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

Submission date
27/05/2016

Recruitment status
No longer recruiting

Registration date
06/07/2016

Overall study status
Completed

Last Edited
02/03/2022

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 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 is 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

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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 at 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
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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
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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?
Participant information sheet		06/06/2016	06/07/2016	No	Yes
Interim results article		23/03/2020	02/03/2022	Yes	No