

# Efficacy of Functional Relaxation and Patient Education in the Treatment of Somatoform Heart Disorders: A Randomized, Controlled Clinical Investigation

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**Background:** Recurrent heart problems and, especially, chest pain in the absence of somatic heart disease is a common finding, although challenging to treat. **Objective:** The authors assessed a body-oriented approach to the somatic fixation frequently seen in these patients. **Method:** They conducted a controlled study to assess the effect of functional relaxation in 22 patients with non-specific chest pain. The primary outcome measures were self-reported changes on the subscales Somatization and Anxiety of the Symptom Checklist of Derogatis, as well as the subscale Cardiovascular Complaints of the Giessen Inventory of Complaints. **Results:** Significant improvements of the primary outcome measures were observed in patients treated with functional relaxation, whereas no significant improvements could be seen in the control group. **Conclusion:** Functional relaxation appears to be a safe and effective, non-pharmacological approach in the treatment of non-specific chest pain. (Psychosomatics 2008; 49:378–385)

Cardiologists frequently encounter patients with chest pain;<sup>1–3</sup> however, in approximately 50%, no structural heart disease or other serious physical disorders are found.<sup>4</sup> Although 2%–5% of all admissions to the Emergency Department are related to non-specific chest-pain (NSCP),<sup>5,6</sup> the prevalence of NSCP in the community ranges from 23% to 33%.<sup>5,7</sup>

To some extent, NSCP results from over-investigation, non-indicated somatic pharmacotherapy, and other iatrogenic factors. NSCP is associated with considerable distress for patients<sup>8</sup> and is often complicated by co-existing

psychiatric disorders, such as depression or anxiety disorders.<sup>9</sup> Also, a variety of etiological factors have been proposed, including coronary spasm, micro-vascular coronary artery disease,<sup>10</sup> alcohol and cigarette use,<sup>11</sup> hyperventilation,<sup>12</sup> or esophageal dysmotility.<sup>13</sup>

Many patients with NSCP are reassured and discharged without a specific diagnosis or treatment,<sup>14</sup> resulting in a moderate long-term prognosis of their functional disability. Treatment of NSCP patients is very challenging.<sup>15</sup> Less than 50% of patients with NSCP benefit from the reassurance that heart disease does not exist; 75% continue to seek medical advice, and 50% consider themselves to be significantly disabled.<sup>16,17</sup> Patients often continue to experience symptoms, and, as a result, they begin to restrict their daily activities and develop a help-seeking behavior, described as “doctor-shopping,” based on the idea noted above that reassurance alone is almost never effective.<sup>18</sup>

A variety of pharmacological interventions, including beta receptor-blockers, nitrates, calcium channel-blockers, anxiolytics and antidepressants,<sup>19,20</sup> and psychological in-

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terventions are used for the treatment of NSCP patients. Because of the etiological importance of dysfunctional cognitions in NSCP, cognitive/behavioral-oriented approaches are recommended as appropriate interventions;<sup>16,21,22</sup> but psychodynamic approaches are also frequently applied in such patients.

Often, complex psychosomatic treatment approaches are accompanied by patient resistance, caused by their somatic interpretation of symptoms.<sup>23</sup> In the present study, we focused on an approach called functional relaxation (FR), which includes psychosomatic education and a relaxation technique, both of which have proven to be effective in previous clinical trials, particularly in tension headache<sup>24</sup> and asthmatic diseases modulated by psychosomatic influences.<sup>24–28</sup>

The aim of the present study was to investigate the efficacy of an intervention with 10 sessions of FR supplemented by a short patient-education session in the treatment of NSCP. Because of the high demand of NSCP patients for additional information regarding their medical condition, a 60-minute education session was added to the relaxation sessions.<sup>29</sup>

## METHOD

The study was planned and performed in accordance with the Declaration of Helsinki and ethical laws pertaining to the medical profession. The trial design was approved by the Ethics Committee of the Regensburg Medical School, and written informed consent was obtained. The study was conducted independently of any institutional influence and was not funded.

### Participants

The patients were recruited via inpatient screening of two cardiology departments and referrals from the Emergency Department of the University Hospital of Regensburg, Germany, as well as from local general practitioners in Regensburg. Inpatients were included after they had been discharged from the hospital. The screening criterion was a history of cardiac complaints with no evidence of somatic disease. Patients included in the study were over the age of 18 years who presented with NSCP. The diagnosis was confirmed by means of a structured interview. Reasons for exclusion of participants in the study included any underlying somatic disorders; any severe and disabling psychiatric disorder, such as schizophrenia or dementia; as well as patients undergoing psychotherapy and those currently enrolled for retirement payment.

Of the 43 eligible patients, 40 agreed to take part in the study (Figure 1). The participants underwent a psychosomatic face-to-face interview and thorough cardiological diagnostic procedures, including a physical exam, blood work, an electrocardiogram (ECG), non-invasive blood pressure (NIBP) measurement, echocardiography, bicycle ergometry tests, and a long-term-ECG, either an ECG event-recorder or cardiac catheter examination, if indicated. A detailed medical history was also taken.

On the basis of the above-mentioned criteria, 22 patients (10 men, 12 women) were eligible to take part in the study. The required sample size was calculated for a Type I error of 5% ( $z_1 = 1.96$ ) and a power analysis of 80% ( $z_2 = 0.842$ ). The calculation was based on the mean value ( $m_1: 65.2$  and  $m_2: 56.4$ ) and standard deviation ( $s_1: 7.4$  and  $s_2: 7.2$ ) of the somatization subscale of the SCL-90, which were obtained from a small pilot study. The formula<sup>30</sup> is  $n$  (per group) =  $[(z_1 + z_2)^2 \times (s_1^2 + s_2^2)] / (m_1 - m_2)^2$ . This resulted in a group size of  $n = 11$  patients. The participants were randomized in a 1:1 ratio either to the FR group or a control-group with enhanced medical care. Randomization was carried out confidentially, with allocation concealment implemented by the hospital's administration department.

### Assessment

The study was performed with the Symptom Checklist of Derogatis (SCL-90) and the Giessen Inventory of Complaints (GIB), which are both self-administered tests. The SCL-90 measures psychiatric symptoms by 90 possible physical and psychological symptoms during the previous 7-day period. The items were grouped into 9 subscales: Somatization, Obsessive-Compulsiveness, Interpersonal Sensitivity, Depression, Anxiety, Hostility, Phobic Anxiety, Paranoid Ideation, and Psychoticism, and 3 global scales, of which the most important is the Global Symptom Index (GSI).

The conversion of the raw data to T-values, with sociodemographic factors taken into consideration, allows an orienting classification of the individual case. T-values starting at 60 are considered to be slightly elevated; at 65, obviously elevated; at 70, strongly elevated; and at 75, very strongly elevated. The internal consistency<sup>31</sup> (Cronbach's  $\alpha$ ) ranges between 0.75 and 0.87.

Subjective physical complaints were assessed by the Giessen Inventory of Complaints (Braehler and Scheer<sup>32</sup>). The 57 items are rated on a 5-point Likert scale, and 6 items each are summarized under 4 factor-analytically-derived scales: Exhaustion, Gastrointestinal, Musculo-

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