Behavioural activation for depressed adolescents

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON46637

Source
ToetsingOnline

Brief title
BA adolescents

Condition

- Mood disorders and disturbances NEC

Synonym
depression sad

Research involving
Human

Sponsors and support

Primary sponsor: ProPersona (Nijmegen)
Source(s) of monetary or material Support: Pro Persona

Intervention

Keyword: Activation, Adolescents, Behavioural, Depressed

Outcome measures

Primary outcome

The PHQ-9 is a 10-item self-report instrument assessing depressive symptoms over the past 2 weeks. The internal reliability is excellent (Cronbach*s alpha 0.89), as is the test-retest reliability. In adolescents the PHQ-9 has a high sensitivity (89,5%) and good specificity (78,8%) for detecting major depression (Richardson et al., 2010). In this study we use the PHQ-9 weekly in line with previous research that has shown that the PHQ-9 can be used as a reliable indicator for weekly mood changes as well(Aguilera, Schueller & Leykin, 2015). It can be administered in a few minutes (Kroenke, Spitzer & Williams, 2001).

Secondary outcome

- Before including the participant in the study the M.I.N.I. KID will be administered to classify the existence of a depressive disorder. The M.I.N.I. KID is a diagnostic interview that assesses current psychological disorders, based on DSM-IV diagnostic criteria. The sensitivity and specificity are good to excellent (Sheehan et al., 2010). This semi-structured interview take 60 minutes to complete in total and a maximum of 15 minutes for the section depression.

- General functioning will be measured by the SDQ (Goodman, 1997; Dutch version: van Widenfelt, Goedhart, Treffers, Goodman, 2003): a brief behavioral screening questionnaire. The SDQ consists of 25 items on psychological attributes which are divided between 5 scales: emotional symptoms, conduct

problems, hyperactivity/inattention, peer relationship problems and prosocial behavior. The internal consistency for the various SDQ scales were generally satisfactory (mean alpha was 0.70 for the parent version and 0.64 for the self-report version). Furthermore, substantial correlations were found between SDQ total difficulties scores and CBCL total scores (r = 0.70; Muris, Meesters, & van den Berg, 2003). Completing the questionnaire takes a maximum of 20 minutes.

- The severity of general anxiety will be measured by the SCARED (Birmaher et al. 1997; Dutch version: Wijsbroek, Hale, Raaijmakers & Muris; 2005): a self-report instrument consisting of 69 items The items measures the symptoms of the most important anxiety disorders. The internal consistency is 0.93 (Birmaher et al., 1997).Completion of the questionnaire takes a maximum of 20 minutes.

Study description

Background summary

The worldwide prevalence of unipolar depression is 4-5% among adolescents, with severe implications both in the short term and the long term.
Several therapies have been developed and studied for the treatment of depression. These therapies vary in theoretical background, duration and intensity. With respect to psychotherapy for depression, cognitive behavioral therapy and interpersonal therapy have the most empirical support. The specific effective elements of these recommended treatments for depression are however still unknown.
One of the elements which is used during cognitive behavioral therapy is behavioral activation (BA). A meta-analysis by Weisz et al (2006) on the effectiveness of psychotherapy with adolescents has shown that therapies with a focus on behavior-inducing strategies have as much effect as cognitive treatments. Several studies have been conducted to investigate the effectiveness of protocols based on BA with promising results for improving

depressive symptoms.
However, more research is required to determine if activation as a stand-alone treatment is sufficient to improve the depressive symptoms. Currently there is no protocol available in the Netherlands for depressed adolescents, which uses behavioral activation as a stand alone treatment. This study will be the first to use and investigate the effects of behavioral activation in the treatment of depressed adolescents in the Netherlands.

Study objective

The present study aims to examine if BA has a positive effect on the severity of depressive symptoms as measured by the PHQ-9 in adolescent depressive participants.
In addition, several additional objectives are included (classification of the depressive disorder, general wellbeing and anxiety).

Study design

This study aims to include 10 participants, aged between 12 and 17 after pre-assessment and after signing an informed consent. Participants will be randomly assigned to a baseline phase (varying between 2-6 weeks), followed by a treatment phase (8 weeks) and a post-treatment phase (varying between 6-10 weeks). During these 20 weeks in total, there will be a weekly assessment measuring depressive symptoms (primary outcome). In addition to this primary outcome, there are also 3 single time points (before treatment phase, after treatment phase and follow up after 12 weeks) that consists of a clinican-administred interview and self-report measures. All treatments and assessments will be conducted in Dutch.

Intervention

This study uses a specific adapted protocol, based on a protocol which was developed for adults and designed by Martell et al. (2013). The original protocol aims to increase activation levels by helping adults engage in rewarding activities and to break patterns of avoidance and withdrawal that diminish distress in the short term but have adverse consequences in the long term. For this study we received permission of the researchers to use and alter the protocol which was developed for adults to use for adolescents. To alter the protocol in order to use it more specifically for adolescents we incorporated the recommendations of earlier studies on behavioral activation with adolescents. The protocol consists of 8 sessions, with a duration of 45 minutes per session (total of 360 minutes).

Study burden and risks

- Benefits:

The burden on the participants is minimal. In BA participants are encouraged to increase their activity levels, engage in more reinforcing and pleasurable activities, and modify avoidance and withdrawal patterns, based on their own functional analyses. This means that only behavior that is functional or potentially pleasant for the patient will be stimulated. In this study the timespan of the assessment is limited as much as possible, the maximum time for an assessment is 60 minutes. The participants are not withheld treatment. In case the treatment proves not to be successful (the depressive symptoms have not improved after treatment) participants are offered to receive further treatment within ProPersona Youth within a maximum of two weeks after the final treatment session.
- Risks:
The risk of participation in this study can be considered negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

- Current DSM-5 diagnoses of a depressive disorder (major depressive disorder, major depressive episode, persistent depressive disorder, other specified depressive disorder and unspecified depressive disorder)
- Age between 12 and 17 years

Exclusion criteria

- Acute suicidality
- Psychosis or deliusion disorders (current or in the past)
- Manic or hypomanic episodes (current or in the past)
- Mental retardation
- Substance abuse or dependence or alcohol abuse or dependence
- Insufficient ability to speak, read and write Dutch

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-03-2019
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	12-09-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL65442.091.18

Study results

Date completed:	04-04-2020
Actual enrolment:	3

Summary results
Trial is onging in other countries