Investigating new process-focused treatments for posttraumatic stress disorder : attentional bias modification and mindfulness-based cognitive therapy

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Attentional bias modification in posttraumatic stress disorder: A randomized controlled trial

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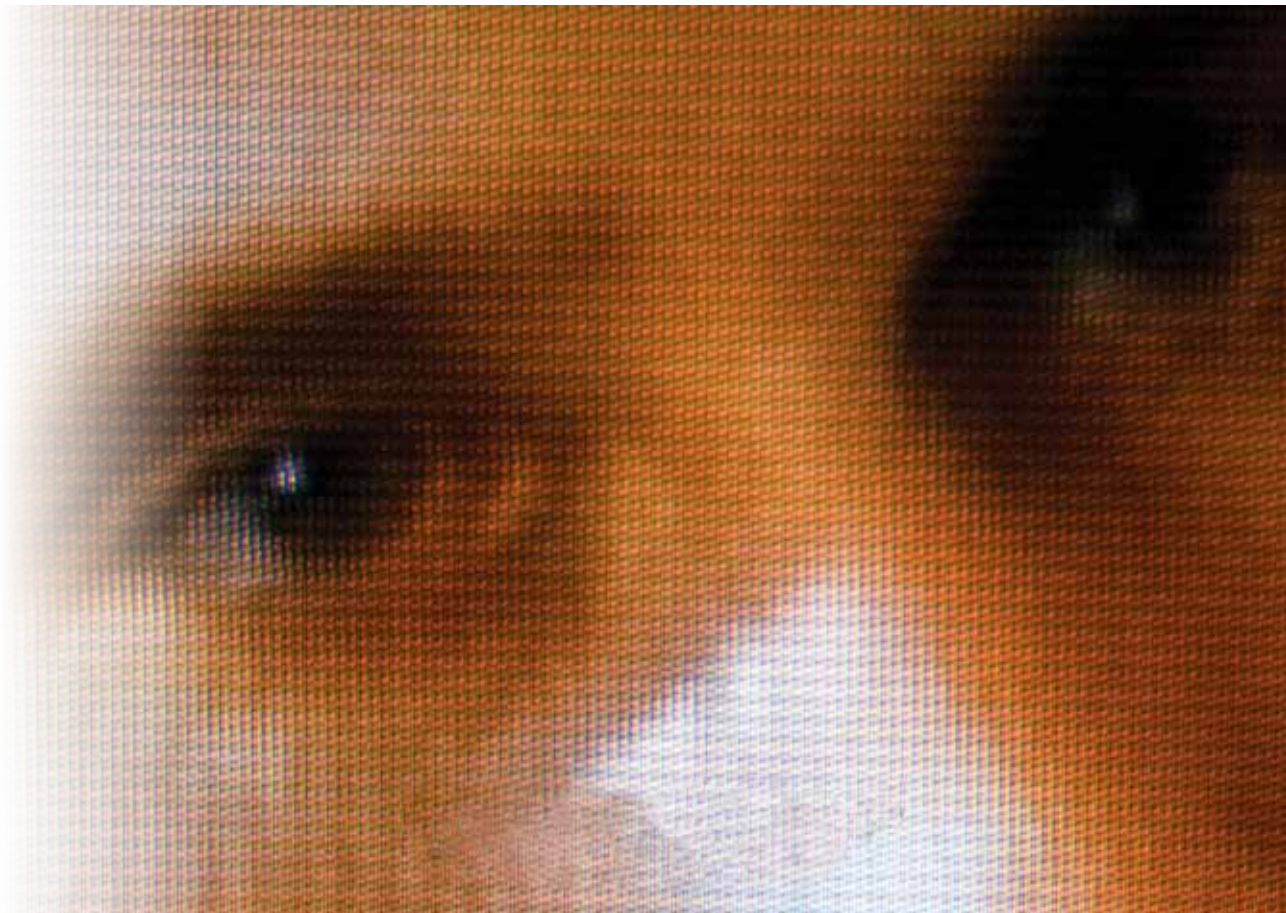


Abstract

Attentional Bias Modification (ABM) is a new treatment for anxiety disorders. Three randomized controlled clinical trials have shown positive effects of ABM in social anxiety disorder and generalized anxiety disorder. This study investigated the efficacy of ABM in outpatients (N = 102) with chronic posttraumatic stress disorder (PTSD) in a randomized controlled double-blind trial. ABM and control treatment consisted of eight 20-minute sessions over the course of three weeks. Symptoms and attentional bias were assessed pre- and post-treatment and at three-week follow up. ABM and the control treatment were equally effective in reducing the symptoms of PTSD. The effect sizes of the improvement (pre-post) were 0.66 for ABM and 0.46 for the control treatment, which is comparable to the effect sizes of pill-placebos in pharmacotherapy trials of chronic PTSD. Both treatments did not affect attentional bias. The acceptability and tolerability of ABM were moderate.
We conclude that this version of ABM is not an effective treatment of PTSD.

Introduction

A large body of evidence has shown that patients with anxiety disorders selectively attend to threatening information (Bar-Haim, Lamy Pergamin, Bakermans-Kranenburg, & Van IJzendoorn, 2007). This increased cognitive processing of threatening information may increase and maintain symptoms. (Mathews & MacLeod, 2002). Attentional Bias Modification (ABM) is a novel computerized treatment for anxiety disorders. It involves brief (approximately 20-minutes) sessions in which participants are trained to keep their attention away from the threatening stimuli to which they automatically attend.

Recent randomized clinical trials suggest that ABM may be effective in patients with anxiety disorders. A meta-analysis called the approach promising (Hakamata et al., 2010), but was based on the results of only three relatively small trials that have been conducted in clinical populations. Two of the ABM trials have examined the treatment's effectiveness in patients with generalized social anxiety disorder (SAD). The first study randomly assigned 36 patients to eight sessions of ABM or control training over the course of four weeks (Schmidt, Richey, Buckner, & Timpano, 2009). In the ABM condition, 72% of the patients no longer met diagnostic criteria for SAD, compared with 11% in the control group. These results were largely maintained at a four-month follow up. Another study in 44 SAD patients (Amir et al, 2009b) found 50% responders in the ABM condition and 14% in the control condition. These treatment gains were also maintained at four-month follow up. The third reported trial of ABM tested the treatment in 29 patients with generalized anxiety disorder (GAD) (Amir, Beard, Burns, & Bomyea, 2009a). Fifty percent of the participants in the ABM condition were classified as responders, compared with 13% in the control condition.

Since AB has also been observed in posttraumatic stress disorder (PTSD) (Bar-Haim et al, 2007; Williams, Mathews, & MacLeod, 1996) and ABM seems to generate positive results in anxiety disorders, the goal of the present study was to investigate the effects of ABM in patients with PTSD. The primary outcome was clinician-rated improvement of PTSD symptoms. The secondary outcome was self-reported symptoms. Attentional bias change was assessed as the potential mediator of treatment effects.

Methods

Design and randomization

We carried out a double-blind randomized controlled trial, comparing a three-week attention training program with a control treatment. The randomization was done using a computerized randomization sequence of permutated blocks of 20 patients and was coordinated by a person independent of the study. All researchers, assessors, hospital staff and patients remained blind to treatment condition until completion of the project.

Participants

Patients were recruited while they were on the waiting list for treatment at a mental health care department for PTSD. Inclusion criterion was diagnosis of chronic PTSD (duration at least three months). Exclusion criteria were a psychotic disorder (lifetime); alcohol or drug dependency (current); deficits in motor skills prohibiting the use of a computer keyboard; color blindness. Participants also had to be able to complete the measurements in Dutch or English. Medication usage was checked at each assessment.

Instruments

Diagnoses

The Mini-International Neuropsychiatric Interview 5.0 (Sheehan et al., 1998) was used to assess DSM-IV Axis I psychiatric diagnoses.

Symptoms

Frequency and intensity of PTSD symptoms were assessed at pre- and post-treatment and follow-up with the Clinician Administered PTSD scale (CAPS) (Blake et al., 1990), a semi-structured interview that has been validated in a Dutch population (Hovens, Luinge, & Van Minnen, 2005). Symptom severity was also assessed with the Self-Rating Inventory for Posttraumatic Stress Disorder (SRIP) at pre-treatment and at follow up. Test-retest for the scale was 0.92 and coefficient alpha was 0.90-0.94 (Hovens, Bramsen, & Van Der Ploeg , 2000). The Hospital Anxiety and Depression scale (HADS) (Zigmond, & Snaith, 1983; Spinhoven et al., 1997) was used to measure depressive and anxiety symptoms. Both the MINI and CAPS interviews were conducted by the first author, who is a licensed and experienced clinical psychologist, and two trained junior psychologists. The training protocol consisted of several training interviews and role-plays. Next, they co-rated a live interview by the first author and conducted at least two interviews in her presence. Interrater reliability was not assessed, however the junior interviewers received weekly supervision

during which the assessments were discussed. Feedback on audiotaped interviews was provided in approximately 15% of the CAPS interviews.

Attentional bias (AB)

AB Assessment

Each of the 96 trials of the Dot-probe Test (DPT) started with a fixation cross that lasted 500 ms. Next, two pictures (one neutral and one trauma-related) were presented simultaneously for 500 ms, above and below the fixation location. Next, a target ('E' or 'F') appeared in the spatial location of either picture. Patients were instructed to discriminate the target as fast as possible by pressing one of two response keys. Target, target position (top or bottom) and picture type (neutral or trauma-related) were fully counterbalanced. AB was calculated by subtracting the mean reaction time to congruent trials from the mean reaction time to incongruent trials.

AB Modification

Both treatment conditions consisted of eight sessions over the course of three weeks. Each session lasted approximately 15 minutes and consisted of 200 trials. Of these, 80% were neutral/trauma-related pairs, and 20% were neutral/neutral pairs. In the ABM condition, the target always appeared in the location of the neutral picture. In the neutral/trauma-related pairs in the control condition, the target appeared in the location of the neutral picture in 50% of the trials. The control treatment was similar to the AB assessment but lasted 200 instead of 96 trials, and the assessment did not contain neutral/neutral trials. Different sets of pictures were used in the training and assessment DPT, to test for generalizability of the training to a new set of stimuli.

We used pictures as stimuli instead of words, to make the project feasible for patients from different cultural backgrounds for whom Dutch was not their first language. To create two sets of interchangeable stimuli, we first conducted a pilot study in which we selected 105 pictures taken from the International Affective Picture System (IAPS) (Lang, Bradley, & Cuthbert, 1999). Next, five PTSD-patients rated the pictures on valence and arousal levels on 0 – 5 scales. Nine pictures with very low (≤ 2) average valence rating (0 = happy, 5 = sad) or very low or very high (≤2 or > 4) average arousal ratings were excluded. The mean valence and arousal ratings of the 48 trauma-related pictures in both set A and B were 3.6 and 3.2, respectively. A list of the selected IAPS pictures is presented in appendix A. The pre- and post-assessments were programmed and presented in E-Prime V1, the training was programmed using PHP, Flash AS3 and MySQL.

Procedure

The trial was carried out in a double-blind fashion. Assessments took place at pre- and post-treatment and at a three-week follow-up. Therapists screened patients during intake, and if eligible, patients received a letter of information. If they decided to participate, the first assessment was planned. Assessments lasted approximately 2.5 hours. Assessments were performed at the clinic but participants could do all of the treatment sessions at home on a secured website. Treatment adherence (date, time and duration of the sessions) was monitored through the secured internet connection.
The study was approved by an independent medical ethics committee (METIGG, Utrecht). All patients gave informed consent before any assessment took place. Patients received €10 for participating. Traveling costs were also reimbursed.

Data reduction and statistics

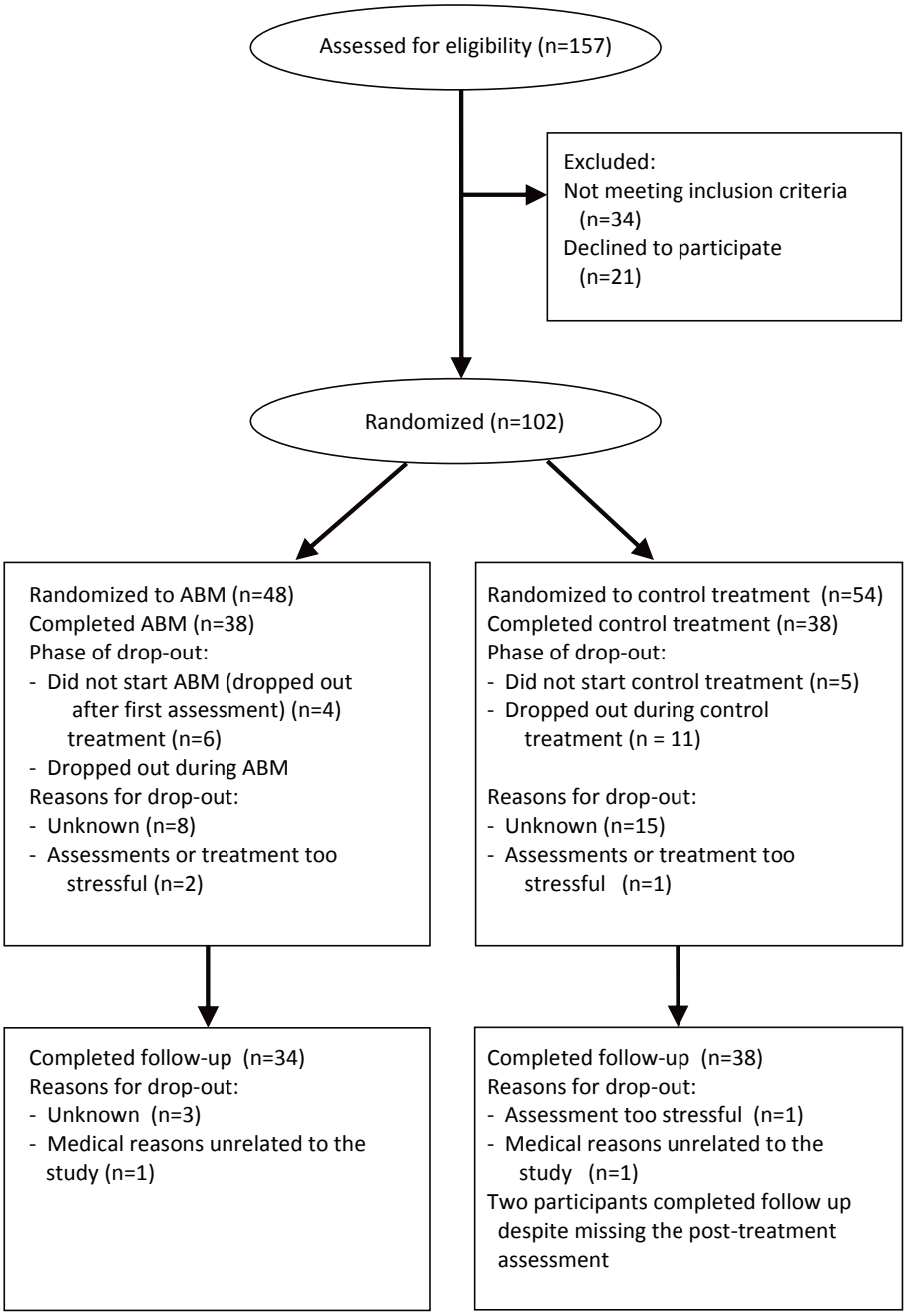
All analyses were performed on the intention-to-treat sample. Demographic and baseline clinical characteristics were compared between groups, using independent samples t-tests for continuous variables and chi-square tests for categorical variables. The effects of the interventions were analyzed using a repeated measures general linear model. Attentional bias scores were calculated by first excluding erroneous responses from analyses. Furthermore, trials with reaction times ≤ 300 ms or more than three standard deviations above the mean were also removed. This led to elimination of 5.5% of the trials at pre-treatment assessment and 5% and 4.8% of the trials at post-treatment and follow-up assessments, respectively. At the time when the present study was designed, no published data were available on the effects of attention training in patient samples on which to base a power analysis. At conferences however, significant effects had been presented in relatively small samples (N = 29 and N = 44; now published (Amir et al., 2009b; Amir et al., 2009a). We aimed to recruit 100 participants (50 per group), which gives a power of 0.80 to detect an effect size of 0.75 (between medium and large) with alpha set at 0.05.

Results

Participant flow

Figure 1 summarizes the flow of participants. 157 patients were screened, 102 of whom (65%) were randomized. Of the 55 patients who were excluded, 34 did not meet inclusion criteria. Twenty-one eligible patients declined to participate. In the ABM condition, 38 patients (79.2%) completed the training, compared to 70.4% in the control condition. Four patients in the ABM condition and two patients in the

Figure 1. Flow chart



control condition did not show up for the follow-up assessment. In two cases this was due to medical reasons unrelated to the project or to their psychiatric condition. Two patients who had completed treatment but missed their post-treatment assessment could be assessed at follow-up.

Data screening

Prior to analysis, all data were screened for accuracy of data-entry, missing values, normal distribution and outliers. We replaced missing values (last observation carried forward). The distribution of the scores on the CAPS, SRIP and HADS was explored with a Kolmogorov-Smirnov test. For both the ABM and control conditions the CAPS, SRIP and HADS scores at baseline, post-treatment and follow-up were normally distributed and there were no outliers. Six cases were outliers on the DPT at one or more of the assessments. These cases were removed for analyses involving the DPT, but not for the main study questions.

Patient characteristics

The baseline characteristics of both samples are summarized in table 1. The two samples had similar gender distributions, mean age, level of education, and ethnic backgrounds. The majority of participants were Dutch. The others were migrants from Morocco, Turkey and the former Dutch colonies who had been living in The Netherlands for many years, sometimes decades. Refugees represented 14.6% of the sample in the ABM condition, and 9.3% in the control condition. Most of these people had also been living in The Netherlands for several years. All participants completed all assessments in Dutch, except one who filled in an English version of the questionnaires.

Most of the patients had experienced multiple traumas (93.1%). More than half (56.9%) of the patients had been traumatized in childhood and 40.6% had experienced both childhood trauma and more recent trauma. Almost half (48%) of the patients received medication while they participated in the study, most of this group were prescribed antidepressants. There were no significant differences between groups in number of co-morbid clinical diagnoses ($t(99) = 0.61$; $p = 0.55$). The total number of additional diagnoses varied between zero and seven, with an average of 2.6 diagnoses per patient. At baseline the groups did not differ significantly on any of the symptom scores nor on attentional bias score ($t(97) = 1.14$; $p = 0.26$).

Table 1. Demographic and clinical characteristics of the samples

	Attention training (N = 48)	Control Training (N = 54)	*p*-value
Gender (N, % women)	37 (77.1)	40 (74.1)	0.7
Age *(SD*)	36.8 *(11.4)*	37.3 *(11.7)*	0.8
Education *(SD)*	1.9 *(0.8)*	1.7*(0.8)*	0.4
Ethnicity (N, %)			
Dutch	28 (58.3)	29 (53.7)	0.6
Migrants	13 (27.1)	19 (35.2)	0.4
Refugees	7 (14.6)	5 (9.3)	0.6
Trauma (N, %)			
Two or more events	43 (89.6)	52 (96.3)	0.2
Age 12 or younger	27 (56.2)	31 (57.4)	0.9
Comorbidity (N, %)			
Depression	34 (70.8)	37 (68.5)	0.9
Dysthymia	7 (14.6)	6 (11.1)	0.6
Panic disorder	15 (31.2)	19 (35.8)	0.6
Social anxiety disorder	15 (31.2)	22 (40.7)	0.3
General anxiety disorder	18 (37.5)	21 (38.9)	0.8
Obsessive-compulsive disorder	10 (20.8)	6 (11.1)	0.4
Somatization disorder	5 (10.9)	3 (5.8)	0.1

Note: Education: 1=low, 2=moderate 3=high educational level

Treatment effects on primary and secondary outcomes

Table 2 presents the means and standard deviations of the outcome variables and the results of the GLM analyses. Results revealed significant main effects of Time on clinician-rated symptoms (CAPS) ($F(1.86, 185.56) = 40.38$; $p < 0.001$) and on self-reported posttraumatic symptoms (SRIP) ($F(1, 98) = 31.15$; $p < 0.001$) and anxiety (HADS-A) ($F(2, 194) = 29.37$; $p < 0.001$). The main effect of Time on self-reported depression severity (HADS-D) did not reach significance ($F(2, 194) = 2.20$; $p = 0.11$). The effect sizes of the improvement (pre-post) on the CAPS were d = 0.66 for ABM and d = 0.46 for the control treatment. Post-hoc analyses with medication use and

Table 2. Primary and secondary outcomes

	Baseline		Post-treatment		Follow-up		
	ABM	Control	ABM	Control	ABM	Control	Time x Treatment effect
CAPS	80.7 *(16.4)*	80.5 *(18.7)*	65.1 *(23.3)*	70.4 *(21.7)*	64.3 *(23.7)*	66.9 *(24.1)*	F(1.9,185.56) = 1.18; p = 0.31
SRIP	62.1 *(9.6)*	63.9 *(8.3)*	-	-	57.2 *(13.7)*	58.6 *(11.5)*	F(1,98) = 0.07; p = 0.79
HADS-A	15.2 *(2.8)*	15.3 *(2.5)*	13.4 *(3.7)*	13.6 *(4.1)*	12.5 *(4.2)*	13.2 *(4.0)*	F(2,94) = 0.36; p = 0.70
HADS-D	12.0 *(2.8)*	11.5 *(3.2)*	11.7 *(4.9)*	11.7 *(4.2)*	11.0 *(4.7)*	11.3 *(4.4)*	F(2,94) = 0.91; p = 0.40
DPT	-4.9 *(53.5)*	3.2 *(58.5)*	-1.0 *(37.8)*	-0.1 *(34.7)*	-3.4 *(41.4)*	-3.3 *(35.5)*	F(1.8,142.79) = 0.24; p = 0.76

Note: Means *(Standard Deviations). Abbreviations:* ABM = Attentional Bias Modification; CAPS = Clinician Administered PTSD Scale; SRIP = Self-Rating Inventory for PTSD; HADS-A = Hospital Anxiety and Depression Scale – Anxiety; HADS-D = Hospital Anxiety and Depression Scale – Depression; DPT = Dot-probe Test

depression history as covariates did not change this pattern of results, nor did an analysis of treatment completers

GLM analyses on DPT scores did not reveal any significant main or interaction effects of Time or Treatment. However, the mean DPT score in both groups at pre-treatment was close to zero with a large standard deviation. We therefore conducted unplanned post-hoc analyses only in patients who showed at least moderate attentional bias (i.e., positive congruency scores) to threat (n=46). This revealed the same pattern of results.

Discussion

The aim of this study was to investigate the effects of ABM on symptoms and attentional bias in patients with PTSD. Although ABM led to a reduction of symptoms with a moderately high effect size (d = 0.66), the reduction was not significantly larger than in the control treatment (d = 0.46). Theoretically, this could mean that both treatments were effective, since we cannot be sure that the control condition acted as a real (neutral) placebo. For patients with anxiety disorders who have attentional bias towards threat, one could speculate that training at 50/50 contingency may actually be a low-dose version of ABM. However, this interpretation is untenable. Both effect sizes are below published effect sizes of pill-placebo in pharmacotherapy trials of chronic PTSD (Marshall, Beebe, Oldham, & Zaninelli, 2001; Davidson, Rothbaum, van der Kolk, Sikes, & Farfel, 2001; Brady et al., 2000). In one study an effect size of d = 0.81 was found for pill-placebo, even after a two-week placebo lead-in (Brady et al., 2000). In another study (Davidson et al., 2001) the same decline in CAPS-scores was observed after pill-placebo as in the present study for ABM. These effects were reached in the first four weeks of the pharmacotherapy trials. Consequently, we cannot even exclude the possibility that both the ABM and control treatment are less effective than placebo. The lack of effect was unexpected since positive effects of ABM had been shown in generalized anxiety disorder (GAD) (Amir et al., 2009a) and in social anxiety disorder (SAD) (Amir et al., 2009b).

Although previous research has shown that AB to threat is also a feature of PTSD, we did not observe a mean positive AB score in the present sample at pre-treatment. We did not test a healthy control group, matched for age, gender and education with the present version of the DPT, so the AB scores of our patients may still be different from healthy controls. Although healthy participants do not show AB on average (Bar Haim et al, 2007), some studies that assessed AB in anxiety disorders found *avoidance* of threat in the control group (Mogg et al.,2000).

Furthermore, in previous ABM studies the absence of AB has not been crucial in producing positive results (Amir et al., 2009a). The lack of AB at pre-treatment in the present study does not affect our conclusion that this version of ABM is ineffective for PTSD. The treatment has been investigated in and is being advocated for

patients with anxiety disorders, not only those who show high DPT scores. Moreover, a post-hoc analysis in the subgroup of patients who did show AB at baseline revealed the same pattern of results.

The feasibility and acceptability of the training was lower than expected. Given the fact that this treatment was short and could be carried out at home, we expected fewer drop-outs compared to traditional treatments for PTSD (i.e., Cognitive Behavioral Therapy, CBT). However, our mean drop-out rate (25.2%) fell within the range of drop-out rates in CBT (e.g., 32% (Van Emmerik, Kamphuis, & Emmelkamp, 2008) and 15% (Hensel-Dittmann et al., 2011; Dorrepaal et al., 2012).

The present study is the first study that was carried out in patients with PTSD. Participants were recruited in a mental health care setting. Previous studies in GAD and SAD included younger and more highly educated patients and may be less representative. The sample sizes of these studies were also notably smaller. About 70% of our patients also met criteria for a depressive episode. In the ABM-study on GAD (Amir et al., 2009a), however, the positive effects of ABM treatment were not limited to anxiety but extended to depressive symptoms, implying that these symptoms may also be sensitive to AB manipulation.

Our sample was relatively heterogeneous: some patients had suffered from childhood traumas and others were traumatized later in life. Since we aimed to test a representative clinical sample, we decided not to exclude patients based on the nature of the traumatic event.

Limitations of this study include the fact that we did not assess interrater reliabilities for the standardized diagnostic interviews and that we did not measure Axis II diagnoses. Regular supervision sessions for the diagnostic interviews were held however, and patients were only invited for participation if they had been diagnosed with PTSD in a clinical interview during the intake procedure of the outpatient clinic.

Research on cognitive-behavioral treatment shows that anxiety disorder patients with and without personality disorders benefit equally well (Mersch, Jansen, & Arntz, 1995). The relatively short follow-up period (three weeks) may also be seen as a limitation, but a delayed effect on symptoms after a longer time period is theoretically implausible.

In conclusion, we found no evidence that this version of ABM is effective in patients with chronic PTSD. A change of AB, which is the presumed mechanism of action, was also not observed. The field of ABM research is in its infancy and instead of continuing with more randomized controlled trials for new indications, we think that it will be more useful to further investigate the presumed mechanism of action in order to understand what the effects of this treatment are. This question is urgent. ABM is already commercially available (www.managingyouranxiety.com, 2012) for SAD, GAD and obsessive-compulsive disorder and given the number and the size of the studies we think that this is premature.

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Appendix A. IAPS numbers

Test (Set A)

Neutral		Trauma	
1333	5764	2703	9041
1419	578-	2799	9050
1450	7035	3022	9230
1540	7037	3181	9250
1590	7038	3215	9252
1603	7052	3500	9402
1670	7057	3550.1	9404
1810	7090	5970	9419
2235	7130	6010	9424
2514	7140	6021	9425
2980	7150	6190	9427
5010	7161	6210	9429
5200	7175	6241	9435
5390	7185	6243	9470
5471	7190	6250	9471
5500	7205	6313	9495
5531	7230	6540	9594
5534	7233	6821	9611
5600	7234	6836	9620
5621	7490	6840	9630
5628	7491	6940	9900
5629	7547	7361	9902
5660	7595	9000	9910
5700	7950	9010	9912

Training (Set B)

Neutral		Trauma	
1500	5631	2811	6550
1600	5635	2900	6560
1602	5711	3180	6561
1604	5720	3210	6562
1620	5731	3216	6570
1740	5750	3225	6571
1812	5760	3530	6610
1910	5800	5972	6800
1920	5811	6020	6825
2191	5870	6022	6830
2383	5891	6200	6834
2745.1	7002	6211	6838
5000	7004	6230	9007
5020	7006	6242	9160
5130	7009	6260	9254
5201	7010	6311	9421
5300	7036	6312	9426
5510	7041	6314	9428
5520	7059	6315	9592
5530	7080	6350	9622
5532	7160	6360	9635.2
5535	7179	6370	9901
5623	7211	6510	9903
5626	7260	6530	9911