: (i) deterioration in parent/child outcomes; (ii) acute adverse events (e.g. self-harm); and (iii) adverse effects and/or harm attributed directly to research procedures or the new technology. A distinction will be made with clinically normative stress experienced by some participants in the course of treatment, and adverse reactions due to other circumstances.

Adverse events identified by participants, research staff or service clinicians will be reported immediately to the Trial Co-ordinator and Research Therapist Supervisor who will assess significance. They will ensure that appropriate and timely actions are taken in accordance with agreed study and NHS procedures. A Serious Adverse Event Form will be completed when adverse events fall into predetermined risk categories.

Adverse events will be reported promptly to an established Data Monitoring and Ethics Committee (DMEC), as per governance requirements of the sponsor and funder. This may lead to recommendations for participant withdrawal; the modification of research, screening or intervention procedures; and/or suspension of the research. Regular reports will be collated on the prevalence of specific adverse events, severity, resulting actions, and relationship to study procedures and health technology.

Ethical issues

Ethical review. The proposed research will only commence once independent NHS REC and local NHS R&D approvals are obtained. In addition, key documents (e.g. participant information sheets/consent forms, research protocol) will be reviewed internally by a Service User Advisory Panel, DMEC and ethics consultant (Richard Ashcroft, Professor of Bioethics, Queen Mary, University of London).

Participant screening. Clinical staff in collaborating services will be trained by our research team 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.

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

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