Antidepressant for the prevention of DEPression following first episode Psychosis trial

ADEPP STUDY
PATIENT INFORMATION SHEET

Summary of the ADEPP study

- This study aims to find out if an antidepressant medication (sertraline) can help to prevent depression in people who have experienced a psychotic episode for the first time.
- Joining the study is voluntary and your participation should be freely given. Before you decide, we would like to give you information about why the research is being done and what it will involve.
- Please take time to read this information sheet fully. Feel free to talk to others about the study if you wish.
- You will have the opportunity to discuss the study with a member of the research team and there will be time to ask any questions you may have.

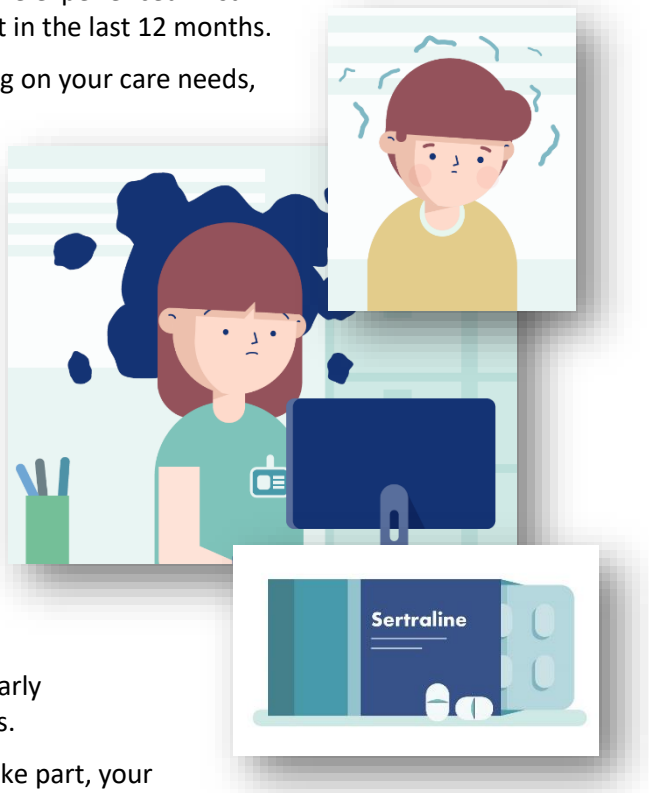
FUNDED BY NIHR | National Institute for Health Research

Why have I been invited?

We are inviting you to take part in this study because you have experienced First Episode Psychosis (FEP) and you have started your treatment in the last 12 months.

At the moment, the standard care for FEP will vary depending on your care needs, but this typically includes:

- A full assessment of your needs
- Medicine
- Psychological therapies
- Social, occupational and education interventions



The standard care helps to treat psychotic symptoms, but people may struggle to return to previous social and work roles. We think this may be related to depression experienced after FEP.

This study aims to find out if an antidepressant medication (sertraline) can reduce the risk of depression happening after FEP, and if preventing depression can improve recovery. This study will recruit 508 patients from Early Intervention in Psychosis Services (EIP) in England and Wales.

Taking part in this study is voluntary. If you decided not to take part, your normal care will not be affected in any way and you will continue to be cared for by your normal care team.

What would taking part involve?

If you do choose to take part in the trial, the research team will ask you to do the following over the next 12 months:

- Sign the main study consent form
- Complete baseline and follow up assessments, which involve answering a series of questions in the form of interviews and questionnaires at certain time-points (8 visits in total)
- Have a blood sample taken
- Take a medication (either sertraline or placebo with no active ingredient) every day for the next 6 months

A placebo is used to find out what effect the active treatment has, over any effect that may be caused because someone thinks they have had the active treatment or any additional monitoring. This is done in most good medication trials.

Neither you nor the researchers will be able to choose which medication you receive. Instead, you will be randomly put in either the sertraline group or placebo group by a computer. You will have a 50/50 chance of being put in either group. This is a method called

randomisation. Studies do this to make sure there is an equal chance of receiving either type of medication.

The random placing of participants into one of the two groups removes any bias from the researchers selecting the group as well as any bias from participants opting for a particular group themselves.

Neither you nor the research team will know your allocation until 6 months into the study This is a process called blinding and is done to reduce the likelihood of any changes seen from the study being a consequence of knowing the treatment group.

What will I be asked to do if I agree to participate in the study?

We will ask you to meet a member of the research team either at your hospital or at home. This first visit will last about two hours. If necessary, this visit and any other visits during the trial could also be done by phone or video call. The research team will explain the study to you and answer any questions you may have.

If you agree to take part, the research team will ask you sign a consent form. You should only do this if you are happy that you understand the study and want to take part.

We will collect further information from you and your medical notes. This will include a series of questions in the form of interviews and self-reported questionnaires. You will then be randomly allocated to a group and the research team will prescribe the medication you have been allocated to.

We will follow your progress every month for 6 months and then once at 12 months either at the hospital or at your home. During these visits, you will be asked to repeat some, if not all, of the questionnaires and interviews completed at the first visit. The visits at 1, 6 and 12 months may take around an hour to complete and the visits at 2-5 months may take around 30 minutes to complete.

At the 1 month visit we will also take a blood sample from you to check the level of sertraline in your blood. This will be 9ml, or less than 2 teaspoons. This sample will be sent to the University of Birmingham for analysis.

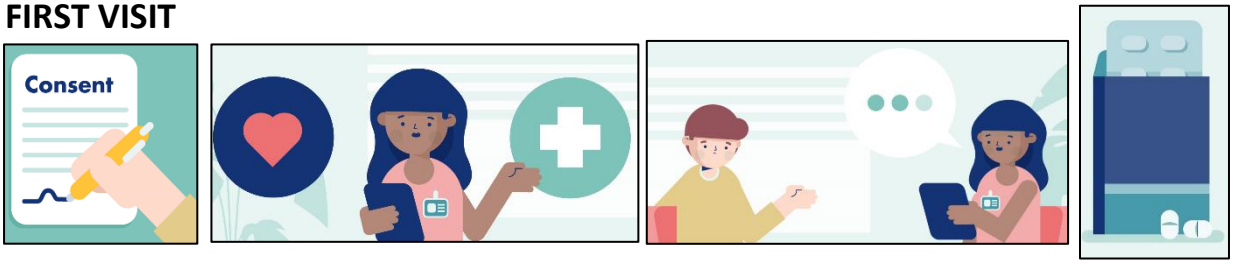
At the 6 month visit we will let you know which group you have been allocated to. Your care team will then decide with you whether to start (if in the placebo group), continue or stop (if in the sertraline group) sertraline.

Your study participation will end at the 12 month visit, after completing your final interviews and questionnaires.

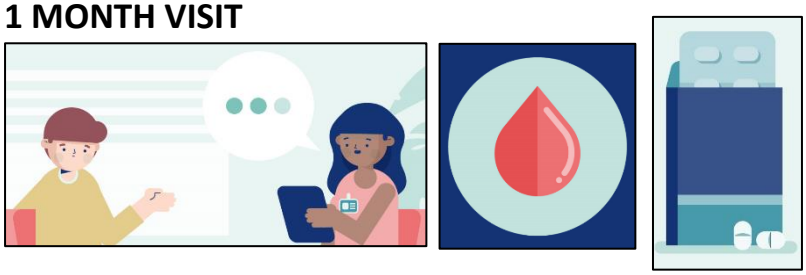
Figure 1 shows a summary of the visits:

Figure 1: Summary of the visits and time expected to take
First visit (takes ~2 hours)
• Sign main trial consent form • Complete interviews and self-reported questionnaires • Research team will collect your personal details, medical • history, and current medications • Collect and take allocated medication
1 month visit (takes ~1 hour)
• Review progress and medication with research team • Complete interviews and self-reported questionnaires • Collect and take allocated medication • Blood sample
2-5 month visits (takes ~30 mins)
• Review progress and medication with research team • Complete interviews and self-reported questionnaires • Collect and take allocated medication
6 month visit (takes ~1 hour)
• Review progress and medication with research team • Complete interviews and self-reported questionnaires • Your allocation will be revealed. Your doctor will decide with you whether to start (if in placebo group) or continue (if in sertraline group) with sertraline
12 month visit (takes ~1 hour)
• Review progress and medication with research team • Complete interviews and self-reported questionnaires
End of study participation

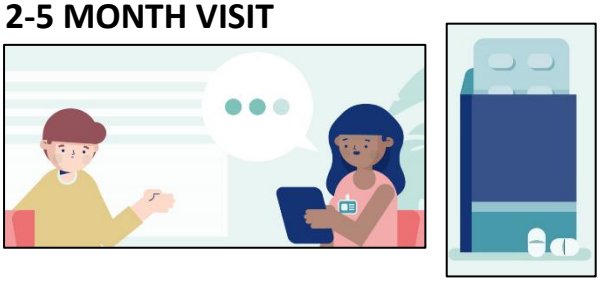
FIRST VISIT



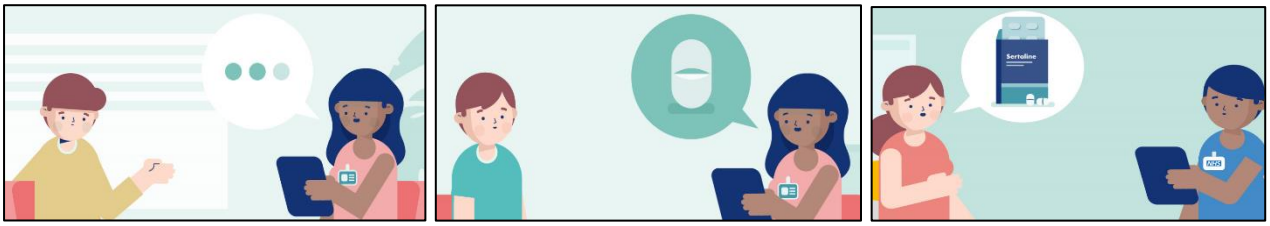
1 MONTH VISIT



2-5 MONTH VISIT



6 MONTH VISIT



12 MONTH VISIT

Is the treatment safe?

Sertraline is a type of antidepressant known as a selective serotonin reuptake inhibitor (SSRI). Sertraline 50mg is the standard dose for men and women age over 18 years. Sertraline has been shown to work for the treatment of moderate depression and for the prevention of depression in other conditions.

As with any drug, there are potential minor side effects but serious complications are very rare. The side effects of sertraline which can be difficult to tolerate in about 1 in 100 patients include: feeling sick, diarrhoea, anorexia, indigestion, tremor, dizziness, being unable to sleep, feeling sleepy,

increased sweating, dry mouth, and sexual dysfunction. Other less common side effects include headaches, vomiting and abnormal vision. We will carefully monitor any side effects and take action where needed. If you experience any side effects unexpectedly or have any concerns about side effects whilst taking the study medication, please speak to a member of the care team or research team immediately. If you become unwell during your treatment, seek medical help.

Sertraline is routinely used by women during pregnancy. However, female participants of childbearing potential will be asked to do a pregnancy test at screening (before taking part) and won't be able to take part if they are pregnant, or are planning to become pregnant. For female participants you will be required to use effective contraception during treatment and for a week after you stop study treatment.

If you or your partner do become pregnant during the trial please inform a member of the research team. With your permission, we will make sure your GP knows, although there are no special interventions needed for a pregnant patient taking sertraline.

How will I receive the medications?

The research team will supply your medication every month at a convenient location for you. This could be a routine clinic visit or home. You should take the study medication regularly as directed and continue **all other regular medications**.

What are the possible benefits of taking part?

This study will help us to find out if sertraline helps patients by preventing depression. Whilst there may be no immediate benefits to you, the aim is to improve the longer-term care for people with psychosis.

The research team will give you £40 as a thank you for your time and support after completing the first visit, and then £20 after the visits at 1, 6, and 12 months. We can also reimburse your travel expenses if you had to travel to these visits. Please speak to a member of the research team for more details.

What are the possible disadvantages and risks of taking part?

We do not know whether sertraline will help you manage your illness or not, which is why we are doing the study. Sertraline can have side effects that you might experience, but the research team will closely monitor you and your health. If you have any concerns during the study, please contact the research team. If you become unwell during your treatment, seek medical help and please let the research team know that you are okay.

What data will you be collecting?

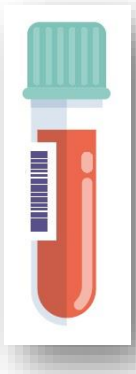
We will ask for your consent before collecting the data below. This is only for use in the study and we will try to make this as non-invasive as possible.

When	What data will be collected
First visit	• Name, date of birth and NHS number • Contact details: phone number and home address • Gender, ethnicity, height & weight • Medical history and pregnancy • Current medications you are taking • Results of medical tests, interviews or questionnaires completed during this visit • Review of ECG results (if taken within the last 12 months)
Follow up visits	• Current medications you are taking • Results of interviews or questionnaires completed during these visits
Study blood samples:	• These will be pseudonymised (labelled with a study number instead of your name) so they can only be linked back to you by key people in the research

	team. Two extra pseudonymised samples will also be stored for future use if you consent to this.

For information on how we will use your information, please see the relevant section in this Patient Information Sheet.

Optional sub-studies?



If you give specific consent we will ask you for an extra sample of blood when the study blood samples are taken. This will be 18ml, or less than 4 teaspoons. This additional blood sample will be sent for storage in a research tissue bank at the University of Birmingham for future ethically approved studies. These may include genetic studies, including those that investigate whether small DNA changes may be related to symptoms of psychosis, or more broader mental and physical ill health. Your data will not be linked in any identifiable way. They may be sent to the University of Cardiff to be analysed. This is optional and whether you choose to donate this blood sample will not affect you taking part in the ADEPP study. The blood test results are just for this study and will remain confidential: you will not be given the results of these tests.

What happens when the research study stops?

The follow up period is 12 months in this study and this will be alongside your routine visits as part of standard care, where possible. After the study visits finish, you will continue with your standard care as normal. You will be able to discuss with your doctor if your medication needs to change.

After the completion of the research study, the results of the study will be available on the ADEPP website. We will send a letter to all participants to give feedback on the results. Names and participant details will be kept confidential in the results.

What if I do not want to carry on?

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.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital. If you do not want this to happen, tell us and we will stop.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. For information on your rights in relation to your data, please see the relevant section in this Patient Information Sheet.

Data collected until withdrawal will be used, anonymously as part of the study outcomes.

What if something goes wrong?

We do not envisage any problems as a result of your participation in the study. However, all patients are covered for negligent harm according to NHS indemnity guidelines. If you have a concern about any aspect of this study, you should ask to speak to a member of the research team who will do their best to answer your questions. The University of Birmingham also arranges clinical research insurance which is renewed annually for all participants taking part in research conducted at the university.

If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you. Copies of these guidelines are available on request. If you wish to complain about how you have been treated during this study please contact Patient Advice and Liaison Service (PALS) at your local hospital. Contact details can be found on the end of this Patient Information Sheet or via this website: https://www.nhs.uk/common-health-questions/nhs-services-and-treatments/what-is-pals-patient-advice-and-liaison-service/

Who are we?

The study is sponsored by the University of Birmingham, which means the University of Birmingham has certain legal and ethical responsibilities for the study (RG_19-172). It is being coordinated by Birmingham Clinical Trials Unit (BCTU) and it is funded by the government through the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme (ref: NIHR127700). The chief investigator for the study is Professor Rachel Upthegrove.

Will my GP be informed of my involvement?

Yes, we will inform your GP of your participation in the study.

How have patients and the public been involved in this study?

Members of the University of Birmingham Patient and Public Involvement and Engagement group (Think4Brum) and Young Patient Advisory Group (YPAG) were involved in the design of the study. We have taken into account patient opinions on the frequency of visits and the tests or assessments that will be carried out. Patients are involved in the study as co-applicants, as chairs of Patient & Public Involvement (PPI) groups, as members of oversight committees, as co-researchers and in dissemination of information.

The conduct of the study is entirely in the hands of very experienced researchers and no PPI group or lay person has any access to your personal healthcare records or is able to influence your treatment.

Who has reviewed the study?

All research which takes part in the NHS is looked at by an independent group of people who protect patient interests. This group is called a Research Ethics Committee (REC). Before we asked any patients to join, the study was reviewed and approved by East Midlands - Leicester South Research Ethics Committee.

How will we use information about you?

We will need to use information from you and your medical records for this study. Please refer to 'What data will you be collecting' section for a list of information we will be collecting. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

If you consent to it, the researchers involved in ADEPP may, in the future, access electronic data from your central NHS records, for example through NHS Digital until the study ends in 5 years. This will give researchers information that is routinely collected during your visits to your GP and hospital, and lets researchers find out about your use of NHS services and about your health after the study has ended without contacting you further. To do this, we would send your name, gender, date of birth and NHS number with any request for information. You may withdraw your consent for researchers to access electronic data from your central NHS records this at any time without giving a reason by speaking with your consultant or the researcher who recruited you onto the study.

- 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.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records and your hospital. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

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

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- in the leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by contacting the University of Birmingham Data Protection Officer:
  Mrs Carolyn Pike OBE, The Data Protection Officer, Legal Services, The University of Birmingham, Edgbaston, Birmingham B15 2TT
  Email: dataprotection@contacts.bham.ac.uk Telephone: 0121 414 3916

How long will my personal data be kept?

Your data will be kept for 25 years once the study has finished. If you withdraw from the study, we will keep the information we have already obtained but, to safeguard your rights, we will use the minimum personally-identifiable information possible.

How will my personal data be kept secure?

The University of Birmingham takes great care to ensure that personal data is handled, stored and disposed of confidentially and securely. Our staff receive regular data protection training, and the University has put in place organisational and technical measures so that personal data is processed in accordance with the data protection principles set out in data protection law.

The University has an Information Security Management System based on ISO27001 with a range of controls covering the protection of personal information. Annual security awareness training is mandatory for staff and the University is accredited under the NHS Information Governance Toolkit, the Payment Card Industry Data Security Standard and is in the process of gaining Cyber Essentials Plus for defined services.

In relation to this study, any paper records will be kept in a locked filing cabinet, in a locked room in a building with controlled access. Any electronic data will be stored securely on our University of Birmingham servers that are password protected and access is user defined.

Who is the data controller?

The University of Birmingham, Edgbaston, Birmingham B15 2TT is the data controller for the personal data that we process in relation to you.

What data are we processing and for what purpose will we use it?

We will collect and process your personal data to conduct this study, as explained in the relevant section in this Participant Information Sheet.

What is our legal basis for processing your data?

The legal justification we have under data protection law for processing your personal data is that it is necessary for our research, which is a task we carry out in the public interest. This means that it is a legal requirement that the data we collect about you will only be used for research purposes to benefit public health. These data will not be used to make decisions about you.

What happens if new information becomes available?

If any new information becomes available we will review our study methods and if we think changes are needed a member of the research team will discuss them with you.

What will happen to the results of the research study?

We would like to publish our results in medical journals, to help other doctors to learn, and patients to benefit. If we are successful with this it will be in an anonymous manner so you cannot be identified.

Do you have any further questions?

Thank you for taking the time to read this information sheet and for considering taking part in this study. Should you require further information or would like to speak to someone about the study please contact:

< Contact Name > <Job Title>

<Telephone and/or E-mail>

If you would like to gain independent advice relating to trial participation you can contact the NHS Patient Advisory and Liaison Service (PALS):

Tel: *<insert local PALS contact number(s)>* Email: *<insert local PALS email address>*

Alternatively, you can contact the ADEPP trial team:

Address: ADEPP trial office, Birmingham Clinical Trials Unit, University of Birmingham, Edgbaston, B15 2TT.

Email: ADEPP@trials.bham.ac.uk

Tel: 0121 415 9125

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