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THE PROMDEP STUDY

A study to see if giving personal feedback to patients with depression would be useful. Can you help?

We would like you to consider taking part in a study.

We would like your help please with a research study which is testing ways of helping people who are being seen with depression become more involved in their own care, by reporting on how they are feeling.

Before you decide whether to take part, it is important that you understand why the study is being done, and what you will be asked to do.

Please take time to read through this leaflet carefully, and take time to decide whether you want to take part.

It is up to you whether you want to take part or not. The care you receive from your GP won't change if you say no.

Please contact us if you have any questions or would like more information.

The PROMDEP Study: what is it about?

We would like to see whether giving personal feedback to people with depression can help them to get better more quickly.

The idea is to involve people more in their own care, by asking them to fill out a set of "patient reported outcome measures", or "PROMs".

These include questions about your symptoms, life problems, how you're managing your daily activities, and about your quality of life.

The results of the questionnaires would be used in an appointment with the doctors and nurses. Using PROMs could help people understand if they are getting better, and help doctors and nurses make changes to treatment to

suit their particular needs.

The PROMDEP study aims to check whether PROMs work in depression.

In the study, some people will receive their usual care from their doctor. Others will be asked to complete the PROMs and take them to their next doctor's appointment, as well as receiving usual care. These people will be selected at random.

All people taking part in the study will also be asked to meet with a researcher from the University of Southampton 3 times over the 6 month period, to complete some more questionnaires, to see how your mood changes over time.

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Thank you for taking time to read about the PROMDEP study

1. Why are we doing this study?

We are looking to see whether PROMs work for people with depression to get better more quickly. Psychology and psychiatry specialists sometimes use PROMs with people and it has been shown to be helpful, but we don't know if it works in general practice.

This is a feasibility study which means we are looking to see whether the way we run our study works, as well as seeing what patients and their doctors and nurses think about the study. This will be useful for when we run a larger study in the future.

2. Why am I being asked to take part?

You have been to see your doctor for low mood or depression.

Your doctor will have either told you about this study during your appointment, or the practice has run a search of their patient records and identified you as being eligible to take part.

We are looking to recruit 48 patients from practices around the Hampshire area. Your practice is helping us to recruit people to the study.

It is entirely up to you if you want to take part or not. Even if you decide to take part, you can decide to stop at any time, without giving a reason. This will not affect the care you receive from your doctor or nurse.

3. What do I need to know about how PROMs are being tested?

PROMDEP is testing if PROMs work or not by putting patients into one of two groups:

1: People will use PROMs during their appointments with their doctor or nurse, as well as receiving usual care.

2: People will receive usual care from their doctor or nurse, and won't use PROMs.

This means that only half of the patients recruited to the study will be able to use PROMs. Whether you use PROMs or not is completely by chance, and you will be told which group you are in once you have met with one of the research team.

All people involved in the study will still be given treatment and care as usual by their doctor or nurse. These may be antidepressants (medicines for depression) or psychological treatment (talking treatment), which are well known treatments provided by the NHS. The only difference is that people in the PROMs group may use the answers from their questionnaires to make decisions about their treatment.

4. What will I need to do if I take part?

If you decide to take part, one of the research team will phone you to introduce themselves and ask whether you are still interested in taking part in the study.

If you are, the researcher will arrange a time and place to meet you, and when it suits you. We can meet with you at either your GP Surgery or at your home.

There are 3 times when you will meet with the researcher, if you decide to take part:

- 1: initial meeting (approximately 45 minutes)**
- 2: after 3 months (approximately 20 minutes)**
- 3: after 6 months (approximately 50 minutes)**

You will be asked to complete questionnaires about your education, employment, past history of depression, symptoms of depression and anxiety, quality of life, personal life problems, work, and home life.

Option: Interview (approximately 30 minutes)

We are interested to hear about your opinions of the study in terms of how it was run, and whether you found the PROMs useful, if you used them with your doctor or nurse. You will be asked if you would like to take part in an interview with one of our researchers at the end of your 6 month appointment, and if you do, we will then arrange a time and place to meet to have the interview.

5. What are the benefits and disadvantages of taking part?

As we are testing whether PROMs work or not, we do not know whether your treatment will be improved.

You will have to give your time to be seen by one of the research team three times (four if you want to take part in the interview). We will do our best to meet at a time and place that is convenient for you.

There may be some questions that you may find sensitive or difficult to answer. You are not under any pressure to answer questions if you don't want to.

6. Will taking part in the study be confidential?

Yes. Any personal contact details will only be accessible by the research team and not passed onto any other people or organisations.

The only people outside of the research team who will know you are taking part in the study are your doctor or nurse at your GP surgery.

When we write up the results, no data that can identify you will be used.

7. What will happen to the results of PROMDEP?

We hope to publish our results in a scientific journal.

We will not include any personal information about you.

We will also send you a report of the results for your information.

8. Who is organising and funding the research?

The study is being run by researchers from the University of Southampton.

The study is being funded by the National Institute of Health Research School for Primary Care Research, which is funded by the UK Government.

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This study has been approved by NRES Committee South Central– Oxford A (reference 14/SC/1067).

9. What if there is a problem?

If you are worried about the way the study is being run, then please get in touch with one of the research team (details below).

You may also contact Barbara Halliday, Director of Legal Services at the University of Southampton (email rgoinfo@soton.ac.uk or telephone 02380 595058).

If you remain unhappy and wish to complain formally you can do this through the NHS complaints procedure. Details are available from your own practice.

10. What do I do now?

Having read this leaflet, you may like to take part, or would prefer not to.

Yes, I would like to take part:

Please get in touch with one of the research team by telephone call, email, or returning the reply slip in the FREEPOST envelope included in this pack. You do not have to pay for postage.

All contact details are on the back of this leaflet.

Please note, completing this form does not mean you are committed to taking part. This is just for you to say that you would like to meet with one of the researchers to find out more.

No, I don't want to take part:

If you do not want to take part in PROMDEP, that's fine. However it would be useful for us if you could return the reply slip in the FREEPOST envelope saying why you are not interested. This will help us understand why people are not interested in taking part in this type of research. You do not need to include your name and we will not contact you any further.