ISRCTN92443999 https://doi.org/10.1186/ISRCTN92443999

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
gfeixas@ub.edu

Study website
http://www.ub.edu/terdep

Contact information

Type(s)
Scientific

Contact name
Prof Guillem Feixas

Contact details
Universitat de Barcelona
Campus Mundet - Psicologia
Edifici Ponent, despatx 3601
Passeig Vall d'Hebron, 171
Barcelona
Spain
08035
+34933125100
gfeixas@ub.edu

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01542957

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
http://www.ub.edu/terdep

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

Secondary outcome measures
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

Overall study start date
20/11/2011

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
112 patients. To achieve minimal requirements of statistical analysis, some additional recruiting will be needed if too few men or dysthymic patients are included for the study.

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)

Sponsor details
Department of Personality
Assessment and Psychological Treatment
Faculty of Psychology
Campus Mundet (UB)
Passeig Vall d'Hebron, 171
Facultat de Psicologia
Barcelona
Spain
08035
+34933125100
gfeixas@ub.edu

Sponsor type
University/education

Website
http://www.ub.edu/terdep

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

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	17/05/2013	25/10/2013	Yes	No
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