Informed consent form

Online Training Program on Social Cognition for Patients With Schizophrenia

NCT ID not yet assigned

ULaguna
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PATIENT INFORMATION SHEET

version 2 of December 18, 2019

STUDY TITLE: TRAINING IN COGNITION AND SOCIAL COMPETENCE IN PATIENTS WITH SCHIZOPHRENIA

MAIN RESEARCHER: Dr. D. Francisco Rodríguez Pulido. Professor of Psychiatry ULL. HUC Nursing Building.

CENTER: ULL/SINPROMI

INTRODUCTION

We are writing to inform you about a research study in which you are being invited to participate. The study has been approved by the corresponding 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. For this purpose, 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.

GENERAL DESCRIPTION OF THE STUDY

The objective of this study is to evaluate the efficacy of a training program in cognition and social competence (e-Motional Training) in patients with schizophrenia when it comes to improving the recognition of basic emotions, social cognition, emotional intelligence and social competence.

To this effect, an assessment will be carried out with the following instruments before the delivery of the training with the e-Motional training program and once the sessions with it have finished. There will be two groups (training and control) that will be randomly assigned. If you are assigned to the social skills training group, you must attend a weekly session of 1h 30 min. for 4-5 months. In this training, a member of the research team (different from the person who interviews you and will do the evaluation) will be present to answer your questions. In the event that you are assigned to the control group, you will continue to be part of the employment team that corresponds to your area and after 4-5 months we will contact you again to reassess you and see if with the activities you carry out, with a job if you have got one or simply with the passage of time you improve your social skills. The purpose of this study is to evaluate the efficacy of a multicomponent social skills training program in people with schizophrenia.

The instruments that will be used for the evaluation are the following:

- Insinuations Test.
- Faux Pas.
- F. Happé Theory of Mind Test.

- Ekman 60 Face Test.
- Ambiguous Intentions Hostility Questionnaire.
- Mayer- Salovey- Caruso Emotional Intelligence Test.
- Movie for the Assessment of Social Cognition.
- Positive and Negative Symptom Scale.
- Social Functioning.

All test results will be recorded anonymously by assigning each person an identification number. Test location: SINPROMI offices (Insular Society for the promotion of people with disabilities).

Benefits: You are not expected to benefit directly from participating in this study. It is unknown if the social skills training program will be beneficial, and that is precisely why we want to investigate. The only benefit sought, therefore, is to discover its usefulness with the hope that in the future it will have application in the treatment of impaired social cognition, understood as the improvement in the ability to recognize emotions and interpret social situations, of people who, like you, suffer from schizophrenia.

Risks: There are no physical risks, discomfort or any type of inconvenience from participating in this study. If during the course of the study relevant information becomes known that affects the relationship between the risk and the benefit of your participation, it will be transmitted to you so that you can decide to abandon or continue.

CONFIDENTIALITY

The treatment, communication and transfer of the personal data of all the participating subjects will comply with the provisions of Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights, and the application of the Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on Data Protection (RGPD), so it is important that you know the following information:

- In addition to the rights that you already know (access, modification, opposition and cancellation of data) you can now 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, contact the main investigator of the study. We remind you that the data cannot be deleted, even if you stop participating in the study to guarantee the validity of the research and comply with legal duties and drug authorization requirements. Likewise, you have the right to contact the Data Protection Agency if you are not satisfied.

- The Center as well as the Promoter and the Researcher are respectively responsible for processing your data and undertake to comply with current data protection regulations. The data collected for the study will be identified by a code, so that information that can identify you is not included, and only your study doctor and collaborators will be able to relate said data to you and your medical history. Therefore, your identity will not be disclosed to any other person except the health authorities, when required or in cases of medical emergency. The Research Ethics Committees, the representatives of the Health Authority in matters of inspection and the personnel authorized by the Promoter, may only access to check the personal data, the clinical study procedures and compliance with the standards of good clinical practice. (always maintaining the confidentiality of the information).

The Researcher and the Promoter 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, and if permitted by applicable law and ethical requirements.

ADDITIONAL INFORMATION

As required by law, to participate you must sign and date the informed consent document.

The main investigator of this study at this center is Dr. Francisco Rodríguez Pulido.

If during the performance of this study any question arises about it, you can consult with Dr Francisco Rodriguez Pulido from the Psychiatry Service of the Hospital Universitario de Canarias at the telephone number 609116523.

The results of this study will be published in scientific papers for dissemination, but no data that could lead to the identification of the participants will be transmitted.

If you wish, you will be provided with a summary of the study results. You will also be able to receive the results of the tests that are performed on you if you request it. These results may not have a clinical application or a clear interpretation, so if you want to have them, they should be discussed with the relevant technician.

INFORMED CONSENT

STUDY TITLE: TRAINING IN COGNITION AND SOCIAL COMPETENCE IN PATIENTS WITH SCHIZOPHRENIA

PRINCIPAL INVESTIGATOR Dr. D. Francisco Rodríguez Pulido. Professor of Psychiatry ULL. HUC Nursing Building.

CENTER: ULL/SINPROMI

I (name and surname)

……

In the case of having a guardian:

I ……..……..…… as guardian of ……..……..……

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:

……

(Researcher's name)

I understand that my participation is voluntary.

I understand that I can withdraw from the study:

1st At any time

2º Without having to give explanations.

3º Without this affecting my medical care.

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

Paticipant Signature: **Researcher Signature:**

Name: **Name:**

Date: **Date:**