Improving treatment of severe major depressive disorder by reducing negative future-oriented mental imagery

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

Summary

ID

NL-OMON56695

Source
ToetsingOnline

Brief title
PROFIT-project

Condition

- Mood disorders and disturbances NEC

Synonym
Major Depressive Disorder; depression

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Future-oriented negative mental imagery, Imagery Rescripting, Major Depressive Disorder

Outcome measures

Primary outcome

The primary objective of this pilot study is to test the acceptability of

imagery rescripting.

Secondary outcome

• To measure feasibility, we will assess recruitment/admission ratio, dropout

and (serious) adverse events.

• To estimate the variance of effects, group effects on depressive symptoms

measured with the BDI-II and SCID-5-s (module A)will be tested at

post-treatment and 3 months follow-up (corrected for baseline).

• Screening for other disorders (SCID-5 Dutch version); sections on depressive

disorder, substance use disorder, psychotic disorders, anxiety disorders

andposttraumatic disorder

• Behavioral activation (Behavioral Activation for Depression Scale - Dutch

version)

• Affect: The International Short-form of the Positive and Negative Affect

Schedule (I-PANAS-SF)

• Quality of life (EQ-5D-5L)

• Anxiety measured with Generalized Anxiety Disorder scale (GAD-7)

• Vividness and likelihood of prospective positive and negative scenarios with

prospective imagery task (PIT)

• Ratings of mental images on emotions (sad, guilty, ashamed, anxious, angry, helpless), vividness, uncontrollability, distress and core belief, using 0-100 visual analog scales ranging

• Monitoring of treatment as usual will be asked to the therapist at baseline (*which treatment (including medication + dose; possible in-patient treatment) does the patient receive currently?') and at posttreatment and follow-up ("which therapy has the patient received in the past 6/12 weeks (including medication + dose; possible in-patient treatment)?")

Study description

Background summary

About 50% of patients with depressive disorders do not (sufficiently) respond to treatments, hence optimizing treatment as usual is crucial. One explanation for limited treatment effects is that patients with depression often suffer from distressing negative mental imagery . Mental imagery can be defined as *seeing with the mind*s eye, or hearing with the mind*s ear etc.* and, relative to verbal cognitions, it typically has a greater impact on emotion, cognition, and behavior. Several studies have shown that treating negative mental images related to past experiences leads to decreased depressive symptoms. Yet, there are several reasons why targeting future-oriented negative mental images is also important. First, future-oriented mental imagery directly affects the motivation to act upon the visualized event . This is in line with the observation that *flashforwards* of suicide are related to higher suicidal ideation, which in turn, has been associated with higher risk of suicide. Reversely, patients with depressive disorders who repeatedly imagined positive future events showed more behavioral activation . Second, future-oriented mental imagery also influences current emotions. For example, patients with anxiety disorders report distress of *flashforwards* of feared scenarios. Indeed, positive future-oriented mental imagery can reduce anticipatory anxiety and can increase positive affect. Third, individuals who envision future events may perceive these events as more likely to occur . For example, when individuals were asked to focus on factors that could impair their performance, they evaluated their performance as poor, relative to individuals who concentrated on factors that could facilitate their performance (while there were no group differences in actual performance). This illustrates how

future-oriented negative imagery directly impacts the way you perceive your behavior (e.g., reduced feelings of self-efficacy). Thus, to sum up, future-oriented negative imagery may put individuals at risk for maladaptive behavior, negative emotions and an availability heuristic for negative events. Because future-oriented negative mental imagery, such as suicidal flashforwards, is common in patients with depressive disorders it is vital to successfully treat these images in this population.

Study objective

The primary aim of this pilot study is to determine the acceptability of the intervention. The secondary aim is to elucidate factors that may facilitate or hinder the feasibility of the follow-up RCT (e.g., recruitment process) and to estimate the variance of the effect on reduction of depressive symptomatology, which informs the sample size calculation of the follow-up RCT. To study acceptability, we assess depressive symptoms (BDI-II and BADS) and treatment satisfaction (SRS and CSQ-8). To measure feasibility, we will assess recruitment/admission ratio and dropout. Finally, to estimate the variance of effects, group effects on depressive symptoms measured with the BDI-II and SCID-5-S (module A) will be tested at post-treatment and follow-up (corrected for baseline).

Study design

The design is a randomized, controlled, pragmatic, multicentre, trial with five Dutch participating sites: Amsterdam UMC, GGzE, Praktijk V, Psychologenpraktijk De Amsterdamse, eppGGZ and Mental Care group (HSK/Mentaal Beter).

Intervention

Future-oriented imaginary rescripting (ImRes): ImRes is an imagery technique in which patients change a negative image in a positive way. These negative future-oriented mental images (for example images of suicide) may maintain the symptoms. This treatment should reduce depressive symptoms. Sessions are scheduled weekly and the intervention lasts 6 weeks.

Treatment as usual (TAU): Participants in both arms will receive TAU. The clinical practices of the sites involved rely heavily on the use of antidepressants and/or cognitive behavioral therapy (CBT). These interventions generally do not target (future-oriented) negative mental images, even though this is proposed to be an important maintaining factor of depression. All regular interventions are allowed in TAU, except eye movement desensitization and reprocessing (EMDR) and imagery rescripting interventions. We monitor and register what TAU entails.

Study burden and risks

There are no risks associated with imagery rescripting and treatment as usual. However, a disadvantage of the research is that it takes up time. Participation in the study will consist of interviews and questionnaires. There will be a max. 55 minute screening interview. Following, there is a baseline measurement and two follow-up measurements. The questionnaires and interviews are conducted by telephone or online. Participants will be rewarded with a reimbursement for their participation.

The project will contribute to improving care for people with depression. The design of this pilot study allows us to set up a large intervention study in the future with well-substantiated prior knowledge to determine the effectiveness of imaginary rescripts on a large scale. The findings from this pilot study will be presented at (inter)national conferences.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) Aged 18 years or older ;
2) Meet DSM-5 criteria for major depressive disorder;
3) Be able to understand questionnaires and study information letter;
4) In case of medication use: are stable on medication for six weeks or longer;
5) Presence of at least one negative future-oriented mental imagery, which causes distress.

Exclusion criteria

1) Psychosis and/or bipolarity
2) Severe cognitive impairment (e.g., mental retardation) as evidenced by clinical impression;
3) Current EMDR or imagery rescripting therapy
4) Other circumstances that might affect participation (e.g., severe medical disorder, relocation).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-06-2024
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	29-03-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-07-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-12-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-02-2025
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL85551.018.23