

PARTICIPANT INFORMATION SHEET

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)

We would like to invite you to take part in a research study exploring the effectiveness of an online toolkit to help relatives (or close friends) of people with psychosis or bipolar disorder. Before you decide whether you would like to take part, we want to explain why this research is being done and what it will involve. Please take the time to read the following information and discuss this with others if you wish. You may download this sheet and print it off to read at your own convenience. Please ask us if there is anything that is unclear or that you would like more information about. Contact details for the research team are at the end of the sheet.

What is the Relatives Education And Coping Toolkit (REACT)?

REACT contains lots of information to help relatives (or close friends), ideas of strategies to manage common problems, and stories from other relatives (or close friends) about their experiences. Through the site you can contact a REACT Supporter who is a trained relative who can provide additional support relevant to your personal needs. The REACT Supporter will monitor the site during office hours. There is also an online forum (REACT Group) where you can talk directly with other relatives (or close friends) using the site.

What is the study about and why have I been approached?

We are a team of researchers, clinicians and relatives from Lancashire Care NHS Foundation Trust, Lancaster University, Liverpool University and University College London developing a new online toolkit (REACT) to help relatives (or close friends) of people with psychosis or bipolar disorder. Our aim is to make REACT available to relatives (or close friends) of people with psychosis or bipolar disorder across the UK so that everyone can access it. First we have to find out if it works. In order to do this the current research study, funded by the National Institute for Health Research Health Technology Assessment 14/49/34, will test the effectiveness of REACT for reducing distress and increasing wellbeing for relatives (or close friends) of people with psychosis and bipolar disorder and explore the costs involved in delivering this intervention.

You have been approached because we think that you could make a valuable contribution to this research study. Sharing your experiences with us will help us to determine how helpful this toolkit is for reducing distress and increasing wellbeing for relatives (or close friends).

Am I eligible to take part?

We are looking for a large sample of relatives (or close friends providing regular support) of people with psychosis or bipolar disorder living in the UK to take part in this study. Participants must be aged 16 years old or over, have access to the internet, and be able to understand written and verbal English (we don't currently have translated versions of the site available). Participants need to be willing to engage with online support for distress linked to their supporting role.

People who are caring for the same individual are more likely to have similar experiences and stress level which will affect the result of our study (further details can be found in the study protocol – visit www.reacttoolkit.co.uk) Therefore, **it is essential that only one relative (or close friend) per service user takes part in this study.** However, we do encourage you to share the knowledge you gain from REACT with other members of your family including the service user if they are interested.

Do I have to take part?

No. It's completely up to you to decide whether or not you take part.

What will I be asked to do if I take part?

If you decide you would like to take part, you will firstly be asked to answer some questions to check you are eligible for the study and consent to take part online. We will ask you to give us multiple forms of contact (e.g. email, mobile / landline, and postal address) so that we can contact you for follow-up assessments and check you are the same person. It is also important that we can verify you are a real person (and not an automated spamming program). To do this we will send a code by text message to the phone number you provide and ask you to input this into the website.

You will then be asked some questions on the website about your experiences as a relative (or close friend) of someone with psychosis or bipolar disorder. This should take about 30 minutes to complete. You will then be *randomly* allocated by computer to receive **either** the REACT online intervention (including access to a Resource Directory) **OR** the Resource Directory only plus your current treatment.

Participants allocated to receive the REACT intervention will be given a link to the REACT website and login details to access the toolkit. Access to the site will continue for participants until the end of the study funding period (September 2018). We will send reminders to visit the website over the following 24 weeks (you can opt out of this if you wish).

If the REACT site is more effective than access to current support offered through the Resource Directory, we will endeavour to make REACT available to all relatives (or close friends) of people with psychosis or bipolar disorder in the UK. However, we must test how

well it works first so the NHS can decide whether it is worth the cost of providing REACT in the future.

Participants allocated to receive the Resource Directory will be given a link to the Resource Directory. Towards the end of the study this group will be able to view the content of the toolkit modules providing information to relatives (without peer support through the REACT Group forum or direct support online from the REACT Supporters).

What is the Resource Directory?

The Resource Directory lists details of how to access the full range of support currently available to relatives (or close friends) of people with psychosis or bipolar disorder including links to the websites of the main national mental health organisations and details of how to access support through NHS health services. This ensures you get access to the best support currently available.

In order to examine how helpful REACT is for relatives (or close friends) we will ask you to complete the same online questions about your experiences as a relative (or close friend) of someone with psychosis or bipolar disorder that you completed at baseline, 12 and 24 weeks after you start the study.

It is really important that you try to complete all follow-up assessments, whichever group you are allocated to, and even if you stop making use of the online sites. This ensures we have all the information we need to properly test how well each site works in improving outcomes for relatives (or close friends).

Ground rules for using the REACT site

REACT is a private, secure website in which you can access support and share experiences with other relatives (or close friends) of people with mental health problems. The REACT Supporter will monitor the site to ensure that it is a supportive, positive space for all participants.

Key things to remember when using the site:

1. *The site will be monitored for inappropriate use and risk indicators by the REACT Supporter during office hours*
2. *Inappropriate or hostile language will not be tolerated*
3. *Please respect other users, their views and experiences*
4. *The REACT Supporter is not there in a clinical capacity (e.g. to provide therapy) but to support your use of the site*
5. *The REACT site is not crisis service, if you feel you are struggling please contact the services provided at the end of this sheet or those in the Resource Directory for support*
6. *Try to ask any questions without revealing personal identifiable information*

What data will be collected from me?

Data will be collected to help understand how REACT is used and how well it works. This data includes:

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- Online questionnaire responses (to examine the clinical and cost effectiveness of the online toolkit for relatives/close friends of people with psychosis or bipolar disorder)
- Your use of the REACT site e.g. how often you use it, for how long (to explore whether the way in which people use the toolkit is linked to its effectiveness).
 - Online forum posts (to examine the way in which the REACT Group discussion board is used and the kinds of shared experiences relatives/close friends find helpful).
 - Direct messaging to REACT Supporter (to explore the way in which the support functions are used by the relatives/close friends, in particular what issues they primarily seek help for, and the impact of the different responses from the REACT Supporter)

Will anyone else have access to my data?

We will never share your personal details with anyone outside the research team (unless clear evidence of immediate and serious risk of harm to an individual is identified, in which case we will contact the police/social services-see below).

The REACT website is a private, closed site. You will be asked to use a 'fake' username and an optional anonymised picture when logging on so that all activity is anonymous. Discussions with the REACT Supporters will be private and confidential. The REACT Group will be monitored by the REACT Supporters during office hours. If some questions are repeatedly asked in discussions with the REACT Supporters we may post a generic version of these under Frequently Asked Questions (FAQs) to help other users who may have the same question in the future. Again, the FAQs will be completely anonymous.

All responses to the study questionnaires will be strictly confidential. All study data will be anonymised and pooled prior to analysis and any data used in the write up of the study will not be identifiable. The online questionnaire data collected for this study will be stored on a secure university server at the Clinical trials Unit (CTU), Liverpool. Data regarding your use of the REACT site, online forum posts and direct messaging to the REACT Supporters will be stored on a secure university server at Lancaster University. Data may be used for future research but no identifiable personal information will ever be shared outside the research team.

It is important for us that you are assured that all measures will be taken to guarantee the confidentiality and/or anonymity of your participation. However, if you disclose information that causes us concern for your immediate safety, or the safety of someone else during the study, we will have to break confidentiality and inform the police or social services.

Can I change my mind and withdraw from the study?

If you **do** decide to take part you will be asked to complete a consent form online, you can keep a copy of this form for your reference.

If you decide to take part but change your mind later you are free to withdraw at any time without giving a reason (though you will be invited to give a reason so we can learn from your experience). You will be given the option to withdraw from the follow-up questionnaires and/or use of the website. Any questionnaire data you have provided up until this point can only be removed if you withdraw within 2 weeks of data collection. After this point your data

cannot be retracted and may be used in analysis but you won't be contacted for any further questionnaire data. Web usage data, online forum posts and direct messages cannot be removed, therefore any data you have provided/continue to provide on the website will still be used for research purposes. If you decide **not** to take part, or withdraw at any time, this will not affect any services or care you or your relative (or close friend) may be receiving or your ability to take part in future research.

What will happen to the results?

If you participate in this study you will be provided with a summary of the findings at the end of the study. The findings will also be presented at appropriate academic and mental health conferences and events and will be published in mental health journals and other publications with the aim of reaching a wide audience of mental health professionals, relatives (or close friends) and service users.

Are there any risks?

There are no risks anticipated with participating in this study. However, if you experience any distress following participation you are encouraged to inform the REACT team and/or contact the resources provided at the end of this sheet.

Are there any benefits to taking part?

We hope that you will find the information provided in this study helpful and that you will find participating interesting and feel that you have made an important contribution to research aimed at improving support for relatives (or close friends) of people with psychosis or bipolar disorder. Participants will also be given a high-street voucher in appreciation of completing the questionnaire measures at each time-point.

Who has reviewed the study?

This study has been extensively peer reviewed, funded by the National Institute of Health Research, and approved by an NHS Research Ethics Committee responsible for ensuring that ethical considerations and issues are addressed in the conduct of research.

What do I do if something goes wrong?

It is unlikely that you will be harmed by participating in this study. However, if you wish to raise concerns or make a complaint about any aspect of this study then, in the first instance, please contact the Chief Investigator:

Professor Fiona Lobban
The Spectrum Centre for Mental Health Research
Faculty of Health and Medicine
(Department of Health Research)
Lancaster University
Lancaster
LA1 4YG
Tel: +44 (0)1524 59375
Email: f.lobban@lancaster.ac.uk

If you would prefer to speak to someone outside of the research team then please contact the Associate Dean for Research at Lancaster University:

Professor Roger Pickup
Faculty of Health and Medicine
(Division of Biomedical and Life Sciences)
Lancaster University
Lancaster
LA1 4YG
Tel: +44 (0)1524 593746
Email: r.pickup@lancaster.ac.uk

Where can I obtain further information about the study if I need it?

If you have any questions about the study, please contact the REACT team:

REACT Team
The Spectrum Centre for Mental Health Research
Faculty of Health and Medicine
(Department of Health Research)

Lancaster University
Lancaster
LA1 4YG
Tel: insert once have REACT mobile phone contract
Email: react@lancaster.ac.uk

Resources for further information and support

Should you require further information or feel distressed either as a result of taking part, or in the future, the following resources may be of assistance:

If you are already in contact with mental health services you might find it help to contact them

If you are not in contact with mental health services the following might be helpful:

Your own GP
Your local out of hours GP or A+E (visit <http://www.nhs.uk/pages/home.aspx> if you're unsure where to find the services)

Carers UK 0808 808 7777(UK)

NHS emergency services:
Call 999 (UK)

NHS for non-emergencies:
Call 111 (England)
Call 0845 46 47 (NHS Direct Wales)

Visit www.nidirect.gov.uk for Out of Hours GP contacts in your area (Northern Ireland)

Samaritans: call 08457 90 90 90 (UK)

Thank you for taking the time to read this information.