Title of project: Debt Counselling for Depression in Primary Care: An Adaptive Randomised Controlled Trial

We are inviting you to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read this information carefully and discuss it with others if you wish. Please do not hesitate to ask us if there is anything that is not clear. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of the study?

Depression and associated anxiety are common among patients seen in general practices (GPs). Many of these patients also have difficulties with debt and prolonged absence from work. The purpose of this study is to find out if debt advice for patients with debt & depression, accessed through general practices, makes a difference to their recovery.

Why have I been asked to take part?

You have been asked to take part in this study either because the medical notes at your GP practice indicate that you may have had low mood or depression, or because you have contacted a researcher at [name university] indicating that that you are experiencing depression and are also currently experiencing difficulties with debt.

Do I have to take part?

No. It is up to you to decide whether or not you take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You will be free to withdraw at any time without giving a reason. Should you withdraw from the study then the information collected so far cannot be erased and this information may still be used in the project analysis. If you decide not to take part, or to withdraw from the study, it will not affect the standard of care you receive.

What does taking part involve?

Initial assessment

If you are interested in taking part in the study a researcher will ask to meet with you at your home or at an alternate venue if you would prefer. At the start of this meeting, you will have the opportunity to ask any questions you might have about the study and you will be asked to complete a written consent form. After you have completed the consent form, you will be asked to complete a questionnaire to check if you are eligible for the study. If you are eligible for the study, you will then be asked to complete a series of questionnaires that will include questions about your health, current psychological, social and life difficulties (including severity and type of debt) and the health care services you receive. This interview may take up to two hours to complete.

Debt advice

This study compares two different ways of providing debt advice via GP surgeries. Half of the people taking part in this study will get debt advice provided in one way and half in a different way. In total, around 450 people will take part from three areas of UK. If you take part, a computer will allocate you at random (by chance – like tossing a coin) to one of the two ways of getting debt advice. You will not be given specific details about the type of debt advice you have been allocated to receive, to reduce the effect of any prior knowledge or beliefs (bias). In some GP practices access to debt advice might include appointments with the Citizens Advice Bureau (CAB) whilst in other GP practices it will not.

Whilst taking part in the study, you will also continue to receive your usual care from your GP.

What happens next?

Once you have been allocated to one of two ways to access debt advice, you will be contacted by a member of staff at your GP practice to arrange an appointment to see one of the GPs at the practice who is helping with the study. A member of the study team will also contact the GP practice to let them know which type of debt advice you have been allocated to receive. The researcher who conducted the assessment visit with you will not be told which type of debt advice you have been allocated to receive. At the GP appointment, the GP will carry out an assessment, advise you of the debt advice you have been allocated to receive and discuss your future care.

Further assessments

Whichever type of debt advice you receive you will also take part in two further assessment visits with the researcher. The second visit will take place four months after the initial visit and the third visit will take place 12 months after the initial visit. During the time that you are taking part in the study, your medical notes at the GP practice may also be examined to assess for any changes and to collect information about GP appointments, health care and other services you may have received.

We will ask some people who take part in the study to take part in two further meetings with a second researcher to tell us about their experiences of debt, the impact this has had on their life and their experience of health care. This information will help us to think about what else might be done in the future to help people experiencing debt and depression.

Audio-recorded interviews

We will ask for your consent to audio-record part of the assessment visits with the researcher and both of the two additional meetings with the second researcher (should you consent to take part in these additional meetings). **You may decline permission for us to audio record the three assessment interviews with the researcher at any time and still take part in the study**. However, we will only be able to ask you to take part in the two additional interviews with the second researcher if you are willing to consent to audio-recording of those particular meetings.

Will my taking part in the study be kept confidential?

Yes.

We will follow ethical and legal practice and all information which is collected about you during the course of the research will be kept strictly confidential; the only exception to this would be if the interview revealed a significant risk of harm to yourself or others. Due to our duty of care to you, in extreme cases it may be necessary to breach the confidentiality of this study and inform your GP of your responses. This would include cases where the specific intent to hurt yourself or others has been made clear. This would only be done after discussion with you first.

Relevant sections of your medical notes at the GP practice and data collected about you during the study may be looked at by responsible individuals from regulatory authorities and the NHS Trust, where it is relevant to you taking part in this research study - to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and nothing that could reveal your identity will be disclosed outside the research site.

How will my information be stored?

The Peninsula Clinical Trials Unit (part of Plymouth University) will store your name and address for the purpose of this study only, and these details will be held separately from the main study information. All participants will be assigned a study number, which will be used to match responses. All paper-based information (e.g. Questionnaire Booklet) will be stored in a locked filing cabinet within a locked office in the Clinical Trials Unit. Information kept on computers by the Clinical Trials Unit will be stored securely on a system maintained by Plymouth University.

Personal data will be stored under strict security and destroyed after the statutory time period. Completely anonymous data may be retained for up to 10 years after the study.

What will happen if I do not want to carry on with the study?

If you wish to withdraw from the study, you can do so at any point without it affecting your care now or in the future. If you do withdraw from the study, we will destroy all your identifiable data, but we will need to use the anonymous clinical data collected up to your withdrawal.

What are the alternatives for treatment?

You can access treatment in the usual way, via your GP practice, regardless of whether you take part in this research trial or not.

What are the possible benefits of taking part?

It is hoped that individuals may find debt advice beneficial in their recovery from depression.

What are the possible risks or disadvantages of taking part?

It is possible that people may find it distressing when talking about current difficulties. If you become distressed during the interview, the researcher will check if you wish to continue. At any point during the interview, you can ask for it to be stopped altogether, or you can have a break, or you can ask for the audio-recorder to be switched off. If appropriate, the researcher may suggest that you visit your GP for further support.

What if relevant new information becomes available?

Sometimes we get new information about the intervention being studied. If this happens, a member of the research team will tell you about this new information and discuss whether you would like to continue in the study. If you decide not to carry on, arrangements will be made for your care to continue. If you decide to continue in the study you may be asked to sign an updated consent form.

Expenses and payment

You will receive a £10 shopping voucher for each assessment visit and each interview you attend with a researcher. You will receive the shopping voucher at the end of each assessment visit/interview. You will not receive any additional payments for the telephone calls from the researcher or for attending appointments at the GP practice. If interviews with the researcher(s) do not take place at your home and you have to travel to an alternate venue, travel expenses will be paid.

What happens when the research study stops?

You will continue to receive your usual care. You will no longer be able to access the specific debt advice provided by the study.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have any questions, you are welcome to ask the researchers, whose contact details are listed at the end. If you wish to make a complaint, you can contact [Names of local PI]. You can also seek independent advice from [insert 'The Patient Advice and Liaison Service (PALS)' for sites in England and 'the Community Health Council]' for sites in Wales]: [Add contact details for Local site PALs for sites in England and Community Health Council for sites in Wales]

Harm

In the event that something does go wrong and you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the University of Liverpool but you may have to pay your legal costs.

Involvement of the General Practitioner/family doctor (GP)

We will write to your GP practice to inform them that you are involved in this research. A copy of your signed consent form will be held with your medical records at your GP surgery.

What will happen to the results of the research study?

Results of the study will be published in academic and professional journals and a report of the results will be sent to the funding organisation – the National Institute for Health Research. The study results will be fed back to members of the public through our service user group colleagues and contacts. We may use quotes from the qualitative interviews in reports, papers and presentations of the findings. All quotes will be anonymised and any identifiable information will be removed. If you are interested in receiving a copy of any publications from this study, please tell the research assistant when you meet with them.

We will also work with commissioners and GPs to explore how best to put the study findings in to practice.

Who is organising and funding the research?

This project was funded by the National Institute for Health Research HTA Programme (project number: 11/148/01). The research is sponsored by the University of Liverpool.

Who has reviewed the study?

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 study has been reviewed and given a favourable opinion by: [Ethics Committee Reference]

Further information and contact details

If you require any further information you can contact:

Name Local PI [NW Site, SW Site, South Wales site]
Role in study
Address
Contact telephone no.
E-mail

Name Local site Research Assistant
Role
Name
Address
Contact telephone no.
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