Gedragsmatige activering bij ouderen met een depressie: een alternatieve effectieve behandeling?

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29645

Source
NTR

Health condition

depression in elderly
depressie bij ouderen

Sponsors and support

Primary sponsor: Riagg Maastricht in collaboration with Maastricht University, University of Amsterdam & VU University Amsterdam
Source(s) of monetary or material Support: Riagg Maastricht

Intervention

Outcome measures

Primary outcome

The primary outcome measure will be the change in depression severity between respectively the intervention and exploration phase versus the baseline condition (Î” treatment effect). For the purpose of this study, we have chosen the GDS-15 as primary outcome measure, because Longwell and Truax (2005) warn for weekly administration of the

BDI-II leading to decreasing scores merely as a result of the short re-administration period.

Secondary outcome

The secondary outcome measures are the BDI-II, the 17-item Hamilton Rating Scale for Depression (HRSD), patient acceptability of intervention (i.e. take up and drop out rates), medication use, patient attrition, happiness (one item question), and quality of life (EuroQol). We will apply the criteria for clinical response and remission as proposed by Dimidjian et al. (2006). They define response as a minimal 50% decline of symptoms compared to baseline, and remission is accomplished if the HRSD scores â‰¤ 7 and BDI â‰¤ 10. The SCID-I will be used to evaluate at pre- and post-treatment whether the major/minor depression is still present or in remission.

Study description

Background summary

Rationale: Behavioural activation (BA) has known a revival after the Jacobson study (1996). It showed that BA was equally effective as Cognitive Therapy (CT) to alleviate depression. Dimidjian (2006) replicated the findings in an RCT. A meta-analysis by Cuijpers et al. (2007) pointed in the same direction. In the elderly, psychotherapy research receives, relatively speaking, less attention, and there is also a lack of studies into psychological treatment of depression. In our experience, cognitive techniques are often not suitable for elderly patients with depression. Therefore, we wish to study the applicability of BA in elderly.
Objective: To evaluate the effectiveness of BA in reducing acute major and minor depression in elderly.
Study design: The present study will use a multiple baseline case series design. By applying multiple baseline periods over patients and comparing baseline, exploration and treatment phase a patient serves as its own control subject.
Study population: Elderly patients (60-99 yrs) with a primary diagnosis of acute major or minor depression referred to secondary mental health care (RIAGG Maastricht Elderly Care).
Intervention: BA belongs to the third-generation behavioural treatments. Based on individual case conceptualisation and functional analysis of withdrawal behaviour and ruminative thinking, an activation plan is made and implemented to activate the patient and increase reward. If indicated, skill training is offered to increase reward levels.
Primary outcome measure: GDS-15.
Secondary outcome measures: BDI-II, HRSD, BADS, post-treatment absence of major/minor depression, EuroQol, happiness question.
Ethical considerations: As BA is a component of Cognitive Behavioural Therapy (CBT), an evidence-based therapy for both adults and elderly, no adverse events are expected. If suicidal behaviour is encountered, appropriate measures will be taken.

Study objective

Behavioural Activation is effective in reducing acute major and minor depression in elderly.

Study design

Weekly assessments by mail or internet
Primary outcome: GDS-15.

Face-to-face assessments at t-1 (start baseline phase, duration 6-10 weeks due to randomised variation in waiting list), t0 (start exploration phase, duration 5 weeks), t1 (start intervention phase, duration 12 weeks), t2 (mid-treatment), t3 (end-treatment) and t4 (3 months FU)
Secondary outcomes: BDI-II, BADS, HRSD, happiness, EuroQol

Pre- and post-treatment assessment
SCID-I
Checklist DSM-5 criteria major and minor depression
Patient acceptability of intervention and attrition
Medication use
Demographic variables at pre-treatment

Intervention

Behavioural activation belongs to the third-generation behavioural treatments (Dimidjian & Davis 2009), and focuses at activating the patient to increase reward and at conceptualising ruminative thinking in its context and consequences. It is developed by Lewinsohn in the seventies, and showed a revival in the past 20 years when research trials and meta-analyses demonstrated its effectiveness as a stand-alone treatment method (Cuijpers et al. 2007, Dimidjian et al. 2006, Cuijpers et al. 2006). However, less evidence exists for the use of BA in elderly. We will use the book by Martell et al. (2010) as guideline in composing the BA treatment protocol for elderly, taking into account possible age-related sensory and memory problems.

Contacts

Public
Universiteitssingel 50
M. Hanssen
Maastricht 6229 ER
The Netherlands
+31 (0)43 3884259

Scientific
Universiteitssingel 50
M. Hanssen
Maastricht 6229 ER
The Netherlands
+31 (0)43 3884259

Eligibility criteria

Inclusion criteria

Inclusion criteria are 1) primary diagnosis of acute (i.e. started at least 12 months prior to referral) major and minor depression as assessed with the SCID-I; 2) a recurrent depressive episode is allowed; 3) a cut off score of 5/6 on the GDS-15 at screening (12); 4) age range 60-99; 5) can understand and speak the Dutch language; 6) willingness to participate in the study (signed informed consent).

Exclusion criteria

Exclusion criteria are 1) psychotic features, psychotic disorder or bipolar disorder; 2) IQ<80 (clinical impression); 3) acute suicide risk; 4) substance dependence; 5) start of new medication within 3 months before start of the study (medication used for longer periods can be continued; stopping medication during the study is allowed); 6) medical condition that causes depression directly or through medication intake; 7) unstable medical condition; 8) MMSE score <20.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2014
Enrollment:	20
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4454
NTR-old	NTR4577
Other	Riagg Maastricht financiert studie : ECP (ethical committee psychology)-133 4-10-2013

Study results