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Positive Emotions Program for Schizophrenia (PEPS)

Submission date
12/05/2015

Recruitment status
No longer recruiting

Registration date
18/05/2015

Overall study status
Completed

Last Edited
01/10/2015

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, long term mental health condition that causes a wide range of psychological symptoms broadly categorised as positive and negative. The positive symptoms of schizophrenia include hallucinations (hearing or seeing things that are not real), delusions (believing things that cannot be true), and disorganised thinking and behaviour. Negative symptoms include apathy (general lack of interest) and anhedonia (inability to feel pleasure) which describe an individual's limited ability to experience life events. Other significant negative symptoms are associated with people's inability to express themselves, namely emotional blunting (inability to express feelings) and alogia (inability to verbally express oneself). People with schizophrenia who show mainly negative symptoms often have a poorer prognosis compared to patients who show mainly positive symptoms, and people who express symptoms of apathy-anhedonia fare even worse than those expressing emotional blunting and alogia. This is because there are very few effective drug-based and psychological treatments for negative symptoms in schizophrenia, particularly ones targeting apathy-anhedonia. The Positive Emotions Program for Schizophrenia (PEPS) is a new psychological treatment that has been developed to tackle the symptoms of apathy and anhedonia in people with schizophrenia. PEPS aims to teach participants various skills to help them overcome feelings of hopelessness, and to increase the anticipation and maintenance of positive emotions. The aim of this study is to see how well PEPS works to reduce the symptoms of anhedonia and apathy in patients diagnosed with schizophrenia or schizoaffective disorders.

Who can participate?
French-speaking adults diagnosed with schizophrenia or a schizoaffective disorder.

What does the study involve?
All participants attend eight weekly 1-hour PEPS sessions which involve a presentation and group discussion. Participants are asked to fill in questionnaires before the start of the study, then again 1 week after the PEPS sessions have been completed.

What are the possible benefits and risks of participating?
This study has no specific physical or psychological risks. Some people may not appreciate the intervention, feel uncomfortable or tired. In this case, there is no obligation to speak to the

group, or even to continue following the sessions. In case of discomfort, participants are free to stop their participation in the study at any time.

Where is the study run from?
1. Organisation de Soins à Domicile (OSAD) SISP SA (Switzerland)
2. Fondation HorizonSud (Switzerland)
3. Fondation Pro-Home (Switzerland)

When is the study starting and how long is it expected to run for?
May 2014 to February 2015

Who is funding the study?
This study is supported by a donation from Dr Alexander Engelhorn (Switzerland)

Who is the main contact?
Prof J Favrod
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Positive Emotions Program for Schizophrenia (PEPS): a pilot intervention to reduce anhedonia and apathy

Acronym
PEPS pilot

Study objectives
Eight sessions of PEPS will reduce anhedonia and apathy, as measured using the Scale for the Assessment of Negative Symptoms (SANS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Vaud Cantonal Ethics Commission on Human Research, 06/05/2014, ref: 127/14.

Study design
Open pre-/post-comparison within subject design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Anhedonia and apathy in schizophrenia

Interventions
Eight 1-hour group PEPS sessions, administered using visual and audio materials and presented as a PowerPoint presentation. PEPS is an intervention intended to reduce anhedonia and apathy in patients with schizophrenia. The program teaches skills to help overcome defeatist thinking and to increase the anticipation and maintenance of positive emotions.

Intervention Type
Behavioural

Primary outcome measure

Scale for the Assessment of Negative Symptoms (SANS) at pre and post-test. Baseline assessment is done the week before participation in PEPS, and one week following the end of PEPS intervention. Duration of PEPS is 8 weeks overall.

Secondary outcome measures
Calgary Depression Scale for Schizophrenia (CDSS) at pre and post-test.

Overall study start date
13/05/2014

Completion date
03/02/2015

Eligibility

Key inclusion criteria
1. ICD-10 criteria for a diagnosis of schizophrenia or a schizoaffective disorder
2. Presenting a score of at least 2 on the overall SANS anhedonia scale
3. Aged 18-65
4. Read and understand French
5. Capacity for consent according to the San Diego Brief Assessment of Capacity to Consent. This tool measures a patient's understanding of an information sheet. If the potential participant is unable to respond correctly to the questions asked after reading the sheet, the patient is excluded. The procedure can be conducted a maximum of twice.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
Failure to demonstrate capacity for consent according to the San Diego Brief Assessment of Capacity to Consent.

Date of first enrolment
20/05/2014

Date of final enrolment
30/11/2014

Locations

Countries of recruitment
Switzerland

Study participating centre
Organisation de Soins à Domicile (OSAD) SISP SA
Avenue des Oiseaux 13
Lausanne
Switzerland
1018

Study participating centre
Fondation HorizonSud
Route de la Rotonde 25
case postale 41
Marsens
Switzerland
1633

Study participating centre
Fondation Pro-Home
Appartements FOND-VERT
Chemin de l'Eglise 8
Gilly
Switzerland
1182

Sponsor information

Organisation
La Source School of Nursing Sciences (HEdS La Source)

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Sponsor type
University/education

Website
http://www.ecolelasource.ch/

Funder(s)

Funder type
Other

Funder Name
This study is supported by a donation from Dr Alexander Engelhorn (Switzerland)

Results and Publications

Publication and dissemination plan
Results of this pilot study will be submitted to a peer review journal. The results of this study will be used to calculate the power of the intervention to apply for a grant for a randomised study. The grant has been submitted to the Swiss National Scientific Fundation request number 320030_163355.

Intention to publish date

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	results	29/09/2015		Yes	No