

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

<b>Submission date</b> 09/02/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 04/03/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/05/2020	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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 intends 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

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### **Study website**

[http://www.cektos.dk/cektos/index.php?option=com\\_content&view=article&id=130&Itemid=157](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

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## **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 Alliance 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

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Denmark

2300

**Sponsor information**

**Organisation**

University of Manchester (UK)

**Sponsor details**

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**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-publicly available repository in Manchester university/Cektos

## IPD sharing plan summary

Stored in repository

### Study outputs

Output type

[Participant information sheet](#)

[Results article](#)

Details	Date created	Date added	Peer reviewed?	Patient-facing?
	29/12/2016	29/12/2016	No	Yes
results	12/05/2020	12/05/2020	Yes	No