

"e-Motional Training": randomized controlled trial of a novel social cognition online program for patients with schizophrenia

Submission date 02/07/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 24/07/2015	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/08/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background study and aims

Social cognition (SC) refers to the ability to understand what the others are thinking or feeling. SC includes perception of emotions in faces, voices and body language and interpretation of the intentions and behaviors of others in social situations. In recent years, disorders in SC have been described in patients with schizophrenia and other mental disorders. The study of these deficits is important because SC appears to have greater impact on social function than other factors. Moreover, rehabilitation of SC deficits is possible using different therapeutic models; unfortunately all systems available require a significant number of rehabilitation sessions (between 12 and 45), typically applied in a group setting and requiring specific training by the therapists, a factor that can hinder their application in clinical settings. With this aim our research group designed a SC rehabilitation online program called e-Motional Training®. Our main objective is to assess the effectiveness of e-Motional Training® in patients with schizophrenia.

Who can participate?

Patients aged 18-50 with schizophrenia.

What does the study involve?

Participants will be randomly allocated into two groups. In the intervention group patients will attend 12 weekly sessions of 1 - 1.5 hours duration where they are going to play different tutorials and computer games designed by our team. The first four sessions will involve improving recognition of emotions and the next eight sessions will involve watching a cartoon depicting different communication woes that the patient has to explain. The control group will receive treatment as usual: occupational therapy and leisure activities. All participants will be evaluated before the intervention and 1 month after completing it using psychological tests that take around two hours with a brief rest.

What are the possible benefits and risks of participating?

The possible benefit is an improved ability to understand other people's facial expressions and intentions, and no side effects are expected.

Where is the study run from?
Complejo Hospitalario Universitario de Ourense (Spain).

When is the study starting and how long is it expected to run for?
From January 2015 to December 2015.

Who is funding the study?
Servizo Galego de Saúde (Galician Health Authority) (Spain).

Who is the main contact?
Dr Alejandro Garcia-Caballero
alejandro.garcia.caballero@sergas.es

Contact information

Type(s)
Public

Contact name
Dr Alejandro Garcia-Caballero

Contact details
Servicio de Psiquiatría
Complejo Hospitalario Universitario de Ourense (CHUO)
Hospital Santa Maria Nai
Rúa Ramón Puga 52-55
Ourense
Spain
32005

Additional identifiers

Protocol serial number
AAGC-EMOESQ-2014

Study information

Scientific Title
"e-Motional Training": randomized controlled trial of a novel social cognition online program for patients with schizophrenia

Acronym
E-MOSCH

Study objectives
E-Motional Training online program improves social cognition (emotion recognition and theory of mind) in comparison with treatment as usual.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Clinical Research Ethics Committee of Galicia (Comité Autonómico de Ética da Investigación de Galicia), EC registry code: 2014/459

Study design

Interventional randomised multicenter single-blind controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Schizophrenia

Interventions

1. Intervention group attends 12 weekly sessions of 1 - 1.5 hours duration. The first 4 meetings (1 h each session) are dedicated to recognizing facial emotions. This includes a pretest and posttest, a number of tutorials, facial minigames that include isolated parts of the face (eyes and mouth), as well as training in recognizing microexpressions (<250 ms) and morphing (faces change from a neutral expression to a specific emotion; the user must determine as quickly as possible what emotion the face will change to).

The next 8 sessions (1 h each) include watching a short interactive animated cartoon in which a couple invites their friends to their home for a party. Over the course of the story, various communication woes occur between the actors, which cause emotions and various mental conditions such as anger, affection, appreciation, jealousy, etc. After each scene, the user is presented several questions on what happened, including questions about ToM (interpreting irony, insinuations, faux pas, 2nd-order false beliefs, etc.), social perception, attributive style and control questions. The game provides user feedback and, in the event of error, can display a hyperlink with information, whose objective is to help understand the scene the user just watched.

The e-Motional Training® has a software platform that stores the results of each session individually, storing the results in a database with access restricted to the practitioner.

2. Treatment as usual: occupational therapy and leisure activities

Intervention Type

Behavioural

Primary outcome(s)

Patients are going to be studied with the following battery prior to randomisation and 1 month after the intervention.

1. Ekman 60 Faces Test (Ekman, 1976): A computer test based on the facial recognition of emotional expressions. The test contains 60 photographs of faces with expressions of the 6 basic emotions: anger, disgust, sadness, fear, surprise and happiness.

2. Hinting Task (Corcoran, Mercer, & Frith, 1995) (Spanish version of Gil, 2012): The individual must identify what the story's character really meant to say.

3. Recognition of Faux Pas (Baron-Cohen, 1997): The participant must identify the embarrassing

situations or gaffes.

4. Strange Stories of F. Happé (Spanish Version of Pousa, 1999): The participant must understand the emotions, intentions and thoughts of the characters in the various stories.

5. Positive and Negative Symptom Scale (PANSS) (Kay, Fiszbein and Opler, 1987): Assesses positive and negative symptom severity.

6. Lahera G, Boada L, Pousa E, Mirapeix I, Morón-Nozaleda G, Marinas L, Gisbert L, Pamiàs M, Parellada M. Movie for the Assessment of Social Cognition (MASC): Spanish Validation. Journal of Autism and Developmental Disorders (2014).

Key secondary outcome(s)

Prior to randomisation and 1 month after intervention, both groups (e-Motional Training & TAU) will be studied with:

1. Ambiguous Intentions Hostility Questionnaire (AIHQ) (Combs, Penn, Wicher and Waldheter, 2007): Assesses attributional biases in 3 types of situations (ambiguous, intentional and accidental).

2. The Social Functioning Scale. The development and validation of a new scale of social adjustment for use in family intervention programmes with schizophrenic patients. Birchwood M, Smith J, Cochrane R, Wetton S, Copestake S. Br J Psychiatry. 1990 Dec;157:853-9. Spanish version: Torres A, Olivares JM. Validation of the Spanish version of the Social Functioning Scale. Actas Esp Psiquiatr. 2005 Jul-Aug;33(4):216-20.

Completion date

01/12/2015

Eligibility

Key inclusion criteria

1. Patients who voluntarily agree to participate in the study
2. Aged 18-50 years
3. Diagnosis of schizophrenia (DSM-5)
4. Clinically stable
5. No comorbidity with other psychiatric or neurological diseases (International Neuropsychiatric Interview-MINI) or current substance abuse
6. Score at F. Happé's Strange Stories test lower than 14

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

50 years

Sex

All

Total final enrolment

60

Key exclusion criteria

1. Psychiatric, neurological comorbidity, or active substance disorder
2. Acute schizophrenic symptomatology
3. Suicidal ideation
4. ToM score in F. Happé's Strange Stories >14

Date of first enrolment

01/01/2015

Date of final enrolment

30/11/2015

Locations**Countries of recruitment**

Spain

Study participating centre**Complejo Hospitalario Universitario de Ourense**

Rúa Ramón Puga 54

Ourense

Spain

32005

Study participating centre**Complejo Hospitalario Universitario de Santiago de Compostela**

Santiago de Compostela

Spain

-

Study participating centre**Complejo Hospitalario Universitario de A Coruña**

A Coruña

Spain

-

Study participating centre

Complejo Hospitalario Universitario de Vigo

Vigo

Spain

-

Study participating centre

Asociación Doa

Vigo

Spain

-

Study participating centre

Asociación APEM

A Coruña

Spain

-

Study participating centre

Asociación Morea

Ourense

Spain

-

Study participating centre

Asociación Virxe da Cerca

Santiago de Compostela

Spain

-

Sponsor information

Organisation

Servizo Galego de Saúde (Galician Health Authority)

ROR

<https://ror.org/0591s4t67>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Servizo Galego de Saúde (Galician Health Authority)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/02/2018	18/08/2023	Yes	No