THE UNIVERSITY of EDINBURGH

NHS Lothian

Participant Information Sheet

Childhood experiences, beliefs about self and others and paranoia

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The purpose of this study is to help inform our understanding of the relationship between difficult and/or traumatic events in childhood and paranoia in people with experience of psychosis and to help identify the factors that might explain this relationship.

Why have I been invited to take part?

You have been asked to take part as you have been previously diagnosed with psychosis, are in contact with NHS mental health services in NHS Lothian, NHS Greater Glasgow and Clyde, NHS Forth Valley or NHS Lanarkshire and have current personal experience of paranoia.

We are interested in hearing from people with a wide variety of different experiences during childhood and you do not need to have experienced traumatic events during childhood in order to take part in the current study.

Do I have to take part?

No, it is completely up to you whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form. If you do decide to take part, you are still free to withdraw from the study at any time and without giving a reason. Deciding not to take part or

withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

How do I take part?

There are two ways in which to express your interest in taking part in the study.

The first way is to contact the researcher directly through the email address or contact number given on the posters advertising the study displayed in your mental health clinic and on this information sheet. The researcher will then contact you via telephone to discuss the study in more detail. During this contact, the researcher will give you further information about the study, answer any questions you may have, and will ask you some questions to find out whether you meet the criteria for the study. The researcher will also ask for your explicit permission to contact your keyworker/ care-coordinator to find out if they think you meet the criteria for the study. The researcher will then send you a copy of this form. You can decide whether you would like the researcher to get back in touch with you to remind you about the study after receiving this form. If you would like to be reminded about the study you will always have at least 48 hours to consider this form before the researcher contacts you again to find out if you remain interest in participating.

The second way in which to express your interest in taking part in the study is through a member of your mental health care team. A member of your mental health team will approach you about the current study and ask you if you would be interested in taking part. If you are interested in taking part in the current study, a member of your mental health team will ask for your consent to pass your contact details to the researcher and for the researcher to contact your keyworker/ care-coordinator in order to find out if you meet the criteria for the study. You will always have at least 48 hours to consider this form before the researcher contacts you to find out if you remain interested in participating in the study.

If you don't meet criteria to take part in this study, the researcher will explain why you don't meet criteria for the study.

What will happen if I take part?

If you have agreed, the researcher will contact you at least 48 hours after you have received this form. If you did not agree to be reminded about the study, the research will wait to hear from you. If you are interested in participating and meet criteria for this study, the researcher will arrange a meeting that is convenient.

You can choose to complete the study in either one or two sessions. There will be two main parts to the current study. The first part will involve a 45 minute- 1 hour interview about your experiences which have attracted the labels of paranoia and psychosis. If you choose to complete the study in one session, after this interview there will be a 5 minute break for the researcher to look over your responses to this interview. This break is to allow the researcher to find out whether you meet criteria for the second part of the study.

If you meet criteria for the second part of the study, you will be invited to complete a further 3 questionnaires and a second interview lasting approximately 30 minutes. If you don't meet criteria for the second half of the study, the researcher will explain why this is the case and will thank you for your time.

If you choose to complete the study over two sessions, the first session will be the 45 minute – 1 hour interview about your experiences. If you meet criteria for the second part of the study, the researcher will arrange to meet you in another occasion lasting approximately 30 minutes.

Some people might prefer to be accompanied by someone they know while they participate in the study. If this is the case, you can discuss with your keyworker/ care coordinator if they would be available to accompany you while you participate in the study.

What are the possible benefits of taking part?

It is unlikely taking part will benefit you directly but you can ask for information gathered during the study to be shared with your mental health care team to help clarify your care needs.

Your participation and feedback will help us to better understand the relationship between traumatic events in childhood and paranoia in people with psychosis. Understanding the factors involved in this relationship may contribute to better mental health care and treatment for people experiencing similar difficulties in the future. In addition, raising awareness of the link between childhood trauma and paranoia in people with psychosis may result in mental health clinicians being more likely to ask the people they are working with about trauma. This may increase the likelihood that individuals are offered specific support and treatment for trauma related difficulties. Finally, contributing to the research in an attempt to improve our understanding of psychosis and paranoia has the potential to reduce stigma associated with these experiences.

What are the possible disadvantages and risks of taking part?

There is no evidence to suggest that asking people experiencing psychosis and paranoia about difficult events during childhood results in any serious or long-lasting harm. It is possible however that the researcher might ask you about things that you find upsetting (e.g. experiences during childhood). The researcher will check in with you about how you are feeling throughout the study and will make sure there is time available to discuss how you are feeling at the end of the study. The study will always take place at your usual mental health clinic, meaning that we can seek the support of your keyworker/ care-coordinator in the unlikely event this is required.

It is also possible that you may find the interview and questionnaires tiring. You can have as many short breaks as you need and are free to stop the interview at any point.

Will my taking part in the study be kept confidential?

Once we have your permission, we will inform your care team and GP that you are taking part in the study. Information collected during the study will **NOT** be fed back unless you ask us to do so.

The only time the researcher may need to share information would be if you disclosed information during the study that gave the researcher concerns about your safety or the safety of others. If this were to occur, the researcher would follow standard NHS procedures and share this information with your keyworker/ care-coordinator or a member of your mental health team in order to keep you and others safe. The researcher would discuss why information has to be shared and who this will be shared with if this were to happen. If you have any questions about this, please do ask the researcher.

What will happen to my data?

Your name and contact details will be stored securely by the researcher in a locked filing cabinet on NHS Lothian premises and then destroyed once the study is finished in April 2018. A copy of your consent form will be stored in a separate locked filing cabinet.

All completed study questionnaires will be stored securely in another separate locked filing cabinet. Finally, audio records of interviews will be stored on a password protected database on a password protected NHS Lothian computer. Documents and audio recording will be linked to one another by being given a numerical code.

Fully anonymised data (data with all identifiable information removed) will then be transferred to a University of Edinburgh password protected computer for analysis. You can ask for your data to be removed from the study until the point that results are due to be published. After this time, it will not be possible to remove your data from the study.

To ensure that the study is being run correctly, we will ask your consent for responsible representatives from the Sponsor and NHS Institution to access your medical records and data collected during the study, where it is relevant to you taking part in this research. The Sponsor is responsible for overall management of the study and providing insurance and indemnity.

What will happen to the results of the study?

This study forms part of the researcher's Doctorate in Clinical Psychology training. Anonymised data, including anonymised quotes from audio recordings of interviews may be written up for publication or presented at a conference. You would not be identifiable in any output.

You may request a summary of study findings.

Who is doing this study?

I (David Carmichael) am a Trainee Clinical Psychologist based in NHS Lothian and affiliated with the University of Edinburgh. This study is part of my training for the Doctorate in Clinical Psychology Programme. I work within mental health services in NHS Lothian.

What if there is a problem?

If you have a concern about any aspect of this study please contact David Carmichael at david.carmichael1@nhs.net or 0131 537 6905 He will do his best to answer your questions.

In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Who is organising the research?

The research has been designed and is being carried out by a Trainee Clinical Psychologist undertaking a Doctorate in Clinical Psychology at the University of Edinburgh. The study is being supervised by Dr Karen Goodall (Lecturer, University of Edinburgh), Dr Sean Harper (Consultant Clinical Psychologist and Lead Psychologist for Psychosis and Complex Mental Health, NHS Lothian) and Dr Paul Hutton (Honorary Consultant Clinical Psychologist, NHS Lothian and Associate Professor in Therapeutic Interventions, Edinburgh Napier University). Funding and sponsorship has been provided by the University of Edinburgh.

Who has reviewed the research?

The study proposal has been reviewed by representatives from the University of Edinburgh and NHS Lothian, NHS Greater Glasgow and Clyde, NHS Forth Valley and NHS Lanarkshire. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. A favourable ethical opinion has been obtained . NHS management approval has also been obtained.

Who can I contact if I have a complaint?

You are free to discuss any concerns about the study with the researcher (contact details at the end of this leaflet) who will do his best to address your concerns. If you remain unhappy and wish to complain formally, you can do this by contacting:

NHS Lothian Complaints Team
2nd Floor, Waverley Gate, 2-4 Waterloo Place
Edinburgh
EH1 3EG
Tel: 0131 536 3370

Email: feedback@nhslothian.scot.nhs.uk

Who can I contact about this study?

If you would like any further information about the study or think you might like to take part, please contact the researcher:

David Carmichael, Trainee Clinical Psychologist, NHS Lothian
Email: david.carmichael1@nhs.net
Tel: 0131 537 6905

If you would prefer, you can ask a member of your care team to contact the researcher on your behalf.

If you wish, you can also contact the supervisors of the study, Dr Karen Goodall, Dr Sean Harper or Dr Paul Hutton at:

karen.goodall@ed.ac.uk or 0131 651 3947
sean.harper@nhslothian.scot.nhs.uk or 0131 537 6912
p.hutton@napier.ac.uk or 0131 455 3335

If you would like to discuss this study with someone independent of the research team, please contact:

Dr Helen Sharp
Lecturer
University of Edinburgh
School of Health in Social Science
Doorway 6, Medical Quad
Teviot Place
Edinburgh
EH8 9AG

Tel: 0131 651 3949
Email: helen.sharp@ed.ac.uk

Thank you for taking the time to read this information sheet