

## A Randomized Controlled Biofeedback Intervention Study On Heart Rate Variability In Unemployed Subjects

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### Abstract

**Background:** Unemployment is a chronic stressor which is associated with higher levels of impaired physical and mental wellbeing, e.g. reduced heart rate variability (HRV) and decline in self-esteem and self-efficacy. The present study investigated the effectivity of a HRV-biofeedback-training in increasing HRV and general self-efficacy.

**Method:** A total of  $n = 22$  unemployed individuals with adjustment disorder participated in this study [14 females, mean ages  $42.53 \pm 8.88$  years]. All participants performed randomized the "stress tests" for heart rate (HR) and HRV assessment: timed breathing, d2-attention-stress-test and math-test drawn from the Trier Social Stress Test (TSST). Four sessions HRV-biofeedback à 20 min within 2 weeks were administered. HR and HRV were assessed before and after biofeedback training. ECG preprocessing and analysis were performed with the Stressball software program (BioSign GmbH, Ottenhofen, Germany). The RMSSD time domain measure was calculated as HRV index. Clinical outcome measures were the ADNM total score and the general self-efficacy scale (GSE).

**Results:** Participants were well matched in terms of demographic and clinical characteristics. ANOVA didn't demonstrate significant time x group interaction effects neither for HRV parameters (HR, RMSSD) nor for psychological parameters (ADNM, GSE).

**Conclusion:** Our findings do not indicate that HRV-biofeedback can increase HRV nor general self-efficacy in unemployed subjects with adjustment disorder. Implications for future studies are discussed.

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## Introduction

Unemployment is a growing problem. The unemployment quota ranged at 18.3% at the beginning of this study in the year 2005 [1]. It is well known that unemployment brings to bear negative effects on the psychological [2-5] and physical state of health of those affected [6,7,8], e. g. decline in self-esteem [9], increased prevalence of depression [10] and increased risk of cardiovascular disease [11] were observed. Even higher mortality rates [12-16] and suicidal tendencies [14,16] have been reported. Therefore it is even more important to research the influencing factors causing these negative results as well as evaluating intervention strategies to minimize these negative effects.

Unemployment is a chronic stressor potentially disturbing autonomic balance when adjustment to job loss fails. Heart rate variability (HRV) is an established marker of autonomic flexibility, or in the case of depressed HRV, of autonomic inflexibility in response to changing external and internal stressors [17]. Jandackova, Paulik, and Steptoe (2012) demonstrated decreased HRV parameters in unemployed subjects [18]. Unemployment may be associated with factors that negatively influence HRV parameters, such as smoking, drinking, physical inactivity and high body mass index that could account for the increased prevalence of cardiovascular diseases [18]. HRV is defined as the beat to beat variability of consecutive heartbeats [19]. It is regulated by the balanced interaction of the sympathetic and the parasympathetic nervous system. Parasympathetic activity is reflected in adjustments of the heart rate (HR) in response to changes in blood pressure or respiratory status; the sympathetic tone controls changes in HR in response to physical or mental stress [20]. In medical science and practice, HRV has established itself as an independent predictor for an increased risk of mortality after a myocardial attack [21]. In clinical psychological research, decreased HRV parameters were associated with negative affectivity, especially with anxiety [22] and anger [23] and with mental disorders such as depression [24-32] and anxiety disorders [22,33].

Up to now, there is little evidence for interventions providing support to unemployed subjects in reducing distress [34] and existing studies focused primarily on re-employment. Interventions supporting

adjustment to job loss could also focus the associated negative health effects, e.g. the previous finding of reduced HRV [18]. Studies documented a positive effect of HRV-biofeedback training on HRV [35-37]. Biofeedback is a scientifically based method in which physiological bodily processes, which normally are not perceived consciously, are made visible and, thus, individually amenable to influence. Physiological signals (e.g. heart rate) are registered, amplified, and visually or acoustically confirmed. Thus, seemingly unable to be influenced bodily functions can be controlled via biofeedback processes [38]. Recent studies further indicate that HRV biofeedback is effective in the treatment of depression [39-41], posttraumatic stress disorders [42,43], sleeping disorders [43], stress disorders/stress reactions [44-46], anxiety disorders [47], the attention-deficit-hyperactivity-syndrome [48], fibromyalgia [39], and bronchial asthma [49,50].

The processes by which HRV biofeedback improves health and well-being are not yet understood. It is suggested that HRV biofeedback produces resonance condition between HR, breathing rate and baroreceptor activity allowing for maximized amplitudes of the HRV [37]. Resonance frequency differs interindividually but on average it is 0.1 Hz, corresponding to 6 breathes per minute [37]. Further, biofeedback improves interoceptive awareness of any senses stimulated within the body [51]. With the help of biofeedback, participants learn to perceive and control somatic functions that actually are not perceived consciously. Thus biofeedback may help to improve well-being by increasing self-efficacy and the sense of control. This idea agrees with Turner, Kessler, and House (1991) who recommended providing interventions to unemployed subjects that bolster self-efficacy [52]. Work is one major source of self-efficacy that declines following job loss and is regained with re-employment [9]. Further self-efficacy is crucial in motivating job-seeking behavior since low self-esteem is associated with inhibition of job-seeking activities [53].

The aim of the present study is to evaluate the effectivity of HRV-biofeedback in normalizing HRV (increased RMSSD, decreased mean HR) and increasing ratings on self-efficacy in a sample of unemployed subjects.

## Methods

### Study Participants

The data were collected from April 2005 to October 2007. The examined group ( $n = 22$ ) consisted of unemployed individuals from the vicinity of Dresden. To be eligible, participants needed to be aged between 18 and 60 years, fluent in German, unemployed for at least six months and they needed to meet the criteria for an adjustment disorder following unemployment. Exclusion criteria included alcohol and substance abuse, pulmonary (e. g. chronic obstructive or restrictive functioning disease), cardiac (e. g. arrhythmia, heart insufficiency, cardiac valve disease), endocrinological (e.g. thyroid conditions, diabetes mellitus) or neurological diseases (e.g. polyneuropathy), arterial hypertony, malnutrition, underweight or the intake of heart frequency modulating medications, especially beta blockers, tricyclic antidepressants or thyroid hormones. Participants were randomly assigned to either the biofeedback treatment group ( $n = 11$ ) or the waiting control group ( $n = 11$ ). All the study participants provided written informed consent. The study protocol was approved by the local Ethics Committee of the Medical Faculty of the Technical University of Dresden, Germany (No# EK148082006).

### Procedures

**Stress Tests.** For the determination of the HRV, the so-called "stress tests" were carried out at a two-week-interval at two measuring times. These consisted of five parts, for which the RMSSD [ms] as well as the mean heart frequency (bpm) were calculated, respectively. The stress tests were the following: (1) 1-minute timed breathing interval (deep respiration), (2) 3-minute measurement under stress condition (concentration), (3) 1-minute timed breathing interval (deep respiration), (4) 3-minute measurement under stress condition (math task), (5) 1-minute timed breathing interval (deep respiration).

First of all, the participant was instructed to inhale and exhale as deeply as possible in the given breathing rhythm of six breaths per minute. This was carried out by way of a visual beam which was moved up and down, thus instructing the participant about the inspiration and the expiration phase. Paced breathing with six breaths per minute allows for maximum amplitudes of the HRV [20].

The following tasks were used for stress induction: The d2-attention-stress-test (d2) [54] is a performance test (concentration test) which serves to record the general requirements for obtaining different performances (e.g. logical thinking, spatial imagination). This measure calls for a high degree of attention/concentration, however no special aptitudes. It is a widely applicable measure, whereby the necessary attention/concentration was used as stress-inducing component in the framework of this study. The d2 is a homogenous test with 14 test lines containing 47 letters each (d's and p's with 1 to 4 strokes each). The test participants' task was to score out all d's with two strokes at an allotted time of 20 seconds per line, respectively. The tests consist of working through the standardized instruction as quickly and as accurately as possible. As there was a stress period of three minutes scheduled for this study, the work process went through line nine.

The math test also used for stress induction is an element drawn from the Trier Social Stress Test (TSST) [55]. The test participants were instructed to count backwards from the figure 2046 in steps of 17 and to announce the respective results out loud. There was no reaction to any of this from the study coordinator to indicate the correctness of a result, compelling the test participant to automatically continue with the task. If a result was incorrect, the study participant had to begin anew at 2046. The TSST is a well-established tool for stress induction.

**Biofeedback.** Participants in the biofeedback group were trained for four sessions within two weeks, at approximately at the same time of day for each subject. Inter-individual noise was reduced by instructing participants to abstain from food and drink consumption preceding testing [56]. Further participants confirmed that they had not drunk alcohol or caffeine-containing beverages or smoked during the previous three hours.

The Stressball biofeedback system (BioSign, Ottenhofen, Germany) was used. Participants were seated in a comfortable chair and instructed to metronome-controlled breathing with six deep breathes per minute (0.1 Hz) allowing for maximized amplitudes of HRV [37]. A balloon on a computer screen that moved up for inspiration and down for expiration was used for pacing respiration. The parameter being

displayed was the overall HRV. Each session was 20 minutes long. Additionally, participants of the biofeedback group were asked to perform a breathing exercise at home three times the day lasting 5 to 10 minutes. The breathing exercise guided participants to breathe with the aforementioned metronome of 0.1 Hz with the help of a rising and falling tone indicating inspiration and expiration. This exercise was introduced at the first measuring time. The participants received an audio disc and an instruction paper to facilitate at-home practicing as well as a protocol to minute all exercises. Both the biofeedback and waiting control group were tested again for HRV assessment with the stress-tests after cessation of the biofeedback training.

## Measures

### Clinical Assessments

The individual's ability to adjust to job loss was evaluated by assessing the manifestation of an adjustment disorder using the 29-item-self-report questionnaire adjustment disorder new module (ADNM) which consists of two parts [57]. In part one, the respondent is asked to report stressful life events out of seven categories (severe illness, family conflicts, divorce/separation, conflicts with colleagues/at work, illness of relative, financial problems, leaving working life) and to decide which one was the most distressing. The second part involves the diagnostic criteria for an adjustment disorder belonging to the core symptoms of intrusion, avoidance and failure to adapt and the subtype criteria (anxiety, depressed mood, impulse disturbance). Part two is rated on a 4-point Likert-scale. Two out of three of the core anxiety or depressive symptoms have to be present for subtype manifestation.

To differentiate psychological and physical impairment the Complaint List (BL) [58] was used which consists of 24 items with a four-point rating scale (range 0-72). Severity of depressive symptoms was self-evaluated using the Beck-Depression-Inventory II (BDI-II) [59,60]. The respondent is asked to choose the most appropriate alternative out of 21 items matching the DSM-IV major depression criteria that best describes the way he or she felt during the past two weeks (range 0-63). Subjects' sense of personal competence to deal effectively with stressful situations was evaluated with the general self-efficacy scale (GSE) [61]. This self-

report instrument contains 10 items which are rated on a four-point Likert scale (range 10-40).

### Heart Rate Variability

The Stressball software program (BioSign GmbH, Ottenhofen, Germany) was used for the computer-aided recording of the HRV. The recording of the pulse-wave was carried out by an infra-red sensor positioned on the earlobe. The HRV-Scanner software program (BioSign GmbH, Ottenhofen, Germany) was employed for the evaluation of the data. It first of all served the automatic determination of the HR by way of the pulse wave. This was followed by the automatically recorded heartbeats were checked manually for all the individual measurements; artifacts as well as possible extra systoles were manually filtered out. The adaptation of the data was carried out according to extensive product instruction by the author. Maximally two extra systoles or artifacts each were accepted per measurement. Hence, it was permissible to delete two RR-intervals. The subsequent calculation of the parameters then took place automatically with the above mentioned software program. For HRV assessment, the root mean square of successive differences (RMSSD) as an established time-domain parameter of HRV was calculated [62]. The RMSSD parameter is a robust index of high-frequency variations in HR due to parasympathetic control of HR [19]. The most recent studies, among them that of Nussovitch et al. (2011), were able to show that the RMSSD reliably represented the HRV even in short (1 min) and ultra-short (10 sec) recordings [63].

### Statistical Analysis

Group differences in sociodemographic and clinical characteristics were tested using univariate ANOVA for continuous variables and chi-squared test for dichotomous variables. The effect of biofeedback on HRV (mean HR, RMSSD) was examined using repeated measures ANOVA with group [2] as between-subject factor and stress test condition [3] and measuring time [2] as within-subject factors. ANOVA results were corrected by Greenhouse-Geisser whenever necessary. Data analyses were performed using SPSS v. 22 (SPSS Inc., Chicago, IL, USA).



## Results

The group's characteristics are described in Table 1. Groups were well-matched on sociodemographic and clinical variables.

Means and standard deviations for each HRV parameter are displayed in Table 2 as a function of stress test condition and measuring time. ANOVA revealed a main effect of stress test condition for the RMSSD ( $F_{1,471;29,425} = 39.707, p < 0.001, \zeta^2 = 0.665$ ) and mean HR ( $F_{1,897;37,948} = 42.386, p < 0.001, \zeta^2 = 0.679$ ). Pair-wise comparisons revealed significant differences for all stress test conditions ( $p \leq 0.021$ ), except for comparing mean HR during the d2-attention-stress-test and math-test ( $p = 1.000$ ). As expected, increased RMSSD was observed during timed breathing with 0.1 HZ. ANOVA didn't demonstrate a main effect of group neither for the RMSSD ( $F_{1,20} = 2.400, p = 0.137, \zeta^2 = 0.107$ ) nor for mean HR ( $F_{1,20} = 0.011, p = 0.919, \zeta^2 = 0.001$ ) as well as no interaction effect between study group and stress test condition.

Regarding ADNM sum score, ANOVA failed to reveal a main effect of time ( $F_{1,18} = 1.029, p = .324, \zeta^2 = 0.054$ ) and of group ( $F_{1,18} = 1.121, p = .304, \zeta^2 = 0.059$ ) or time x group interaction effect ( $F_{1,18} = 2.085, p = .166, \zeta^2 = 0.104$ ). With regards to the GSE sum score ANOVA didn't demonstrate a main effect of time ( $F_{1,20} = 1.547, p = .228, \zeta^2 = 0.072$ ) or group ( $F_{1,20} = 1.083, p = .310, \zeta^2 = 0.051$ ) nor time x group interaction effect ( $F_{1,20} = 2.614, p = .122, \zeta^2 = 0.116$ ).

## Discussion

This study investigated the effectivity of heart rate variability (HRV)-biofeedback in improving HRV and general self-efficacy in unemployed subjects. To date, there is little research addressing intervention strategies to minimize negative effects on wellbeing following job loss. Previous studies demonstrated decreased HRV [18] and impaired general self-efficacy in unemployed subjects [9]. HRV-biofeedback is suggested to improve HRV as well as self-efficacy [51]. In this study, we found no significant effect of HRV-biofeedback on HRV and general self-efficacy.

Our results are in contrast to those of studies that reported increased HRV parameters following HRV-biofeedback-training [35,36]. Our findings didn't show significant alterations in HRV parameters following HRV-Biofeedback. The samples of Bacior et al. (2004) as well as Larsen et al. (2004) included patients with chronic heart failure who showed decreased HRV. Since this study didn't investigate a reference population, we couldn't state if HRV parameters were decreased in our sample compared to healthy control participants. To reliably evaluate HRV parameters in reference to normal ranges, this study should have included a healthy control group that should have passed the stress tests as well to serve as a reference population. According to a study by Agelink et al. (2001) both male and female participants of our study showed RMSSD parameters that are in line with established standard values [64]. This reduces the plasticity of improving initial RMSSD. Further, our data failed to show significant alterations regarding self-efficacy and the ADNM sum-score following HRV-

Table 1. Characteristics of the total sample. Mean (SD) are listed except where noted

	Biofeedback group (n = 11)	Control Group (n = 11)	Test statistic	p
Age (years)	41.09 (7.77)	44.36 (8.73)	$F_{1,21} = 0.863$	.364
Females, n (%)	7 (63.6)	7 (63.6)	$\chi^2 = 0.00$	.670
Body mass index	29.55 (7.49)	26.65 (6.08)	$F_{1,21} = 0.994$	.331
ADNM	13.18 (1.94)	13.11 (1.69)	$F_{1,19} = 0.007$	.933
BDI	18.91 (6.28)	19.73 (6.64)	$F_{1,21} = 0.088$	.770
CL	38.50 (9.77)	42.90 (10.05)	$F_{1,19} = 0.986$	.334

Note. ADNM = adjustment disorder new module sum score; BDI = Beck-Depression-Inventory sum score; CL = Complaint List sum score.

Table 2. HRV parameters and psychological assessment as a function of study group and stress test condition. Mean (SD) are listed

		Biofeedback-group (n = 11)		Control group (n = 11)	
		Pre	Post	Pre	Post
<b>HRV parameters</b>					
Mean HR	Timed breathing	75.51 (9.34)	74.28 (11.22)	73.76 (10.54)	76.44 (9.80)
	D2-attention-stress-test	84.88 (9.72)	79.75 (11.47)	81.17 (10.46)	82.07 (9.59)
	Math-test	85.27 (8.33)	80.11 (13.16)	81.29 (9.89)	82.60 (9.19)
RMSSD	Timed breathing	1.66 (0.32)	1.69 (0.29)	1.56 (0.23)	1.47 (0.24)
	D2-attention-stress-test	1.36 (0.21)	1.42 (0.18)	1.31 (0.13)	1.27 (0.14)
	Math-test	1.42 (0.16)	1.46 (0.24)	1.38 (0.16)	1.31 (0.17)
<b>Psychological assessment</b>					
ADNM		13.18 (1.94)	11.27 (4.13)	13.11 (1.69)	13.44 (2.56)
SWE		21.36 (4.78)	23.45 (5.48)	24.73 (5.76)	24.45 (4.72)

Note. Pre = before the biofeedback training; Post = after the biofeedback training; HR = heart rate; RMSSD = square root of successive R-R interval differences. RMSSD was log10 transformed.

biofeedback. On a descriptive level, the biofeedback group was able to improve their RMSSD and to decrease their mean HR in all stress-test-conditions. Failure to reach significance may result from the small sample size or short intervention time.

HRV assessment was largely performed in accordance with the recommendations of the Task Force [19]. Two variations were made. First, HR was derived by way of the pulse wave, and not via recommended ECG recording. But this method appears just as well reliable and not more interference-prone like ECG recording. Second, the Task Force recommends 5 minutes duration of ECG recording for short-term HRV assessment. In the present study, stress conditions lasted only 3 minutes and paced breathing was performed for 1 minute. ECG analysis was restricted to RMSSD time domain measure, and previous findings report on the reliability of the RMSSD for HRV assessment from recording of 1 minute and even of 10 seconds [63]. Hence the present recording duration appears to be sufficiently reliable.

There are some limitations that should be noted. First, the sample size was small. Another limitation of this study is that no baseline HRV resting condition had been included. Paced breathing can induce stress and hence doesn't serve well as resting condition. Future studies should include a resting session to compare resting and stressful conditions in HRV assessment.

Future studies should also include a real control group without adjustment disorder and a reference population for the establishment of normal ranges of HRV parameters. Moreover, the present study included only a short interval of two weeks to observe changes in HRV. This may be too short to detect adaptation in the autonomous nervous system. Future studies should extend the intervention interval.

In conclusion, we found no significant effect of a 2-week HRV-biofeedback-training. Thus, we didn't find evidence to support HRV-biofeedback-training in the present form to be an efficacious intervention to increase HRV and self-efficacy. Future studies should include a control group and extend the intervention interval.

### Acknowledgements

The present work was part of a graduate thesis.

### Conflict of Interest

All authors declare that they have no conflicts of interest.

### Ethical Approval

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

## Informed Consent

Informed consent was obtained from all individual participants included in the study.

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