Dear Patient

COBRA (**C**ost and **O**utcome of **B**ehaviou**R**al **A**ctivation):
A Randomised Controlled Trial of Behavioural Activation versus Cognitive Behavioural Therapy

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 trial is taking place for depression comparing two psychological treatments for depression – Behavioural Activation and Cognitive Behavioural Therapy, both 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 freepost 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
(COBRA: (**C**ost and **O**utcome of **B**ehaviou**R**al **A**ctivation)

Participant Summary Information Leaflet

COBRA (Cost and Outcome of BehaviouRal Activation):
A Randomised Controlled Trial of Behavioural Activation (BA) versus Cognitive Behaviour Therapy (CBT)

Introduction:
We are carrying out a trial that looks at two types of psychological therapy used in the treatment of depression. We are writing to you because your GP surgery has agreed to help us with this by sending information to you after you visited your GP reporting symptoms that are experienced by many people with depression.

This letter asks you to consider taking part in the research study and for your permission for the researcher to contact you.

What is the treatment that is being tested?
This study is investigating the effects of two psychological therapies for depression. We are interested in whether a relatively simple treatment called 'Behavioural Activation' (BA) is as effective as 'Cognitive Behavioural Therapy' (CBT), which is widely used in the UK. Although both treatments are known to be helpful for people with depression we need to test to see if BA can be used instead of CBT for some people. We will also be comparing how much each treatment costs.

What will happen to me if I take part?
We are asking people from a number of different GP surgeries in this area if they would like to take part. If you decide you would like to do this, a researcher will interview you to see if you are eligible for the study and to explain it in more detail. If you are eligible and agree to take part you will receive one of the treatments. Both treatments involve a maximum of 20 appointments with a trained therapist over a four month period with possibly four more booster sessions later. Once you have been allocated to one of the treatments you will also be seen again for follow-up appointments with a researcher at six months, 12 months and finally at 18 months to complete a number of questionnaires.

This study is a randomised controlled trial which means that once you have been interviewed by a researcher and have decided you would like to take part, the decision about which treatment you receive is made totally by chance. Therefore, half of our participants will be treated by Behavioural Activation and half by Cognitive Behaviour Therapy. What we then do is compare the progress and experiences of patients who received each of the two treatments.

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 you can return the 'Permission for Researcher to Contact' form at the end of this summary, or call the COBRA trial team on local site number. Someone working on the study will then contact you with 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

‘Permission for Researcher to Contact’ Form
Study Title: COBRA (Cost and Outcome of BehaviouRal Activation):
A Randomised Controlled Trial of Behavioural Activation versus Cognitive Behaviour Therapy

Patient’s GP Surgery name:

I confirm that I have read and understand the summary sheet for the above study and I 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.....
(Please print name)

Address.....

.....

.....

Signature.....

Telephone contact details:

Day.....

Evening.....

Mobile.....

Email address.....

Return in enclosed pre-paid envelope to:

Local Site Details

Telephone No:

Participant Information Sheet

COBRA (Cost and Outcome of BehaviouRal Activation): A Randomised Controlled Trial of Behavioural Activation versus Cognitive Behavioural Therapy

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 drug treatments are effective, talking therapy (psychological) treatments are a very popular alternative. We are interested in whether a treatment called 'Behavioural Activation' (BA) is as effective as 'Cognitive Behavioural Therapy' (CBT), which is widely used in the UK. Although both treatments are known to be helpful for people with depression, we need to compare the progress and experiences of people who receive each of the two treatments; we will also be comparing how much each treatment costs. By comparing the *cost* and the *outcome* of the therapies we hope to find out which one of the treatments will be most useful for the treatment of depression.

Why have I been invited?

Your GP surgery is taking part in this trial and you have recently visited your GP reporting symptoms that are experienced by many people with depression. The letter from your GP asks you to consider taking part in this research study because after your recent visit s/he feels that you may have some of the depression symptoms we are treating in this study. This information sheet is for you to keep, if you decide to take part one of our research team will go through the information sheet with you and answer any questions you have. You will also be asked some questions by the researcher to see if you are eligible to be included for the treatments being tested. However, if you are already receiving one of the treatments then you would not be eligible. Although you would need to be excluded from taking part in this specific study, you will continue with the treatment you are already receiving.

Do I have to take part?

No. 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 or not to take part will not affect the care you receive in any way.

What is the treatment that is being tested?

We are testing two treatments - Behavioural Activation (BA) and Cognitive Behavioural Therapy (CBT) which are two different types of treatment, talking therapy (psychological therapy), recommended by the UK National Institute for Health and Clinical Excellence

(NICE) for the treatment of depression. NICE has recommended that further research is needed to directly compare the effects of the treatments and the costs of BA and CBT.

Behavioural Activation (BA) Is based on the idea that behaviours such as inactivity and ruminating (pondering) on certain thoughts can be key factors in maintaining depression. The therapist aims to help you to combat these behaviours. The treatment involves a planned programme of arranging increased contact with positive activities and reducing people's avoidance of important situations, other people and activities.
Cognitive Behavioural Therapy (CBT). Is based on the idea that certain ways of thinking can trigger, or fuel, certain mental health problems such as depression. The therapist helps you to understand your thought patterns. In particular, to identify any harmful or unhelpful ideas or thoughts which you have that can make you depressed. The aim is then to change your ways of thinking to avoid these ideas and to help your thought patterns to be more realistic and helpful, to achieve changes in the way that you think, feel and behave.

What will happen to me if I take part?

If you decide you might like to take part, a researcher will interview you and ask some questions to see if you are eligible to take part in the study and to explain it in more detail, but only after you have agreed to be contacted by us and we have allowed you time to think about whether you want to take part or not. We will arrange to meet with you at (*site details)* over the phone. If you are eligible and agree to take part you will receive one of the treatments. However, if after you have been interviewed by the researcher and answered some questions it is found that you are not eligible to take part, we are really sorry if it causes you disappointment and thank you for your interest and time that you have given. If you are not eligible to take part we would refer you back to your GP to continue treatment in the way s/he feels is appropriate.

If you are eligible to take part we need to explain that this study is a randomised controlled trial which means that once you have been interviewed by a researcher and have decided you would like to take part, the decision about which treatment you receive is made totally by chance. In this trial half of our participants will be treated by Behavioural Activation and half by Cognitive Behaviour Therapy. We will allocate you to either BA or CBT by assigning you a personal identification number, known only to the research team, which will be entered into a secure computer system that picks the numbers at random and allocates them to one of the treatments at random.

Whichever treatment you are allocated to, you will receive a maximum of 20 sessions of one-hour in duration with a therapist, once per week, spread over 16 weeks, with the option of four additional booster sessions. You will receive face-to-face sessions, with the option of the session being conducted up to twice weekly over the first two months and then weekly thereafter.

Once you have been allocated to one of the treatments and received the sessions over the 16-week period, you will be seen again for follow-up appointments with a researcher at six months, 12 months and finally at 18 months to complete a number of questionnaires. Your involvement in the study will only be for eighteen months as described above although the research study will last for four years.

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 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 be able to ask any questions you may have about the study. This meeting will take about 90 minutes.

We expect that the follow-up appointments described above will take no more than 45 minutes. We will collect some questionnaires from you at these follow-ups. 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 people the opportunity to describe their experiences of the treatment. To do this, we will ask some people selected at random to attend a longer interview of about 60 minutes after they have completed the treatment and we would like to audio or video record this interview. There is a separate part to the consent form to allow for this and you do not have to agree to this part of the interview and recording if you do not want to. It will not affect the standard of care you receive if you choose not to. If you agree, the recordings 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 recorded conversations. We will ensure all information in these copies is anonymous by removing all named references to you or your family and friends to protect your confidentiality.

We want to make sure that all participants are offered the best service possible, so in a bid to maintain quality we would like to audio or video record some of the sessions with the therapist that delivers your therapy. This is so that we can check the quality of the treatment that is given by the therapist. Recordings will be reviewed by experts in the UK and the US. The recordings will be given a code and securely stored for a maximum of 20 years before being destroyed and the same process will be followed as described above to protect your confidentiality. However, if you would rather the sessions were not recorded, 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?

No, 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?

Many people find that BA or CBT are helpful as both have been shown to have a positive effect for some people with depression. We hope that you will find the treatment you are given will help you. However, we cannot guarantee that you will benefit from the treatments. 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 or I have a complaint?

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 through the Patient Advice and Liaison Service (PALS) *(insert local contact here).*

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 research assistant, 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 2016. To request the study summary and articles please contact Professor David Richards, whose details are at the end of this information leaflet. The patient organisation Depression Alliance, are collaborating with the research team and will be 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 National Institute for Health Research Health Technology Assessment Programme has funded this research study, which is supported by the Department of Health. It is not a commercially funded industry trial; this means that the GP that invited you to express your interest and the research team will not receive any extra money for conducting this study. The study is sponsored by the University of Exeter.

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 well-being and dignity. The study has been reviewed and given a favourable opinion by the NRES Committee South West – Exeter.

Further Information – Next Steps

Please look at the 'Participant Flow Chart' that provides the assessment and treatment process in a clear way which we hope you find helpful. An appointment will be arranged and at a time to suit you, 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 then want 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 David 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
XXXX

COBRA (Cost and Outcome of BehaviouRal Activation) – A Randomised Controlled Trial of Behavioural Activation versus Cognitive Behaviour Therapy

CONSENT FORM

Please see that the consent form is in two parts, you do not have to sign both parts:

Part 1 on Page 1:
This is the main consent for your general participation in the study and if you agree to taking part.

Part 2 on Page 2 is optional; you can choose if you wish to take part.
This is about whether you would agree to being audio/video recorded and being interviewed about your experiences of taking part in the study. It also includes a similar section about data collection.

PART 1: MAIN STUDY CONSENT FORM

Site Details:

	Please initial box
1. I confirm that I have read and understand the information sheet dated 21st May 2012 (Version 4.0) 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 my GP being informed of my participation in this study and updated with information from this study relevant to my medical care.	
4. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in the research. I give permission for these individuals to have access to my records.	
5. I understand that data already collected as part of the research study can be retained for up to 20 years, even if I decide to withdraw from the study and that it will only be used for this study.	
6. I agree to take part in the above study.	

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

Name of Participant *(BLOCK CAPITALS)*	**Date**	**Signature**

I have explained the study to the above patient and he/she has indicated his/her willingness to take part in the study.

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

COBRA

COBRA (Cost and **O**utcome of **B**ehaviou**R**al **A**ctivation) – A Randomised Controlled Trial of Behavioural Activation versus Cognitive Behaviour Therapy

PART 2: OPTIONAL CONSENT FORM

Part 2: This section is optional; you can choose if you wish to take part or not and it will not affect your participation in the main part of the study.
This consent form is about whether you would agree to:

- *Being audio/video recorded?*
- *Being interviewed about your experiences of taking part in the study?*
- *The data from one or both of the above in the optional consent being retained?*
- *Non-identifiable data being shared for the purposes of health research only*

Please only initial the boxes that you wish to consent to, thank you.

Site Details

	Please only initial the boxes that apply
1. I am willing to have some of my sessions with the health worker audio or video tape recorded and reviewed by experts in the UK and the US for research purposes only.	
2. I am willing to be interviewed about my experiences of taking part in the study and for this interview to be audio or video recorded for research purposes only.	
3. I agree to the data collected for this additional part of the above study being retained for up to 20 years, even if I decide to withdraw from the study and that it will only be used for this study.	
4. I agree to my data from this study being shared with other health researchers after my personal identifying information has been removed. I understand that it will only be used towards improving health outcomes by assessing the types of treatment that I have agreed to participate in for the main study.	
5. I agree to this additional part of the above study and consent **only** for the sections where I have clearly initialled in the boxes.	

Name of Participant *(BLOCK CAPITALS)*	**Date**	**Signature**

I have explained the additional part of study to the above patient and he/she has indicated which parts apply.

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

LOCAL SITE ADDRESS

Participant Name
Address1
Address2
Address3
Postcode

Date

PRIVATE & CONFIDENTIAL

Dear Participant Name,

Thank you for your ongoing participation in the COBRA trial, we have learnt a lot from your experiences so far and really value you sharing these with us. When you first consented into the trial you agreed to be contacted about an additional interview to ask you about your experiences of taking part in the trial. We are carrying out these interviews at the moment and would be very keen to speak to you.

The interview is about your general experiences of the treatment and would be carried out over the telephone. Because the interview will include questions about the particular treatment you received, it would be carried out by a researcher from Exeter/Durham/York University so that your usual researchers in Exeter/Durham/York do not find out which therapy you had.

We will be phoning you soon to see if you would like to take part in this extra interview. Please note that because this phone call will be from Exeter/Durham/York University, you may not recognise the number. If you would like to speak to us before then, either to say that you would or would not like to take part, or for further information, you can contact me on PHONE or EMAIL, or you can contact your usual research team in Exeter/Durham/York. If your contact details have changed recently, please also let us know so that we can get in touch.

I look forward to speaking to you soon.

Yours sincerely,

Researcher Name
COBRA Researcher
Exeter/Durham/York University

Local Site Address and contact info

<Insert name and address of GP>

<Insert current Date>

Dear <Name of Doctor>,

Re: <Name of Patient>, <DOB>

As you are aware, <Name of Patient> was invited to take part in the COBRA trial comparing Behavioural Activation with Cognitive Behavioural Therapy for the treatment of depression. As part of the trial a researcher from the COBRA team interviewed <Name of Patient> to assess his/her suitability for the trial.

During this interview <Name of Patient> was found to be eligible for the COBRA trial. He/she will be randomised to receive either Behavioural Activation or Cognitive Behavioural Therapy from a COBRA therapist. However, clinical management of all patients in the COBRA trial remains the responsibility of their GP.

Please find enclosed a copy of the Participant Consent Form for the COBRA trial, signed by <Name of Patient>, for your information.

Yours sincerely,

<Insert Name of Researcher>
COBRA Researcher

Enclosed: Participant Consent Form

Local Site Address and contact info:

<Insert name and address of GP>

<Insert current Date>

Dear <Name of Doctor>,

Re: <Name of Patient>, <DOB>

As you are aware, <Name of Patient> was invited to take part in the COBRA trial comparing Behavioural Activation with Cognitive Behavioural Therapy for the treatment of depression. As part of the trial a researcher from the COBRA team interviewed <Name of Patient> to assess his/her suitability for the trial.

During this interview <Name of Patient> was found to be ineligible for the COBRA trial and will therefore not be receiving treatment from a COBRA therapist.

Yours sincerely,

<Insert Name of Researcher>
COBRA Researcher