

An intervention for parents with severe personality difficulties whose children have mental health problems: a feasibility RCT

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Scientific summary

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Scientific summary

Background

Emotional and behavioural disorders are common in children and young people, and severe parental personality difficulties are a substantial risk factor. Although parenting intervention programmes are a proven method for improving child outcomes, implementation to date has mainly focused on generalised populations rather than on parents and children with comorbid mental health risks and needs. This research focused on the development and initial evaluation of a specialised parenting programme for parents with severe personality difficulties who have children with emotional and behavioural problems.

Primary research aims

The primary research aims were (1) to develop a new psychoeducational technology for parents with severe personality difficulties, including personality disorders, who have a child with significant emotional and behavioural difficulties; (2) to assess the new technology's initial acceptability and the viability of evaluation methods in a pre-trial feasibility study; and (3) to evaluate the technology and evaluation methods in a randomised feasibility trial.

Design

A three-phase pragmatic, mixed-methods design was used to produce generalisable research findings and a deeper understanding of the new technology. The research was conducted over 45 months in mental health services of two NHS mental health foundation trusts, with additional recruitment through concomitant children's social care departments.

Health technology

Two existing validated psychoeducational health technologies were used as the platform for the new technology: (1) Psycho-Education with Problem-Solving, a psychoeducational programme for adults with a personality disorder, and (2) the Helping Families Programme, a parenting programme for families with complex psychosocial difficulties. The resulting new technology, Helping Families Programme-Modified, was a 16-session specialised psychoeducational parenting intervention delivered one-to-one by trained and supervised mental health therapists. The Helping Families Programme-Modified used manualised, structured, goal-orientated parenting strategies and collaborative therapeutic methods intended to improve parenting, and child and parent functioning.

An additional single-session assessment and psychoeducational guidance session, Being a Parent, was developed and it was included in the usual-care arm of the planned randomised feasibility trial.

Research plan

Phase 1: screening and intervention development (9 months)

1. Content and methods of the Helping Families Programme and Psycho-Education with Problem-Solving were synthesised; findings from a scoping review and consultative focus groups (including 26 clinicians and eight service users) were incorporated.
2. Draft screening methods and a new health technology manual, Helping Families Programme-Modified, were produced.

Phase 2: pre-trial feasibility study (13 months)

1. Four research therapists were trained to undertake feasibility testing of the Helping Families Programme-Modified in a clinical case series ($n = 4$).
2. Preliminary acceptability, process and impact evaluation were conducted using individual case observations and key informant interviews ($n = 10$).
3. Referral and recruitment pathways in candidate services were established.
4. A description of usual care for the target population was obtained.
5. The Helping Families Programme-Modified manual was revised in the light of phase 2 findings.
6. The research protocol for a randomised feasibility trial was developed.
7. Independent ethics scrutiny of intended procedures for the planned randomised feasibility trial was obtained.

Phase 3: randomised feasibility trial (23 months)

1. A randomised feasibility trial ($n = 48$) was conducted that compared the Helping Families Programme-Modified with usual care including the Being a Parent session (usual care), with outcomes collected at baseline, post intervention and at the 4-month follow-up.
2. A parallel process evaluation was conducted using key informant interviews (parent participants, $n = 27$; keyworkers, $n = 12$).
3. Predefined trial feasibility parameters were assessed.
4. Variance estimates for parent and child outcomes were obtained.
5. Detailed understanding of evaluation design and methods, intervention acceptability and related contextual factors were developed.
6. Intervention costs were measured and preliminary estimates of cost-effectiveness were made.
7. Recommendations for a definitive trial were decided.

Eligibility criteria (phases 2 and 3)

The inclusion criteria were:

- Parent – being aged 18–65 years, having severe personality difficulties [phase 2: Structured Clinical Interviews for *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition Axis II Disorders research diagnosis; phase 3: Standardised Assessment of Personality – Abbreviated Scale score of ≥ 3], being proficient in English and having the capacity to consent to participation.
- Index child – being aged 3–16 years, living at home with index parent, having mental health issues [phase 2: assessment with Development and Well-Being Assessment/Pre-School Age Psychiatric Assessment; phase 3: Strengths and Difficulties Questionnaire Total Difficulties score of ≥ 17].

The exclusion criteria were:

- Parent – presence of psychosis, being currently engaged in structured psychotherapy and/or another parenting intervention, receiving inpatient care and/or language/cognitive difficulties affecting consent and participation in research procedures.
- Index child – presence of a neurodevelopmental disorder, not residing with index parent and/or currently being considered for/subject to local authority care/supervision proceedings.

Outcomes

- Child mental health: Concerns About My Child, Eyberg Child Behaviour Inventory, Child Behaviour Checklist-Internalising Scale, Strengths and Difficulties Questionnaire (phase 2 only).
- Parenting: Arnold–O’Leary Parenting Scale, Kansas Parental Satisfaction Scale.
- Parental mental health: Symptom Checklist-27.
- Treatment alliance: Working Alliance Inventory-Short Revised.
- Service use, costs and quality-adjusted life-years: Client Service Receipt Inventory; EuroQol-5 Dimensions and EuroQol-5 Dimensions (Youth).

Analysis

Statistical analyses aimed to provide estimates of key trial parameters and to inform power calculations for a future definitive trial. Phases 2 and 3 used descriptive statistical analyses of relevant observational data together with interpretative phenomenological analysis and thematic content analysis of parent and keyworker qualitative data, respectively. In phase 3, the feasibility of trial procedures was assessed using proportions of predetermined parameters and their estimated 95% confidence intervals. Clinical outcomes were analysed using regression models to estimate the likely range of intervention effect (by assessing 95% confidence interval) post treatment, with pre-randomisation values as a covariate. Population variances for future power calculations were determined using the upper 80th percentile of confidence intervals around the estimated population variance. Health service costs were used in cost–consequences and cost–utility analyses.

Service user involvement and independent ethics review

These were embedded across the research programme to (1) ensure a rich and accurate understanding of service users’ priorities and experiences, and (2) identify and act on predicted and emergent ethics issues related to the implementation of the new technology and evaluation methods.

Results

Phase 2 case series findings indicated that it was feasible to implement the Helping Families Programme-Modified, with initial evidence of participant acceptability. The use of participant eligibility based on personality disorder criteria proved to be a recruitment barrier in phase 2.

Phase 3 findings supported the feasibility of trial recruitment methods using eligibility criteria based on non-diagnostic participant identification criteria using the Standardised Assessment of Personality – Abbreviated Scale and the Strengths and Difficulties Questionnaire. Trial recruitment took 4 months longer than planned. The participant recruitment target was revised to 48, owing to recruitment delays in one research site; this was 68.8% of the originally planned trial sample. Referring keyworkers and other service staff were not able to provide reliable estimates of the proportion of potentially eligible parents identified

from caseloads. It was therefore not possible to estimate the proportion of eligible parents who were then referred to the trial. Researchers made telephone contact with 87 (97.7%) referred service users. At initial contact, 60 (69.7%) referred service users met the criteria and completed screening procedures. Substantial research time was required to collect data, mainly owing to participant cancellation and adverse life events.

Forty-eight service users met both parent (Standardised Assessment of Personality – Abbreviated Scale) and child (Strengths and Difficulties Questionnaire) screening criteria. Five (8.3%) service users were excluded because they met neither parent nor child screening criteria. All participants fulfilling eligibility criteria entered the trial, representing 80.0% of service users completing screening measures and 53.9% of referred service users. Thirty-six (75.0%) trial participants were referred from site 1.

Uptake was higher for eligible parents randomised to the Helping Families Programme-Modified than for those randomised to usual care (Helping Families Programme-Modified, 87.5%; usual care, 62.5%). All participants completed time 1 assessment measures. Trial retention exceeded the a priori rate (66.7%, 95% confidence interval 51.6% to 79.6%). The majority of participants who declined intervention following randomisation did not complete time 2 measures ($n = 10$, 83.3%, 95% confidence interval 51.6% to 97.9%).

The trial sample had high levels of disadvantage and multiple morbidity (psychiatric diagnosis, 86.2%; parent physical pain/discomfort, 47.2%; child Eyberg Child Behaviour Inventory problem caseness, 89.1%). Qualitative findings provided an insight into parents' understanding of the effect of personality difficulties on their parenting and previous adverse help-seeking experiences. The majority of trial procedures were satisfactory. Significant reservations were expressed about the acceptability and the emotional effects of randomisation.

Quantitative findings supported the Helping Families Programme-Modified acceptability in comparison with the usual-care condition (Working Alliance Inventory-Short Revised: Helping Families Programme-Modified, mean 73.8, standard deviation 10.4; usual care, mean 56.2, standard deviation 18.8). The Helping Families Programme-Modified duration was longer than planned, owing to participant appointment cancellation and participant life circumstances. The usual-care condition was less acceptable, which had an effect on participant retention. Qualitative findings supported the structured format, parenting content and methods of the Helping Families Programme-Modified. The brief nature of the one-session usual-care condition was generally assessed more negatively.

Clinical effects on key child and parenting outcomes were identified across both trial arms, with some potential advantages of the Helping Families Programme-Modified (Concerns About My Child problem 1, effect size 1.2, 95% confidence interval 0.4 to 2.0; Eyberg Child Behaviour Inventory intensity, effect size 0.4, 95% confidence interval 0.3 to 1.1; Kansas Parental Satisfaction Scale, effect size 0.4, 95% confidence interval 0.3 to 1.1). No effects were detected for parenting behaviour and adult mental health outcomes. The wide confidence intervals suggested that these results should be treated with caution. At initial follow-up, with parental quality-adjusted life-years, the Helping Families Programme-Modified dominated usual care, and child quality-adjusted life-years resulted in higher costs and more quality-adjusted life-years. However, at second follow-up, the Helping Families Programme-Modified was associated with greater costs and quality-adjusted life-years than usual care. Using child quality-adjusted life-years, controlled for baseline EuroQol-5 Dimensions, three-level version, usual care dominated the Helping Families Programme-Modified. Qualitative findings provided insight into subjective improvements experienced by parents and reported benefits to child outcomes. Caution needs to be exercised in the interpretation of quantitative findings, owing to the smaller than expected sample size.

Dissemination

The research has resulted in two peer-reviewed publications, conference papers and numerous service presentations. The findings have influenced the establishment of a Helping Families parental mental health team in one large NHS trust. The research team has collaborated with service users to produce a short film for educational and training purposes about the effects of severe mental health difficulties on parenting and parents' experiences of mental health care.

Conclusion

This research programme was effective in developing an acceptable specialised psychoeducation parenting intervention for a specific high-risk population of parents and their children who are exposed to significant multimorbidities, and in testing the feasibility of potential trial methods. Synthesis of quantitative and qualitative results broadly supported the feasibility of trial methods and it identified areas to address in a subsequent definitive trial. Findings usefully identified potential threats to recruitment, retention and intervention delivery that need to be taken account of in the plans and the protocol of a definitive trial. The Helping Families Programme-Modified proved to be largely acceptable to participants, although delivery duration was longer than planned. The usual-care condition was less acceptable to participants, with some associated effects on trial retention.

Results produced indicative variance estimates for parent and child outcomes, and measured intervention and participant service costs. Cross-sectional process evaluation provided a fine-grained understanding of key contextual factors that affected the conduct of the trial and its interventions.

The research findings provided an insight into the personal, family, social and economic adversity experienced by many families with a parent affected by severe personality difficulties. Process findings suggested that participant parents may often have been aware of the ways in which their own experiences and mental health difficulties combined to impair their parenting, resulting in parental resignation and distress.

A definitive trial will need realistic research resources to undertake trial site preparation, so as to ensure sufficient recruitment flow and a proactive approach to participant data collection. A revised comparator condition providing equipoise and face validity without distorting usual care will be necessary, such as the existing Being a Parent session plus an ongoing parent support group. A subsequent cost-effectiveness analysis should include a wider range of costs, including time lost from school. It should also use modelling methods to extrapolate costs and outcome beyond the trial period.

Trial registration

This trial is registered as ISRCTN14573230.

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This report

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