All research in the NHS is looked at by an independent group of people, called a National Research Ethics Committee (NRES). This study has been approved by NRES Committee: West of Scotland REC 5.

10. 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 the Research Governance Office 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 GP practice.

You may also contact your local Patient Advice and Liaison Service (PALS). PALS has been introduced to ensure that the NHS listens to patients, their relatives, carers and friends, and answers their questions and resolves their concerns as quickly as possible. Your local PALS service can be found at The Royal South Hants Hospital (Tel: 023 8120 8498, Email: patientsupportservices@uhs.nhs.uk, address: Brintons Terrace, Southampton, Hampshire, SO14 0YG).

11. 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 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.

WAYS TO GET IN TOUCH:

Email:

TBC

Telephone:

Study Coordinator: TBC

FREEPOST Address (no stamp required)

PROMDEP Study
FREEPOST TBC

Thank you for taking time to read about the PROMDEP study

THE PROMDEP STUDY

A study to see if giving personal feedback to patients with depression, or low mood, 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, or low mood, become more involved in their own care, by reporting to their GP or nurse on how they are feeling, using questionnaire measures of their symptoms.

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, or low mood, 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 "patient reported outcome measure", or "PROM".

This includes questions about your symptoms, and how you're managing your daily activities.

The results of the questionnaire would be used in an appointment with your doctor or nurse. Using a PROM 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 a questionnaire PROM works in depression, or low mood.

In the study, some people will receive their usual care from their doctor. Others will be asked to complete the PROM and take it with 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 Universities of Southampton, Liverpool, or UCL, three times over the six month period, to complete some more questionnaires, to see how their mood changes over time.

Contents

UNIVERSITY OF Southampton
UNIVERSITY OF LIVERPOOL
UCL

IRAS Ref no: 250225

1. Why are we doing this study?

We are looking to see whether PROMs work for people with depression, or low mood, 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 randomised controlled trial, which means we are allocating half the patients at random to use the PROMs, see whether their depression benefits, as well as seeing what patients and their doctors and nurses think about the PROMs. If they prove useful we will try and roll out their use across the NHS.

2. Why am I being asked to take part?

You have been to see your doctor or nurse recently, for depression, or low mood. 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 676 patients from practices around Southampton, Liverpool, University College London, and surrounding areas. 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 at random 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 after you have met with one of the research team and agreed to take part.

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 (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 help their doctors or nurses 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, for 60-90 minutes each time, if you decide to take part:

1: *initial meeting* 2: *after 3 months* 3: *after 6 months*

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

Option: Interview *(approximately 30 to 60 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 additional 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. After the study ends it will be up to you and your doctor whether you continue to use PROMs.

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 details will only be accessible by the research team and not passed onto any other people or organisations. The only exception would be if interviews with you revealed any risk of harm to you or others, when this information would be shared with your GP. The only people outside of the research team who will know you are taking part in the study are your doctor or nurse. When we write up the results, no data that can identify you will be used.

7. How will you use my information?

The University of Southampton is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information by contacting the Trial Coordinator, TBC email: TBC, Tel: TBC

GP practices will collect information from you and your medical records for this research study in accordance with our instructions. The Universities of Southampton, Liverpool, and UCL London will use your name, and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the University of Southampton and regulatory organisations may look at your medical and research records to check the accuracy of the research study. GP practices will pass these details to the University of Southampton along with the information collected from you and/or your medical records.

The only people in University of Southampton who will have access to information that identifies you will be people who need to contact you as part of the intervention or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details. The University will keep identifiable information about you from this study for 10 years after the study has finished.

8. 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.

9. Who is organising and funding the research?

The study is being run by the Universities of Southampton, Liverpool, and UCL, and funded by the National Institute for Health Research.The study is being funded by the National Institute of Health Research, which is funded by the UK Government.