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Meta-cognitive Therapy (MCT) versus Cognitive Behaviour Therapy (CBT) for Depression

Submission date
09/02/2013

Recruitment status
No longer recruiting

Registration date
04/03/2013

Overall study status
Completed

Last Edited
19/05/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Depression is considered the second leading cause of disability caused by illness affecting about 121 million people around the world. Cognitive behaviour therapy (CBT) is an evidence-based treatment for depression. However, only approximately 5 out of 10 of patients respond and only a third remain recovered at follow-up. Initial studies show that meta-cognitive therapy (MCT) might optimize effectiveness. The present study intents to compare 128 depressed Danish outpatients randomly assigned to up to 24 weekly sessions of either CBT or MCT. The approach of the data-analysis consists of a mixed-model analysis of variance and analysis of co-variance to assess relative treatment effects. The results of the trial will have significant impact on enhancing treatment methods for depression.

Who can participate?
Participants are patients referred from their general practitioner (GP) to get psychological treatment at the CEKTOS center for their depression who want treatment within 2 weeks and are willing to participate in a trial.

What does the study involve?
After screening and diagnosis the participants are randomly allocated to receive either treatment as usual - CBT or MCT.
Patients who are suitable for the trial receive either up to 24 sessions of CBT or MCT.

What are the possible benefits and risks of participating?
No known risks or side effects from either CBT or MCT.

Where is the study run from?
It takes place at CEKTOS Center for Kognitiv Terapi og Supervision in Næstved. Supervision is given at Manchester University where the manager of the trial is a PhD student.

When is the study starting and how long is it expected to run for?
The trial started in 2010 and is expected to run for at least 4 years.

Who is funding the study?
It is a privately funded study sponsored by CEKTOS- Center for Kognitiv Terapi og Supervision.

Who is the main contact?
Pia Callesen
pcallesen@gmail.com
Pia.callesen@cektos.dk

Study website
http://www.cektos.dk/cektos/index.php?option=com_content&view=article&id=130&Itemid=157

Contact information

Type(s)
Scientific

Contact name
Ms Pia Callesen

Contact details
Riddergade 7, 1
Næstved
Denmark
4700
+4522684281
Pia.callesen@cektos.dk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Meta-cognitive Therapy (MCT) versus Cognitive Behaviour Therapy (CBT) for Depression: A randomised clinical trial

Acronym
MetaDep

Study objectives
The null hypothesis is that MCT is just as effective as CBT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Danish Ethical Committee, 13 December 2010

Study design
Randomised parallel between-groups design. Groups are stratified for gender and level of depression.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Screening

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Depression

Interventions
Cognitive behaviour therapy versus metacognitive behaviour therapy.

The two therapists in the trial give both treatment. Patients are referred according to therapist availability. They are offered up to 24 sessions of 50-60 mins. once a week. Treatment is terminated when they score below depressive threshold on the BDI-II in two consecutive sessions. Patients symptoms are evaluated before, mid, post and at 6 months follow-up.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Depressive symptoms (Hamilton Depression Inventory administered by blind assessor)
2. Depressive symptoms on self report questionnaire (Beck Depression Inventory BDI-II

Measured before, mid, post and at 6 months follow-up.

Secondary outcome measures

1. Anxiety related symptoms (Beck Anxiety Inventory - BAI)
2. Co-morbidity (SCID I)
3. Patients expectancies about treatment outcome
4. Meta-cognitive scales (Meta-cognitive Questionnaire - MCQ-30, negative and positive beliefs about rumination scales (NBRS PBRS), Rumination Response Scale (RRS)
5. CBT specific scales (Dysfunctional Attitude Scale DAS and Youngs Schema Inventory - short version)
6. Patient-therapist alliance (Havarth Aliance Inventory HAI)
7. Objective measure (Concentration and attention subtests from the WAIS)

Measured before, mid, post and at 6 months follow-up.

Overall study start date
01/11/2010

Completion date
01/06/2017

Eligibility

Key inclusion criteria
1. Patients (male and female, aged 18-68 years) who have a main or primary diagnosis of major depressive disorder (MDD) according to Structured Clinical Interview for DSM-IV Disorders (SCID) I.
2. Patients who only attend therapy in this trial and have not received other psychological treatments for the current episode.
3. Patients in combined medical treatment as long as they are stable or willing to remain stable on their medication for the period of the trial.
4. Patients who sign informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
68 Years

Sex
Both

Target number of participants
128

Total final enrolment
174

Key exclusion criteria
1. Patients suffering from psychosis or bipolar disorder as screened by SCID I
2. Patients suffering from substance and alcohol-abuse as screened by SCID I
3. Patients suffering from borderline personality disorder as screened by SCID II
4. Patients with organic brain syndrome or mental retardation
5. Female patients who are pregnant or lactating
6. Participants who had not responded favorably to an earlier adequate trial of either CBT or MCT

Date of first enrolment
01/11/2010

Date of final enrolment
01/11/2015

Locations

Countries of recruitment
Denmark

England

United Kingdom

Study participating centre
University of Manchester
School of Psychological Sciences
Section of Clinical and Health Psychology
Rawnsley Building
MRI
Manchester
United Kingdom
M13 9WL

Study participating centre
Cektos
Amagerbrogade 114
1 sal
København S
Denmark
2300

Sponsor information

Organisation
University of Manchester (UK)

Sponsor details
c/o Adrian Wells, Ph.D
Professor of Clinical and Experimental Psychopathology
School of Psychological Sciences
Division of Clinical Psychology
Rawnsley Building
MRI
Manchester
England
United Kingdom
M13 9WL
+44 161 276 5399
adrian.wells@manchester.ac.uk

Sponsor type
University/education

Website
http://www.manchester.ac.uk/

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (UK)

Results and Publications

Publication and dissemination plan
Publication is planned in a high-impact peer reviewed journal at the start of 2017

Intention to publish date
31/03/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository in Manchester university/Cektos

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		29/12/2016	29/12/2016	No	Yes
Results article	results	12/05/2020	12/05/2020	Yes	No