Shifting the interpretation bias and attention bias with an online training in borderline personality disorder

Published: 07-04-2022
Last updated: 28-09-2024

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

Summary

ID

NL-OMON51684

Source
ToetsingOnline

Brief title
BIAS

Condition

- Personality disorders and disturbances in behaviour

Synonym
borderline personality disorder

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Centraal (Amersfoort)
Source(s) of monetary or material Support: interne gelden

Intervention

Keyword: Attentionbias, Borderline personality disorder, Interpretationbias, Training

Outcome measures

Primary outcome

Primary outcome measures:

- Effectiveness of the IBT: the threshold on the continuum from an angry to happy face on day 1 is compared to the threshold measured on day 7

- Effectiveness of the ABT: the mean reaction time for finding the happy face among angry faces within the premeasurement on day 1 is compared to the mean reaction time for finding the happy face among angry faces within the postmeasurement on day 7

Secondary outcome

Secondary outcome measure.

- A shift on the questionnaire assessing quality of life between the premeasurement on day 1 and the follow-up measurements on day 7, after one month and after three months.

- A shift on the questionnaire mapping perceived social support between the premeasurement on day 1 and the follow-up measurements on day 7, after one month and after three months.

Study description

Background summary

Borderline personality disorder (BPS) is characterized by a predominant pattern of instability and problems with affect regulation, impulse control,

interpersonal relationships, and self-image (Lieb et al., 2004). BPS is a psychiatric disorder associated with high suicide rates, significant functional impairment, high prevalence of comorbid disorders, intensive use of treatments, and high costs to society (Lieb et al., 2004; Oldham, 2006).

Emotional dysregulation is the core of the disorder and all other symptoms follow from this disorder (Linehan, 1993 in Baer et al., 2012). This emotional dysregulation is again strongly associated with several maladaptive cognitive processes that are overly focused on negativity (Lis & Bohus, 2013). One of these maladaptive cognitive processes is called interpretation bias (IB), which is the tendency to interpret ambiguous scenarios or interactions as positive or negative (Holmes et al., 2011). Several studies have concluded that people with BPS have a negative bias when interpreting neutral or ambiguous faces (see, for example, Domes et al., 2008; Dyck et al., 2009; Wagner & Linehan, 1999). Another maladaptive cognitive process is attention bias (AB), which represents the tendency to focus or assign attention to certain types of emotional stimuli (Mathews & MacLeod, 2005). For example, in the case of BPS, a person has an attentional bias for negative emotional stimuli (Baer et al., 2012).

Given the finding that these maladaptive processes are at the core of the disorder and influence all other symptoms of BPS (Linehan, 1993 in Baer et al., 2012), it is important to shift these cognitive biases to a more positive interpretation. The current study builds on a previous study by Van de Pas (2020), in which participants completed an online training course to shift interpretive and attentional bias. The study was conducted on a group of healthy adult participants, where the goal was to obtain a more positive interpretation of faces and disconnect attention from negative cues. The results of this study indicated that the online training was effective in shifting both biases: the participants had a more positive interpretation of faces and a faster attention rate for happy faces over angry faces. Thus, the training appeared to be effective with healthy participants. In Van de Pas's (2020) study, all participants received the training, meaning there was no control group to test for effectiveness of the training. To replicate and demonstrate the effectiveness of these findings, this study will conduct an RCT within a non-clinical sample.

In addition, an RCT will be conducted within a clinical norm group, consisting of patients with borderline personality disorder who are in treatment at a mental health institution. Also within this clinical norm group, the effectiveness of the interpretation bias training (IBT) and attention bias training (ABT) will be investigated. The training in the clinical group will, just like the non-clinical group, be randomized controlled. This is to carefully examine the effectiveness of the training. Without a control group, a possible effect of the training may be linked by the treatment the patients are receiving in addition to taking the training. It is important to know that the effects are purely the result of the training and not a consequence of their treatment. The training being studied here is an "add-on" training, added to

the treatment-as-usual that patients with borderline personality disorder normally receive.

Finally, it is clinically relevant to investigate whether the shifting of the attention and interpretation biases also has an effect on the daily functioning of the patient. Therefore, a short questionnaire on quality of life (MHQoL), a questionnaire on social interactions (SSL-12) and a short questionnaire with some questions on how contact with others is perceived will be administered before the training, after the training, one month and three months after the training to give an indication of improvement in quality of life and social interactions.

Study objective

The purpose of the current study is to test the effectiveness of both trainings (IBT and ABT) in a non-clinical and clinical sample, with the future goal of making the training available to all patients with BPS.

The central objectives for this project:
1. To test effectiveness of interpretation-bias training (IBT) and attention-bias training (ABT) in a non-clinical sample.
2. Effectiveness of interpretation-bias training (IBT) and attention-bias training (ABT) tests in a clinical sample.
3. To investigate whether the trainings have an impact in daily life and daily interactions in the clinical sample.

The research questions for the research project are:
1. Is the IBT effective in shifting one's interpretation bias to a more positive interpretation of facial stimuli?
2. Is the ABT effective in shifting one's attention bias toward happy faces?
3. Do the IBT and ABT have a positive effect on a person's quality of life and social interactions?

Study design

Randomised Controlled Trial

Intervention

Interpretation Bias Training:
The goal of the training is to shift the interpretation bias toward a more positive interpretation of faces. Subjects are shown a face for a brief moment, after which they must indicate whether the face shows a happy or an angry emotion. They do this by keying in a "c" for a happy face and an "m" for an angry face.

On day 1 of the study, a pre-measurement is done. This measures where the boundary lies for a person between an angry and a happy face. On day 2 to day 6 the training starts with a pre-test to measure where the border lies for a test subject between an angry and a happy face at that moment. Based on that boundary, feedback is given in the training. The test subject is shown after each answer he gives whether this answer was correct.
In the experimental group, the feedback is based on a boundary that has moved two faces toward the happy face. This means that two faces that were perceived as angry in the pre-test are now referred to as happy in the feedback to the subject. In the control group, this boundary does not shift. The training will take place from day 2 to day 6 and will last 10 minutes each time. Per the training, one person's face will be used each time. In total there are four different persons whose faces are shown.

The post measurement is the same task as the pre-measurement, whereby the borderline between a happy and an angry face is measured again. For the pre- and post-measurement, a different face is used than during the training sessions. This is to investigate whether the effect can also be generalized to other stimuli.

Effectiveness of the IBT:
- The pre-measurement (day 1) will be compared with the score on the post-measurement (day 7). In the pre- and post-measurement other stimuli are used than those in the training tasks of day 2 to 6. The difference in threshold between day 1 and day 7 is used as a measurement of effectiveness, whereby it can be examined whether the training effects can also be generalized to other stimuli.

Attention bias training:
The goal of this training is to shift the attention bias toward happy faces rather than angry faces. The subject in the experimental condition is shown nine faces, where he has to click as quickly as possible on the happy face that is among eight angry faces. The control group, doing the placebo training, has to click as quickly as possible on the neutral face which is among eight angry faces. At the pre- and post-measurement, both groups are asked to click the happy face among the angry faces. The reaction times of the pre- and post-measurement will be compared. The training will take place from day 2 to day 6 and will last 10 minutes each time. These pre- and post-measurements will be done with different stimuli than those used in the training tasks on days 2 through 6 to investigate whether the results can be generalized to other face stimuli.

Effectiveness of the ABT:
- Measured by reaction times at the premeasurement and postmeasurement on days

1 and 7 (Attention bias assessment).

Study burden and risks

There is no risk to subjects.
There is slight cognitive load due to the training having to be done on several days at a computer. The training can be done from home, so there is no additional burden due to travel time.
There is also a slight burden due to filling out the questionnaires for this study (10 to 20 minutes per research moment).

Since this research is subject to the WMO, an exemption has been requested for a trial subject insurance.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

The patients in the clinical group are in treatment at GGZ Centraal, a mental health institution. They will be approached through GGZ Centraal. BPD has been determined in these patients with the SCID-5P. The non-clinical group will be approached through the SONA-system of Utrecht University. The patients and healthy individuals will be between 18 and 65 years old.

Exclusion criteria

Exclusion criteria for participants: Participants should not have any problems with their vision. In the non-clinical group, participants with a score above cut-off point on the BSL-23 will be excluded. In the clinical group, participants with acute psychotic symptoms, a neurological disease or being under influence of addictive substances will be excluded.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-09-2022
Enrollment:	92
Type:	Actual

Ethics review

Approved WMO Date:	07-04-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-10-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL80948.075.22