Sponsor: association pour la Complémentarité des Connaissances et des Pratiques de la Pneumologie (aCCPP)
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Validation by three-dimensional actimetry measurements of a predictive algorithm for excessive inactivity in COPD patients

INFORMED CONSENT FORM

Dear Madam, Dear Sir,

As part of the care management of your Chronic Obstructive Pulmonary Disease (COPD), your pulmonologist wants to understand more precisely your daily physical activity to adapt your care management. To do this, he will write you a prescription for a device called an actimetry sensor which will record all your movements day and night for a full week (7 days). The analysis of these movements is called "actimetry".

Write you a prescription for an actimetry sensor

This measurement can be performed as part of a scientific study that also uses information collected during the consultation (e.g. age, level of breathlessness, smoking habits, breathing measurement, etc.) and compiled by your pulmonologist on a digital medical record called Colibri-Pneumo (www.colibri-pneumo.fr).

The purpose of this study is to test the reliability of a predictive algorithm for daily physical activity in COPD patients. An algorithm is a mathematical model that predicts a patient's daily physical activity. If this algorithm is indeed reliable, your pulmonologist could do without the actimetry as it is currently proposed.

This study will be under the responsibility of an association of pulmonologists called aCCPP: "Association for Respirology Knowledge to Practice Congruence"
You are free to participate or not in this study.
You may also revoke your decision to participate in this study at any time.
Your refusal does not have to be justified and will not affect your care.

Once you have been informed by your doctor, you will have a minimum of 1 hour to decide whether to participate**.**

What does an actimetry sensor look like?

The actimetry sensor you will wear is the Actigraph wGT3X-BT. It has the appearance of a watch (weight: 19 grams). The device is worn on the belt, without connection to the skin. It is designed to be disturbance-free and does not present any risk. The only constraint is that it must be worn for 7 consecutive days.

The expected benefits are multiple:
It allows your doctor to obtain objective data on your level of physical activity, enabling him or her to direct those who need it towards an adapted care. This improves the patient's quality of life.
More broadly, this study aims to validate an algorithm for predicting extreme inactivity. Used in consultation, this simple and reliable measure could eventually replace actimetry without requiring the involvement of the patient.

How will the actimetry be performed?

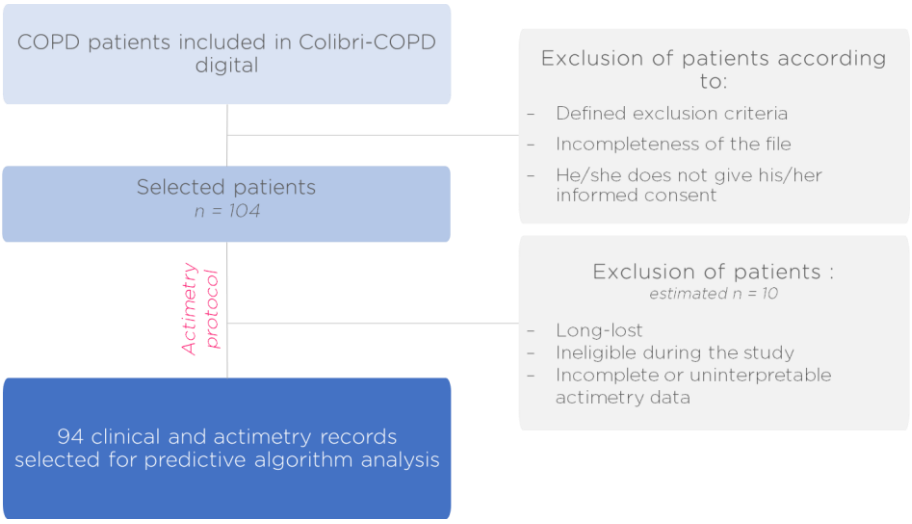

Figure 1: Diagram of the study process

During or after your consultation, your pulmonologist will ask you to complete 4 questionnaires ("CAT", "DIRECT", "HADS", "MRC Scale") about your quality of life. The estimated time to complete each questionnaire is 3 minutes.

You will then be contacted by phone by a team of professionals from Icadom who are responsible for setting up the actimetry sensors. They will explain the process in detail and take care of sending and receiving the actimetry sensor. Do not hesitate to ask them any questions you may have.
You will find all the useful information in a booklet that will be sent to you with the actimetry sensor.

What information is collected and what will happen to it?

☞**The information entered during the consultation** includes clinical data (weight, age, frequency and severity of exacerbations, sputum, chronic cough, dyspnea), lifestyle data (daily walking time, activities, smoking), respiratory functional explorations, current medications, history and comorbidities.

All data is collected securely and confidentially in a computer database and stored on a certified health data hosting server (HDS).
Only your doctor has access to your identifying data. When the data is analyzed, your file will be identified by a code number specific to Colibri-Pneumo,

You will find the contact details of the person responsible for data security in the paragraph "Your contacts", Data Protection Officer.

☞**The information collected by the actimetry sensor** is a measure of your activity. These measurements are anonymized and stored on a health data host certified for the 6 HDS levels. Only Icadom's project manager has the contingency table between the coded research number and your identity.

These data, collected from about 100 COPD patients, will allow to validate or invalidate the predictive algorithm.
You can be informed of the findings of this study by your pulmonologist or by contacting the Scientific Director of the aCCPP at recherche@accpp.fr.

Following this research study, the database will be retained in the promoter's information system for 2 years after the last publication in case researchers wish to verify the statistical analysis and come back to the source data to verify certain findings. At the end of the 2 years, all data will be archived.

What are my rights?

You have several rights regarding the information about yourself:

- **Right of access**: You can request access to the information about you in order to obtain a copy of it and the indication of the uses which are made of it;
- **Right of rectification**: You can ask to correct and update information about you;
- **Right to object**: You may object to the use of this information for research purposes. This opposition prevents any use or conservation of these data;
- **Right to erasure**: You can obtain the erasure of this data.

Your contacts

☞ To contact your pulmonologist:

Doctor XX YY, 47 rue de Champ Rochas 38240 Meylan - FRANCE
+33675348952 - drxxyy@gmail.com

☞To exercise your rights or for any questions about your personal data you can write a letter or send an email to:

aCCPP Data Protection Officer	Person in charge of the treatment
✉ 19 avenue Marcelin Berthelot, 38 100 Grenoble dpo@colibri-pneumo.fr	contact@colibri-pneumo.fr www.accpp.fr

☞ You can also exercise these rights with your doctor, who alone knows your identity and can forward your request to the aCCPP.

If you consider that the processing of your personal information constitutes a violation of the General Data Protection Regulation, you may file a complaint with the CNIL (right to lodge a complaint with a supervisory authority).

https://www.cnil.fr/
☎ +33153732222

I, Dr./Pr. ....., certify that I have explained all the information about this research to Mrs, Ms, Mr (add Last Name, First Name and Date of Birth) .....
I certify:
That this person does give his/her informed consent to the research ☐
That this person does not give his/her informed consent to the research ☐

A copy of the Informed Consent Form has been given to him/her, and a copy is kept in his/her file. The informed consent is traced in the medical file.

INVESTIGATOR:
Last name: First name:
Date signed: Investigator's signature: