

Helping Families: Psychoeducational Intervention for Parents with Personality Disorders

Submission date 19/05/2014	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/05/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/03/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The aim of this study is to develop and test a new psychological intervention related to adult personality disorders and child emotional and behavioural difficulties. Personality disorder refers to the long-term problems that some people have in managing their feelings and in relating to others. People with a personality disorder are highly sensitive to stress and prone to extreme mood swings, self-harm, substance use and interpersonal challenges. Such difficulties affect 4% of all adults in the UK and 40% of adults in mental health services, with high costs to the NHS and social services. Emotional and behavioural problems affect nearly 1 in 10 children. Common examples are disruptive behaviour and anxiety. These can interfere with family life, friendships and school achievement, and increase long-term risks for poor adult mental health, substance use, unemployment and crime. The likelihood of severe and persistent problems is increased when a parent has a personality disorder. This is because personality difficulties can make it harder for a parent to provide the consistent care and nurture required for healthy child development. Having a child with emotional and behavioural difficulties is also stressful in itself, and may worsen a parents own mental health. Routinely available parenting interventions often achieve worse results when parents have mental health problems. Our study aims to improve care for families with needs in both of these areas. We will focus on psychoeducation, which is a widely used approach in healthcare that teaches service users and carers about the nature of health conditions and useful ways of managing symptoms and impacts. Other research has shown that psychoeducational support is generally effective at helping parents to manage childrens difficulties.

Who can participate?

Parents with personality disorders whose children have emotional and/or behavioural disorders. We will recruit participants from two NHS Mental Health Foundation Trusts in London that serve large and diverse populations with high rates of adult and child mental health problems. This will be augmented by additional fieldwork in children's social service teams operating within the same catchment areas.

What does the study involve?

We have previously developed and evaluated a promising psychoeducational treatment for adults with personality disorder, and another for parents with complex psychosocial needs. Phase 1 of the proposed study will combine these two existing treatments to create a new psychoeducational intervention manual. We will also produce a screening manual detailing suitable methods for identifying and selecting eligible parents. We will work closely with service users and clinicians to ensure that our methods are practical, acceptable to parents and alert to the ethical issues involved. In Phase 2, trained clinicians will deliver the intervention to 12 consenting parents. The parents will complete assessments and take part in interviews about their experiences. This information will then be used to refine our screening and intervention methods where necessary. Phase 3 will involve an initial study to compare the newly refined intervention with the usual care that parents receive. Seventy consenting parents will be allocated at random to receive the new intervention or usual care. Parents will complete follow-up assessments and interviews after the intervention and 6 months later. This study will carefully test research and clinical procedures to obtain reliable information about what is feasible, effective and acceptable for participants. The results will show whether the intervention can and should be tested in a larger, more definitive study with a view to wider use in the NHS.

What are the possible benefits and risks of participating?

The intervention may help to enhance parenting skills and confidence, improve parent-child relationships, and reduce child mental health difficulties. Parent participants will also learn strategies for managing stressful situations that may benefit their own mental health. It is possible that some participants might feel upset while discussing topics related to parental and child mental health, but therapists will be trained to provide appropriate practical and emotional support. Participants may be provided with information about other help as needed. Research assessments might be difficult for some parents if they have English as a second language or difficulties reading and writing. A researcher will be present during data collection in case a participant requires help or becomes distressed.

Where is the study run from?

The study is being run from South London and Maudsley NHS Foundation Trust and Central and North West London NHS Foundation Trust in the UK.

When is study starting and how long is it expected to run for?

The project will run for 37 months starting in June 2014

Who is funding the study?

NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 12/194/01

Study information**Scientific Title**

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

Study objectives

Does psychoeducational support for parental caregivers with personality disorders, who have children with severe emotional and behavioural problems, improve parental mental health and their children's emotional development?

More details can be found at: <http://www.nets.nihr.ac.uk/projects/hta/1219401>

Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0018/118341/PRO-12-194-01.pdf

Ethics approval required

Old ethics approval format

Ethics approval(s)

The South East Coast - Brighton & Sussex Research Ethics Committee, 21/03/2016, REC ref: 16/LO/0199; IRAS project ID: 197474

Study design

Pragmatic phased design with iterative development of health technology; feasibility testing in linked case studies; and piloting in a two-arm parallel randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

In preparation

Health condition(s) or problem(s) studied

Personality disorders

Interventions

Two existing, validated psychoeducational health technologies will be used as the platform for the new technology:

1. Psycho-Education with Problem-Solving (PEPS), a psychoeducational programme for adults with personality disorder
2. The Helping Families Programme (HFP), a parenting programme for families with complex psychosocial difficulties

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Child mental health:

1. Strengths and Difficulties Questionnaire (SDQ)
2. Eyberg Child Behavior Inventory (ECBI)
3. Child Behavior Checklist-Internalising Scale (CBCL-Int)
4. Concerns About My Child (CAMC)

Parental mental health:

1. Symptom Checklist-27 (SCL-27)

Secondary outcome measures

1. Parenting satisfaction: Kansas Parental Satisfaction Scale (KPSS)
2. Parenting behaviour: Arnold-OLeary Parenting Scale
3. Treatment alliance: Working Alliance Inventory-Short-Revised (WAI-SR)
4. Quality-adjusted life years (QALYs): EQ-5D and EQ-5D-Y
5. Service use and costs: Client Service Receipt Inventory (CSRI)

Overall study start date

01/06/2014

Completion date

30/06/2017

Eligibility**Key inclusion criteria**

Parent:

1. Primary parental caregiver for index child
2. Aged 18-65 years
3. Presence of any personality disorder
4. Proficient in written and spoken English
5. Capacity to provide informed consent to participate

Child:

1. Living at home with index parent
2. Aged 3-16 years
3. Presence of an emotional or behavioural disorder
4. Attending, or being considered for, CAMHS

Participant type(s)

Patient

Age group

Other

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

Pre-pilot feasibility study: N=12. Pilot RCT: N=70

Total final enrolment

48

Key exclusion criteria

Parent:

1. Presence of psychosis
2. Engaged in individual or group psychotherapy directly related to personality disorder
3. Engaged in another structured parenting intervention
4. Receiving inpatient care
5. Insufficient language or cognitive abilities to participate fully in trial procedures

Child:

1. Presence of neurodevelopmental or psychotic disorder
2. Not residing with index parent
3. Considered for or subject to an application for care or supervision proceedings

Date of first enrolment

01/04/2016

Date of final enrolment

30/11/2016

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

South London and Maudsley (SLaM) NHS Foundation Trust

London

United Kingdom

SE5 8AZ

Study participating centre

Central and North West London NHS Foundation Trust

London

United Kingdom

NW1 2PL

Sponsor information

Organisation

South London & Maudsley NHS Foundation Trust (UK)

Sponsor details

Joint South London & Maudsley NHS Foundation Trust/Institute of Psychiatry Research Office
Room W1.11
Institute of Psychiatry
King's College London
De Crespigny Park
London
England
United Kingdom
SE5 8AF

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/015803449>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme; ref. HTA 12/194/01

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Submission of peer-reviewed papers (to be made publicly available through open-access publication) and associated abstracts to relevant conferences, including scientific meetings of the British Psychological Society, Royal College of Psychiatrists, British and Irish Group for the Study of Personality Disorder (BIGSPD), and International Society for the Study of Personality Disorders (ISSPD). The trial protocol will also be published and made publicly available.

Research participants will receive an interim newsletter and final summary of findings. These will be co-produced by Service User Advisory Panel. We will also seek to disseminate findings through service user and public engagement events, such as national NIHR CRN events and local network meetings.

The Centre for Parent and Child Support (SLaM NHS Foundation Trust) will lead dissemination of outputs for services. Managers and practitioners will be invited to in-service seminars in the dissemination phase of the trial.

Intention to publish date

01/01/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/02/2020	10/02/2020	Yes	No
Results article	results	01/03/2020	17/03/2020	Yes	No
HRA research summary			28/06/2023	No	No