Participant Information Sheet

You are being invited to take part in a research study. It is important for you to understand why the research is being done and what it will involve. Please take time to read the information carefully, and discuss it with others if you wish. Feel free to ask us if there is anything that is not clear, or if you would like more information. You may wish to read the information sheet more than once, and should take time to decide whether or not you wish to take part.

What is the purpose of the research?

Previous research has suggested that people who have experiences of psychosis, such as hearing voices or having beliefs that others do not seem to share or agree with, may have patterns of thinking that dwell on symptoms, traumas and social problems. This **self-focussed attention** may serve to reinforce and maintain these experiences. We know from previous research that an intervention called **Attention Training** can be effective in treating disorders such as generalised anxiety disorder, post-traumatic stress disorder, obsessive compulsive disorder and depression. This research aims to investigate whether Attention Training is helpful for people with experiences of psychosis.

Why have I been given this information?

We are looking for people who have a diagnosis of Schizophrenia or meet the criteria for early intervention in psychosis, and suffer with either (1) auditory hallucinations; and /or (2) unusual or troubling beliefs. If you fit these criteria, we would like to invite you to take part in our research study.

Do I have to take part?

No. Your participation in the study is entirely voluntary; it is up to you to decide whether or not to take part. You should not feel under any pressure to make the decision. If you decide to take part, you will be asked to sign a consent form. Even after signing this form you will still be free to leave the study at any time without giving a reason. If you choose to withdraw from the research, this will not affect any care that you may receive now or in the future.

What will happen if I take part?

You will be invited to meet one of our researchers at a convenient location for you to discuss the study in more detail. Here we will explain the exact nature of the research, explaining our reasons for conducting this study and answer any questions you may have. If you decide that you wish to

participate in this study you will be asked to sign a consent form. Following this, you will meet with the research assistant to complete the initial assessment. This will involve an interview in addition to completing 7 short questionnaires. In total this will take approximately two hours to complete.

As part of the research, we will arrange to see you again for two follow-up appointments. These will be planned for eight weeks and three months after you initial appointment and will be very similar to the initial assessment. You may also be asked to take part in an intervention called Attention Training (see below).

Will this study involve treatment?

Sometimes, because we do not know which way of treating individuals is best, we need to make comparisons. Therefore, people who take part in this trial will either be allocated to receive Attention Training plus their usual treatment **or** treatment as usual alone. The allocation to either Attention Training plus treatment as usual or treatment as usual alone is done at random i.e. by chance. We will compare those who receive Attention Training from the trial to those who receive only their treatment as usual. This means that half of the people that agree to take part will be offered a psychological intervention (Attention Training) in addition to their usual treatment.

The Attention Training intervention will consist of eight sessions, once per week. Each session will last approximately half an hour and will involve listening to a variety of different sounds and switching your attention as instructed by the therapist. This audio task comprises approximately 12 minutes of the session. The remaining time will be spent reviewing your week and discussing any problems relating to practicing the attention tasks. Again, these sessions will take place in a location that is convenient for you, such as your home or GP surgery. The appointments will be within working hours, typically between 9am and 5pm. Attention Training sessions will be carried out by a trained therapist, your therapist will be a different person to the researcher that carries out your assessments.

Some sessions will be recorded so that the quality and content of the intervention you receive can be assessed, to ensure all participants have a similar experience. These audiotapes will be available for you to listen to if you wish, and afterwards, any such recordings will be kept confidential in a locked cabinet and destroyed at the end of the study in October 2015.

What are the advantages and disadvantages to taking part?

We hope that the Attention Training intervention and the assessments will help you. It is possible that they will improve mental health difficulties that you are experiencing. However, this cannot be guaranteed. The information we get from this study may help us in the future to better treat people who have problems related to psychosis.

It is also possible that talking about some of these issues during the assessments may be upsetting. You will have the opportunity to discuss any concerns you have with the researchers and you are

free to withdraw from the study at any point without giving a reason. If you later decide you would like to withdraw from the research, this decision will not affect any care you may receive now or in the future.

Will taking part in the research cost me anything?

No. The research will only involve your time. In order to compensate you for this you will receive a payment of £10 at each of the assessment points, i.e. at the initial assessment, at eight weeks and again at three months (£30 in total).

Who will know if I am participating in the research?

We will inform other people that are involved in your care, such as your GP, care co-ordinator or psychiatrist.

Will my information be kept confidential?

All of the information that we collect about you will be kept strictly confidential (i.e. private). When you enter the research, all personally identifiable information including your name, address and date of birth, will be kept in a locked filing cabinet in a locked private office at an NHS site. All of your information will be coded using an ID number instead of your name, to ensure that your personal information is safe.

The information that you provide (research data such as questionnaires, interviews and audio recordings) will not be shared with other people i.e. medical staff or people involved in your care unless you say it is OK to do so. However, if you tell us information that gives us concern that you may harm yourself or that there is risk to other people we may have to break your confidence and share this information with your care co-ordinator and GP, and sometimes the police. However, we would always aim to discuss this process with you first before proceeding any further. We would only break your confidence in order to secure the best possible care for you and the public and to ensure we keep everyone safe.

What will happen to the results of the research?

After the study is completed, we will analyse the results and submit them for publication in a scientific journal. Presentations may also be given at scientific conferences. Results will be used to improve services. You will not be identified in any publication or presentation. If you wish to know the outcome of the research please let us know.

Who is organising the research?

The chief investigator is Dr Sophie Parker from the School of Psychological Sciences Department at the University of Manchester. This study has been approved by the National Research Ethics Committee North West (REF: 14/NW/0043).

What do I do if I wish to make a complaint?

If you have a concern about any aspect of this trial, you should ask to speak to the researchers who will do their best to answer your questions. If they are unable to resolve your concern or you wish to make a complaint regarding the trial, you can contact the Patient Advisory Liaison Services or the complaints manager on 0800 587 4793/ 0161 772 3642.

Harm

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

Please keep this information sheet for future reference.

Thank you for considering this proposal.

If you want to discuss this research any further please contact either:

Dr Sophie Parker (Chief Investigator): 0161 358 1395/ 07767755790

Heather Law (Trial Manager): 0161 358 1395/ 07788586496

Rachel Sellers (Assistant Psychologist - research) 0161 358 1408/ 07798852289