

INFORMATION SHEET FOR PEOPLE PARTICIPATING IN THE ADMIT DEMONSTRATION PROJECT



September 2025 NCT: NCT07408882

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INFORMATION SHEET FOR PEOPLE PARTICIPATING IN THE ADMIT DEMONSTRATION PROJECT – Transformation of Integrated Home Care

ADMIT is a project aimed at transforming the current care model into a comprehensive and integrated social and healthcare model, in order to improve the time lived at home and the quality of life of people over 70 years old who are frail and have complex care needs while remaining in their homes.

To achieve this, it proposes new ways of working among health and social service professionals, supported by technology that connects individuals, caregivers and professionals. The ADMIT project is promoted and funded by the Servei Catal  de la Salut (Catalan Health Service) and is part of the transformative projects of LGAI. The project's sponsor is Parc Sanitari Pere Virgili (hereinafter PSPV).

A demonstration project is planned, meaning a trial to see how this new ADMIT Integrated Care Model and its accompanying technologies work, ensuring the consistency of the model, verifying its validity, and assessing the potential of the technology to support continuous improvement in the future.

To make this demonstration project possible, PSPV has signed agreements with various social and healthcare entities that will provide integrated care (hereinafter referred to as Data Controllers) and has signed contracts with different providers (hereinafter referred to as Data Processors).

Participation in the ADMIT demonstration project is voluntary. You are free to decide whether or not you wish to participate. At any time, you may change your mind and withdraw from the project without giving any explanation for your decision and without any negative consequences for you.

By participating in the ADMIT demonstration project, you will obtain the following benefits:

- The new ADMIT Care Model offers comprehensive care, focused on the needs and preferences of each individual. This means that you will be able to take part in some decisions related to your health and well-being, helping you better understand your own needs.
- Access to new technologies and more advanced ways of working, which help health and social service professionals care for you better and prevent problems before they occur.
- Improved coordination of services, reducing the need for multiple visits to different professionals, as health and social care professionals work together.
- Contributing to the improvement of health and social systems for future generations, helping to develop better practices.
- More continuous support with closer follow-up for the duration of the project.
- An opportunity to share experiences and learn from the process.

Your participation in this project will not involve any risks to your health or your family. You may feel uncomfortable when talking about your experiences. Sensitive topics may be discussed, such as your personal situation or your relationship with your family. This could cause some discomfort for certain individuals. You may refuse to answer questions or leave discussions at any time if you feel uncomfortable.

If you agree to participate in the ADMIT project, you will be asked to do the following:

- During your participation, you will receive care at home from social and healthcare professionals, so you will need to facilitate this care.
- Take part in an initial assessment: once your inclusion in the program has been explained, you will be asked questions to understand your personal and family health situation.
- Participate in follow-up visits by health and social service professionals (nurses, physiotherapists, doctors, social workers and social educators).
- A small number of participants in the demonstration project will be assigned home technology (such as sensors or robots). If you are considered a candidate for this, you will need to authorize it in advance by signing a consent form.
- Some participants will be offered the use of a technology with a monitoring system that allows early detection of any health deterioration and alerts your caregivers or the professionals who care for you.
- Randomly, some individuals and families may be selected to participate in interviews with researchers from some of the participating institutions to better understand their opinion about the program.
- If your Primary Care Center (Centre d'Atenci  Prim ria: CAP) is assigned to the control group, you will have to wait a few months to participate in the program. However, you and your caregivers will be asked to complete questionnaires at different times.
- Allow the entry of the necessary social and health data into the Integrated Care Platform (Plataforma d'Atenci  Integrada: PAI) to provide integrated care.
- Allow the use of your data in an anonymized way for evaluation and research purposes related to the new ADMIT Care Model and its supporting technological tools.

If you authorize interviews for evaluation and research purposes, you will be asked to answer questionnaires for up to 18 months from the start of the program, so you may remain in the study for almost 2 years.

INFORMED CONSENTS

1. Informed consent for the use of the virtual assistant LOLA

LOLA is a virtual assistant based on artificial intelligence, designed to contact you by phone and monitor your well-being while you remain at home. Its main purpose is to provide healthcare and social professionals with up-to-date information about your health status, avoiding the need for you to travel.

Although LOLA is not a real person, it has been programmed to interact in a friendly and understandable way, asking simple questions aimed at detecting possible changes in your physical or emotional condition. You only need to respond calmly; all the information you provide will be securely transmitted to the healthcare or social service professionals who care for you.

It is important to note that LOLA is not able to handle emergency situations and cannot contact emergency services. Its role is exclusively for follow-up and telephone support, acting as an additional aid.

During the conversation, personal data may be discussed, including health data, which will be used exclusively for care, organizational, or informational purposes within the ADMIT demonstration project.

The phone number you will see when LOLA calls you is: +34 931 203 023

I authorize the use of LOLA:

☐ Yes

☐ No

2. Informed consent for the use of sensor technology

The sensor technology includes the use of two kits:

- Use of medical devices and sensors that collect data on vital signs, biometric measurements, and physical activity, either continuously or at specific times, to improve clinical monitoring and healthcare.
- Use of medical devices and sensors installed in homes that allow the identification of daily activity patterns.

This data enables healthcare professionals to remotely monitor vital parameters, detect early changes in your health status, and personalize treatments and care plans.

I authorize the use of sensor technology:

☐ Yes

☐ No

3. Informed consent for the use of robotic technology

Robotic technology includes:

- Use of automated or semi-automated devices that support or perform social interaction tasks under professional technical supervision.
- Use of automated or semi-automated devices that support or perform assisted feeding tasks and the handling of rigid and deformable objects.

These systems help improve precision in procedures, facilitate personalized treatments, and increase patient safety and comfort.

I authorize the use of robotic technology:

☐ Yes

☐ No

Granting your explicit consent for any of the purposes described above does not guarantee or imply the automatic and immediate application of the mentioned technologies. Your consent allows us to assess your suitability for the use of these technologies.

If you are considered an appropriate candidate, you will be provided with detailed information prior to any application. This information will include:

- Details about how the technology works.
- Instructions on how to use it.
- The procedure for delivery and/or installation in your home, if applicable and necessary.

Information about the processing of personal data to be carried out:

Detailed information on Data Protection	
Who is responsible for processing your data?	
Identity:	XXX – CIF XXXX
Postal address:	XXX
Phone:	XXX
DPD contact email:	XXX
Identity:	XXX – CIF XXX
Postal address:	XXX
Phone:	XXX
DPD contact email:	XXX
Identity:	XXX – CIF XXX
Postal address:	XXX
Phone:	XXX
DPD contact email:	XXX
Identity:	XXX – CIF XXX
Postal address:	XXX
Phone:	XXX
DPD contact email:	XXX
For what purpose do we process your personal data?	
<p>The purpose of the processing is your participation in the ADMIT demonstration project to receive integrated social and healthcare services, in order to obtain the benefits of joint actions by social and healthcare professionals and organizations. These actions aim to achieve good health and well-being outcomes, appropriate use of resources, and a positive care experience, ensuring comprehensive and person-centered care.</p> <p>The personal data collected through your participation in the ADMIT demonstration project will be processed exclusively for the following purposes:</p> <ul style="list-style-type: none"> • To improve the quality of your care by providing integrated healthcare and social support. • For the evaluation of the results of the new ADMIT Care Model. 	
How long will we keep your data?	
<p>Health data will be kept for a minimum period of 5 years, in accordance with Article 12 of Law 21/2000, of December 29, on the rights of information regarding health, patient autonomy, and clinical documentation.</p> <p>Other data collected solely for the purpose of evaluating the project will be kept until the analysis and study of the project have been completed. In any case, the data will be retained for as long as necessary to comply with legal obligations.</p>	
What is the legal basis for processing your data?	
<ul style="list-style-type: none"> • To improve the quality of your care by providing integrated healthcare and social support: The legal basis that allows the processing of this data is Article 6.1.e of Regulation (EU) No. 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (GDPR). The circumstance that justifies the processing of special category data is Article 9.2.h of the GDPR, based on the Twelfth and Fifteenth Additional Provisions of Law 12/2007, of 11 October, on social services, which authorizes the communication of data between public health and social services without the consent of the individuals concerned, according to the criteria set out in the articles, in order to ensure effective comprehensive care, as well as Law 15/1990, of 9 July, on the organization of healthcare in Catalonia, and Law 21/2000, of 29 December, on the rights of information regarding health and patient autonomy, and clinical documentation. 	

Additionally, the legal basis for processing your data within the ADMIT project is your consent, in accordance with Articles 6.1.a + 9.2.a of the GDPR.

- For the evaluation of the results of the new ADMIT Care Model, analyzing anonymized data to expand the knowledge base and continue improving integrated care practices and policies for the target population of the ADMIT project (since the data is anonymized, PSPV, as the project promoter, will not have any access to your personal data. Furthermore, if the study results are to be published in whole or in part, no personal data of participants in the ADMIT demonstration project will be provided under any circumstances).

In the event that recordings, personal interviews, etc., are required for this evaluation, you will be informed and must complete the corresponding informed consent form to give your authorization in accordance with Article 6.1.a. + 9.2.a. of the GDPR and Additional Provision 17.2.a. of the Organic Law on Data Protection and Guarantee of Digital Rights (Llei Oficial de Protecci  de Dades i Garantia dels Drets Digitals:LOPD-GDD).

All of this takes into account the Guide for the evaluation of aspects derived from data protection regulations in research projects regarding special categories of data, such as health data for research purposes. We must use one of the lawful bases under Article 6 of the GDPR, as well as lift the prohibition on processing this special category of data established in Article 9.1 of the GDPR, by applying one of the exceptions in Article 9.2 of the GDPR, and in relation to Article 89 of the GDPR. The use of these legal bases is specified in several cases that allow the use of data for research and are developed through Additional Provision 17 of the LOPD-GDD.

To interpret this regulatory framework, the following recitals should also be considered: 26, 28, 33, 34, 52, 53, 54 and 83. Likewise, we must take into account various opinions issued by national and European data protection authorities that have interpreted and clarified the scope of these provisions. These opinions include::

- APDCAT - Opinion 15/2019 regarding a consultation from a healthcare center on the need for consent in the use of pseudonymized health data in biomedical research, dated May 14, 2019.
- APDCAT - Opinion 18/2019 regarding a consultation from a healthcare association on various aspects related to section 2 of Additional Provision Seventeen of Organic Law 3/2018, of December 5, on the protection of personal data and the guarantee of digital rights, dated May 14, 2019.
- EDPB - Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection Regulation (GDPR) (Art. 70.1(b)), adopted on January 23, 2019.
- EDPB - Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak, adopted on April 21, 2020.
- APDCAT - Opinion 14/2020 regarding a consultation from a hospital on access to data of its professionals within the framework of a scientific study carried out in another hospital, dated April 27, 2020.
- BIOETHICS – Report of the Spanish Bioethics Committee on ethical and legal requirements in research with health data, dated April 8, 2020.

Who will your data be shared with?

Your data may be shared between public healthcare and social services, based on Law 12/2007, of October 11, on social services, which authorizes this communication without the consent of the individuals concerned, in order to ensure effective comprehensive care, as well as Law 15/1990, of July 9, on the organization of healthcare in Catalonia, and Law 21/2000, of December 29, on the rights of information regarding health and patient autonomy, and clinical documentation.

However, the data may also be communicated to Data Processors. The providers who may have access to the project data as Data Processors are the following:

- UTE AMADIP: Development of the ADMIT Care Model, development and management of the Integrated Care Platform (PAI), deployment of home technology, implementation and monitoring of the demonstration project for the evaluation of the new model and supporting technological tools, and development and implementation of the operational and maintenance model.
- Aronte: Information security for the ADMIT project.
- Sayoscarrera: Technical management office for the ADMIT project promoted by PSPV.

We only work with data processors who provide sufficient guarantees of compliance with current data protection legislation and solely for the purpose entrusted to the processor.

What are your rights when you provide us with your data?

Anyone has the right to obtain confirmation as to whether or not we are processing personal data concerning them.

Data subjects have the right to access their personal data, as well as to request the rectification of inaccurate data or, where appropriate, request its deletion when, among other reasons, the data is no longer necessary for the purposes for which it was collected.

In certain circumstances, data subjects may request the restriction of the processing of their data, in which case we will only retain it for the exercise or defense of claims:

- You may request the suspension of the processing of your data:
 - When you contest the accuracy of your personal data, for a period that allows the controller to verify it.
 - When you have objected to the processing of your personal data carried out by the controller based on legitimate interest or a mission of public interest, while verifying whether these grounds override yours.
- You may request the controller to retain your data:
 - When the processing is unlawful and you oppose the deletion of your data and instead request the restriction of its use.
 - When the controller no longer needs the personal data for the purposes of processing, but the data subject needs it for the formulation, exercise, or defense of claims.

In certain circumstances and for reasons related to your particular situation, data subjects may object to the processing of their data. The data will no longer be processed unless there are compelling legitimate grounds, or for the exercise or defense of possible claims

Under the right to data portability, data subjects have the right to receive the personal data concerning them in a structured, commonly used, and machine-readable format and to transmit it to another controller.

When the legal basis for processing is consent, the data subject has the right to withdraw or revoke it at any time. Withdrawal or revocation of consent is not retroactive. Therefore, it does not affect the lawfulness of processing based on consent prior to its withdrawal.

How can you exercise your rights?

By sending a written request to:

- XXX: XXX
- XXX: XXX
- XXX: XXX
- XXX: XXX

What complaint channels are available?

If you believe that your rights have not been properly addressed, you have the right to file a complaint with the Catalan Data Protection Authority.

I, _____(name and surname)

- ☐ have read the information sheet that was given to me about the project to the person.
- ☐ have been able to ask questions about the ADMIT project.
- ☐ understand that my participation is voluntary.
- ☐ understand that I can withdraw from the project:
 - Whenever I wish, before data analysis begins,
 - Without having to give any explanation, and
 - Without this affecting the care I or my family receive.

Authorizations:

- ☐ I give my consent to participate in the ADMIT demonstration project
 - Full Name:
 - ID Number (DNI):
 - Contact Phone:
 - Contact Email:
- ☐ I authorize access to my social and healthcare data necessary to carry out the ADMIT demonstration project to the following authorized person (professional caregiver, family member, legal guardian):
 - Full Name:
 - ID Number (DNI):
 - Relationship to the participant:
 - Contact Phone:
 - Contact Email:
- ☐ I authorize the Data Controllers to use my image for informational, promotional, and dissemination purposes related to the ADMIT project, through any media or social networks.
- ☐ I authorize being contacted for interviews aimed at evaluating the new ADMIT Integrated Care Model and/or the supporting technological tools.

Signature:

....., on the day of, 20.....

If you have any questions or doubts about the project in general, you can contact:
admit@tunstall.es or call 935134580.