

# Employment and health of people with severe mental illness

<b>Submission date</b> 19/03/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<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

### Type(s)

Scientific, Principal Investigator

### Contact name

Dr Francisco Rodriguez Pulido

### Contact details

Hospital Universitario de Canarias

La Laguna

Spain

38200

+34 (0)609116523

fpulido@ull.edu.es

### Type(s)

Principal Investigator

### Contact name

Dr Dacil Oramas

### Contact details

Santa Cruz de Tenerife

Santa Cruz de Tenerife

Spain

38003

+34 (0)615912995

dacilop@hotmail.com

### Type(s)

Public

### Contact name

Dr Nayra Caballero

### Contact details

Calle Suarez Guerra 19

Santa Cruz De Tenerife

Spain

38003

+34 (0)609752202

nayra.caballero@universidadeuropea.es

## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Workplace

**Study type(s)**

Quality of life

**Participant information sheet**

No participant information sheet available

**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 with 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 (ECMS) and basic health areas.

The participants were recruited from the Community Mental Health Teams (ECMS) 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 measure

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)

## Secondary outcome measures

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

## Overall study start date

01/04/2024

## 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

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Both

**Target number of participants**

550

**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

Spain

38005

# Sponsor information

## Organisation

SINPROMI

## Sponsor details

Calle Góngora  
Santa Cruz De Tenerife  
Spain  
38005  
+34 (0)922249199  
sinpromi@tenerife.es

## Sponsor type

Other

## Website

<https://sinpromi.es>

## ROR

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

# Funder(s)

## Funder type

Not defined

## Funder Name

no funder

# Results and Publications

## Publication and dissemination plan

Planned publication in a peer-reviewed journal

## Intention to publish date

01/05/2025

## 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

