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Assessment of an enhanced program for depression management in primary care: cluster randomised controlled trial

Submission date
19/01/2007

Recruitment status
No longer recruiting

Registration date
02/02/2007

Overall study status
Completed

Last Edited
25/08/2015

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
We put into place a new programme based on the chronic care model to improve the management of depression in primary care and compared its effectiveness with the usual care. The goal of the study was assessed the effectiveness of the new programme in terms of the severity of depression, response to treatment, remission of depression and quality of life related to health. We invite the reader to watch an informative video http://vimeo.com/34126848 and to visit our web page www.projecteindi.cat

Who can participate?
Participants were 338 adult patients, age 18 years or over, from 20 primary care centres of the Catalan Health System in Spain, with diagnostic criteria for major depressive episode according to DSM-IV, who had not taken antidepressants in the last three months and were willing to take antidepressants.

What does the study involve?
Over a period of two years, we recruited 149 patients into the control group (usual care) and 189 in the intervention group (new programme). We compared the effectiveness of the two treatments. The treatment in the new programme involved clinical, educational and organisational procedures including primary care nurses who worked as care-managers. Outcomes were measured at 0, 3, 6 and 12 months.

What are the possible benefits and risks of participating?
The study confirmed that the new programme was more effective than the usual care and showed an improvement of the clinical outcomes of depression in the short (3 and 6 months) and long terms (12 months).

Where is the study run from?
20 primary care centres of the Catalan Health System in the province of Tarragona in Spain.

When is the study starting and how long is it expected to run for?
Recruitment of patients took two years, from June 2007 to June 2009. Results were analysed one year after the recruitment of the last patient in June 2010.

Who is funding the study?
Carlos III Health Institute of the Spanish Ministry of Health and Consumption (Fondo de Investigaciones Sanitarias- Instituto de Salud Carlos III - Ministerio de Sanidad y Consumo) and the Catalan Institute of Health (Institut Català de la Salut), Spain.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PI060176

Study information

Scientific Title
Assessment of an enhanced program for depression management in primary care: cluster randomised controlled trial

Acronym
INDI (INterventions for Depression Improvement)

Study objectives
The implementation of a structured programme for managing depression will provide better health outcomes for individual patients than usual primary care management.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the Jordi Gol i Gurina Primary Care Research Institute (IDIAP) Jordi Gol i Gurina, Barcelona, 29/03/2006, ref: P06/16

Study design
Cluster-randomised controlled trial (cluster: primary care medical centres)

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Moderate to severe, or mild persistent, episode of Major Depression (DSM-IV) who initiate a new antidepressant treatment episode.

Interventions
Two groups, one of which is a control group comprising patients receiving usual primary care management and the other is the intervention group comprising patients on a structured programme for treating depression.

Intervention group:
Implementation of a multicomponent programme for managing depression. It includes training for the general practitioners (eight hours workshop and periodical follow-ups) and availability of evidence-based clinical guidelines based on the National Institute for Health and Clinical Excellence (NICE) depression guideline. It also includes care managers, role developed by staff primary care nurses trained to provide educational and emotional support for the patients, to promote treatment adherence and to provide active and systematic clinical monitoring. The program establishes a minimal number of structured visits: in the acute phase, one week after the incorporation and later monthly up to obtaining the remission; in the continuation phase will be every two months; nevertheless, the plan of follow-up visits will be individualised. The optimal supervision and consultation mechanisms will be implemented with the psychiatric level.

Control group:
Usual primary care management.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Severity of the depressive symptoms at three, six and 12 months
2. Response rate at three, six and 12 months
3. Remission rate (Patient Health Questionnaire [PHQ-9]) at three, six and 12 months

Secondary outcome measures
1. Health-related quality of life (Short Form health survey [SF-12])
2. Satisfaction
3. Medical care conformity with clinical guidelines
4. Adherence to treatment
5. Use of resources
6. Costs

Overall study start date
01/01/2007

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Primary care patients over 18 years of age
2. An episode of major depression (Diagnostic and Statistical Manual of mental disorders - fourth edition [DSM-IV]), moderate to severe, or persistently mild
3. Who need to initiate anti-depressant treatment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
396 patients, 20 primary care centres

Key exclusion criteria

1. Limitations that prevent the participation (e.g., severe illness, language limitations, etc)
2. Bipolar disorder
3. Psychotic disorder
4. Dependence of alcohol or drugs
5. Pregnancy or lactation

Date of first enrolment
01/06/2007

Date of final enrolment
01/06/2009

Locations

Countries of recruitment
Spain

Study participating centre
Centre d'Atenció Primària de Constantí
Constantí
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Sponsor information

Organisation
Jordi Gol i Gurina Primary Care Research Institute (Institut D'Investigació en Atenció Primària) (IDIAP) (Spain)

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Sponsor type
Government

Website
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ROR

https://ror.org/0370bpp07

Funder(s)

Funder type
Government

Funder Name
Health Research Fund - Carlos III Health Institute of the Spanish Ministry of Health and Consumption (Fondo de Investigaciones Sanitarias - Instituto de Salud Carlos III-Ministerio de Sanidad y Consumo) (Spain)

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	15/12/2012		Yes	No