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Training programme in facial emotions imitation among patients with schizophrenia

Submission date
24/03/2017

Recruitment status
No longer recruiting

Registration date
26/04/2017

Overall study status
Completed

Last Edited
18/12/2018

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Schizophrenia is a serious mental health condition in which thought and emotions are impaired, causing a person to lose touch with reality. The main symptoms include experiencing hallucinations (hearing and/or seeing things that aren't there) and delusions (holding strong beliefs that aren't shared by others, such as believing people are trying to harm them). In addition, people with schizophrenia often have difficulties interacting with others, such as being able to effectively recognise different emotions by people's facial expressions (emotional recognition). Some studies have shown that facial imitation can help to improve emotional recognition. The aim of this study is to look at the effectiveness of an online game of imitation of facial emotions in patients with schizophrenia.

Who can participate?
Patients aged between 18 and 55 years old with schizophrenia.

What does the study involve?
Participants are randomly allocated to one of two groups. In the first group, participants do not receive any specific training and continue as normal. In the second group, participants complete training in imitation of facial emotions, using a computerised game program. Training takes place in two 30 minute sessions per week over eight weeks. At the start of the study and after two months, participants complete tasks to assess their facial recognition skills and questionnaires to assess their symptom severity and knowledge.

What are the possible benefits and risks of participating?
Participants may benefit from better being able to recognise emotions from facial expression which could help in their day to day functioning. There are no notable risks involved with participating.

Where is the study run from?
Treatment centers Albores Monforte-Chantada (Spain)

When is the study starting and how long is it expected to run for?
September 2015 to March 2017

Who is funding the study?
Galician Public Health Service (Spain)

Who is the main contact?
Mrs Carmen Armas Barbazán

Study website
http://www.e-motionaltraining.com/

Contact information

Type(s)
Scientific

Contact name
Mrs Carmen Armas Barbazán

Contact details
Hospital Comarcal de Monforte
Corredoira s/n
Monforte de Lemos
Spain
27400

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2016/189

Study information

Scientific Title
Facial emotion imitation training in outpatients with schizophrenia: Demonstrating the effectiveness of facial imitation to improve the recognition of facial emotions

Study objectives
The aim of this study is to evaluate applicability as well as to obtain preliminary data on the effectiveness of an online game of imitation of facial emotions in people with schizophrenia when it comes to improving facial recognition.

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: 2016/189

Study design
Interventional multi-centre single-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Schizophrenia

Interventions
Participants are randomised into one of two group using a sequence of random numbers (N / 2) assigning that sequence to the intervention or random control group.

Intervention group: Participants attend two 30-minute sessions per week for eight weeks of imitation simulation of facial emotions, including e-Motional Training®. For training in imitation of facial emotions, facial recognition software by Sightcorp is used, which has been gamified by the research team. The software detects faces and evaluates, in real time, the intensity of each facial expression according to Ekman's six main emotions (happiness, sadness, anger, surprise, fear and disgust) through the use of a webcam. In addition, an audio tag is played automatically. The patient hears the instruction of the type of emotion that occurs while the imitation takes place. E-Motional Training® offers the patient the opportunity to play and provide feedback at the same time. This occurs by assigning values to the accuracy of the imitation (measuring range: 0-10) until the exact imitation is achieved and the errors that appear throughout the session are corrected in such a way that the patient is encouraged to play.

Control group: Participants do not receive any specific training.

Follow up takes place at reference mental health centers and involves an evaluation before and after the intervention in both groups using a set of neuropsychological tests (cited in the next section)

Intervention Type
Device

Primary outcome measure

Facial recognition of emotional expressions is measured using the Ekman 60 Faces Test (Ekman 60) and the Penn Emotion Recognition Task (ER-40 test) at baseline and 2 months.

Secondary outcome measures
1. Symptom severity is assessed using the Positive and Negative Syndrome Scale (PANSS) at baseline and 2 months
2. Verbal and non-verbal knowledge are measured using the Intelligence Test (K-BIT) at baseline and 2 months

Overall study start date
04/09/2015

Completion date
01/11/2017

Eligibility

Key inclusion criteria
1. Provision of informed consent to participate
2. Aged between 18 and 55 years old
3. Diagnosed with schizophrenia (DSM-5)
4. Clinically stable
5. Users of mental health facilities in the moment of the research
6. Treated with atypical antipsychotics

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Target number of participants: 50 aprroximately

Key exclusion criteria
1. Presence of a comorbid psychiatric or neurological disorder, intellectual disability
2. Abuse of toxic substances in the moment of the research (excluding nicotine)

Date of first enrolment
24/11/2015

Date of final enrolment
01/02/2017

Locations

Countries of recruitment
Spain

Study participating centre
Asociación de Apoyo al enfermo mental ALBORES
Ronda de María Emilia Casas Baamonde, 2
Monforte de Lemos (Lugo)
Spain
27400

Study participating centre
Asociación de Apoyo al enfermo mental ALBORES
Parque Eloísa Ribadulla.
Chantada. (Lugo)
Spain
27500

Study participating centre
Centro de Día de Salud Mental de Torrero. Fundación Adunare
C/ Biescas, 11
Zaragoza
Spain
50007

Study participating centre
Hospital de Día (Hospital Nicolás Peña).
Avda. Camelias, 109
Vigo
Spain
36211

Study participating centre
Hospital de Día (Hospital Santa María Nai)
Rúa Ramón Puga, 54
Orense
Spain
32005

Sponsor information

Organisation
Servicio Gallego de Salud (SERGAS)

Sponsor details
Edif. Admtvo. San Lázaro s/n
Santiago de Compostela
Spain
15700

Sponsor type
Government

Website
http://www.sergas.es/

ROR
https://ror.org/0591s4t67

Funder(s)

Funder type
Research organisation

Funder Name
Fundación Biomédica Galicia Sur

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal.

Intention to publish date
18/01/2020

Individual participant data (IPD) sharing plan
The data has been stored in an Excel database guarded by the research team. The data controller is Carmen Armas Barbazán and the rest of the team.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		29/03/2017	26/04/2017	No	Yes
Basic results		18/12/2018	18/12/2018	No	No