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"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

Registration date
24/07/2015

Overall study status
Completed

Last Edited
18/08/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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?
Complexo 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?
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Contact information

Type(s)
Public

Contact name
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32005

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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).

Secondary outcome measures
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.

Overall study start date
01/01/2015

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
N=60, 30 patients in the intervention group and 30 in the control group

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
Complexo Hospitalario Universitario de Ourense
Rúa Ramón Puga 54
Ourense
Spain
32005

Study participating centre

Complexo Hospitalario Universitario de Santiago de Compostela
Santiago de Compostela
Spain
-

Study participating centre
Complexo Hospitalario Universitario de A Coruña
A Coruña
Spain
-

Study participating centre
Complexo 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)

Sponsor details
Edificio Administrativo San Lázaro
Santiago de Compostela
Spain
15703

Sponsor type
Government

Website
http://www.sergas.es/

ROR
https://ror.org/0591s4t67

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Servizo Galego de Saúde (Galician Health Authority)

Results and Publications

Publication and dissemination plan
Communication of preliminary results in National (Spanish) psychiatric and psychological conferences.
Communication of final results at European Congress of Psychiatry or World Congress of Psychiatry
Publication in Schizophrenia Research or Sch Res Cognition

Intention to publish date
31/05/2016

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