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# Cognitive therapy for unipolar depression: effect of a dilemma-focused intervention

**Submission date**
04/08/2012

**Recruitment status**
No longer recruiting

**Registration date**
23/08/2012

**Overall study status**
Completed

**Last Edited**
16/04/2019

**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
Depression is one of the most common mental disorders worldwide. The symptoms of depression can vary greatly from person to person, but generally include low mood, problems with sleeping and/or eating, and loss of interest in life. Depression comes in many forms, and two of the most recognised are major depressive disorder (MDD), and dysthymic disorder (DD). MMD is diagnosed when symptoms begin suddenly, last for at least two weeks and are serious enough to affect day to day life. The symptoms of DD are not quite as severe as in MDD, but last for at least two years. Although a good deal of progress has been made, the success in the treatment of these disorders is limited, as patients have a tendency to relapse. One of the reasons for this is thought to be that people suffering from these disorders have an internal struggle going on, which creates suffering and blocks their personal development (cognitive conflict). The aim of this study is to find out whether having individual dilemma-focused therapy (DFT) in combination with cognitive behavioural therapy (CBT) will be more effective than CBT alone in treating patients suffering from MDD and DD.

Who can participate?
Adults suffering from moderate to severe MDD or DD who have at least one cognitive conflict.

What does the study involve?
At the start of the study, the participants undergo a psychological assessment, in order to establish a definitive diagnosis. All participants are then given eight weekly 2 hour sessions of group CBT. They are randomly allocated into two groups. One group are given 8 individual CBT weekly sessions. The second group are given 8 individual DFT weekly sessions. After the participants have finished the course of individual therapy, they are assessed again in order to see if there is any change to their condition. This assessment is repeated twice more after three months and then after one year.

What are the possible benefits and risks of participating?
A potential benefit of participating is that participants will have access to therapies which are not usually offered, which may help their conditions. There are no notable risks of taking part in the trial.

Where is the study run from?
Universitat de Barcelona (Spain)

When is study starting and how long is it expected to run for?
November 2011 to June 2014

Who is funding the study?
Ministry of Economy, Secretary of Research, Development and Innovation (Spain)

Who is the main contact?
Dr Guillem Feixas
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# Contact information

### Type(s)
Scientific

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# Additional identifiers

### ClinicalTrials.gov (NCT)
NCT01542957

### Protocol serial number
PSI2011-23246

# Study information

### Scientific Title
Cognitive therapy for unipolar Depression: efficacy of a dilemma-focused intervention, a randomised controlled trial

### Acronym
CTFORDEP

### Study objectives

A new brief intervention focused on the dilemma(s) specifically detected for each patient in addition to CBT will be more efficacious than CBT alone. Patients diagnosed with Major Depressive Disorder and those with Dysthymic Disorcer allocated in the combined dilemma-focused and CBT will show higher reductions in depressive symptoms and more general improvement in functioning and wellbeing.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
University of Barcelona Ethics Committee, 04 July 2011, ref: IRB00003099
Hospital of Mataró Ethics Committee 21 December 2011

### Study design
Randomised single-blind treatment efficacy study

### Primary study design
Interventional

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Major Depressive Disorder, dysthymic disorder.

### Interventions
Combined Group Cognitive Behavioral (8, 2-hour weekly sessions) and Individual Dilemma-Focused Therapy (8, 1-hour weekly sessions)
Cognitive Behavioral Therapy (8, 2-hour group weekly sessions and 8, 1-hour individual weekly sessions)

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome(s)
Change from baseline in Beck Depression Inventory-Second Edition (BDI-II) at the end of therapy.

### Key secondary outcome(s))
1. Change from baseline in Clinical Outcomes in Routine Evaluation - Outcome Measure (CORE-OM) at the end of therapy
2. Change from baseline in Hamilton Anxiety Rating Scale (HARS) at the end of therapy
3. Change from baseline in measures of the Repertory Grid Technique

### Completion date
30/06/2014

## Eligibility

### Key inclusion criteria
1. Aged 18 to 70 years old
2. Both genders
3. Meeting diagnostic criteria for Major Depressive Disorder (MDD) or Dysthymic Disorder (DD) according to the DSM-IV-TR (APA, 2002) criteria assessed using SCID-I
4. A score above 19 on the BDI-II Questionnaire
5. Presenting at least one cognitive conflict (implicative dilemma or dilemmatic construct) as assessed using the Repertory Grid Technique
6. Enough level of competence to communicate in Spanish or Catalan

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Total final enrolment
128

### Key exclusion criteria
1. Bipolar disorders
2. Psychotic symptoms
3. Substance abuse
4. Organic brain dysfunction
5. Mental retardation
6. Serious suicidal ideation
7. Receiving psychological treatment (unless it is suspended at the time of inclusion in the study itself, in agreement with the patient and the practitioner applying it)
8. Substantial visual, hearing or cognitive deficits

### Date of first enrolment
20/11/2011

### Date of final enrolment
30/06/2014

## Locations

### Countries of recruitment
Spain

**Study participating centre**
**Universitat de Barcelona**
Barcelona
Spain
08035

# Sponsor information

**Organisation**
University of Barcelona (Spain)

**ROR**
https://ror.org/021018s57

# Funder(s)

**Funder type**
Government

**Funder Name**
Ministry of Economy, Secretary of Research, Development and Innovation (Spain) ref: PSI2011-23246

# 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 | 01/09/2016 | 16/04/2019 | Yes | No |
| Results article | results | 01/01/2017 | 16/04/2019 | Yes | No |
| Results article | results | 13/12/2018 | 16/04/2019 | Yes | No |
| Protocol article | protocol<br>Participant information sheet | 17/05/2013 | 25/10/2013 | Yes | No |

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|---|---|---|---|---|---|
| Participant information sheet | Study website | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | | 11/11/2025 | 11/11/2025 | No | Yes |