INFORMATION SHEET
COMPUTERIZED COGNITIVE STIMULATION THERAPY IN ADOLESCENTS WITH A FIRST PSYCHOTIC EPISODE: RANDOM CONTROLLED TRIAL

APROVED: 09 – 30 – 2019

Dear Sir / Madam,

We suggest you participate in a study
Computerized Cognitive Stimulation Therapy in Adolescents with a First Psychotic Episode: Randomized Controlled Trial
Before confirming your participation in the study, it is important that you understand what it is all about. Please read this document carefully and ask any questions you deem appropriate.

OBJECTIVES OF THE STUDY

Cognitive deficits (CD) are considered one of the essential characteristics in psychotic disorders and occur throughout the course of the disease. Recent meta-analyzes have shown that cognitive recovery therapy can reduce CDs in basic cognitive processes such as attention, memory, and problem solving, and can have an impact on social functioning. The aim of this study is to evaluate the effectiveness of a computerized cognitive stimulation intervention in cognitive and functional improvement in patients with a psychopathologically stable first psychotic episode, but with cognitive impairment. Patients receiving computerized cognitive remediation therapy + treatment as usual are expected to improve in verbal memory, visual care, executive function, social cognition, and overall functioning versus patients receiving only routine treatment.

VOLUNTARY PARTICIPATION

Their participation is entirely voluntary. Refusal to participate in the research will have no effect on treatment. In any case, whether or not you participate in the study, you will continue to receive regular visits.

PROCEDURE AND DURATION

Your referring professional will inform you of the study and ask for your informed written consent. If you decide to collaborate in this study, you should know that some data about your health will be used.
If you decide to collaborate in this study, you should know that some data about your health will be used. The study consists of two randomized groups (Group CCRT = computerized cognitive remediation therapy (cCR) + treatment as usual; Group TAU = treatment as usual). For clinical reasons, group TAU will immediately initiate cCR after the second evaluation (re-test). Group CCRT will be re-evaluated at 5 months and at 11months. Group TAU will not be assessed atfollow-up. The 5-month/11 month re-test and assessment consist of the same tests performed in the baseline assessment.

BENEFITS AND RISKS

HCV intervention is expected to benefit patients with CD. They will be informed of the results of the intervention.

You should know that this study will provide information of great scientific interest in improving treatment for patients with a first psychotic episode. Neither you nor your child are at risk of participating in the study.

CONFIDENTIALITY AND PROTECTION OF PERSONAL DATA

The confidentiality of personal data is guaranteed. The results of the study will be stored, in compliance with the legal conservation deadlines, in files created specifically for this purpose and will be protected with the security measures required by current legislation. No health or personal data that allows your identification will be accessible to anyone other than your doctor / ssa, nor may they be disclosed by any means, maintaining at all times the doctor / ssa-patient confidentiality. The results obtained may be consulted by the researchers of the study and be presented at national and international conferences, as well as published in scientific journals, without the personal data of the participants. If you wish, and once the study is completed, we will inform you of the results obtained and their scientific significance.

You may at any time exercise your rights of Access, Rectification, Cancellation / Deletion, Opposition (ARCO rights) and any other rights recognized in the terms and conditions established by current legislation on Data Protection (LOPD in force, General Data Protection Regulation of the European Union, RGPD-EU, 679/2016), such as requesting your personal data, rectifying them if necessary, as well as revoking the authorization for inclusion in the study. To exercise these rights, you must contact, in person or in writing, the Principal Investigator or the Centre's Customer Service Unit, clearly indicating your request and attaching a copy of an identifying document (DNI / NIE). Address of the Center: Hospital Sant Joan de Déu (HSJD), Passeig Sant Joan de Déu, 2 08950 Esplugues de Llobregat (Barcelona) - Spain. The Head of Treatment (Treatment Activities in the "RESEARCH" area) is HSJD. In case of disagreement with the processing of your data or with the exercise of your rights, you can write to the Data Protection Officer of the HSJD (dpd@sjdhospitalbarcelona.org) at the address indicated above or claim directly before the Control Authorities (Catalan Data Protection Authority: http://apdcat.gencat.cat/ca/contacte/apdcat@gencat.cat or Agencia de Protección de Datos, http://www.agpd.es /portalwebAGPD/CanalDelCiudadano/index-ides-idphp.php). This document and the personal data collected and generated during the study will be kept in the custody of HSJD for a period of not less than 10 years. This study does not generate automated decisions or profiling, nor does it involve the international transfer of personal data, collected and generated, outside the scope of legal protection of the European Union.

QUESTIONS / INFORMATION

If you would like to ask a question or clarify a topic related to the study, or if you need help with any health issues related to the study, please do not hesitate to contact the principal investigator of the study:

Dr. / Dra. Ester Camprodon. Phone: __34 932804000. ext 80440_____