NHS
Tees, Esk and Wear Valleys
NHS Foundation Trust

Imperial College London

REMEDY

Assessing approaches aimed at improving sexual functioning

We would like to invite you to take part in our research study

- Before you decide we would like 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 before you decide. Discuss it with your friends, family or doctor if you wish.
- Please ask us if there is anything that is not clear or if you would like more information.
- You are free to choose whether you would like to take part. If you decide not to take part, it will not affect any care you may be receiving.
- Thank you for taking the time to read this information. If you decide to take part, please keep this information sheet.

1 Why are we doing this study?

Lots of people who take medication to help with health problems like psychosis find that they get sexual problems. Both men and women can be affected by sexual problems, which may include a lower sex drive or getting less pleasure from sex. Men may struggle to get or keep an erection. Women may suffer from vaginal dryness even when they are sexually excited. And some people are not able to reach orgasm.

At the moment, we don't know the best way to help people who have sexual problems that are associated with taking antipsychotic medication. One possible option is to change to a different medication, but we don't know if this will help as it hasn't been tested in a big research study. In the REMEDY study, we will offer all people who have sexual problems that are associated with taking antipsychotic medication advice and support aimed at helping improve their sexual functioning. In addition to this we will arrange for half the people in the study to switch to a different medication and half to stay on their existing medication to see if there is a difference between the two groups.

2 Why am I being asked to take part?

We believe that you have experienced some type of sexual problem since taking antipsychotic medication. For this reason, we would like to invite you to take part in the study.

3 Do I have to take part?

No, it is up to you to decide. We will describe the study, go through this information leaflet with you, and then give you a copy to keep. Even if you do agree to take part, you are free to withdraw at any time without giving a reason. If you choose not to take part or later withdraw, our researchers may ask the reason for this so that we can understand people's thoughts on the study. You do not have to answer, and if you do, nothing you say will affect the care that you are entitled to and the standard of care you receive.

4 What will happen to me if I take part?

If you are interested in learning more about the study we will arrange a meeting with a researcher to discuss taking part and give you the opportunity to ask any questions. If you are happy to take part in the study the researcher will ask you to complete and sign a consent form to say that you would like to be included.
With your permission, we would also like to have contact details of a relative or friend that the research team could contact if they were unable to get in contact with you directly. If you would rather we didn't contact a relative or friend, you do not have to give us their details.

Checking that the study is right for you

Once you have told us that you would like to take part in the study, we will ask some questions to check if the study is right for you and whether changing your antipsychotic medication might be a good option. We will ask you some questions about your current mental health. We will also ask you to fill in a short questionnaire about any sexual problems that you have. These checks should take no longer than 20 minutes to complete.
To ensure your privacy, we will ask you to answer questions about sex on a touch screen computer, this is so you won't have to tell the researcher your responses during study visits.

Allocation to a study group

If the checks show that the study is right for you, you will be randomly allocated to one of the two study groups: A or B. People in both groups will be offered two sessions with a trained doctor or nurse where they will be given advice about things that might help with the sexual problems that they have.

People in group A will also have their antipsychotic medication switched for a different one.

People in group B will stay on the antipsychotic medication that they are already taking.

The way we decide which group people who take part in the study will be put into is by chance. We have designed the study to ensure that everyone who takes part has an equal chance of being in group A.

You will be told which group you have been put into by a doctor or nurse. We will also let the Principal Investigator at the site know which group of the study you have been allocated to. To ensure that there are no outside influences on the results of the study, the researcher who will contact you for further study visits and maybe to invite you to the end of study interview, cannot know which study group you are in. They will remind you before you begin the study visits not to reveal the group you have been allocated to.

Study visits

At the beginning of the study we will gather some information from you e.g. your date of birth, gender, marital status and also complete questionnaires with you about your physical and mental health. We will ask about your social life and activity in the community. We will also ask if we can take some blood from you, about 1 teaspoon worth (5mls) so we can look at a particular hormone 'prolactin' in your blood. We want to find out if any changes in the level of this hormone have any effect on whether people benefit from the treatment they receive. If you do not want to give blood, you can still take part in the study. It will take just under 2 hours of your time to complete the questionnaires and give blood.

3 months: We will contact you after 3 months of study participation to check your contact details are current and ask you to complete a questionnaire about your sexual problems. This will take no more than 10 minutes of your time.

6 months: Following 6 months of study participation we will assess your physical and mental health again. We will ask you to complete questionnaires on your sexual problems. We will also ask if we can take some blood from you, about 1 teaspoon worth (5mls) so we can see if the hormone level we are interested in has changed over the course of the study. It will take just over 1.5 hours of your time to complete the questionnaires and give blood.

To help us complete some of the study questionnaires, with your permission we would like to check your medical records specifically hospital and community services you may have used and medication you may currently be taking or have previously taken. After you have completed the 6-month visit, we would like to check the same things again in your medical records until the study finishes.

End of study Interview

At the end of the study, we may ask if we can interview you to find out your experiences of taking part in the study. We are interested in people's views about the different stages of the study, including the study visits, being assigned to one of the two study groups and the impact of taking part in the study has had on your life. We are hoping to interview up to 24 people across the study. If you are invited to an interview, the researcher will audio-record the interview using a dictaphone. However, if you are not comfortable being recorded the researcher can make notes during the interview instead. The interview will take no longer than 60 minutes of your time to complete.

Further research

A further part of the REMEDY study will involve participants being asked if they would take part in longer term research. We would like to contact you again to check your contact details are correct and check on your long-term health by asking you some of the same questions we asked you during the study. We would also like to check your medical records to add to the information we already know about you. You would be given an Information Sheet detailing the additional research and a Consent Form. If you decided you did not want to take part in this additional research it would not affect your participation in the study.

Study interventions

Advice and support sessions

At the start of the study you will be offered two advice and support sessions with a doctor or nurse, which will typically last 30 minutes. You will be able to choose if you would like these sessions with a male or female doctor. In the first session, the doctor will discuss the sexual problems you are experiencing and provide you with advice and information on what might help. In the second session, the doctor will find out if the sexual advice and support you received during the first session has helped and give you more information if you need it.

If, during the advice and support sessions the doctor (or nurse) is made aware of any physical health problems that may be having an effect on sexual functioning, with your permission they will write to your GP informing them of the problem and asking them to follow-up with you.

Change of antipsychotic treatment

If you have been allocated to the group that will receive a change in your antipsychotic treatment, your doctor will make an appointment with you to discuss the three different antipsychotic drugs you can change to. The antipsychotic medications being assessed in this study (aripiprazole, quetipine and olanzapine) have been chosen because we think it is possible that they will cause fewer sexual problems. Once you and your doctor has chosen the right antipsychotic medication for you, the dose of your current antipsychotic medication will gradually be reduced and the new antipsychotic medication will be introduced over the course of one month.

6 What are the possible benefits of taking part?

It is possible that sexual problems will improve in some of the participants in the study but we cannot promise the study will help you. The information we get from this study should improve our understanding of sexual problems associated with antipsychotic medication.

7 What are the disadvantages of taking part?

If you decide to take part, one disadvantage is that you will be asked to give up some time to meet with a member of the research team over the 6 months for the study visits. We do not anticipate participants having a negative response to the advice and support sessions. Participants allocated to study group A may experience side effects changing to a new antipsychotic medication. During the study we will ask carefully about any side effects that have developed, and discuss these with you and how we can deal with them.

8 What happens when the research stops?

When your participation in the study finishes, you will continue to have access to the usual services delivering standard care. This will include continuing review of any medication you are taking. The advice and support sessions that have been offered during this study will not be available after the study has ended.

9 Will my taking part in the study be kept confidential?

If you take part, the information collected from you will be kept confidential. You will be given a unique study identification number which will appear on all study information including the responses to the sex questions and also the audio recording from the end of study interview, instead of your name, so that the information you provide or is collected about you will remain confidential. The information collected on a touch screen computer will be transferred and kept on a secure database after each study visit. If you take part in the end of study interview, the audio recording will be kept securely on a computer until the study has finished. The recording will then be securely sent to a professional transcription company where the interview will be written up and the recording deleted.

The blood samples we take from you will be destroyed after being tested and will not be used for any other purpose.

The Principal Investigator responsible for the study at your trust will keep a document that links your identification number and personal information, that will only be used for the purposes of identifying and contacting you. Health care research is sometimes monitored to ensure that is being

conducted satisfactorily and that the interests of those taking part are protected. Such monitoring will be organised by the regulators responsible for healthcare research, the sponsor (Imperial College London) and/or the NHS trusts responsible for your mental health service. These monitors will need to look at information collected for this research, which may include sections of your medical notes and research notes. No personal information is ever collected.

In the rare event that a person tells us something, which involves a risk to their safety or the safety of someone else, we would talk to them about how to manage this and encourage them to share this information with others involved in their treatment. We may also seek consent to discuss these concerns with others. We would normally only discuss these concerns if a person agrees to us doing this. However, if we judge that there was a major risk to safety we could be obliged to share this information without their agreement. Under these circumstances we would let the person know of our intention to pass on the information and why we were doing so.

If during the course of the study a member of your clinical team or a study researcher becomes concerned that you seem to be having difficulties understanding information and making decisions, they may decide it is in your best interests to leave the study. In the unlikely event this happens, we would still keep and use the data we have collected from you.

All research data will be stored securely for up to 10 years within the NHS Trust where the research is being conducted before being destroyed. The anonymised data which includes the information gathered on touch screen computers will be stored securely at Imperial College London for a period of 10 years before also being destroyed. Only authorised staff will have access to the research and anonymised data for the purposes of ensuring the quality of the study. In the event that a researcher wishes to replicate the study or elaborate on its findings, only anonymised data will be provided with prior permission from the Chief Investigator (Professor Mike Crawford).

Further privacy information

Imperial College London is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep identifiable information about you for 10 years after the completion of the study, until 2028.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information

http://www.imperial.ac.uk/admin-services/legal-services-office/data-protection/

Further information

1 What happens if I don't want to carry on with the study?

You can withdraw from the study at any time without giving a reason and this will not affect your entitlement to receive usual care offered by the trust. The information already collected will still be used.

2 What if there is a problem?

Imperial College London holds insurance policies which apply to this study. If you experience serious and enduring harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Professor Joe Reilly: joe.reilly@nhs.net) The normal National Health Service complaints mechanisms are also available to you; your local PALS can give you information [Freephone: 0800 052 0219 / Tel: 01642 283546 / Mobile: 077755 18086] or [tewv.pals@nhs.net]. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office.

3 Involvement of the General Practitioner/Family Doctor (GP)

We would like to let your GP know that you are taking part in the study. We will ask your permission to do this. You can however still take part in the study even if you ask us not to contact your GP.

4 What will happen to the results of the research study?

We will produce a summary of the results and post them on the study website www.remedystudy.co.uk. A message on our facebook page [**The Remedy Study**] and twitter account [**@REMEDYstudy**] will be posted when the results are available. We will ask you if you would like to be sent a copy of the results at the end of the study and you can choose how you would like to receive them. The results will also be published in scientific journals and presented at conferences.

The reports and presentations we write will not include personal details of the people who take part.

5 Who is organising the study?

The study is organised by Imperial College, Centre for Psychiatry. The only funding for this study comes from the Health Technology Assessment programme, which is part of the National Institute for Health Research.

6 Who has reviewed the study?

The Health Technology Assessment programme reviewed the study before they funded it. Like all research in the NHS, it has been 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 by the West Midlands-Solihull Research Ethics Committee.

7 Expenses and payments

If you do decide to take part, you will be offered a £10 voucher at the 3-month study visit and a £20 voucher upon completion of the 6-month study visit. In addition, any travel costs that you incur in the process of travelling to and from study visits will be reimbursed.

8 More details

If you would like further general information about research and clinical trials, the following websites may be helpful:

- INVOLVE promotes public involvement in the NHS, for more information please visit their website: http://invo.org.uk.

- The MRC Clinical Trials Unit provides advice for potential participants and questions that people may wish to ask researchers, for more information please visit their website: http://www.ctu.mrc.ac.uk/about_clinical_trials.aspx.

For information about this research study, please contact your PI Joe Reilly [joe.reilly@nhs.net] or a member of the local research team Alex Carne [alexandracarne@nhs.net]. These are also the people to contact if you have any concerns during the study.