What happens if something goes wrong?
Your normal NHS channels of complaint are open to you if you are unhappy about the clinical care you receive. If you have any complaints about the conduct of this trial you should contact Dr Hilary Pinnock, who is leading the study *(help.copd@ed.ac.uk).* If you remain unhappy about any part of the project or any activity of a member of the research team and wish to complain formally, you can do this by contacting Lucy McCloughan, Centre for Population Health Sciences, The University of Edinburgh, Medical School, Teviot Place, Edinburgh EH8 9AG. (0131) 6503195.

Will my taking part in this study be kept confidential?
All information which is collected about you during the course of this study will be kept confidential. Any information collected about you will be coded so that you cannot be identified. Only Dr Pinnock and the research team will have access to the codes which connect study data to you personally.

What will happen to the results of the research study?
We will send you a summary of the results. The results of the study will be discussed at scientific medical meetings and published in medial journals. Health care professionals will therefore learn what this research has shown and use the results when looking after other people who suffer from COPD.

Who is organising and funding the research?
The research is being organised by Dr Hilary Pinnock, a general practitioner and a researcher at the University of Edinburgh. The trial is funded by a grant from the **Dunhill Medical Trust**.

The **Dunhill Medical Trust** is a UK based charitable company funding research focussing on care of older people, including rehabilitation and palliative care.
Information about the Dunhill Medical Trust is available http://www.dunhillmedical.org.uk/

Who has reviewed the study?
The study has received ethical approval from the South East Scotland Research Ethics Committee 01 and governance approval has been granted by NHS Lothian Research & Development. This means that your rights will be respected and that any risks to you have been reduced to a minimum and balanced against any possible benefits, and that you have been given sufficient information on which to make an informed decision.

What do I do now?

If you have decided you are interested please complete the enclosed form with your contact details and return it to the specialist nurse Susie Ferguson.

Who can I contact for further information?

Marilyn Kendall or Susan Buckingham will be pleased to answer any questions.
Tel: (0131) 651 4152 E-mail: *help.copd@ed.ac.uk*
The study secretary is Cristina Matthews
Centre for Population Health Sciences, The University of Edinburgh
Medical School, Teviot Place, Edinburgh EH8 9AG

http://www.cphs.mvm.ed.ac.uk/projects/help-copd/
ClinicalTrials.gov Identifier: NCT01650480

If you wish to speak to someone who is not involved in the study directly, for impartial advice at any stage, please contact Lucy McCloughan on (0131) 6503195.

(Please note that we can only answer questions about the trial – you should discuss any concerns about your COPD with your general practitioner or respiratory specialist in the normal way)

Thank you for reading this and showing your interest.
Please keep a copy of this information sheet safe for future reference.

HELP-COPD action plan

This is an invitation to take part in a research study.

Before you decide whether you would like to take part, it is important that you understand why the study is being done and what it might mean for you.
Please take time to read the following information and discuss it with others if you like.
Please ask us if there is anything which you do not understand or is not clear to you.
Take time over deciding whether or not you wish to take part.

Thank you for reading this leaflet

What is the purpose of the study?

Chronic Obstructive Pulmonary Disease (COPD, sometimes called emphysema, bronchitis) is one of the commonest conditions in Scotland. People with COPD have many symptoms, but often the most troublesome is breathlessness. People with more severe symptoms may find it difficult to get out, and to carry out normal household tasks. They may worry about how they will be able to cope if things get worse, and may sometimes become depressed. Although medical and social care is available, doctors and nurses do not always understand the difficulties people with COPD have with day to day life and so services that could make a difference are not always provided.

In this study we are developing and testing a new idea to help patients with COPD. The HELP-COPD action plan is a one-page document designed to prompt a specialist nurse to ask specific questions about any particular concerns and difficulties and, if there are any problems, develop an action plan to help manage these needs. After talking with people with COPD and professionals who provide care, we have developed a first version of the action plan which we are ready to test in a pilot trial. This trial is explained in this leaflet.

People who agree to take part in the trial will be randomised to the HELP-COPD action plan or 'usual care' group. This means that when you agree to take part in the trial you will not know which group you will be in. The group will be chosen by chance using a computer programme. You have more chance of falling into the HELP-COPD action plan group.

Why have I been invited to take part?

The specialist research nurse, Susie Ferguson, based on the respiratory ward at the Royal Infirmary of Edinburgh, has given you this leaflet because you have been admitted due to your COPD. If you think you might be interested in helping with the research, the nurse will ask you to complete a form with your contact details which she will hand on the research team. (Your name will not be given to the researchers without your permission). One of the researchers will then contact you to arrange a time to meet you, to explain the trial so that you can decide if you want to take part.

Do I have to take part?

It is up to you to decide whether or not you want to take part. If, when you discuss this with the researcher, you decide to take part we will ask you to sign a consent form. If you change your mind at any time you are free to withdraw from the study without having to give a reason. If you decide not to take part or withdraw at any time it will not affect the care that you receive.

What will happen to me if I take part in the trial?

If you are interested in taking part, the research nurse will pass on your contact details to the researchers.

Meeting the researcher

A researcher (Marilyn Kendall, Susie Ferguson or Susan Buckingham) will then arrange to meet with you to answer any questions you may have about the trial and if you are willing to take part will ask you to sign a consent form.
To find out about your COPD the researcher will:

- Ask a few questions about how long you have had breathing problems, and what treatment you take.
- Ask you to fill in nine questionnaires which we estimate will take about 20 minutes, about how your breathing problem affects your life and how you feel about your treatment and managing your condition.

You will NOT have to give blood, or take any tests. The meeting will take about 45 minutes, but you can stop at any time if you feel tired.

You will then be entered into the trial. The computer will be used to select, by chance, whether you go into the usual care or the HELP-COPD action plan group.

Clinical care in both groups

People in both groups will continue to receive their usual care from their GP and any other help/care they currently receive from other services. We will inform your GP that you are participating in the trial: this will not affect the normal clinical care that you receive.

The HELP-COPD action plan

In addition, if you are in the HELP-COPD action plan group the specialist nurse, Susie Ferguson, will work through the HELP-COPD action plan with you. This will involve discussing your COPD and identifying any areas of particular concern or difficulties that you may have with your COPD in your daily life. The nurse can refer you for any help that you need now, or discuss any concerns that you may have about the future. You will be given a copy of the completed HELP-COPD action plan to keep, and a copy will be given to your GP. If you and the nurse decide that a referral for treatment or help in the home would be useful, we will also send a copy of the completed HELP-COPD action plan' to these other services. The specialist nurse will check with you (probably by telephone) after a month and again after 3 and 6 months to check on progress with the HELP-COPD action plan.

Research visit

Three months after joining the study a researcher will arrange to send you the questionnaire booklet to complete at home, and finally after 6 months the researcher will arrange to meet you again and ask you to complete the questionnaires once more.

Data from clinical records

At the end of the trial a researcher will look at your medical record and collect information about any admissions, or other problems you have had with your COPD, and how much treatment you have needed since the beginning of the trial.

Does the study involve me in taking any drugs? Could there be any side effects?

This is not a trial to look at the effects of drugs. Any treatments recommended will be standard treatments for COPD, and will be prescribed in line with national COPD guidelines. We will not ask you to stop any medication for the trial. As you will not be receiving any new trial drugs so there will be no side effects due to the trial.

What happens if new information comes along during the study?

We do not anticipate any new information during the course of the trial which would cause us to stop the trial. Any changes in national COPD guidelines will be incorporated into the clinical care that you receive.

What else might I be invited to do?

We wish to interview a few people (about 10) who are taking part in the trial to find out about their experience of using the HELP-COPD action plan. During the year, we will write to some participants inviting them to help with this aspect of the trial. This is a separate part of the study: taking part in the trial does not commit you to helping with the interviews. If you decide to take part in interviews, the researcher (Marilyn Kendall or Susan Buckingham) can meet you at your home, in your doctor's surgery or in the University – wherever is most convenient for you. The researcher may also ask if they may approach your carer, and may speak to your GP and other professionals who have been sent copies of your HELP-COPD action plan to find out whether they found the plan useful.

Will the interview be recorded?

Yes. We will, with your permission, record the interview which will then be transcribed for analysis. Your contributions will be identified by a code number, not by name, so that what you say will be anonymous. The recordings will be destroyed after the completion of the project.

Other questions about the study

What information will be needed about me?

The only personal information we will request is your age, gender, how long you have had COPD and the treatment that you take.

What are the possible disadvantages and risks of taking part?

All participants will be asked to complete questionnaires, and some will be invited to be interviewed. Those in the HELP-COPD action plan group will also complete the 'HELP-COPD' action plan. This only involves speaking with a nurse about any problems you may have because of your COPD: it would be up to you to decide to accept any suggested actions or referrals. This will not affect your treatment in any way and therefore we do not believe that there will be any risk to you in taking part.

What are the possible benefits of taking part?

The HELP-COPD action plan is designed to help identify and manage any unmet needs you may have as a result of your COPD. You may find talking to the research nurse helps you to explain your needs, and helps you to think about any help you would like. You may be referred to services that can help you further. By taking part in the trial you will also be helping us to understand whether or not the HELP-COPD action plan is helpful.

Will taking part, or not taking part, affect my usual treatment?

No. Taking part, or declining to take part, in the study will not affect the usual care you receive from your practice. You may make an appointment at any time that you want to see your GP or other health professional about your COPD or any other condition in the normal way.

Will it cost me anything?

No. Usually the researcher will come to you, but if you decide you prefer to meet her in your doctor's surgery or the University, we will pay reasonable expenses to cover the cost of travel.

What if I decide not to take part?

If you decide you do not want to take part, or if the baseline assessment shows that you are not eligible for this trial, you will continue to be treated in the usual way by your GP and other health professionals.