ISRCTN32545295 https://doi.org/10.1186/ISRCTN32545295

Efficacy of a psychoeducational programme to reduce the burden associated with caring for a patient with schizophrenia or schizoaffective disorder

Submission date
02/03/2012

Recruitment status
No longer recruiting

Registration date
15/03/2012

Overall study status
Completed

Last Edited
08/02/2016

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Caring for mentally ill patients is stressful and could increase the risk of developing several health problems. A preventative measure such as a psychoeducational intervention could be useful to decrease the burden associated with caregiving. The main aim of this study is to assess the effectiveness of a psychoeducational intervention to caregivers of people diagnosed with schizophrenia.

Who can participate?
Informal caregivers of schizophrenia and schizoaffective patients.

What does the study involve?
Participants are randomly allocated into two groups. One group receives the usual support from the day centres where the patient is being treated. The other group receives the same support plus a psychoeducative intervention of 12 sessions lasting 90-120 minutes. It includes information about the disease and training on different cognitive and behavioral skills. The study runs for 8 months. There are three assessment points at the start of the study and after 4 and 8 months.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Institute of Psychiatric Research (Spain).

When is the study starting and how long is it expected to run for?
March 2012 to October 2012.

Who is funding the study?
Carlos III Institute of Health (Spain).

Who is the main contact?
Dr Manuel Martín Carrasco
iip@fundacion-iip.org

Contact information

Type(s)
Scientific

Contact name
Dr Manuel Martín Carrasco

Contact details
Maria Josefa Recio Foundation
Institute of Psychiatric Research
Egaña 10
Bilbao
Spain
E-48010
-
iip@fundacion-iip.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PI10/01049

Study information

Scientific Title
Efficacy of a psychoeducative intervention program to prevent or reduce the burden associated with caring for a patient with schizophrenia or schizoaffective disorder: a two arm, evaluator blind, multicentre, randomized controlled trial

Acronym
EDUCA-III

Study objectives
1. The caregivers allocated to the psychoeducative intervention program will present less burden at endpoint (4 months), and at follow up (8 months), than the caregivers allocated to the control condition.

2. The caregivers allocated to the psychoeducative intervention program will present better mental health at endpoint (4 months), and at follow up (8 months), than the caregivers allocated to the control condition.
3. The caregivers allocated to the psychoeducative intervention program will present less anxiety at endpoint (4 months), and at follow up (8 months), than the caregivers allocated to the control condition.
4. The caregivers allocated to the psychoeducative intervention program will present less depression at endpoint (4 months), and at follow up (8 months), than the caregivers allocated to the control condition.
5. The patients whose caregivers have been allocated to the psychoeducative intervention program will present less problems at endpoint (4 months), and at follow up (8 months), than the patients whose caregivers have been allocated to the control condition.
6. The patients whose caregivers have been allocated to the psychoeducative intervention program will present less psychiatric institutionalitation at endpoint (4 months), and at follow up (8 months), than the patients whose caregivers have been allocated to the control condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical and Scientific Research Committee of Navarra, Spain, 10/10/2011, ref: Project 74/11

Study design
Two-arm evaluator-blind multicentre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Burden associated with schizophrenia or schizoaffective disorder caregiving

Interventions
Control group: Caregivers allocated to this group received the usual support from the day centre where the patients had a multifaceted/multiprofessional care which aimed at improvement or maintaining as long as possible functional, social, and cognitive abilities. The caregiver received periodical interviews and information about the situation and clinical course of the patient.

Intervention group: Caregivers allocated to this group were exposed to the same usual care the control group received plus a psychoeducative intervention program. This intervention was administered in 12 group sessions of 90-120 minutes each and the sessions were administered weekly. The caregiver received standardized information about the clinical course of schizophrenia and training on different cognitive and behavioral skills to increase care abilities, communicative skills, pleasant events, seek support, and relaxation.

Intervention Type
Behavioural

Primary outcome measure
Change since baseline to endpoint in the caregiver burden as assessed by the Zarit Burden Interview and the Involvement Evaluation Questionnaire.

Secondary outcome measures
1. Change since baseline to endpoint in the caregiver mental health as assessed by the General Health Questionnaire, 28 items (GHQ-28)
2. Change since baseline to endpoint in the caregiver anxiety as assessed by the State-Trait Anxiety Inventory (STAI)
3. Change since baseline to endpoint in the caregiver depression as assessed by the Center for Epidemiologic Studies Depression Scale (CES-D)
4. Change since baseline to endpoint in the patients problems as assessed by the Health of the Nation Outcome Scales. (HONOS)
5. Number of institutionalizations since baseline

Overall study start date
05/03/2012

Completion date
30/10/2012

Eligibility

Key inclusion criteria
1. Males or females with age more than or equal to 18 years, giving care to a familiar person with a diagnosis of schizophrenia or schizoaffective disorder according to Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM IV) -TR criteria
2. The caregiver was not professionally paid for caregiving
3. The familiar diagnosed of schizophrenia or schizoaffective disorder was receiving appropriate care as outpatient in a day centre or ambulatory centre
4. The caregiver spent a minimum of 4 hours/week to attend the patient with schizophrenia or schizoaffective disorder
5. The patient cared for had received a first disease diagnose or had had a first disease episode at least two years before trial recruitment
6. Signed informed consent, for both the patient and the caregiver, to participate in the trial

Participant type(s)
Carer

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Caregivers without time to attend the psychoeducative intervention training
2. Caregivers receiving currently or recently (last year), any standardized psychoeducative intervention similar to the one administered in the trial
3. The patient has been hospitalized the last month for a time over 30 days
4. The patient has been diagnosed of mental retardation, dementia or another cognitive disorder
5. The patient lives in a home supervised by professionals

Date of first enrolment
05/03/2012

Date of final enrolment
30/10/2012

Locations

Countries of recruitment
Spain

Study participating centre
Maria Josefa Recio Foundation
Bilbao
Spain
E-48010

Sponsor information

Organisation
Institute of Psychiatric Research (Spain)

Sponsor details
Maria Josefa Recio Foundation
Egaña 10
Bilbao

Spain
E-48010
-
iip@fundacion-iip.org

Sponsor type
Research organisation

Website
http://www.fundacion-iip.org/

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Carlos III Institute of Health [Instituto de Salud Carlos III] (Spain) ref: PI10/ 01049

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016		Yes	No