PATIENT INFORMATION SHEET / POSSIBLE PARTICIPANT

TITLE OF THE STUDY: BARIATRIC SURGERY IN PATIENTS WITH SCHIZOPHRENIA

STUDY CODE: IIBSP-BAR-2022-30

PROMOTER: Sant Pau Hospital Research Institute la Santa Creu– IIB Sant Pau

PRINCIPAL INVESTIGATOR: Inka Miñambres, Endocrinology and Nutrition Service. Phone 935565661

CENTRE: 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 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 affecting your treatment.

GENERAL DESCRIPTION OF THE STUDY

It is known that schizophrenia is associated with obesity in a significant number of patients and it implies a poor prognostic factor, with weight loss being important in this population. However, data about the prognosis of weight loss surgery in subjects with schizophrenia is scant. The objective of this study is to retrospectively analyze the cases of patients with schizophrenia (study group) who have undergone weight loss surgery with the

intention of analyzing the beneficial effects of the surgery, as well as the complications. in this group of patients. In parallel, the data of patients who do not suffer from any psychiatric illness (control group) will be collected. You will be invited to participate as a study group or as a control group depending on your characteristics.

As it is a retrospective data collection, the study does not require additional visits or tests to the usual ones and does not entail any additional risk for the patient. No adverse effects are anticipated as no procedure will be performed.

The total number of patients expected to be included in the study will be 20 patients and 80 controls aproximately

BENEFITS AND RISKS DERIVED FROM YOUR PARTICIPATION IN THE STUDY

It is likely that the present study does not result in a direct benefit on the health of the subjects participating in the study. However, it is intended to expand knowledge about the prognosis of weight reduction surgery in subjects with schizophrenia and this knowledge may in the future improve the selection of which cases should undergo bariatric surgery and which cases the risks of surgery would outweigh the benefits. .

CONFIDENTIALITY

The treatment, 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, 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 associate said data with you and your medical history. Therefore, your identity will not be disclosed to any person, except for exceptions, in case 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 sponsor (study

monitors, auditors), when needed to verify the study data and procedures , but always maintaining their confidentiality in accordance with current legislation.

In accordance with the provisions of the 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 transfer to a third party (portability) the data that you have provided for the study. To exercise your rights, you can contact the main researcher 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 the data cannot be deleted even if you stop participating in the study, to ensure the validity of the research and to comply with legal duties.

The investigator and the sponsor are obliged to keep the data collected for the study for at least 5 years after its completion. Subsequently, your personal information will only be kept 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 law and applicable 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 data protection authorities. data. If the participant wants to know more about it, they can contact the Principal Investigator of the study or the Promoter's Data Protection Officer by email at dpo_ir@santpau.cat .

ECONOMIC COMPENSATION

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

OTHER RELEVANT INFORMATION

If you choose to withdraw consent to participate in this study, no new data will be added to the database and you may require the destruction of all identifiable samples previously withheld to prevent further testing.

By signing the attached consent form, you agree to abide by the study procedures that have been disclosed to you.

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

Thank you very much for your help.

INFORMED CONSENT

Study title: BARIATRIC SURGERY IN PATIENTS WITH SCHIZOPHRENIA

I (first and last name)..... .....

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:

....

(first and last name of the researcher)

I understand that my participation is voluntary.

I understand that I can withdraw from the study:

1º Whenever I 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 Signature**
Date :	**Date** :

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

INFORMED CONSENT

Study title: BARIATRIC SURGERY IN PATIENTS WITH SCHIZOPHRENIA

I (name and surname) ……..in the capacity of…….(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:

....

(first and last name of the researcher)

I understand that patient participation is voluntary.

I understand that I can withdraw from the study:

1º Whenever I 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 their level of understanding and they agree 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 representative	**Signature of investigator**
Date :	**Date** :

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

INFORMED CONSENT

Study title: BARIATRIC SURGERY IN PATIENTS WITH SCHIZOPHRENIA

I…….(name and surname of the witness) declare under my own responsibility that …….. …….(name and surname of the participant)

You have read (or it has been read to you, in the case in which the patient cannot read), the information sheet that has been given to you.

You have been able to ask questions about the study.

You have received enough information about the study.

Has spoken with:

....

(first and last name of the researcher)

You understand that your participation is voluntary.

You understand that you can withdraw from the study:

1º Whenever I want

2º Without having to give explanations.

3º Without this affecting your medical care.

- You have freely expressed your agreement to participate in this study and give your consent for the access and use of the data under the conditions detailed in the information sheet.

.....	**..... .....**
Witness signature	**Investigator Signature**
Date :	**Date** :

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