

Implementation of a Relatives Toolkit (IMPART) Study

Submission date 09/03/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/08/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/08/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Relatives of people with psychosis and bipolar disorder provide a huge amount of care. This caring role can cause them a lot of distress and financial stress with relatives reporting high levels of stigma, worry, shame and guilt, trauma, and loss. NICE Guidelines include a recommendation to provide information and support to all relatives. The Relatives Education and Coping Toolkit (REACT) was developed to offer an easy to use online supported intervention (program) for relatives. The intervention was developed with a lot of involvement from clinicians and relatives, provides relatives with information and support, and has been shown to reduce relatives' distress. The next challenge is to understand how this kind of intervention can be successfully implemented into routine clinical practice. This is important because despite investment in the development and evaluation of new health technologies (such as REACT) there is a huge gap between these technologies, and what people receive in the NHS. This is called the "implementation gap". It has been recognised that more research is needed to understand how new effective technologies can be successfully implemented in real world clinical settings to ensure patients and relatives benefit from them. The IMPART study will investigate how the REACT toolkit is implemented into Early Intervention Services as part of routine clinical practice in NHS Trusts. Researchers will carry out detailed analysis of what happens in each NHS Trust during the process of adopting the REACT intervention. The aim is to understand what factors support successful implementation of REACT so that it can be improved. The findings will have broader implications for understanding how other similar interventions can be successfully implemented.

Who can participate?

Relatives using REACT and healthcare staff involved in implementing REACT in participating NHS Trusts.

What does the study involve?

This study involves interviews and observations of meetings with staff responsible for implementing the REACT toolkit and relatives using the REACT toolkit, and involves 6 NHS trusts (3 in the north and 3 in the south). IMPART occurs in three waves (steps), in each wave there is 1 north site and 1 south site. The waves occur every six months, during which interviews, focus groups, and observations of key meetings are conducted with mental health service NHS staff.

Interviews with relatives or carers that have used the REACT toolkit are also conducted to understand relative's experiences of using the REACT toolkit. In addition to this, information using google analytics are collected to identify relative's usage of the site.

What are the possible benefits and risks of participating?

The research team cannot promise that the study will help participants directly you but the information we gain from your interview will be used to help improve our knowledge and inform a national implementation plan for online interventions. The research team does not think that there are disadvantages to taking part although the interviews will require 45-60 minutes of your time.

Where is the study run from?

This study is being run by Lancaster University and takes place in UK NHS trusts.

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

March 2016 to December 2018 (as of 04/10/2018)

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Professor Fiona Lobban (scientific)

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Contact information

Type(s)

Scientific

Contact name

Prof Fiona Lobban

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Implementation of a relatives' toolkit (IMPART Study): Examining the critical success factors, barriers, and facilitators to the implementation of an online supported self-management intervention in the NHS

Acronym

IMPART

Study objectives

The study aims to understand the critical success factors, facilitators, barriers, and resources needed to integrate an online supported self-management intervention for relatives of people with recent onset psychosis into routine clinical care, and to use this information to develop a national Implementation Plan. Findings from this study will also be used to develop the growing evidence base investigating the translation of research findings into clinical practice, particularly regarding supported self-management interventions in mental health.

Objectives:

1. Measure the uptake and use of REACT by NHS EIS teams and relatives
2. Identify the critical success factors, facilitators and barriers to implementation of REACT
3. Identify the resources (and costs) needed for successful implementation of REACT in EIS teams
4. Investigate the impact of REACT on self-reported relatives' outcomes
5. Develop a user friendly REACT Implementation Plan and related resources (inc Fidelity Scale) to facilitate widespread use and dissemination within the NHS
6. Use the findings from this study to further develop theories of implementation of supported self-management interventions in the NHS

Ethics approval required

Old ethics approval format

Ethics approval(s)

East of England - Cambridge South Research Ethics Committee, 26/01/2016, ref: 16/EE/0022

Study design

Iterative case series design

Primary study design

Observational

Secondary study design

Case series

Study setting(s)

Community

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

Relatives and friends supporting people with mental health problems in early intervention teams

Interventions

IMPART is an implementation study and not a trial. Essentially the study will conduct interviews and observations of meetings with staff responsible for implementing the REACT toolkit and relatives using the REACT toolkit, across 6 trusts (3 in the north and 3 in the south). IMPART occurs in three waves, in each wave there is 1 north site and 1 south site. The waves occur in 6 monthly intervals. During each wave interviews and observations of key meetings will be conducted with early intervention mental health service NHS staff. Interviews with relatives or carers that have been offered the REACT toolkit will also be conducted to understand relative's experiences of using the REACT toolkit. Information using google analytics will also be obtained to identify relative's usage of the site.

Intervention Type

Behavioural

Primary outcome measure

Identification of the barriers and facilitators to the implementation of an online intervention to support relatives of people with bipolar and psychosis.

Secondary outcome measures

The impact of the REACT toolkit on relatives' self reported outcome measures.

Overall study start date

01/03/2016

Completion date

31/12/2018

Eligibility

Key inclusion criteria

Inclusion for relatives:

Any relative receiving care through the participating EIS service will be eligible to be invited to use the REACT toolkit.

However, to take part in the data collection for the research study (questionnaires and interviews), relatives will be required to be:

1. Aged 16 and over
2. Able to give legal consent
3. Good working use of English language as no translation available

Inclusion for the EIS staff and IMPART lead observations and Interviews:

1. Interviews and qualitative analysis: key people from relevant stakeholder groups responsible for implementing REACT in the 6 selected mental health trusts, these will include service commissioners, service managers, supporters, relatives.

2. Interviews, observations and document analysis: all staff involved in the implementation of REACT across the six trusts selected

Good knowledge of spoken and written English is essential

Participant type(s)

Mixed

Age group

Adult

Lower age limit

16 Years

Sex

Both

Target number of participants

100

Key exclusion criteria

Relatives:

Not receiving clinical support from participating EIS teams

Staff:

Not working in participating EIS services

Date of first enrolment

14/10/2016

Date of final enrolment

31/08/2018

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Lancaster University

Lancaster

United Kingdom

LA1 4YT

Sponsor information

Organisation

Lancaster University

Sponsor details

Research Support Office
B58 Bowland Main
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LA1 4YT
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Sponsor type

University/education

Website

www.lancasteruniversity.ac.uk

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

Current publication and dissemination plan as of 30/10/2017:

We aim to publish the study protocol, main outcome paper, and development of the implementation guide in relevant academic journals

We aim to present the findings at academic conferences, and relevant NHS and carer conferences

We hope to hold workshops to disseminate the toolkit to none-participating Trusts, and to consider the generalisability of the findings to other digital technology interventions.

Previous publication and dissemination plan:

Publication plan:

1. Systematic Review Protocol, Journal of Implementation Science
2. Implementation Guide for REACT for users: The exact nature of the Implementation Plan cannot be determined at this stage but will include: a video rationale for the use of REACT including research and policy context; a step-by-step guide to successful implementation of REACT; a Fidelity Scale to enable Trusts to self-monitor fidelity to the Implementation Plan; online REACT supporter training toolkit; a summary of resources needed to implement REACT; measures/evaluation tools to evaluate uptake and outcome for relatives; case examples describing the process of implementation across participating Trusts – where the focus is on identifying and overcoming key barriers. Journal of medical internet research/NIHR website
3. Costs of delivering healthcare online – what does it really save? Analysis of initial set up – but also costs of any strategies to facilitate implementation and sustain delivery. Journal of health service research.
4. Theory & methodology Development. Journal of implementation science
5. Implications of findings for development of underlying theoretical framework, Journal
6. Experiences of running iterative case study implementation study in the NHS – lessons learned Journal
7. Digital Interventions Journal

Dissemination Plan:

1. A workshop to facilitate the uptake of REACT by none participating EIS teams;
2. A dissemination event focusing on development of theory underlying implementation of supported self-management interventions within the NHS that can be used to inform service development in other clinical areas where supported self-management interventions are being used for people with long term health conditions and their carers
3. Study website to keep everything held on and up to date www.reactclinic.co.uk
4. Conference – family intervention in psychosis
5. Conference – implementation science
6. Conference – digital health

Intention to publish date

31/12/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study is not expected to be made available due to confidentiality reasons. The vast majority of the data in this study is qualitative data from interviews with individual staff members in key NHS Trust roles. Publishing the data would not be appropriate as it would be easy to identify the staff member and therefore would not be anonymous. The data will be held at Lancaster University.

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		01/09/2020		Yes	No
Protocol article		28/12/2017	10/08/2022	Yes	No
HRA research summary			28/06/2023	No	No