PATIENT INFORMATION SHEET / POTENTIAL PARTICIPANT

TITLE OF THE STUDY: **USEFULNESS OF TELEMONITORING IN THE PROCESS OF ADAPTATION TO HOME MECHANICAL VENTILATION**
STUDY CODE: **IIBSP-TEL-2022-132**
PROMOTER: Research Institute of the Hospital de la Santa Creu i Sant Pau – IIB Sant Pau
PRINCIPAL INVESTIGATOR: Patricia Peñacoba, Pulmonology Service. Tel: 935565972.
CENTER: HOSPITAL DE LA SANTA CREU I SANT PAU

INTRODUCTION

We are writing to inform you about a research study in which you are invited to participate. The study has been approved by the corresponding Clinical Research Ethics Committee.
Our intention is only that you receive 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.

OVERVIEW OF THE STUDY

The Pulmonology Service of the Hospital de la Santa Creu i Sant Pau is carrying out a study to assess the usefulness of telemonitoring in the process of adaptation to non-invasive home mechanical ventilation (HMV).
You have a ventilatory disorder that gives you chronic respiratory failure that requires treatment with HMV.
HMV is a respiratory support therapy commonly used in clinical practice that involves applying pressurized air to the airways through a nasal or nasooral mask connected to a mechanical ventilator. In this way, airway pressures are increased, helping to improve respiratory function and gas exchange.
The latest generation of home mechanical ventilators incorporates technology that allows remote information to be obtained that is useful for monitoring or monitoring treatment (telemonitoring), such as, for example, hours of use, the presence of excessive air leakage or any other interaction between the patient. and the ventilator that could compromise therapy. Until now, in order to obtain this data, the patient had to go to the hospital so that specialist professionals could download the information directly from the device or its memory card. Once known, the pertinent modifications were made to the fan, an aspect that can currently also be done remotely.

In recent years, telemonitoring has begun to be incorporated into routine practice in some selected patients. However, we do not know whether therapy compliance improves or not with telemonitoring. This study will try to assess whether telemonitoring applied during the adaptation process to HMV (first 6 months of treatment) could increase its success rate, compared to exclusively in-person follow-up. That is, whether including telemonitoring in the usual follow-up of patients could control the pathology in a more efficient way, improve compliance and satisfaction with treatment.
If you agree to participate in this study, your HMV follow-up model will undergo randomization; That is to say, it will be drawn whether their monitoring will be carried out regularly (exclusively in person) or whether it will be carried out incorporating telematic monitoring (or telemonitoring).
Patients who are included in the exclusively in-person follow-up model will attend control visits 2 weeks, 1, 2, 4 and 6 months after starting HMV, as is currently done in normal clinical practice. During these visits, a clinical and blood gas control, nocturnal pulse oximetry, questionnaires and download of ventilator data will be carried out. Depending on the data obtained, appropriate adjustments will be made to your therapy.
Patients who are included in the telemonitoring follow-up model will undergo a remote review of HMV data daily for the first 2 weeks and, subsequently, weekly for up to 6 months. The team of professionals will contact the patient in case of any eventuality and make adjustments to the therapy, if deemed appropriate. In addition, patients will attend in-person follow-up visits 2, 4 and 6 months after starting HMV. During these visits, a clinical and blood gas control, nocturnal pulse oximetry, questionnaires and download of ventilator data will be carried out. Depending on the data obtained, appropriate adjustments will be made to your therapy.

During the duration of the study, you will be able to communicate during working hours with the health professionals assigned to you, who are part of the Center for Comprehensive Care of Respiratory Diseases (CAIDER) of the Ventilation Unit and who will be responsible for monitoring your therapy. If you are outside working hours, you can contact the following email address: pneumologia@santpau.cat. In the event of an urgent technical incident outside of working hours, you must contact the home respiratory therapy company that corresponds to you or go to the Emergency Services, if it involves healthcare.
Once 6 months have been reached, your participation in the study will end. From then on, monitoring will continue according to the usual clinical practice of the Mechanical Ventilation Unit. Subsequent controls will consist of in-person visits, incorporating telemonitoring as a complementary measure at the discretion of the healthcare professional and always agreed with you.
In any case, you will be provided with a telephone number where, during business hours, you can ask any questions you may have, report any incident or notify any event related to your respiratory therapy. In addition, it would be possible to schedule an unscheduled in-person visit, if the incident required it.
In no case will the patient be subjected to unconventional or extraordinary tests different from those already carried out in normal clinical practice and follow-up.
It is expected to include about 48 patients in the study (24 in each of the groups).

If you do not wish to participate in this study, you will continue monitoring according to the usual clinical practice of the Mechanical Ventilation Unit.

BENEFITS AND RISKS ARISING FROM YOUR PARTICIPATION IN THE STUDY

This study aims to evaluate whether telemonitoring as a simple remote monitoring tool could optimize adherence and satisfaction with HMV, in addition to correcting respiratory failure more quickly and efficiently. Knowing this would be especially useful, for example, in patients far from their hospital center or with mobility problems.
There may also be no health benefit from participating in this study, but it will help clarify whether it would have a positive impact on the overall impact of the disease and the costs of its management.
Participation in this study does not have to pose an added risk to your health. In addition, during working hours, you will have a direct contact telephone number with the Mechanical Ventilation Unit in case of any eventuality and the possibility of scheduling an unforeseen in-person visit, if applicable.

CONFIDENTIALITY
The processing, communication and transfer of personal data of all participating subjects will comply with the provisions of Regulation (EU) No. 2016/679 and Organic Law 3/2018, of December 5, on the Protection of Personal Data and Guarantee of Digital Rights.
Both the Center and the Promoter are respectively responsible for the processing of your data and undertake to comply with the data protection regulations in force. The data collected for the study will be identified by a code and only your study doctor/collaborators will be able to relate said data to you and your medical history. Therefore, your identity will not be revealed to anyone except in cases of medical emergency or legal requirement.

Access to your personal information will be restricted to the study doctor/collaborators, health authorities, the Research Ethics Committee and personnel authorized by the promoter (study monitors, auditors), when they need it to verify the data and procedures of the study. , but always maintaining their confidentiality in accordance with current legislation.
In accordance with what is established by data protection legislation, you can exercise the rights of access, modification, opposition and cancellation of data. You can also limit the processing of data that is incorrect, request a copy or have the data that you have provided for the study transferred to a third party (portability). To exercise your rights you can contact the principal investigator of the study. You can also exercise your rights by sending a written communication to the following address: c/Sant Quintí 77-79 08041 Barcelona. Likewise, you have the right to contact the Data Protection Agency if you are not satisfied.
If you decide to withdraw consent to participate in this study, no new data will be added to the database. However, you should note that data cannot be deleted even if you stop participating in the study, to ensure the validity of the research and comply with legal duties.

The researcher and the sponsor are obliged to retain the data collected for the study for at least 5 years after its completion. Subsequently, your personal information will only be retained by the health care center and by the sponsor for other scientific research purposes if you have given your consent to do so, or if permitted by applicable law and ethical requirements.
If we transfer your encrypted data outside the EU to our group entities, service providers or scientific researchers who collaborate with us, the participant's data will be protected with safeguards such as contracts or other mechanisms by the data protection authorities. data. If the participant wants to know more about it, they can contact the Principal Investigator of the study or the Data Protection Officer of the promoter by email at dpo_ir@santpau.cat.

ECONOMIC COMPENSATION

Your participation in the study will not entail any expenses or financial compensation. You will not have to pay for the study procedures.

OTHER RELEVANT INFORMATION

If you decide to withdraw consent to participate in this study, no new data will be added to the database.
By signing the attached consent form, you agree to comply with the study procedures outlined to you.

If you have any questions or would like more information, you can contact the principal investigator of the study.

Thank you very much for your help.

INFORMED CONSENT FORM

Title of the study: **USEFULNESS OF TELEMONITORING IN THE PROCESS OF ADAPTATION TO HOME MECHANICAL VENTILATION**

I (name and surname) .....

I have read the information sheet that has been given to me.
I have been able to ask questions about the study.
I have received enough information about the study.
I have spoken with: ....
(name and surname of researcher)
I understand that my participation is voluntary.
I understand that I can withdraw from the study:

1º Whenever you want
2º Without having to give explanations.
3º Without this affecting my medical care.
- I freely give my consent to participate in the study and give my consent for the access and use of my data under the conditions detailed in the information sheet.

.....	**.....**
Patient's signature	**Investigator's signature**
Date:	**Date**:

This document will be signed in duplicate, keeping one copy for the researcher and another for the patient.

INFORMED CONSENT FORM

Title of the study: **USEFULNESS OF TELEMONITORING IN THE PROCESS OF ADAPTATION TO HOME MECHANICAL VENTILATION**

I (name and surname) ……..as…….(relationship with the participant) of…… …….(name and surname of the participant)
I have read the information sheet that has been given to me.
I have been able to ask questions about the study.
I have received enough information about the study.
I have spoken with: ....
(name and surname of researcher)
I understand that patient participation is voluntary.
I understand that you can withdraw from the study:

1º Whenever you want
2º Without having to give explanations.
3º Without this affecting your medical care.

- In my presence,……(name of participant) has been given all relevant information adapted to his/her level of understanding and agrees to participate. I give my consent for ……(name of participant) to participate in this study and I give my consent for the access and use of the data under the conditions detailed in the information sheet.

……	**……**
Signature of the legal representative	**Investigator's signature**
Date:	**Date**:

This document will be signed in duplicate, keeping one copy for the researcher and another for the patient.