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Auditory perception training program in people with schizophrenia

Submission date	Recruitment status	[_] Prospectively registered
20/09/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/09/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/04/2019	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Schizophrenia is a mental health condition that causes abnormal social behaviour and can make people be unable to understand what is real and what is not real. It is present in 1% of the world population and can cause a lot of disability. Some of the symptoms such as hallucinations and delusions can usually be controlled with pharmacological (medical) treatment. Other symptoms, such as the lack of initiative, the impoverishment of the personality, or the social disinterest or problems in the management of emotions presented by this type of patients, are treated at the present time to decrease with rehabilitation programs, without reaching get a "cure" of them at the present time. People suffering from Schizophrenia or Schizoaffective Disorder present a greater difficulty in recognizing emotions in the voices than people without this disorder. The “Voices” programme was developed to help patients with schizophrenia be able to recognise emotions. The aim of this study is examine if that programme can improve social functioning.
Who can participate?
Adults aged 18 to 60 years old who have Schizophrenia and are enrolled in psychiatric services.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the rehabilitation programme in two 30 minute sessions twice a week for four weeks. Those in the control group do not receive any training. Participants are evaluated before and after the study with neuropsychological tests.

What are the possible benefits and risks of participating?
Participants may benefit from improving their auditory perception, which could mean better communication and better social integration. There are no direct risks with participation, other than the time the participant has spent undergoing the tests.

Where is the study run from?
This study is being run by the Hospital Universitario de A Coruña (Spain) and takes place in treatment centres in Spain.

When is the study starting and how long is it expected to run for?
October 2016 to August 2017

Who is funding the study?
Fundación Biomédica Galicia Sur (Spain)

Who is the main contact?
Miss Maria Lado Codesido

Contact information

Type(s)
Scientific

Contact name
Miss María Lado Codesido

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Contact details
Hospital Universitario de A Coruña
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Spain
15006

Additional identifiers

Protocol serial number
2016/548

Study information

Scientific Title
Prosodic rehabilitation program in patients with schizophrenia

Study objectives
The aim of this study is to evaluate the applicability of a pilot program dedicated to prosodic training in patients with schizophrenia to improve their recognition of basic and complex emotions, resulting, secondarily, in the simultaneous improvement of social cognition and social competencies.

Hypothesis:
Participants in this prosodic rehabilitation program have better results in prosodic tests than the ones that participate in ordinary psychosocial rehab program.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethics Committee of Galicia (Comité Autonómico de Ética da Investigación de Galicia), 26/01/2017, ref: EC registry code: 2016/548

Study design
Interventional randomized multicenter single-blind controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
The training program "Voices" was designed by the initial selection of 100 simple phrases of neutral content. 34 of them contain two answer options in which two simple emotions are expressed, 33 of them contain three options with simple and complex emotions and the last 34 contain a selection of answers in which four complex emotions are expressed.

These phrases are later recorded by professional actors based on the emotion prompted. A Microsoft Powerpoint® presentation wass created to include these audio recordings and the corresponding answer options.

Next, the programme was tested with 20 independent testers (11 women and 9 men) and 82 phrases have been extracted and deemed valid (with over 70% agreement among testers). The new version was applied to a sample of 164 healthy control subjects, recruited in the faculty of Medicine at the University of Santiago de Compostela (with 101 women and 63 men, aged 19 – 44 years). On this occasion, answer time wass limited to 10 seconds per question. The test duration was approximately 14 minutes. On this occasion, 63 phrases were selected, which achieved a majority agreement of 79.9%.

This definitive selection that defines the Voices programme has been uploaded to a software platform suitable for patient use (e-Motional Training®), in which a personal user account and password are created. In the "Voices" programme, the various phrases are shown randomly, with the goal of selecting the correct answer of the two, three, or four options. In this selection, there is no set time limit to answer, and there exists the possibility to repeat the audio fragment. At the end of the game, points are registered and compared with the score obtained in previous games.

Participants are randomly allocated to one of two groups. In the intervention group, participants complete prosodic training, during a period of four weeks, two sessions of 30 minutes twice a week. The control group does not receive any specific training. All participants are evaluated before and after the intervention using neuropsychological tests.

Eight sessions are carried out, with a biweekly frequency lasting approximately 20-30 min/day during which time the Voices programme are applied in its entirety. In each session, the test content are randomised. The control group does not receive any specific training.

An evaluation is executed before and after the intervention applying a set of neuropsychological tests.

Intervention Type

Device

Primary outcome(s)
Prosodic level is measured using the Spanish version of the Reading Mind in the Voices" programme at baseline and one month after the intervention.

Key secondary outcome(s))
1. Severity of the schizophrenia is measured using the Positive and Negative Syndrome Scale (PANSS) at baseline and one month
2. Verbal and non-verbal knowledge is measured using the Intelligence Test (K-BIT) at baseline and one month

Completion date
30/08/2017

Eligibility

Key inclusion criteria
1. Capacity to consent
2. Given willing consent to participate in the study, after being informed of the objectives of the study
3. Diagnosed with Schizophrenia or Schizoaffective Disorder according to the DSM-5 criteria
4. Enrolled, at the time of the study, in Psychiatric Services
5. Receiving neuroleptic pharmacological treatment
6. Within the age range of 18 - 60 years old at the time of participation in the therapy program

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Does not give willing consent to participate in the study
2. The patient is incapacitated
3. Suffering from a severe comorbid mental disorder or showing a history of severe brain damage or neurological disorder that could act as a confounding variable, or intellectual disability (examples: organic type associated disorder or diagnosis of limited or low intelligence quotient)

4. Demonstrates hearing problems
5. Currently participating in a program in skills to improve social adjustment
6. Practices active substance abuse

Date of first enrolment
18/11/2016

Date of final enrolment
01/08/2017

Locations

Countries of recruitment
Spain

Study participating centre
Asociación Pro-Enfermos Mentales
Avenida Cristina nº2º.
Carballo, A Coruña
Spain
15105

Study participating centre
Hospital de Día (Hospital Nicolás Peña).
Avda. Camelias, nº109.
Vigo, Pontevedra
Spain
36211

Study participating centre
Hospital de Día (Hospital Santa Maria Nai)
Rúa Ramón Puga, nº54.
Ourense
Spain
32005

Study participating centre
Residencia Ceboliño
Avda. Pontevedra, nº5
Ourense
Spain
32005

Study participating centre
Hospital de Día (Hospital Naval)
Av. da Residencia
Ferrol, A Coruña
Spain
15405

Study participating centre
A.F.A.E.S. Porta Nova
C/Río Sil 1-3 Bajo. Piñeiros.
Narón, A Coruña.
Spain
15570

Sponsor information

Organisation
Servicio Gallego de Salud (SERGAS)

ROR
https://ror.org/0591s4t67

Funder(s)

Funder type
Charity

Funder Name
Fundación Biomédica Galicia Sur

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. In the repository data we are storing the results of the pre and post neuropsychological tests, in paper in the investigator center (Hospital Universitario de A Coruña). The proccess of requesting access is using the email contact that is written in the patient information sheet (Maria.Lado.Codesido@sergas.es). The results of the rehabilitation is

storaged in the weblink www.e-motionaltraining.com, and all the data are anonymised. The way of contact would be the same, contacting through the same e-mail. We don´t have any other persistent link. The timing for availability will be 1 year after the publication of the study. The participants consent will be storaged in the same place as the results and the same timing. About the anonymisation: The data will be collected in a consecutive manner in written and electronic form. For this, a database will be used in which participants' information will be encrypted such that the variables collected will not be identified with the participating individuals. The questionnaires and recorded data from each participant will be identified only with the reference number or code. In no case will personal data be published nor revealed to individuals outside of the research or the Committee for Ethical Clinical Investigation.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/01/2019		Yes	No
Participant information sheet	Participant information sheet		07/02/2019	No	Yes
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Protocol file	Study website		02/04/2019	No	No
Study website		11/11/2025	11/11/2025	No	Yes