antidepressants to prevent relapse in depression

Participant Information Sheet

We invite you to take part in a research study

- Before you decide whether to take part, it is important you understand why the research is being done and what it will involve.
- Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. Take time to decide whether or not you wish to take part.
- You are free to decide whether or not to take part in this research. If you choose not to take part, this will not affect the care you get from your GP.
- Ask us if there is anything that is not clear or if you would like more information.
- Thank you for reading this information sheet. If you decide to take part, please see the attached letter for details of what to do next.

Important things you need to know

- We want to find out, in people who have got better on antidepressants, if taking antidepressant medication long term can prevent worsening of depression.
- If you agree to take part in the research, you will be randomised to either carry on with your current medication or take an inactive placebo (a "dummy" pill).
- By completing questionnaires at the beginning and at 3, 6, 9, and 12 months we can find out if the antidepressants have been effective.
- You can stop taking part in the study at any time, without giving a reason.

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How to contact us

If you have any questions about this study please talk to:

Alison Burns
University of Bristol
Oakfield House, Oakfield Grove
Bristol BS8 2BN

Tel: 0117 3313342
Email: Antler-trial@bristol.ac.uk

Why we are doing this study

What are we studying?

Many people visit their General Practitioner (GP) with depression and are prescribed antidepressants. Some people continue taking antidepressants for months or years after they have improved in order to reduce the chance of a worsening of depression. We call this long term maintenance treatment and it is far more common than often realised, and may not be necessary in all cases. Doctors do not know if people on long term maintenance for more than 9 months are still benefiting from the treatment.

What do we hope to find out?

We want to find out if long term maintenance treatment for depression is effective. The results of the study will let doctors give better advice to people who have taken antidepressants for some time, about whether to continue with antidepressants or to stop the treatment. We hope around 500 people will agree to take part.

2 How the study works

How do we find out whether it is safe to come off antidepressants?

People who agree to take part in the study will be given study medication. This medication will either be your existing antidepressant (though the tablet will look different) or an identical placebo or "dummy" tablet that will not contain antidepressant. For those that start the placebo, the tablets for the first two months will contain a reducing amount of active antidepressant to lower the risk of withdrawal symptoms.

How is it decided who gets a drug and who gets a "dummy"?

A computer will choose which treatment you will receive – this is called 'randomisation'. It is a bit like rolling a dice to decide and it means you have an equal chance of being allocated either to your current medication or the placebo tablet.

The rest of this leaflet explains how you might be involved in our research study.

3 Why am I being asked to take part?

Your GP is involved in the study and thinks you may be suitable for the study as you have been taking antidepressants for at least nine months.

4 What will happen to me if I take part?

Enrolling you in the study

If you are interested in taking part you will need to post back a reply slip, **or** ask your GP to refer you into the trial (see the attached letter for more details on what to do next).

The researcher will then need to check whether you are eligible to take part in the study. To do this, they will send you a brief screening questionnaire by post. The questionnaire will ask about your symptoms and current medication for depression.

Not everyone who completes the screening questionnaire will be suitable to take part in the study, but we will contact you to let you know and thank you for returning the questionnaire.

Collecting information

If you are eligible to take part and you are happy to proceed with the study, the researcher will invite you to attend an appointment to talk about the study in more detail. The appointment will take about 1 hour and 30 minutes. The researcher will explain the study and answer any questions you may have. You do not have to enter the study unless you feel completely happy with what you are being asked to do.

The researcher will ask you to complete a consent form, and to answer some more questionnaires on paper and on a computer. The questions ask about you, your current symptoms, general health, and medication. Based on the answers you give, the researcher will tell you whether you are eligible to take part in the next stage of the study. If you are not eligible, or do not want to take part in the next stage of the trial, you will continue your usual care with your GP.

If your answers suggest you are suitable for the study, and you are willing to take part, you will then be randomised (allocated to one of the two study groups) and sent the study medication.

Follow up

If you take part in the study, the researcher will arrange 4 follow up visits at 3, 6, 9 and 12 months after your first meeting. The follow up meetings can take place at your home, your GP surgery or University buildings. You will choose the location. The follow up meetings at 3, 6, 9, and 12 months will take about 40 minutes; you will be asked to complete questions on paper or the computer and some computerised tasks like those you complete at the first appointment.

At the end of the study we will give you a short questionnaire about your experiences of taking part.

As part of the consent process, we will ask for your permission for us to have access to your medical notes to collect the number of consultations and prescriptions you have received. If you agree, any information we record will have your name and address removed so that you cannot be recognised from it.

5 How is taking part in the study different from usual GP care?

In usual care patients either continue to take the antidepressant medication or stop it and take nothing. In this study those who are being taken off the medication will be given the placebo instead, so they won't know whether they are still taking the antidepressant or not. This allows us to make a fair and accurate assessment of whether the antidepressants is still working.

6 What is the drug that is being tested?

The study is investigating the antidepressant treatment that you are already taking for long term maintenance. This will be citalopram, sertraline, fluoxetine, or mirtazapine.

What are the side effects?

The tablet will look different but the active ingredient will be the same, so the side effects of the tablets will be those that you may have already experienced from taking it already. A leaflet that comes with your medication will have detailed information on all possible side effects.

7 Possible benefits and disadvantages of taking part

What are the possible benefits of taking part in the trial?

Some people find it rewarding to take part in medical research, and appreciate the additional monitoring and contact with the researchers. The results of the study may improve treatment and increase understanding of depression for future patients even if you do not directly benefit from taking part.

What are the possible disadvantages and risks of taking part in the trial?

This is a randomised controlled trial therefore you cannot choose which treatment you receive. Your allocation will be determined by chance and neither you, your GP, nor the researchers you meet will know which treatment you are receiving.

Some people experience withdrawal symptoms when they stop their antidepressant. For those in the placebo group, we have introduced a period when the amount of antidepressant is gradually reduced so that withdrawal symptoms are uncommon.

If you get worse you may be advised to stop the study medication and then ask your GP for advice on further treatment. If you stop your medication, Your GP can find out which study treatment you have been given in order to give you the best advice.

You can stop taking the study medication at any time. We would ask you to discuss this with your GP (and let us know) so they can advise you and provide any future care. You should not stop the medication suddenly unless advised to do so by a doctor.

Your progress in the study will be monitored by the researchers including the local Principal Investigator who is a clinician. You can contact them on **0117 331 3342** with any questions about the study, your medication or anything else. You can still see your usual GP at any time with any health issues you may be worried about.

Whilst you are a participant in this study the "University of Bristol" will be responsible for all study procedures including the administration of the medication and subsequent follow up for the duration of the study.

Some of the assessment questions will ask about low mood and self-harm. Whilst most people do not mind answering these questions, some people may feel upset. You don't have to answer any questions you don't want to. The researcher will be able to offer support during the appointment if you are upset, but will also contact your usual GP if further support might be necessary.

8 More information about taking part

Do I have to take part?

It is up to you to decide whether or not to take part. We will describe the study and go through this information sheet with you. The standard or type of care you receive is not affected if you choose not to take part.

Will I receive any payment?

Although there is no travel expenses or other payment for taking part in the study, you will have an opportunity to win between £2 to £9 if you do a computerised task. You will be offered to complete the task at least 3 times in the course of the study and on average people win £3.50 each time.

What happens if new information becomes available during the course of the study?

Sometimes during a study, new information becomes available about the treatment being

studied. If this happens, the research team will tell you and discuss whether you want to continue in the study. If you decide to stop taking part in the study your usual GP care will continue. If you decide to continue in the study you may be asked to sign an updated consent form. If we think you should withdraw from the study, we will explain the reasons and arrange for your care to continue.

What happens if the study stops?

Very rarely a study is stopped early. If this happens, the reasons will be explained to you and arrangements made for your GP care to continue as usual.

What if there is a problem?

If you have a concern about any aspect of this study you should ask to speak to the researcher who will do their best to answer your questions.

If you are harmed by taking part, or if you are harmed due to someone's negligence, then you may be able to take legal action. If you suspect that the injury is the result of the Sponsor's (University College London) negligence then you may be able to claim compensation. After discussing with your local PI, Dr David Kessler, please make the claim in writing to Prof Glyn Lewis Glyn.Lewis@ucl.ac.uk.
He will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. Although you may have grounds for a legal action, you may have to pay your legal costs initially. Participants may also be able to claim compensation for injury caused by participation in this study without the need to prove negligence on the part of University College London or another party. You should discuss this possibility with your local Principal Investigator, Dr David Kessler, in the same way as above.

What will happen to information about me collected during the study?

All information will be held securely and in strict confidence. We keep the information we collect about you separately from your personal details and we can only link this information together with a secure code. Only authorised members of the research team will have access to your information. The research team will occasionally need to allow monitors from Regulatory Authorities to inspect the trial paperwork, in order to meet legal, ethical and safety requirements. All individuals who have access to data will be bound by strict data protection and confidentiality rules.

We will use the information we collect to look at how best to help people with depression. We will keep it for up to 5 years after the end of the study and then destroy your personal details so that they can no longer be linked to the information we have collected.

What will happen if I don't want to carry on with the study?

You can stop taking the study treatment at any time, but we would still like you complete the follow-up questionnaires so that we can monitor your progress. If you don't want to carry on with the study assessments, you can withdraw from the study at any time. The information already collected may still be used.

Involvement of your GP

We will tell your GP that you are taking part in the study. With your permission, we will inform them of your results on the initial screening questions we use to check if you are eligible to take part.

At the end of your involvement in the study, we will also send your GP information about your treatment allocation and ask you to see your GP for a review. This will help them to plan your ongoing care.

If we are worried that you are having thoughts about harming yourself or others, we will need to discuss this with your GP. We will of course discuss this with you. In rare situations, if you or someone else is in danger, we might have to contact your GP without your consent.

If you send us a questionnaire through the post and we are worried that you are having thoughts about harming yourself, we will let your GP know of our concerns.

What will happen to the results of the study?

When the study is completed, the results will be published in a medical journal so that doctors and other health care professionals can read the results. Your identity and personal details will be kept confidential. No named information about you will be published in any report about this study. We will also provide you with a summary of our findings from the study.

Who is organising and funding the study?

The study is funded by the NHS National Institute for Health Research. The study is also is supported by the NHS Primary Care Research Networks (PCRN).

Who has reviewed the study?

The study has been reviewed by the an independent group called a Research ethics Committee and the study has been given a favourable opinion by the NRES Committee Cambridge South Research Ethics Committee

9 Contact for further information

If you have any questions regarding the study or how you might be involved further contact information can be found below.

Local researcher

Alison Burns
University of Bristol
Oakfield House
Oakfield Grove
Bristol BS8 2BN

Tel: 0117 331 3342
Email: Antler-trial@bristol.ac.uk

Chief Investigator

Professor Glyn Lewis
0207 679 9711
Glyn.Lewis@ucl.ac.uk

Study Manager

Larisa Duffy
0207 679 9282
larisa.duffy@ucl.ac.uk

Thank you for taking the time to consider taking part in this study.