

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	☐ Prospectively registered ☒ Protocol
Registration date 16/04/2014	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 08/06/2020	Condition category Mental and Behavioural Disorders	☐ 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

Protocol serial number
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) - Conselleria de Salut - Govern de les Illes Balears); 29/01/2014; ref. IB 2144/13 PI

Primary study design

Interventional

Study design

Multicenter controlled randomized clinical trial in four parallel groups

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

Spain

07122

Sponsor information**Organisation**

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

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

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	05/06/2020	08/06/2020	Yes	No
Protocol article	protocol	07/05/2015		Yes	No