INFORMATION FOR PATIENT

Title: Early Assisted Discharge for COPD Exacerbations With Telemonitoring. NCT01951261. Version 1. 01/02/2012.

INTRODUCTION

We write to you about a research study in which you are invited to participate. The study has been approved by the Ethics Committee of the Puerta de Hierro Majadahonda Hospital, in accordance with current legislation, and is carried out with respect for the principles set forth in the Helsinki declaration.

Our intention is only that you receive the correct and sufficient information so that you can evaluate and judge whether or not you want to participate in this study. To do this, read this information sheet carefully and we will clarify any doubts that may arise after the explanation. In addition, you can consult with the people you consider appropriate.

VOLUNTARY PARTICIPATION

You should know that your participation in this study is voluntary and that you can decide not to participate or change your decision and withdraw your consent at any time, without altering your relationship with your doctor or causing any harm to your treatment.

GENERAL DESCRIPTION OF THE STUDY:

Chronic Obstructive Pulmonary Disease (COPD) is a very frequent disease, approximately 10% of the population suffers from it. Exacerbations are the most frequent cause of hospitalizations and act as an adverse prognostic factor, that is, they deteriorate the disease, progressively worsening discomfort.

In the pulmonology department of our hospital, the exacerbation of COPD means an average of 10 days of stay in the hospital. During the first half of this period, the patient needs hospital health care: close clinical control, intravenous medication, oxygen, aerosol therapy, etc.). During the second half of the hospital stay, if the clinical evolution is favorable, intensive

treatment is gradually withdrawn. For this reason, for 2 years there has been a home hospitalization program with nursing support and medical supervision, which ensures that this second phase can take place in the patient's home. With this, it is possible to shorten days of hospital admission, improve the patient's quality of life in the short term and reinforce health education.

The use of telemedicine, monitoring clinical parameters (tensión blood pressure, heart and respiratory rates, temperature and oxygen saturation) at home with immediate delivery to the hospital's Clinical Unit could improve the effectiveness of home hospitalization.

The objective of our study would be to assess the efficacy of telemedicine in our home hospitalization program.

Patients will be divided into two groups of similar size, the telemedicine group and the control group. The distribution between the groups will be carried out randomly, that is, as if it was decided heads and tails, so as not to alter the results of the study. If you participate as a control group, an initial visit by the doctor and nurse will be carried out to include the patient in the program, and subsequent successive home visits will be carried out by the nurse, depending on the patient's clinical evolution, degree of control and knowledge of the disease and its level of security and confidence in the program.

If you belong to the telemedicine group, your constant measurements will be monitored daily with the portable monitor: Omicrom safe, which will be taken to your home on the day of visit 1. This monitor will measure: Blood pressure, ECG strip (DII long), oxygen saturation, heart rate and respiratory rate. You will also be provided with a mobile phone to send the constants for free. In addition, a thermometer will be delivered for the daily recording of the temperature.

Constant measurements will be carried out twice a day (morning and afternoon). And the patient will receive a call from their responsible physician after each referral.

If deemed necessary, extra measurements and shipments may be made.

The data of the constants sent will be reviewed by the doctor throughout the day and in turn

he will receive an alarm signal on his mobile if any of the signals recorded by the patient show abnormal values. At that time the doctor will contact the patient by telephone and the action plan will be explained, which will include an extraordinary home visit if necessary or a recommendation to go to the emergency room.

In both groups, the nurse and the doctor attend the discharge visit from the home hospitalization program again, and the patient is given the discharge report and the treatment to be followed, as well as an appointment for a review one month after discharge.

BENEFITS AND RISKS ARISING FROM YOUR PARTICIPATION IN THE STUDY

Whether you participate or not, you will receive the most adequate control of your disease. Whether you participate in the telemedicine group or in the control group, the information obtained from your participation will help to improve the home control of future patients. Participation in this study hardly involves added risks to the risks of your medical situation and the usual medication for this disease. Possibly, some of the patients may have symptoms of anxiety and concern about managing their disease.

CONFIDENTIALITY

The treatment, communication and transfer of personal data of all participating subjects shall comply with the provisions of Organic Law 15/1999, of December 13, 1999, on the protection of personal data, and in its development regulation. In accordance with the provisions of the aforementioned legislation, you can exercise the rights of access, modification, opposition and cancellation of data, for which you must contact your study doctor.

Your data collected for the study will be identified by a code and only your study doctor and collaborators will be able to link this data to you and your medical history. Therefore, your identity will not be revealed to any person except for exceptions in case of medical emergency or legal requirement.

Only the data collected for the study will be transmitted to third parties and other countries,

with prior notification to the Spanish Data Protection Agency, which in no case will contain information that can directly identify you, such as name and surname, initials, address, number of the social security etc. In the event that this transfer occurs, it will be for the same purposes of the study described and guaranteeing confidentiality at least with the level of protection of the legislation in force in our country.

Access to your personal information will be restricted to the study doctor / collaborators, health authorities, the Puerta de Hierro Majadahonda Research Ethics Committee and authorized personnel, when they need it to check the study's data and procedures, but always maintaining the confidentiality thereof in accordance with current legislation.

Financing Project financed by the project file DGPY 1419-09 belonging to the Research Grants Program for Emerging Groups within the Intramur Program of the Carlos III Health Institute.

OTHER RELEVANT INFORMATION

If you decide to withdraw your consent to participate in this study, no new data will be added to the database, although those responsible for the study may continue to use the information collected about you up to that time, unless be that you expressly object.

You should also know that you can be withdrawn from the study in case those responsible for it consider it appropriate, either for security reasons, for any adverse event that occurs due to or because they consider that you are not complying with the established procedures. In either case, you will receive an adequate explanation of the reason for your withdrawal from the study.

WRITTEN PATIENT CONSENT

Clinical trial title: **Early Assisted Discharge for COPD Exacerbations With Telemonitoring. NCT01951261. Version 1. 01/02/2012.**

Efficacy of telemedicine in home hospitalization COPD patients

I, (name and surname) ....

I declare under my responsibility that:

I have read the information sheet given to me

I have been able to ask questions about the study

I have received enough information about the study

I have spoken to (name of investigator) ....

I understand that my participation is voluntary

I understand that I may withdraw from the study:

1st Anytime

2º Without having to give explanations

3º Without this having an impact on my medical care

And I have expressed agreement to participate in the study.

_____ _____

Participant's signature Date

_____ _____

Investigator's Signature Date

PATIENT ORAL CONSENT TO WITNESSES

Clinical trial title: **Early Assisted Discharge for COPD Exacerbations With Telemonitoring. NCT01951261. Version 1. 01/02/2012.**

I, (name and surname) ....

I declare under my responsibility that: (name of the participant in the trial)

....

You have received the study information sheet

You were able to ask questions about the study

You have received enough information about the study

Has been informed by (name of researcher) .....

Understand that your participation is voluntary

You understand that you may withdraw from the study:

1st Anytime

2º Without having to give explanations

3º Without this having an impact on your medical care

And she has expressed her agreement to participate in the study.

_____ _____

Witness signature Date

_____ _____

Investigator's Signature Date

REPRESENTATIVE'S CONSENT IN WRITING

Clinical trial title: **Early Assisted Discharge for COPD Exacerbations With Telemonitoring. NCT01951261. Version 1. 01/02/2012.**

I, (name and surname) ....

As (relationship with the participant) ....

FROM (name of participant) ....

I declare under my responsibility that:

I have read the information sheet given to me

I have been able to ask questions about the study

I have received enough information about the study

I have spoken to (name of investigator) ....

I understand that your participation is voluntary

I understand that you may withdraw from the study:

1st Anytime

2º Without having to give explanations

3º Without this having an impact on your medical care

In my presence, (name of participant) has been given ....

..... all information adapted at your level of knowledge

and agree to participate. And I agree that (name of participant) .....

..... participate in this study.

_____ _____

Representative's signature Date

_____ _____

Investigator's Signature Date