Your invitation to participate in a research study

Can you help?

We would like to invite you to take part in our research study. Before you decide, it is important for you to understand why the study is being done and what it will involve. Please take time to read this information sheet carefully and discuss it with your family or friends if you wish. Ask us if there is anything that is not clear or if you would like help with completing the forms – our contact details are given at the end of this leaflet.

What is the purpose of the study?

There may be times in your life when you have felt fed-up or miserable, these feelings usually pass after a few days. However, sometimes they can last for longer or they could go away but then re-appear again and again. They may also start interfering with your everyday life. These feelings are important and as researchers we use the term “mental wellbeing” to cover a wide range of these thoughts and feelings.

As researchers we have found that mental wellbeing can be characterised by a number of different elements such as feeling positive or miserable, happy or sad, feeling motivated or fed-up, calm or anxious, having a good nights sleep or sleeping poorly; feeling energised or slowed down; spending time with friends or avoiding company. How you feel in these parts of your life contributes to your mental wellbeing.

In this study, we would like to find out whether a new method of delivering care (Collaborative Care) will help to improve mental wellbeing amongst those over the age of 65. We will compare care people already receive from their GP (Usual Care) with collaborative care plus usual GP care.

Why have I been approached?

A number of local GP practices are supporting this study by writing to patients aged over 65 and registered with their practice. Your practice has identified you as someone who is over 65 and potentially eligible to take part in the study if you choose to do so.

Do I have to take part?

No, you have the choice to take part or not. This information sheet provides you with details of all the different parts of the study. If you would like more information then please feel free to contact us, our details are at the end of this leaflet. If you want to take part please keep this information sheet. You will be asked to sign a consent form, a copy will be returned for you to keep. If you take part you are still free to withdraw at any time, without giving a reason. Your decision to withdraw, or not take part, will not affect the standard of care you receive.

Expenses and payments

Unfortunately, we are not able to offer any expenses or payments to patients who participate in the study.

What will be involved if I agree to take part in the study?

If you agree to take part in the study you will be asked to complete some questionnaires about yourself to be returned to us in the prepaid envelopes provided. You may also receive a telephone call from one of our researcher to ask you to complete another short questionnaire over the telephone. We will then send another set of questionnaires to you 4, 12 and 18 months later for you to complete.

In addition, we may contact you to ask if you would like to take part in an interview with one of our research team to discuss your views about mental wellbeing or the new method of delivering care. During the study we will request information from your GP and from local

hospitals about the medication you are taking and to find out what NHS services you have used while participating in the study.

The study results will then be written up and published, a summary of which will be made available to you.

What will happen if I agree to participate in the study?

We don't know if collaborative care is any better than the care that is already offered by your GP to improve mental wellbeing. In order to see if there is a difference we need to compare these two methods of delivering care – this is called a 'trial'. Once you have returned some questionnaires to us, we will look through the questions on mental wellbeing to find out who is eligible to take part in the trial.

If you are eligible to take part in the trial you will be allocated to either the collaborative care group or the usual care group. This allocation will be done according to the play of chance (randomly), like using the toss of a coin, to decide which group you will be in.

What will being in the collaborative care group involve?

Collaborative care is a relatively new way of delivering care to improve mental wellbeing for those over the age of 65. Patients in this group will be assigned a specialist health worker, we call them Case Managers, who will work closely with you and other health professionals to deliver care to help improve your mental wellbeing.

Your case manager will contact you to set up a convenient day and time to meet with you in the first instance, after this you will have weekly contact for up to 10 weeks. The contact you have will either be face to face or by telephone. During your weekly contact your case manager will discuss a range of issues with you, *e.g.* how you have been feeling since your last contact and address any negative feelings you have had. Each contact will last up to 1 hour, and at the end of each contact session you and your case manager may set some activities to try before your next contact session.

What will happen if I am randomly assigned to the usual care group?

If you are allocated to the usual care group your normal GP care will continue as usual. We

would still ask you to complete and return the questionnaires mentioned above. Participants in this group play a very valuable part in the study. The information they provide enables us to measure whether the treatment works by comparing the collaborative care and usual care groups. It is useful for us to have lots of different kinds of people taking part in the study.

What will happen if I am not eligible to participate in the trial?

If you are found not to be eligible for the trial, this means your symptoms of low mood or depression are not at the level we need for this study. You will not be randomly allocated to either the collaborative care or usual care group. Your involvement in the trial will finish at this point. The care you normally receive from your GP will continue as usual.

What are the possible benefits of taking part in this study?

We cannot promise that taking part in this study will help you, but the information we get from this study will help improve the treatment of people with poor mental wellbeing. Collaborative care has been officially recommended by the government for use in the NHS, but not all patients are able to receive this form of treatment. By participating in this study you may get access to this treatment which may not be available to your GP practice or area.

What are the possible disadvantages?

Taking part in this study will involve some of your time to complete questionnaires. If you are randomly allocated to the collaborative care group you will be contacted by a case manager over 8-10 weeks for up to 1 hour each time. After each contact you may have some activities to try before your next contact date. We cannot think of any other disadvantages.

Will the information in the study be confidential?

Any information you provide us with will be treated in confidence. We will store all information securely. Your name will not be mentioned in any publications arising from the study, and we will ensure that individuals cannot be identified from details in reports of the study results. Medical information will be checked each year for a minimum of 2 years, but will not be made available to anyone not involved in the study.

Will I be approached about taking part in any other studies?

If you agree to take part in this research, you may be invited to join other research studies on mental wellbeing being carried out by researchers in the CASPER team and their colleagues. You do not have to take part in any related studies, and will be sent more information about them before you decide.

Will my GP be involved?

We will inform your GP if you agree to participate in this research. We will also contact your GP if we have any concerns about your health during your participation.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the study co-ordinator who will do their best to answer your questions, their details are at the end of this leaflet. If you do not want to speak to the study co-ordinator you can contact the local principal investigator ([PI name and contact telephone]) or the chief investigator, Professor Simon Gilbody (telephone number: [redacted], email: [redacted]).

While we anticipate no harm or distress to anyone as a result of this study it is important to state that there are no special compensation arrangements. If you are harmed due to someone's negligence, then you have ground for legal action but you may have to pay for it. Regardless of this if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you.

Yes, I would like to take part in the study – what do I need to do now?

Please complete and sign the enclosed yellow consent form and background information form and return them in the prepaid envelope provided. If you need any help with completing the forms, please phone us and we'll be happy to help. We will write to you again in a few weeks time to ask you to complete some simple questionnaires. If you have decided to participate in the study, we will let you and your GP know how you are involved in the study.

I'm not sure about taking part – where can I get more information about the study?

We would be very pleased to answer any questions you may have. Please contact [name]the study co-ordinator, on [local co-ordinator's phone number].

No, I do not wish to take part in the study – what do I need to do now?

Please complete the enclosed blue 'decline' form and background information form and return them in the prepaid envelope provided. **We will not be able to identify you from these forms, and we will not contact you again.** We will use the anonymous information you provide to help us see if there are any differences between those who agree to take part and those who decline.

Is there anyone else I can talk to about the study?

For further general information about research please contact INVOLVE (**tel:** [redacted]).
For further general information about mental wellbeing please contact Mind (**tel:** [redacted])

How can I find out about the results of the study?

This study is due to finish in the summer of 2015. All patients who have consented to take part in the research will be sent a summary of the results. If you decide not to take part in the study but would like to receive a copy of the results you can contact your GP practice or us directly, our details are at the end of this leaflet.

Who is involved in organising and funding this study?

This study is being organised by the University of York, the University of Leeds, Durham and Tees, Esk and Wear Valleys PCTs, Northumberland, Tyne & Wear NHS Foundation Trust, Northumberland Care Trust and Newcastle Primary Care Trust. The research has been funded by the Department of Health, National Institute of Health Research Health Technology Assessment programme. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This research has been reviewed and approved by Leeds East Research Ethics Committee.

Thank you for reading this information sheet

If you require any further information please contact us. A friend or relative may speak to us on your behalf if you wish. There is an answering machine available 24 hours a day, so please leave a message and one of the research team will contact you as soon as possible. The CASPER study also has a website at http://www.casperstudy.org.uk/home.htm

Contact details:-

Study co-ordinator: [local name]

Tel: [local phone number]

Address: [local study centre address]