

Glenfield Hospital  
Groby Road  
Leicester  
LE3 9QP

Tel: 0300 303 1573  
Fax: 0116 258 3950  
Minicom: 0116 287 9852

## Patient Information Sheet

### InterSPACE – COPD Self-Management Programme

InterSPACE: Feasibility of an integrated Telehealth and Self-Management programme for individuals hospitalised with an exacerbation of COPD

Principal Investigator: Sally Boyce

Co- Researchers: Chrissie Mitchell-Issitt  
Christopher Brough  
Sally Singh

You may contact Sally Boyce on 0116 2502671

## **Invitation**

You are being invited to take part in an evaluation study being conducted by the Respiratory Nursing and Pulmonary Rehabilitation team. Before you decide it is important for you to understand why this evaluation study 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. Thank you for reading this.

## **What is the purpose of the study?**

Recent evidence has shown pulmonary rehabilitation for patients with chronic obstructive pulmonary disease (COPD) to be of benefit. However, despite its proven benefits, pulmonary rehabilitation programmes can be unappealing to a large number of patients. A recent audit identified that less than 10% of eligible patients completed a course of rehabilitation following an exacerbation of their COPD. There is a need to develop alternative ways to support patients being discharged from hospital with COPD to manage their breathlessness, stress levels, and regain their physical and social abilities.

This study is to offer an online interactive web-based self-management programme with facilities to have face to face video chats with the specialist respiratory nurse to patients with COPD for a period of 6 months after discharge from hospital following an exacerbation of their condition, to help guide, support and encourage patients to better understand and manage their condition and thereby reduce unnecessary readmission to hospital. Patients can access this on line interactive web-based self-management programme by using their own computer at home. If patients do not have access to a computer or laptop at home they will be provided with an iPad or similar device with instructions on how to access the online programme.

Patients will be given a login activation code prior to discharge from hospital and instructions, together with a User Guide, on how to access the on-line interactive web-based self-management programme. For patients requiring an iPad or similar device these will be preloaded with the web-based programme. The iPads and devices given to patients will be locked with only access to the on-line web-based programme. Patients who have been given an iPad or similar device will be required to sign for responsible use and safe return of device on completion of programme or if patients chose to drop out of the study.

This study is needed in order to inform the current delivery of patient information, support on discharge from hospital, rehabilitation service and the optimisation of patient care as well as aid the development of new COPD rehabilitation programmes.

## **Why have I been chosen?**

As an individual with COPD who has been admitted to hospital with an exacerbation of your condition you have been identified as a potentially suitable participant of the study. It is important to us to see how people progress using the recently developed on-line interactive web-based self-management programme. This knowledge will help us develop and improve future services.

**Do I have to take part?**

It is up to you to decide whether or not to take part. If you 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. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. The data collected to the point of withdrawal may still be used.

**What will happen to me if I take part?**

If you agree to take part in the study, you will sign a consent form and a device loan agreement if you require an iPad or equivalent to access the programme.

All patients will then complete a set of baseline questionnaires about your health status and knowledge about your lung condition. These will be given to you by the respiratory specialist nurse before discharge from hospital and usually take around 20 to 30 minutes in total to complete.

Overall your involvement will last up to 12 months and will not affect any aspect of your usual care.

**What do I have to do?**

Once you have agreed to take part in this evaluation study and have signed the consent form you will be introduced to the on-line interactive web-based programme in hospital by one of the respiratory specialist nursing team. Then you will be provided with a login activation code to access the on-line interactive web-based self-management programme.

It is expected that you will use the web site most days. The on-line interactive web-based programme will outline how to manage your condition including information on drug and symptom management, exercise and nutrition. Included will be some home-based exercises you can carry out in your own time. You will receive a follow up phone call 48 hours post discharge from the respiratory specialist nursing team as per usual care. This will be an opportunity for the nurses to enquire how you are getting and for you to ask any questions you may have. The specialist nurses will ask you if you have logged onto the on-line self-management website or may prompt you to do so.

You will receive usual invite to participate in pulmonary rehabilitation if eligible as per usual care. You will receive repeat questionnaires at 3 months and 6 months about your health status and knowledge about your lung condition in the post from us with a pre-paid addressed envelope for returning to us. After 6 months and up to 12 months, participants of the on-line interactive web-based self-management programme may be invited to take part in a semi structured interview. This will involve a discussion about using the on-line web-based programme on discharge from hospital for up to 6 months and is an opportunity to feedback what was useful about the website and any suggestions for improvement. This should not last longer than an hour and can take place in your own home or at the hospital. With your consent we would like to record the interview. You do not have to do this interview to still be part of this research study.

**What are the possible disadvantages and risks of taking part?**

If you agree to participate in this evaluation study of an on-line interactive web-based self-management programme, you will not be disadvantaged as usual care will not be affected. This on-line web-based programme is in addition to usual care. However if you do not feel it was beneficial or if you wish to withdraw from the study, you can withdraw at any time.

**What are the possible benefits of taking part?**

We hope that the being part of this evaluation study with access to additional support on discharge from hospital will aid you in your understanding of your lung condition and help you to better self-manage your condition. In addition it may inform your understanding of exercise and rehabilitation and inform both present and future services for patients with COPD including pulmonary rehabilitation programmes therefore benefiting COPD patients.

**What if something goes wrong?**

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 (Sally Boyce 0116 2502671). 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. Advice can be sought from the Patient Information and Liaison Service (PILS) (Telephone no. : 08081 788337; Email: [pils.complaints.compliments@uhl-tr.nhs.uk](mailto:pils.complaints.compliments@uhl-tr.nhs.uk)).

**Will my taking part in this study be kept confidential?**

All information that is collected about you during the course of this evaluation study will be kept strictly confidential. Any information about you, which leaves the hospital, will have your name and address removed so that you cannot be recognised from it. Participants will not be identified in any subsequent written material; for example, numbers will be used to refer to participants' names. Results will be reported in such a way that completely preserves confidentiality.

**What will happen to the results of the study?**

The results of the study will be disseminated 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 letter of the results.

**Who is organising and funding the research?**

This study is being funded by the Academic Health science Network for the East Midlands which is part of the funding body National Institute for Health Research (NIHR). The Respiratory Specialist nursing team will be recruiting participants to the study. The study is also supported by the NIHR Collaboration and Leadership in Applied Health Research and Care for East Midlands and the Leicester Respiratory Biomedical Research Unit.

**Who has reviewed the study?**

All research that involves NHS patients or staff, information from NHS medical records or uses NHS premises or facilities must be given a favourable opinion by an NHS Research Ethics Committee before it goes ahead. A favourable opinion does not guarantee that you will not come to any harm if you take part. However, it 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. This study has been reviewed and given favourable opinion by the NHS Health Research Authority (NRES) Committee East Midlands – Northampton.

**Contact for further information**

For further information please contact:

Sally Boyce  
Centre for Excellence in Science and Rehabilitation Department  
University Hospitals of Leicester NHS Trust  
Glenfield Hospital  
Grobby Road  
Leicester  
LE3 9QP  
0116 2502671

Thank you for reading this information leaflet.

