Cognitive bias modification for patients with cluster-C personality problems (CBM-I ST) a pre-therapy

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Primary Objective: * Is CBM-I successful in changing the cognitive bias in patients with cluster-C personality disorders or personality disorder NOS?Secondary Objective(s): * Will patients following CBM-I show a significant reduction in symptoms and...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Personality disorders and disturbances in behaviour
Study type	Interventional

Summary

ID

NL-OMON38948

Source
ToetsingOnline

Brief title
CBM-i ST

Condition

- Personality disorders and disturbances in behaviour

Synonym
cluster C personality problems (avoidant, dependent), obsessive-compulsive

Research involving
Human

Sponsors and support

Primary sponsor: G-kracht psychomedisch centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Wordt betaald door de onderzoeker zelf

Intervention

Keyword: CBM-i, cluster C personality problems, schema therapy

Outcome measures

Primary outcome

The main parameter within this research is the score on the daily measurements; the PANAS and VAS-cluster C. It is to be expected that patients with personality disorder benefit by following the / computer task training. The scores are expected to be significantly lower on the PANAS and the VAS-cluster C - after the intervention - in comparison to the control condition (baseline condition) .

Secondary outcome

The second parameters are the modi measured in accordance with the Scheme Mode Inventory (SMI-2), the Schema Questionnaire (SQ), the Global Severity Index measured with the SCL-90, findings of the Assessment of the DSM-IV Personality Disorders (ADP-IV), the Inventory of Interpersonal Problems Circumplex (IIP-32 items). To measure the predictor mental flexibility the subscales SOM and PSY of the Dutch Short MMPI (NVM) and the BRIEF-A will be used.

Study description

Background summary

Rationale: The proposed study investigates whether a Cognitive Bias Modification Imagery (CBM-I) intervention will change cognitive biases of patients with cluster-C personality disorders or personality disorder NOS in a more positive way. It is hypothesized that they will end up with having a more positive perspective on who they are, on others and the world around them. Objective: Positive change in cognitive bias and secondary a positive change in

symptomatology.
Study design: Multiple baseline design.
Study population: 24 patients with Cluster C personality or personality disorder NOS.
Intervention: After a variable baseline period subjects will receive CBM-I via a computer on a daily bases during 2 weeks.
Main study parameters/endpoints: The main parameter within this research is the score on the daily measurements; the VAS-MCB and the PANAS. It is to be expected that patients with personality disorder benefit by following the computer task training. The scores are expected to be significantly lower on the VAS-MCB and the PANAS - after the intervention - in comparison to the control condition (baseline condition).
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Benefits of this study will be, if successful, that an extra therapeutic tool can be added to Schema therapy for cluster C patients. It could have the potential to become a first step in ST to treat this patient group after which one can decide to proceed or not with a longer term ST after this first step intervention. The risks of this study are assessed as low. It can be tiring to fill out the questionnaires and other assessment instruments and perhaps boring to do the computer task, but no other negative reactions are to be expected.

Study objective

Primary Objective:
* Is CBM-I successful in changing the cognitive bias in patients with cluster-C personality disorders or personality disorder NOS?

Secondary Objective(s):
* Will patients following CBM-I show a significant reduction in symptoms and personality problems?
* Can mental flexibility predict successfulness in changing cognitive bias in patients who have underwent the CBM-I?

Study design

Multiple baseline case series design (also called stepped wedge or staggered baseline design) using an A-B design with follow up.
Control condition = (randomized) variable waiting time in baseline condition

Start

-Written informed consent
-Administration of sociodemographic measures, MINI and SCID-II
-Verification of eligibility

Measure 1: SQ, SMI-2, SCL-90, ADP-4, IIP, NVM, BRIEF-A

Max. 2 days

Baseline Phase (baseline is variable):
Daily ratings: PANAS and VAS at home each day for a minimum of 2 weeks and a maximum period of 8 weeks

Measure 2: SQ, SMI-2, SCL-90, ADP-4, IIP

Face-to-face treatment individual orientation session:
*Participants were instructed and trained in generating mental imagery with a particular emphasis on using a field perspective and not engaging in verbal processing, before completing a first session of CBM-I with the researcher.
*First session of CBM-I with the researcher

Max. 2 days

Intervention Phase: 2 weeks
*Complete a session of CBM-I independently each day at home for 14 days
*Daily ratings: PANAS and VAS each day at home for 14 days

Measure 3: SQ, SMI-2, SCL-90, ADP-4, IIP

Max. 2 days

Individual interview about experience patients of completing the CBM-I

4 weeks

Follow up phase: SQ, SMI-2, SCL-90, ADP-4, IIP, Feedback interview question guidev1.3f 2011.05.11 (Blackwell & Holmes, 2010)

Intervention

CBM-I-computer task
During the 2 weeks of CBM-I training patients will receive 64 positive paragraphs each day (total amount of 896 positive paragraphs). The positive training paragraphs are targeted at the 5 primary schema*s and the primary schema domain which are; 1. Abandonment/ instability (AB), 2. Mistrust/ Abuse (MA), 3. Emotional deprivation (ED), 4. Defectiveness / shame (DS), 5. Social isolation / alienation (SI) and Disconnection and rejection (DR). Each paragraph is designed to have a positive outcome at the end. For example (Abandonment/ instability): *Your boyfriend comes home and looks worried. He says that he has to go away for a couple of weeks for work. He then says that he only will go if you will go with him.* To focus participants on generating

imagery (Holmes et al., 2006), after each training they rated the vividness of their imagery (*How vividly could you imagine the situation than was described?*) on a 5-point scale (1 not at all and 5 very). Each session starts with a neutral practice item of which the vividness is not rated and not recorded.
The positive paragraphs are organized into eight blocks of eight paragraphs. Short self-paced breaks are allowed between the blocks, during which task instruction reminders are displayed. The order of
presentation of the paragraphs is randomized for all participants..
Half of these 896 positive paragraphs will be read in a female voice and the other half will be read in a male voice. Paragraphs will last 10-15 seconds and are digitally recorded. They will be stereophonically presented via headphones, which will be borrowed to the participants for the purpose of this study. The CBM-I will be presented via an Internet programme called SOTO which is developed by the Faculty of Psychology and Neuroscience of the Maastricht University.

Study burden and risks

Benefits of this study will be, if successful, that an extra therapeutic tool can be added to Schema therapy for cluster C patients. It could have the potential to become a first step in ST to treat this patient group after which one can decide to proceed or not with a longer term ST after this first step intervention. The risks of this study are assessed as low. It can be tiring to fill out the questionnaires and other assessment instruments and perhaps boring to do the computer task, but no other negative reactions are to be expected.

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

Cluster C personality disorder, able to participate for three months, motivated to participate for a computertask, IQ heigher dan 80, able to read, speak, understand, write in Dutch language, able to work with a computer, having a computer at home with internet connection.

Exclusion criteria

Lifetime psychotic disorder other dan brief psychotic disorder, substance dependence needing detox, ADHD, (subthreshold) Narcissistic personality disorder or Anti-social personality disorder, serious medical illness, previous schema therapy for more than three months.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-01-2014
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	12-11-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL46102.058.13