

# Effectiveness of add-on group behavioral activation treatment for depression in psychiatric care

<b>Submission date</b> 21/10/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 26/10/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/05/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Major depressive disorder, often simply called depression, is a mental disorder that causes people to experience low mood, low self-esteem, and loss of interest or pleasure in normally enjoyable activities. Treatment is often only partly successful, with many patients suffering from persisting symptoms. A combination of different types of treatment is likely to be more effective than a single treatment. The aim of this study is to find out whether adding low-cost group treatments can improve patients' symptoms.

### Who can participate?

Patients aged 18-65 with major depressive disorder

### What does the study involve?

Participants are randomly allocated to one of three groups. Participants in the first group receive the usual treatment for depression, which consists of antidepressant medication and psychotherapy (talking therapy). In addition to the usual treatment the second and third groups attend group sessions weekly for 8 weeks. In the second group (peer support), participants discuss their problems helped by a former patient who has recovered from depression. In the third group (behavioral activation), participants analyse their daily activities and are encouraged to participate in meaningful rewarding activities. In all groups, participants' symptoms are assessed before the first session, 8 weeks later, and at 6 months after the end of the treatment.

### What are the possible benefits and risks of participating?

The benefits include access to psychosocial support and possibly an increased chance of recovery. Participants must be willing to discuss their problems in a group of patients.

### Where is the study run from?

University of Helsinki and Helsinki University Hospital (Finland)

### When is the study starting and how long is it expected to run for?

January 2016 to December 2017

Who is funding the study?  
Helsinki and Uusimaa Hospital District (Finland)

Who is the main contact?  
Prof. Erkki Isometsä

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Erkki Isometsä

**ORCID ID**  
<http://orcid.org/0000-0001-5956-2399>

**Contact details**  
PO Box 22  
Helsinki  
Finland  
00014

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**  
Effectiveness of group format behavioral activation treatment for depression or peer support groups added on usual treatment vs treatment as usual for depression in psychiatric care

**Acronym**  
BAPS-D

**Study objectives**

1. Group behavioral activation plus treatment as usual (TAU) is more effective than either peer support plus TAU or TAU alone
2. Peer support plus TAU is more effective than TAU alone
3. Effectiveness of behavioral activation is mediated by patients' adherence to homework, and consequent reduction in experiential avoidance and anhedonia

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

1. Helsinki and Uusimaa Hospital District ethics committee, 19/05/2016, ref: 178/13/03/03/2016
2. Department of Psychiatry, Helsinki University Hospital, 26/08/2016, ref: HUS/242/2016

## **Study design**

Randomized three-arm parallel-group study

## **Primary study design**

Interventional

## **Secondary study design**

Randomised parallel trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

See study outputs table

## **Health condition(s) or problem(s) studied**

Major depressive disorder

## **Interventions**

Participants are randomised to one of three treatments:

1. Treatment as usual, plus behavioral activation treatment for depression (BATD) in group format weekly for 8 weeks at the premises of the outpatient clinic. The sessions last 90 minutes and are delivered by two therapists who are experienced mental health professionals (mostly psychiatric nurses or psychologists).
2. Treatment as usual, plus group peer support weekly for 8 weeks, in which a group of patients regularly meet to discuss their problems at the premises of the outpatient clinic, facilitated by an expert by experience having recovered from depression and received brief training for the task by Finnish Central Association for Mental Health. The sessions last 90 minutes, and one psychiatric nurse participates in the session, but does not have an active facilitator role.
3. Treatment as usual, mostly comprising antidepressant pharmacotherapy and low-intensity psychotherapeutic support provided by a specialized nurse. Number of visits not predefined.

In all groups, symptoms are evaluated before the first session or visit after randomization in the TAU group, and 8 weeks later (primary outcome 8-week PHQ-9). Six months after the end of intervention, there is a follow-up measurement using the PHQ-9 (one of the secondary outcomes).

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Depression score, measured using the Patient Health Questionnaire (PHQ-9) at baseline and after the 8-week intervention

### **Secondary outcome measures**

1. Response, defined as  $\geq 50\%$  decline in PHQ-9 score, measured at 8 weeks
2. Remission, defined as PHQ-9 score  $< 5$ , measured at 8 weeks
3. Functional impairment, measured using the Sheehan Disability Scale Score at baseline and 8 weeks
4. Depression score, measured using the PHQ-9 at baseline and 6 months after the intervention

### **Overall study start date**

18/01/2016

### **Completion date**

31/12/2017

## **Eligibility**

### **Key inclusion criteria**

1. Psychiatric outpatient at the Helsinki University Hospital Department of Psychiatry Mood Disorder Division
2. DSM-5 major depressive disorder
3. Fluency in Finnish
4. Age 18-65 years

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Upper age limit**

65 Years

### **Sex**

Both

### **Target number of participants**

288

### **Total final enrolment**

140

### **Key exclusion criteria**

1. Psychotic features
2. Chronic major depressive disorder (uninterrupted duration  $> 2$  years)
3. Principal clinical diagnosis borderline personality disorder

4. Principal clinical diagnosis substance use disorder
5. Imminent threat of suicide
6. Need of psychiatric hospitalization
7. Any illness or symptom hampering participation in the treatments
8. Other ongoing weekly psychotherapy

**Date of first enrolment**

07/09/2016

**Date of final enrolment**

30/04/2017

## **Locations**

**Countries of recruitment**

Finland

**Study participating centre**

Department of Psychiatry, University of Helsinki and Helsinki University Hospital

PO Box 22

Helsinki

Finland

00014

## **Sponsor information**

**Organisation**

University of Helsinki and Helsinki University Hospital

**Sponsor details**

PO Box 22

Helsinki

Finland

00014

**Sponsor type**

University/education

**ROR**

<https://ror.org/02e8hzf44>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Helsinki and Uusimaa Hospital District

## Results and Publications

**Publication and dissemination plan**

To be published as scientific articles in international journals as soon as possible after the trial has been completed and analysed.

**Intention to publish date**

31/12/2018

**Individual participant data (IPD) sharing plan**

Participant level data not available due to constraints of the Finnish data protection legislation and ethical and research permissions.

**IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>		26/10/2016	26/10/2016	No	Yes
<a href="#">Results article</a>		30/04/2024	08/05/2024	Yes	No