Reducing vulnerability for victimization in depressed patients through emotion-regulation training: a randomized controlled trial.

Published: 22-02-2016
Last updated: 15-05-2024

Since previous findings underline the hypothesis that ER may play a key role as an underlying mechanism leading to (re)victimisation, we suggest that a clinical intervention aimed at enhancing ER skills may decrease (re)victimisation risk. Therefore...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50172

Source
ToetsingOnline

Brief title
ALERT: Anti-victimisation: online emotion-regulation training.

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
Depression, mood disorders

Health condition

Victimisatie (slachtofferschap)

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: NWO

Intervention

Keyword: depression, e-mental health, emotion regulation, victimisation

Outcome measures

Primary outcome

The primary endpoint is the total number of violent crime occurrences during the three years follow up, as measured with the Integrale Veiligheidsmonitor (IVM).The IVM is developed by the Dutch Central Agency for Statistics, the Ministry of the Interior and Kingdom Relations and the Ministry of Justice. Approximately 65,000 people in the general population are screened yearly with the IVMS to determine national victimization rates. The IVM is a self-report instrument, which is more reliable in measuring victimization than a police report (Hiday, 1999). Other primary outcome measures are depression symptoms (as measured with the IDS-SR) and emotion regulation (as measured with the Difficulties of Emotion Regulation Scale; DERS).

Secondary outcome

The secondary outcome measures are:

1. Subjective safety (Module 3 of the IVM);

2. Depression (Inventory of Depressive Symptoms; IDS-SR and QIDS);

3. Diagnosis of depression and comorbid disorders (Mini-International

Neuropsychiatric Interview; MINI);

4. Emotion Dysregulation (Difficulties in ER Scale; DERS);

5. Mood (Visual Analogue Mood Scale; VAMS);

6. Coping (Utrechtse Coping Lijst; UCL)

7. Dysfunctional attitudes (Dysfunctional Attitudes Scale; DAS-A-17);

8. Brooding (Brooding subscale of the Rumination Response Scale; RSS-NL);

9. Locus of control (Mastery scale);

10. Positive affect (PANAS);

11. Psychiatric distress (Brief Symptom Inventory; BSI);

12. Quality of life (EuroQol; EQ-5D);

13. Self-esteem (Self-esteem rating scale; SERS-SF-20);

14. Interpersonal functioning (Inventory of Interpersonal Problems; IIP-64);

15. Direct and indirect costs (Trimbos/iMTA questionnaire for Costs associated

with Psychiatric Illness; TiC-P);

16. Working alliance (Working Alliance Inventory-Short Form; WAI-SF);

17. Client Satisfaction (Client Satisfaction Questionnaire; CSQ);

18. Personality (NEO-FFI);

19. Posttraumatic Stress symptoms (Posttraumatic Symptoms

Diagnostic scale; PDS)

20. Negative Life Events (Brugha)

21. Victimisation during the Covid 19 measures in spring 2020.

22. Psychological complaints due to the Covid 19 measures in spring 2020.

Characteristics such as sex, age, level of education, ethnicity, living

conditions and area, early victimisation and (sexual) maltreatment in the youth

(Childhood Trauma Questionnaire; CTQ-SF), will be used as mediators and

moderators.

Study description

Background summary

Depressed patients are 3.8 times more likely to be a victim of a violent crime in comparison to people in the general population. In a sample of 104 depressed outpatients, 34% were victim of at least one violent crime in the previous 12 months (Meijwaard et al., 2015). Depressed patients seem to be particularly vulnerable to violent crimes such as assault, threat and sexual crimes. The high victimisation rates found in depressed patients, combined with the notable prevalence rates of depression, underline the relevance of an intervention aimed at reducing victimisation in depressed patients, which does not yet exist.

Apart from previous victimisation, symptom severity and depression (Cougle, 2009; Teasdale, 2009; van Weeghel, 2009; Iverson, 2011), emotion regulation (ER) is assumed to be an underlying mechanism in victimisation (i.e., Marx et al., 2005). Emotion dysregulation (ED) is considered to be a consequence of and a risk factor for both victimisation and depression. The influence of ED on victimisation seems highly relevant for patients with depression. Many studies have shown that symptom severity of (past) depression is likely to coincide with ED (Campbell-Sills, 2006; Garnefski & Kraaij, 2006; Ehring, 2008). Depressed patients report increased ER problems such as experiencing, differentiating, attenuating and modulating emotions as compared to healthy controls (Brockmeyer, 2012). Therefore, the addition of an emotion regulation training to regular treatment is expected to reduce victimisation risk in previously victimized depressed patients.

Study objective

Since previous findings underline the hypothesis that ER may play a key role as an underlying mechanism leading to (re)victimisation, we suggest that a clinical intervention aimed at enhancing ER skills may decrease (re)victimisation risk. Therefore, in this study we want to examine the effectiveness of the addition of online Emotion-Regulation Training (ERT) to Treatment As Usual (TAU) in reducing future victimisation in high risk outpatients suffering from a depression, who have been violently victimized at least once in the past three years. Patients will be randomly allocated to TAU or to TAU complemented with ERT. We expect patients in the experimental

condition, who receive additional ERT training, to be more resistant to future victimisation as compared to patients in the control condition.

Study design

A 2-arm randomized controlled trial examining the (cost-)effectiveness of ERT added to standard treatment (TAU), as compared to standard treatment alone in outpatients with a depression. Patients in both the control and experimental condition receive TAU. Patients in the experimental condition also receive ERT. Assessments will take place at baseline, 8 and 14 weeks after start of treatment, and 6, 12, 24 and 36 months after baseline. An additional questionnaire will be assessed in August 2020 regarding the Covid-19 measures. The primary endpoint is the total number of violent crime occurrences during the three years follow up, as measured with the Integrale Veiligheidsmonitor (IVM). An economic evaluation will be conducted alongside the RCT.

Intervention

The experimental intervention will consist of an abbreviated and adapted version of the ER skills training (ERT, a short version of the Affect Regulation Training [ART]) as developed by Berking (2007). ERT will be provided as an online training and will be added to Treatment As Usual. ERT is a highly structured intervention that enhances ER skills and contains techniques from CBT, dialectical behavioural therapy, emotion-focused therapy, mindfulness-based interventions, self-compassion trainings and problem-solving therapies. ERT starts with a thorough psycho-education of emotional reactions and seven neuroaffective vicious cycles that are considered important for long-term maintenance of negative emotions. Then, seven skills that are designed to interrupt these cycles are taught to the participants.In our abbreviated version, we will focus on four ER skills Non-judgmental awareness, Acceptance and tolerance, Identification of emotions and Modification of emotions. The selection of skills that we will focus on, is completely based on existing literature regarding emotion dysregulation in depression and victimization.

Study burden and risks

Burden:
Subjects will have to invest time when participating in this study. Subjects in the experimental condition will need to invest more time than subjects in the control condition. On the other hand, they will participate in an extra intervention of which we assume that it improves emotion regulation skills and reduced vulnerability for victimisation. A more specific overview of time investment for this study can be found in section E2.
Participants in both conditions will complete questionnaires at baseline (2 assessments), 8 weeks, 14 weeks and 6 months after start of treatment and 12,

24 and 36 months after randomisation. An overview of these questionnaires can be found in section K1.

Risks:
There are no anticipated risks involved in participating in this research.

Contacts

Public
VUmc.

De Boelelaan 1118
Amsterdam 1081 HZ
NL
Scientific
VUmc.

De Boelelaan 1118
Amsterdam 1081 HZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

(1) Primary diagnosis of a Major Depressive Disorder according to DSM-IV criteria, or a secondary diagnosis of a Major Depressive Disorder next to a primary anxiety disorder (other than obsessive-compulsive disorder) according to DSM-IV criteria.
(2) Indicated for outpatient psychotherapy aimed at a depression or anxiety

disorder
(3) Having been victim of at least one violent crime (such as a threat, assault or sexual abuse) during the past three years;
(4) Access to a computer or tablet with internet connection;
(5) Aged 18 years or older.

Exclusion criteria

(1) Psychotic symptoms, according to the DSM-IV, as measured with section L of the M.I.N.I.;
(2) Current high risk for suicide requiring intervention;
(3) Insufficient understanding of the spoken and written Dutch language;
(4) Bipolar disorder, according to section D of the M.I.N.I.;
(5) Substance dependency that requires treatment;
(6) Obsessive-compulsive disorder, according to the DSM-IV.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-07-2016
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	Online Emotion Regulation Training

Registration:	No

Ethics review

Approved WMO Date:	22-02-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-07-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-08-2020
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

ID: 26288
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL54940.029.15

Register	ID
OMON	NL-OMON26288