

# DECIDE Study: Shared decision making for treatment at discharge with schizophrenic inpatients

<b>Submission date</b> 27/05/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 06/07/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 02/03/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Schizophrenia is a serious mental health problem that affects how a person thinks, feels and behaves. Schizoaffective disorder is a serious mental illness that has features of both schizophrenia, and an affective (mood) disorder, such as depression (low mood). Traditionally, deciding upon the most appropriate treatment for patients is done by doctors. This study is looking at a shared decision making (SDM) approach, in which patients work with nurse to present a summary of the patient's preferences regarding treatment. The aim of this study is to find out whether this participative way of making decisions of which treatment to take at discharge from acute (sudden) hospitalization is better than a more doctor-driven decision making in treatment compliance and readmissions at 12 months.

### Who can participate?

Adults diagnosed of schizophrenia or schizoaffective disorder who have been admitted to Jerez Adult Psychiatric Hospitalization Unit and will be prescribed antipsychotic medication at discharge.

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group take part in the shared decision making (SDM) program, which is made up of two stages, the informative stage and the deliberative stage. The informative stage is made up of three sessions, lasting for 30-90 minutes in which the patients are given the information they need about different treatments and put together a summary of their treatment preferences with a nurse. The deliberative stage involves the treatment proposal being reviewed by the psychiatrist and patient together in a further 90 minute session in which the decision of treatment is finalized. Those in the second group take part in usual care, which involves the patient's treatment being decided by the medical team. Participants in both groups complete a number of questionnaires at the start of the study, and again after 3, 6 and 12 months in order to find out if their symptoms has improved, as well as the patients' confidence about the treatment decisions made.

What are the possible benefits and risks of participating?

There will be no immediate direct benefit to those taking part but there should be benefits in the future, as the results of the study are likely to influence the implementation of shared decision making and empowerment policies and in our care system. There are no notable risks to participants in the study as both groups will receive the best available treatment options.

Where is the study run from?

Jerez General Hospital (Spain)

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

January 2014 to June 2017

Who is funding the study?

Andalusian Regional Government (Spain)

Who is the main contact?

1. Dr José Ildefonso Pérez-Revuelta (public)
2. Dr José M. Villagrán-Moreno (scientific)

## Contact information

### Type(s)

Public

### Contact name

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# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PI-0309-2013

## Study information

### Scientific Title

DECIDE Study: Effectiveness of shared decision making in the choice of antipsychotic treatment at discharge from a hospitalization after an acute episode in schizophrenic patients

### Acronym

DECIDE Study

### Study objectives

A two-stage shared decision making program on antipsychotic drug choice is better than treatment as usual with respect to long term compliance and rehospitalisations among schizophrenic inpatients to be discharged from an acute hospitalization.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Comité de Ética de la Investigación (CEI) del Área Sanitaria Jerez-Costa Noroeste y Sierra de Cádiz (Research Ethics Board Jerez-Costa Noroeste-Sierra de Cádiz Health Area), 21/11/2013, ref: PI-0309-2013

### Study design

Prospective single-centre randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

See additional files (available in Spanish)

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

Schizophrenia and schizoaffective disorders

## **Interventions**

Following provision of informed consent, participants are randomly allocated to one of two groups.

Shared decision making (SDM) group: Participants receive the SDM program which is delivered by trained psychiatrists and nurses and consists of two stages: informative and deliberative. The informative stage (IS) includes three sessions:

1. An introduction to the program by the nurse (30 minutes) in which information sheets adapted at patient's educational level are used
2. An exploratory session (Es) run by psychiatrist and nurse (90 minutes) in which they convey information on the disorder, appropriate management and different treatment options by using treatment decision aids, whereas the patient expresses his/her preferences and values
3. A confirmatory session (Cs) (30 minutes) in which patient and nurse jointly elaborate a personal decision guide which summarizes patient's preferences.

The IS will be implemented in 48-72 hours. Once the IS has been completed, psychiatrist and patient engage in the deliberative stage (DS), a 90 minute-session that includes deliberation upon the personal decision guide of the patient and adopting a consensual decision on the antipsychotic treatment at discharge. The DS will be implemented in the 48 hours before the discharge.

Treatment as usual (TAU) group: Participants receive treatment as usual for the duration of the intervention. The treatment used for each participant is decided upon by each participants usual care team.

Participants in both groups will be evaluated at 3, 6 and 12 months after discharge. Those in the SDM group will receive SDM booster sessions (45 minutes) at 3 and 6 months whereas those in TAU will receive routine care.

## **Intervention Type**

Other

## **Primary outcome measure**

Antipsychotic treatment adherence is measured using the Brief Adherence Rating Scale (BARS) and the Drug Attitude Inventory (DAI) at baseline, 3, 6 and 12 months

## **Secondary outcome measures**

1. Readmission rate is measured through medical record review at 3, 6 and 12 months
2. Quality of doctor-patient relationship measured using the Working Alliance Inventory Short Version (WAI-S) at baseline, 3, 6 and 12 months
3. Patient satisfaction with intervention and confidence on decision taken is measured using the Combined Outcome Measure Communication and Treatment Decision making Effectiveness Scale (COMRADE Scale) at baseline, 3, 6 and 12 months
4. Patient perception of hospitalization is measured using the Picker Patient Experience Questionnaire (PPE-15) at discharge

## **Overall study start date**

01/01/2014

**Completion date**

01/06/2017

## Eligibility

**Key inclusion criteria**

1. Patients aged 18 years and over
2. Diagnosed of schizophrenia (ICD-10: F20) or schizoaffective disorder (ICD-10: F.25)
3. Admitted to Jerez Adult Psychiatric Hospitalization Unit
4. Prescribed antipsychotic medication at discharge

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

120

**Key exclusion criteria**

1. Patients who refuse to sign informed consent
2. Patients who lack capacity in the moment of entering the study, as measured by the Aid to Capacity Evaluation (ACE)
3. Patients with a comorbid diagnosis of severe or moderate mental retardation
4. Patients with poor knowledge or communication skills in Spanish

**Date of first enrolment**

01/03/2014

**Date of final enrolment**

30/06/2017

## Locations

**Countries of recruitment**

Spain

**Study participating centre**

Hospital de Jerez de la Frontera

Unidad Hospitalaria de Salud Mental

Servicio Andaluz de Salud

Carretera de Circunvalación S/N  
Jerez de la Frontera  
Cádiz  
Spain  
11407

## Sponsor information

### Organisation

Foundation for Biomedical Research Management Cadiz (Fundación para la Gestión de la Investigación Biomedica de Cádiz)

### Sponsor details

Avda. María Auxiliadora, 2  
Cádiz  
Spain  
11009

### Sponsor type

Research council

### Website

<http://www.fundacioncadiz.es/>

### ROR

<https://ror.org/02hrw4545>

## Funder(s)

### Funder type

Government

### Funder Name

Andalusian Regional Government

## Results and Publications

### Publication and dissemination plan

Planned publication in a peer reviewed journal.

### Intention to publish date

30/06/2019

## Individual participant data (IPD) sharing plan

Not provided at time of registration

## 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>		06/06/2016	06/07/2016	No	Yes
<a href="#">Interim results article</a>		23/03/2020	02/03/2022	Yes	No