brighton and sussex
medical school

Sussex Partnership NHS
NHS Foundation Trust

ViBE

Voices in Borderline Explored

PARTICIPANT INFORMATION SHEET

Research Invitation

Would you like to take part in this research study? Before you decide, it is important for you to understand why the research is being done and what it would involve. Please take time to read the following information carefully and discuss it with friends, relatives, care team and your GP if you wish.

Ask us if there is anything that is not clear or if you would like more information (please see our contact details at the end of this document). Please take time to decide whether or not you wish to take part.

Note: Reading this information sheet does not mean that you will automatically be eligible to take part in the study.

Brief summary

Purpose of the study

We are investigating the **psychological and brain mechanisms underlying voice hearing experiences in people with a diagnosis of Borderline Personality Disorder** (BPD). We know that voice hearing is common in people who receive a BPD diagnosis, but unfortunately this is often **not recognised by mental health professionals.** Very little research has been done to understand what these experiences are like for people with BPD. We are hoping that this research will i**ncrease our understanding of voice hearing**, and lead to the **development of new therapies** for voice hearers with a BPD diagnosis. This study will also contribute towards a doctoral award.

What does the study involve?

The study involves **three phases**;

Phase 1

- **Meeting with a researcher at your local clinical service (2 hours)**
- This will involve talking to a researcher about your voices and mental health symptoms. We will also ask you to complete some questionnaires online.

Phase 2

- **Online survey at home (1 hour)**
- This will involve answering a series of questions about your voices, emotions and other unusual experiences you might have.

Phase 3

- **Meeting with researcher at University of Sussex, Brighton (2 hours)**
- This will involve doing some simple tasks while lying down for an hour in an MRI scanner. After a break, we will ask you to do two more simple tasks outside the scanner.

During the meetings, you will be offered **regular breaks**. At the **end of each meeting** you will be offered **£15 in exchange for your participation (£30 in total)**, and your **travel expenses will be reimbursed**.

There is more information about the study on the next few pages. Please take your time to read about the study and if you have any questions feel free to call or email us (see contact information at the end of this information sheet).

Why have I been invited?

We are inviting you to take part because **you or a member of your care team** have told us that you might be eligible to take part.

Can I take part in this project?

We are looking for people to take part in the study who:

- ⇒ **are aged 18-65**
- ⇒ **are currently receiving treatment from mental health services based in Sussex Partnership NHS Foundation Trust**
- ⇒ **are right-handed**
- ⇒ **are fluent in speaking and reading English**
- ⇒ **have healthy to corrected eyesight (e.g. using glasses or contacts)**
- ⇒ **have healthy hearing**
- ⇒ **have heard voices at least once over the past week**
- ⇒ **have been hearing voices for at least the past 6 months**
- ⇒ **have a diagnosis of borderline personality disorder (BPD)**

Unfortunately, you are ***not eligible*** to take part if you:

- ⇒ **have a fear of enclosed spaces or loud noises that might stop you from entering an MRI scanner**
- ⇒ **have any non-removable metal in or on your body**
- ⇒ **are pregnant**
- ⇒ **your voices are due to taking substances or medication, or due to a non-mental health-related medical condition (e.g. metabolic disorders, auto-immune or immune-deficiency disorders, etc.)**
- ⇒ **have a diagnosed neurological or neurodegenerative disorder**
- ⇒ **have a diagnosis of schizophrenia or schizoaffective disorder**

Do I have to take part?

You are **free to choose** whether you would like to take part in the study. If you decide not to take part **this will not affect the care you receive**.

If you decide to take part you will be asked to sign a consent form and you will be **free to withhold any personal information or to withdraw at any time, without giving a reason** and without this affecting the care you receive.

What would taking part involve?

Telephone call from a research assistant

First, you will receive a **telephone call from a research assistant**, who will explain the study and answer any questions you may have. If you are interested in taking part, they will book in an appointment for an eligibility assessment, to see whether you meet the criteria to take part (see page 3).

Pre-Study Eligibility Assessment

The eligibility assessment will take about **15 minutes**, and you can choose to do this over the **telephone, using an online form, or in-person with a researcher**. The assessment involves answering a **series of 'yes or no' questions** about your voice hearing experiences and mental health. If you meet the criteria (page 3), we will send you information about Phase 1 of the study.

Phase 1: Meeting with a researcher at your Local Clinical Service

You will be invited to **meet with a researcher at your local clinical service** to;

i) find out more about the next steps of the study;
ii) sign a consent form (if you decide that you would like to continue);
iii) check whether you meet the study eligibility criteria;
iv) begin the study assessment process.

At this meeting you will be free not to consent to the study and not to sign the consent form.

If you choose to take part, the researcher will check that you are eligible to continue by repeating the eligibility assessment, and asking some further questions about your experiences of borderline personality disorder.

If you are eligible to take part, the researcher will start the assessment by asking you some more in depth **questions about your voice hearing experiences and other mental health symptoms**. These questions aim to get a better understanding of what hearing voices is like for you, and will take about 45 minutes.

Next, you will be asked to complete a 20-minute online questionnaire. This questionnaire will ask you about things like; i) your experiences in close relationships; ii) your experiences in childhood. **Some of these questions are of a sensitive and personal nature, and you do not have to answer anything that makes you feel uncomfortable.** The research assistant can support you to complete this questionnaire by reading out the questions, or you may prefer to complete them on your own.

Finally, you will be asked to complete a 20-minute computer-based task, involving (**cont.**)

answering a series of ’true’ or ’false’ questions about different aspects of your voice hearing experiences. There is no right-or-wrong answer to these questions—we are just seeking to get a full understanding of your experiences.

Phase 2: Online Survey

This survey will involve answering a number of questions about your voice hearing experiences, emotions, and other ‘unusual’ experiences.

This survey will take about **1 hour**, but **you can complete it at your own pace at home** (or anywhere with a computer), **or in-person with a researcher**. The researcher will be available by phone if you have any problems whilst completing the survey.

Phase 3: Meeting with a researcher at the University of Sussex, Brighton

This meeting will take place at the University of Sussex, as this is where the MRI scanner is based.

The researcher will first go with you to meet with a radiographer, who will explain what will happen in the MRI scanner, and **ask you to sign another consent form to say that you are willing to take part in the scanning part of the study.**

The purpose of the scan is to capture images of your brain as you do some simple activities, like listening to words, talking to yourself in your mind, or pressing a button to tell us if you are hearing voices.

The scan will involve **lying as still as you can for about an hour**, on a bed in a narrow tube-shaped fMRI machine (pictured). Only the part of you that is being scanned goes into the machine, so for a head scan that will be at least to your shoulders. A small, open frame-like structure goes in front of your face, with padding on both sides to support your head. You’ll be able to see a screen in front of you, with some text and images related to the study.

During the scanning, there are lots of clicking and buzzing sounds, and other quite loud noises, but we’ll provide you with some earplugs beforehand to make it a bit quieter. **You will also be given a button to hold, which you can press at any time during the scanning to let us know if you’re having any trouble, or to stop the study if you wish.**

After you come out of the scanner, you will be given a break before taking part in some final tasks (45 minutes). For example, one of these tasks involves listening to a buzzing sound through headphones and telling us whenever you hear a ‘beep’ within the sound.

Is anything else involved?

1. Accessing your medical notes

In order to take part, we will need your permission for members of the study team to access your medical notes in order to; a) collect information relevant to the study, such as your current medication; b) record basic information about your involvement in the study.

2. Notifying your lead practitioner/key worker

In order to take part, we will need your permission to notify your key worker of your involvement in the study.

3. Choosing a 'nominated supporter'

It is possible that some of the questions that we ask (e.g. about your mental health symptoms, or experiences in childhood) may bring up difficult emotions. We will encourage you to choose a friend or family member, or someone in your care team, who you can turn to for support if you find anything particularly difficult. This person can also attend study assessment sessions with you if you wish.

4. Audio recording of assessment sessions

We would like to make audio recordings of your assessment sessions, to make sure the study is being run correctly. **If you do not agree to this, you are still able to take part in the study.**

How much time will the study take in total?

The total length of your participation in this study will be around five and a half hours.

Where will I have to go?

The first meeting with the research assistant will take place at your local clinical service, whilst the second meeting will take place at the University of Sussex. The cost of travelling to the meetings will be covered by the study.

What are the advantages and disadvantages of taking part?

Advantages

There are no direct advantages to taking part in this research. However, the research will contribute to understandings of voice hearing and potentially lead to the development of improved interventions for distressing voices in people with BPD.

Disadvantages

Some of the questions asked are of a personal/sensitive nature, particularly those relating to difficult experiences in childhood, and about your mental health (**cont.**)

symptoms and experiences. Talking about these experiences can be difficult. During the study **you do not have to say or do anything that you do not want to.** If you experience any distress, we encourage you to speak to your nominated supporter or key worker, and we can help you to do that. You can also speak to a member of the research team, and the **phone numbers for the research team are on the last page of this information sheet.**

The study assessment will take about five and a half hours in total, and is likely to become tiring. You will be offered regular breaks, and can ask for additional breaks whenever you wish. **You can also choose to stop or withdraw from the study at any time if you become too tired.**

Is there any reimbursement?

You will be reimbursed £15 for attending each research assessment session (£30 in total). Your travel expenses in attending these sessions will also be reimbursed.

Confidentiality

This study complies with data protection laws. All information that is collected during the course of assessment meetings will be kept strictly confidential and stored securely. Members of the research team will have access to these records. Monitors or auditors from regulatory authorities or from the host NHS Trust may have access to personal data during the study for the purpose of auditing the study. **Confidentiality may be broken in two cases;** i) the research team have an obligation to share information if they have concerns about your personal safety or about the safety of other people; ii) if there are any unexpected findings that need further investigation, the researcher will, with your consent, inform your GP who will notify you if further tests are needed.

Who is organising and funding the research?

The study is being funded by the Medical Research Council, and is sponsored by Sussex Partnership NHS Foundation Trust.

Who has reviewed the study?

The study has been reviewed by other service users with experience of BPD and hearing voices. The study has also been reviewed and approved by the Research and Development Department within your local NHS Trust, and an NHS Research Ethics Committee (IRAS ID: 234904 ; 18.12.17).

What will happen to the results of the study?

The results of this study will be written-up by the end of 2018 and submitted to an international mental health journal. You will not be identified in any publication. You can choose to receive feedback on the results of the study if you wish.

RESEARCH TEAM CONTACT DETAILS

If you are interested in taking part in the study, **please discuss this with a member of your care team. They (or you) can make a referral via the study website:**

www.sussex.ac.uk/spriglab/research/current/vibe

For further information, please contact the study coordinator, Sarah Fielding Smith:

Name:	**Dr Sarah Fielding Smith**
Position:	Study Coordinator
Telephone:	**07738 758447**
Email:	**S.Fielding-Smith@bsms.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 Patient Advice and Liaison Service (PALS):

Contact:	**Patient Advice and Liaison Service (PALS)**
Telephone:	0300 304 2198
Address:	Sussex Partnership Swandean Arundel Road Worthing West Sussex BN13 3EP
Website:	https://www.sussexpartnership.nhs.uk/patient-advice-and-liason-service-pals

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 Sussex Partnership NHS Foundation Trust (with respect of any harm arising out of the participation in the research study).

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course 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 telephone or write to the PALS Complaints Team (contact details above) or to the study sponsor:

Name:	**Taffy Bakasa**
Position:	Study Sponsor
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