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

Submission date
21/10/2016

Recruitment status
No longer recruiting

Registration date
26/10/2016

Overall study status
Completed

Last Edited
08/05/2024

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
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

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Additional identifiers

Protocol serial number
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 experiental 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

Study type(s)
Treatment

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

Key secondary outcome(s))
1. Response, defined as ≥ 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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

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
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Sponsor information

Organisation
University of Helsinki and Helsinki University Hospital

ROR
https://ror.org/02e8hzf44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Helsinki and Uusimaa Hospital District

Results and Publications

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?
Results article		30/04/2024	08/05/2024	Yes	No
Participant information sheet		26/10/2016	26/10/2016	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes