ISRCTN64664414 https://doi.org/10.1186/ISRCTN64664414

Darwinian psychotherapy for depression

Submission date
10/06/2013

Registration date
20/06/2013

Last Edited
16/06/2020

Recruitment status
No longer recruiting

Overall study status
Completed

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 affects almost 7% of the population and is the most important cause of disease burden in middle- and high-income countries. Psychotherapists normally focus on events within the lifespan of a patient and examine the immediate causes of depression. Recent advances in Evolutionary Psychology, however, propose that low mood has an adaptive function. Therefore the aim of this study is to test whether interventions on the evolutionary causes of depression are beneficial for patients.

Who can participate?
Romanian-speaking adults diagnosed with increased levels of depressive symptoms are eligible to participate in this project.

What does the study involve?
The participants are randomly allocated to receive either cognitive therapy or evolutionary-driven cognitive therapy for depression. Each group undergoes 12 free one-hour therapy sessions, one session per week. The participants are evaluated psychologically at the beginning, during and at the end of treatment.

What are the possible benefits and risks of participating?
Cognitive behavioural therapy does not present known risks for the patients, most of whom will benefit from it , at least to some degree.

Where is the study run from?
This project is run from the Department of Clinical Psychology and Psychotherapy, Babes-Bolyai University (Romania).

When is the study starting and how long is it expected to run for?
The duration of the study is three years (November 2011 November 2014).

Who is funding the study?
The study is funded by the Romanian Authority for Scientific Research (Romania).

Who is the main contact?
Cezar Giosan
cgiosan@gmail.com

Study website
http://www.DarwinianPsychotherapy.com

Contact information

Type(s)
Scientific

Contact name
Dr Cezar Giosan

Contact details
33-40 88th Street
Jackson Heights
United States of America
11372

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PN-II-ID PCE 2011-3-0230

Study information

Scientific Title
Darwinian psychotherapy: A clinical trial for an evolutionary-driven type of intervention for depression

Study objectives
This study examines the efficiency of an evolutionary-driven cognitive therapy for depression, contrasted with classical cognitive therapy for depression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Commission, Department of Clinical Psychology and Psychotherapy, Babes-Bolyai University, 05/05/2013, DCMP: 31205/24.05.2013

Study design
Uni-center randomized interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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

Interventions
Experimental group: Evolutionary-driven cognitive therapy for depression (EB-CBT). This group receives 12 EB-CBT therapy sessions, one session per week.

Control group: Cognitive therapy for depression (CBT). This group receives 12 CBT therapy sessions, one session per week.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Depressive symptomatology measured with the Beck Depression Inventory (BDI)
2. Depression diagnosis, assessed by the Structured Clinical Interview for DSM-IV (SCID).

Both primary outcomes measured at baseline, fourth, eight, 12th session, and three months after the completion of the treatment.

Secondary outcome measures
1. Perceptions about quality of life
2. Social and occupational functioning

Both secondary outcomes measured at baseline, fourth, eight, 12th session, and three months after the completion of the treatment.

Overall study start date
01/10/2011

Completion date
30/09/2014

Eligibility

Key inclusion criteria
1. Romanian-speaking adults, either sex (18 years old and up) with elevated Beck Depression Inventory scores (>13)
2. Current diagnosis of Major Depressive Disorder or Episode with or without co morbid dysthymia

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
Participants presenting panic disorder, substance abuse, psychotic symptoms, organic brain disorders (e.g., dementia), imminent risk of suicide, self-injury or harming others, serious legal or health issues that would prevent from regularly attending are excluded.

Date of first enrolment
01/10/2011

Date of final enrolment
30/09/2014

Locations

Countries of recruitment
Romania

United States of America

Study participating centre
33-40 88th Street
Jackson Heights

United States of America
11372

Sponsor information

Organisation
Romanian Authority for Scientific Research (Romania)

Sponsor details
Str. Mendeleev nr. 21-25
Sector 1
Bucharest
Romania
010362

Sponsor type
Research council

Website
http://www.cncs-nrc.ro/

Funder(s)

Funder type
Research council

Funder Name
Romanian Authority for Scientific Research: CNCS-UEFISCDI (Romania) Grant number: PN-II-ID
PCE 2011-3-0230

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
31/12/2019

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	19/03/2014		Yes	No
Basic results		10/06/2020	16/06/2020	No	No