GP Headed paper

Dear Patient

Treatment of depression in primary care

At this surgery we have decided to take part in a research study being co-ordinated at SITE DETAILS which may be of interest to you. A new treatment is being tested called Collaborative Care for depression and is explained in the leaflet that comes with this letter. Please take the time to read this and consider if participating in this research would be right for you.

As stated in the information sheet, if you are interested in participating in the study please complete the "permission for researcher to contact" form and send it free post to the address given. If you have any questions, or are interested in finding out more about the study please ring the research team on the number listed.

In the next week or so you may receive a call from the surgery to check that you have received this letter and to ask if you are interested. To help the surgery please let the practice know if your telephone number has changed.

If you are certain that you do **not** want to take part in the research you may return the slip at the bottom of this letter to the surgery and you will not be contacted again.

Thank you for taking the time to read this letter.

Yours sincerely,

Surgery GP's name

I DO NOT want to take part in this study and DO NOT want a follow-up call

Name:

Signature:

Please return to GP SURGERY ADMINISTRATOR NAME, at SURGERY NAME
(CADET: Collaborative Depression Trial)

Collaborative Depression Trial (CADET)

Treatment of Depression in General Practice

We are looking at a new treatment called collaborative care which has been shown to be very helpful in the treatment of depression. We are writing to you because your GP surgery has agreed to help us with this and you have visited your GP reporting symptoms experienced by many people with depression. This letter asks you to consider taking part in the research study.

What is the treatment that is being tested?

The new treatment is called **Collaborative Care for Depression**. People receiving Collaborative Care are allocated a **case manager** who is a health worker specially trained to help people with depression, they will help to organise your care and give you advice on overcoming depression. You will still carry on seeing your GP to help you deal with your depression but you will also regularly speak to this case manager. The case manager will have more time to discuss the management of your care and will offer advice about medication and explain some things you can do to start to make you feel better. The case manager will see you face to face initially, at a time and place to suit you, and the meeting will usually take about 40 minutes. After this first meeting, you will usually speak to the case manager over the telephone, but there is the opportunity for more face to face meetings if you wish. They will arrange to call you at regular times to support you in your treatment. These calls take about 15 minutes, and will be booked at times that you find easiest. Usually, they will call you once a week for the first month and then once a fortnight for the next three months, but how often they call is totally up to you. You will have contact with the case manager for four months.

What will happen to me if I take part?

This study is a randomised controlled trial. Sometimes, because we do not know which way of treating patients is best, we need to make comparisons. We are asking people from a number of different GP surgeries in the area if they would like to take part. Every patient who takes part in the study will continue to have their treatment managed by their GP, but people from **half** of the GP surgeries will **also receive Collaborative Care**. What we do is compare the progress and experiences of patients who received collaborative care with those who didn't. The decision about whether a surgery will offer collaborative care is made totally by chance, and you will not know which group your GP surgery is in until you decide to take part in the study. 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 Care.

We would also want to meet you to ask you some questions about how you are feeling and we will ask you to fill out some short questionnaires. We try to see everyone three times, once when they agree to take part and then four and twelve months later. These meetings will take between 45 and 90 minutes.

Will my taking part in this study be kept confidential?

All information collected about you during the course of the research will be kept strictly confidential.

How do I find out more?

This is a very short summary about the study, if you would like to find out more then you can return the 'permission for researcher to contact' form or call site researcher on xxxxx. Someone working on the study will then send you more information about this study and arrange a time to meet you to answer any questions that you may have.

Thank you for reading this and for considering taking part in this study.

Collaborative Depression Trial (CADET)

Treatment of Depression in General Practice

Permission for researcher to contact

Patient's GP Surgery name:

I confirm that I have read and understand the summary sheet for the above study and am happy for a researcher to contact me to discuss whether or not I would like to take part.

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.

Name _____

Address _____

_____

Signature _____

Telephone contact details

Day _____
Evening _____
Mobile _____

Email address_____

Return in enclosed pre-paid envelope to:
Relevant site details here – including phone number

Collaborative Depression Trial (CADET)

Treatment of Depression in General Practice

You are being invited to take part in a research study. Before you decide whether you want to take part or not it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Depression causes misery to many people and is a major health problem in the UK. Although effective treatments are available, many people do not have access to them and we are always looking for treatments that are easier and quicker for patients to receive. New ways of organising treatment have been developed in the United States but we do not know if they are better than usual care in the UK. Therefore, this study will investigate a way of organising the way we deliver treatment for depression. This is called 'collaborative care for depression' and it is being compared with the usual care given by GPs.

Why have I been chosen?

Your GP surgery is taking part in this trial and you have recently visited you GP reporting symptoms experienced by many people with depression. This letter asks you to consider taking part in this research study.

Do I have to take part?

It is entirely up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form. You will still be still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive in any way.

What is the treatment that is being tested?

The new treatment is called Collaborative Care for Depression. People receiving Collaborative Care are assigned a case manager who is a health worker specially trained to help people with depression. Case managers help to organise the person's care and will give them advice on overcoming depression. For example, the case manager may advise about medication or explain some very simple ways that a person can help themselves to start to feel better. Case managers see people face to face initially, at a time and place to suit them, and the meeting will usually take about 40 minutes. After this first meeting, they will telephone the person at regular times to support them in their treatment, these calls take about 15 minutes, and will be booked at times to suit the patient. Usually, the case manager will call once a week for the first month and then once a fortnight for the next three months, but how often they call is totally up to the patient. Patients have contact with the case manger for four months.

What will happen to me if I take part?

This study is a randomised controlled trial. Sometimes, because we do not know which way of treating patients is best, we need to make comparisons. We are asking people from a number of different GP surgeries in the area if they would like to take part. Every patient who takes part in the study will continue to have their treatment managed by their GP, but people from **half** of the GP surgeries will **also receive Collaborative Care**. What we do is compare the progress and experiences of patients who received collaborative care with those who didn't. The decision about whether a surgery will offer collaborative care is made totally by chance, and you will not know which group your GP surgery is in until you decide to take part in the study. 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 Care.

What information do you need from me?

If you agree to take part in the research the first thing we will want to do is to find out about you. We will need to ask about your current and past mental health as well as your life more generally. We have already arranged to meet with you at site details, if you are happy to take part in this study we will ask you some questions about how you have been feeling recently and there will be a few questionnaires that we would like you to fill out. You will also have an opportunity to ask any questions you may have about the study. This meeting will take about 90 minutes.

We would then arrange to see you in four and twelve months time. These meetings will be a little shorter as they only involve you filling out some questionnaires. We expect these meetings to take about 45 minutes. We also need to collect some information from your medical records. The research study will last for two-and-a-half years, but your involvement will only be for twelve months.

We are also interested in finding out what it was like to be part of this study and will be giving a small number of you the opportunity to describe your experiences of the treatment and the ways in which you think it could be improved. To do this, we will ask some of you to agree to a longer interview of about 60 minutes. If you agree, we would like to tape record this interview. The tapes will be given a code and securely stored for a maximum of 20 years

before being destroyed. We will also make typed copies of the taped conversations. We will ensure all information in these copies is anonymous by removing all named references to you or your family and friends from the copies.

We want to make sure that all patients are offered the best service possible, so in a bid to maintain quality we would like to tape record some of the contact sessions with the case managers. This is so that we can check the quality of the advice given to you by the case manager. The tapes will be given a code and securely stored for a maximum of 20 years before being destroyed. We will also make typed copies of the taped conversations. We will ensure all information in these copies is anonymous by removing all named references to you or your family and friends from the copies. However, if you would rather they weren't taped, you can refuse. This will not affect your care at all and you can still take part in the study.

Will I have to do anything differently?

There are no restrictions in your lifestyle from taking part in this research. You should continue to follow the advice of your GP.

Are there any side effects, 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 hope that both the new treatment and usual care from your GP will help you. The information we get from this study may help us to treat future patients with depression better.

What happens when the research study stops?

Throughout the study and afterwards, your GP will continue to treat you as s/he feels is best for you and with your agreement.

What if something goes wrong?

We do not expect any harm coming to you from being in this study. However, 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.

Will my taking part in this study be kept confidential?

All information collected about you during the course of the research will be kept strictly confidential. Any information about you that is collected from the questionnaires or interviews will have your name and address removed so that you cannot be recognised from it. As your GP is involved in your treatment, s/he will be informed of your progress as part of the research study, with your permission. Should your condition worsen to a point where it is felt by either a researcher or the case manager that you may be a danger to yourself or others, your GP will be informed of this, with or without your permission. However, this is the only time we would ever break confidentially.

What will happen to the results of the research study?

We will publish the results of this research study widely. As well as producing a research report and writing articles for health professionals to read, you will be given a summary of the findings on request at the end of the trial in 2012. To request the study summary and articles please contact Prof. David Richards, whose details are at the end of this information leaflet. We will also ensure patient organisations such as Depression Alliance are informed of the results of the trial. You will not be personally identified in any publications from this trial.

Who is organising and funding the research?

The Medical Research Council has funded this research study. Your GP is not being paid any extra money for being involved in the study.

Who has reviewed the study?

This research study has been reviewed and approved by the South West Research Ethics Committee.

Next Steps

An appointment has been arranged for you to come and see site details and during this meeting you will have the chance to ask any questions you have. If you are still happy to take part in the study we will ask you to sign a form to say so and then get you to fill out some questionnaires about yourself.

If you need further information to help you decide, please contact Professor Dave Richards at the address below.

Thank you for reading this and for considering taking part in this study.

Contact for Further Information

If you need further information about this study please contact:

David Richards
Professor of Mental Health Services Research
School of Psychology
University of Exeter

Office: XXXX
Email: XXXX

Collaborative Depression Trial (CADET)
Treatment of Depression in General Practice

CONSENT FORM

Patient Identification Number for this trial:

Site Details

	Please initial box
1. I confirm that I have read and understand the information sheet dated ..... (version .....) for the above study and have had the opportunity to ask questions.	
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 agree to take part in the above study.	
4. I agree to my GP being informed of my participation in this study.	
5. I understand that research staff will contact my GP or specialist if they feel that my condition has deteriorated and further action is needed	

In addition to the above, I would also be prepared to consent to the following;

6. I understand that sections of any of my medical notes may be looked at by research staff. I give permission for these individuals to have access to my records.	
7. If my surgery is one where collaborative care is offered, I am willing to have some of my sessions with the health worker tape recorded.	
8. I am willing to be interviewed about my experiences of taking part in the study and for this interview to be tape recorded.	

When you have initialled all the boxes above, please complete below, including the date yourself:

Name of Patient _____

Signature _____ Date_____

Name of Person taking consent _____

Signature _____ _____ Date_____

Multi-Centre Randomised Controlled Trial of Collaborative Care for Depression

Serious Adverse Event

A Serious Adverse Event (SAE) is defined in accordance with ICH/GCP as "Any untoward medical occurrence that:

- Is fatal or life threatening
- Requires hospitalisation or prolongs existing hospitalisation
- Results in significant or permanent disability or incapacity
- Is a new primary cancer
- Is a congenital anomaly or birth defect
- May jeopardise the patient and may require medical or surgical intervention to prevent one of the outcomes listed above"

Even in a clinical trial of a non-investigational medicinal product (non-CTIMP) like CADET the study investigator should report any SAE **that is both related to the research procedures and is unexpected**. An immediate report (within 24 hours) must be made orally or in writing to the Research Sponsor (University of Exeter). The immediate report must be followed by a detailed written report on the event. This report must also be sent to our main REC (South West REC) within 15 days of the CI becoming aware of the event.

If you are alerted to an SAE that is both related to CADET research procedures and is unexpected, please telephone the CADET coordinating centre immediately, and fax the *CADET disclosure/adverse event recording form* to XXXX, so that both the Sponsor and the Main REC can be notified within the relevant time period.

Recording adverse events

1 At both 4 and 12 month assessments serious adverse events that might have occurred since the previous visit should be elicited from the participant. If a participant (or a patient's GP or next of kin) discloses a serious adverse event please document it using the *CADET disclosure/adverse event recording form.* As CADET is a non-CTIMP we are not required to log all non-serious adverse events, however the *CADET disclosure/adverse event recording form* allows researchers to record other adverse events when it is not immediately clear that it falls into the "Serious Adverse Event" category, or which causes concern.

2 General completion guidelines:

3 Ask patient the date and start and stop time of event. If the patient cannot remember, then as near as possible. Document the outcome of the event and any actions taken. Confirm it with your site lead and have them countersign it.

4

Please note that ALL instances where the risk protocol is enacted must be recorded in the usual manner on the *CADET Risk Form* and countersigned by the site lead or their nominated deputy.

CADET Disclosure/Adverse Event Recording Form

Date of Incident:	**Patient ID:**	**Patient Initials:**	**Sex:**

Details of disclosure

Outcome:

Please indicate type (tick all that apply):

Self harm:	☐	**Hospitalisation or prolongation of hospitalisation**	☐
Life threatening	☐	**Persistent or significant disability or incapacity**	☐
Death:	☐	**Other**	☐

ADDITIONAL RELEVANT INFORMATION

Action taken by research team (if any)

Name of Researcher (BLOCK CAPITALS)	**Date**	**Signature**
Name of PI (BLOCK CAPITALS)	**Date**	**Signature**

Report of Serious Adverse Event (SAE)

The Chief Investigator should report any SAE that is both related to the research procedures and is unexpected. Report the SAE to the sponsor within 24 hours and send the Report to the Research Ethics Committee that gave you favourable opinion of the research within 15 days of the CI becoming aware of the event.

1. Details of Chief Investigator

Name	Prof David A Richards
Address	Mood Disorders Centre School of Psychology Washington Singer Laboratories University of Exeter
Telephone	XXXX
Email	XXXX
Fax	XXXX

2. Details of study

Full Title of Study	Multi-Centre Randomised Controlled Trial of Collaborative Care for Depression
Name of Main REC	South West Research Ethics Committee
Main REC reference	09/H0206/1
Research Sponsor	University of Exeter
Sponsor's reference for this report (if applicable)	

3. Type of Event

Please categorise this event, ticking all appropriate options

Death □	Life Threatening □	Hospitalisation or prolongation of hospitalisation □
Persistent or significant disability or incapacity □	Congenital anomaly or birth defect □	Other □

4. Circumstances of the event

Date of SAE	
Location	
Describe the circumstances of the event (attach copy of detailed report if necessary)	

What is your assessment of the implications, if any, for the safety of study participants and how will these be addressed?	

5. Declaration

Signature of Chief Investigator	
Print Name	
Date of submission	

6. Acknowledgement of receipt by main

The South West Research Ethics Committee acknowledges receipt of the above

Signed	
Name	
Position on REC	
Date	

Signed original to be sent back to Chief Investigator (or other person submitting the report). Copy to be kept for information by main REC