ISRCTN08808171 https://doi.org/10.1186/ISRCTN08808171

Effectiveness of the follow-up of depressed patients by nurses

Submission date	Recruitment status	[X] Prospectively registered
27/11/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/12/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/12/2007	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PI061281

Study information

Scientific Title

Acronym
MADEIRA

Study objectives
1. The average depressive symptoms at the end of six months of follow-up among the group of depression patients treated by the primary care nurse and the group treated by the family doctor do not exceed the difference of 2.5 on the BDI scale, which is considered a difference not clinically relevant.
2. There will be no significant difference in change in the quality of life between the two groups.
3. Level of satisfaction will be similar in both groups, or greater among patients followed by nurses than the participants who are treated by the doctors
4. Adherence to treatment will be similar in both groups, or higher in patients followed by the nurses

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Research Ethics Committee of the Jordi Gol i Gurina Primary Care Research Institute (IDIAP), Barcelona, on 4 July 2006 (ref: P06/39)

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Major depression

Interventions
Half of the participants will be allocated to the intervention group and another half into the control group. This trial involves 23 doctors and 23 nurses from 12 primary care teams in Barcelona.

Intervention group: Implementation of a depression management protocol, based on evidence-based clinical guidelines, by the primary care nurse. This protocol includes pharmacological treatment with fluoxetine or another Selective Serotonin Re-uptake Inhibitor (SSRI), and the

participants will have at least 6 appointments with the nurses during the 6 months of follow-up. At each visit, each patient will be informed about the disease and pharmacological treatment. In addition, the nurse will ask the patient about changes in mood and try to enhance compliance. Nurses will also provide emotional support. If the patient does not improve, he will be referred to his doctor.

Control group: Six-month follow-up by family doctors. Family doctors will provides usual care management. They can prescribe fluoxetine or another SSRI. Participants will have at least 6 appointments with their doctor during the 6 months of follow-up.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Differences between groups in the average of decrease in depression symptoms, measured by BDI at 6 months
2. Increase in quality of life, measured by the 12-item Short Form health survey (SF-12) at 6 months
3. Increase in satisfaction with the professional, measured by the satisfaction questionnaire of Baker at 6 months

Secondary outcome measures
1. Percentage of acceptance of the intervention (comparison of the two groups): patient satisfaction and losses that occur at different times of follow-up
2. Average of differences between the two groups with respect to:
2.1. Frequency and duration of visits
2.2. Referrals
2.3. Drug treatment
3. Comparison of adherence to treatment between the two groups

Overall study start date
01/01/2008

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Patients between 25 and 70 years of age
2. Rating of 20 or more points in the Beck Depression Inventory Scale (BDI)
3. Whose family practitioner thinks they suffer from depression and they need to initiate anti-depressant treatment

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
460

Key exclusion criteria
1. Pregnancy or breastfeeding
2. Background of severe psychiatric disorders: psychosis, paranoia, severe personality disorders, delusional thoughts
3. Existence of suicidal ideation or attempts
4. Two or more episodes of major depression, or one or more episodes that might require hospitalization
5. Patients who have received antidepressant medication in the past year
6. Patients with mental health problems who have been referred to psychiatric specialists for these reasons
7. Substance abuse and/or drugs
8. Treatment for Parkinson's disease or epilepsy
9. Temporal residents (plan to move in the next six months)
10. Unable to communicate in Spanish or Catalan languages

Date of first enrolment
01/01/2008

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Spain

Study participating centre
Lope de Vega 138
Barcelona
Spain
08005

Sponsor information

Organisation
Jordi Gol i Gurina Primary Care Research Institute (IDIAP Jordi Gol i Gurina) (Spain)

Sponsor details
Gran Via de les Corts Catalanes
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08007

Sponsor type
Government

Website
http://www.idiapjgol.org/

ROR
https://ror.org/0370bpp07

Funder(s)

Funder type
Government

Funder Name
Carlos III Health Institute of the Spanish Ministry of Health and Consumption (Fondo de Investigación Sanitaria, Instituto de Salud Carlos III, Ministerio de Sanidad y Consumo), Health Research Fund (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