The efficacy of Inquiry Based Stress Reduction (IBSR) for depression, a randomized clinical trial.

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The primary goal of this research project is to improve mental healthcare for patient suffering depression in the Netherlands as well as in other countries. The outcomes can help increase the quality of life for a large group of people and it can...

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

Summary

ID

NL-OMON47093

Source
ToetsingOnline

Brief title
IBSR for depression

Condition

- Mood disorders and disturbances NEC

Synonym
Depression, Melancholy, Sadness

Research involving
Human

Sponsors and support

Primary sponsor: FortaGroep
Source(s) of monetary or material Support: Ministerie van OC&W,FortaGroep

Intervention

Keyword: CBT, Depression, IBSR, RCT

Outcome measures

Primary outcome

The primary outcome measure of this study is the severity of the depressive symptoms measured with the BDI-II-NL. The score-range of this 21-item questionnaire is 0 to 63. Higher scores reflect more severe depressive symptoms. Several studies have shown that the BDI-II is a strong screening measure for depression (Beck, Steer, & Brown, 1996; van der Does, 2002; Whisman, Perez, & Ramel, 2000). It is a widely used instrument measuring the severity of depression. In 1998 the BDI had already been used in over 2000 studies (Richter, Werner, Heerlein, Kraus, & Sauer, 1998).

Secondary outcome

Secondary outcome measures (see the research proposal in the appendix for more information on the listed questionnaires):

General psychological distress

SQ-48: Symptom Questionnaire 48 (Carlier, Schulte-Van Maaren, Wardenaar, Giltay, Van Noorden, Vergeer, & Zitman,2012).

48 multiple choice items

Quality of life

SF-36: Short Form Health Survey (Ware & Sherbourne, 1992). Dutch version by Aaronson, et al. (1998).

36 multiple choice items

Acceptatie

AAQ-II: Dutch version (Jacobs, Kleen, de Groot, & A-Tjak, 2008) of the

Acceptance and Action Questionnaire-II (Bond, et al., 2011).

10 multiple choice items

Dysfunctional Attitudes

DAS-A-17: The 17-item Dutch version (Leefregelvragenlijst; de Graaf, Roelofs, &

Huibers, 2009) of the Dysfunctional Attitude Scale (DAS-A; Weissman, 1978)

17 multiple choice items

Stait and trait anxiety

ZBV: Zelfbeoordelingsvragenlijst (van der Ploeg, 2000).

40 multiple choice items

Presence of an Axis I disorder (DSM-IV-TR: APA, 2000)

SCID-I: The Structured Clinical Interview for DSM-IV Axis I Disorders (Dutch

version: van Groenestijn, et al., 1998).

Completion time variable

Paralingual aspects of speech

Analysis with PRAAT (Boersma & Weenink, 2018) of the recordings of the therapy

sessions: Pitch, pitch variability and speech rate

Study description

Background summary

Background (see the research proposal in the appendix for a list of cited articles)
Depression is a serious illness. In the Netherlands 18.7% of the population experiences an episode of depression in their lifetime and each year 5.2% of the Dutch population suffers from a depressive disorder (de Graaf, ten Have, & van Dorsselaer, 2010). About half of all patients have episodes that last shorter than 3 months (Spijker, et al. 2002). For up to one-third of all patients that period is longer than 2 years (Keller, 2001). In 15-20% of all cases patients develop a chronic depression (Eaton, 2008). In the Netherlands 58.5% of patients with a clinical depression receive health care (GGZ Nederland, 2013). The annual costs in the Netherlands are almost 3 billion of which a third are cost for the treatment of depression (Slobbe, Smit, Groen, Poos, & Kommer, 2011; de Graaf, Tuithof, Dorsselaer, & ten Have, 2011). The costs of depression in the Netherlands in 2011 were calculated to be 164.000 Disability Adjusted Life Years (DALY's; Poos, Gool, & Gommer, 2014). Using the DALY, unipolar major depression was the third leading burden of disease worldwide in 2004 and the World Health Organisation estimated that it will be the leading cause of disease burden worldwide by 2030 (Lépine & Briley, 2011).

Psychotherapeutic interventions
Of the psychotherapeutic interventions for depression the most researched and empirically validated are cognitive behavioural therapy (CBT) and Interpersonal psychotherapy (IPT; Cuijpers, van Straten, Andersson, & van Oppen, 2008; Lemmens et al., 2011, Cuijpers et al., 2011). Both psychotherapies are empirically-supported psychological therapies for the treatment of patients with a mood disorder (EST's; Hollon & Ponniah, 2010). Cuijpers, et al. (2013) calculated the effect size of CBT for depression based on 115 RCT studies and found (after correction for possible publication bias, for which they found strong indications) a g of 0.53. Another way of reviewing the effects of CBT for depression is looking at remission rates. Schindler, Hiller, and Witthöft (2011) found in a sample of 338 depressive patients treated with CBT in an university outpatient clinic that 48% remitted and 5.7% deteriorated. When restricted using the Reliable Change Index (RCI; Jacobson & Truax, 1991) as described by Seggar, Lambert, and Hansen (2002) the remission rate dropped to 43.2% and 3.2% deteriorated. Gibbons et al. (2010) found that 61% of their outpatient sample of 217 depressed patients improved and 8% deteriorated significantly using CBT. The recovery rate was 45% using RCI as described by Jacobson and Truax (1991) when only those patient were included that scored

above the cutoff before treatment (36% of the complete sample). Reaching remission is important, because patients not reaching full remission are 5 times more likely to relapse than fully remitted patients (Judd et al., 2000), which increases costs.
A significant number of depressive patients treated with CBT who reach remission or recovery show relapse or recurrence of the depression. Vittengl, Clark, Dunn, and Jarrett (2007) performed a meta-analysis and found that the relapse/recurrence rate in patients treated in the acute phase (with the goal of reducing depressive symptoms and producing initial remission) was 29% within the first year and 54% within two years. After continuation phase treatment was added (treatment applied to sustain remission and reduce the probability of relapse/recurrence) the average relapse percentage was between 10 and 12% at post-treatment and between 40 and 42% at follow-up (average duration between 114 and 153 weeks). The numbers above show that CBT treatment is good, but insufficient in terms of remission and relapse. There is need for better treatments or improvement of existing treatments. In this research project we will test the efficacy of a relatively new and promising treatment method, Inquiry Based Stress Reduction.

Inquiry Based Stress Reduction (IBSR), an introduction
IBSR is a psychological treatment method, focusing on a structured process of self-inquiry. It is considered as a way of identifying and investigating one's thoughts in order to alleviate suffering. IBSR is a process developed in 1986 by Byron Katie (Katie, 2002). The main premise is that the only time that people suffer emotionally is when they believe a thought that argues with reality. The method contains a structured way of identifying and inquiring thoughts. Inquiry is done by asking four questions and turning a thought around to opposite statements (a broader explanation is done in the theoretical background section). IBSR has been practiced by people in more than 30 countries (www.thework.com). Katie trained thousands of people in IBSR through her school. The IBSR method is estimated to be used by hundreds of psychologists in the Dutch Health care system (derived from the number of psychologists trained by van Rhijn, the fourth author). The Dutch Association of Behavioural Therapy and Cognitive Therapy (VGCt) allows students to make use of IBSR-courses in their training to become a registered cognitive behavioural therapist. Other specialized psychological associations, such as the Federation of Health Psychologists (FGzP), the Dutch Association of Psychologists (NIP) and the Association of Educationalists in the Netherlands (NVO), allow IBSR-courses to be used for recertification purposes.
IBSR has been proven to reduce a range of psychological symptoms, including depressive symptoms (Nye, 2011; Gaanderse, 2011; Leufke, Zilcha-Mano, Feld, & Lev-ari, 2013, Lev-ari, Zilcha-Mano, Rivo, Geva, & Ron, 2013; Smernoff, Mitnik, & Lev-ari, in press). The effects of IBSR are assessed using studies with a waiting list control group (Nye, 2011; Lev-ari & Arber, 2014) as well as in a study which used a waiting list control group and a group which received an alternative intervention (Gaanderse, 2011). IBSR is a promising treatment method. We stress the need for a well powered randomized clinical trial (RCT)

to test the efficacy of IBSR in a sample of depressed patients. We want that depressive patients have the opportunity to gain from the best possible treatment. In line with the guidelines described by Chambless and Ollendick (2001) we will test the effectiveness of IBSR in comparison with an EST. In this RCT we choose CBT instead of IPT as control treatment for IBSR, given our work setting. CBT is the most common therapy our colleagues are trained in and work with. This has an additional advantage because we will be able to do a mediation analysis to test the presumed underlying working mechanisms of IBSR and CBT and the presumed difference between both methods.

Emotion, cognitive change and voice acoustics
There is evidence that dysfunctional attitudes in depression are mood-state dependent (Segal, Kennedy, Gemar, Hood, Pedersen & Buis, 2006). In other words, a sad mood triggers dysfunctional attitudes which triggers a depressive response. Therefore it is plausible that in order to change dysfunctional attitudes during psychotherapy, these attitudes need to be accessible by experiencing the triggering emotions during the therapy sessions. A method to examine different emotional states is by analysing the paralinguistic aspects of speech. Emotional states such as fear, anger, or sadness activate the stress system and influence muscle tones. Vocalisation is a product of different muscle tones in the chest and the throat which influence different kinds of paralingual aspects of speech, for instance pitch, pitch range, pitch variability, loudness and rate of speech (Darby, 1981; Scherer 1986).

This research project is a collaboration between FortaGroep and the Erasmus University Rotterdam. We want to assess the effects of IBSR and CBT on depressive (and other psychological) symptoms in a sample of 88 depressive patients, on short and longer term. Furthermore, we will investigate the underlying mechanisms of change of IBSR and CBT for depression and test their specificity. The treatments will be performed between 2015 and 2018. Experts in the field of IBSR treatment for depression and CBT treatment for depression are involved in the project. This unique collaboration of psychologists and researchers aims to perform high quality research according to international standards. If IBSR for depression is proven to be superior to CBT treatment, we will actively share the information on IBSR to make the therapy available for depressive patients all over the Netherlands. A better treatment, which results in larger symptom reduction, decreases symptoms in more patients and is better in preventing relapse, will increase wellbeing for a substantial proportion of the Dutch society.

Main questions
Is IBSR an effective intervention for outpatients suffering depression compared to treatment as usual (CBT) in reducing depressive symptoms measured by the BDI-II-NL, on short term (post-treatment)? And on long term (after 1 and 2 years)?

Hypothesis
Main hypothesis
In treating an outpatient sample of depressive patients IBSR in relation to CBT is:
more effective in reducing depressive symptoms (between pre-treatment and post-treatment/follow-up)
more effective in preventing relapse (measured with the BDI-II-NL using the RCI)
more effective in reaching absence of clinical depression (between pre-treatment and post-treatment)

There is a relation between baseline measures of paralingual aspects of speech (pitch, pitch variability and speech rate) and depression severity as measured with the BDI-II-NL.
Paralingual aspects of speech (pitch, pitch variability and speech rate) change over the course of psychotherapy.
Changes in paralingual aspects of speech during the course of psychotherapy are associated with diminishing in depressive severity
There is a difference between CBT and IBSR in eliciting emotions as measured by paralingual aspects of speech (pitch, pitch variability and speech rate) and these differences are related to the diminishing of depression severity as measured with the BDI-II-NL.
The amount of emotions of the therapist are related to therapy outcome
There is a relation between the emotional responses (as measured by pitch, pitch variability and speech rate) of the therapist and therapy outcome.

Study objective

The primary goal of this research project is to improve mental healthcare for patient suffering depression in the Netherlands as well as in other countries. The outcomes can help increase the quality of life for a large group of people and it can decrease costs for mental healthcare and reduce the indirect costs of depression. In this research project we want to assess the effectiveness of a relatively new and promising treatment, IBSR.

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more effective in reaching absence of clinical depression (between

pre-treatment and post-treatment)

An important subquestion for us is:*
Is the underlying mechanism in IBSR different from CBT?

Our sybhypothesis to this question are:
The underlying mechanism in IBSR is different from CBT
A decrease in depressive symptoms in the IBSR-group is mediated by an increase in acceptance.
A decrease in depressive symptoms in the CBT-group is mediated by a decrease in dysfunctional attitudes.
*more subquestions and hypothesis can be found in the research proposal in the appendix

There is a relation between baseline measures of paralingual aspects of speech (pitch, pitch variability and speech rate) and depression severity as measured with the BDI-II-NL.
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Study design

To asses our research questions in the best possible manner we chose to set up a randomized clinical trial (RCT). This design (RCT) is not only the standard for the evaluation of effectiveness of psychiatric treatments (Schulz, 2010), but is also very valuable in studying mechanisms of therapeutic change (Haaga & Stiles, 2000; Nock, 2007). Because we will assess the effects of IBSR in relation to an effective treatment, CBT, we expect a small to medium effect size.

Intervention

The intervention in the experimental group is IBSR. In the control group the intervention is treatment as usual, CBT.

The IBSR intervention consists of psycho-education on depression and the influence of thought on how we feel. After that dysfunctional thoughts are

identified in a structural manner. The next step is to inquiry those thoughts using a structured protocolized set of questions and turning a thought around to opposite statements (see the research proposal in the appendix for a broader explanation). The worksheet that are used can be found in the appendix. Participant will perform homework assignments which mainly consist of inquiring thoughts. During the endfase of the treatment a plan for the future will be made which consists of the discoveries the participant made during the treatment. This is for the purpose of relapse prevention.

Study burden and risks

Participants will have two intake appointments with tho different psychologists and a treatment of 16 sessions. The treatment can be shorter (the data of a participant will be included when he receives at least 5 therapy sessions and the termination of the treatment is in accordance with therapist advice). The burden of having two intake appointments and the treatment sessions is identical to the current procedure when someone is referred with a depressive disorder.

Participant however will have an extra burden when participating, such as the administration of the SCID-I during the intake phase and the filling of additional questionnaires. During standard procedure Routine Outcome Measurements (ROM's) are performed using the SQ-48 (48 multiple choice items) at intake, evaluation and the end of the treatment. The questionnaire specific to this research project which administration is 'extra' are the BDI-II-NL (21 multiple choice items), the SF-36 (36 multiple choice items), the ZBV (40 multiple choice items), the AAQ (10 multiple choice items) and the DAS (17 multiple choice items).
The SCID-I, the SF-36 and the ZBV are administered at intake, post-treatment and at the follow-ups after 1 and 2 years. The BDI-II-NL, the AAQ and the DAS are administered at intake, the 4th session, the 8th session, the 12th session, post-treatment and at the follow-ups after 1 and 2 years.

There is no indication of higher risks because of this research project. Both treatments are currently in use for treating patients with a depression. Earlier research showed no indications for hinger risks. All sessions are with professional psychologists (who receive supervision). In case symptoms rise or there is a crisis situation (such as when a patient becomes suicidal of there is another serious disturbance which obstructs treatment in accordance with the treatment protocol) dropout will take place and adequate care will be provided. It is possible that participants receive suboptimal treatment when the experimental treatment is inferior to the standard treatment. On the other hand, there is the possibility that they, in accordance with our expectations, will receive a better treatment and that they will be the first to profit from the 'new' treatment.

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. Patients will be eligible to participate if they meet the DSM-IV (APA, 2000) criteria for a major depressive disorder, mild to moderate, as the principal diagnosis on the Structured Clinical Interview for DSM-IV Axis I Disorders * Dutch version (SCID-I; van Groenestijn, et al., 1998).
2. Aged 18 years and older
3. Not making use of other treatment for depression at the time
4. No history of psychotherapy in the last year
5. No medication for depression or unchanged dosage of medication during the last two months
6. All participants must be willing to refrain from engaging in additional psychological treatments or making changes to their medication status during the course of the trial. (changes in medication dosage will result in dropout)

7. All participants are required to have sufficient knowledge of the Dutch language

Exclusion criteria

Patients will only be excluded if they:
1. have active suicidal intent (which is asked during the interviews and further operationalized with help of the ninth item in the BDI-II-NL at pre-treatment: If patients marked the statement **I would kill myself if I could**, they are classified as being at risk of suicide),
2. meet the DSM-IV-TR criteria for severe major depressive disorder, psychotic disorder, or bipolar disorder,
3. suffer from mental impairment or neurocognitive disorders such as Alzheimer,
4. have substance abuse requiring specialist treatment,
5. have no time for homework.

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):	15-10-2015
Enrollment:	88
Type:	Actual

Ethics review

Approved WMO

Date:	08-09-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-09-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL51699.078.15