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Heart Rate Variability Biofeedback Stress Relief Program for Depression*

A Replicated Single-Subject Design

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Keywords
Heart rate variability, stress reduction, depression, resilience

Summary

Background: Depressive disorders often have a chronic course and the efficacy of evidence-based treatments may be overestimated.

Objective: To examine the effectiveness of the Heart Rate Variability Stress Reduction Program (SRP) as a supplement to standard treatment in patients with depressive disorders.

Methods: The SRP was individually administered in eight weekly sessions. Seven participants completed the full protocol and were enrolled in a single-subject ABA multiple baseline experimental design. To perform interrupted time-series analyses, daily measures were completed in a diary (depression, resilience, happiness, heart coherence and a personalized outcome measure).

Results: Five out of seven patients improved in depressed mood and/or a personalized outcome measure. The effect of treatment was reversed in four patients during the withdrawal phase. One patient reliably improved on depression, whereas two patients recovered on autonomy and one on social optimism. No consistent relationship was found between the heart rate variability-related level of coherence and self-reported mood levels.

Conclusions: The SRP is beneficial in some domains and for some patients. A prolonged treatment or continued home practice may be required for enduring effects. The intervention had more clinical impact on resilience-related outcome measures than on symptoms. The small sample size does not permit generalization of the results. We recommend future investigation of the underlying mechanisms of the SRP.

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1. Introduction

Depression is a major debilitating mental disorder, often with a chronic course and recurrent episodes. Approximately eighty percent of the people suffering from a depressive disorder will experience two or more episodes, with a lifetime average of four episodes [1–3].

Extensive research on treatment for depression has shown that psychotherapy and pharmacotherapy are equally effective for depression [4–6]. For both chronic and acute depression, combining these therapies is more effective than either psychotherapy or medication alone [7–9]. However, the modest benefit from evidence-based interventions asks for additional interventions [10].

In this study, we focus on the Heart Rate Variability Biofeedback Stress Relief Program (SRP; [11]) as a supplement to standard psychiatric treatment for depression. The SRP combines two factors associated with increased HRV: (i) regulation of breathing and (ii) changing negative affect into positive affect. Changes in HRV are mediated through the autonomic nervous system. Every person has an ideal breath rate, the so-called resonant rate (mostly 5–6 breaths per minute) which optimizes HRV [12]. Regular practice in optimizing HRV using breathing techniques, initially guided by biofeedback, is thought to normalize and optimize the autonomic function [13]. Some studies have shown that patients with a depressive disorder show abnormal low HRV and dysfunctions in their stress-response system, and that regulation of breathing results in significant improvements [14–18]. A critical analysis presented mixed findings concerning the HRV-depression relationship and reported that HRV-related measures are a relatively weak indicator of depression [19].

Central to the SRP is the concept of heart coherence. Heart coherence is described as a harmonious, ordered heart rhythm pattern [20]. It reflects a regular, sine-wave-like pattern in HRV. High coherence scores have a very narrow, high-amplitude peak in the low-frequency region (around 0.1 Hz) of the HRV power spec-

trum and no major peaks in the very low and high frequency regions ([20] pp. 7–8). High coherence is associated with enhanced cognitive functioning, positive emotions, and emotional stability [20]. Low coherence is associated with stress, negative emotions, and feelings of instability [20]. When experiencing positive emotions, heart rhythms are harmonious, creating an ordered, coherent pattern. When experiencing negative emotions, heart rhythms become disordered and chaotic, indicating a stress response in the body. SRP has demonstrated to reduce anxiety and to improve stress management [21–23]. Likewise, people with a vulnerability for depression may show negative affect in response to minor stressors in daily life [24]. The SRP might protect them against relapse or increase of depressive symptoms due to such stressors.

We chose the single-subject experimental design to investigate this novel intervention for depression. Single-subject experimental designs are especially suited to show evidence of benefit and harm from therapy in individual patients [25, 26]. In addition, they allow investigating at which treatment stage the best results have occurred.

2. Objective

The aim of our study is to assess the effectiveness of the individually administered Heart Rate Variability Biofeedback Stress Relief Program to reduce depressive symptoms and to improve resilience in patients who did not respond satisfactorily to treatment with psychotherapy and antidepressants.

3. Methods

3.1 Participants

Participants were outpatients of the Center for Integrative Psychiatry (CIP), a department of Lentis Mental Health Organization. Inclusion criteria were: (a) a diagnosis of 'major depressive disorder' according to the Diagnostic and Statistical Manual of mental disorders (DSM-IV; [27]); (b) a score of at least 15 on the Beck Depression Inventory-II (BDI-II; [28]) for a period of minimal four weeks. This cut-off score is considered optimal for the screening of full syndromal expression of depressive disorder [29]; (c) having been treated with both cognitive behavioural therapy (CBT) and antidepressant medication. Exclusion criteria were: following a treatment for depression other than antidepressant medication, and being diagnosed with a neuropsychiatric disorder, a psychotic disorder, a personality disorder (traits were allowed), substance dependence or mental retardation.

Ten persons were included in the study (nine female). Three female participants dropped out during the treatment phase due to lack of motivation to fill out the daily diary questions. Seven participants completed the full protocol. Mean age of the completers was 46.4 years (SD = 14.0; range 23–62). Six patients (five female, one male) met the DSM-IV criteria for recurrent major depression; one patient met the criteria for major depression. Two patients had co-morbid avoidant personality traits and one patient had co-morbid dependent personality traits. All patients had received psychological and psychotropic treatment in the past, with a mean treatment duration of 23.0 years (SD = 11.5; range 1–39). During the study three of them still received psychotropic medication.

3.2 Study Design

An ABA-withdrawal design combined with a non-concurrent multiple baseline across subjects design was used [30]. The duration of phase A (baseline phase) was determined randomly by an independent researcher with the SPSS Random Number Generator, with the restriction that this phase should last three weeks at least and eight weeks at most. During this phase participants attended supportive sessions weekly and filled out a mood diary daily. After completing the baseline phase, participants attended eight weekly sessions of the SRP program (treatment phase B). The treatment phase was succeeded by six weekly supportive sessions (withdrawal phase A). Participants continued to complete the daily diary during the entire study period.

This study was approved by the Medical Research Ethics Committee for Mental Health Care (reference number 9221).

3.3 Procedure

3.3.1 Inclusion

The files of all patients registered at the CIP and diagnosed with a depressive disorder were selected. Subsequently, patients who received past treatment of CBT and antidepressant medication were identified. Eligible patients were offered an information brochure about the study by their practitioner. If they were interested in the study, they were invited for a screening interview in which they received detailed information about the study and completed the BDI-II. For those who scored higher than fourteen on the BDI-II, personalized therapy goals for the daily diary were determined. Those scoring above fourteen on the BDI-II in the second interview four weeks later, also completed a questionnaire on medical and demographic information, the Positive Outcome List (POL; [31]), and the Happiness Index (HI; [32]), whereas heart coherence was assessed using biofeedback equipment (Heartmath emWave PC version 1, 2007). Both interviews lasted 60–90 minutes each. Written informed consent was obtained from all participants.

3.3.2 Baseline and Withdrawal

The baseline phase involved 3–8 weekly supportive sessions lasting 45–60 minutes. In these sessions the participants were free to come up with topics they wanted to discuss. The therapists were instructed to adopt a supportive and empathic attitude. The withdrawal phase involved 6 weekly sessions following the same principles. Before the withdrawal phase, participants had to return the biofeedback equipment and were not allowed to perform the techniques administered during treatment, because this phase served to examine whether discontinuation of treatment and home practice would lead to a reversal of the effects observed during treatment. The purpose of administering supportive sessions during the baseline and withdrawal phase was to determine whether changes in outcomes during treatment were a result of SRP-

specific ingredients or were merely due to non-specific factors, such as the therapeutic relationship. If a change occurred during treatment and was reversed during the withdrawal phase, the changes would likely be related to the specific ingredients of the SRP treatment rather than to non-specific treatment factors.

3.3.3 Treatment

The HRV Stress Relief Program consists of eight weekly individual sessions, each lasting 45 to 60 minutes (SRP; [11]). During the first two sessions participants explore their sources of stress, stress reactions and coping strategies. They are also requested to recall a positive and negative event, thereby to re-experience the associated emotions. Thus, awareness of the effect of both negative and positive feelings on their mental, emotional and physical state is enforced. Session three focuses on the breathing technique. First, participants learn to focus on the heart area. Second, slowing down and controlling optimal breathing (five to six breaths per minute) is supported by visual biofeedback on a computer screen. Finally, the therapist will encourage the participant to practise the breathing technique three times a day for 5–10 minutes, using a portable biofeedback device. In sessions four and five, the participants are trained to combine the breathing technique with a recall of positive feelings related to positive memories. Thereupon, participants are encouraged to sustain the positive feelings by expanding the duration of the daily exercise to 20 minutes. Session six and seven focus on changing negative affect into positive affect when feeling stressed. In an exercise called the Freeze-Frame, participants are invited to identify a stressful situation and to recognize the stressful feeling. The next step is to take a time-out (Freeze-Frame) and to shift the attention towards the heart area, whilst breathing at a paced rate, recalling a positive memory and re-experiencing the accompanying positive feeling. Then the therapist will ask to evoke the stressful situation and to describe what would be a more efficient and effective response to the situation from this coherent state of being. Participants have to practise this at home too. In session eight, the participants' experiences are discussed and the Freeze-Frame exercise is repeated. In the last session the pitfalls and successes are evaluated and the participants explore how the exercises could be used in future stressful situations to better cope with or to recover faster after such situations. At the start of each session in the intervention phase, HRV biofeedback measures are taken during five minutes. In all phases, sessions are administered by a psychologist and a nurse practitioner, both licensed trainers in the SRP.

3.4 Measures

The daily measures of depressive symptoms were completed in a paper and pencil diary during the entire study period, to enable performing interrupted time-series analyses [33]. The BDI-II, POL, Happiness Index and Heart Coherence were administered and measured at the start of the baseline-, treatment- and withdrawal phase, and at the end of the withdrawal phase.

3.4.1 Primary Outcome Measures

Daily levels of depressive symptoms were assessed with the following two diary items: "I feel down, depressed or empty" and "I lost my interest for things which usually give me pleasure". Items were scored on a Visual Analogue Scale (VAS) ranging from 0 (not at all) to 10 (very much) and assess a depressed mood and loss of interest or pleasure in daily activities, which are the two core symptoms of depression according to the DSM-IV [27].

Participants were asked to formulate a self-chosen personalized therapy goal or symptom associated with depression they would like to improve. This item was included in the diary. Some examples of the personalized outcome measures were: "I am self-confident"; "I am optimistic"; "I accept my situation". Scores were assessed on a VAS scale from 0 (not at all) to 10 (very much).

3.4.2 Secondary Outcome Measures

Depression: severity of depression was assessed with the Beck Depression Inventory (BDI-II; [28]), a 21-item self-report questionnaire assessing the cognitive, affective and neurovegetative symptoms of depression. Each item is represented by four statements in terms of increasing severity. Each statement is assigned a score of 0–3, resulting in a total score ranging from 0 to 63. In the present study, the Dutch version of the BDI-II was used, which was shown to have a high internal consistency in a Dutch sample of psychiatric patients (Cronbach's alpha=.92) as well as an adequate construct validity with related depression scales [34].

Resilience: the Positive Outcome List (POL; [31]) was used to assess the level of resilience. This 10-item self-report questionnaire measures two dimensions of resilience: POL-Autonomy (e.g., "I am in control over my life" and "I have insight into myself and my situation") and POL-Social Optimism (e.g., "I feel socially skilled" and "When needed, I can lean on others"). Each item is scored on a 4-point scale, higher scores indicating a higher level of resilience. The POL was validated in the Dutch population showing sufficient psychometric properties; Cronbach's alpha=.88 [31].

Happiness: Happiness was measured with the Happiness Index (HI; [32]). The HI consists of one question "How happy have you been during the past month" [32]. The answer is scored on a 10-point Likert scale, a higher score indicating more perceived happiness.

Heart coherence: the heart coherence scores were assessed using the Heartmath emWave PC version 1 (2007). This biofeedback program was also used during the training sessions. The coherence score is based upon a composite score. In the biofeedback program, a coherence bar chart displays the percentage of time a user has spent in three categories of coherence: low, medium and high. The composite coherence score is computed by assigning two points for high coherence, one point for medium coherence, and no point for low coherence, and can range from 0–200. Thus, higher scores reflect more coherence, which is assumed to be better. The Heartmath's emWave has four challenge levels at which the coherence scores are judged to be low, medium or high. The second level was selected during the measurements of

Variable	Participant number	Level change (Estimate)	Slope baseline (Estimate)	Slope change (Estimate)
Depressed mood	1	.10	–.05	.03
	2	–.61	.03	–.05
	3	.19	.01	–.02
	4	3.57***	–.03	–.07*
	5	3.04***	–.04*	–.00
	6	.40	.01	–.02**
	7	.12	.08***	–.10***
Loss of interest in activities	1	.25	–.05	.03
	2	-.30	.01	–.02
	3	.61	–.03	.01
	4	4.10***	–.05*	–.04
	5	2.30**	–.02	–.02
	6	.44	–.01	–.01
	7	.05	.07***	–.09***
Irritation	1	.10	–.07**	.06*
Acceptance	2	.66	–.06*	.08**
Self-confidence	3	.08	–.03	.05*
Satisfaction	4	–2.64*	.01	.04
Positive interpretation	5	–2.26***	.05***	–.05**
Optimism	6	–.39	–.01	.03
Courage	7	–.20	–.09***	.09***

*p < 0.05; **p < 0.01; ***p < 0.001

Table 1 Results of ITSA performed on daily diary data for each participant (treatment phase compared to baseline phase).

the present study. Heart coherence (HC) was measured at both the start and the end of the baseline and withdrawal phases and at the beginning of each session in the treatment phase. Each measurement takes five minutes with the instruction "to be as coherent as possible". In order to prevent artefacts, participants were instructed to avoid heavy aerobic exercise during the hour prior to measurement.

3.5 Statistical Analysis

3.5.1 Interrupted Time-Series Analysis

In order to determine whether the variables under study have changed from the baseline phase to the intervention phase, and from the intervention phase to the withdrawal phase, and whether they changed gradually or abrupt, we analyzed the daily diary data using interrupted time-series analysis (ITSA; [33]). ITSA is especially suited to evaluate behaviour change interventions using single-subject experimental designs [35]. Level (abrupt change in the mean level of the data) and slope (gradual changes) effects were estimated following the recommendations of Huitema and McKean [36]. The time-series analysis was controlled for autocorrelation (serial dependency) by fitting ARIMA models to the residuals [33].

3.5.2 Visual Analysis and Clinical Significance

The BDI-II, POL and HI were not administered frequently enough to be submitted to ITSA. In accordance with Kazdin [37], we used visual inspection of these data to identify changes over the different phases. To examine if the observed changes were clinically significant we applied the Jacobson and Truax method [38]. Clinically significant change was calculated by the Reliable Change Index and the passing of the cut-off between dysfunctional and functional score range on the basis of the BDI-II and POL norm scores for the general community and psychiatric outpatients.

4. Results

The baseline phase A varied across participants from 24 to 58 days (M = 42.4 days; SD = 12.4).

4.1 Interrupted Time-Series Analysis

Results of ITSA conducted on variables of the daily mood diary are summarized in ▶Table 1 and 2. Seven patients completed the study. ITSA analysis revealed statistically significant improvements in five of the seven patients on at least one of the outcome variables following the start of treatment (P2, P3, P4, P6 and P7). Slope changes were observed more often than level changes, indicating that the impact of SRP on outcome measures was mostly gradual. In P4 the improvement had already started in the baseline phase and was preceded by an abrupt deterioration (level change) on the daily outcome measures at the start of the treatment. One patient (P1) showed improvement during the baseline phase and deteriorated seriously during the treatment phase in depression and could not fill out the daily diary during the withdrawal phase. In four of the remaining six patients a significant deterioration in slope change was observed during the withdrawal phase (P2, P4, P6 and P7). In three patients an abrupt deterioration in level change was found at the start of the withdrawal phase (P3, P5 and P7).

4.2 Visual Analysis of the BDI-II, POL, HI and HC Scores

Each participant's scores obtained on the BDI-II, POL, HI and the HC throughout the study are shown in Figure 1 (available as ▶Online Supplementary Material). Visual inspection of the figures suggests that scores on the POL-Social Optimism and HI remained relatively stable during all phases of the study. Five participants

showed a decrease in BDI scores and an increase in POL-Autonomy scores during treatment, and in four of them the decrease in BDI scores had already started in the baseline phase. In three of the participants BDI scores further decreased during the withdrawal phase, whereas in the other participants these scores increased during the withdrawal phase. In five participants a progressive improvement in HC scores was observed following the treatment. One participant showed substantial reduction of HC scores during treatment and one participant remained stable in HC scores during all phases of the study. Only one participant showed a consistent relation between depression and HC scores in all phases of the study. An increase in HC scores was associated with a decrease in depression and vice versa in this patient.

4.3 Clinically Significant Changes of the BDI-II and POL

To examine whether the visually observed changes in the BDI-II and the POL were clinically significant, we applied the Jacobson and Truax method [38, 39]. This method operationalizes recovery in a relatively objective and unbiased way. Clinically significant change is related to the return to normal functioning and is based on two criteria: the Reliable Change Index and passing the cut-off between the dysfunctional and functional score range. The criteria were calculated based on the Dutch norm scores of the BDI-II [28] and the POL [31] for the general community and psychiatric outpatients. To be 'recovered', participants would need to make a reliable change in the direction of functionality and should cross the cut-off. Participants showing 'improvement' have made reliable change in the direction of functionality but did not cross the cut-off. 'Unchanged' participants have not made reliable change (whether they crossed the cut-off or not) and 'deterioration' implicates reliable change but in the opposite direction of functionality. We calculated clinical significance only for the change observed during the treatment phase, as this was the phase in which SRP was administered. Due to missing values on the POL, clinical significance for the POL scores was calculated for six (out of the seven) patients.

Table 2 Results of ITSA performed on daily diary data for each participant (withdrawal phase compared to treatment phase).

Variable	Participant number	Level change (Estimate)	Slope treatment (Estimate)	Slope change (Estimate)
Depressed mood	1	n.a.	n.a.	n.a.
	2	.59	−.02***	.03*
	3	.96**	−.01	−.02
	4	1.02	−.11***	.12***
	5	2.05*	−.04**	−.00
	6	−.08	−.02**	.05***
	7	−.69	−.02**	.05
Loss of interest in activities	1	n.a.	n.a.	n.a.
	2	−.31	−.01	.02
	3	1.10*	−.02*	−.02
	4	.45	−.09***	.12**
	5	1.80*	−.03**	−.01
	6	−.15	−.02**	.05***
	7	−.64	−.02*	.02
Irritation	1	n.a.	n.a.	n.a.
Acceptance	2	−.41	.03	−.01
Self-confidence	3	−.30	.02***	−.01
Satisfaction	4	−.73	.06**	−.05
Positive interpretation	5	−.32	−.00	.03
Optimism	6	−.13	.01*	−.04***
Courage	7	1.28**	.01	−.07**

*p < 0.05; **p < 0.01; ***p < 0.001
n.a. = not assessed. Participant 1 did not fill out the diary during the withdrawal phase.

▶Table 3 presents the clinical status of the participants at the end of the treatment period. The number of subjects that showed reliable improvement on the BDI-II was small: only one patient improved. The number of patients improved and recovered in POL-Autonomy was higher. Two (out of the six) patients recovered and one improved in POL-Autonomy. In POL-Social Optimism one participant recovered. Also, one patient deteriorated significantly in POL-Autonomy and POL-Social Optimism during treatment.

5. Discussion

The results of our study suggest that the SRP is beneficial for some but not all patients. The clinical significance of the improvement in depressed mood was small and suggests that the intervention had more clinical impact on resilience-related outcome measures than on psychological symptoms. In contrast, one patient's resilience deteriorated during treatment. This may be explained by the so-called 'backdraft' phenomenon, described in studies on the effect of self-compassion [40–42]. The shifting from negative to positive affect in the SRP may evoke feelings of (self-)compassion. Patients who are used to constant self-criticism may erupt with intense negative emotions when they take a more gentle, self-compassionate approach towards themselves. An exploration of HRV responses to compassion-focused imagery has found a similar threat-like response after inducing positive emotions such as acceptance and kindness, resulting in a re-

Status	End of treatment					
	BDI-II		POL-Autonomy		POL-Social Optimism	
	N	%	N	%	N	%
Recovered	0	0	2	33.3	1	16.7
Improved	1	14.3	1	16.7	0	0
Unchanged	6	85.7	2	33.3	4	66.7
Deteriorated	0	0	1	16.7	1	16.7

BDI-II: Beck Depression Inventory-II; POL: Positive Outcome List. Recovered: passed cut-off and reliable change index; Improved: passed reliable change index but not cut-off; Unchanged: did not pass reliable change index; Deteriorated: passed reliable change index but worsened. Reference is pre-treatment score (start of phase B).

Table 3 Clinical status according to the BDI-II and POL scores.

duction in HRV in people with insecure attachment styles [43].

This study raises important questions about the relationship between levels of heart coherence and depression. Slow breathing and shifting negative to positive affect are considered as the main underlying working mechanisms of coherence increase, and coherence increase in turn is thought to decrease depression [44, 45]. Increased coherence scores should thus lead to a decrease of psychological symptoms. Visual analysis of the data showed that there was no clear association between the self-reported depression levels and the heart coherence scores. This is consistent with other studies involving the underlying working mechanisms of this SRP program and slow-breathing, in which no reliable association was found between optimizing heart coherence and psychological symptoms [22, 46]. Other mechanisms may explain the (small) improvements in psychological symptoms and resilience observed in our study. The proposed 'relaxation response' by Benson may be one such mechanism. Relaxation practices such as yoga, meditation, and breathing techniques are known to down-regulate the stress response systems and to stimulate a relaxation response by increasing parasympathetic nervous system activity [47]. It may be that this relaxation response also explains the observed improvements in some of our patients, but that this relaxation response is not adequately reflected in our measure of heart coherence. Other mechanism may also have played a role. The SRP also contains elements such as increasing awareness of emotional states, stress appraisal and shifting negative affect towards positive affect. Thus, another mechanism underlying the improvements may have been the element of shifting negative to positive affect. Fredrickson [48] has demonstrated that enhancing positive emotions can be beneficial in several respects. Further, the program may have enhanced feelings of control and agency, which can be useful in regulating stressful emotions. This may have been reflected in the clinically significant change in autonomy in three of the participants. Moreover, the therapists involved in the study know from clinical experience that patients keep using the technique as a means to increase their feelings of control and agency during or after stressful experiences.

The multiple baseline ABA design controlled for non-specific factors such as the therapeutic alliance and the therapist's competence. Thus, the therapeutic gains observed during the treatment phase can be attributed with more reliability to the specific intervention. However, the fact that in a number of participants improvements started already during the baseline phase, suggests that non-specific therapy factors may also have played a role.

This study has some limitations. First, the small sample size does not permit generalization of the results to the entire population of depressive patients who did not recover from treatment with CBT and antidepressants. Second, it is not quite clear to what extent antidepressant medication has influenced HRV-related measures. Some studies found that selective serotonin reuptake inhibitors (SSRIs) elevate or suppress HRV-related measures [49–51], whereas other studies suggest that SSRIs do not influence HRV levels [52–54]. The effect of medication on three participants' HC scores has not been explored and remains unclear. Third, it is possible that the participants in this study differed from other patients with depression. The sample mainly consisted of female patients (6 females and 1 male), and although the sample included a wide age range, the mean duration of treatment was 23 years, indicating a sample with chronic mental disease. Fourth, we did not measure long-term effects of the intervention.

Future research may examine the underlying mechanisms, not only for a better understanding of how the SRP may lead to improved psychological outcomes, but also to explore which patients will be at risk for 'backdraft'. Also, it should be explored whether the results of the program would benefit from a prolonged treatment or continued home practice.

6. Conclusion

The Heart Rate Variability Biofeedback Stress Relief Program is beneficial in some domains and for some but certainly not all patients. The intervention had more clinical impact on resilience-related outcome measures than on psychological symptoms. A prolonged treatment or continued home practice may be required. Future studies should focus on the underlying mechanisms, the 'backdraft' phenomenon and on adaptation of the program to enhance its effects.

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