Sussex Partnership NHS
NHS Foundation Trust

Study Title: The Early Youth Engagement in first episode psychosis (EYE-2) Study: Effectiveness and Cost-effectiveness sub-study

Information sheet: (Service User Effectiveness and cost-effectiveness sub-study) Version 2 26/04/18

Invitation: You are being invited to take part in a research study. It is up to you whether or not you would like to take part. Before you decide, we would like to tell you about the study, answer any questions that you may have and give you time to think about it and discuss it with family, friends, care team or GP if you wish. Information on how to contact us and other independent advice is at the end of this sheet.

Why is the study being done? This study is based on a successful pilot study. The study is being done because some service users are likely to stop using early intervention in psychosis services (EIP)**.** We have listened to what service users want from services, and have made a new approach to treatment called EYE-2, which includes staff training, booklets and website. We are now testing EYE-2 to see if it reduces the number of people who stop using services, and to see if young people who receive it have better mental health and wellbeing. **If you have stopped using EIP services already, your views are especially important to us and we will keep these confidential.**

What is the study about? This research is testing the EYE-2 treatment with young people who have used early intervention in psychosis services. EYE-2 involves working together with you and your important family or friends. It offers social groups, booklets and a website to help you to get the most out of services. EYE -2 aims to offer better services by focussing on your goals and needs and by working together with you in an open and honest way. In the research, some services will use EYE-2 and some won't. This project is to find out whether the treatment helps young people with their health and satisfaction, with what they do day-to-day like working, studying and socialising, and is affordable.

Why me? You have been invited to take part because you are someone who has used EIP services that are involved in testing out the EYE-2 treatment.

What would taking part mean? Taking part would involve completing a short questionnaire that takes about 20-30 minutes, by telephone or in person, with a researcher from the study. The questionnaire asks about your health and service use, your satisfaction with services, and any employment, education and use of other services and supports. We will keep this information completely confidential and will store your answers in an anonymous way so that you cannot be identified. There are no right or wrong answers. It's your view that is important to us. A researcher will get basic information from your medical notes confidentially.

Where would I have to go and when? You can answer the questions on the telephone or in person if you prefer, at an NHS base or somewhere else local to you, and at a time that suits you.

Would I receive any reimbursement for taking part? You will be reimbursed **£20** (or a lower amount or vouchers if you prefer) and will also get basic travel expenses if you travel to meet the researcher.

Confidentiality: Any information you give will be treated confidentially. This means that we will not tell anyone anything that you tell us as part of the research study.

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Would confidentiality ever be broken? If you say something that suggests there is a risk to your own or someone else's safety we are obliged to tell your care team or GP.

Do I have to take part? No, it's up to you. If you decide to take part, someone from the research team will contact you. Whether you decide to take part or not will not affect your care through the NHS. If you decide to take part and then change your mind, you are free to withdraw at any time without having to give a reason.

What are the advantages of taking part? Importantly, the findings will help us to decide whether the EYE-2 treatment is helpful and affordable for use in EIP services, so we can offer the best service. There are no immediate advantages to taking part in the study but some people enjoy taking part in these types of projects, where you can share your views and experiences.

What are the disadvantages of taking part? It is possible that talking about your health, work or services might make you feel upset, or talking for this long might make you feel tired. You can take a break or stop at any time during the interview, without having to give a reason. If you have any concerns, please talk to someone. You can talk to your friends, family, an independent person, or a researcher. The names of an independent person and a researcher are on the next page.

Who will know if I decide to take part? If you are still with Early Intervention in Psychosis services your care-team or care co-ordinator will know you have been invited to take part in the study. If you are not with EIP services anymore, your GP will know that you have been invited to take part in the study. Your EIP service or GP will not have any information about what you say in the interview though and no-one else will know you are taking part.

Who will see my data, how will it be used and what will happen to it?
Your data is your records and responses to the questions and questionnaires that are part of this study. Your data may be written down, or stored on audio-files or computers. All your study data will be anonymous so no-one outside of the research team will know it belongs to you. Only the research team will have access to the data that you give as part of the study. Paper data will be stored in locked filing cabinets and audio and computer data will be stored electronically in secure NHS files and will be protected by a password known only to the study team. Your data will only be used for this study and closely related studies. Your personal information. Like your name and address will be stored in the same secure way but separate from your study data. Your study data will be stored for 10 years, and your personal data for up to one year after the end of the study. After this time data will be deleted or shredded.

What would happen to the results of the study? The results of the study will be published in a mental health journal, but the information will be confidential and anonymous and your name will not be included. If you are interested we can send you a summary of the findings from the study.

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What will happen if I am unable, or don't want to carry on with the study? You can withdraw from the study at any time without having to give a reason. Any data that you have provided up until that point will be included in the study.

Who is funding this study? This study is funded by a grant from the National Institute of Health Research.

What if there is a problem? If you have a concern about any aspect of the study, you should ask to speak to the researchers, using the contact information below. They will do their best to answer your questions. If you remain unhappy you can contact the R&D department, or Patient Advice and Liaison Service using the contact information below.

What if I have a complaint: If you have a complaint about the way you are approached or treated during the course of this research study, you may want to talk to the Patient Advice and Liaison Service (PALS) who will advise you on what to do. Their contact information is below.

Is the study insured? In the unlikely event that something goes wrong and you are harmed during the research, Sussex Partnership NHS Foundation Trust has insurance in place to cover their legal liabilities in the event of injury or damage to you arising from this study. If you experience any distress, you can contact your GP.

Who has reviewed this study? This research study has been reviewed and approved by the Research and Development department within your local NHS Trust and by London-Dulwich National Research Ethics Committee (Ref no.18/LO/0362). It has also been reviewed by people who use EIP services.

Who can I contact to talk about taking part in this study?
If you have any questions about the study, please contact me:

Dr. Kathryn Greenwood
School of Psychology
Pevensey 1
University of Sussex
Brighton
BN1 9HQ

Email: k.e.greenwood@sussex.ac.uk

If you have any questions about taking part in research in general, you can contact your local NHS Research and Development Department:

Taffy Bakasa
Research and Development Department
Nevill Avenue
Hove
Sussex Education Centre

Tel: 0300 304 0088
Email: Taffy.Bakasa@sussexpartnership.nhs.uk

BN3 7HY

If you want to talk to someone independent about research, you can contact your local Patient Advice and Liaison Service (PALS):

Aldrington House
35 New Church Road
Hove, Brighton
BN3 4AF

Tel: 01273 716588
Email: PALS@sussexpartnership.nhs.uk

Thank you for reading this

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Consent Form: (Service User Effectiveness and Cost-effectiveness sub-study) Version 2 26/04/18

Please read the following points and put your initials in each the box after the point to show that you agree, and then sign your name at the bottom:

1. I have read the information sheet (version 2 26/04/18; IRAS ref. number 18/LO/0362) and taken the time to think about whether or not to take part. ☐
2. I have been given the contact details for people who I can talk to about whether or not to take part. ☐
3. I agree to take part in this study ☐
4. I understand that this involves me answering questions about health, services, and day-to-day activities. ☐
5. I understand that taking part will involve an interview with a researcher of about 20-30 minutes on the telephone or in person. ☐
6. I understand that if I tell the researcher something which suggests there is a risk to me or someone else, the researcher may need to pass this on to my care team, GP or other services. ☐
7. I give my permission for my medical records to be viewed by the study team for the purposes of this research study. ☐
8. I understand that research data collected during this study may be looked at by people from the research team, sponsors or regulatory research authorities. I give permission for these people to access my research data. ☐
9. I understand that I can change my mind and withdraw at any time without having to give a reason. ☐
10. I understand that if I decide to stop doing the research, unless I ask otherwise, the information I have already given will still be used in an anonymised form (without my name). ☐
11. I am willing to be contacted in the future to be asked about taking part in additional related research. ☐
12. I understand that my care team will be informed that I am taking part, or my GP if I have stopped using EIP services ☐
13. I understand that this research is completely confidential and all my data will be used in a confidential manner. My name will not be published in any way. ☐

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Please sign and print your name to show that you consent to take part in this research study and agree with the points previously asked:

SIGNED:

PRINT NAME: DATE:

WITNESS SIGNATURE:

PRINT NAME: DATE: