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Randomised controlled trial of COPe-support online resource for carers

Submission date
26/02/2018

Recruitment status
No longer recruiting

Registration date
02/03/2018

Overall study status
Completed

Last Edited
27/10/2022

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
Psychosis is the most common severe mental illness that affects 1% of the population. Coping with psychosis is often a challenging demand for the individual as well as for everyone close to them, including family members, relatives, partners and close friends (referred to as carers from now on). Carers are more vulnerable to mental ill health, partly due to the burden and distress associated with caregiving demands. Conversely, increased wellbeing and coping in carers is believed to have positive effects in shaping the service users' prognosis. Effective interventions for maintaining and promoting the wellbeing of carers are needed. Recent research indicates that the internet can be a promising medium for providing such an intervention for carers. The EFFIP (E-support for Families & Friends of Individuals affected by Psychosis) Project aims to develop and test an online resource to promote the wellbeing and caregiving experiences of carers supporting a loved one with psychosis. In the last two years (2016-2017), findings from studies and ideas collected from carers, service users and healthcare professionals have been used to produce the online resource. The resource provides information, peer support and coping strategies for their caregiving roles and promotes self-care. The aim of this study is to test the effectiveness of the online resource at improving carers' wellbeing and other health related outcomes (such as caregiving experience, knowledge).

Who can participate?
Carers aged 18 or over supporting a loved one affected by psychosis

What does the study involve?
Participants are randomly allocated to be given access to either the online resource or a non-interactive resource for 40 weeks. Participants are advised to actively use the resource for the first 20 weeks (recommended as about 45 minutes per week) to go through the relevant content and use the new skills learnt in their personal circumstances. From week 21 to week 40, participants continue to have access to the resource, but no active use or participation is expected from them. After 40 weeks, some of the participants are invited to an interview about their experience of using COPe-support. The interview is conducted by phone or internet suiting the participants' preference. The participants' mental wellbeing is assessed at weeks 10, 20 and 40.

What are the possible benefits and risks of participating?
It is hoped that participants will find the information provided in the study helpful, and their participation will make an important contribution to research for carers. Access to the online intervention will be arranged for those allocated to the non-interactive resource after completion of follow-up data collection. The risk involved in participating in this study is minimal. The online intervention aims to provide information about caring for a loved one with psychosis and ways for looking after oneself. Participants may find some of the content of particular resonance to their own experience.

Where is the study run from?
1. South West London & St George's Mental Health NHS Trust (UK)
2. South London & Maudsley NHS Foundation Trust (UK)
3. Berkshire Healthcare NHS Foundation Trust (UK)
4. Kent and Medway NHS and Social Care Partnership Trust (UK)
5. Cambridgeshire and Peterborough NHS Foundation Trust (UK)
6. Norfolk & Suffolk NHS Foundation Trust (UK)
7. Hertfordshire Partnership University NHS Foundation Trust (UK)
8. Leeds and York Partnership NHS Foundation Trust (UK)
9. Avon & Wiltshire Mental Health Partnership NHS Trust (UK)

When is the study starting and how long is it expected to run for?
March 2018 to December 2020

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

Who is the main contact?
Dr Jacqueline Sin

Study website
http://cope-support.org

Contact information

Type(s)
Scientific

Contact name
Dr Jacqueline Sin

ORCID ID
http://orcid.org/0000-0003-0590-7165

Contact details
Cranmer Terrace
London
United Kingdom
SW17 0RE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
37010

Study information

Scientific Title
EFFIP (E-support for Families and Friends of Individuals affected by Psychosis): a randomised controlled trial of a co-produced online intervention for carers

Acronym
EFFIP

Study objectives
Psychosis is the most common severe mental illness that affects 1% of the population. Coping with psychosis is often a challenging demand for the individual as well as for everyone close to them, including family members, relatives, partners and close friends (referred to as carers hereafter). Extant research has identified an increased vulnerability to mental ill health among carers, partly due to the burden and distress associated with caregiving demands. Conversely, increased wellbeing and coping in carers is believed to have positive effects in shaping the service users' prognosis. Effective interventions for maintaining and promoting the wellbeing of carers are needed and indeed now part of the legal requirement of the Care Act 2014. Recent research indicates that the internet can be a promising medium for providing such an intervention for carers.

The EFFIP (E-support for Families & Friends of Individuals affected by Psychosis) Project aims to develop and evaluate an online resource to promote the wellbeing and caregiving experiences of carers supporting a loved one with psychosis. The overall EFFIP project lasts for 5 years (from 2016) and uses mixed methods combining qualitative, quantitative, usability-testing and randomised controlled trial (RCT) with inbuilt process evaluation methods, along the development, feasibility and evaluative phases of the Medical Research Council (MRC) framework for complex interventions. In the last two years (2016-2017), we have successfully undertaken five studies and meta-synthesised findings from systematic reviews and ideas collected from carers and service users, and health care professionals to co-produce the online resource. The resource provides information, peer support and coping strategies for their caregiving roles and promotes self-care. The current parallel-arm RCT, with an inbuilt process evaluation study, aims to evaluate the clinical effectiveness of the online resource in improving carers' wellbeing and other health related outcomes (such as caregiving experience, knowledge), compared to the waitlist-control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central - Oxford C Research Ethics Committee, 01/03/2018, ref: 18/SC/0104

Study design
Randomised; Interventional; Design type: Treatment, Prevention, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
http://cope-support.org/wp-content/uploads/2018/03/Advertising-text_RCT-of-COPe-support_v1_20180124.pdf

Health condition(s) or problem(s) studied
Psychosis

Interventions
Following detailed information-giving about the study, potential participants will be guided through the eligibility screening process online, supported by the research team member. Eligible participants will then be guided through the informed consent-seeking procedure online (through our study system). Support via phone or online will be provided by the study team as required. Consented participants will be invited to provide some demographic information about themselves and their caring situation. Data entry will be directly made by participants through our online system.

Participants will be allocated according to the randomisation and be given access to their allocated condition for which they have access to online 24/7 for 40 weeks. A unique user-account will be created for each randomised participant to log in and to use the allocated intervention. Participants are advised to have active use for the initial 20 weeks (recommended as about 45 minutes per week) to go through the relevant content and implement new skills learnt into their personal circumstances. Participants allocated to the waitlist control will have access to a non-interactive resource directory which is also run online, for the same duration of time.

From week 21 to week 40, participants will continue to have access to the allocation condition online, but no active use or participation is expected from them. After the completion of 40-week follow-up outcome data collection, 20% of the participants from the active intervention arm will be invited to give an individual interview for their experience of using COPe-support. The interview will be conducted via phone or internet suiting the participants' preference.

At week 10, week 20 and week 40 after randomisation, participants will be invited to complete outcome measure data collection online where data entry is direct from the participants onto the online study system.

Intervention Type

Other

Primary outcome measure
Carers' mental wellbeing, assessed using Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS), at end of intervention use (i.e. 20 weeks)

Secondary outcome measures
Secondary outcomes include the following domains, assessed using the respective tools, at 20 weeks:
1. Carer's mental health knowledge, assessed using Mental Health Knowledge Schedule (MAKS)
2. Carer's caregiving experiences, both negative appraisal and positive appraisal, measured by subtotals of Experience of Caregiving Inventory (ECI)
3. Family relationship and communication, assessed by Family Questionnaire (FQ)
4. Carer's perceived social support, measured with Carer Wellbeing and Support Questionnaire (CWS)
5. Quality of life, assessed using EuroQoL 5-level EQ-5D (EQ-5D-5L).

Overall study start date
02/03/2018

Completion date
31/12/2020

Eligibility

Key inclusion criteria
The online intervention COPe-support is designed for carers supporting a loved one affected by psychosis. Carers include family members with a biological or non-biological relationship (e.g. parents, siblings, spouses, and other relatives) or a close friend supporting a loved one affected by psychosis. Only one carer per psychosis patient will be included in the study. Specific inclusion criteria include carers who are:
1. Adult aged 18 or over
2. Those who have at least weekly contacts with the cared-for person, although these contacts could be in a variety of formats, e.g. face to face, phone calls, emails, or social media such as facebook, twitter, text messages
3. Living in England during the study period
4. Able to communicate in English in usual online communications
5. Have regular access to the internet

Participant type(s)
Carer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 360; UK Sample Size: 360

Total final enrolment
464

Key exclusion criteria
Regrettably, carers with the following characteristics cannot be accepted into the RCT:
1. Those aged below 18
2. Those who cannot communicate in English
3. Those not able to access and use online communications
4. Those who cares for a loved one affected by psychosis but another relative/close friend who also shares a caring role for the same individual has already participated in the study (to avoid a clustering effect)

Date of first enrolment
05/03/2018

Date of final enrolment
14/02/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
South West London & St George's Mental Health NHS Trust (lead centre)
61 Glenburnie Road
London
United Kingdom
SW17 7DJ

Study participating centre
South London & Maudsley NHS Foundation Trust
Monks Orchard Road
Beckenham
London
United Kingdom
BR3 3BX

Study participating centre

Berkshire Healthcare NHS Foundation Trust
Fitzwilliam House
Skimped Hill Lane
Bracknell
United Kingdom
RG12 1JX

Study participating centre
Kent and Medway NHS and Social Care Partnership Trust
Barnsole Road
Gillingham
United Kingdom
ME7 4JL

Study participating centre
Cambridgeshire and Peterborough NHS Foundation Trust
Fulbourn Hospital
Fulbourn
Cambridge
United Kingdom
CB21 5EF

Study participating centre
Norfolk & Suffolk NHS Foundation Trust
Drayton High Road
Norwich
United Kingdom
NR6 5BE

Study participating centre
Hertfordshire Partnership University NHS Foundation Trust
Head Office
The Colonnades
Beaconsfield Road
Hatfield
United Kingdom
AL10 8YE

Study participating centre
Leeds and York Partnership NHS Foundation Trust
2150 Century Way

Thorpe Park
Leeds
United Kingdom
LS15 8ZB

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

Sponsor information

Organisation
St George’s, University of London

Sponsor details
c/o Dr Deborah McCartney
Joint Research & Enterprise Office
St George's, University of London and St George's Healthcare NHS Trust
Cranmer Terrace
London
United Kingdom
SW17 ORE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/040f08y74

Funder(s)

Funder type
Government

Funder Name
NIHR Trainees Co-ordinating Centre (TCC); Grant Codes: PDF-2015-08-035

Results and Publications

Publication and dissemination plan

Additional documentation about the study is available from the study website http://cope-support.org/. After the trial has completed (in 2021), the trialists will prepare a written lay summary that will be made available for any participants who would like this; as well as all the NHS and non-governmental organisations who help recruiting for the study. They also have planned publications in a high-impact peer reviewed journal.

Intention to publish date

31/12/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available, in accordance with Sponsor's policy.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	intervention development	06/08/2019	09/08/2019	Yes	No
Protocol article	protocol	17/03/2020	19/03/2020	Yes	No
Other publications	results of an interview study assessing the acceptability of the intervention and carer experiences	02/02/2022	03/02/2022	Yes	No
Results article		01/05/2022	27/10/2022	Yes	No
HRA research summary			26/07/2023	No	No