

**INFORMATION SHEET FOR PARTICIPANTS
YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET**



**EFFIP (E-support for Families & Friends of Individuals affected by Psychosis)
-A randomised controlled trial of a co-produced online intervention for carers**

We invite you to participate in this research study. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

About the EFFIP Project

Psychosis is a medical term to describe a mental illness which commonly includes a range of distressing symptoms including hallucinations, delusions and paranoia. Coping with psychosis is often a challenging demand for the individual as well as everyone close to them, including family and friends (referred to as “carers” who provide caring support on an unpaid basis). The “EFFIP” project is a 5-year study aiming to develop and evaluate an online resource dedicated for carers to gain information about psychosis, and glean support and advice from others in the same position.

What is the study about?

We have developed an online resource, called COPE-support (which stands for **Carers fOr People with Psychosis e-support**) accessible via <http://cope-support.org> This study aims to find out if COPE-support works to improve carers’ wellbeing and how well they cope with caring, using a randomised controlled trial design. We invite carers to join the study and divide them randomly on a 1:1 ratio to have access to either COPE-support or a non-interactive information website (the so-called ‘control’, representing the usual internet resources on caring), for 8 months. We will ask the participants to fill in some questionnaires online to see how they are feeling at 4 time points over this period. We will also invite a selection of carers for an individual interview afterward for their experiences of using COPE-support. We will compare wellbeing and coping for people using COPE-support with people using the ‘control’. After all the data collection is completed, we will offer the participants who were originally allocated to the control group access to COPE-support.

Who are we inviting to participate?

We are inviting carers who provide caring support for a loved one with psychosis for the study. Carers can be parents, partners, siblings, other relatives or close friends who do not have a biological relationship with their cared-for person. Carers need to 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, social media such as facebook or text messages. All participants need to be aged 18 or above, living in England, able to communicate in English, and have regular access to the internet.

Who must we exclude?

Regrettably, we cannot include carers if the individual they care for suffers from a mental illness other than psychosis or those who cannot communicate in English or use online facilities due to our resource limitation. We cannot include more than one carer who might share the caring for the same individual, although we would encourage the carer to share the information learnt through the study with others in their family/social network.

Where and when will the study take place?

This study is scheduled to run from early 2018 to late 2020. Nonetheless, participation in the study will take 8 months for each carer when they will have access to either COPE-support or the 'control', on top of any other usual care they may receive (examples include attending a local carer group, having ad hoc support from a carer support worker from the NHS or the Social Service, using voluntary sector support). Participants can use and access either online resource 24/7, from their own home, fitting their own lifestyle and other demands in day to day life. We will ask the participants to fill in some questionnaires online to see how they are feeling at the start, half way through, after 4 months and 8 months of using either resource. We encourage participants to spend about half an hour to an hour a week during the initial 4 months to use COPE-support (or the control), And we anticipate that each round of online questionnaires will take about 15 minutes to complete.

What will you be asked to do if you take part in the study?

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 both your email address and mobile phone number so that we can (1) verify you are a real person (and not an automated spamming programme), and (2) communicate with you via phone and emails. You will be invited to complete some online questionnaires after you consented. You will then be randomly allocated by computer to receive either COPE-support or an online information webpage (on top of any other services you are receiving).

Participants will be given a user-account to access the online resource they have been allocated to and will have access to it for 8 months. For the initial 4 months, participants are encouraged to use the resource and its various content-elements, for about half an hour to an hour weekly. The online resources are moderated and facilitated by a qualified clinician and we will send weekly reminders to visit the website over the following months (for which you can choose to not to receive them or to receive them at your preferred frequency, e.g. monthly). We will invite participants to complete some online questionnaires to see how you are feeling after 2 months, 4 months, and 8 months of using the resource. The resource platform is also designed to record automatically how participants use it, such as how often they log in, what sections they visit.

After all the data collection is completed, participants allocated to receive the online information webpage (the control) will be offered access to COPE-support. We will also invite about 30 participants who were allocated to receive COPE-support for an individual interview for their views of using it. We will arrange the interview via phone or the internet (e.g. using skype) suiting the participant's preference. We will ask the participant to agree for us to audio-record the interview which will take about 30 minutes.

Will you be compensated for your time?

To thank you for taking the time to participate, we will offer you a goodwill payment, upon completion of each of the 4 rounds of online questionnaires (i.e. £10 for the first, £5 for the second and third respectively, and £10 for the fourth and last). We will offer an additional £10 goodwill payment for those who give an interview.

Are there any risks involved in participating?

The risk involved in participating in this study is minimal. The resource aims to provide information and facilitate sharing experiences about caring for a loved one with psychosis and ways for looking after yourself. You may find some of these of particular resonance to your own experience. Participants who experience any distress are encouraged to get in touch with our online support mechanism or the research team.

Support and resources for participants

The online forums are moderated and facilitated by qualified mental health professional(s). You can contact the facilitator for support by a direct link through the COPE-support online resource or by email. The facilitator will get back to you within 3 working days to arrange a time to discuss your concerns and give you support. S/he may also suggest other services and/or

support mechanisms you may consider, e.g. seeing your GP, seeking Talking Therapies, or contacting a non-governmental agency for support. In addition to this inbuilt support mechanisms, the online resource (and the control) include a list of independent advice and information resources and their contact details, e.g. Rethink Mental Illness, SANE, local primary healthcare and mental health services.

Are there any benefits involved in participating?

We hope that you will find participating in this study interesting and the information provided in this study helpful. We hope you recognise that you have made an important contribution to research aimed at advancing support for carers of people affected by psychosis. If COPE-support is found to be more effective than current information and support offered through usual online sites, we hope to make COPE-support widely accessible to more carers like yourself in the future. It is therefore important for us to run this study, with your support.

How will we maintain your privacy and confidentiality?

All contribution and discussion will remain confidential within the limits of the law. However, we are legally bound to disclose any information that is illegal in the communications or that conveys serious concerns about an individual's safety made by anyone, to the appropriate authorities.

Only enrolled participants can use our online platform securely by logging on with a unique username (which comprises a pseudonym and a code but no real name) and password. We ask all participants to observe the [ground rules](#) at all times when using the resource to help us keep the online environment safe and all discussions shared on the resource confidential.

All data collection and analysis will be processed by the research team within St George's, University of London premises. Your personal details that are collected for administrative purposes (e.g. consent form, payment record) will be stored securely. Only the research team will have access to this information.

Only the audio-recording of the individual interviews will be sent to an external transcribing agency for transcribing. This is an agency approved by St George's, University of London which is fully compliant with confidentiality and privacy codes. Written and anonymised transcripts (so that any person-identifiable details, if mentioned, will be anonymised) will be made from the recording and the analysis will be conducted on the transcribed materials. The recording will be erased after the transcripts have been checked to be accurate (about 1 month's time)

All study data, including the transcribed interviews and questionnaire results, will be anonymised and will be kept securely on encrypted computers and separately from the personal data. No names or other information that might identify you will be used in any publication or documentation arising from this study.

At the end of the study, data collected will be kept securely in SGUL designated archive space for 10 years. At the end of this period, they will be disposed of securely.

Who is organising and funding the research?

This study is part of a bigger project entitled "EFFIP (E-support for Families and Friends of Individuals affected by Psychosis): A randomised controlled trial of a co-produced online intervention for carers" which is organised by a team of researchers at St George's, University of London and King's College London. The primary researcher is Jacqueline Sin. The study is funded by the National Institute of Health Research, and sponsored and insured for indemnity by St George's, University of London.

What if I have questions about the project?

Please contact Jacqueline Sin, NIHR Post Doctoral Research Fellow, by email at: jasin@sgul.ac.uk; or by telephone at: 07817027035; or by post at: Population Health Research Institute, St George's, University of London, Cranmer Terrace, London SW17 0RE.

It is up to you to decide whether to take part or not. If you decide to take part you are still free to withdraw at any time throughout the study and without giving a reason. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form.

If this study has harmed you in any way or if you want to raise a complaint, you can contact:

1. Dr Jacqueline Sin (Chief Investigator)
Population Health Research institute
St George's, University of London
Cranmer Terrace, London SW17 0RE
Email: jasin@sgul.ac.uk
2. If unresolved, please then contact:
Dr Steve Gillard
Population Health Research Institute
St George's, University of London
Cranmer Terrace, London SW17 0RE
Email: sgillard@sgul.ac.uk

This study has been reviewed and approved by South Central – Oxford C Research Ethics Committee (18/SC/0104) and Health Research Authority (IRAS 240005)