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Research paper

The long-term effects of ABM on symptom severity in patients with recurrent depression: A randomized sham-controlled trial

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ABSTRACT

Background: The present study reports on long-term outcomes of ABM over one year in self-reported and clinician-rated depression symptoms, anxiety symptoms, and relapse rates.
Methods: We conducted a double-blind randomized sham-controlled trial in 301 participants with recurrent major depression disorder between January 2015 and October 2016 (#NCT02658682). Participants were allocated to ABM or sham condition twice daily for 14 consecutive days. Long-term effects of ABM were assessed by BDI-II, HDRS and BAI at one-, six-, and 12-months follow-up. Relapse rates at 12-months follow-up were also assessed.
Results: There was no long-term effect of ABM (as compared to sham) on clinician-rated depression symptoms, on anxiety symptoms, nor in relapse rates. By 12 months follow-up, there was a small effect on self-reported depression favoring ABM over sham.
Limitations: The lack of an assessment-only condition hinders comparison to natural trajectories of depression symptoms.
Conclusions: The overall long-term effect of ABM was limited, and currently there is no convincing evidence for implementing this as a viable treatment option in clinical populations. We speculate if the sham condition should be replaced by another control condition when investigating the clinical utility of ABM.

1. Introduction

Attention bias modification (ABM) is a computerized intervention aiming at modifying negative attentional bias (Browning et al., 2010), that is causally related to depressive symptoms (Wells and Beevers, 2010). By means of positive conditioning, attention is implicitly led away from negative stimuli. The intervention has shown promise in reducing depressive symptoms, leading to changes of small effect sizes over short time periods (Fodor et al., 2020). Studies of long-term effect are inconclusive.

The earliest small-scale studies on the long-term effect of ABM were largely positive. In a study of 77 students with subclinical depressive symptoms (Yang et al., 2015), ABM was associated with favorable outcomes compared to waitlist and placebo conditions after three months, but not after seven months. Another study by the same group (Yang et al., 2016) found greater reductions in depression after twelve months for ABM versus placebo in 45 adolescents with major depressive disorder (MDD). At shorter follow-ups, Browning et al. (2012) ($N = 61$) and Dai et al. (2019) ($N = 32$), respectively examining patients with MDD in remission and ongoing MDD treated with antidepressants, reported favorable outcomes one month after ABM when compared to a sham condition. However, later large-scale studies with longer follow-ups

Abbreviations: AB, Attention bias; ABM, Attention bias modification; BAI, Beck's Anxiety Inventory; BDI-II, Beck's Depression Inventory- II; HDRS, Hamilton Depression Rating Scale; MDD, Major Depressive Disorders.

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have abated some of the optimism. In a large-scale trial of 202 adults with subthreshold depression levels, a combined attention and interpretation modification procedure did not lead to the desired effects on several indices of depression compared to a control condition after one year (Basanovic et al., 2020). Also, in a sample of adult participants with mixed ongoing depression and depression in remission, with or without comorbid anxiety ($N = 101$), ABM did not lead to better outcome in terms of depression after six months compared to sham (Bø et al., 2023). Yet another null finding was reported by de Voogd et al. (2016) in a study of 340 unselected adolescents, comparing the effect of online ABM to sham after one year. Hence, the positive effects of ABM seem to diminish or even vanish when studies involve larger samples and longer follow-ups.

Regarding the long-term effect on anxiety symptoms, a study by Carleton et al. (2016) investigated the effect of online ABM compared to sham in a sample of patients with social anxiety ($N = 113$) and found no effect of ABM on anxiety symptoms up to eight months. Furthermore, a study by Price et al. (2019) found no effect of ABM on anxiety symptoms in a clinical group ($N = 70$) after one year when compared to a control condition. There was also no effect of combined ABM and cognitive bias modification compared to the control condition on anxiety symptoms in a non-selected adolescent population up to one year (Basanovic et al., 2020), and no effect on anxiety symptoms in a mixed clinical sample up to six months (Bø et al., 2023). Hence, the long-term effect of ABM on anxiety symptoms is not convincing.

Both depression and anxiety are recurrent- (Burcusa and Iacono, 2007; Scholten et al., 2021) and comorbid disorders (Kessler et al., 2005; Kessler et al., 2015), and residual symptoms are increasing the risk of relapse (Paykel, 2008). If ABM fails at modifying symptom load or the long-term prognosis of these disorders, clinical scientists need to reconsider whether this is an attainable treatment- or secondary prevention option for the future or whether repeat sessions or boosters may be needed. Given the inconclusive nature of the existing studies, it is necessary to further investigate the long-term treatment effects of ABM.

The present study examined the long-term effects of ABM in patients with recurrent depression (including comorbid disorders) using data from a large scale RCT of ABM ($N = 301$; Jonassen et al., 2019). This study demonstrated a significant effect of ABM on clinician-rated (but not self-reported) depression symptoms immediately after the intervention (the primary outcome). The present study reports on the secondary outcomes, examining the effect of ABM at 1, 6, and 12 months after the intervention. Capturing the breadth of the depressive phenomenon, we report both self-reported and clinician-rated symptoms of depression (Uher et al., 2012), and investigate the relapse rates of full depressive episodes up to twelve months. We also report on the long term-effect on self-reported anxiety, as ABM might be more relevant for reducing anxiety compared to depressive symptoms (Fodor et al., 2020). Considering the lack of long-term effects between ABM and control conditions in previous studies (e.g., Bø et al., 2023), we hypothesized that there were no beneficial long-term effects of ABM on any of the measures of symptom severity or relapse.

2. Materials and methods

2.1. Participants

A total of 301 participants, aged 18–72, were randomized and received either ABM or a control condition (a sham) for two daily sessions over 14 consecutive days. The majority of participants were recruited from an outpatient clinic in Oslo, Norway, some from other treatment sites, and some responded to local advertisements and posts in social media. They were pre-screened by telephone and excluded if they were diagnosed with current- or former neurological disorders, psychosis, bipolar spectrum disorders, substance use disorders, attention deficit disorder, and head trauma. All included participants fulfilled the criteria for at least two previous episodes of MDD and were currently in remission (except for 37 who were currently depressed, and therefore included by mistake). Since the trial followed an intention to treat approach, these were also included in the analysis. Please see Jonassen et al. (2019) for a detailed report.

2.2. Intervention

The intervention involved the exact same specifications as detailed in (Browning et al., 2012; Jonassen et al., 2019), and consisted of a face-based ABM procedure or a sham control condition. The intervention was composed of pairs of facial stimuli displaying one out of three emotional expressions: negative (fear or anger), neutral and positive (happy). Stimuli pairs derived from two out of three valences were displayed horizontally for 500 ms or 1000 ms. The order of these were at random. Participants were asked to fast and accurately respond to one or two dots appearing at the computer screen in the location of the previously displayed stimuli. In the active condition, the dots were displayed in the location of the more positive stimuli 87 % of the time, reinforcing an implicit tendency to attend towards the relatively more positive stimuli, whereas in the sham condition there was no contingency between the dots and the stimuli.

A total of 28 sessions (twice daily for 14 consecutive days) with 96 trials equally derived from each stimuli pair, were administered, each lasting for approx. 5–7 min. Sessions were conducted at home on laptop computers provided by the research group. Fidelity to the intervention was high (Jonassen et al., 2019).

2.2.1. Randomization and masking

Participants were informed that the trial would investigate the relationship between attention and mood. They were also informed about the randomization procedure (1:1) but were kept blind to their allocation. They were not given any details on the difference between conditions. An independent lab technician programmed the laptops delivering the intervention and randomized the participants according to a randomization list. All assessors were blind to the treatment allocation of the participants hence, the study was double-blinded. The randomization list revealing the allocation of participants was opened after the data collection ended. See Fig. 1 for flow diagram of the trial.

2.3. Symptom measures

A semi-structured clinical interview, the MINI International Neuropsychiatric Interview PLUS 5.0.0 (M.I.N·I) was used to assess patients at baseline based on DSM-IV criteria. At 12-month follow-up, participants underwent a repeated interview of part A (MDD) to assess whether they had experienced relapses during the trial. Interviews were conducted by trained professionals or psychology students under supervision, all blinded for the study allocation.

Self-reported depression was assessed by means of the Beck's depression inventory-II (BDI-II; Beck et al., 1988b). Clinician-rated depression was assessed by means of the Hamilton depression rating scale (HDRS; Hamilton, 1960). Self-reported anxiety was assessed by the Beck's Anxiety Inventory (BAI; Beck et al., 1988a).

2.4. Statistical analysis

Baseline characteristics of participants in the two treatment groups were reported using frequency distributions and descriptive statistics including measures of central tendency and dispersion. The analysis was conducted for the participants who received the allocated interventions ($N = 301$).

2.4.1. Outcomes

This study was registered in January 2016 on ClinicalTrials.gov (#NCT02658682). We report on the following secondary outcomes: recurrence of major depressive episodes after 12 months and change in

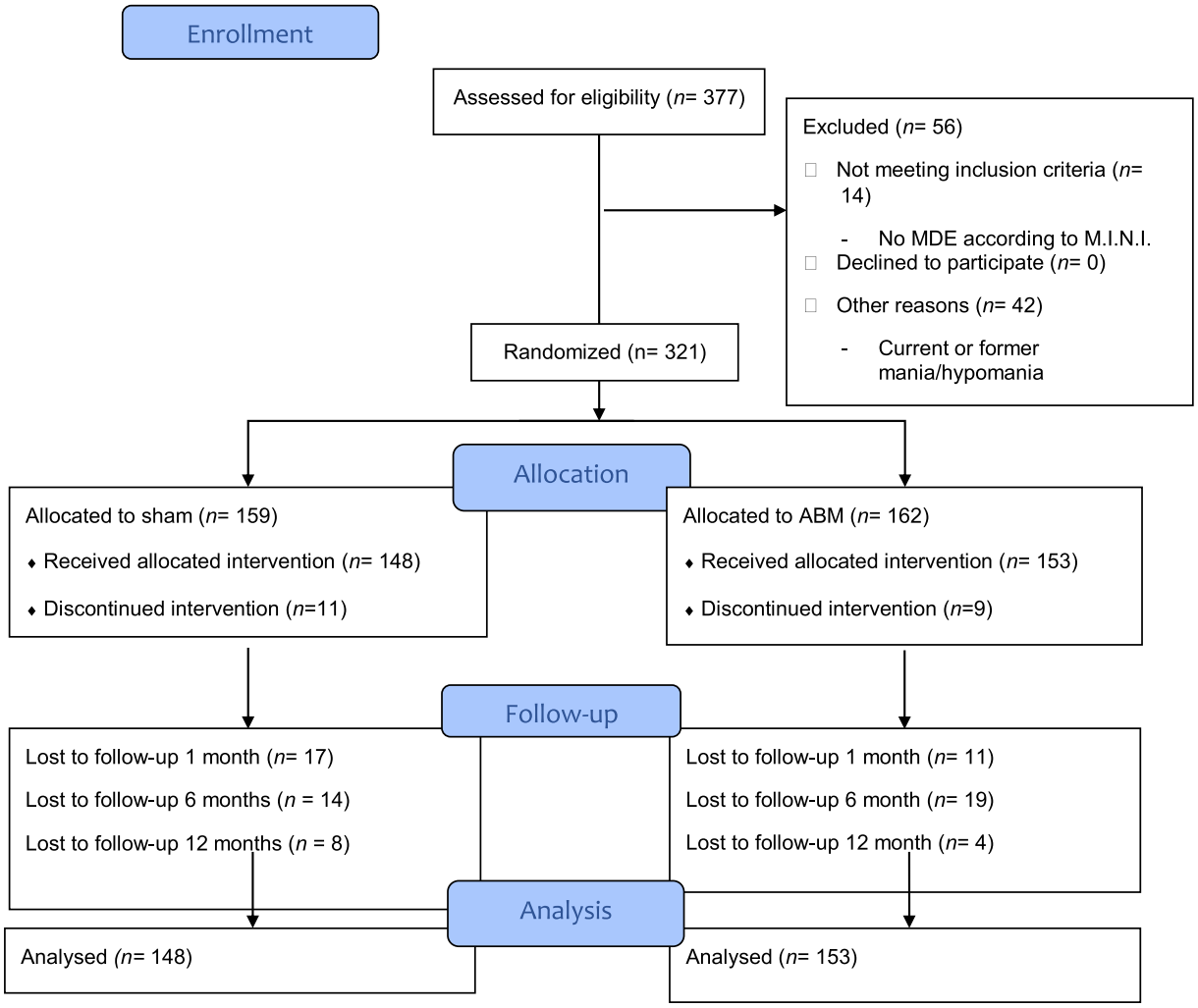

Fig. 1. Consort flow diagram.

symptoms of anxiety (BAI) at 1-, 6-, and 12-months follow-up. We also report on change in residual symptoms of depression (BDI-II and HDRS) at 1-, 6-, and 12-months (listed under "Other outcomes").

Outcomes were analyzed using three mixed model analyses with random intercepts. For BDI-II, BAI and HDRS, the models included condition (ABM, sham) and assessment point (baseline, post-intervention, one-, six-, and 12-months follow-up) and Condition X Assessment point interaction as fixed factors. We treat time as a categorical variable due to the different intervals between assessment points, having baseline as the reference category. If a Condition x Assessment point interaction effect was significant, pairwise analysis was used for decomposing the interaction effect. The lme4 package in R (Bates et al., 2015) was used to fit the model based on restricted maximum likelihood. The ABM treatment effect was operationalized as the least squares mean difference at follow-ups at 1-, 6-, and 12-months. The LS mean p-value $< .05$ was used to assess statistical significance.

Relapse during the trial (0 = no, 1 = one or more) was investigated between conditions by means of Pearson Chi-Square. This analysis was conducted only for participants in remission at the time of inclusion (n = 264). Sixty-two of these were lost to 12-months follow- up.

All analyses were conducted using SPSS (version 27) and R (version 4.2.0).

2.4.2. Missing data

The dataset was complete for all 301 participants at baseline and post-intervention. Twenty-eight (9.3 %) participants did not take part in the assessments at one-month follow up, 64 (21.3 %) at six-months follow-up, and 69 (22.9 %) at 12-months follow-up. Ten participants had missing data regarding relapse status of MDD. We did not impute data for participants who were lost to follow-up as the mixed model approach without any ad hoc imputation is shown to be more powerful compared to other alternatives (Chakraborty and Gu, 2009).

2.5. Ethical approval

The study was approved by the Regional Committee for Health Research for South-Eastern Norway (2014/217). All participants gave written informed consent to take part after fully informed about the procedures of the study. Authors assert that this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.

3. Results

Demographic statistics are presented in Table 1. The majority of participants were middle-aged females with an education level equivalent to a bachelor's degree or above. A minority were treated with SSRIs at inclusion and had on average had 4.1 previous depressive episodes. Overall, depression symptom levels at inclusion were mild. With regard to current comorbid anxiety disorders, 29 fulfilled criteria for social phobia, 26 for panic disorder, 17 for obsessive-compulsive disorder, 16

Table 1
Demographic and sample characteristics at baseline.

	Sham (n = 148)	ABM (n = 153)
Age, *M* years (*SD*)	41.5 (13.6)	40.2 (12.7)
Gender, *n* females (%)	103 (69.6)	109 (71.2)
Using psychotropic medication, *n* (%)	43 (29.1)	38 (24.8)
Number of previous MDE, *M* (*SD*)	4.1 (4.6)	4.1 (4.9)
Comorbid anxiety disorder, *n* (%)	41 (27.8)	43 (28.1)
BDI-II, *M* (*SD*)	13.8 (9.7)	14.9 (10.5)
BAI, *M* (*SD*)	9.0 (7.4)	9.6 (9.4)
HAMD, *M* (*SD*)	8.3 (5.0)	9.2 (5.9)

Note. BAI = Beck's Anxiety Inventory, BDI-II = Beck's Depression Inventory, HAMD = Hamilton Depression Rating Scale. MDE = Major depressive episode.

for generalized anxiety disorder, 26 for agoraphobia and seven for post-traumatic stress-disorder (note that some participants had more than one anxiety disorder).

3.1. Drop-Out

Independent samples *t*-tests showed that there was a statistically significance difference in age between completers ($M = 41.8$, $SD = 13.3$) and non-completers ($M = 37.4$, $SD = 12.1$) at 12-months ($t = -2.46$, two-tailed $p = .014$). Non-completers were also marginally less likely to use SSRIs at baseline ($n = 13$; 18.9 %), than completers ($n = 67$; 28.9 %), X^2 (1, $N = 301$) = 2.746, $p = .097$. Other baseline characteristics, like symptom severity or comorbidity, were not associated with drop-out.

3.2. BDI

There was no significant interaction effect between ABM condition x Assessment point from baseline to post-intervention, t (1005.4483) = −1.079, $p = .28$, $d = 0.07$, from baseline to one-month follow-up, t (1014.1644) = −0.295, $p = .77$, $d = 0.02$, from baseline to six-months follow-up, t (1021.1290) = 0.776, $p = .44$, $d = 0.05$. However, there was an interaction effect from baseline to twelve-months follow-up, t (1021.6258) = −2.181, $p = .030$, $d = -0.14$. Hence, there was a small, but significant, difference between ABM and sham at the longest follow-up.

Post-hoc pairwise comparisons (two-tailed) between baseline and 12-months follow-up within groups showed that the ABM condition was associated with a reduction of 3.53 BDI points ($SD = 9.7$), t (118) = 3.935. $p < .001$, $d = 0.72$, but sham was not (mean change = −0.89, $SD = 11.1$), t (108) = 0.826, $p = .411$, $d = 0.16$. Overall, there was a significant reduction in self-reported depression from baseline to post-intervention, t (1005.4483) = −3.545, $p < .001$, $d = -0.22$, from baseline to one-month post-intervention t (1015.9458) = −3.679, $p < .001$, $d = -0.23$, from baseline to six-months follow-up, t (1021.6500) = −4.468, $p < .001$, $d = -0.28$, but not from baseline to twelve-months follow-up, t (1022.4307) = −1.490, $p < .001$, $d = -0.09$. There was no main effect of ABM condition, t (524.6053) = 1.5658, $p = .18$, $d = 0.14$, between these time points. The estimated marginal means of BDI from baseline to 12-month follow-up are presented in Fig. 2.

3.3. HAMD

There was, as previously reported in Jonassen et al. (2019), a significant interaction effect between ABM condition x Assessment point from baseline to post-intervention, t (997.8586) = −2.042, $p = .04$, $d = -0.12$, but not from baseline to one-month follow-up, t (1013.1945) = −0.842, $p = .40$, $d = -0.05$, from baseline to 6-months follow up, t (1022.1179) = −0.714, $p = .48$, $d = 0.04$, or from baseline to 12-months follow-up, t (1022.2906) = −0.510, $p = .61$, $d = -0.03$. Hence, the effect of ABM on clinician-rated depression was limited to the intervention period.

Overall, there were no significant reductions in clinician-rated depression from baseline to post- intervention, t (997.8586) = 0.892, $p = .37$, $d = 0.06$, from baseline to one-month follow-up, t (1016.2238) = −0.360, $p = .72$, $d = -0.02$, from baseline to six-months follow-up, t (1022.8765) = −0.361, $p = .72$, $d = -0.02$, or from baseline to 12-months follow-up, t (1024.0441) = 0.399, $p = .69$, $d = 0.02$. There was no main effect of ABM condition, t (677.8984) = 1.527, $p = .13$, $d = 0.12$. The estimated marginal means of HAMD from baseline to 12-months follow-up are presented in Fig. 3.

3.4. BAI

There was no significant interaction effect between ABM condition and any of the assessment points, all t's < +/− 1.4, all p's > 0.16. Hence, ABM and sham did not differ significantly at any point during this trial.

Overall, there was a significant reduction in self-reported anxiety from baseline to post- intervention, t (966.5235) = −2.313, $p = .02$, $d = -0.15$, from baseline to 1-month post-intervention t (978.5501) =

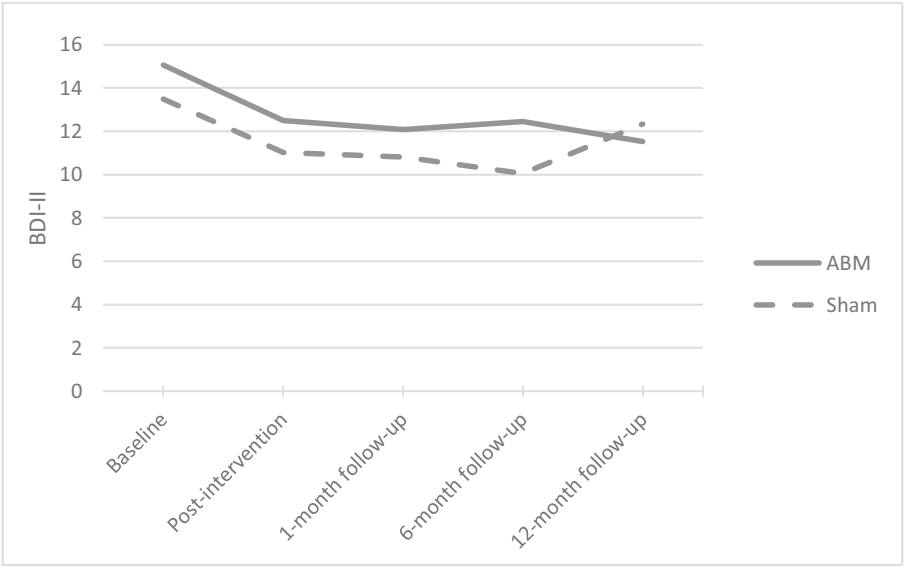

Fig. 2. Self-reported depression at various time points of the trial.
Note. ABM = Attention Bias Modification, BDI-II = Beck's depression Inventory-II.

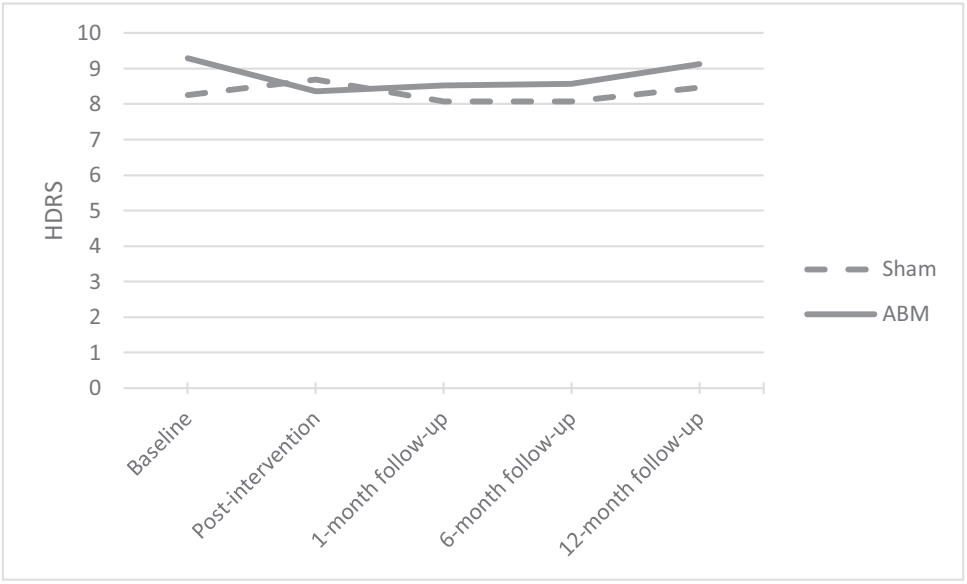

Fig. 3. Clinician-rated depression at various time points of the trail.
Note. ABM = Attention Bias Modification, HDRS = Hamilton Depression Rating Scale.

−3.149, $p = .002$, $d = -0.20$, a marginal reduction from baseline to 6-months follow-up, t (982.8342) = −1.8668, $p = .062$, $d = -0.12$, but not from baseline to 12-months follow-up t (982.6675) = −0.393, $p = .69$, $d = -0.03$. There was no main effect of ABM condition, t (516.4152) = 0.513, $p = .61$, $d = 0.05$. The estimated marginal means of BAI from baseline to 12-months follow-up are presented in Fig. 4.

3.5. Relapse

There were no statistically significant differences in MDD relapse rate during the 12-months of follow-up, with 31 (31.3 %) experiencing relapse in the ABM condition and 31 (33.3 %) in the sham condition X^2 (1, $N = 192$) = 0.090, $p = .77$.

4. Discussion

We examined the long-term effects of ABM compared to sham in a sample with recurrent MDD. There was no overall reduction in clinician-rated depression beyond the immediate treatment effect previously reported (Jonassen et al., 2019), and no long-term differences between ABM and sham except for a small difference in self-reported depression up to 12-months follow-up. In terms of clinician-rated depression and anxiety, there was difference between ABM and sham. There was also no difference between ABM and sham on MDD relapse rates during the 12 months of follow-up.

At twelve months, we found a small effect on self-reported symptom improvement in ABM compared to sham, while clinician ratings remained unchanged for both conditions. Self-reported symptom improvements may be influenced by factors such as social desirability bias or placebo effects, which may not be evident when evaluated by clinicians using validated clinical assessments. However, these factors would supposedly affect both conditions equally independent of the passing of time, and this suggests that some process specifically related to ABM may account for the difference in self-report at 12-months follow-up. A

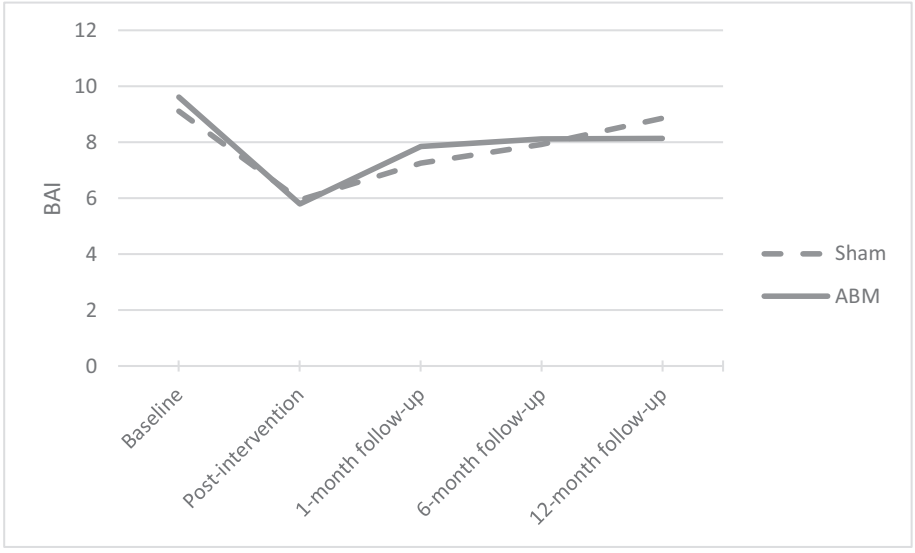

Fig. 4. Self-rated anxiety at various time points of the trail.
Note. ABM = Attention Bias Modification, BAI = Beck's Anxiety Inventory.

more likely explanation for the difference is which specific symptoms self-reports and clinician-rated inventories assess, and the relative weighting of various symptoms (Uher et al., 2012), but one should also not exclude the possibility that this is a chance finding.

In accordance with previous literature (e.g., Basanovic et al., 2020; Bø et al., 2023; Carleton et al., 2016; Price et al., 2019), we did not find any effect of ABM on anxiety symptoms at any of the timepoints. While there was an overall reduction in anxiety symptoms up to 1 month in both conditions, it is unknown how this compares to no treatment. The lack of an effect in this trial could possibly be related to low symptom severity in this sample, introducing a floor effect. While awaiting replication in samples with more pronounced symptomatology, there is reason to believe that the previously identified positive effect of ABM on anxiety compared to depression (Fodor et al., 2020), primarily is present at shorter follow-ups.

Some studies suggest that the lack of long-term evidence for ABM might be due to the closely resembling control condition. For example, some studies that have demonstrated null findings have identified long-term reductions in symptoms irrespective of which condition patients were randomized to (Basanovic et al., 2020; Bø et al., 2023; Carleton et al., 2016; de Voogd et al., 2016), however none has included an assessment only condition. The sham condition was originally intended for investigating the mechanism of the intervention (i.e., the effect of bias change) and not for determining whether the intervention delivers clinically relevant benefit (Blackwell, 2020). Hence, the close resemblance between the ABM condition and the sham condition could potentially hide important effects, so also in the current trial. For example, participants are exposed, irrespective of conditions, to emotional stimuli, engaging in computer training tasks requiring focus and commitment, having social contact with researchers, undergoing repeated assessments, and experiencing the passage of time (Blackwell, 2020), all of which potentially could affect symptoms. The initial self-reported symptom reductions could be attributed to taking part in a structured daily activity, the effect of doing something concrete to support one's own recovery process, or some other unbeknownst factors other than bias modification. The 32.4 % relapse rate across our sample may possibly indicate that taking part in this trial, either sham or active, limited relapse. In comparison, a study by Johansson et al. (2015) showed that 61 % experienced a new depressive episode within one year in a group of clinically depressed patients successfully treated in an outpatient setting. The lack of an assessment only condition in the current trial obviously hinders further conclusion as to what would have happened had they not taken part in this trial. Future studies should therefore control for the natural trajectory of symptoms in patients with recurrent MDD and use control conditions which are better suited to clarify the clinical utility of ABM (Blackwell et al., 2017).

4.1. Limitations

Inclusion of some participants started before trial registration, which is not in line with good practice. However, un-blinding of results was conducted after full trial registration. The target population that was registered was patients with recurrent MDD currently in remission. Unfortunately, an unwanted protocol deviation led to the inclusion of 37 participants with ongoing MDD. However, for exploratory purposes we have also redone the analysis without these participants, and the results remained essentially the same.

While a considerable proportion of the participants fulfilled the criteria of an ongoing anxiety disorder, most did not, and the finding may not be generalizable to samples with more pronounced anxiety symptoms. There are indications that type of anxiety disorder, in particular PTSD defined as a stress-disorder in DSM-5 but not DSM-IV, is a moderator for the effect of ABM (Fodor et al., 2020). Due to the low number of participants in each diagnostic group, we did not separate the effect of the intervention based on type of anxiety disorder, and this may be followed-up on in future studies.

We did not register data on race/ethnicity, as this is not typically inquired in Norway.

It has been suggested that one of the prerequisites for symptom reduction following ABM is change in AB away from negative stimuli (i.e., the process; Grafton et al., 2017). In this trial, ABM did not change AB compared to sham (Jonassen et al., 2019) . This suggests that ABM may be working through another process than change in AB, and it leaves us with insufficient evidence regarding the long-term effect of bias change on depressive symptoms, but this could also possibly be related to the poor reliability of AB when assesed by means of a dot probe task (e.g., Meissel et al., 2022).

5. Conclusion

Among participants with a known vulnerability for recurring depressive episodes, ABM compared to sham led to a small, but significantly better outcome in self-reported depression up to 12 months. However, there was no effect on long-term clinician-rated depression symptoms, anxiety symptoms, or MDD relapse rates, and based on the current knowledge we question the utility of offering ABM to this population. Nevertheless, the close resemblance between ABM and sham condition may hide important long-term effects and call for the use of other types of control conditions.

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CRediT authorship contribution statement

Conceptualization: CJH, NIL. Methodology, software, resources: CJH, NIL, RJ. Formal analysis: RB, MLP. Investigation: BK, RJ. Data curation: RB, BK, RJ. Writing – Original draft: RB. Writing – Reviewing and editing: all authors. Visualization: RB. Supervision: NIL. Project administration: BK, NIL, RJ. Funding acquisition: NIL.

Declaration of competing interest

NIL has received consultancy fees and travel expenses from Lundbeck outside this work. CJH has received consultancy fees from P1vital, Lundbeck, Sage Therapeutics, Compass Pathways, Zogenix outside of this work. Other authors report no financial relationships with commercial interests.

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