<insert Trust Logo>

ADEPP Screening Patient Information Sheet

Invitation to take part in screening for a clinical trial to improve the way First Episode Psychosis is managed.

What is this about? We are inviting you to take part in screening for a clinical trial. This involves answering some questions about you and your health to see if you would be suitable to take part in the ADEPP study.

Taking part is voluntary. We have provided this information for you to consider carefully before you make your decision. Please feel free to discuss it with others. If there is anything that is not clear, do not hesitate to speak to a member of the research team or care team.

What is this trial for? First Episode Psychosis (FEP) is when a person experiences psychotic symptoms (such as hallucinations, unusual ideas, confusing thoughts and other symptoms) for the first time. Normal NHS care helps to treat the psychotic symptoms, but young people struggle to return to previous social and work roles, and we believe this may be related to depression experienced after FEP.

We want to find out if an antidepressant medication (sertraline) can reduce the risk of depression happening at all after FEP, and if preventing depression can improve recovery.

Why have I been invited? We are asking you to take part in this screening because you have been diagnosed with FEP and have started treatment in the last 12 months. The screening assessments are to see if you could be invited into the main study.

What will happen to me if I take part? We will ask you to sign a consent form to confirm you are happy to take part in screening. You will then be asked to answer some questions about you and your health. It should take no more than one hour. For female participants of childbearing potential a urine pregnancy test will be done as part of the screening process. This sample will only be used for the pregnancy test and will not be kept.

What will happen next? The answers you provide will help the research team to confirm whether you are eligible for the study. If you are eligible, we will provide you with the full information sheet (you can ask for one of these now, if you wish) and explain the main trial to you in more detail. If you are not eligible, you will continue with your standard care as normal.

Do I have to take part? No, this is entirely up to you. You do not have to take part if you do not want to and this will not affect the standard of care you receive. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. You will not be obliged to take part in the main trial if you are suitable for it and this will not affect the standard of care you receive. You are free to withdraw at any time and without giving a reason.

How will we use information about you? We will need to use information from you and from your medical records for this research project.

This information will include your NHS number, name 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.

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.

What are your choices about how your information is used? 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 you find out more about how your information is used? You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients
- our 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

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.

Who is organising and funding the research? 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 and is funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme (ref: NIHR127700).

Who can I contact for further information? <insert local contact details>