ISRCTN35157287 https://doi.org/10.1186/ISRCTN35157287

Cognitive rehabilitation to improve vocational outcomes for people with psychosis

Submission date
01/02/2017

Recruitment status
No longer recruiting

Registration date
16/02/2017

Overall study status
Completed

Last Edited
15/02/2017

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Schizophrenia is a long-term mental health condition that affects how a person thinks, feels and behaves. It can cause hallucinations (hearing and/or seeing things), delusions (believing something that is not true), and changes in behaviour. The causes of schizophrenia are unknown. Schizophrenia is usually treated with a combination of antipsychotic medicine and therapy however patients may still find it hard to manage their symptoms. This can make it hard for people with schizophrenia to find and keep a job. In Spain, there are programmes such as the Individual Placement and Support (IPS) programme that provides support and guidance to those with mental health problems to help them find a job. However, this programme does not have a therapy component that addresses the mental condition of patients. A therapy that addresses cognitive function (mental skills) could be beneficial to those with mental health problems seeking jobs. This study aims to see if the effectiveness of the IPS programme is improved by having additional support that works on improving cognitive function.

Who can participate?
Adults with schizophrenia who are unemployed.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the standard job search support. Those in the second group receive the standard job search support as well using a computer program that aims to improve cognitive functioning (mental skills). This program improves memory, attention, problem-solving, learning and motor skills. Participants also receive feedback, support and strategies for improving the skills they have problems with. Participants are followed up 8 months and one year after the programme to test their cognitive function and to see if they are employed.

What are the possible benefits and risks of participating?
Participants may benefit from the possibility of being employed and improving their cognitive functions through participation in this study. There are no risks to participants.

Where is the study run from?
SINPROMI (Spain)

When is the study starting and how long is it expected to run for?
October 2013 to October 2015

Who is funding the study?
SINPROMI (Spain)

Who is the main contact?
Dr Francisco Rodriguez Pulido
fpulido15@yahoo.es

Contact information

Type(s)
Scientific

Contact name
Dr Francisco Rodriguez Pulido

ORCID ID
https://orcid.org/0000-0003-1973-5640

Contact details
Carretera General La Cuesta Sn
Santa Cruz De Tenerife
Spain
38075
+34 60 911 65 23
fpulido15@yahoo.es

Additional identifiers

Protocol serial number
SINPROMI

Study information

Scientific Title
Cognitive remediation to improve vocational outcomes for people with psychosis experience: A randomised controlled tiral

Study objectives
The aim of this study is to determine the effectiveness of the Individual Placement and Support (IPS) model in two groups: one with supported employment only and other with supported employment and cognitive rehabilitation.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Obtaining ethical approval was unnecessary as there are no psychotherapeutic techniques used in any of the groups as the goal was employment strategies. All participants gave informed consent.

Primary study design
Interventional

Study design
Single-centre randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
1. Schizophrenia
2. Schizoaffective disorder

Interventions
Participants in the Individual Placement and Support programme are randomly allocated to one of two groups using a computer generated randomisation list.
All participants undergo baseline assessment to assess cognitive functioning.

Group one (cognitive rehabilitation group): Participants receive 32 one hour sessions of cognitive rehabilitation as well as the standard employment search support. This involves computer cognitive exercises with COGPACK program (version 8.4). The COGPACK prgoram involves a variety of cognitive activities that measure memory, attention, executive functions, verbal learning and psychomotor speed. The first 6 cognitive training sessions are focused on practicing in all of these areas. The following sessions focus on the cognitive functions that participants struggle with. Sessions take place once or twice a week for 45-60 minutes. Different cognitive exercises are explained and demonstrated. Sessions are individually tailored, and participants are provided with feedback, support and strategies for improving their performance on challenging exercises.

Group two (control group): Participants in the control group receive employment search support according to the standard level of practice.

Follow up is done at 8 months and 1 year post treatment to measure cognitive function (this includes tests that measure memory, attention, executive functions, verbal learning and psychomotor speed).

Intervention Type
Behavioural

Primary outcome(s)
Employment outcomes are measured through hours worked, wages earned, and job tenure at baseline, 8 months and one year.

Key secondary outcome(s)
Cognitive outcomes are assessed using Digit Span, Trail Making Test, Rey Auditory Verbal Learning Test, Wisconsin Card Sorting Test and Digit Symbol at baseline, 8 months and one year.

Completion date
10/10/2015

Eligibility

Key inclusion criteria
1. Meets state definitions of severe mental illness (SMI), that includes psychotic disorders with a CIE-10 diagnosis
2. Difficulties keeping a competitive job
3. Currently desires a competitive job
4. Follow up commitment with the individual placement and support team

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients with no desire to gain employment

Date of first enrolment
15/11/2007

Date of final enrolment
20/12/2007

Locations

Countries of recruitment
Spain

Study participating centre
SINPROMI
Góngora s/n
Santa Cruz de Tenerife
Spain
38005

Sponsor information

Organisation
SINPROMI

ROR
https://ror.org/040ehf661

Funder(s)

Funder type
Not defined

Funder Name
SINPROMI

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Enrique Gonzalez Davila egonzale@ull.es

IPD sharing plan summary
Available on request