CASPER

Your invitation to take part in a research study

Can you help?

We would like to invite you to take part in our research study. It is important for you to understand why the study is being done and what taking part involves, before you decide. Please read this information sheet carefully and discuss it with your family or friends if you want to. There may be something which needs to be made clearer, or perhaps you would like help to complete the forms. If so, please call us – our contact details are given at the end of this leaflet.

What is the purpose of the study?

This study is trying to find out more about the physical and mental health of people aged 65 and over. It is important to see if a new and different way of providing care is a better way of helping you than the care GPs usually give you. The study results may help us make choices about how to provide care to people who are feeling depressed or not feeling their best.

The way that people feel can affect many other parts of their life. Feeling low is often linked to other things like sleeping badly, not wanting to see people, having no motivation to do anything and not seeing a future – to name a few. As people get older they often have to deal with physical health problems and long-term conditions. Many have to cope with the loss of loved ones or loss of their job or role in society. Not being able to move about so freely anymore can lead to loss of independence and feelings of being isolated and lonely. Any of these different things can affect how people feel, and one thing on top of another can in some cases lead people to feelings of hopelessness and despair.

We are trying to learn more about the health and wellbeing of older adults to try to improve services and treat people as a whole person.

Why have you been approached?

A number of local GP practices are supporting this study. They are writing to patients who are 65 and over registered with their practice. Your practice has identified you as someone who may be suitable to take part.

Do you have to take part?

No, it is up to you to choose whether to take part or not. This information sheet explains all the different parts of the study. Please feel free to contact us if you would like more information, our details are at the end of this leaflet. You will be asked to sign a consent form if you decide to take part. We will send you a copy for you to keep. Please keep this information sheet as well. Even if you consent to take part you are still free to stop at any time without giving a reason. The standard of care you get from your GP won't change if you decide not to take part, or if you decide to stop once you've started.

Expenses and payments

We will pay for all postage but we are not able to offer any expenses or payments to those who take part in the study.

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

You will be asked to complete a questionnaire about yourself. You will send it back to us in the stamped addressed envelope provided. You may also receive a telephone call from one of our research team to ask you a few more questions over the telephone. You will then be sent a questionnaire: after 4 months, 12 months and 18 months – to be filled in and sent back in addressed envelopes. No stamps required. You may be asked if you would like to take part in an interview to discuss your views about mental wellbeing and the new way of giving care. We will only invite a very small number of people to do this and taking part is voluntary. When the study has finished the results will then published, a summary of which will be made available to you.

What taking part in the trial involves

We don't yet know if the new type of care is any better than the care already offered by your GP to treat depression and improve the feelings of people who are finding life difficult. We need to compare the two methods of giving care to see if there is a difference. Comparing these two different types of care is called a 'trial'. It means half the people in the trial will get the new care and half will get usual GP care.

Once you have sent back your questionnaire to us, we will look through your replies to see if you fit with our needs for the trial. If you do, one of our team will call you to ask you some more questions. We will then place you in one of the three groups – either collaborative care, usual GP care or self-help workbook group. This is done by a computer purely by chance.

At the end of your time in the study, we will ask your GP about any medicines you were prescribed and the number of visits you made to the practice whilst taking part in the study.

What will happen if you are allocated to the collaborative care group?

It means you will get a new type of care called collaborative care. This is when health workers work together as a team with patients and GPs. In your case, you will have a health worker called a case manager to work with you on a one to one basis. He or she will set out to help you. Together you will plan changes that could make your mental health, your wellbeing, and your life – better.

If you are chosen to receive collaborative care, your case manager will contact you to arrange a convenient time to meet you. The first meeting may take place at your home, at your GP practice or over the telephone. After this, you will speak with your case manager each week for up to 10 weeks. This is normally done over the telephone but if you prefer it can be face to face. During your weekly sessions your case manager will discuss a range of issues with you, *e.g.* how you have been feeling since you last spoke, and how to deal with any bad feelings you have had since then. Each time you speak it will last up to 1 hour and at the end, you and your case manager may plan some things for you to do before your next speak.

Taking part in this study does not require you to travel. A case manager will come and visit you at your home or over the telephone if that is what you prefer. Any other discussions can be done over the telephone with the research team, so you do not need to travel anywhere.

What will happen if you are randomly allocated to the usual care group?

Your GP care will continue as normal if you are allocated to the usual care group. We will still ask you to fill in and send back the questionnaires mentioned above. By being in this group you still play a vital part in this study. The information you provide enables us to see whether collaborative care gives better results than usual GP care. We need to compare the two different groups.

What will happen if you are randomly allocated to the self-help booklet group?

It means that you will get a new method of delivering care in the form of a self-help workbook. You will be sent a self-help workbook through the post to read and work through in your own time at a pace that suits you. You will receive up to three telephone calls from a research assistant to offer assistance with the workbook and answer any questions that you may have.

What will happen if you are not eligible to take part 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 allocated to the collaborative care, usual care or self-help workbook groups. 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. Taking part could help improve the treatment offered to people suffering depression in the future. Collaborative care has been recommended by the government for use in the NHS, but it is not widely available. By taking part in this study you may receive treatment that isn't normally offered to people.

What are the possible disadvantages?

It takes up some of your time. It takes time to complete questionnaires. It takes a bit more time for those who receive collaborative care – up to 1 hour per week for 8-10 weeks. There will also be some short bits of homework to do that you agree with your case manager. For those in the self-help workbook group, some time will be spent reading the booklet and working through the activities.

Will the information in the study be confidential?

We will treat any information you provide us with in confidence. We will store all your information safely. We will not mention your name in any publications about the study and we will make sure that no individuals can be identified in the study results.

Will you 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 the CASPER team. You do not have to agree to take part in any other similar studies. If you do agree, we will send you more information about these to help you decide.

Will your GP be involved?

We will tell your GP if you agree to take part in this research. We will also get in touch with your GP if we have any concerns about your health while you are helping us with the study. If you are in the collaborative care group, your case manager will liaise with your GP about your care at regular intervals during the time you spend with them.

What if there is a problem?

Get in touch with us if you have any concerns or if there is anything you'd like to ask about the study – our contact details are at the end of this leaflet. If you would prefer to speak to the local principal investigator ([PI name and contact telephone]) or the chief investigator, Professor Simon Gilbody (telephone number: 01904 321370, email: sg519@york.ac.uk) you can contact them directly.

We don't expect the study to cause any harm or upset: but we want to make it clear that we cannot compensate you. If you are harmed due to someone's negligence, then you have grounds for legal action. Please be aware that you may have to pay for it. If you want to complain about anything to do with this study the normal National Health Service complaints service is still there for you.

If you would like to take part in the study, what do you need to do now?

Please fill in and sign the yellow form and its background information sheet. Then return them both in the addressed envelope provided. You do not need a stamp. We are happy to help you complete the forms. Please phone us, our contact details are at the end of this leaflet. If you decide to take part in the study we will write to you in a few weeks' time to let you know that you are registered on the study. We will ask you to fill in a simple questionnaire. We will also let your GP know that you are involved in the study.

If you're not sure – where can you get more information about the study?

We are happy to answer any questions. Please get in touch with [name] the study co-ordinator, on [local co-ordinator's phone number].

If you don't want to take part in the study, what do you need to do now?

Please complete the blue form and its background information sheet. Return them both in the addressed envelope provided. You do not need a stamp. **We will not be able to know who you are from these forms, and we will not get in touch with you again.** We will use the information you send back to find out if there are any differences between those who agree to take part and those who decide not to.

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

Please contact INVOLVE (**Tel:** 02380 651088) for general information about research. Please contact Mind (**Tel:** 0845 766 0163) for more general information about mental wellbeing.

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

We will send a summary of the results to everyone who has taken part in the study when it has finished and the results have been published. You can contact your GP practice or us directly if you decide not to take part in the study, but would still like to receive a copy of the results.

Who is involved in organising and funding this study?

The Department of Health's National Institute of Health Research Health Technology Assessment programme has funded this research study. It is organised by the University of York who is working with teams at different sites in areas around Leeds, Durham and Newcastle. All research funded by the Department of Health is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This research was looked at and approved by Leeds East Research Ethics Committee.

What will happen to all your documentation from the study?

We will store any documentation you send us safely for a minimum of 5 years after the study ends. It will then be professionally destroyed. Paper records will be handled by researchers and statisticians and kept in locked cabinets. Electronic records will be locked onto a computer server at York Trials Unit. Only a few people will be able to use it.

Thank you for reading this information sheet

If you need any further information please get in touch with 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 www.casper.org.uk

Contact details:-
Study co-ordinator: [local name]
Tel: [local phone number]
Address: [local study centre address]