Participant Information Sheet
Exploring voice hearing experiences in daily life

Introduction

We would like to invite you to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with friends, relatives and your care coordinator if you wish. Ask us if there is anything that is not clear or if you would like more information.

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Exploring VOices in daiLy lifE

Take time to decide whether or not you wish to take part. It is entirely up to you if you wish to take part in the study. If you do not wish to join in, your medical care will not be affected in any way. If you do decide to take part, you are still free to withdraw at any time, without giving a reason.

What is the purpose of the study?

We are interested in speaking to people who hear a voice or voices that other people cannot hear *most days*. We are doing this in two sites, in Sussex and South London, so that we may be able to talk to a wide variety of people.

Recent research has shown that many people describe having 'unusual' experiences like hearing voices. Voice hearing experiences (like any other experience) can be interpreted and responded to in different ways. For some people these experiences have a negative impact on their life and result in input from mental health services. For others these experiences have a positive impact and can be life-enriching. This research will attempt to identify any differences between the day-to-day experiences of people whose voices have a positive impact on their lives, and the experiences of people whose voices cause them distress. We hope that this will allow us to identify any day-to-day factors that trigger or protect against people feeling distressed by their voices during the course of daily life.

You may worry that this project might involve negative judgements of people whose experience and beliefs might be considered unconventional or unusual - this is *NOT* the aim of the study. On the contrary, we are interested in gaining a fuller understanding of the different ways in which people interpret and respond to unusual experiences. We hope a better psychological understanding of these types of experiences will, in the long term, help other people to accept them more readily. This study will also be student research that will form part of a PhD.

Why have I been invited?

You have been invited to participate because your care-coordinator or nurse has identified that you might be having distressing voice hearing experiences.

Do I have to take part?
It is entirely up to you to decide whether or not to take part. Your decision whether or not to take part will have no effect on any treatment you are currently receiving. You may choose to ask for independent information or advice about your rights as a research participant or about being involved in this particular research study by contacting the local Service Experience Team (please see below for contact details).

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. You are still free to withdraw at any time in the process of the study without giving a reason.

What will happen if I start but then don't want to carry on with the study?
Participants can withdraw from the study at any time without having to justify their decision. If you decide to withdraw from the study you can tell us whether you are happy for us to use the information obtained up to that point. If you are not, any information that you have given will be destroyed and you will not be contacted by us again.

What will happen to me if I take part?
Taking part will involve meeting with a researcher on two separate occasions. In between these meetings, you will be asked to carry a mobile phone around with you (either your own or one provided by the research team for the duration of the study) for nine days, as you go about your usual daily activities. Ten times each day (during waking hours), this mobile phone will make a beeping sound, prompting you to answer a number of short questions on the phone's screen about your current activities, thoughts, feelings and voice hearing experiences. Each day, you will additionally be asked to fill in a 'morning' and 'evening' questionnaire on the screen of the phone. The 'morning' questionnaire will appear on the screen when you first turn the phone on each morning. This questionnaire asks a number of short questions about the quality of your sleep the night before, providing us with a sense of how sleep might influence voice hearing experiences during day-to-day life. The 'evening' questionnaire, which you answer each night shortly before going to bed, consists of just one question, which asks you to rate how 'typical' your day has been. This will give us a sense of whether the answers that you have provided to the questions are representative of your experiences more generally.

In addition, at the first meeting with the researcher, you will be asked to complete a set of questionnaires. We are interested in a wide range of factors in your life which may be of relevance, and the questionnaires will be asking about your current situation (including what it's like where you live, your current religious practices and drug use); your current mood (including your view of the world and yourself); your voice hearing experiences (including how you feel about these experiences); and your relationships with other people (including how you feel when you are with these people). The researcher is fully trained in talking to people about such experiences in a sensitive, non-judgemental and empathic way. Breaks will be available as needed at any point during the session.

At the second and final meeting with the researcher, you will be asked to complete two questionnaires asking how you found participating in the study. Overall it will

take approximately eight hours to complete the study, spread over a period of about two weeks.

Will anything else happen?
Before participating in the study we would like your consent to view your medical notes to obtain some additional information regarding diagnoses, how long you have been with mental health services, and any medication that you are currently prescribed. We will not view this information unless you give your consent.

What are the possible disadvantages, risks or side effects of taking part?
During the first meeting with the researcher, some of the questionnaires that you will be asked to complete may cover issues that are sensitive and/or distressing for you, such as drug/ alcohol use and questions asking about your voice hearing experiences. These questions are chosen to help us understand why some people become distressed by their experiences and to find ways to help. You can stop at any stage of the interview if you feel uncomfortable and you can refuse to answer any questions that you feel are too distressing.

In the part of the study where you are asked to answer questions on a mobile phone about your daily activities and experiences, it is possible that you might experience some distress and/or disruption due to the fact that these questions will be repeated ten times per day while you are going about your daily life.

Whilst we hope that you will try your best to complete as many questionnaires as possible per day, we recognise that there are likely to be moments in which it will be difficult to complete all the questions, or specific questions that you may feel uncomfortable answering on a regular basis. It is fine if you are unable to complete every question every time the phone beeps. The researcher will make arrangements to speak to you via telephone at least twice over the course of the study in order to check how you are getting on, and you will be provided with the researcher's contact details to use in the event that you experience any difficulties. In this situation, the researcher will discuss with you any ways in which the study could be modified in order to make things easier for you. If at any point however you find the process too much, you can choose to withdraw from the study without needing to give a reason, and without it affecting your current or future clinical care. If you require support and do not wish to speak to the study team, we would encourage you to talk to a member of your care team.

At the end of the study you will have a chance to tell us what your experience of participating in the research was like, and we will take this into consideration for this and future studies.

What are the possible benefits of taking part?
You will be offered individual feedback about how your voice hearing experiences vary in different situations during your daily life. The research will contribute to understandings of voice hearing and potentially lead to the development of improved interventions for distressing voices.

Will I be compensated for my time?
We are able to reimburse any travel expenses that you incur and offer you £60 in cash for your time. You will receive £20 at the end of the first meeting with the researcher, and the remaining £40 at the end of the second meeting. Reimbursement payment must be declared for tax or benefit purposes.

Will my taking part in the study be kept confidential?
All the information which is collected about you during the course of the research will be kept strictly confidential. The only limits to this confidentiality would be if you were to tell us something that suggested that there would be a reason for us to be worried about harm to yourself, or to someone else. In these circumstances it would be important for us to share this information appropriately- this would mean in the first instance sharing it with your care-coordinator or key nurse. Please note that this is likely to be a very rare occurrence.

The data will be collected and stored in accordance with the Data Protection Act 1998, secured against unauthorised access.

What will happen to the results of the study?
The research should be completed by the end of 2015. You will be offered a copy of the results of the study once it is completed, if you wish. The results of the study will be published in a peer-reviewed journal, with all data completely anonymised. No individual will be identifiable from the published results.

What if there is a problem?

Complaints
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have a concern about any aspect of this study, you can speak with the researcher in the first instance or the Project Supervisor (Dr Mark Hayward) who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure (see below) or through the Research and Development Manager (see below).

Harm
Compensation for harm arising from an accidental injury and occurring as a consequence of your participation in the study will be covered by Sussex Partnership NHS Foundation Trust. If you are harmed and this is due to someone's negligence then you may have grounds for legal action for compensation against the University of Sussex (with respect of any harm arising out of the participation in the research study).

Who has reviewed the study?
This research was reviewed and funded by the University of Sussex and Sussex Partnership NHS Foundation Trust. People with personal experience of hearing voices have been involved in providing advice on the measures and ways to conduct the study in the best possible manner. All research in the NHS is also looked at by an independent group of people, called a Research Ethics Committee, to protect your

safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion (approved) by the Camberwell St Giles REC (23/04/2014).

Contact Details

If you have any questions relating to this research, or concerns about participation, please contact:

Researcher:
Sarah Fielding Smith
Tel: 01273872776
Email: s.fielding-smith@sussex.ac.uk

Primary Project Supervisor:
Dr Mark Hayward
Tel: 01273877240
Email: mih21@sussex.ac.uk

If you would like to speak to someone to get some independent advice about your rights as a research participant, you can contact the local Service Experience Team:

Service Experience Team
Sussex Partnership
Swandean
Arundel Road
Worthing
West Sussex, BN13 3EP
Tel: 01903 843026

If you wish to make a complaint about the conduct of this study, you can do this through the NHS complaints procedure. You may speak to your care-coordinator, clinic manager or person in charge initially. If you would like to make a formal complaint, you can write to:

The Service Experience Team at:

Sussex Partnership
Swandean
Arundel Road
Worthing
West Sussex, BN13 3EP
Tel: 01903 843026

Or the Research and Development Manager (Tanya Telling) at:

Sussex Education Centre
Mill View Hospital
Nevill Avenue
Hove
BN3 7HZ

Or you can use the Trust web site link below:
http://www.sussexpartnership.nhs.uk/service-users/experience/comments

We wish to thank you for taking the time to read this sheet and considering taking part in the research study.

INFORMED CONSENT FORM
Title of Project: Exploring voice hearing experiences in daily life

Name of Researchers: Sarah Fielding Smith/Dr Mark Hayward

		Please initial box
1.	I have read and understand the Participant Information Sheet dated 25.04.2014 (version 2) for the above study.	☐
2.	I have had the opportunity to ask questions about the study and have taken the time to think about whether or not to take part.	☐
3.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without any penalty.	☐
4.	I understand that if I decide to stop doing the research, unless I ask otherwise, the information that I have already given will be used in an anonymised form.	☐
5.	I understand that some of the information required for this study is in my medical notes and I give my permission for my medical records to be viewed by the study team for the purposes of this research study.	☐
6.	I understand that research data collected during the study may be looked at by individuals from the research team and responsible representatives of the sponsor or the NHS trust, the ethics committee and regulatory research authorities. I give permission for these individuals to have access to my research data.	☐
7.	I give permission for the research team to use the information collected from me during this study for future research projects. This information will be kept under anonymous codes.	☐
8.	I understand that if I tell the researcher something which shows that there is a risk to me or someone else, the researcher may need to pass this information on to my care team.	☐
9.	I am willing to be contacted in the future to be asked about taking part in additional related research. I give permission for my personal data to be stored after the end of the study for this purpose.	☐
10.	I agree to take part in the above study.	☐
11.	I give permission for the research team to contact my care coordinator to inform them of my participation in the study.	☐

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Title of Project: Exploring voice hearing experiences in daily life

Name of Researchers: Sarah Fielding Smith/Dr Mark Hayward

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

Full Name in Capitals:……

Signed:……..

Date:……..

Full Name of Researcher:……

Signed:……

Date:……..

When completed, 1 copy for participant, and 1 copy for research site file.