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Efficacy of low-intensity psychological intervention applied by (ICTs) for treatment of depression in primary care

Submission date
11/03/2014

Recruitment status
No longer recruiting

Registration date
16/04/2014

Overall study status
Completed

Last Edited
08/06/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Low-intensity psychological approaches using modern means of communication (telephones and computers) could be an effective and cost-effective option for the treatment of depression. This study will compare four different approaches.

Who can participate?
240 depressive patients from primary care centers in Spain.

What does the study involve?
Over a period of seven months, general practitioners from primary health care centers will be invited to refer patients with depressive symptoms. Different investigators will run the psychological assessment and check whether the patients are eligible. Then they will be randomly allocated to one of four groups: treatment as usual (TAU), TAU + mindfulness, TAU + healthy lifestyle, or TAU + positive affect. Patients will be assessed at the start of the study, after the treatment, 6 months and one year later.

What are the possible benefits and risks of participating?
Mindfulness, healthy lifestyle, and positive affect training has been shown to reduce intensity and frequency of symptoms in depressive patients. Due to its low intensity, no side effects are anticipated in any group.

Where is the study run from?
The lead study center is the University of Balearic Islands. The study is being run in association with University Jaume I of Castelló, University of Valencia, University of Zaragoza, and University of Málaga (Spain).

When is the study starting and how long is it expected to run for?
January 2014 to December 2016.

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

Who is the main contact?
Professor Margalida Gili Planas
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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
PI13/01171

Study information

Scientific Title
Efficacy of low-intensity psychological intervention applied by (ICTs) for treatment of depression in primary care: a randomised clinical trial

Study objectives
The project will use four arms to treat depression in primary care centers, treatment as usual (TAU) and three combinations of TAU with another effective techniques dealing with depressive symptoms: mindfulness, healthy lifestyle, and positive affect training. This will allow to detect which approach is the most effective to reduce symptom severity in mild and moderate depressive patient from primary health care centers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee (IEC) - Department of Health - Government of the Balearic Islands (Comité d'Ètica de la Investigació(CEI) - Consellería de Salut - Govern de les Illes Balears); 29/01/2014; ref. IB 2144/13 PI

Study design
Multicenter controlled randomized clinical trial in four parallel groups

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
Depression in primary care patients

Interventions
240 patients will be randomly assigned to one of four treatment arms with sixty patients each one:
1. Treatment As Usual (TAU)
2. TAU + healthy lifestyle
3. TAU + positive affect
4. TAU + mindfulness

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Depressive symptom severity assessed via PHQ-9. It will be registered at three times: baseline, 6 month follow-up, and 12 month follow-up.

Secondary outcome measures
1. Demographic variables
2. Health-related quality of life measured by SF-36
3. Mini-international neuropsychiatric interview

Overall study start date

01/01/2014

Completion date
01/01/2017

Eligibility

Key inclusion criteria
1. Age over 18
2. DSM 5 diagnose of Major Depression or Dysthymia
3. Mild or moderate depression expressed as score lower than 14 in PHQ-9
4. Depressive symptoms presented for at least last two months
5. Be able to read and understand Spanish language
6. Sign informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
240

Total final enrolment
221

Key exclusion criteria
1. Any diagnose of disease that may affect central nervous system (brain pathology, traumatic brain injury, dementia, etc)
2. Any psychiatric disorder other than Major Depression, Dysthymia, anxiety disorders or personality disorders
3. Any medical, infectious or degenerative disease that may affect mood
4. Presence of delusional ideas or hallucinations consistent or not with mood
5. Suicide risk

Date of first enrolment
01/01/2014

Date of final enrolment
01/01/2017

Locations

Countries of recruitment
Spain

Study participating centre
Ctr. Valldemossa km 7,5 - Universidad de las Islas Baleares
Palma de Mallorca
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07122

Sponsor information

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

Sponsor details
Avda. Monforte de Lemos, 5
Madrid
Spain
28029

Sponsor type
Hospital/treatment centre

Website
http://www.isciii.es/

ROR
https://ror.org/00ca2c886

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Carlos III Institute of Health (Instituto de Salud Carlos III) (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?
Protocol article	protocol	07/05/2015		Yes	No
Results article	results	05/06/2020	08/06/2020	Yes	No