RESEARCH ETHICS COMMITTEE

University Hospital Complex of the Canary Islands

(Province of S/C de Tenerife)

Outpatient Activities Building, Floor -2

C/ Ofra s/n 38320 La Laguna Santa Cruz de Tenerife

REQUEST FOR EVALUATION OF THE STUDY BY THE CEIm

Code:

Principal Investigator: Dr. D. Francisco Rodríguez Pulido

Title: Training in cognition and social competence in patients with schizophrenia

The following will participate as collaborating researchers in this study:

Nayra Caballero Estebaranz, Alejandro Alberto García Caballero, Enrique González Dávila, Celia León Palacín, Beatriz Domínguez Fernández, María del Carmen Hernández Álvarez de Sotomayor, Susana López Reig, María Jesús Melián Cartaya, Patricia Inés Vílches de León

(Add other information that is considered relevant for the evaluation by the CEIm)

Protocol for evaluation is attached.

La Laguna, November 18, 2019

Signed: Francisco Rodríguez Pulido.

Your data and those of the collaborators will be processed by the Canary Islands Health Service in compliance with the General Data Protection Regulation 2016/679. For the administrative and accounting management, if the financing of the study is approved, the data will be processed by the Canarian Foundation for Health Research (FUNCANIS), in a mandatory manner and without constituting a transfer of data, as an entity collaborating with the task. of executing administrative and accounting functions. These data will allow the Foundation to carry out the tasks of economic-administrative management of its research work, send you information related to it and with various procedures on reimbursements, payments, etc. On the other hand, it will allow the Foundation to carry out periodic research reports and pertinent tasks. All these guaranteeing the necessary security measures for the treatment of information.

BIOMEDICAL RESEARCH PROJECT PROTOCOL

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

CODE:

VERSION:

09/24/2019

PROMOTER:

ULL

SINPROMI

RESEARCHER/S:

Francisco Rodríguez Pulido. Tenured Professor of Psychiatry ULL.
Nayra Caballero Estebaranz. Doctor of Medical Sciences and Bachelor of Psychology. Responsible EAIE Syndrome.
Alejandro Alberto García Caballero. Psychiatry University Hospital Complex of Ourense.
Enrique González Dávila. Professor of statistics ULL.
Celia León Palacín. Graduate in Psychology. Master of General Health Psychology USAL.
Beatriz Domínguez Fernández. Degree in Psychology.
María del Carmen Hernández Álvarez de Sotomayor. Degree in Psychology. Technician EAIE Synpromi.
Susana López Reig. Degree in Psychology. Technician EAIE Synpromi.
María Jesús Melián Cartaya. Degree in Psychology. Technician EAIE Synpromi.
Patricia Inés Vílches de León. Degree in Psychology. Technician EAIE Synpromi.

PLACE OF REALIZATION:

SINPROMI. INSULAR SOCIETY FOR THE PROMOTION OF PEOPLE WITH DISABILITIES.

Supporting document: Biomedical Research Project Protocol Scheme.

BIOMEDICAL RESEARCH PROJECT PROTOCOL

Supporting document: Biomedical Research Project Protocol Scheme.

1 INDEX

2 INTRODUCTION

Interpersonal relationships are paramount to achieve adequate performance and conservation of various social roles that individuals have to cover throughout their life, which in turn becomes a determining factor for their social integration and adaptation in the long-term. For this reason, people need a number of cognitive, behavioral and emotional skills that allow and facilitate cohabitation and social exchange.

Schizophrenia is a disorder characterized by the presence of deficits in social and interpersonal functioning, being these key elements in its definition, in addition to involving a source of stress for the

patients and contributing to relapses and the exacerbation of symptoms[1], also generating enormous personal, socio-family, healthcare and economic costs[2].

In recent decades hundreds of investigations have focused on the study of these non-social cognitive deficits, such as executive functioning, attention or memory[3], but in recent years researchers have also included the study of social cognition[4]. The reason lies in the fact that social cognition was included in the list of key cognitive deficits in schizophrenia, largely due to the appearance of empirical evidence that relates social cognition to social functioning[5,6] and that assigns it a role of mediating variable between basic social cognition or neurocognition and social functioning[7,8].

From an operational point of view, we can classify the skills and functions involved in the regulation of social behavior into two categories:

- Social skills[9], a construct that includes activities such as:
  - o Communicate our needs and thoughts.
  - o Listen, understand and respond appropriately to other people.
  - o Produce and interpret nonverbal communications.
  - o Adapt eye contact, facial expressions and body language to social interaction.
  - o Regulate our emotions during them.
- Social cognition[10], a construct that includes activities such as:
  - o Perception of emotions, both in faces and in people's voices.
  - o Social perception, that is, the interpretation of a series of clues about what happens in a given social context and applying social knowledge to develop the most appropriate behavior for said context.
  - o Theory of Mind (ToM), understood as the ability we have to realize that others have ideas and intentions different from ours and that allows us to behave with these people in an appropriate way.
  - o Attributive style, understood as the tendency that individuals have to explain the events that happen to them in life and that often leads to considering negative events as caused by the bad intentions of others.

People with schizophrenia tend to isolate themselves, showing little initiative and motivation towards activities, especially social ones, than before the onset of the illness. They suffer from social isolation because they find it difficult to establish contact with other people and carry on a conversation, they have difficulty functioning normally under stressful conditions, in part due to their difficulties in social skills and problem solving.

3 OBJECTIVES AND PURPOSE OF THE STUDY

3.1 MAIN OBJECTIVE

Assessing the efficacy of a cognition and social competence training program (e-Motional Training) in patients with schizophrenia in improving basic emotion recognition, social cognition, emotional intelligence and social competence.

3.2 SECONDARY OBJECTIVES

Improving the cognitive functions of people with severe mental disorder.

Improving employment outcomes.

4 METHODS

4.1 DESIGN

A single-blind randomized clinical trial (Annex I) will be carried out in patients suffering from schizophrenia and who have the legal capacity to consent. Study participants will be randomized to either the experimental group (e-Motional Training) plus Individual Placement and Support (IPS) or the control group (IPS alone).

Sample size calculation:

Taking as a reference the results of the pilot study in schizophrenia carried out by the research team in Galicia (Alejandro Alberto García Caballero et al), where the average reached in the group before the intervention in the Stories of Theory of Mind by F. Happé in his Spanish version by Pousa (1999) was 8.5 points with a standard deviation of 3.61 points and where, after the intervention, the mean score achieved was 11.67 and the standard deviation was 4.72, for a power of 80% and a confidence level of 95%, the necessary sample in each group would be 30 patients, assuming losses of 5%. An attempt will be made to obtain a total sample of 80 people, taking into account losses during follow-up.

4.2 SUBJECTS

Participants will be recruited from the following centers:

USMC SANTA CRUZ – SALAMANCA (Anaga, Barrio de La Salud, Duggi Centro, Los Gladiolos, Parque Marítimo, Salamanca and Toscal Centro).

USMC OFRA (Arico, Añaza, Candelaria, Güimar, Ofra-Delicias and Ofra-Miramar).

USMC HUC (Barranco Grande, El Rosario – San Isidro, La Cuesta, La Laguna – Finca España and Taco).

USMC LA LAGUNA (Las Mercedes, Rosario – Geneto and Tejina – Tegueste).

USMC TACORONTE (La Matanza, La Victoria and Tacoronte).

USMC PUERTO CRUZ (La Guancha, La Vera, Los Realejos, Orotava – Dehesa, Puerto – Botánico, San Antonio and Santa Úrsula).

USMC ICOD (Icod and Los Silos).

USMC ARONA (Arona Costa, Arona Vilaflor and Granadilla).

USMC ADEJE (Adeje, Guia de Isora and Santiago del Teide).

4.2.1 INCLUSION CRITERIA

The inclusion criteria will be the following:

- ✓ People with severe mental disorder between 18 and 50 years old.
- ✓ Have the diagnosis schizophrenia according to DSM-V criteria.
- ✓ The patient has the capacity to consent.
- ✓ Having given their free consent to participate in the study, once informed about its objectives.
- ✓ Be a patient under the Psychiatry Service of the USMC at the time of the study.
- ✓ Be motivated to get ordinary employment.

4.2.2 EXCLUSION CRITERIA

The exclusion criteria will be the following:

- × Not having given their free consent to participate in the study.
- × Present a severe comorbid mental disorder or present a history of severe brain damage or neurological disorder that may function as a confounding factor, or intellectual disability (examples: associated organic mental disorder or diagnosis of borderline or lower IQ).
- × Inability to work.
- × Current participation in a skills program designed to improve social adjustment.
- × Current abuse of toxic substances (except nicotine).

All patients who meet all the inclusion criteria and none of the exclusion criteria will be included.

4.2.3 CRITERIA FOR THE WITHDRAWAL OF SUBJECTS FROM THE STUDY

- Explicit request from the subject to stop participating in the study.
- Change of place of residence, outside the autonomous community in which the study will be carried out.
- Death of the subject who will participate in the study.

4.3 MAIN AND SECONDARY VARIABLES

Main study variables: improvement in the recognition of basic emotions, social cognition, emotional intelligence and social competence.

Secondary variables: improvement in symptoms and work results.

4.4 DATA COLLECTION

For the pre- and post-training averages, the following instruments will be used:

- *Hints Test*: it is the Spanish adaptation of Gil et al. of the Hitting Task[11], a test created by Corcoran et al. This test includes ten short stories, in all of them two characters appear, and at the end of each one, one of the characters drops a hint. The subject is asked what the character in the story really meant by the comment they made. The ability to infer the real intention of the speaker, underlying this indirect use of language, implies the use of ToM.
- *Faux Pas*[12]: it is a widely used test to evaluate ToM, it consists in understanding socially embarrassing situations, in which one of the characters involuntarily says or does something

inappropriate or incorrect. After this short story, the patient is asked several questions: a control question; another one for blunder detection and others for blunder comprehension; finally, there is a question that measures empathic understanding.

- *F. Happé's theory of mind test* (adapted by Pusa 1999)[13]: these are stories that use figurative language, not literal, the characters are ironic, lie or tell white lies. In one of the stories, the character says something that should not be understood in a literal sense, and the subject is asked to explain why the character says that.
- *Ekman 60 Faces Test*[14]: 12 photographs of actors showing one of the six basic emotions (sadness, anger, fear, disgust, surprise and happiness), two of each emotion, one played by a man and one by a woman. Participants are asked to choose the appropriate verbal label to describe what the actor in the photograph was feeling.
- *Ambiguous Intentions Hostility Questionnaire* (AIHQ)[15]: evaluates cognitive social biases based on different comic strips in which a series of situations are presented in which the intentions of the characters are ambiguous. The participant is asked to rate on a Likert scale why they think the protagonist acts in this way (AIHQ HB subscale, the hostility score), whether the other person has done the action on purpose (AIHQ IS subscale, the intentionality score) and how much they would blame them (AIHQ BS subscale, guilt score). Additionally, it also rates how angry this situation makes the subject feel (AIHQ AS, the anger score) and how they would respond to this situation (AIHQ AB, aggressiveness score). Higher scores reflect more hostile, negative, personal, and aggressive attributions.
- *Mayer-Salovey-Caruso Emotional Intelligence Test* (MSCEIT)[16]: This allows an evaluation of general emotional intelligence based on the subject's performance. It is made up of 141 items and the duration of its completion varies between 30 and 45 minutes, approximately.
- *Movie for the Assessment of Social Cognition* (MASC)[17]: the Spanish version of Lahera (2014) will be used. In this test, the subject must understand the various interactions established between the four characters and is asked about them through 40 multiple-choice questions. Questions include jokes comprehension, double meanings, innuendos, easily expressed emotional reactions, nonverbal cues or blunders. The test gives a social cognition score, but it also allows classifying the predominant type of error (hypo-mentalization, or a tendency to infer less social meaning than there is, or hyper-mentalization, or a tendency to over attribution).
- *Positive and Negative Symptom Scale* (PANSS)[18]: It consists of 30 items that evaluate the schizophrenic syndrome from a dual perspective; a dimension that evaluates the severity of the positive syndrome, the negative syndrome and the general psychopathology of the schizophrenic disorder; and another category that classifies it as positive, negative or mixed.
- *Social Functioning Scale* (SFS)[19]: This is a reliable instrument, specifically designed for the evaluation of the social functioning of people with schizophrenia. It is useful for researchers and clinicians interested in the variables involved in social functioning and, particularly, for those who work in family interventions or other psychosocial intervention programs in schizophrenia. It is composed of seven subscales: isolation/social integration, interpersonal communication, independence-execution, interdependence-competence, free time, prosocial activities, employment/occupation.

4.5 SAMPLE COLLECTION AND HANDLING

100 people with severe mental disorder will be selected. All records will be made anonymously, assigning each patient an identification number. All data will be kept for 5 years.

4.6 STATISTICAL ANALYSIS OF DATA

All data will be analyzed with the SPSS program.

5 WORK PLAN

The purpose of this study is to assess the efficacy of a multicomponent social skills training program in people with schizophrenia.

The expected duration of the study will be one year and will be carried out at the Sinpromi center. Participants will be randomly assigned to receive employment support (IPS control group) or employment support with cognitive rehabilitation (ET + IPS experimental group).

The experimental group (e-Motional Training + Individual Placement and Support) will receive a total of twelve sessions (one hour and a half per week for four months) for training. The training program will consist of the individual practice of tasks related to social skills through the use of an interactive video game, using a computer. During the training, a member of the research team will be present to answer questions. This program has been developed and initially tested by the Psychiatry Service of the Hospital Complex in Ourense.

To assess the level of social cognition, both groups will perform an evaluation before and after rehabilitation to determine whether the intervention has been advantageous or not (blinded investigator).

In addition, once the rehabilitation is finished, the two study groups will be searched for employment and all their variables will be analyzed, such as hours worked, maintenance, salary, etc.

6 ETHICAL CONSIDERATIONS

The study will be carried out in accordance with the ethical principles that have their origin in the Declaration of Helsinki adopted by the 18th World Medical Assembly, Helsinki, Finland in 1964 and amended in Tokyo (1975), Venice (1983), Hong Kong (1989) , South Africa (1996), Edinburgh (2000), Washington (2002), Tokyo (2004), Seoul (2008), Brazil (2013); and the Laws and Regulations in force in Europe and Spain, and with respect to the current legislation.

The rights, safety, and welfare of the study subjects take precedence over the study. The benefits obtained involve achieving an improvement in cognitive functions and getting a job.

Free informed consent will be obtained from each subject prior to their participation in the study. The procedure used to obtain it will be specified. The confidentiality of records that could identify subjects is protected by respecting privacy and confidentiality standards in accordance with relevant legislative requirements.

The patient must give her consent before being admitted to the clinical study. The doctor must explain the nature, purposes and possible consequences of the study, in a way that is understandable to the patient. The information provided by the doctor must also be recorded.

The subject of the study will grant their consent by signing the corresponding model that must also bear the signature of the researcher. In Annex II (page 16-18), a copy of the informed consent model is attached. The investigator will not initiate any research corresponding to the study without the patient's consent.

In order to guarantee the confidentiality of the data of the patients participating in the study, only the following individuals will be able to acess this information: the researcher and their team of collaborators, the representative of the sponsor who will carry out the monitoring tasks, the auditor in the event that the study was submitted to an audit, the CEIm and the Health Authorities.

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 the Council of April 27, 2016 on Data Protection (RGPD).

7 BIBLIOGRAPHY

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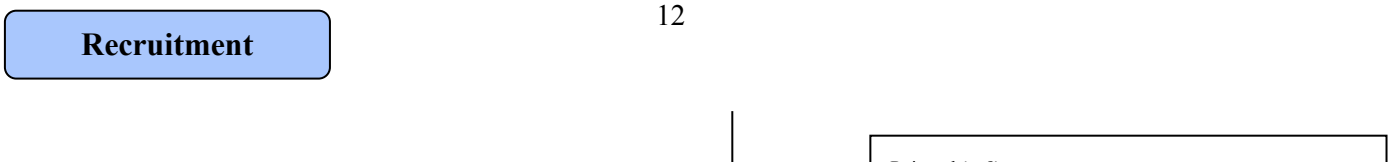
ANNEX I

FLOWCHART



Suitability assessment (n=100)

ANNEX II

PATIENT INFORMATION SHEET

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 information contained must be relevant, expressed in clear and understandable terms for the subjects)

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.

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.

** Explanatory note: in this document the aspects that are fixed for all studies appear in normal font, and in italics the variable aspects depending on the characteristics of the study, but which must be completed.

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)

……

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.

Guardian (name and surname):

……

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.

Patient / Guardian Signature: **Researcher Signature:**

Name: **Name:**

Date: **Date:**

COMMITMENT OF THE MAIN INVESTIGATOR AND COLLABORATORS

Dr. Francisco Rodríguez Pulido states that:

He knows and agrees to participate as the main investigator in the study entitled: Training in cognition and social competence in patients with schizophrenia.

Promoter code:

The study complies with the relevant ethical standards for this type of study.

He agrees to participate as the main investigator in this study.

He has the required material and human resources to carry out the study, without this interfering with the realization of other types of studies or with other tasks that are usually assigned to him.

He commits to treat and monitor each subject in accordance with the provisions of the protocol authorized by the Research Ethics Committee and by the Spanish Drug Agency and Medical Devices.

He will abide by the ethical and legal standards applicable to this type of study.

He commits to comply with the provisions of Organic Law 3/2018, of December 5, on the Personal Data Protection and guarantee of digital rights, and the application of Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 of Data Protection (RGPD).

We count on the collaboration of:

In Santa Cruz de Tenerife on November 18th, 2019.

Main investigator

Dr.Francisco Rodriguez Pulido
Investigador Principal

Investigadores Colaboradores
Dr/Drs: Nayra Caballero Estebaranz., Alejandro Alberto García Caballero,Enrique González Dávila,Celia León Palacín,Beatriz Domínguez Fernández,María del Carmen Hernández Álvarez de Sotomayor,Susana López Reig,María Jesús Melián Cartaya,Patricia Inés Vílchez de León

Research Partners

Your data and the collaborators' will be processed by the Canary Islands Health Service in compliance with the General Data Protection Regulation 2016/679. For the administrative and accounting management, if the funding for the study is approved, the data will be processed by the Canarian Foundation for Health Research (FUNCANIS), on a mandatory basis and without constituting a transfer of data, as a collaborating entity when executing administrative and accounting functions. These data will allow the Foundation to carry out the tasks of economic-administrative management of its research work, send you information related to it and to various procedures on reimbursements, payments, etc. On the other hand, it will allow the Foundation to carry out periodic research reports and relevant statistics. All this guaranteeing the security measures necessary for the treatment of information.

Study title: TRAINING IN COGNITION AND SOCIAL COMPETENCE IN PATIENTS WITH SCHIZOPHRENIA

Project summary:

A single-blind randomized clinical trial will be carried out in patients suffering from schizophrenia and who have the legal capacity to consent to the study. Study participants will be randomized to either the experimental group (e-Motional Training) plus Individual Placement and Support (IPS) or the control group (IPS alone).

The efficacy of a training program in cognition and social competence (e-Motional Training) will be evaluated in patients with schizophrenia when improving the recognition of basic emotions, social cognition, emotional intelligence and social competence.

INFORMATION ON THE USE OF RESOURCES AND FUNDING

(mandatory compliance)

Do you need funding for this study?								YES		NO	X				
Do you have required funding for this study?								YES	X	NO					
How many hours of your time during work hours will you dedicate to this study?								25%							
Do you have the material means (equipment, techniques, others...?								YES	X	NO					
Where will the study take place?															
CONSULTING ROOM		DAY HOSPITAL		UICEC		HOSPITALIZATION	X	OTHERS		SINPROMI					
Will additional tests be performed outside of routine clinical practice?*								YES		NO	X				
*If YES, indicate below:															
Use of biological samples:								YES		NO	X				
*If YES, indicate their location below:															
SERVICE / DEPARTMENT: PSYCHIATRY SERVICE. ULL.															
COLLECTION								YES		NO	X				
BIOBANK								YES		NO	X				
Use of patient clinical data:															
Transfer of encrypted data (pseudonymized) outside the EU to the entities of our group, to service providers or to scientific researchers who collaborate with us								YES		NO	X				

La Laguna, November 18, 2019

Name:

Principal Investigator Signature