

Trial to examine the clinical and cost effectiveness of different approaches in the treatment of depression.

You are being invited to take part in a research study for people with symptoms of depression. Before you decide whether you would like to join in, it is important for you to understand why the research is being done and what it involves. Please read the following and feel free to discuss it with friends and relatives. You may ask the researcher when you see him/her if anything is unclear. You can also contact the organisers of the study if you require more information - please see page 3 for contact details.

Why are we doing the study and what is it about?

Depression is a common condition and low mood impairs our quality of life and can lead to difficulty with everyday activities. Psychological or “talking” therapies may be helpful, but we are not certain what forms of such treatment are of most benefit. We plan to study how older people can use psychological treatments and which sort of treatment may be most helpful for them. We will offer people identified with depression one of three possibilities: (1) a specific treatment tackling thoughts and feelings known as Cognitive Behaviour Therapy, (2) a general talking treatment, or (3) usual GP care.

Why have I been chosen?

We are approaching all people registered at this practice who are aged 65 years and over and who may have depression.

Do I have to take part?

No, it is up to you. If you do decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form. **You are free to withdraw at any time after having agreed to take part**, without giving a reason. This will not affect the care you receive from your GP.

What will happen to me if I decide to take part?

Providing you are suitable for the study you will be placed in one of three groups. Those in group 1 will be given Cognitive Behaviour Therapy (CBT) from a therapist. This treatment teaches you to challenge the negative thinking styles and behaviours often associated with depression. People will be offered up to 12 sessions of fifty minutes each to take place over 14 weeks. Those in group 2 will be asked to see a therapist and offered up to 12 sessions of fifty minutes (again each over 14 weeks) to discuss anything you feel may be helpful. Those in group 3 will be referred to your GP for usual care. Generally you will be seen in the surgery, but in some circumstances provision will be made for you to be seen in your own home. Everyone in all three groups will always have access to usual GP care.

Everyone taking part will be asked to complete questionnaires at the beginning and end of the study. All the questionnaires and information given by you will be confidential and coded to make it anonymous, so that your name is not on it. The

researcher will help you with questionnaires, which will cover areas like: how low your mood gets; how depression has affected your social life; and, your opinions about the treatment

If the people conducting the study or running the sessions have serious concerns about your health, they will contact your GP. No other information from the study will be given about you to your GP.

How do you decide which group I am in?

This study is what we call a 'randomised trial'. Because it is very important to evaluate ALL treatment options, you will be allocated randomly by computer to one of these three groups. Once allocated you will not be able to change groups. The computer has no information about people, so selection is by chance. You will have a one-in-three chance of being in one of the groups. Once allocated you will not be able to change groups, although we would like to know which group you would have preferred.

What do I have to do?

If you are in groups 1 or 2 you will have the opportunity to have regular meetings with the therapist. Up to 12 sessions of 50 minutes will be available, but if you feel you are better you may not need all the sessions. If you are chosen to receive treatment as usual through your GP, we will review your depression at 14 weeks, to see whether things have improved, and again at ten months. If you are in this study you will not have to change your medication at all and your usual treatment will not be affected in any way.

What are the possible disadvantages of taking part?

The only potential disadvantage is that you have to have enough time available for treatment and you will also have to complete some questionnaires. Your treatment as usual will not be affected in any way. Travel expenses and transport are not provided, but this would be true of any person receiving such therapy in a GP setting.

What are the possible benefits of taking part?

There are many advantages of taking part. On a personal level, your depression will have been correctly diagnosed and brought to the attention of your GP. You may receive a treatment over and above that usually received. On a general level you will be helping researchers to collect more information about the benefits of different treatments for depression in older people, so that further research in a very important area can be done. In the long term, you will therefore be helping other people suffering from a similar condition.

If you have any concerns during the study you should approach the Research Fellow, Deborah Haworth, at the Department of Mental Health Sciences, Royal Free and University College Medical School, on 020 7472 6839 (direct line). The researcher will telephone you back to discuss how best to proceed.

The PPP Foundation, a charitable organisation, who are funding this study, would also be sympathetic to any complaints in cases where people may have suffered harm as a result of being in the study, but where there is no suggestion of negligence. If there is a concern about personal negligence, you may have grounds for legal action, but you may have to pay for this.

Will my taking part in this study be kept confidential?

Yes. All information collected about you during the study will be kept strictly confidential and in accordance with the Data Protection Act 1998. Any information about you that leaves the surgery will have your name and address removed and will be given a special code number. This code number will also be used to identify the questionnaires which you are sent and the key to the code will be kept in a locked cabinet at the research centre.

What happens to the results of the study?

None of the people taking part in the study will be identified in reports or publications. The study results will be presented at conferences and published in relevant medical journals. Copies of publications can be obtained at the end of the study from the study organisers and sent to any study participants and GPs who wish to have them.

Who is organising and funding the research?

This study is organised by the Department of Mental Health Sciences at the Royal Free & University College Medical School, London. It has received funding from the PPP Foundation, a charitable organisation and also ethical approval from local ethical committees.

Contact for further information

This study is being run in the practice by Deborah Haworth (tel: 020 7472 6839) and at the Royal Free Medical School by Dr Marc Serfaty (tel: 020-7830-2293). Please telephone either person if there is any further information you would like or if you have any questions you would like answered. They will take your number and phone you back.

If you agree to take part in this trial, you will be given a copy of this information sheet and a signed consent form to keep.

Thank you for taking the time to read this.