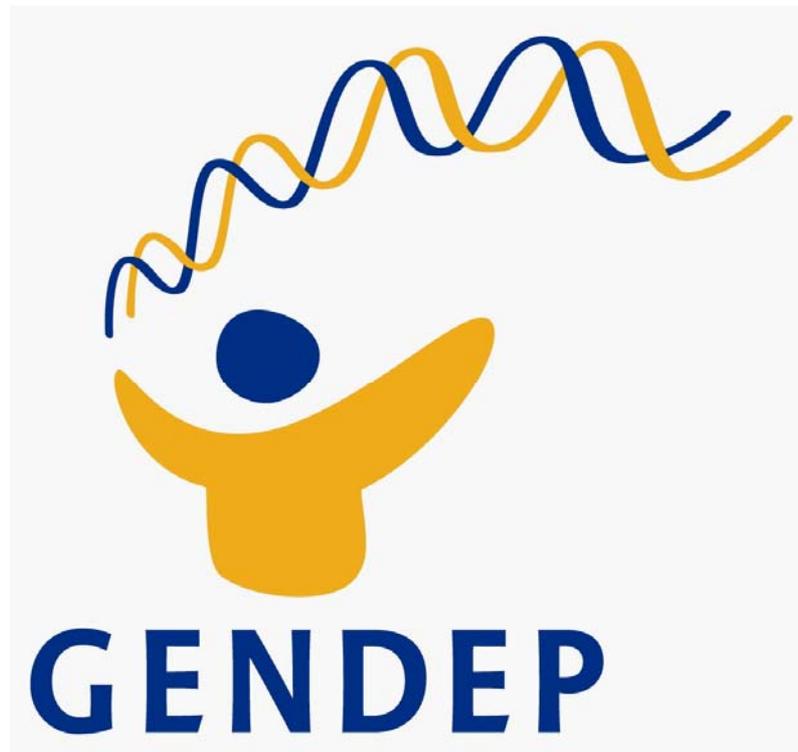


## Information Leaflet



### **A study for people with depression**

How your genes might affect how you respond to different medications for depression



# The GENDEP Study

## Introduction

This leaflet is about the GENDEP Study and gives you the information about the reasons for doing this project, and who the researchers are.

If you have any questions about the GENDEP study, then please call the FREEPHONE information line: 0800 542 4940.

## What is the GENDEP study about?

At any one time at least 1 in every 10 people is taking medication for depression. Although modern medicines for depression are very good, we still need to find better ways of choosing the right treatment for each person. While one antidepressant may get one person completely better, the same medication may not work at all for someone else. For others, the medication may cause difficult side effects so that they cannot continue taking it.

Recent research suggests that genes have an affect on how the body reacts to different medication for depression. We want to find out how genes affect depressed individual's reaction to medication, such as whether they get better or not, or experience troublesome side effects.

By understanding how genes can affect each person's response to medication, we will be able to develop tests so that doctors will know which treatment for depression is best for each individual.

## Who is doing the study?

GENDEP is large project that is funded by the European Union. We are working with 8 other sites throughout Europe including Croatia, France, Italy and Poland. In the UK, GENDEP is based at the Institute of Psychiatry, which is a world centre for research on mental health, and is part of King's College, London.

We are hoping that 1000 people will take part in GENDEP. This study only forms one part of the research into depression that is being funded by the European Union.

## Who can take part in GENDEP?

We are looking for people who are currently depressed to take part in the study. It does not matter if you are already taking medication for your depression – you can still take part. We will ask you to take one of the two kinds of depression medication used in the study.

## What am I being asked to do?

If you take part in GENDEP you will become an outpatient at the South London and Maudsley NHS Trust. This means that we will be responsible for your clinical care, while you are taking part in the study.

There are three parts to the study:

- 1) The assessment before you take the new medication
- 2) An ongoing weekly contact while you take the medication
- 3) A final review after taking the medication for 12 weeks

After this, your care will be returned to your GP or another medical professional who may provide support for you.



# The GENDEP Study

## The study in more detail

Any person taking part in GENDEP will be closely monitored by the researcher worker and psychiatrist.

We will be asking you take a specific medication for 12 weeks as treatment for your depression, which will either be Escitalopram or Nortriptyline. If you are already taking medication for depression, we will ask you to change from that antidepressant to the ones used in the study. There are three parts to the study:

### 1) *The assessment before you take the new medication*

Before you take the antidepressant, we will need to meet and to talk with you about the study. We want to make sure that you get all the information about the study before taking part.

We will also ask to you complete some questionnaires, and take part in an interview to tell us about your depression. We will also need to take a blood sample, which we will then use to get a DNA sample. The psychiatrist will then discuss the study medication with you. This beginning session should take about 2 hours to complete.

We are asking people who take part in GENDEP to come to the Institute of Psychiatry, which is based at Denmark Hill in South London. We are happy to speak to you about doing the interview at your home, if this would be easier.

### 2) *Ongoing weekly contact while you take the medication*

We are asking you to take the medication for 12 weeks. After you start taking the antidepressant, the research worker will contact you (usually by telephone) at a convenient time every week, to ask you some questions about how you are feeling and to find out if you are having any side effects from the medication.

After eight weeks the study researcher will see you again for another blood sample. We will also ask you to fill in some more questionnaires about your mood to see if there has been any change, and to find out about any side effects.

### 3) *Final review after the 12 weeks of taking the medication*

We would like to meet with you again after you have been taking the medication for 12 weeks, to do the same interview and questionnaires that you completed at the beginning. This way, we will be able to see if there has been any change in your mood. We will also take a final blood sample from you.

We will then hand the responsibility of your further care back to your doctor (GP). With your consent, we will tell the doctor about the study and the details of the medication you are taking. [If you were taking escitalopram as the study medication, then your doctor can continue your medication as an equivalent dose of citalopram.](#)



# The GENDEP Study

## Some questions you might have about GENDEP

There are lots of questions that you might have about GENDEP, and we have a few answers here to help you. When you meet the research worker and psychiatrist, you will have an opportunity to get more information. Alternatively, you can call the Freephone number: 0800 542 4940 to find out more information about the study.

*Why has GENDEP chosen Escitalopram and Nortriptyline as the two different antidepressant medications?*

These two antidepressants have been chosen because they work in quite different ways. Escitalopram increases the amount of **serotonin**, while Nortriptyline works on **noradrenaline**. These are two different chemicals in the brain, and we believe that depression is caused by a lack of either serotonin or noradrenaline (or sometimes both).

Some people find the antidepressants that affect serotonin to be helpful, and other people only get better taking medication that increases noradrenaline. At the moment doctors cannot tell who will be best helped by these two different antidepressant medications. This means that prescribing treatment for depression is often done with a quite bit of guesswork.

In this study we will look at how you respond to the antidepressant, and see if there is a link your genes. This will help us to find out whether a genetic test could predict your response to either of the two kinds of medication for depression.

*Who decides which medication I take?*

Both you and the psychiatrist will know which medicine you are taking – but this will be determined randomly (a bit like tossing a coin). Only the research worker will not be told – this will avoid any possibility of the interview being affected by this knowledge. We will use a computer program to decide whether you will take Escitalopram or Nortriptyline.

*Can I take part, even if I am already using antidepressants?*

We are expecting that a lot of people will already be taking medication for depression. You can still take part in the study, if you are willing to change on to either of the antidepressants used in the study. The psychiatrist from the study will give you advice about changing your medication.

For most people this will mean slowly reducing the dose of the medication you are already taking, and at the same time slowly increasing the dose of Escitalopram or Nortriptyline over a 4-week period. The psychiatrist will give you written instructions about how to do this. Also with your consent we will inform your doctor (GP).

*What happens if my depression does not get better with the medication given to me?*

While you are taking part in the study, the research worker will contact you each week to ask how you are feeling. If you tell us that you are not feeling any better, the research worker will let the research psychiatrist know, who will in turn contact you about increasing the dose.

If increasing the dose to the maximum still doesn't get you better we will offer you the opportunity to switch to the other antidepressant.



# The GENDEP Study

## Some questions you might have about GENDEP

*What are the main side effects of the two different depression medications?*

Unfortunately, all antidepressants have side effects and this is true of the medication we are using in the study.

Common side effects for Escitalopram include: stomach upsets (feeling sick), and headaches. Some people can also feel quite anxious and shaky for a few days when they first start taking Escitalopram but this usually wears off. We often suggest that patients take Escitalopram in the morning, as it can keep you awake at night if taken in the evening.

The main side effect of Nortriptyline is a dry mouth. Some people also feel quite sleepy when they've taken their medication so it's best to take it in the evening. Some people have found that when they start taking Nortriptyline they feel dizzy and faint when standing up too quickly after lying or sitting down. The simplest way to dealing with this is to take your time when changing your body position until the faint feeling passes.

Both of the medications used in the study might interfere with concentration when driving, especially when starting taking them. We always suggest that people are cautious about driving until they are used to the medication.

Each week, we will contact you and ask in detail about any side effects from taking antidepressant medication. However, if you are feel worried about any other symptoms that you think may be caused by the medication, then you should call our Freephone number: 0800 542 4940.

*What happens if I have bad side effects from the medication given to me?*

The research worker will be asking you, each week, for details about any side effects you might have been experiencing. If these side effects become bad, the psychiatrist will contact you about reducing the dose. However if this doesn't relieve the side effects, we will offer you the chance of switching to the other medication used in the study.

*How do I switch to the other medication?*

The psychiatrist will arrange to meet you to let you know how to switch the medication over a 4-week period. This will mean slowly reducing the first antidepressant before stopping, as you slowly increase the second. You will be given written details of how to do this. In addition we will ask your permission to let your GP know.

If you do change medication at any time in the study we will continue to contact you each week for 12 weeks from the time you start the second antidepressant. When you see the psychiatrist to switch medication, we will also need to take another blood sample to check the level of antidepressant.

*How do I get the medication?*

We will give you directly the appropriate medication for the study. This includes any smaller doses of different antidepressants that you might be switching from.



## The GENDEP Study

### Some questions you might have about GENDEP

#### *What if I decide I don't want to continue in the study?*

You are under no obligation to take part in GENDEP, and you can withdraw from the study at any time. However, we would really like to understand your reasons for not wanting to take part in the study and stopping taking the medication. This could give us some helpful information about these two different kinds of antidepressants.

This means that we would like to meet you and find out your reasons for not wanting to continue. We would also like to take another blood sample to measure the levels of antidepressant medication. We will need to let your GP know that we are no longer going to be helping you.

#### *What if I'm feeling bad and need to contact someone?*

Please call our team using our Freephone number: 0800-542 4940. There will be someone available during office hours (9am-5pm). Outside of those times you can leave a message and we will call you back on the next working day.

#### *What happens to the blood samples?*

Some of the blood that we take will be sent to our laboratory so that we can get a sample of your DNA - the building blocks of genes. We will store this sample to use in genetic research. We will also examine the level of antidepressants, as well as other proteins and chemicals in your blood.

Both the DNA and blood samples are coded so that neither your name nor any other personal information will appear on the container tube. This means that any samples will be kept anonymously. The information from any part of the study is strictly confidential and only members of the GENDEP research team will have access to it. This means that we will be unable to give you, or any other person, specific information about your DNA or genes.

#### *What happens to the information from the study?*

As your clinical care is under the auspices of the South London and Maudsley NHS Trust, there will be clinical notes about your treatment. This clinical information is highly confidential and only members of the clinical and research team will have access to this personal information.

Any information used for the research study will be kept strictly confidential and only the research team will have access to it. Only group information will be given in any published outcomes from the study, with no indication of any patient's identity. This means it will not be possible to identify any person when we publish the results of the study.

We will not be able to give you genetic information, as any DNA or blood sample is coded anonymously.

We will send you newsletters about the study to let know how the research is progressing and about some of the investigators who are leading the research teams in the UK & other countries.