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Feasibility trial of support and skills course for mental health carers

Submission date
14/06/2024

Recruitment status
No longer recruiting

Registration date
08/07/2024

Overall study status
Ongoing

Last Edited
26/03/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
People with complex emotional needs and/or chronic emotion dysregulation or a diagnosis of Emotionally Unstable Personality Disorder have chaotic relationships, experience highly distressing changes in mood and have urges to harm themselves and others. It is also one of the most challenging mental health conditions to live with for a carer or family member. Carers, therefore, often become overwhelmed with the needs of the person they care for. Currently, there is a lack of research into the most effective way of supporting carers of these people.

'Family Connections' (FC) is an intervention designed specifically for carers of people with chronic emotion dysregulation, originally developed in the US and adapted for the UK. It consists of 12, 2-hour, weekly, peer-supported group sessions delivered online, to inform carers about chronic emotion dysregulation; stress the importance of maintaining personal wellbeing; and equip carers with skills to support loved ones in crisis. However, we don't know whether FC benefits carers or the people they support, so we plan to undertake a feasibility trial.

The trial will offer FC to one group of carers and another group will be offered the support currently available. We will ask carers and their loved ones if there is any improvement in their lives at the end of the intervention and after a 9-month follow-up period. We will interview carers, people with chronic emotion dysregulation and healthcare staff, to assess their views on the acceptability of the trial and the intervention.

This study was initially devised by a mental health carer with lived experience of supporting a family member, a service user in NHS mental health services, with chronic emotional difficulties, including multiple suicide attempts and self-harm. The study aims to evaluate the value of such carers participating in a 12-week support and skills course. The study also aims to evaluate if improving carers' wellbeing and skills has an impact on the person they are supporting: the service user. The study is a feasibility trial to determine whether a full trial is possible, since recruitment of both carers and service users to a research trial for such an intervention has not been done before in the UK.

Who can participate?
Carers of people with complex emotional needs or a diagnosis of borderline personality disorder

or emotionally unstable personality disorder in each of the three study sites are able to participate, along with their respective service users.

What does the study involve?
The study requires the carer to be randomised into one of two groups: either receiving the 12-week course immediately, or, after the end of the trial. Both sets of carers will be asked to complete a set of questionnaires before the start of the course, after completing the course, and 6 months following the end of the course. Their respective service user will also be required to complete a set of questionnaires at these time points. Some participants will also be invited to take part in a qualitative interview to find out more about their perceptions of the course and their participation in the research trial.

What are the possible benefits and risks of participating?
We do not envision that there are any risks to those participating in the study. The course requires that participants consider alternative ways of managing their own stress and of communicating with others. They will also learn more about the condition that their loved one is experiencing. Service Users will not be subject to any intervention themselves, so they will only encounter the time imposition of completing three sets of questionnaires, which we estimate will take 30-40 minutes each time for both carers and service users. The benefits of carer participation are assumed to include: improved sense of wellbeing and relationship with loved ones, leading to fewer harmful episodes and challenging interpersonal interactions.

Where is the study run from?
The study is run from the University of York. There are three study sites: Bristol, Essex and South Yorkshire/South Humberside (UK)

When is the study starting and how long is it expected to run for?
March 2024 to January 2026

Who is funding the study?
NIHR Research for Patient Benefit programme (UK)

Who is the main contact?
Co-Chief Investigator Prof Martin Webber, University of York, martin.webber@york.ac.uk
Co-Chief Investigator Karen Bulsara, University of York, k.bulsara@nhs.net
Trial Manager: Laura Tucker, University of York, laura.tucker@york.ac.uk

Study website
https://www.york.ac.uk/business-society/research/spsw/the-carers-trial/

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
339642

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 62945, NIHR204033, IRAS 339642

Study information

Scientific Title
A feasibility trial of a skills enhancing programme for carers of people presenting with complex emotional needs and/or chronic emotion dysregulation – Carers All Require Emotional support, Resilience and Skills: the CARERS trial

Acronym
CARERS

Study objectives
The aim of the study is to investigate whether a definitive trial is feasible and acceptable and to optimise the design of such a trial.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/07/2024, Cambridgeshire and Hertfordshire Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 20 7104 8096; cambsandherts.rec@hra.nhs.uk), ref: 24/EE/0131

Study design
Interventional randomized controlled feasibility trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Care home, Community, Home, Internet/virtual

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Complex emotional needs and/or chronic emotion dysregulation

Interventions
We will randomise carers (and their associated service user) to either the intervention group or a control group. Carers in the intervention group will receive the 12-week 'Family Connections' (FC) course, which will be delivered online within their NHS Trust by a trained clinician and carer. This will be in addition to any other support they receive. Carers in the control group will continue to receive support available to them from with the NHS Trust, Local Authority or voluntary sector carer services. Service users will continue to receive care and support from their community mental health team throughout the study and this will not be affected.

At the end of the FC course (14 weeks after the baseline measurements), the participants will be asked to complete the same outcome measures as they did at the beginning.

A final follow-up point for participants will come at 40 weeks after the baseline measurements, when all the the participants will be asked to complete the outcome measures for a final time. Data will be assessed for completeness and analysed for indicative change over time and between the groups.

We will also conduct semi-structured interviews with service users, carers and clinicians to help determine the acceptability and feasibility of the trial design. Carers and service users who decline consent for the main study will be asked whether they would like to take part in a qualitative interview about why they declined. Up to 25 carers and service users participating in the trial will be interviewed in the follow-up period (after the intervention has been delivered) to explore experiences of FC; it's impact on their lives; positive and negative aspects of the course; and potential benefits for service users. Course facilitators will be interviewed about the delivery of FC; the value of the training and supervision; and the acceptability, strengths and weaknesses of the intervention. All qualitative data will be anonymised, transcribed and then coded using qualitative analysis software.

Intervention Type
Behavioural

Primary outcome measure
Feasibility outcome:
Number of eligible carers and service users recruited within 6 months

Secondary outcome measures
For carers:
1. Burden is measured using the Burden Assessment Scale (BAS) at baseline, 14 weeks and 40 weeks post randomisation
2. Mental wellbeing is measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at baseline, 14 weeks and 40 weeks post randomisation
3. Family relationships are measured using The Family Questionnaire (TFQ) at baseline, 14 weeks and 40 weeks post randomisation
4. Health-related quality of life is measured using the EQ-5D-5L at baseline, 14 weeks and 40 weeks post randomisation
5. Capability wellbeing is measured using the ICECAP-A at baseline, 14 weeks and 40 weeks post randomisation
6. Carer costs are measured using the Client Services Receipt Inventory at baseline, 14 weeks and 40 weeks post randomisation
7. Experiences of FC; it's impact on their lives; positive and negative aspects of the course; and potential benefits for service users measured by interview during follow-up period

For service users:
1. Mental wellbeing is measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at baseline, 14 weeks and 40 weeks post randomisation
2. Social functioning is measured using Work and Social Adjustment Scale (WSAS) at baseline, 14 weeks and 40 weeks post randomisation
3. Health-related quality of life is measured using the EQ-5D-5L at baseline, 14 weeks and 40 weeks post randomisation
4. Capability wellbeing is measured using the ICECAP-A at baseline, 14 weeks and 40 weeks post randomisation
5. Service user costs are measured using the Client Services Receipt Inventory at baseline, 14 weeks and 40 weeks post randomisation

Course facilitators will be interviewed about the delivery of FC; the value of the training and supervision; and the acceptability, strengths and weaknesses of the intervention during follow-up period

Overall study start date
01/03/2024

Completion date
08/01/2026

Eligibility

Key inclusion criteria
Potential carer participants must satisfy the following criteria to be enrolled in this study:
1. Adults aged >=18 years
2. Self- or service user-identified carer or support person. We recognise that the identification and recording of carers in patient records is not routine and we will explore the best identification mechanisms during the study
3. Willing to attend Family Connections groups
4. Willing to provide written, informed consent to take part
5. Access to PC/laptop/smartphone and good quality internet for the purpose of completing the intervention sessions as well as completing questionnaires and possible qualitative interviews online
6. Has not attended and completed Family Connections sessions previously

Potential service user participants must satisfy the following criteria to be enrolled in this study:
1. Adults aged >=18 years
2. Presenting with complex emotional needs and chronic emotion dysregulation, and/or a clinical diagnosis of borderline personality disorder or emotionally unstable personality disorder
3. Competent and willing to provide written, informed consent to take part
4. Access to PC/laptop/smartphone and good quality internet for the purpose of completing questionnaires and possible qualitative interviews online

Participant type(s)
Carer, Service user

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 96; UK Sample Size: 96

Total final enrolment
102

Key exclusion criteria
Literacy levels such that the study materials are inaccessible. This will be established through discussion with the service user's care coordinator during the eligibility assessment. Given this is a feasibility study the researchers will not have the resources to support non-English literacy /speaking participants.

Date of first enrolment
15/07/2024

Date of final enrolment
19/03/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Avon and Wiltshire Mental Health Partnership NHS Trust
Bath NHS House
Newbridge Hill
Bath
United Kingdom
BA1 3QE

Study participating centre
Rotherham Doncaster and South Humber NHS Foundation Trust
Woodfield House
Tickhill Road
Doncaster
United Kingdom
DN4 8QN

Study participating centre
Essex Partnership University NHS Foundation Trust
The Lodge
Lodge Approach
Runwell
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SS11 7XX

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University/education

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ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
28/02/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Professor Martin Webber (martin.webber@york.ac.uk). Anonymous feasibility trial data will be available after publication of the findings for a period of ten years. It will be provided to researchers wishing to undertake secondary analysis on provision of a study protocol. It will be sent online via an encrypted file sharing server. Consent for sharing has been obtained from participants.

IPD sharing plan summary
Available on request