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REACT Trial: Supporting relatives of people with psychosis or bipolar disorder

Submission date
19/11/2015

Recruitment status
No longer recruiting

Registration date
19/11/2015

Overall study status
Completed

Last Edited
10/08/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Approximately 1 in 100 people will experience mental health problems at some point in their lives.
Bipolar disorder, previously known as “manic depression”, is a disorder characterised by extreme mood swings, alternating between mania (extreme highs) and depression (extreme lows). People suffering from BD can also show signs of psychosis. Psychosis is a serious mental disorder in which thought and emotions are impaired, causing a person to lose touch with reality. These conditions are thought to affect more than 6 million people in the UK alone. Many relatives of people with psychosis or BD provide a large amount of vital unpaid care, but at huge personal cost in terms of high levels of distress, a significant practical, financial and emotional burden, and increased use of healthcare services. The UK Government recognises the need to support relatives in a caring role and NICE (National Institute for Health and Clinical Excellence) recommends that this is done by providing them with structured information and support. However, evidence shows that relatives often are not able to access the information and support they need. A recent review of the quality of mental health services has shown that improving support for relatives should be a national priority. REACT is an online resource which has been developed to provide relatives with the information and support they need. It works by providing information about how best to cope with a relative suffering from BD or psychosis, as well as providing a support network with other people in a similar situation. The aim of this study is to find out whether the REACT online toolkit is an effective and cost-effective way of supporting relatives of people suffering from BD or psychosis.

Who can participate?
Adults who are relatives or close friends with someone suffering from bipolar disorder or psychosis.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are given login details to access to the REACT toolkit. The toolkit is divided into a number of different modules which provide information about psychosis and BD, ideas of strategies they could use to manage common problems and stories (retold by actors) from other relatives about their experiences. Participants are also able to contact “REACT supporters” (people with experience

caring for someone with psychosis or BD) throughout the 24 week study, during office hours. Participants in the second group are given access to a “resource directory”, which lists details about how to access support that is currently available to relatives as well as information about how to get help through the NHS. Throughout the study, participants in both groups continue to receive any support or care that they usually receive. At the start of the study, 12 and 24 weeks, participants complete questionnaires in order to measure their level of distress.

What are the possible benefits and risks of participating?
Participants may benefit from being able to talk about and explore their personal experiences. Additionally, the resource directly available to all participants could help them to develop a better understanding of bipolar disorder and psychosis and potential avenues for support as a relative of someone with mental health problems. Participants are given high-street voucher(s) in appreciation of their contribution to this research. The most likely risk to participants in this trial is increased distress (note that participants must be distressed in order to take part in the study).

Where is the study run from?
The study takes place online, and is run from Lancaster University (UK).

When is the study starting and how long is it expected to run for?
October 2015 to September 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
1. Dr Heather Robinson (Public)
2. Professor Fiona Lobban (Scientific)
f.lobban@lancaster.ac.uk

Study website
www.reacttoolkit.co.uk

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19695

Study information

Scientific Title
An online randomised controlled trial to evaluate the clinical and cost effectiveness of a peer supported self-management intervention for relatives of people with psychosis or bipolar disorder: Relatives Education And Coping Toolkit (REACT)

Acronym
REACT

Study objectives
The aim of this study is to evaluate the clinical and cost effectiveness of an online peer supported self-management intervention (REACT) for relatives of people with psychosis or bipolar disorder.

Ethics approval required
Old ethics approval format

Ethics approval(s)

RES Committee North West – Lancaster, 21/09/2015, ref: 15/NW/0732

Study design
Single-blind multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

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
Topic: Mental Health, Primary Care; Subtopic: Bipolar affective disorder, Psychosis, Primary care; Disease: Bipolar affective disorder, Psychosis, All Diseases

Interventions
Current interventions as of 23/10/2017:
Participants are randomly allocated to one of two groups. Participants in both groups continue to receive treatment as usual (TAU) throughout the duration of the study period (i.e. any support and/or help that they currently receive).

Group 1: Participants in this group receive the REACT intervention, a facilitated online intervention for relatives of people with psychosis/BD. The toolkit is comprehensive and modular in format so that the content is divided into manageable sections which can be used flexibly depending on the individual needs of the relative. Although the information is by necessity standardised, the toolkit is designed to help relatives tailor this information to make it more specific to their family. Case examples, activity tasks (including reflective questionnaires), and self-assessment tasks are used extensively to aid illustration. To enhance peer support and interactivity the toolkit includes the REACT Group (a peer support discussion board) and a Direct Messaging facility, which allows participants to ask for further information in a private context from REACT Supporters. REACT Supporters all have experience of caring for someone with psychosis or BD, and work to facilitate the website.
Group 2: Participants receive a Resource Directory which lists details of how to access the full range of support currently available to relatives. The Directory will include websites of the main national organisations including MIND, Carers Trust, Rethink Mental Illness, Carers UK, SANE, Bipolar UK, Samaritans, and NHS Choices, amongst others.

The current treatments used for participants in both groups are assessed using the adapted CSRI which will include contact with health, social and voluntary sector services. No direct changes will be made to current treatment as part of the trial. Relatives will be informed that taking part in the trial will not affect any support or services that they, or their relative, receive. Therefore,

this study compares the addition to treatment as usual of a standardised way to deliver this intervention via the REACT website (including Resource Directory), with treatment as usual plus a Resource Directory which signposts relatives to currently available support in the NHS and voluntary sector.

Both REACT and The Resource Directory will be available from the point at which people enter the study for at least the 6 month follow-up period, and then continuing to the end of the funded study. Participants in the resource directory arm will have access to the content of the modules after the final follow-up.

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Group 1: Participants in this group receive the REACT intervention, a facilitated online intervention for relatives of people with psychosis/BD. The toolkit is comprehensive and modular in format so that the content is divided into manageable sections which can be used flexibly depending on the individual needs of the relative. Although the information is by necessity standardised, the toolkit is designed to help relatives tailor this information to make it more specific to their family. Case examples, activity tasks (including quizzes), and self-assessment tasks are used extensively to aid illustration. To enhance peer support and interactivity the toolkit inlcudes the REACT Group (a peer support discussion board) and an “Ask the Experts” facility, which will feed into a “Frequently Asked Questions” information page. The REACT website will be facilitated by “REACT Supporters” with experience of caring for someone with psychosis or BD.

Group 2: Participants receive a Resource Directory which lists details of how to access the full range of support currently available to relatives. The Directory will include websites of the main national organisations including MIND, Carers Trust, Rethink Mental Illness, Carers UK, SANE, Bipolar UK, Samaritans, and NHS Choices. It will also explain how to access support through NHS health services. This information is included in one of the modules on the REACT site but will be available to control participants via a separate link. This ensures that all relatives in the trial have access to current best practice.

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Both REACT and The Resource Directory will be available from the point at which people enter the study for at least the 6 month follow-up period, and then continuing to the end of the funded study.

Intervention Type
Other

Primary outcome measure

Relatives' distress is measured using the General Health Questionnaire (GHQ-28) at 24 weeks

Secondary outcome measures
Current secondary outcome measures as of 23/10/2017:
1. Relatives' distress is measured using the General Health Questionnaire (GHQ-28) at 12 weeks
2. Relatives' well-being is measured using the Carers' Well-Being and Support Measure (CWS) at 12 and 24 weeks
3. Costs of delivering the intervention versus NHS and productivity cost savings in use of health services and paid work (adapted version of the CSRI) at baseline, 12 and 24 weeks
4. Cost effectiveness – cost of significant unit change (defined as 3 point reduction) in primary outcome (GHQ-28) at baseline, 12 and 24 weeks
5. Cost utility – marginal cost of any changes in marginal change in quality adjusted life years (QALYs) (making use of the EQ-5D-5L, as recommended by NICE) at baseline, 12 and 24 weeks
6. Mechanism of change for the REACT intervention is measured using the Brief Illness Perception Questionnaire (BIPQ) and Brief COPE at baseline, 12 and 24 weeks

Previous secondary outcome measures:
1. Relatives' well-being is measured using the Carers' Well-Being and Support Measure (CWS) at 24 weeks
2. Costs of delivering the intervention versus NHS and productivity cost savings in use of health services and paid work (adapted version of the CSRI) at baseline, 12 and 24 weeks
3. Cost effectiveness – cost of significant unit change (defined as 3 point reduction) in primary outcome (GHQ-28) at baseline, 12 and 24 weeks
4. Cost utility – marginal cost of any changes in marginal change in quality adjusted life years (QALYs) (making use of the EQ-5D-5L, as recommended by NICE) at baseline, 12 and 24 weeks
5. Mechanism of change for the REACT intervention is measured using the Brief Illness Perception Questionnaire (BIPQ) and Brief COPE at baseline, 12 and 24 weeks

Overall study start date
01/10/2015

Completion date
30/09/2018

Eligibility

Key inclusion criteria
1. Aged 16 or over.
2. Are the relative or close friend of someone with a psychosis or bipolar disorder (removed 23/10/2017: friends are required to have a period of at least 6 months within the last 2 years during which there was regular contact)
3. Distressed (according to GHQ score)
4. Currently seeking help
5. Regular access to a computer which is connected to the internet
6. A good working knowledge of written and spoken English

Participant type(s)
Carer

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 666; UK Sample Size: 666; Description: We require 666 relatives to take part based on our power calculation.

Total final enrolment
800

Key exclusion criteria
(Removed 23/10/2017: Currently taking part in another research study evaluating an intervention for relatives of people with mental health problems)
1. Living outside the UK
2. Living in any of the 6 areas involved in the IMPART study

Date of first enrolment
22/04/2016

Date of final enrolment
31/08/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Lancaster University
Division of Health Research
Faculty of Health & Medicine
Room C07
Furness Building
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United Kingdom
LA1 4YG

Sponsor information

Organisation
Lancaster University

Sponsor details
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Bowland Main
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Sponsor type
University/education

ROR
https://ror.org/04f2nsd36

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. All products will be widely disseminated to all relevant stakeholders including service users, relatives, NHS managers and frontline clinical staff including GPs; clinical academics; the general public. A study website will additionally provide updates and outputs from the study and links to all publications and presentations.
2. A trial protocol paper will be submitted for publication before the end of the data collection period of the trial

3. A full report will be submitted to NIHR within 6 months of the end of the funding period
4. A main outcome paper will follow the end of the study
5. Additional papers describing health economic and mechanistic process will follow

Intention to publish date
30/11/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the Trial Management Group (TMG) Chair Prof. Fiona Lobban (f.lobban@lancaster.ac.uk). The data will be available indefinitely once the trial papers have been published. Participants have consented to their data being used for secondary analysis of broader research questions related to improving outcomes for relatives of people with psychosis or bipolar disorder. All data will be anonymised. Consent for any analysis must be confirmed by the TMG Chair.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/04/2020	12/05/2020	Yes	No
Results article	results	01/06/2020	02/07/2020	Yes	No
Protocol article		18/07/2017	10/08/2022	Yes	No
HRA research summary			28/06/2023	No	No