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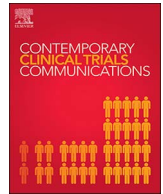
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Feasibility trial of a psychoeducational intervention for parents with personality difficulties: The Helping Families Programme



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ABSTRACT

The Helping Families Programme is a psychoeducational parenting intervention that aims to improve outcomes and engagement for parents affected by clinically significant personality difficulties. This is achieved by working collaboratively with parents to explore ways in which their emotional and relational difficulties impact on parenting and child functioning, and to identify meaningful and realistic goals for change. The intervention is delivered via one-to-one sessions at weekly intervals over a period of 16 weeks. This protocol describes a two-arm parallel RCT in which consenting parents are randomly allocated in a 1:1 ratio to either the Helping Families Programme plus the usual services that the parent may be receiving from their mental health and/or social care providers, or to standard care (usual services plus a brief parenting advice session). The primary clinical outcome will be child behaviour. Secondary clinical outcomes will be child and parental mental health, parenting satisfaction, parenting behaviour and therapeutic alliance. Health economic measures will be collected on quality of life and service use. Outcome measures will be collected at the initial assessment stage, after the intervention is completed and at 6-month follow-up by research staff blind to group allocation. Trial feasibility will be assessed using rates of trial participation at the three time points and intervention uptake, attendance and retention. A parallel process evaluation will use qualitative interviews to ascertain key-workers' and parent participants' experiences of intervention delivery and trial participation. The results of this feasibility study will determine the appropriateness of proceeding to a full-scale trial.

1. Introduction

One in ten children in developed economies experience emotional or behavioural difficulties that interfere with developmental progress, family life and school achievement [1]. They are also at risk for poor health and social outcomes in adolescence and adult life [2]. The likelihood of long-term negative outcomes is increased when a parent also has significant personality difficulties for which they may or may

not have received a formal diagnosis of Personality Disorder [3]. A substantial number of adults - around 4% in community samples and 40% in mental health services - experience persistent, pervasive and impairing difficulties in managing their emotions and relationships [4,5]. Such difficulties are associated with developmental trauma or unmet needs and are often called personality disorder [6].

Persistent problems in areas of personality functioning, such as emotional instability [7] and interpersonal hypersensitivity [8], can

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affect a parent's capacity to offer the stable and responsive care required for healthy child development [9]. Children of parents with these complex interpersonal needs are more likely to require support from child mental health and social care professionals [10]. Moreover, having a child with emotional and/or behavioural difficulties can increase the risk of a mental health crisis for vulnerable parents with limited interpersonal coping resources [3].

Interventions that support parents in developing parenting skills, in understanding the emotional needs of the child and in developing effective emotional communication lead to significant benefits in child mental health and developmental outcomes. The strongest effects are obtained for programmes that use structured 'psychoeducation', in which parents learn about child development, and the skills and application of positive parenting and personal coping strategies [11]. Unfortunately, families affected by personality difficulties experience comparatively high dropout rates and worse outcomes from the typical group format of standardised parent psychoeducation interventions [12,13].

The 'Helping Families Programme' (HFP) was originally developed for families with a range of complex needs including parental emotional dysregulation, interpersonal hostility, early school exclusion and risk of child maltreatment. Within this feasibility trial the HFP was adapted for use with families affected by clinically significant personality difficulties. HFP uses parent-focussed cognitive, behavioural and interpersonal strategies to optimise parents' use of positive parenting strategies and their understanding of child development and the tasks of parenting. This manualised approach incorporates systematic personalisation methods to assertively engage parents who have difficulties often associated with personality disorder to develop intervention goals that reflect the needs and preferences of individual families.

Evaluations of HFP have indicated positive parent engagement and clinically significant changes on a range of child and parent outcomes. The current trial will be a test of HFP in a larger sample of families with complex intergenerational needs, using a more rigorous randomised controlled trial (RCT) design.

1.1. Trial aims and objectives

The aim of this study is to investigate the feasibility of undertaking a full clinical trial of the HFP psychoeducational parenting intervention for families affected by personality difficulties. The specific objectives are:

- (i) To assess the feasibility of research procedures and intervention delivery, as needed to design a full-scale trial
- (ii) To investigate the influence of contextual factors on implementation and outcome generation for the intervention
- (iii) To obtain variance estimates for parent and child outcomes necessary to power a full-scale trial
- (iv) To measure intervention costs and make preliminary estimates of cost-effectiveness
- (v) To produce a full-scale trial protocol

2. Methods

2.1. Design

A two-arm, parallel RCT will randomly allocate consenting parents in a 1:1 ratio to: (i) the Helping Families Programme, a 16-session psychoeducational parenting intervention, plus usual services from mental health and/or social care providers; or (ii) standard care (usual services plus brief parenting advice). Primary clinical outcomes will be child and parental mental health. Secondary clinical outcomes will be parenting satisfaction, parenting behaviour and therapeutic alliance. Health economic measures will be collected on quality of life and service use. Outcome measures will be collected at baseline (T1), post-

intervention (T2) and 6-month follow-up (T3) by research staff blind to group allocation. Trial feasibility will be assessed using rates of trial participation (participant identification, screening, eligibility, consent, randomisation); data collection at T1, T2 and T3; and intervention uptake, attendance and retention. A parallel process evaluation will use observational and interview measures to understand keyworkers' and parent participants' experiences of intervention delivery and trial participation.

2.2. Eligibility criteria

Eligibility for the trial depends upon both parent and (index) child meeting criteria.

Parents will (i) be the primary parental caregiver for the index child; (ii) be aged 18–65 years; (iii) have significant personality difficulties (assessed by a score of 3 or more on the 'Standardised Assessment of Personality - Abbreviated Scale' (SAPAS) [14], (iv) be proficient in written and spoken English, and (v) have capacity to provide informed consent to participate.

The index child will be aged 3–11 years, living at home with the index parent and have significant emotional and/or behavioural difficulties (score 17 or over on the 'Strengths and Difficulties Questionnaire' Total Difficulties Score) [15].

Parents will be excluded if there is (i) the presence of psychosis; (ii) they are engaged in another structured parenting intervention; (iii) they are receiving inpatient care or (iv) they have insufficient language or cognitive abilities to participate fully in trial procedures.

Children with a pervasive developmental disorder will be excluded from the trial, and children not residing with the index parent will also be ineligible.

2.3. Interventions

2.3.1. Intervention arm

The Helping Families Programme (HFP) is a psychoeducational parenting intervention that aims to improve outcomes and engagement for families with personality difficulties. This is achieved by working collaboratively with parent participants to: (i) explore the ways in which parental emotional and relational difficulties impact on parenting and child functioning; (ii) identify meaningful and realistic goals for change; and (iii) understand and use a range of evidence-based parenting and self-care strategies. The intervention is delivered over 16 weekly sessions. HFP will be delivered by specially trained and supervised trial therapists according to a detailed manual. This will primarily involve 1:1 sessions with the primary parental caregiver, although other family members may be involved when appropriate. Parent participants will be supported to practice newly developed skills with their child(ren) in between sessions. Sessions will take place in the family home and/or local clinics if preferred by the parent.

HFP will be delivered in conjunction with usual services available to participating families. A standard care coordination protocol has been developed in concert with collaborating services, based on best practice and local guidelines. This describes: (i) research staff roles and responsibilities; (ii) coordination and continuity of care for participating parents and their children; (iii) effective management of safeguarding concerns; and (iv) information-sharing procedures between trial therapists and other professionals.

2.3.1.1. Control arm. Participants in the control arm will be offered standard care. This will consist of usual services, augmented by one parent information and support session (lasting 60–90 min), derived from an existing evidence-based parenting programme [16]. Parenting advice will be delivered by a trained parent facilitator and will involve: (i) supporting conversations about children's emotional and behavioural functioning, and (ii) discussion of relevant parenting strategies. Parents will also be provided with contact details for

sources of additional support and information. A standard care coordination protocol will apply, as per the intervention arm.

2.3.2. Concomitant interventions

Participants in both arms of the trial are permitted to continue with their current medication, and to receive other interventions or treatments. These will be noted using the Client Service Receipt Inventory [17] at the follow-up stage.

2.4. Measures

2.4.1. Participant characteristics

Descriptive data from participating families will be collected about parent and child age, sex and ethnicity, family household composition and family socio-economic status. Basic information (professional background, service type) about clinicians who participate in key informant interviews will also be collected.

2.4.2. Feasibility outcomes

Structured record sheets will be used to document key feasibility parameters related to trial procedures and intervention delivery. Relevant fields will be completed prospectively by research staff and trial therapists, as appropriate. Cumulative data will be obtained on:

- (i) Rates of participant identification (initial approach by keyworker, verbal consent for contact by research staff)
- (ii) Rates of trial participation (screening, eligibility, informed written consent, randomisation), and reasons for non-participation
- (iii) Rates of data collection at baseline and follow-up in both arms of the trial, and reasons for missing data
- (iv) Rates of intervention use (uptake, session attendance and retention) from participants in both arms of the trial, and reasons for missed sessions and dropout

2.4.3. Clinical outcomes

Validated parent-report measures with well-established psychometric properties will assess primary and secondary clinical outcomes. These measures have been reviewed by service user representatives to ensure relevance and comparative ease-of-use. The primary outcome (child behaviour) will be measured at three time points: Time 1 (T1), pre-randomisation baseline; Time 2 (T2), post-intervention follow-up (approximately four months from baseline); and Time 3 (T3), 6-month follow-up (approximately ten months from baseline). Secondary outcomes (child internalising behaviour and parental mental health) will be assessed in parallel. Measures will be collected by researchers who are blind to group allocation.

The primary outcome measure will be The Eyberg Child Behavior Inventory (ECBI) [18] which 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.

Secondary outcomes will be child internalising behaviour, parental concerns about the child, and parental mental health, which will be assessed using validated parent-report questionnaires:

- The Child Behavior Checklist-Internalising Scale (CBCL-Int) [19] is a 32-item questionnaire that assesses internalising problems in 6–18 year-olds (school-age version) with an alternate 36-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) [20] 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.

- The Symptom Checklist-27 (SCL-27) [21] is a 27-item questionnaire that assesses psychological symptoms in adults. It will provide a broad measure of parental mental health.

Other secondary outcomes measuring parenting satisfaction, parenting behaviour and therapeutic alliance, will also be assessed using the following validated questionnaires:

- The Kansas Parental Satisfaction Scale (KPSS) [22] which is a 3-item scale that provides a brief measure of stress and dissatisfaction in the parenting role.
- The Arnold-O'Leary Parenting Scale [23] is a 30-item questionnaire that assesses dysfunctional discipline styles in parents of children aged from 2 to 16 years. It correlates significantly with more time-consuming observational ratings of parenting behaviour ($r = 0.84$), and scores have been shown to differentiate between clinic and non-referred groups of children.
- The Working Alliance Inventory-Short Revised (WAI-SR) [24] which is a 12-item questionnaire that assesses therapeutic alliance. It will only be completed at T2 and will be used to assess the quality of therapeutic relationships developed by trial therapists.

2.4.4. Economic evaluations

Economic evaluation will be conducted from (i) a UK National Health Service (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) [17]. 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 [25] 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 [26].

2.4.5. Nested parallel process evaluation

Qualitative interviews will be conducted with key-workers and parent participants following the follow-up assessment and interview with the participant. Key-workers will be selected on the basis of their involvement in recruitment and case management of participants. Parents will be selected to ensure range and diversity in terms of trial allocation, clinical characteristics and outcome. Interviews will be conducted using semi-structured topic guides. These will be employed flexibly and subject to iterative development in order to reflect and explore emergent themes from 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. The interview content, data collection and analytic methods are grounded in Interpretative Phenomenological Analysis [27] in order to gain a detailed understanding of participants' subjective

experiences of the novel intervention and research procedures. This is particularly important given the complex psychological needs of the participant population.

2.5. Timeline

Individual participants will remain in the trial for approximately 11 months from the time of informed consent to the completion of research procedures. This allows 5 months for completing baseline assessments, randomisation and intervention delivery, followed by a 6-month period in which further assessments are completed at T2 (immediately post-intervention) and T3 (6 months post-intervention). The total duration of the trial is expected to be 19 months.

2.6. Sample size

A confidence interval approach [28] 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%. 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, we have determined that a sample size of $N = 35$ in the intervention arm will enable a sufficiently precise estimate of this feasibility objective (95% CI 0.67–0.93). 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 $\pm 10.7\%$ points. A sample size of $N = 70$ will also be sufficient to obtain stable estimates of population variances for future power calculations for which at least 30 patients are recommended to estimate a parameter [29].

The process evaluation will involve qualitative interviews with samples of parent and keyworker participants. The precise number of participants will be determined by data saturation (and may therefore be inflated), but we anticipate that this will be achieved with $N = 30$ informants.

2.7. Recruitment and consent procedures

Recruitment will be directed via child and adult mental health services within the catchment area of the trial, as well as concomitant social care agencies. Potentially eligible participants will be affected by personality difficulties as well as having a child with significant emotional and/or behaviour problems, and will be approached by their usual keyworker or therapist with verbal information and a postcard-sized leaflet about the research. Briefings will be provided to enable keyworkers to accurately convey the basic aims of the research and sensitively broach the topic of participation. Keyworkers will be prompted to think carefully about the risks and benefits that may accrue from research participation, and apply professional judgment when undertaking an exploratory discussion about the research. After outlining what the research entails, the keyworker will determine whether a parent is agreeable to being contacted by a researcher.

Keyworkers will then provide the research team with telephone contact details for potential participants who have provided verbal consent to be approached. The referring keyworker will be informed if contact cannot be made. If contact is successful, more detailed information about the study aims, eligibility criteria and procedures will be given verbally. Parents will also receive a Participant Information Sheet (PIS) by post and/or email, according to their preference. They will be encouraged to discuss the PIS with family members, keyworkers and other professionals in their network.

Parents will be followed up by telephone, 1 week after anticipated receipt of the PIS. If contact is successful, the researcher will seek to address any questions about the research. The potential risks and benefits of being involved in the study will be reviewed, along with

confidentiality issues, randomisation procedures and the right to withdraw from the study at any stage. In the course of this conversation, the researcher will establish if the parent (i) is willing and able to participate, (ii) is unwilling/unable to participate, or (iii) requires additional time/information to make a decision. If the latter, the researcher will follow up as needed. If the parent is agreeable, the researcher will arrange a face-to-face meeting at a convenient time/location to obtain informed written consent. The meeting will start with a further review of the PIS. The researcher will explore the parent's understanding of the research and address any outstanding questions and concerns. If the parent is agreeable, the researcher will obtain two signed consent forms (one for the research team; one for the participant to keep). The researcher will then administer the two brief parent-reported screening measures.

If the family is eligible, the researcher will establish if there is sufficient time to complete some or all of the baseline measures in the same meeting. If needed, a separate meeting will be arranged to complete measures as soon as possible. The measures, in the form of parent-completed pen-and-paper questionnaires, will be administered in a standard sequence and should take approximately 60–90 min to complete. The researcher will be available to help with clarifying questionnaire content and instructions, and will stay alert to any signs of discomfort that may need to be addressed sensitively and supportively. Participants will be paid £10 per hour as reimbursement for the time involved in data completion. This amount has been determined in accordance with good practice guidance [30,31].

2.8. Allocation and randomisation

Each participant will be allocated a unique, anonymised ID number by the trial coordinator. Details will be entered into an independently monitored computer system set up by the accredited Clinical Trials Unit at King's College, London. The outcome of allocation will be communicated to the trial's senior clinical supervisor, who will then arrange for either an HFP therapist (intervention arm) or parent facilitator (control arm) to make contact with the allocated participant in order to communicate the next steps. Other members of the research team (including the Chief Investigator, statistician and research workers) will remain blind to participant allocation status.

Intervention delivery in both arms of the trial will begin as soon as possible after allocation, and continue for 16 weeks. Participants will continue to receive usual services. Care coordination will be managed according to a standard care protocol.

2.9. Data collection

2.9.1. Screening and initial assessments

Participants will receive a text message reminder about the forthcoming follow-up assessment, two weeks prior to the intended assessment date. A researcher will then make contact by telephone one week prior to the intended assessment date. If a participant cannot be reached by telephone after four consecutive attempts, s/he will be sent a standard letter and asked to opt in for any further contact.

If contact is successful, the researcher will arrange a convenient time and location to complete the measures. A reminder text message will be sent 24 h before this scheduled assessment meeting. As with the initial assessment, the measures will be administered in a standard sequence and should take approximately 60–90 min to complete. The blinded researcher will use a standardised script during data collection to remind participants not to disclose their allocation status.

2.9.2. First and second follow-up assessments

Researchers will maintain contact with participants, updating them on research progress and reminding them about arrangements for completion of T2 and T3 assessments. Each participant will also receive a telephone call from a researcher within 1 week of the anticipated

arrival of the newsletter. The purpose is to verify the participant's latest contact details and to review understanding of, and availability for, remaining research procedures. As before, up to four attempts will be made to reach the parent by telephone. Researchers carrying out follow-up interviews will remain blind to the randomisation allocation of the participants and will request that they do not reveal this until the point at which process evaluation interviews are conducted. The randomisation status of participants will be stated in a sealed envelope which researchers will open after they have conducted the follow-up assessment, and before they conduct the interview.

2.9.3. Interview with keyworkers

Parent participants will be informed verbally and in the PIS that we may conduct a separate interview with their keyworker. Purposively selected keyworkers will receive their own PIS and Consent Form prior to taking part in this qualitative interview. Interviews will be conducted by an unblinded researcher. Keyworkers will not be reimbursed for their participation.

2.9.4. Strategies for promoting participant compliance, retention and completing follow-up

Participants' attendance at scheduled sessions will be logged by HFP therapists (intervention arm) and parent facilitators (control arm). The following activities will support adherence to study procedures at first and second follow-up in both trial arms:

- (i) All participants will receive a text message reminder about a forthcoming first or second follow-up assessment; messages will be sent two weeks prior to the intended assessment date, mentioning that a researcher will follow up in a telephone call to confirm a convenient time and location
- (ii) If a participant cannot be reached by telephone after four consecutive attempts (2 calls and 2 text messages), s/he will be texted and asked to opt in for any further contact
- (iii) If contact is unsuccessful at the first follow-up, renewed efforts will be made at the second follow-up unless a parent specifically opts out of all further contact
- (iv) All of the telephone calls, successful and unsuccessful, will be documented
- (v) A further reminder text message will be sent 24 h before a scheduled assessment meeting

Each participant will receive a telephone call from a researcher to check the participant's latest contact details and to review understanding of, and availability for, remaining research procedures. As before, up to four attempts will be made to reach the parent by telephone; details of these calls will be logged.

2.9.5. Data management

Identifiable data, such as participant names and addresses will be removed from completed research measures, and an anonymous identification number will be assigned to each participant to identify the questionnaires and demographic information. Personal data (e.g. participant names and contact details) will only be transferred electronically using encrypted USB drives or secure NHS email servers. Qualitative interviews will be recorded on encrypted devices (e.g. iPhones or iPads), as per the requirement of the sponsor. Completed recordings will be uploaded onto password-protected computers and deleted from recording devices once transcribed. Efforts will be made to upload and transcribe recordings as soon as possible after interviews have been completed. In order to preserve anonymity, participant numbers will be assigned to each participant to identify the interview transcript, and pseudonyms will be used in interview transcripts where participants mention names, places or any other information that could be used to identify them.

The Chief Investigator will act as custodian of the data in

accordance with the UK Data Protection Act and the terms of the Sponsor and Funder. Personal contact details of participants will be retained for the duration of the trial to enable follow-up. Other research data generated by the study will be retained for 7 years to cover contractual liability.

2.10. Analysis plan

2.10.1. Statistical methods

The statistical analysis for this pilot trial 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 [32] 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 [29].

2.10.2. Economic evaluation

Differences in mean total costs between experimental and control 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 [33]. 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 [34]. 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 [32]. A range of threshold QALY values will be used to include the £20–30,000 value used by National Institute of Health and Care Excellence [35].

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.

2.10.3. Process evaluation

The primary aims of the process evaluation analysis are to assess the acceptability of, and adherence to, recruitment procedures in UK NHS and local authority services, and to investigate the impact of contextual factors upon the implementation of HFP and the its outcomes.

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 analysis using the refined coding framework. Validation will be undertaken with a sample of participants. Qualitative themes will be triangulated with a descriptive analysis of quantitative feasibility parameters related to participant enrolment and intervention use.

2.11. Trial governance

2.11.1. Trial Steering Committee

The Chief Investigator will report to an independent Trial Steering Committee (TSC) responsible for ensuring scientific integrity of the trial. The TSC has been established since mid-2014 and has overseen a pre-pilot feasibility study. The Chair is Prof. Peter Fonagy, Freud Memorial Professor of Psychoanalysis at University College London. Other independent members include senior clinicians and academics with expertise in trials and/or families with complex interpersonal needs. The TSC will meet every six months to monitor, review and supervise research progress.

2.11.2. Data Monitoring and Ethics Committee

A Data Monitoring and Ethics Committee (DMEC) will monitor interim safety and efficacy data. The DMEC has been established in parallel with the TSC since mid-2014. The Chair is Prof. Philip Graham (Emeritus professor of Child Psychiatry at the Institute of Child Health, London). The TSC will liaise with the DMEC should safety, ethical or efficacy issues emerge, with implications for continuing, modifying or stopping the trial.

2.11.3. Service user participation and involvement

Service user panels will be convened to inform the development of the intervention manual and recruitment pathways. Service user representatives will be appointed to sit on the Trial Steering Committee and to attend meetings of the Project Management Group. A service user researcher will provide expert guidance on the interpretation of the Process Evaluation findings.

2.12. Ethics, consent and permissions

2.12.1. Research ethics approval

Ethics approval was obtained from Health Research Authority South East Coast - Brighton & Sussex Research Ethics Committee (reference: 16/LO/0199).

2.12.2. Consent and confidentiality

2.12.2.1. Access to databases. The Chief Investigator (CD) will act as custodian of the data in accordance with legislation and the terms of the research sponsor (King's College London) and funder (National Institute for Health Research, UK).

2.12.3. Adverse events

The Chief Investigator will report any serious adverse event that is both related to the research procedures and is unexpected to the Research Ethics Committee that gave a favourable opinion of the research. Researchers carrying out interviews and assessments with participants will be instructed to report any adverse circumstances to the Project Manager and Principal Investigator, no matter how minor the circumstances might appear. Therapists engaged with participants will be asked to impart information on potentially serious adverse events to

their supervisor and/or the Principal Investigator during weekly supervision sessions. A standard form for reporting serious adverse events will be circulated to all trial staff.

3. Discussion

This study focuses on providing help for two marginalised and often linked vulnerable populations 1) parents with clinically significant personality difficulties 2) their young children with emotional and behavioural problems. These parents and their children have very high levels of unmet need and we currently lack robust evidence on the best way to help them. HFP is the first intervention of its kind designed to help these groups and our study will test the feasibility of evaluating HFP using a randomised design.

The primary aim of this study is to assess the feasibility of a full-scale trial to deliver a psychoeducational parenting intervention for families affected by personality difficulties. The Helping Families Programme intervention provides an important alternative to existing group-based interventions for parents whose interpersonal problems present barriers to intervention engagement and achievement of improved outcomes. There is currently a significant gap in evidence-based services for these families, and this feasibility study will test whether a trial of this intervention is possible. Positive feasibility findings for the research and intervention methods and measures will provide a platform for the planning and conduct of a subsequent full-scale trial.

The strengths of the protocol lie in its scope and methods of recruitment. Parents who themselves have personality difficulties and whose children have significant mental health problems can be service users in adult and child mental health services as well as clients of social care services. Often the parental and child needs are under-recognised and care tends to focus on the needs of the individual adult or child. This protocol actively seeks to recruit from across services sectors rather than restricting recruitment to specific service types. The research team will need to engage and communicate with a wide range of practitioners and service provision. The breadth of recruitment routes means that parents located in a range of existing pathways will be given the opportunity to participate in the trial. All parents meeting eligibility criteria will receive support that is additional to the common forms of usual care typically available. Once screened, individual participants will have the chance of allocation to the HFP intervention, an intensive 16 session psychoeducation intervention. Parents randomised to the control arm will receive a manualised one session parenting intervention with a qualified therapist based on an existing evidence based programme [16].

Recruitment through this protocol is intended to include parents who have previously received formal assessment, diagnosis and treatment for their complex interpersonal difficulties. It is also intended to be open to parents who meet eligibility criteria but who have not received previously received formal diagnosis and intervention. The latter group of parents are more likely to be found in child mental health and social care services, where diagnostic assessment of the adult parent is not within the scope of services. The protocol uses eligibility criteria based on the use of the SAPAS as a screening measure rather than formal diagnosis of personality disorder. Earlier feasibility work that informed the development of this protocol indicated that many potentially eligible parents had not received formal diagnosis. In addition, staff and service user consultations expressed concerns about the acceptability of screening procedures for the study using diagnostic instruments such as the Development and Well-Being Assessment (DAWBA) and the Structured Clinical Interview for DSM Disorders-II (SCID) [36]. There are important ethical and personal implications of using a research administration of instruments such as the SCID with parents who have not previously sought diagnosis for complex interpersonal difficulties.

Use of the SAPAS as a screening tool enables participation in the trial of individuals who might otherwise have been excluded because

they have not previously sought a formal diagnosis for their interpersonal difficulties. However, not including diagnosis as an eligibility criteria has potential implications for the interpretation of the trial results against studies which do use such inclusion criteria.

Further limitations to the protocol include the use of parent informant self-report outcome measures which is reliant on parents' accurate and reliable assessment of their own and their children's functioning across a range of domains. The inclusion of third party assessment measures would increase validity but are not feasible within the funding available for this pilot study. Furthermore, consideration needs to be given to the recognised variations and discrepancies between parent, child and other informant ratings of child outcomes.

Evidence suggests that there is an under-recognition of coexisting parent and child mental health problems. Feasibility work underlined the challenges underpinning this under-recognition, in which adult mental health practitioners focussed on the care of their adult service user, gave limited attention to the mental health of their children, and potential parenting difficulties. Within child mental health services, clinician assessment and intervention is focussed on the young person, with limited attention to the interpersonal function of the adult parent and the effects on their parenting. These practice differences are likely to affect the ability of practitioners across referring services to identify potentially eligible participants and confidently involve the parents in an open and informed discussion about participation. The research team has developed proactive methods to support and train practitioners from across service sectors to preliminary identify participants and engage them in the study.

The trial aims to examine the feasibility of conducting a randomised design to test a new intervention for families affected by personality difficulties, whose needs are typically under-served. Although the impact of the active intervention are as yet unknown, parent participants randomised to the Usual Care arm of the trial may be disappointed by their allocation. Such disappointment may lead to participant withdrawal or to further help-seeking outside of the parameters of the trial. Any additional service utilisation will be recorded through the CSRI. Participant retention and withdrawal reasons will be recorded as part of the assessment of trial feasibility.

This is a new intervention for a highly vulnerable population of parents and children where there are significant deficits in evidence based interventions and clinical practice. This paper describes a research protocol for a pilot randomised control trial for a new psychoeducational parenting intervention that will provide feasibility data that will be used to inform the design and planning for a full-scale trial.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

CD (Chief investigator), CD conceived and led the study with contributions from the other authors.

JB contributed to the writing of this manuscript. All authors read and approved the manuscript.

Authors' information

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