Effects of Low-Dose Mindfulness-Based Practice on Patients with Somatoform Autonomic Dysfunction of Cardiovascular System

Mažo intensyvumo įsisąmoninimu grįstų praktikų efektyvumas pacientams sergantiems širdies ir kraujagyslių sistemos somatoformine autonomine disfunkcijai

Ruta MURANOVAITE1, Julius BURKAUSKAS2, WAYNE D. NORMAN1

1LCC International university, Klaipeda, Lithuania
2Behavioral Medicine Institute, Lithuanian university of Health Sciences, Palanga, Lithuania

SUMMARY

Introduction. Mindfulness based practice (MBP) might positively influence cardiovascular disease risk via an indirect pathway including change in emotion regulation. However, this link, to the best of our knowledge, was never tested in patients with Somatoform Autonomic Dysfunction of cardiacological system (SADCS). Objective. This study investigated associations between cardiovascular disease risk reduction (measured by heart rate variability [HRV]) and change in depression symptoms in SADCS patients during 3 weeks of MBP. Methods. The study consisted of a run-in session (consultation and diagnosis by the cardiologist), baseline and final sessions (assessment of physiological and psychological data) before and after three weeks of MBP or waiting. Seventeen of the randomly assigned participants (age 32±10) with SADCS completed a three-week MBP and entered into the experimental group while twelve participants (age 39±13) were randomly assigned to a waiting-list control group. For both groups, physiological measures (central aortic blood pressure [cABP] and root mean square of the successive NN interval squares [RMSSD]) were assessed at baseline and final sessions. Results. Results indicated larger differences in depression symptoms for participants engaged in 3 weeks of MBP when compared to control group (Mdn=–2, interquartile =–2–0 vs. Mdn = 0, interquartile 0–1,75, U=46, p=0.028, r=8.85). Change in RMSSD scores for the experiment group was significantly higher when compared to control group (M=11.58, SD=17.81 vs. M=–1.95, SD=12.3, t(27)=–2.33, p=0.028, d=.88). Correlation was significantly higher when compared to control group (M=11.58, SD=17.81 vs. M=–1.95, SD=12.3, t(27)=–2.33, p=0.028, d=.88). Apikita sąsaą tarp depresijos lygio pokyčio ir RMSSD eksperimentinėje grupėje (β=0,687, p=0,005), bet ne kontrolinėje grupėje (p>0,05). Conclusions. The change in depression scores for participants engaged in three weeks of MBP were significantly greater when compared to control group. Changes in RMSSD scores for the experiment group were significantly higher than for the control group. A significant correlation between HRV and depression symptoms was found only in the treatment group. Keywords: Somatoform autonomic dysfunction, Mindfulness, Depression, Anxiety, Heart rate variability.

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INTRODUCTION

A number of previous studies have demonstrated that as much as one-third of physical symptoms in medical care are medically unexplained symptoms and that these somatic symptoms are associated with an economical burden on the health system and society because of enormous consumption of health resources and reduction in the quality of patients’ lives [1-4]. If untreated in the long run, functional medically unexplained symptoms develop into structural changes of the cardiovascular system and present cardiovascular disease risk, causing negative cardiovascular outcomes, such as atrial fibrillations, strokes and infarcts of vasospastic origin [5, 6].

Research shows that Mindfulness Based Cognitive Therapy (MBCT) is a low-cost and effective intervention for patients with somatization, improving their life quality and reducing the health service burden in general [7]. However, the mechanism of mindfulness interventions for Somatoform Autonomic Dysfunction (SAD) patients seeking cardiological treatment is not well understood.

In a review of mindfulness and cardiovascular disease risk, Loucks and colleagues (2015) propose a plausible mechanism for associations of mindfulness with positive cardiovascular outcomes (Figure 1) [8]. In short, Loucks et al. (2015) explain that mindfulness interventions positively influence cardiovascular disease risk via an indirect pathway including change in: a) emotion regulation; b) attention control; and c) self-awareness [8]. Indeed, numerous imaging studies reveal MBCT attributed changes in gray matter concentration of brain regions (such as left hippocampus, posterior cingulare cortex, temporo-parietal junction and cerebellum) associated with emotion regulation, learning, memory and self-referential processing [9;10]. However, the proposed link between MBCT affected emotional regulation (in depression or anxiety disorders) and cardiovascular disease risk is less explored. Indeed, depression is one of the most common comorbidities of somatoform disorder [11;12] and has been known as a factor associated with lowered HRV [13]. This direct top-down link between central nervous system and heart rate variability (HRV) allows for indexing the central-peripheral integration, organismic self-regulation, and thus better autonomous nervous system condition [14]. Thus, in a simplified version of Loucks et al. (2015) model for SAD patients we would expect that MBCT effect on emotion regulation primarily would be visible in changes of depressive mood [8]. Then, if changes persist for a certain time this would generally affect HRV. While the proposed linkage might sound too reductionistic to the best of our knowledge it was never explored in a scientific literature. Confirming such links would allow future studies to investigate which aspects of MBCT affected emotional regulation contribute to lower depression symptoms.

Therefore, our study aimed investigating if there are associations between Mindfulness Based Practice (MBP) and cardiovascular disease risk reduction in patients diagnosed with Somatoform Autonomic Dysfunction of cardiological system (SADCS) through change in depression symptoms. Our primary aim was to measure if 3 weeks of MBP results in change in depression symptoms and whether change in depression symptoms influence HRV. The secondary aim was to measure if 3 weeks of MBP results in changes in mindfulness, somatic symptom severity, anxiety, and stress.

![Image of conceptual framework](image_url)

Figure 1. Conceptual framework suggesting possible mindfulness based practice mechanisms influencing cardiovascular disease risk factors
METHODS

Participants

Participants were recruited from a secondary health care facility specializing in cardiology. They were informed verbally and in written form about all pertinent aspects of the study. Informed consent was obtained from all participants, and the study was approved by the Institutional Review Board of LCC International University and performed in accordance with the Helsinki Declaration.

The sample consisted of participants diagnosed with SADCS by a cardiologist. Diagnosis was established by a cardiologist after performing ultrasonography; cardiac stress test (stationary exercise ergometer); 24-hour arterial blood pressure monitoring (if deemed necessary); thyroid check-up (if deemed necessary). Eligibility criteria are presented in Table 1. Inclusion criteria were: diagnosed with SADCS (F45.31); between 18 and 60 years old; signed written consent form (ICF); fluency in Lithuanian. Exclusion criteria were: structural cardiovascular disease or any other structural disease affecting autonomic balance (e.g. hypothyroidism); current practice of meditation; current use of beta blocker, benzodiazepine or any other pharmacological treatment known to have affect on cardiovascular system.

A total of 48 potential participants were screened by a cardiologist, 39 subjects met inclusion criteria and continued into the baseline session (V1), 29 participants agreed to participate by signing an ICF. In sum, 17 of the randomly assigned participants completed a three-week MBP program (where mindfulness was practiced for 15 minutes daily) and entered into the experimental group. Twelve participants were randomly assigned to a waiting-list control group. For both groups psychological and physiological measures were assessed at baseline (V1) and final session (V2). Mean age of the study sample was 36 years (SD = 12) and the sample was comprised of 65.5% females and 34.5% males.

Psychological Outcome Measures

Hospital anxiety and depression scale (HADS). Anxiety and depression symptoms were measured using HADS [15]. The scale is used widely in Lithuania [16] and is reported to be a valid measure in assessing anxiety and depression symptom severity in patients with coronary artery disease [17], as well as psychiatric, and primary care patients [18]. Cronbach’s alpha for HADS in this study was .87 for 14 items.

Perceived Stress Scale (PSS-10). Perceived Stress Scale (PSS-10) is a 10 item self-administered scale assessing appraisal of perceived stress. It is reliable and valid instrument measuring experienced stress levels [19]. Validity and reliability study of the scale in Lithuanian sample presented a Cronbach’s alpha of .840 [20]. Cronbach’s alpha of PSS-10 for the population of this study was .89 for 10 items.

Five facet mindfulness questionnaire (FFMQ). Five facet mindfulness questionnaire is a tool based on previously existing mindfulness questionnaires developed by Baer, Smith, Hopkins, Krietemeyer, & Toney (2008), measuring observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience and is one of the most commonly used methods for assessing mindfulness [21]. Construct validity study involving meditator and non-meditator groups supported validity of FFMQ and showed mindfulness facets being significantly related to meditation experience, psychological symptoms and well-being [21]. Cronbach’s alpha for the given sample was .79 for 39 items.

Patient Health Questionnaire (PHQ-15). Somatic symptoms severity was measured using the PHQ-15 questionnaire. Patient Health Questionnaire is a widely used short version of Primary Care Evaluation of Mental Disorders questionnaire, developed from a collaboration of psychological health specialists and general practitioners [22]. PHQ-15 is a self-administered questionnaire allowing for screening for somatoform disorders and assessing somatic symptoms and their severity. PHQ-15 contains symptoms related to heart rate and pain however lacks symptoms relating to arterial blood pressure (ABP). Considering the nature of SADCS “unstable blood pressure” is added to the Lithuanian version as symptom number 16 to the scale. A systematic review of PHQ-15 concluded that this is a valid measure for assessing and monitoring somatization [23]. In the given sample Cronbach’s alpha for PHQ-15 was .79 for 16 items.

Physiological data collection. Central aortic blood pressure (cABP) was measured using the Mobil-O-Graph monitor. This device fulfills the validation recommendations of the British Hypertension Society, which concludes that the device is meets accuracy requirements and can be used for clinical use [24]. For HRV measures the time domain measure of root mean squared successive differences (RMSSD) were obtained using the HeartMath emWave monitor (version 2.2.5.4876; HeartMath LLC, 2012). HRV data analyses were conducted using the Kubios HRV software (version 2.2; University of Eastern Finland, 2014). A recording of 6.5 minutes was trimmed approximately 20 seconds from front and back in order to have a stable 5-minute recording for each participant. No manual corrections were performed. In order to be provided with an artifact-free recording artifact correction was provided.

Table 1. Eligibility Criteria

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
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<tr>
<td>EL1 Able to speak Lithuanian;</td>
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<td>EX3 Current treatment with beta blockers, benzodiazepines or other medication known to have affect on cardiovascular system;</td>
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<tr>
<td>EL4 Signed written informed consent (ICF).</td>
<td>EX4 Participants who withdraw consent.</td>
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was set to medium level. Setting artifact correction to medium level rather than low level might have reduced variability, however for the purpose of ectopy-free data the medium level was used for analysis.

**Study design**

The study consisted of three sessions: initial run-in session (consultation and diagnosis at the cardiologist’s office), baseline session (assessment of physiological and psychological data and brief mindfulness training based session for treatment group), and final session (assessment of physiological and psychological data) after three weeks. A list of participant numbers was generated before the baseline session and all participants were randomly assigned (“random.org”, 2015) to either treatment or waiting-list group before attending the baseline session. Both physiological and psychological data were collected in a procedural room of a clinic. Participants were asked to abstain from food for two hours and stimulant drinks for 24 hours before data recording. HRV measures were taken in a seated position, approximately at the same time of day, on the same earlobe/arm under same conditions in the same environment: in the procedural room while watching a relaxing nature video for 6.5 minutes.

Mindfulness based meditation exercise. The intervention in this study was based on two formal MBCT and MBSR practices: body scan and sitting meditation. Three different practices were audio-recorded by a certified MBCT and MBSR instructor. A website holding the guided meditations for the three weeks including a short online diary under each practice was set up. Participants in the experiment group were instructed to complete a 15-minute practice for 6 days each week for the three-week period starting from the next day after baseline session. Participants were also asked to record experiences of each practice in the online-diary, indicating how involved they were on a scale from 0% to 100%. Reports with participants’ logs and their initials were automatically sent to the investigators’ emails.

**Statistical Analyses**

The IBM SPSS 21 statistical analysis software was used to analyze the data. Independent samples t-test and Mann-Whitney U test were used for examining differences in HRV and depression symptoms between control and experiment groups after 3 weeks of MBP. Dependent samples t-test and Wilcoxon Signed-ranks test were used to assess differences in change in mindfulness, somatic symptom severity, anxiety, stress and depression in experiment group was assessed comparing values at V1 and V2 using paired samples t-test and Wilcoxon Signed-ranks tests for normally distributed and non-normally distributed data respectively. A paired-samples t-test indicated that mindfulness was significantly higher in the treatment group at V2 (post MBP) compared to V1 (pre MBP) (M = 3.38, SD = 0.49 vs. M = 3.2, SD = .46), t(15) = –1.98, p = 0.068, d = .38). Stress was marginally significantly lower only in treatment group at V2 (post MBP) compared to V1 (pre MBP) (M = 17.8, SD = 6.93, t(15)= 2.12, p = 0.053, d = .36). Depression symptoms had also significantly decreased in treatment group at V2 (post MBP) compared to V1 (pre MBP) (M = 15.1, SD = 7.86 vs. M = 17.8, SD = 6.93, t(15) = –1.95, SD = 12.3, t(27) = –2.33, p = 0.028, d = .88).Further analysis using a Wilcoxon Signed-ranks test indicated that RMSSD was significantly higher in the treatment group at V2 (post MBP) compared to V1 (pre MBP) (Mdn = 55.1, interquartile = 34.4–63.6 vs. Mdn = 43.9, interquartile = 31.3–56.1, Z = –2.16, p = 0.031, r = 0.56).

Spearman’s rank-order correlation was used to determine the relationship between change in depression symptoms and change in RMSSD for both groups. Analysis showed a statistically significant correlation between change in depression symptoms and RMSSD in the treatment group, Spearman’s r(15) = 0.687, p = .005 but not in group of control subjects (p>0.05).

Change in mindfulness, somatic symptom severity, anxiety, stress and depression in experiment group was assessed comparing values at V1 and V2 using paired samples t-test and Wilcoxon Signed-ranks tests for normally distributed and non-normally distributed data respectively.

<table>
<thead>
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<th>Measure</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>SD</th>
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<tbody>
<tr>
<td>Age</td>
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<td>59</td>
<td>35.9</td>
<td>12.1</td>
</tr>
<tr>
<td>Height</td>
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<td>193</td>
<td>172.2</td>
<td>9.6</td>
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<tr>
<td>Weight</td>
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<td>125</td>
<td>75.2</td>
<td>17.5</td>
</tr>
<tr>
<td>Body mass index</td>
<td>20.1</td>
<td>36.1</td>
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In short, the total sample was comprised of 17 participants in treatment group (13 females and 4 males), mean age 31.6 years (SD 9.8) and 12 in waiting-list control group (6 females and 6 males), mean age 38.9 (SD 12.9).

Changes in symptoms of depression, anxiety, perceived stress, mindfulness, medically unexplained symptoms, HRV and blood pressure at pre- and post-assessment in both groups are presented in Table 3. A Mann-Whitney U test was performed on the change in depression symptoms between control and experiment groups. Differences in depression symptom score changes for participants engaged in 3 weeks of MBP were significantly lower when compared to control group (Mdn = –1, interquartile = –2–0 vs. Mdn = 0, interquartile = 0–1.75, U = 46, p =0.028, r = 8.85).
and the treatment group at V2 (post MBP) compared to V1 (pre MBP) ($M = 6.8$, SD = 4.49 vs. $M = 10.3$, SD = 4.73, $t(15) = 3.83$, $p = 0.002$, $d = 0.75$). In addition, anxiety also significantly decreased both in the wait-list control group at V2 (post MBP) compared to V1 (pre MBP) ($M = 7.42$, SD = 3.87 vs. $M = 9.25$, SD = 4.59, $t(12) = 3.63$, $p = 0.004$, $d = 0.43$), and the treatment group at V2 (post MBP) compared to V1 (pre MBP) ($M = 7.87$, SD = 4.82 vs. $M = 11.1$, SD = 4.54, $t(15) = 4.41$, $p = 0.001$, $d = 0.68$).

**DISCUSSION AND CONCLUSIONS**

The primary purpose of this study was to measure if three weeks of MBP results in change in depression symptoms. We found that the change in depression scores for participants engaged in three weeks of MBP were significantly greater after the three week MBP practice when compared to control group. Our second aim was supported, as changes in RMSSD scores for the experiment group were significantly higher after the 3 weeks of MBP when compared to the control group. What is more, a significant correlation between RMSSD and depression symptoms was found only in the treatment group, suggesting a relationship between change in depression symptoms and RMSSD changes.

In fact, neuropsychological perspective could help us interpret the observed associations. Variety of psychological disorders including depression are associated with prefrontal cortex hypoactivity and error in the inhibitory processes resulting in hyperactive amygdala, poor executive functioning and emotional regulation [25]. Davidson (2000) states that prefrontal cortex activity is inversely related to subcortical structures, such as amygdala and Lane with colleagues (2001) associates prefrontal cortex activity with HRV [26; 27]. Thayer & Brosschot stress the link between prefrontal cortex hypoactivity, amygdala hyperactivity and low HRV arguing an obvious connection between cognitive and autonomic dysregulation [14]. Thus MBP affecting depression might primarily influence emotional regulation and follow-on affecting HRV measures.

The secondary aim was to measure if three weeks of MBP results in changes in anxiety symptoms, symptom severity, stress, and mindfulness. It was found that mindfulness was significantly higher only in the treatment group at V2 (post MBP) compared to V1 (pre MBP) and stress was marginally significantly lower only in the treatment group at V2 (post MBP) when compared to V1 (pre MBP). In contrast, anxiety and stress symptom changes were similar in both treatment and control groups. Anxiety and somatic symptoms severity significantly decreased for both groups at V2 (post MBP) compared to V1 (pre MBP). However, although not significant, the decrease in somatic symptom severity was higher in treatment group as compared to control. The reduction in symptom severity and anxiety in both groups may be explained by the fact that both groups were informed about the diagnosis and educated about SAD. It is believed that diagnosis of SAD and assurance of absence of any organic dysfunction may have reduced anxiety and stress symptoms related with somatic symptomology.

Research shows that mindfulness is an effective treatment for a variety of anxiety and mood disorders and is especially effective in reducing depression, anxiety, and stress symptoms.
We believe that our study extended these findings by showing that MBP not only influences symptoms of depression but also (through change in depression) positively influence HRV. This in turn might lower cardiovascular disease risk longitudinally. However long term cardiovascular disease risk management was beyond the scope of our study and requires further investigation.

Strengths, limitations and future directions. It is considered that a specific sample, randomization of subjects and well-validated outcome measure instruments are among the major strengths of the current study. Despite our consistent results there are limitations of this study. The major limitation of the study is a small sample size and unequal group sizes might have affected results of this study. Due to a limited number of subjects extreme scores might have influenced the results. Research shows that pre-existing low HRV is a representative of low flexibility and adaptability and perseverance [32]. The pre-existing group and participant differences might have also affected results. Participants that start with a relatively high HRV may reduce variance. Further research might benefit from matching groups for baseline HRV levels, socio-demographic variables such as gender, age, and others. Another limitation is that the MBP intervention was limited to a minimum of three-weeks. Research conducted by Klatt, Buckworth and Malarkey (2008) on a low dose mindfulness program (20 minutes of practice for 6 weeks) reported significant reductions in perceived stress and increases in mindfulness [30]. However, according to Baer, Carmody & Hunsinger (2012) significant changes in mindfulness occur at the second week of practice whereas changes in stress occur at the fourth week of practice in a full 8-week MBSR program [31]. The intervention in this study was limited to 15 minutes of practice per day. It is suggested that further research would explore dose-dependent effects of MBP by manipulating the number of minutes practiced per day and the number of weeks spent in the program. Another limitation concerns treatment compliance. Average practice compliance was 80.7 minutes per week (SD = 20.8) among the experiment group. Average time practiced per week in Baer et. al. (2012) study examining weekly mindfulness change was 227 minutes [31]. Whereas average time practiced in our study was 73 minutes, which is approximately a third less.

The majority of experimental condition participants subjectively reported that their health became better in terms of lowered symptoms of depression, anxiety, stress and A&P. We want to emphasize, that high levels of depression, anxiety, stress and somatic symptoms found for patients diagnosed with SADCS in this study provide solid ground for the necessity for an effective and low-cost intervention to decrease symptomology, regulate autonomic nervous system and lower cardiovascular disease risk for SAD patient group. In light of the literature and visible trends of this study, we conclude that further studies with improved methodology and design would greatly benefit the population with SAD and the society in general.

REFERENCES