# Gedragsactivatie door de POH-GGZ versus gebruikelijke behandeling voor depressie bij oudere volwassenen in de eerste lijn.

No registrations found.

**Ethical review** Positive opinion

**Status** Other

Health condition type -

**Study type** Interventional

## **Summary**

#### ID

NL-OMON20783

Source

NTR

**Brief title** 

BeATDeP65

#### **Health condition**

Late-life depression, depressive symptoms, depressie, depressieve symptomen, depressieve klachten, elderly.

## **Sponsors and support**

**Primary sponsor:** Pro Persona; RadboudUMC; Radboud Universiteit

Source(s) of monetary or material Support: ZonMw

#### Intervention

#### **Outcome measures**

#### **Primary outcome**

Depression severity as assessed with the Quick Inventory of Depressive Symptomatology (Q-IDS) during the 8-week treatment period and follow-up.

#### **Secondary outcome**

When proven effective, our next interest is the cost-effectiveness of BA. The EuroQol (EQ-5D-5L) and TiC-P are used.

Furthermore, several moderators and process variables will be investigated.

# **Study description**

#### **Background summary**

With 12-25% prevalence, clinically significant depression is common in later life. However, the efficacy of current pharmacological and psychological treatments is limited. Behavioural programmes for late-life depression have recently received renewed attention with findings suggesting that Behavioural Activation (BA) may be effective. The primary objective of this study is to compare the effectiveness and cost-effectiveness of behavioural activation (BA) and treatment as usual (TAU) for late-life depression in primary care in the Netherlands. A cluster-randomised and controlled multicentre trial (RCT) is conducted, with two parallel groups: a) Behavioural activation, and b) Treatment as usual, conducted in primary care centres (PCC) with a follow-up of 52 weeks (FU).

#### Study objective

The main hypothesis is that compared to TAU, BA will be more effective and less costly. A secondary goal is to explore several potential mechanisms of change, as well as predictors and moderators of treatment outcome of BA for late-life depression.

#### Study design

Participants in both the BA- and TAU-condition will complete these measures every two to three weeks during the 8 week therapy period, at post-treatment, and every three months during the 52-week follow-up.

#### Intervention

In behavioural activation (BA) patients are encouraged to increase their activity levels, engage in more reinforcing and pleasurable activities, and modify avoidance and withdrawal patterns. BA is a component of cognitive-behavioural therapy (CBT), a more complex approach targeting both thoughts and behaviours.

### **Contacts**

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# **Eligibility criteria**

#### Inclusion criteria

The main inclusion criterion is a PHO-9 score >9.

#### **Exclusion criteria**

Patients will be excluded from the trial in the case of I) severe mental illness in need of specialized treatment, including severe major depression, bipolar disorder, obsessive-compulsive disorder, (history of) psychosis; II) high risk of suicide, III) drug and/or alcohol abuse or dependence, IV) prior psychotherapy received in the previous 12 weeks V) current treatment by a mental health specialist. VI) moderate to severe cognitive impairment (MoCA <18).

# Study design

## **Design**

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Open (masking not used)

Control: Active

#### Recruitment

NL

Recruitment status: Other

Start date (anticipated): 01-07-2016

Enrollment: 200

Type: Unknown

## **Ethics review**

Positive opinion

Date: 25-08-2016

Application type: First submission

# **Study registrations**

## Followed up by the following (possibly more current) registration

ID: 47861

Bron: ToetsingOnline

Titel:

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register ID

NTR-new NL5436 NTR-old NTR6013

CCMO NL54470.091.16 OMON NL-OMON47861

# **Study results**

#### **Summary results**

Hendriks, G. J., Oude Voshaar, R. C., Keijsers, G. P., Hoogduin, C. A. and van Balkom, A. J. (2008). Cognitive-behavioural therapy for late-life anxiety disorders: a systematic review and meta-analysis. Acta Psychiatr Scand, 117, 403-411.<br/>
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Huibers, M. J., et al. (2014). Predicting response to cognitive therapy and interpersonal therapy, with or without antidepressant medication, for major depression: a pragmatic trial in routine practice. J Affect Disord, 152-154, 146-154.

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Lemmens, L. H., Arntz, A., Peeters, F., Hollon, S. D., Roefs, A. and Huibers, M. J. (2015). Clinical effectiveness of cognitive therapy v. interpersonal psychotherapy for depression: results of a randomized controlled trial. Psychol Med, 1-16.<br/>
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Licht-Strunk, E., Van Marwijk, H. W., Hoekstra, T., Twisk, J. W., De Haan, M. and Beekman, A. T. (2009). Outcome of depression in later life in primary care: longitudinal cohort study with three years' follow-up. BMJ, 338, a3079.