

# Activa't per la salut mental! / "Get active!: Increase active participation of people with mental disorders and their families in their recovery processes"

<b>Submission date</b> 18/05/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/06/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 17/10/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English Summary

### Background and study aims

Improvements in the treating mental disorders have moved toward a community-focused approach, leading to a decrease in the use of hospital services. This new approach may be able to improve the quality of life of people suffering from mental disorders, but it also puts more responsibility on relatives who need to take care of their family members. If a relative does not have the rights tools to provide the correct support to the patient, this can actually make their symptoms worse and decrease the quality of life for both the patient and their caregiver. A project called Activa't (Get Active!) that is promoted by the Catalan government in Spain provides mental health training to patients and their caregivers. It aims to empower patients and carers to manage their own care and provide individualised guidance and counselling support. The aim of this study is to investigate the effectiveness of the Activa't programme is at promoting patients and caregivers as managers of own care (through different tools for daily management and empowerment) in improving recovery, and reducing caregiver charge and use of health and social services.

### Who can participate?

Adults aged 18 to 63 years old who have a mental disorder and their caregiver.

### What does the study involve?

Participating patients and their caregivers are randomly allocated to one of two groups. Those in the first group receive the usual treatment through common health and social services. Those in the second group receive the usual treatment as well as the Activa't programme. This programme includes education training, empowerment training modules and peer support groups. Participants also receive guidance and counselling. Participants are followed up at six and 12 months to assess their recovery and mental health symptoms.

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

Participants may benefit from gaining more skills to manage their care and recovery: having

further information, further skills to deal with daily difficulties, better attitude in relation to the recovery process, and strengthened peer support links. There are no notable risks with participating.  
No risks are expected. The treatment has no known specific side effects.

Where is the study run from?

This study is being run by the Catalan Federation of Mental Health (Spain) and takes place in 12 territorial centres in Catalonia (Spain).

When is the study starting and how long is it expected to run for?  
October 2014 to December 2017

Who is funding the study?

The Funders include public and private institutions: Catalan Government (Spain), provincial and local governments, and different private companies and foundations.

Who is the main contact?

Maria Jesús San Pío  
[mjsanpio@federacio.salutmental.org](mailto:mjsanpio@federacio.salutmental.org)

### **Study website**

<http://activatperlasalutmental.org/>

## **Contact information**

### **Type(s)**

Public

### **Contact name**

Mrs Maria Jesús San Pío

### **Contact details**

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**Type(s)**

Scientific

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# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

-

## Study information

### Scientific Title

Promotion of patients with mental disorder and caregivers as managers of own integrated care, as a mean to improve recovery, reduce caregiver charge and reduce use of health and social services

### Acronym

ACTIVAT

### Study hypothesis

Study Aim:

The aim of this study is to investigate the effectiveness of a program to promote patients and caregivers as managers of own integrated care (through different tools for daily management and empowerment) in improving recovery, and reducing caregiver charge and use of health and social services.

Hypothesis:

1. Participating in the activities of the program Activa't (Get Active!) increases recovery and therefore individual capacity of people with mental disorders to manage their severe mental disorders
2. Participating in the activities of the program Activa't (Get Active!) reduces care burden for the main caregiver
3. Participating in the activities of the program Activa't (Get Active!) increases the size of support network of the main caregiver
4. Participating in the activities of the program Activa't (Get Active!) leads to reductions in medical services use and drugs consumption

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Comité Ético de Investigación Clínica Hermanas Hospitalarias del Sagrado Corazón de Jesús, 26 /03/2015, ref: PR-2015-06

### Study design

Interventional multi-centre randomised controlled trial

### Primary study design

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Community

## **Study type(s)**

Treatment

## **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

## **Condition**

People with mental health diagnostics and their caregivers. Diagnostics included: Schizophrenia, schizotypic disorder, schizoaffective disorder, Bipolar disorder and recurrent depressive disorder.

## **Interventions**

Participants are recruited as two units, the patient and their informal caregiver through 12 territories. This study is implemented in two waves. Participants are randomly allocated using stratification to one of two groups.

Control group: Participants in the control group receive the usual treatment through common health and social services.

Treatment group: Participants in the treatment group receive their usual treatment as well as a structured circuit of services addressed to patients and caregivers aimed at promoting that people with mental disorders and their informal caregivers become managers of their own care.

The program includes validated and approved experiences which are consolidated into a single integrated care circuit that flows from the health vision to the social-based community perspective:

1. Psychoeducative training for people with mental health problems (Klau de Re) and family (PROENFA), provided by mental health services. This is given in 14 one and a half hour sessions for caregivers and 22 one hour sessions for people with mental disorders.
2. Training for the empowerment (PROSPECT) of people with mental health problems, family, and professionals, provided by families and patients associations. This includes two modules which take around 20 hours to complete.
3. Participation in peer support groups for people with mental health problems and their families, from associative aspect, in coordination with associations of people with mental health disorders and/or families. This involves 12 sessions which take one and half hour per session.

The total duration of the treatment is around eight to 12 months, depending on the calendar of each activity.

Participants also receive a service of guidance and counselling: Espai Situa't. It is an individualized service aimed at answering advice and orientation demands that people with

mental disorders or their caregivers may have regarding mental health services and recovery process, as well as offering useful information regarding their daily needs. This service acts as a coordination point of all the program.

Participants are followed up with questionnaires at six and 12 months to assess their recovery, and mental health symptoms.

### **Intervention Type**

Mixed

### **Primary outcome measure**

Patient outcomes:

1. Patient recovery (individual skill to manage their mental disorder) is measured using the STORI scale (Stages of recovery) at baseline, six and 12 months after finishing the psychoeducation program
2. Use of medical services is measured using administrative records (records of visits to the public health system) at baseline, six and 12 months after finishing the psychoeducation program
3. Drug use is measured using the administrative records (prescriptions in the public health system) at baseline six and 12 months after finishing the psychoeducation program

Caregiver outcomes:

1. Caregiver burden (objective and subjective family burden) is measured using the ECFOS II (based on the Family Burden Interview Schedule-Short Form (FBIS/SF) at baseline, six and 12 months after finishing the psychoeducation program
2. Caregiver support networks are measured using the Duke-UNK functional support questionnaire at baseline, six and 12 months after finishing the psychoeducation program
3. Use of medical services is measured using administrative records (records of visits to the public health system) at baseline, six and 12 months after finishing the psychoeducation program
4. Drug use is measured using the administrative records (prescriptions in the public health system) at baseline six and 12 months after finishing the psychoeducation program

### **Secondary outcome measures**

There are no secondary outcome measures

### **Overall study start date**

30/10/2014

### **Overall study end date**

31/12/2017

## **Eligibility**

### **Participant inclusion criteria**

Eligibility criteria for the person with mental disorder:

1. To belong to one of the following diagnosis groups: Schizophrenia, Schizotypic disorder, schizoaffective disorder or delusional disorders (F20, F21, F22, F24, F25 (CIE10); 295, 301.22 (CIE9)) or bipolar disorder or recurrent depressive disorder (F31 and F33 (CIE10), 296 (CIE9))
2. More than two years of presence of any of the listed severe mental disorder, without necessarily implying diagnosis or treatment
3. To be aged 18 to 63 years
4. Moderate or severe dysfunction implying a GAF score (Global Assessment of Functioning,

APA, 1987) below 60

5. To accept the participation conditions for the trial and agreeing on transferring personal data under the Spanish data protection regulation

Eligibility criteria for the carer:

1. To be the reference caregiver of the eligible person with a mental disorder
2. To be available to participate in all activities included in the treatment program
3. To accept the participation conditions for the trial and agreeing on transferring personal data under the Spanish data protection regulation

**Participant type(s)**

Mixed

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

240 units of person with mental disorder and its main caregiver

**Total final enrolment**

222

**Participant exclusion criteria**

Exclusion criteria for the person with mental disorder:

1. Diagnosed with borderline personality disorder
2. Present co-morbidity with mental retardation
3. Present a severe associated somatic pathology
4. Disabled people residing in assisted residences and apartments for disabled persons
5. Participated in any training activity or support group similar to the ones offered in the Activa't framework

Exclusion criteria for the caregiver:

1. Suffer from a severe and uncompensated psychiatric or somatic disorder, including moderate or severe alcohol dependence
2. Participated in any training activity or support group similar to the ones offered in the Activa't framework

**Recruitment start date**

01/04/2015

**Recruitment end date**

31/05/2016

**Locations**

**Countries of recruitment**

Spain

**Study participating centre****Federació Salut Mental Catalunya**

Nou de Sant Francesc, 42

Barcelona

Spain

08002

**Study participating centre****Institut d'Assistència Sanitària – IAS**

Parc Hospitalari Martí i Julià

C/ Dr. Castany

S/N

Salt (Girona)

Spain

17190

**Study participating centre****Germanes Hospitalàries**

Benito Menni, Complejo Asistencial en Salud Mental

Dr. Antoni Pujadas

38

Sant Boi de Llobregat (CP.) Barcelona

Spain

08830

**Study participating centre****Gestió de Serveis Sanitaris**

Hospital Universitari de Santa Maria

Alcalde Rovira Roure

44

Lleida

Spain

25198

**Study participating centre****Associació Centre Higiene Mental Nou Barris**

Passeig Valldaura 214

Baixos



Barcelona  
Spain  
08042

**Study participating centre**

**Corporació Parc Taulí**

Parc Taulí  
S/N  
Sabadell (Barcelona)  
Spain  
08208

**Study participating centre**

**Althaia**

C/ Dr. Joan Soler  
1-3  
Manresa  
Barcelona  
Spain  
08243

**Study participating centre**

**Salut Mental Consorci Sanitari de l'Anoia**

Av. Catalunya, 11  
Igualada  
Barcelona  
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08700

**Study participating centre**

**Institut Pere Mata**

Ctra. Institut Pere Mata  
S/N  
Tarragona  
Reus  
Spain  
43206

**Study participating centre**

**Fundació Pere Mata Terres de l'Ebre**

Ctra. Institut Pere Mata

S/N  
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**Study participating centre**  
**Parc de Salut Mar, Barcelona**  
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**Study participating centre**  
**Parc Sanitari Sant Joan de Déu**  
Antoni Pujadas, 42  
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**Study participating centre**  
**16 Associations of patients and caregivers in all the territory**  
You can find the updated list on the website: <http://activatperlasalutmental.org/col%C2%B7laboradors/>  
Spain  
08002

## **Sponsor information**

**Organisation**  
Catalan Federation of Mental Health (Federació Salut Mental Catalunya)

**Sponsor details**  
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**Sponsor type**

Charity

**Website**

[www.salutmental.org](http://www.salutmental.org)

**Organisation**

Government of Catalonia (Generalitat de Catalunya)

**Sponsor details**

Travessera de les Corts, 131

Barcelona

Spain

08028

**Sponsor type**

Government

**Website**

[www.gencat.cat](http://www.gencat.cat)

**Organisation**

Federació Veus

**Sponsor details**

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**Sponsor type**

Charity

**Website**

[www.veus.cat](http://www.veus.cat)

**Funder(s)**

**Funder type**

Government

**Funder Name**

Generalitat de Catalunya

**Alternative Name(s)**

Government of Catalonia

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

Spain

**Funder Name**

Diputació de Barcelona (Barcelona provincial Government)

**Funder Name**

Diputació de Girona (Girona provincial Government)

**Funder Name**

Diputació de Lleida (Lleida provincial Government)

**Funder Name**

Diputació de Tarragona (Tarragona provincial Government)

**Funder Name**

Ajuntament de Barcelona (Barcelona Town Hall)

**Funder Name**

Ministerio de Sanidad, Servicios Sociales e Igualdad

**Alternative Name(s)**

Ministry of Health, Social Services and Equality

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Spain

**Funder Name**

"la Caixa" Foundation

**Funder Name**

Otsuka Pharmaceutical (Spain)

**Funder Name**

Janssen Pharmaceutical (Spain)

**Funder Name**

Lundbeck (Spain)

**Funder Name**

Fundació Privada Roca i Pi

**Funder Name**

Fundació Roviralta

**Funder Name**

Fundació Roca Salvatella

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal.

**Intention to publish date**

30/06/2019

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

The current data sharing plans for the current study are unknown and will be made available at a later date

### 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="#">Results article</a>		26/10/2022	11/07/2023	Yes	No
<a href="#">Results article</a>		16/10/2023	17/10/2023	Yes	No