MANCHESTER 1824

The University of Manchester

Participant Information Sheet

Collaborative case management to aid return to work after long-term sickness absence (CAMEOS).

Introduction

You are being invited to take part in a university research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read this information sheet carefully and feel free to discuss this with colleagues, friends, or family if you wish.

What is the purpose of the study?

Common health problems such as back pain, heart problems and depression can be a big problem for people and for their families. Such health problems are also often a cause of sickness absence (time away from work off sick), which may result in financial hardship. Significant periods of sickness absence can lead to long-term impacts on employment, health and quality of life. Although there is a variety of support for workers on long-term sickness absence through occupational health and employee assistance programmes, many of the interventions provided have limited evidence that they work. This research seeks to develop a simple intervention which will hopefully improve well-being and help support a person's return to work.

What is being tested?

Collaborative Case Management draws on current best practice in the management of a range of long-term conditions (such as depression and back pain) and has been proven effective in a number of randomised trials in a range of contexts and patient populations.

Patients receiving Collaborative Case Management are assigned a case manager who has been specially trained to assess a person's needs and coordinate that persons access to treatment and services that can help them.

This Collaborative Case Management intervention will begin with a 60 minute assessment, which will include collaborative goal setting (agreeing what support you need) and choices of evidence based low intensity treatments (such as help for depression, for pain or problem solving). The case manager will also support information sharing with key health care personnel such as your GP or other primary care providers (where appropriate, and with consent). After the first appointment, sessions will last around 45 minutes. Participants will receive up to 6 sessions with the case manager over 12 weeks. We expect that most sessions will be delivered by telephone. Participants will be followed up at 16th and 24th week after the start of the intervention by their Case managers to monitor their progress by telephone. Case managers (with participant agreement) will also work with your employer and yourself to identify barriers to return to work. We will also request some information from your employer about your participation in the trial and your absence history.

This is an occupational health intervention and the main aim is to see if improvement in a participant's health and well-being will help them return to work and help reduce further time off. Participants will not be pressurised to return to work during or after the 12 week intervention period. Hopefully if participants are feeling better and with continued support from their employer they will feel better able to return to work when they are ready.

Why have I been chosen?
You have been chosen because you are currently on sickness absence from your place of work. We aim to recruit 100 participants from a range of companies who have their occupational health services provided by OH Assist or the Fit For Work Service.

Do I have to take part?
No. It is up to you to decide if you want to be involved in this study. You may wish to take time to discuss this with your family or friends. If you do wish to participate, you will be asked to sign a consent form. You will still be free to withdraw at any time without giving a reason.

What will happen to me if I take part?
If you are interested in taking part, return the contact information sheet with the consent form (signed) and someone from the University will telephone you to discuss the study and ask you some questions to see if this intervention would be right for you.

Every person who takes part in the study will continue to have their treatment managed by their employers Occupational Health services, but **half** of the people who agree to take part will **also receive Collaborative Case Management.** As we do not know which treatment is best we need to make comparisons, what we do is compare the progress and experiences of patients who received Collaborative Case Management with those who didn't. Because this study is a randomised controlled trial the decision about whether a participant will be offered Collaborative Case Management is made totally by chance. So, it is important to note that half of the people who agree to take part will be receiving exactly the same treatment as they would be if they chose not to take part in the study that is, they will not be receiving Collaborative Case Management. With your permission a letter will be sent to your GP to let them know that you are taking part in this research.

You will be asked to complete a questionnaire which will ask about how you are feeling and your current health problems before you take part in any intervention. You will be reimbursed for your time with a £20 gift voucher. After 3 months you will be asked to complete the same questionnaire again, to see if there have been any changes in how you are feeling or in your circumstances. Again you will receive a £20 gift voucher for your time.

We will also ask a few participants to take part in an interview at the end of their time in the study to talk about their experiences and to see what they thought of the intervention. If you indicate that you would be willing to take part in an interview then you will be contacted closer to the time to see if you are still willing to do an interview. Again if you change your mind, you will still be free to withdraw at any time without giving a reason. With agreement, all interviews will be audio recorded.

If you agree to take part and then choose to withdraw from the study before the end you will be contacted by a member of the research team to see if you would like to give a reason why and to see if you would still complete the questionnaire. You will of course be under no obligation to do this but as one of the aims of this study is to see if this intervention is suitable and acceptable to employees, it would help us to know why you didn't feel it was right for you or any circumstances that made it difficult for you to complete the sessions. Your name will be removed from this information and it will not be passed on to your employer or your case manager if you have one.

Will my taking part in the study be kept confidential?
All information collected about you during the course of the study will be kept strictly confidential and stored in secured premises at the University. This includes any written documents or audio recordings. Any information about you will have your name and address removed so that you cannot be recognised from it. All information related to this study will be kept for 10 years and then confidentially destroyed.

We will send a letter informing your GP that you are taking part in the study. Should you become upset during the study or if your condition worsens to a point where it is felt by the researcher that you may be a danger to yourself or others, your GP or other nominated health professional will be informed of this, with or without your permission. However, this is the only time we would ever break confidentiality.

You should be aware that in the (perhaps unlikely) event of a loss of capacity (the ability to make decisions about your care), you would be withdrawn from the study and the research team would retain personal data already collected and continue to use it confidentially in connection with the purposes for which consent is being sought.

What are the possible disadvantages and risks of taking part?
We are not aware of any side effects, disadvantages or risks to you of taking part in this research.

What are the possible benefits of taking part?
We would hope that both Case Management and usual care from your Occupational Health services will help you. The information we get from this study may also help us improve the support people receive when they are on, or at risk of long-term sickness absence.

What if there is a problem?
Complaints
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If they are unable to resolve your concern or you wish to make a complaint regarding the study, please contact a University Research Practice and Governance Co-ordinator on [redacted] or by email to [redacted]

Harm
In the event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against The University of Manchester but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

What will happen to the results?
The findings of the study may be reported in professional publications and conferences. Direct quotes may be used, but you will not be identifiable in any of these.

Who has reviewed the study?
An independent panel of experts have reviewed this study on behalf of the National Institute of Health Research- Public Health Research. The study was given a favourable ethical opinion by Greater Manchester Central Research Ethics Committee (Ref:14/NW/1008).

Contact details
The lead researcher for this study is Professor Peter Bower who is based at the University of Manchester. If you have any queries about any part of this study, or would like more information, please contact:

NAME
EMAIL
PHONE NUMBER

Thank you for taking the time to read this information sheet.

Consent to contact form

If you are possibly interested in taking part in this research or would like more information, **please provide your contact details below and return in the enclosed envelope.**

Your participation is voluntary and you are free to withdraw at any time without giving any reason, without your medical care or legal rights being affected.

If you would prefer to talk to the research team direct, please call (NAME)on(PHONE NO.).

Name	
Telephone (landline)	
Mobile	
Email	
How would you prefer to be contacted? (please circle)	Telephone Mobile Email
What time of day is best to contact you? (please circle)	Morning Afternoon Evening Don't Mind

_____ _____ _____

Name of participant Date Signature

THANK YOU

Participant Consent Form

Name of Researcher: ……

Please initial box

1. I confirm that I have read and understand the information sheet dated 30/10/2014 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that data collected during the study may be looked at by individuals from the University of Manchester, from regulatory authorities or from the NHS trust, where it is relevant to my taking part in this research. ☐

4. I understand that a letter will be sent to my GP advising them of my taking part in this research. ☐

5. I understand that the research team may request access to information from my employer. ☐

6. I would be willing to be considered to take part in an interview. ☐

7. If I am contacted for an interview I agree to a digital audio recording being made of the interview and to the use of anonymised quotes from the interview in publications arising from this study. ☐

8. I agree to take part in this study. ☐

_____	_____	_____
Name of participant	Date	Signature
_____	_____	_____
Researcher	Date	Signature