

**July 30, 2013**

**Integrated Psychological Therapy (IPT) + Emotional Management Therapy (EMT) in chronic schizophrenia: study protocol for a randomized controlled trial**

## **Methods**

### **Design**

This is a randomized study with pre- and post-treatment assessment and with a 6- and 12-month follow-up. The randomized clinical trial will be evaluated by Ethics Committees of the University of the Basque Country and the University Hospital of Donostia (Spain) (CEISH/63/2011). The intervention program will be offered at different Mental Health Centers of Guipúzcoa (Spain).

This clinical trial fulfills the Standard Protocol Items for Interventional Trials. The efficacy of a new intervention program (IPT + EMT) will be compared to that of standard treatment in patients with chronic schizophrenia.

### **Participants**

Patients who meet the inclusion criteria (listed below) are to be included and randomly assigned to one of the two treatment groups. The sample size calculation was performed using data published in the literature related to the main theme of the study. To achieve a power of 80% to detect differences from the null hypothesis, using a bilateral Student's *t* test for two independent samples, with a significance level of 5%, we need to include at least 35 patients in the experimental group and 35 patients in the control group, meaning a total of 70 patients for the study.

#### ***Inclusion criteria***

The study inclusion criteria for both groups are:

1. Having  $\geq$  5 years since disease onset and aged between 25 and 65 years.
2. Being in a stable phase of the illness and under psychopharmacological treatment.
3. Having negative or attenuated positive symptoms.
4. Failing to achieve premorbid functioning in terms of education, work and/or social life.
5. Agreeing to participate in the study and giving written informed consent.

#### ***Exclusion criteria:***

1. Presenting organic brain pathology.
2. Presenting intellectual developmental disorder according to DSM-5 criteria.

### **Assessment**

All the assessment instruments that will be used have been benchmarked in and adapted for the Spanish language and have appropriate psychometric properties.

### *General assessment*

We will carry out an interview to collect sociodemographic data such as sex, marital status, number of offspring, level of education and employment status, as well as the following data related to patients' clinical history: diagnosis, illness duration, total number of psychiatric admissions and usual pharmacological treatment.

### *Symptom assessment*

*Frankfurt Complaint Questionnaire (FBF-3)* [24, 25]. This is a self-report test composed of 98 items measuring the presence of the "basic" symptoms of schizophrenia. These are subjectively experienced disturbances at different domains including perception, thought, processing, language and attention that it could be the neurobiological features of schizophrenia. It contains 10 subscales and 4 factors. We will use a validated version for the Spanish population, in which Cronbach's alpha was above .95 and the test-retest reliability was above .60 [25].

### *Cognitive impairment*

*Screen for Cognitive Impairment in Psychiatry (SCIP)* [26, 27]. This test assesses cognitive impairment through five areas: immediate and delayed verbal learning, working memory, verbal fluency and information processing speed. It is used for identifying cognitive impairment. The test-retest reliability ranged from 74 to 90 and Cronbach's alpha was 73.

### *Cognitive functioning*

*Wechsler Adult Intelligence Scale-Third Edition (WAIS-III)* [28]. Short forms of this scale have been designed for patients with schizophrenia [29]. It assess cognitive functioning. Scores on these short forms are correlated (0.91) with the overall intelligence quotient (IQ) of the full scale in clinical patients.

### *Executive functioning*

*Wisconsin Card Sorting Test (WCST)* [30,31]. This test assesses attention span, planning and execution, and hence is considered a valid measure of executive function. We used the version of the test standardised and benchmarked for the Spanish population by TEA Editions.

### *Psychosocial functioning*

*Social Functioning Scale (SFS)* [32]. We will use the short version of the scale, validated in a Spanish clinical sample [33], with a Cronbach's alpha of 0.76.

### *Quality of life*

*Lancashire Quality of Life Profile (LQoLP)* [34,35]. This instrument assesses patient satisfaction with various aspects of their life, work, leisure time, religion, finances, living situation, safety, family relations, social relations, and health, as well as global wellbeing and self-esteem.

### **Intervention programs**

Patients are to be randomized into two treatment groups: a) the experimental group will receive integrated psychological therapy in conjunction with emotional management therapy (IPT+EMT) composed of 2-hour biweekly 60 group sessions for 32 weeks in addition to psychopharmacological; b) the control group will receive the treatment as usual prescribed by the psychiatrist.

1. In the experimental group the psychological treatment includes 50 sessions of integrated psychological therapy (IPT) (focused on attentional skills training, social perception skills training, verbal communication skills, social skills training, interpersonal problems solving skills) [17] and 10 sessions of specific emotional management therapy (EMT), designed for this research and based on the contents developed by Hodel, Kern and Brenner [23]. The content of this specific emotional therapy sessions is as follows:
  - Session 1: description of the main negative emotions and how these affect behavior, well-being and social relationships.
  - Session 2: specific description of sadness and how sadness can be confused with negative symptoms of the disease. Patients are trained how to cope with sadness.
  - Session 3: description of anger. Often people with schizophrenia misinterpret neutral situations as potentially threatening and become anxious or angry. Therefore patients are trained in anger management techniques.
  - Session 4: description of fear and anxiety. Patients are trained how to handle fear and regulate it in an effective way.
  - Sessions 5-6-7: emotional management strategies. Awareness of negative emotions, analysis of their coping strategies and implementation of more adaptive strategies (problem solving, discussion of maladaptive thoughts and positive self-statement).
  - Session 8: patients are taught to put into practice, by using role playing, the learning about adaptive emotional regulation strategies worked on in the previous sessions.

- Sessions 9-10: training in relaxation techniques. Closure of treatment sessions.

Therapists will be two clinical psychologists with expertise in the treatment of chronic schizophrenia.

2. The control group will receive the treatment as usual (TAU) (pharmacological treatment and activities in a Day Care Center). This standard treatment lasts the same number of weeks as experimental treatment.

In this group the patients received the psychopharmacological therapy provided by psychiatrists and they carried out social and leisure activities in a Day Care Center. This intervention will be held every day of the week (except Saturday and Monday) for 5 hours a day from 9.00 to 14.00 hours.

### **Procedure**

Patients will be assessed after being informed of the objectives of the study and giving their informed consent to participate. All participants will be randomly assigned to one of two treatment groups and they will be individually evaluated in three sessions by a clinical psychologist. Data will be collected following an assessment protocol (see "Assessment" section) that will be implemented at baseline and post-treatment in both groups, and in the experimental group at a 6- and 12-month follow-up.