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Helping Families: Psychoeducational Intervention for Parents with Personality Disorders

Submission date
19/05/2014

Recruitment status
No longer recruiting

Registration date
21/05/2014

Overall study status
Completed

Last Edited
17/03/2020

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
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

Primary study design
Interventional

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

Study type(s)
Treatment

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(s)
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)

Key secondary outcome(s)

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)

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

Healthy volunteers allowed
No

Age group
Other

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

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
United Kingdom

England

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)

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, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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