INFORMED CONSENT FOR REALIZATION OF RESEARCH PROJECT

(Version 1, dated 02/10/2019)

TITLE OF THE STUDY: Smoking cessation in hospitalized patients: Efficacy of an intensive intervention program using APP)

PROMOTER CODE:
PROMOTER:
PRINCIPAL INVESTIGATOR: Patricia García Pazo,
CENTER: Department of Nursing and Physiotherapy, University of the Balearic Islands, telephone 971259943

I, (name and surname)……

☐ 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 with: *( ).*

☐ I understand that my participation is voluntary.

☐ I understand that I can withdraw from the study as long as I have not been anonymized:

- Whenever you want.
- Without having to explain.
- Without this having an impact on my medical care.

☐ I understand that if I decide to withdraw from the study, the results obtained up to that point may continue to be used.

In the event that the results of the investigation provide data that may be of interest to me or my relatives: (insert one of the boxes)

☐ I want to be informed.

☐ I do not want to be informed, but I accept that my doctor contact my relatives if these results may affect them.

☐ I understand that I have the rights of access, rectification, deletion, opposition, limitation of data processing, including transferring my data to an authorized third party (portability), in accordance with the provisions of the new Data Protection Regulation (EU) 2016/679 of the European Parliament and of the Council, of April 27, 2016, regarding the protection of natural persons regarding the processing of personal data and the free movement of these, and in its default, the Organic Law 3/2018, of December 5, on the protection of personal data and guarantee of digital rights.

☐ I freely consent to participate in the study and consent to the access and use of my data under the conditions detailed in the patient information sheet.

Patient's signature: Investigator's Signature:

Name: Name:
Date: Date:

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

PATIENT INFORMATION SHEET FOR THE CONDUCT OF A RESEARCH PROJECT

(v 2.0 of 03/19/2019)

TITLE OF THE STUDY: Smoking cessation in hospitalized patients. Efficacy of an intensive intervention program APP.
PROMOTER CODE:
PROMOTER:
PRINCIPAL INVESTIGATOR: Patricia García Pazo, professor at the Department of Nursing and Physiotherapy, University of the Balearic Islands (UIB), contact telephone number: 971259943.

CENTER: Son Llatzer Hospital

INTRODUCTION

We write to you to inform you about a study in which you are invited to participate. The study has been approved by the Research Ethics Committee of the Balearic Islands, in accordance with current legislation, and is carried out with respect for the principles set forth in the Helsinki declaration and the standards of good clinical practice.

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. If you have any questions, please contact the main researcher, Patricia García Pazo.

GENERAL DESCRIPTION

Most smokers must stop smoking during the hospital stay, so it is an ideal time to influence the cessation of smoking, since otherwise most of them will resume smoking at hospital discharge.
Therefore, the objective of this study is to provide specialized and intensive treatment for smoking cessation during the hospital stay and to improve abstinence rates at one year after hospital discharge.
This specialized treatment will be carried out by the Smoking Cessation Unit (UDT), a unit that belongs to the pulmonology service of the Hospital Son Llatzer and will begin with patients admitted to the cardiology, pulmonology and intensive care units.
This research will compare two treatment branches (A and B) and the patients who wish to participate in the study will be selected to one or the other branch according to chance. Treatment A will consist of the treatment that is usually given to smokers during their hospital stay and treatment B will be the specialized and intensive treatment that the UDT will perform.
In addition, treatment B will have the support of a self-help Guide incorporated through a mobile application (APP). Through this APP you can have help on smoking cessation treatment at any time and contact health professionals.
These new technologies through a mobile APP have proven to be effective in helping to quit smoking thanks to the monitoring and support that the person receives during treatment at any time of the day, including during their working hours.

You should also know that participating in this research does not expose you to any additional risk from regular treatment.
In both branches of treatment you will be treated for your nicotine addiction, what changes is the intensity and specialization of the help received.
Treatment B lasts for one month, even if you are discharged from hospital. Then it has a daily follow-up through the APP and a telephone follow-up per month, 3 months, 6 months and 12 months.
In addition, during that month of treatment, the UDT team, through the APP, will inform you of the possibility of having an informative meeting, in which you can discuss more specific issues and answer your questions.

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As it is a study, you must commit to carry out all the treatment that we propose, to attend group sessions and to attend follow-up visits. As well as communicating whether or not you decide to abandon any treatment activity.

The professionals who carry out the intervention will not receive any remuneration.

OTHER RELEVANT INFORMATION

Pharmacological treatment such as nicotine patches, is a treatment that is licensed and marketed, usually administered to hospitalized smokers with high nicotine dependence. It is added to treatments with the aim of reducing the discomfort they may feel due to the presence of the symptoms caused by the withdrawal syndrome.

If you wish to participate in this study, you must follow the recommendations of the Guide that we provide you through the APP, as well as make correct use of the different options that it will offer you until the end of the study.

If you have any reason why you cannot carry out the treatment, as we indicated, you should notify the principal investigator, by email to the mail: niunacaladamas@gmail.com or through the mobile application, selecting the help button.

If you decide to withdraw your consent to participate in this study, we will not add any new data to the database from that date of withdrawal, although those responsible for the study may continue to use the information collected about you until that time, unless you expressly object.

You should also know that you can be withdrawn from the study in case the study leaders consider it appropriate, either for security reasons, for any adverse event that occurs in the study 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.

If you are withdrawn from the study for any of the stated reasons, your doctor will prescribe appropriate treatment for your disease.

By signing the attached consent form, you agree to abide by the study procedures outlined to you.

BENEFITS AND RISKS ARISING FROM YOUR PARTICIPATION IN THE STUDY

The expected benefits for you and for society are that you can have all the real information, which is provided by health professionals, and you can take advantage of hospital admission to maintain abstinence and quit tobacco after hospital discharge.

This research raises the need for more intensive smoking cessation treatment to help you quit smoking during a hospital stay. that today could have cost him admission to the hospital or may even make his illness worse, with possible readmissions to the hospital.

In addition to the fact that tobacco cessation is linked to an improvement in the quality of life, which you will notice in your day to day.

Treatment B of this research is a treatment recommended by the Clinical Practice Guidelines (CPG) based on the combination of psychological support, cognitive behavioral type and pharmacological support, if necessary. It begins during hospitalization and accompanies you for a year of follow-up. There are no added risks to participating in the study.

You should know that at no time will your name and telephone number (identifying data) be given to other users, in addition to the fact that your data made in the mobile application or in the guide will be identified with a code that will only associate data and user, the main researcher, compliance with the General Data Protection Regulation.

CONFIDENTIALITY

Responsible for the file: Patricia García Pazo

Purpose of the collection: Research project for Doctoral Thesis

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

Legitimation:

Recipients: There will be no transfer to third parties.

Rights: access, rectify and delete data

Additional Information:

The treatment, communication and transfer of personal data of all participating subjects will comply with the provisions of the new Data Protection Regulation (EU) 2016/679 of the European Parliament and of the Council, of April 27, 2016, relating to the protection of natural persons regarding the processing of personal data and their free movement, and failing that, Organic Law 3/2018, of December 5, on the protection of personal data and guarantee of digital rights. In accordance with the provisions of the aforementioned legislation, you can exercise the rights of access, rectification, deletion, opposition, limitation of data processing, even to transfer your data to an authorized third party (portability), for which you must contact the delegate of data protection: Caty Pou. Delegate of Protecció de Dades, Universitat de les Illes Balears, Son Lledó, Carretera de Valldemossa, km 7.5, cp. 07121 Palma. Telephone: 971259793. E-mail:dpo @ uib.cat

Your data will be processed electronically and will be incorporated into an automated file of personal data whose responsible is the Hospital Son Llatzer, which complies with all security measures with restricted access to the objective described in this document.

To guarantee the confidentiality of the information obtained, Your data will be identified by means of a code and only the principal investigator of the study and collaborators will be able to relate these data to you and to your medical history. Therefore, your identity will not be revealed to any person except in the case of a medical emergency, a requirement from the Health Administration or a legal requirement.

Only the essential data necessary to carry out the study will be transmitted to third parties and other countries, and that in no case will they contain information that can directly identify you, such as name and surname, initials, address, Social Security number, 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 Research Ethics Committee of the Balearic Islands and authorized personnel, when they need it to check the study's data and procedures, but always maintaining confidentiality. thereof in accordance with current legislation.

You can file a claim with the Spanish Agency for Data Protection in the event that you consider that your data protection rights have been violated.

Your doctor will not receive any financial compensation for conducting this study and has stated that there are no conflicts of interest.

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 giving any explanation, without thereby altering the relationship with your doctor or the treatment you should receive.

If you decide to revoke your consent, no new data will be collected, but this revocation will not affect the investigations carried out so far.

GRATITUDE

Whatever your decision, the research team would like to thank you for your time and attention. You are contributing to the better knowledge and care of your disease, which in the future may benefit a multitude

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