Efficacy of positive cognitive behavior group therapy for depression in older adults.

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

Summary

ID

NL-OMON56860

Source
ToetsingOnline

Brief title
EIGHTIES study

Condition

- Mood disorders and disturbances NEC

Synonym
depressed mood, depression

Research involving
Human

Sponsors and support

Primary sponsor: Mondriaan Zorggroep (Heerlen)
Source(s) of monetary or material Support: het onderzoek wordt gefinancierd door Mondriaan GGZ in het kader van de opleiding tot klinisch psycholoog BIG van de uitvoerend

onderzoeker

Intervention

Keyword: CBT, Depression, Elderly, Positive

Outcome measures

Primary outcome

The Quick Inventory of Depressive Symptoms (QIDS-SR-16; Trivedi et al., 2004) will be used as primary outcome measure to assess depressive symptoms.

Secondary outcome

The Remission from Depression Questionnaire (RDQ; Zimmerman et al., 2013) will be used as a secondary outcome measurement to assess depressive symptoms.

The Positive and Negative Affect Schedule (PANAS; Watson et al., 1988) and the Joviality subscale of the Positive and Negative Affect Schedule - Extended (PANAS-X; Watson & Clark, 1999) will be used to assess positive and negative affect.

The Life-Orientation Test-Revised (LOT-R; Scheier, Carver, & Bridges, 1994), (Dutch translation: Meevissen et al., 2011), will be used to measure optimism.

Overall happiness will be assessed by using the Subjective Happiness Scale (SHS; Lyubomirsky & Lepper, 1999).

The Mental Health Continuum-Short Form (MHC-SF; Lamers et al., 2011) will be used to measure three components of well-being: emotional, psychological and social.

Personality functioning will be measured conform the Alternative Model of Personality Disorders as described in the DSM-5 (American Psychiatric Association, 2013). Both criterion A (indices of personality functioning) as

well as criterion B (maladaptive personality traits) will be measured.

Criterion A will be assessed with the Level of Personality Functioning Brief Form 2.0 (LPFS-BF 2.0; Weekers et al., 2019). Criterion B will be measured with the Personality Inventory for DSM -5 Brief Form + Modified (PID-5-BF+M; Bach et al., 2020).

Study description

Background summary

According to the WHO, the global population is aging rapidly with estimations predicting that the proportion of the world*s population over 60 years of age, will double from twelve to twenty-two percent between 2015 and 2050. Additionally, the life expectancy will increase. Globally, about fifteen percent of the group of adults aged 60 and older suffer from a mental disorder, with dementia and depression being the most common. In older adults, depression is often underdiagnosed as well as untreated. This has multiple explanations. For example: symptoms of depression in older adults are attributed to a physical problems or seen as a normal part of aging. In addition, older adults are assumed to disclose less about their mental health issues compared to younger adults. Interestingly, older adults who are referred for psychological treatment show better attendance and clinical improvement compared to younger adults. Additionally, older adults benefit just as much from psychotherapy for depression as middle aged adults. This suggests that it is worth investing in the psychological treatment of depression in older adults.

There is ample evidence for the effectiveness of traditional cognitive behavioral therapy (T-CBT) as treatment for depression. It is also the most researched and recommended therapy for depression in most guidelines. However, T-CBT has several limitations. For example, psychotherapy is generally associated with high drop-out and low homework compliance. In addition, only about 42% of patients respond to treatment with T-CBT with a remission rate of 36%. Finally, T-CBT is mainly focused on decreasing on depressive symptoms although research suggests that successful treatment entails more than a decrease in depressive symptoms (with patients rating an increase in positive affect as more important).

In recent years there has been increased attention to 4th generation CBT interventions, such as positive CBT (P-CBT). P-CBT is a novel transdiagnostic treatment which focuses on positive emotions and integrates T-CBT techniques

with solution-focused therapy and positive psychology. Some of the key features of positive CBT are assumed to overcome the previously mentioned limitations of traditional CBT. In adults suffering from depression, positive CBT has shown a stronger improvement in depressive symptoms compared to traditional CBT. In addition, research has shown larger effect sizes from negative and positive affect measures for positive CBT.

Drawing on previous findings, we hypothesize that older adults suffering from depression profit from positive CBT leading to a decrease in depressive symptoms and negative affect and an increase in positive affect, optimism, well-being, subjective happiness and personality functioning.

Study objective

The aim of the current study is to examine the efficacy of positive CBT for the treatment of major depressive disorder in older adults. Drawing on previous findings, we hypothesize that older adults suffering from major depressive disorder profit from positive CBT leading to a decrease in depressive symptoms and negative affect and an increase in positive affect, optimism, well-being and subjective happiness. Additionally, we hypothesize that positive CBT will lead to an improvement in personality functioning in older adults suffering from major depressive disorder.

Study design

The current study will use a replicated single case design. We choose this design because this study, to our knowledge, is the first explorative study on the effectiveness of P-CBT in older adults. The replicated single case design requires relatively few participants because the participants serve as their own control in an extensive longitudinal design. Typical for a replicated single case design are dependent variables which are assessed frequently, thus making it possible to study the effects of time and intervention. This allows for a detailed observation of the changes occurring within each subject in relation to the independent variable and thus the effectiveness of the treatment.

Intervention

Participants in the current study will participate in 8 group sessions of positive cognitive behavioral therapy as described by Bannink (2012) according to the Positive CBT group treatment protocol (Bannink & Geschwind, 2021). The treatment will consist of 8 weekly sessions with a duration of 2 hours per session. The sessions will be led by two health care psychologists who are familiar with the treatment protocol and who will partake in intervision.

All participants (i.e. patients) partaking in the current study will start with

completing the baseline measurements with the primary outcome measure being assessed two times per week for five weeks and the secondary outcome measurements once in total. Next, all participants (i.e. patients) will take part in the treatment phase. During this phase the primary outcome measure will be assessed two times a week for 8 weeks. After completion of the group therapy, participants (i.e. patients) will complete the posttreatment measurements, which will cover the same measurements as the assessment at baseline. After three weeks, the primary outcome measurement will be will be completed two times a week as follow-up for a period of three weeks and the secondary outcome measurement will be completed once again in total. Informants will complete the two informant questionnaires once at baseline, posttreatment and follow-up.

Study burden and risks

For the present study, patients who are diagnosed with depression will participate in eight weeks of cognitive behavioral group therapy. The participation in such therapy is common practice in the treatment of depression, making this no extra burden. In cognitive behavioral therapy, as commonly used in daily practice, it is not uncommon to incorporate positive and solution-based elements. The main difference for the current study is the protocolized use of positive behavioral therapy and the more clear focus on these positive and solution-based interventions while preserving the key elements of (traditional) cognitive behavioral therapy, such as thought records, cognitive restructuring, etc. The more light-hearted, future-oriented, solution-based and positive approach could make this treatment even less of a burden than traditional cognitive behavioral therapy.

Patients will start the actual treatment after five weeks of baseline measurements. This corresponds with a normal waiting time to start treatment after an intake procedure and should impose no extra burden. Patients who are not able to wait five weeks for the start of treatment (e.g. due to a strong crisogenic presentation) will be excluded from the study and will receive other treatment fitting to their symptoms. The treatment interventions used in this study have proven to be beneficial in the treatment of depression in adults. Therefore, no risks are expected for the older adults participating in this study.

During the current study, patients and informant are asked to complete several questionnaires (see Appendix 1). The primary outcome measurement will be assessed during baseline (duration of 5 weeks), treatment (duration of 8 weeks), after treatment (duration of 1 week), and follow-up after a three week interval (duration of 3 weeks). The primary outcome measurement will be assessed two times a week with each assessment taking up a maximum of 5 minutes. This cumulates to 170 minutes in total for the entire study for the primary outcome measurement. In addition, participants will be asked to complete the secondary outcome measurement four times in total (baseline,

treatment, post-treatment, and follow-up). The completion of the secondary outcome measurement is estimated to take up a maximum of 45 minutes each time. This cumulates to 180 minutes in total for the entire study for the secondary outcome measurement. Lastly, an informant will be asked to complete two questionnaires during baseline, after treatment and at follow-up. Completing these questionnaires takes up a maximum of 15 minutes each time, cumulating to an investment of 45 minutes in total for the informant.

In order to support the patients, a weekly monitoring contact with a therapist is provided in the phase before and after te group treatment. No interventions are carried out during these contacts, but the patient's condition is monitored and they are asked whether the completion of the questionnaires is going well.

Participants in the current study will receive no financial compensation for participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Elderly (65 years and older)

Inclusion criteria

The inclusion criteria for participation in this study are (1) age of 65 years or older and (2) diagnosis of major depressive disorder according to DSM-5 criteria (American Psychiatric Association, 2013), lasting no longer than two years (not chronic).

The inclusion criteria for participation in this study for next of kin/informants is that a next of kin (patient) participates in the study.

Exclusion criteria

Exclusion criteria for patients will be (1) not being fluent in Dutch language, (2) comorbid mental disorders which could interfere with the treatment (e.g., major cognitive disorder (MMSE score lower than 24), substance use disorders, psychotic disorders, delirium, bipolar disorder, antisocial personality disorder, autism spectrum disorder, attention deficit hyperactivity disorder, suspected IQ lower than 80, and/or disorders with a strong crisogenic nature). In addition, participants who are expected to be unable to attend all of the required sessions (e.g., due to somatic disorder) will be excluded from participation. Furthermore, participants are required to have an informant (for example, a spouse or close family member). The use of antidepressant medication will be allowed, preferably with no changes for at least one month before the treatment phase until completion of the follow-up. If during the study it becomes apparent that it is medically necessary for changes to be made to the medication, this is permitted. If this is the case, patients are allowed to continue to participate in the study and group treatment..
Finally, the patient should not receive psychological treatment other than the treatment that is part of the current study.

Exclusion criteria for next of kin/informants for participation in this study are (1) not being fluent in the Dutch language and (2) the expectation that they will not be able to participate in all required measurement moments.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	16
Type:	Anticipated

Ethics review

Approved WMO

Date:	02-07-2024
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL85621.096.24