Imagery Rescripting with or without preceding Cognitive Restructuring: a randomized clinical trial

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

Summary

ID

NL-OMON46092

Source
ToetsingOnline

Brief title
Imagery Rescripting with or without preceding Cognitive Restructuring

Condition

- Other condition
- Personality disorders and disturbances in behaviour

Synonym
depression, fear problem, problems with personality

Health condition

stemmingsstoornissen en angststoornissen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cognitive Restructuring, Imagery Rescripting, Psychopathology, Treatment

Outcome measures

Primary outcome

The difference between the encapsulated belief scores at pre-test, post-test

and one week follow up are the primary outcome measures. A scale ranging from 0

(not at all) to 100 (extremely) is used.

Secondary outcome

Change in vividness and distress of the aversive childhood memory addressed is

measured on a scale ranging 0 to 100.

To examine the reduction of overall symptomatology The Brief Symptom Inventory

(BSI) is included as a secondary parameter.

To check whether different emotional states are triggered throughout the study

the Modified Differential Emotions Scale (mDES) will be used.

During the one-week-follow-up the experience of CR and ImRs is investigated

with a qualitative interview.

Study description

Background summary

Previous research has shown treatment efficacy of imagery rescripting (ImRs) for several disorders both as part of a treatment package and as a stand-alone treatment. This technique, which is focused on imagining aversive memories and

changing its course fulfilling the needs of the individual, is used to change the meaning or encapsulated belief and emotional valence people deduce from childhood memories of adverse events. Additionally, ImRs is thought to alter the vividness and distress of this memory. However, little is known regarding necessity of specific ingredients for the ImRs to be efficient. For instance, in some protocols within a treatment session ImRs is preceded by cognitive restructuring (CR) whether other protocols only provide ImRs. CR is a common therapeutic technique aimed at challenging maladaptive beliefs in a verbal way. Some researchers have suggested that it is a necessary prerequisite for ImRs to be successful as it prepares an adult perspective in phase 2 of ImRs (where the adult intervenes in the averse childhood memory). However, others argue against this by claiming that ImRs is powerful enough as a stand-alone technique and CR is not needed to add to the ImRs procedure. The validity of CR as a preceding element in the ImRs protocol has not been systematically studied yet.

Study objective

This research project examines whether there are differences in effects between application of ImRs preceeded by CR and ImRs as a stand-alone treatment technique on the so-called encapsulated beliefs, cognitive beliefs based on the aversive childhood memory. Secondary aims focus on differences in effects between aforementioned conditions with respect to the memory vividness and distress of the aversive childhood memory addressed, overall symptomatology, anxiety and depression symptoms, concepts related to positive psychology such as self-compassion, patient experiences of the techniques and differences of which emotional states are triggered and with what intensity.

Study design

This study is a randomized placebo-controlled clinical trial with a single session intervention and a one-week follow-up session.

Intervention

This research project will employ the following conditions focused on the application of ImRs on an aversive childhood memory 1) CR preceding ImRs, 2) therapist attention placebo and ImRs 3) double therapist attention placebo. The therapist attention placebos are common treatment elements not to be effective to treat the complaints, but will be used as a placebo for therapist attention of CR and ImRs.

Study burden and risks

There are no direct risks involved in the interventions. Every participant will receive or already receives their regular treatment, thus none of the participants will be without adequate treatment for their condition.

Participants can get emotional during retrieval of the aversive memories. The benefit is some reduction of symptoms. Assessment 1 takes approximately 2,5 hours, including a 10-minute break. Assessment 2 has a duration of max. 45 min.

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

- Meet the diagnostic criteria of a one or more diagnoses according to the DSM IV either/and on axis I (clinical disorders) and II (personality disorders)
- Free of medication or at least 2 months of stably set medication and maintaining the same dosage during participation of this study
- Age between 18 and 65 years
- IQ above 80

- Able to read and write in Dutch

Exclusion criteria

- Meet the diagnostic criteria of posttraumatic stress disorder an autism spectrum disorder or psychotic disorder accordingaccording to the DSM IV
- Suicidality or other self-damaging behaviour or damaging behaviour towards others
- Habitual use of benzodiazepines. In case of incidental use of benzodiazepines or betablockers participants are asked to refrain from this medication at the testing day. Participants using SSRI*s, TCA*s, or antipsychotic medication are asked to keep their medication stable till after the one week follow-up.
- Treatment experience with CBT
- Treatment experience with ImRs

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	14-10-2016
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	01-06-2016

Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-06-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL56227.068.15

Study results

Date completed: 05-06-2019

Summary results
Trial ended prematurely