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Hygienic-dietary recommendations in patients with Depression

Submission date	Recruitment status	[ ] Prospectively registered
26/03/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/05/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/07/2010	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

Contact name
Dr Mauro Garcia-Toro

Contact details
Edificio IUNICS
C/ Ctra de Valldemossa Km 7,5
Palma de Mallorca
Spain
07122
mauro.garcia@uib.es

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PI07/0544

Study information

Scientific Title
Effectiveness of hygienic-dietary recommendations as enhancers of antidepressant treatment in patients with Depression

Acronym
HD-Dep

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) approved on in February 2008 (ref: 733-06 IB-PI)

Study design
Multicentre two-arm randomised study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Depression

Interventions
Written recommendations were delivered by the psychiatrist who collaborated in the study. There were only two recommendations options that were allocated at random.

Intervention group:
1. Go to bed when sleepy and not before 11 o'clock at night. Use the bed and bedroom only for sleep and sex (do not read, watch TV or stay in it during the day). If you do not fall asleep after 15-20 minutes get up and deal in any activity until you have the feeling of sleepiness to go back to bed. Get up early, never later than 9 am, whatever you have slept at night. Do not lie or nap during the day.
2. Walk at least 1 hour a day, at a good pace but without having short of breath or being unable

to talk while walking. If you think you have a medical problem which can make your walking troublesome consult your
doctor. Use comfortable footwear for walking and after have a shower or a bath.
3. Be at least 2 hours per day exposed to sunlight, taking precautions to avoid sunburn or sunstroke (sunscreen, hat, etc.)..
4. Try to eat a healthy and balanced diet. Eat at regular hours without turning it between meals, especially sweet or sugary drinks. Eat fish at least three times per week, plus fruit, cereals, nuts and vegetables daily.

Control group:
1. Sleep the hours that your body need to feel you as the good as possible.
2. Adapt the pace of daily physical activity to meet your needs best.
3. If exposed to sunlight take precautions to avoid sunburn or sunstroke (sunscreen, hat, etc.)..
5. Try to eat a healthy and balanced diet.
The total duration of the intervention will be 6 months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Score on Hamilton Scale for Depression (HAMD-17) obtained by blinded assessors before and after intervention.

Secondary outcome measures
1. Self-administered Beck Depression Inventory (BDI-21)
2. Clinical Global Impression scale (CGI)
3. SF-36 Health Status (Short-Form SF-36)
All outcomes were measured in the screening visit and final visit after 6 months.

Overall study start date
11/04/2008

Completion date
31/05/2010

Eligibility

Key inclusion criteria
1. Patients of both sexes over 18 years
2. Patients experiencing a depressive episode according to DSM-IV-TR diagnostic criteria (Major depressive disorder, Dysthymic disorder or Bipolar disorder depressive phase)
3. Patient receiving antidepressant treatment
4. Patient who has the ability to communicate and give informed consent in writing
5 . Women of childbearing age using a secure contraception

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80 patients

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

Date of first enrolment
11/04/2008

Date of final enrolment
31/05/2010

Locations

Countries of recruitment
Spain

Study participating centre
Edificio IUNICS
Palma de Mallorca
Spain
07122

Sponsor information

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

Sponsor details
C/ Sinesio Delgado, 8.
Madrid
Spain
28029
Oficina.informacion@isciii.es

Sponsor type
Research organisation

ROR
https://ror.org/00ca2c886

Funder(s)

Funder type
Research organisation

Funder Name
Carlos III Health Institute (Instituto de Salud Carlos III) (Spain) - Health Research Fund (Fondo de Investigaciones Sanitarias [FIS])

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	09/07/2010		Yes	No