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

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\textbf{A B S T R A C T}

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
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
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