

# Employment and health of people with severe mental illness

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 14/05/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 01/07/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Employment is a critical pathway to recovery and community integration for people with psychotic experiences. It is a process that requires community support networks. The aim of this study was to evaluate non-vocational outcomes (symptomatology, hospital admissions, relapses, self-concept, quality of life and global functioning) when incorporating people with SMI to employment

### Who can participate?

The inclusion criteria used were the following: age between 18 and 65 years, diagnosis of schizophrenia (DSM-5 TR), capacity to consent participation in the study, being clinically stable without acute psychotic symptoms or having been hospitalized during the last months, being followed by the public community mental health teams during the study and being motivated to obtain a job.

### What does the study involve?

Our purpose is to know if in a context of high unemployment rates people with SMI, benefit in their results not vocations to obtain and maintain competitive employment with IPS, versus vocational Rehabilitation

### What are the possible benefits and risks of participating?

None

### Where is the study run from?

Canary Island (Tenerife). Spain

### When is the study starting and how long is it expected to run for?

April 2024 to January 2025

### Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Francisco Pulido, fpulido@ull.edu.es

## Contact information

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Scientific, Principal investigator

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## Additional identifiers

## **Clinical Trials Information System (CTIS)**

Nil known

## **ClinicalTrials.gov (NCT)**

Nil known

## **Protocol serial number**

Nil known

# **Study information**

## **Scientific Title**

The impact of employment on the health of people with severe mental disorder

## **Study objectives**

In a context where the individual finds and maintains employment with the support of an evidence-based strategy, such as the individual placement and support (IPS) strategy, individuals with severe mental illness (SMI) who find employment will improve their non-vocational outcomes related to income, hospitalizations, and quality of life

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

approved 01/04/2024, Universidad Europea De Canarias (La Orotava, Santa Cruz de Tenerife, 38005, Spain; +34 (0)609752202; nayra.caballero@universidadeuropea.es), ref: CI 2024-669

## **Study design**

Open community-based multicenter controlled experimental randomized study

## **Primary study design**

Interventional

## **Study type(s)**

Quality of life

## **Health condition(s) or problem(s) studied**

Severe mental illness

## **Interventions**

Intervention group: Individual Placement and Support strategy, developed in the United States by Becker and Drake (Becker and Drake, 1993), which states that competitive employment should be as quickly as possible based on preferences, of people wit SMI,integration with mental health team and employment technicians , followed with unlimited supports and zero exclusion.

Control group: the traditional vocational strategy. Understand it is better train skills and then place people with SMI.

The participants in this study were recruited from the Community Mental Health Teams (ECSM) and basic health areas.

The participants were recruited from the Community Mental Health Teams (ECSM) and basic

health areas. A sample size of 24 patients per group was estimated, which was increased by 30% due to possible losses to follow-up, leaving a total of 32 patients per group.

A total of 557 participants were recruited from the mental health team and a total of 63 people met the selection criterion and were randomly and blindly assigned each group.

At baseline and at 6-month follow-up, different test batteries were used.

### **Intervention Type**

Other

### **Primary outcome(s)**

Measured at baseline and 6 months:

1. Self-concept: Test de autoconcepto AF5
2. Quality of life: Test de calidad de vida de Lancashire y Escala de Satisfacción con la Vida (ESV)
3. Test Groningen Social Disabilities Schedule (GSDS)
4. Autonomy: Escala de Evaluación Global de Funcionamiento (Test Global Assessment Scale, GAF)
5. Symptomatology: Positive and Negative Syndrome Scale; Escala de ansiedad-depresión (HADS)

### **Key secondary outcome(s)**

Hospitalization: number of persons who during the last 6 months have been admitted to short- or medium-stay beds at the discretion of their regular psychiatrist measured using patient records

### **Completion date**

20/01/2025

## **Eligibility**

### **Key inclusion criteria**

1. Have a diagnosis of schizophrenia according to DSM-5 criteria
2. Have the capacity to consent to voluntary participation in the study, after having been informed of its objectives
3. Be clinically stable, that is, have no acute psychotic symptoms and have not been hospitalized in the last few months
4. Be monitored by the USMC Psychiatry Service (Community Mental Health Unit) during the study
5. Be motivated to obtain regular employment

### **Participant type(s)**

Service user

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

**Upper age limit**

65 years

**Sex**

All

**Total final enrolment**

63

**Key exclusion criteria**

1. Suffering from a common mental disorder (mood disorder) and/or other organic disorder
2. Having a history of head trauma with loss of consciousness
3. Pregnant

**Date of first enrolment**

20/06/2024

**Date of final enrolment**

28/06/2025

## **Locations**

**Countries of recruitment**

Spain

**Study participating centre**

Sinpromi

Calle Góngora

Santa Cruz De Tenerife

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38005

## **Sponsor information**

**Organisation**

SINPROMI

**ROR**

<https://ror.org/040ehf661>

## **Funder(s)**

**Funder type**

Not defined

**Funder Name**

no funder

## Results and Publications

**Individual participant data (IPD) sharing plan**

Data will be anonymised with ethical and legal restrictions

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes