Study: The feasibility and implementation of a psychosis risk prediction algorithm (P Risk) for use in primary care

We would be very grateful for your help with the above study. You may have ideas and experiences which would be extremely valuable to us.

Why have I been asked to take part?

Your GP practice has identified you as someone who has had a GP appointment over the last 6 months for a mental health problem, that is NOT a psychotic disorder. This could be something like depression or a problem with sleep. We are asking patients who have had GP appointments for a mental health problem because this is the patient group that **P Risk** will be used on in the future. You have NOT been asked to take part because you have been identified as being at risk of developing a psychotic disorder.

What is the study about?

We have developed a way to help GPs detect the early warning signs of psychosis, called **P Risk**. Examples of symptoms that people with psychosis might experience are hearing voices or noises that others do not hear (auditory hallucinations) or fixed, unusual beliefs that most other people would not share (delusions). Examples of nonpsychotic mental problems are depression, anxiety or problems with sleep. People who develop these illnesses do much better if they are treated in specialist centres as quickly as possible. GPs often find it difficult to pick up the early symptoms of a psychotic disorder because many of the symptoms are common and can occur in other mental illnesses such as depression. **P Risk** uses information which is stored in electronic medical records, such as previous GP appointments for mental health conditions like depression and anxiety and problems sleeping, along with other information on things like age, sex and ethnicity, to make a risk prediction. The aim is that this risk prediction can be used, along with clinical decision making, to decide whether to refer someone for a psychosis assessment in a specialist mental health team.

We know that **P Risk** works well in theory, but we do not yet know if it will work in real-life. To find this out we would like to interview GPs, mental health staff, patients and carers to ask their views and opinions of **P Risk**. We would be very grateful if you would consider taking part in this study because we think it is vital to take the views of patients into account in the future design and operation of **P Risk**.

Do I have to take part?

Whether you decide to take part or not is entirely up to you. It will not affect your care by your GP either way.

If I take part, what will it involve?

We will ask you to take part in a focus group with other people who have been identified in the same way. There will be about 5 patients in the focus group, which will be run by researchers in our group. The focus group will run for about an hour and will happen on a virtual meeting platform, such as Teams or Zoom. You can have your camera on or off, as you choose. At the start of the focus group the researchers will read aloud the consent form, and will ask for your permission to initial and date the consent form. The consent process will be audio-recorded separately from the rest of the interview. The researcher will then show you an illustration of **P Risk**, by sharing screens. She/he will then start a discussion to ask the group about their views and opinions of **P Risk**. The researchers will encourage everyone to contribute to the discussion. The discussion will be recorded on the virtual platform and then typed up later by the researcher. A copy of the consent form will be sent to you at the end of the interview.

If you are interested in taking part but are unable to make any of the suggested focus group dates and times, we would ask you to take part in an individual interview, which will last up to an hour. The format and structure of the individual interview will be similar to that of the focus group.

The discussion will be recorded on the virtual platform and then transcribed verbatim by a University of Bristol approved professional transcribing service.

Who is funding the study?

The study has been funded by the National Institute for Health and Care Research, which is the research arm of the NHS, and is sponsored by the University of Bristol. It will be managed by research staff at the University of Bristol.

What are the risks and benefits of taking part?

There is a small chance that some patients taking part in the discussion may become distressed when talking about their own experiences. The researchers running the focus groups will be trained to manage this situation if it occurs. At the beginning of the focus group session the researchers will ask anyone who feels very distressed by the conversation to use the confidential chat function to let them know. One of the researchers will then talk privately to that person. If the researcher remains very

concerned about the mental wellbeing of the patient, they will advise the patient to contact their GP or mental health clinician as soon as possible. In the very unlikely situation where the patient is feeling suicidal or saying that they will harm someone else the researcher will contact the patient's GP or mental health clinician.

There are no individual benefits from taking part aside from contributing important information to the **P Risk** research project. You will receive a £25 online shopping voucher to thank you for your time.

Is my data kept confidential?

Once the focus group discussion has been typed up by the researcher, it will be pseudonymised. The original focus group recording will be deleted. Only the research team will be able to link any of the discussion to anyone's identity. All research data will be kept in a secure study folder on password protected University of Bristol computers and only the research team will be able to access the study folder. If any academic publications resulting from this work contain any of your quotes, they will be anonymised. It will not be possible for anyone to identify you from these quotes.

How will we use the information about you?

We will need to use information from you for this research project. This information will include your initials, NHS number and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

What will the data I provide be used for?

The information collected from the focus group discussion will be organised into themes and joined with information collected from GPs, mental health clinicians, patients and carers. It will then be used to help the research team design **P Risk** and work out the best way for it to be used.

Where can I find out more about how my information is used?

You can find out more about how we use your information by sending an email to the study researcher Daniela Strelchuk at this email address daniela.strelchuk@bristol.ac.uk

What are my choices about how my data is used?

You can withdraw the data you provide at any time but if you have already signed a consent form, this will be retained by the study team.

What if I have questions?

If you need to ask any further questions to help you decide whether to take part please email the Chief Investigator, Dr Sarah Sullivan at this address sarah.sullivan@bristol.ac.uk

How long do I have to decide if I want to take part?

We would be very grateful if you could decide in the next two weeks whether you want to take part. If we don't hear from you after two weeks, someone from the GP practice will contact you by phone call or email to ask if you have decided yet.

What do I do if I want to take part?

If you want to take part, please complete the attached/enclosed Expression of Interest (EoI) form and email/post it back to the study research team. If you find filling in the electronic form difficult, you can email the researcher your name, sex, age and ethnicity, and we will take that as confirmation that you have expressed an interest in taking part. The researcher will then be in touch about dates and times for focus groups. Consent will be taken verbally right before the interview.

What do I do if I want to withdraw from the study

If you decide you want to withdraw from the study please email the study researcher Daniela Strelchuk at this address daniela.strelchuk@bristol.ac.uk. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

Who do I contact if I want to complain?

If you want to complain about any aspect of this research, please contact the University of Bristol Research Governance office on research-goverance@bristol.ac.uk