

Families and Carers Training and Support Programme (FACTS) - for families of people with a Borderline Personality Disorder diagnosis

Submission date 22/12/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/01/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 13/01/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Borderline Personality Disorder (BPD) is a serious mental illness characterized by pervasive instability in moods, volatile interpersonal relationships including sudden paranoid reactions, poor self-image, and self-destructive behaviours, which include suicide attempts and self-harm. Families have a unique position of being able to support mental health treatment, but they can only do so if they are aware of what to do and how to manage common situations that present as a result of the illness. BPD is a particularly difficult condition for families to manage as the difficulties often present as a problem in the family relationships. As a result, families of patients with BPD struggle to cope with their own feelings, leaving them traumatized, disempowered and unsure how best to help their relative or loved one. Yet, support and advice for families is rarely available and, when it is, is often misleading, sometimes offensive, confusing, and generally unhelpful.

The Anna Freud Centre (AFC) proposes to evaluate a support programme known as the Families and Carers Training and Support programme, or FACTS programme. The programme is for families, friends, partners and others who are involved with people with BPD with the aim of reducing adverse incidents in the family whilst improving family well-being. It is suggested that these effects may lead to less use of crisis and other services by the person with BPD.

Who can participate?

Families, friends, partners and others who are involved with someone with a clinical diagnosis of BPD or emerging personality disorder can participate.

What does the study involve?

The FACTS programme consists of five group sessions, running one weekday evening per week for five weeks, and run by other family members who have received training to deliver the programme. Families who take part in the study will be randomly allocated to either a group which will receive the FACTS programme immediately, or to a waitlist group which will receive the programme a few months later. Throughout their involvement in the study, participants will submit weekly incident diaries to keep track of adverse incidents arising in the family.

What are the possible benefits and risks of participating?

Expected benefits of taking part in the FACTS programme include improved family well-being and reduced adverse incidents in the family. If a benefit is demonstrated, there could be a much wider potential benefit to health care systems and personality disorder services. FACTS could offer crucial support to families, improving their own mental health and well-being and enabling a reduction in crisis situations with their family member with BPD.

There are few risks. Families could fail to develop skills to manage the family member with BPD and feel more hopeless about their relationship. The implementation of the skills could be inadequate or misguided. However none of the 18 families in the pilot project reported this effect.

Where is the study run from?

The FACTS programme will be running at the Anna Freud Centre (AFC), London.

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

December 2014 to July 2016

The first skills training group will run for five weeks from 12/01/2015. A further three groups will also follow. All four groups will be completed by June 2015. If the groups are found to be beneficial, families will be followed up for 6 months to provide information on the long-term effects of the programme. Recruitment will continue until all four courses are fully booked. It is anticipated that the courses will be fully booked by March 2015.

Who is funding the study?

The Lewis Trust (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

R&D ref: 131609

Study information

Scientific Title

Families and Carers Training and Support Programme (FACTS) - for families of people with a Borderline Personality Disorder diagnosis - a randomised controlled trial

Acronym

FACTS

Study objectives

A psycho-educational and skills programme designed for families, friends, partners and others who are involved with people with BPD will reduce adverse incidents in the family whilst improving family well-being. It is suggested that these effects may lead to less use of crisis and other services by the person with BPD.

This is a randomised controlled trial to test the feasibility of the method for a larger trial and to gather indicative data of the effectiveness of a psycho-educational and skills programme for families of a person with BPD in reducing incidents in the family and crises for the patient. This is a single-centre interventional study with a waitlist control, with the programme being delivered at the Anna Freud Centre in London.

Ethics approval required

Old ethics approval format

Ethics approval(s)

National Research Ethics Service Committee London - City & East. Favourable ethical opinion letter received 07/10/2014, REC reference: 14/LO/1519

Study design

Pilot randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied

Borderline Personality Disorder (BPD)

Interventions

Families of people with BPD will be randomised to the active intervention of 5 modules of a psycho-educational and skills programme or to waitlist control. All patients on waitlist control will be offered the intervention following a wait of 3-4 months. The programme will be delivered by family members of people with BPD who completed FACTS in 2013 and who have since received training to deliver the course.

Intervention Type

Behavioural

Primary outcome measure

The primary outcome objective will be to reduce family incidents and increase family empowerment. It is hypothesised that this will lead to less crisis service use such as hospitalisation, police, A&E by the identified family member with BPD. Thus there will be improvements in the extent to which the family is able to cope with incidents. Incidents are defined as an emotional, behavioural, relationship, or other problems as reported in a weekly incident diary which are related to symptoms of borderline personality disorder and lead to family distress. They include any event which is usually recurrent that creates an interpersonal problem between family members such as withdrawal and refusal to speak, aggressive outbursts (verbal or physical), threats of self harm, suicide attempts. Weekly incident diaries will be completed by participants prior to starting the course and throughout their involvement in the trial.

Secondary outcome measures

The secondary objective will focus on the wellbeing of the family by:

1. Improving the well-being of the attendees;
2. Increasing their understanding of the condition;
3. Helping them support the family member to access and use appropriately available services;
4. Engendering greater empowerment

These outcomes will be measured using a series of questionnaires before and after the intervention:

1. Beck Depression Inventory

2. Burden Assessment Scale
3. Family Empowerment Questionnaire
4. State Trait Anxiety Inventory (STAI)
5. SCORE 15
6. The Warwick-Edinburgh Mental Well-being Scale (WEMWBS)

Overall study start date

01/12/2014

Completion date

12/07/2016

Eligibility

Key inclusion criteria

Must have a family member, friend, partner, or be otherwise involved with someone who has a clinical diagnosis of BPD or emerging personality disorder.

Participant type(s)

Carer

Age group

Adult

Sex

Both

Target number of participants

40

Key exclusion criteria

1. Non-English speaking families
2. The family member with BPD has a history of schizoaffective disorder or schizophrenia
3. The family member with BPD has active psychosis
4. The family member with BPD has a severe substance addiction.

Date of first enrolment

12/01/2015

Date of final enrolment

31/03/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
The Anna Freud Centre
12 Maresfield Gardens
London
United Kingdom
NW3 5SU

Sponsor information

Organisation

Barnet, Enfield And Haringey Mental Health NHS Trust

Sponsor details

3rd Floor Bedford House
125-133 Camden High Street
London
England
United Kingdom
NW1 7JR

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/00d2v4e22>

Funder(s)

Funder type

Charity

Funder Name

The Lewis Trust

Results and Publications

Publication and dissemination plan

Dissemination of the results will be through conference presentation initially and at family/user forums in personality disorder services. Publication of the initial outcomes of the data comparing the treated family group with the waiting list control will be in a peer reviewed journal. Follow-up data will be published either as a separate paper or as part of the main paper.

Intention to publish date

31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No