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NHS Trust

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A self-management programme of activity coping and education - SPACE FOR COPD - in primary care: a pragmatic trial (Version 5 08/05/2015)

You are being invited to take part in research study being conducted by University Hospitals of Leicester NHS Trust. Before you decide whether or not 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 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.

We have developed a self-management manual for patients with Chronic Obstructive Pulmonary Disease (COPD). This has been done with enormous help from patients like yourself. The manual covers issues such as drug and symptom management, exercise and nutrition at home.

In a previous study, we provided this manual for people to work through at home, with one initial meeting with a healthcare professional. While that study showed there were several benefits to having the manual, we would now like to see if the benefits will last longer if support from the healthcare professional is increased. Also patients have told us they would like the manual to be and supported in a peer group environment. This study, therefore, will test the effectiveness of using the manual within a group setting over a number of sessions.

We would like to know how effective the use of this manual may be when delivered and supported in a group environment. This will help us improve future patient care.

2. Why have I been invited?

As an individual with COPD you have been identified as a suitable participant by your GP or your healthcare professional. You might have also been involved in a previous research trial and agreed to be contacted again or agreed to be contacted about future trials for which you might be eligible. It is important we see how people progress using the manual we have developed compared to those who receive standard care from their GP or healthcare professional. This knowledge may help us develop and improve future services.

3. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to

take part you are still free to withdraw at any time and without giving a reason. Your decision to withdraw will not influence any medical care you receive.

4. If you agree to part what will happen?

Once you have provisionally agreed to take part in the research you will be contacted to arrange a date and time to discuss the project in more detail. You will be invited to attend an appointment which will take place at Glenfield Hospital. If you still wish to go ahead at this stage then we will ask you to sign a consent form to take part in the study. Following this we will do some lung function tests. These are tests where you blow out into a tube as hard as you can. This confirms that you do have a diagnosis of COPD. You will then be randomly allocated to one of two arms of the trial. Half of the people in the study will be randomly allocated to receive the self-management group programme. The other half will be randomly assigned to 'usual care' which means that we will not change any of your current treatment or care. You will be randomly allocated to one of these two arms of the study by a computer-based system. This means that we will not know before hand which arm of the study you will be in. It is important that this is done at random in order to keep the results of the study fair.

5. What do I have to do?

If you are assigned to the usual care group you will continue as normal with the treatment you receive from your GP and healthcare team. At your first visit with us, you will be requested to complete some questionnaires about your health status. These will take about 20 minutes to complete. We will also ask you to wear an activity monitor for the following 7 days at home. The monitor is a small device which is worn around your arm, and it measures your activity levels at home. We will arrange to collect this from you after you have finished wearing it. We will ask you to repeat the questionnaires and wearing of the activity monitor after 6 months, and then again 3 months later (9 months from starting the study and your final assessment). In addition to the questionnaires and activity monitor at 6 months and 9 months, we will ask you to attend the hospital to do some walking tests. These will be done at Glenfield Hospital. There will usually be three walking tests, which are done on a flat corridor, walking up and down a 10 metre course. It is usual to become breathless during these tests, however we will only ask you to do as much as you feel you can.

If you are assigned to the self-management group you will undergo the same assessments at the same time points as the usual care group. However, in addition to these we will also ask you to do the walking tests at all three time points (i.e. your first visit, 6 month visit and 9 month visit). These will all take place at Glenfield Hospital. In between your first visit and your 6 month visit we will ask you to attend the group sessions to introduce you to the self-management programme. These will take place at a community centre. There will be approximately between six and 10 people in each group, and all sessions will be led by 2 healthcare professionals. Each session will last approximately two hours. At your first session you will be given the SPACE FOR COPD manual, and each session thereafter will discuss a different topic about how to manage with COPD. You will be advised how you can increase your activities at home, improve management of your breathlessness and learn what to do if you develop a chest infection. You do not have to discuss anything within the group if you do not wish to, and everything discussed within the group will be kept confidential. At the end of the self-management programme we will also ask you to take part in a focus group discussion where you will have an opportunity to discuss your experiences of the programme and whether you thought it was useful to you. The focus group will last

approximately 1 hour. The discussions will be audio recorded and transcribed for research purposes.

During the study, and immediately afterwards the study team will access your medical notes to obtain long term follow up data (for example GP visits, hospital admissions).

6. Are there any risks, disadvantages or side-effects of taking part?

We do not expect there are any risks to taking part in this study.

One potential disadvantage to taking part is the time you give to the study. Your first visit may take up to two hours. Your six-month and nine-month visits may take up to one hour each.

Whilst completing the walking tests, you may become short of breath, however we expect this will recover once you sit and rest. Afterwards, you may experience some achiness in your muscles and feel tired. This is usually only lasts a day or two.

7. What are the possible benefits of taking part?

We hope that the research will aid you in your understanding of COPD and how you can improve your symptoms. Information gathered will inform both present and future research, aiming to provide better care for people living with COPD.

8. What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, 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 would be available to you.

Should you wish to discuss any concerns about this study further, the Patient Information and Liaison Service is a point of contact for you. Their telephone number is 0808 178 8337.

9. Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you, which leaves the medical centre, will have your name and address removed so that you cannot be recognised from it. Some of your anonymised data will be shared with Insignia Health (a healthcare organisation) and entered onto a secure database to help improve patient outcome measures. This will be basic information, for example age, gender and some questionnaire data. Participants will not be identified in any subsequent written material. Results will be reported in such a way that completely preserves confidentiality. Data will be stored at Glenfield Hospital, and on University Hospitals of Leicester secure networks.

We will, with your consent inform your GP of your participation in the trial and share with your GP any relevant test results that have been made during your participation in the trial.

10. What will happen to the results of the research study?

The results of the study will be written in peer and lay journals, professional publications and presentations made at relevant conferences. Results will be reported in such a way that preserves confidentiality. All participants will also receive a summary of the results.

11. Who is organising and funding the research?

This study is being organised by staff employed at University Hospitals of Leicester NHS trust. It is being funded by a Collaboration and Leadership in Applied Health Research and Care East Midlands (CLAHRC).

12. Who has reviewed the study?

All research that involves the NHS is reviewed by an NHS Research Ethics Committee. This study has been reviewed and given a favourable opinion by Hampshire B research Ethics Committee. This does not guarantee that you will not come to any harm if you take part. However, approval means that the committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits and that you have been given sufficient information of which to make an informed decision. The study has also been reviewed and is sponsored by University Hospitals of Leicester.

13. Contact for further information

If you have any concerns or other questions about this study or the way it has been carried out, you should contact the principal researcher Professor Sally Singh:

Contact for further information:

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Thank you for reading this
Yours faithfully

Sally Singh