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Hygienic-dietary treatment of Depression in Primary Care

Submission date
25/06/2012

Recruitment status
No longer recruiting

Registration date
18/07/2012

Overall study status
Completed

Last Edited
18/01/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Depression is a common and disabling mental disorder. The number of people with depression is increasing in the developed world, which has been linked to lifestyle. The most common treatments fail to solve all cases, and there is a significant percentage of depressed patients who respond poorly to these treatments. Hygienic and dietary measures have proven effective when used in conjunction with standard treatments. However, this combination has not yet been proven to be effective in routine clinical practice conditions. We are carrying out a study of 300 major depression patients to test the effect of antidepressants combined with structured hygienic and dietary recommendations in primary care.

Who can participate?
Adult patients who have depression, can understand spoken and written Spanish and are able to give written informed consent to take part in the study.

What does the study involve?
The patient will be assigned randomly one of two groups:
a) hygienic-dietary recommendations
b) unspecific hygienic-dietary recommendations (control group)
Depression, quality of life and consumption of health and social services scales will be administered.

What are the possible benefits and risks of participating?
There is no guarantee that patients participating in this study have a benefit. We hope that one of the two groups have better outcomes in terms of depressive symptoms than the other, but there are no expected side effects or safety issues.

Where is the study run from?
From three research centers of three Spanish cities:
Universitat Illes Balears in Palma de Mallorca
Grupo Aragonés de Investigación en Salud Mental in Zaragoza
Parc Sanitari Sant Joan de Deu in Barcelona

When is study starting and how long is it expected to run for?
Recruitment will begin in September 2012 and data collection is expected to end in December 2013

Who is funding the study?
Instituto de Salud Carlos III (Spanish Government)

Who is the main contact?
Professor Mauro Garcia-Toro
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PI11/01392

Study information

Scientific Title
Hygienic-dietary treatment of Depression in Primary Care: a randomised study

Acronym
HDPC

Study objectives
Depressed patients who follow hygienic-dietary recommendations will experience an improvement in their clinical course compared with a control group

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research and clinical trials ethics committee of the Balearic Islands (CEIC), December 2011, ref: 1563-11 IB-PI

Study design
Multicenter two-arm randomised study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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
Major Depression

Interventions
Patients assigned to the active treatment group received an envelope containing a sheet of paper with the four hygienic-dietary recommendations under consideration.

1. Go to bed when sleepy and not before 11 pm. Use your bed and bedroom only for sleep and sex (do not read, watch TV or lie on the bed during the day). If you do not fall asleep after 15 or 20 minutes get up and start an activity until you feel sleepy enough to go back to bed. Get up early, never later than 9 a.m., no matter how well you have slept the night before. Do not lie down or take a nap during the day.
2. Walk at least 1 hour a day, at a good pace but without becoming short of breath or being unable to talk while walking. If you think you have a medical problem which makes walking difficult or uncomfortable consult your doctor. Use appropriate footwear for walking and have a shower or a bath afterwards.
3. Be exposed to environmental light at least 2 hours per day, taking precautions to avoid sunburn or sunstroke (sunscreen, hat, etc.).
4. Try to eat a healthy and balanced diet. Eat at regular hours without snacking between meals. Avoid especially sweet or sugary drinks. Eat fish at least three times per week, plus fruit, cereals, nuts and vegetables daily.

The control group received an identical envelope, but in this case with unspecified recommendations:

1. Sleep the hours that you feel your body needs.
2. Adapt the pace of daily physical activity to meet your needs best.
3. If exposed to environmental light take precautions to avoid sunburn or sunstroke (sunscreen, hat, etc.).
4. Try to eat a healthy and balanced diet.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Total score on self-administered 21-items Beck Inventory Depression Scale (BDI) before and after intervention.

Secondary outcome measures
1. State-Trait Anxiety Inventory (STAI) Scale
2. Client Service Receipt Inventory
3. EQ-5D Scale

All outcomes were measured in the screening visit and in the 6 and 12 follow up visits

Overall study start date
03/09/2012

Completion date
20/12/2013

Eligibility

Key inclusion criteria
1. Male and female patients over 18 years
2. Patients experiencing a Major Depression episode according to DSM-IV-TR diagnostic criteria and with a Beck Depression Questionnaire total score equal or over 10
3. Patient who has the ability to communicate and give informed consent in writing

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

300

Key exclusion criteria
1. Patients suffering from another disease that affects CNS or who has suffered any serious head injury, dementia, etc
2. Other psychiatric diagnosis or severe psychiatric illness (substance dependence or abuse, schizophrenia or other psychotic disorders, eating disorders, etc.), with the exception of anxious pathology or personality disorders
3. The existence of severe, uncontrolled, medical condition, or potentially interfering with affective symptomatology
4. Presence of delusions or hallucinations at the time of the study
5. Important risk of suicide

Date of first enrolment
03/09/2012

Date of final enrolment
20/12/2013

Locations

Countries of recruitment
Spain

Study participating centre
Edificio IUNICS
Palma de Mallorca
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Sponsor information

Organisation
Carlos III Health Institute (Instituto de Salud Carlos III) (Spain)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00ca2c886

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Carlos III Health Institute (Spain) ref: PI11/01392

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?
Protocol article	protocol	16/11/2012		Yes	No
Results article	results	01/09/2015	18/01/2019	Yes	No