THE BALNEOTHERAPY LINKS WITH SEAFARERS HEALTH IN RANDOMIZED CLINICAL TRIAL

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Summary
Study objective: to evaluate the impact of new origin high salinity geothermal water for reinforcing the comprehensive health of seamen and explore the safety profile of water. Methods. 180 seamen were randomized into three groups: geothermal (65) which has got 108 g/l salinity geothermal water bath for 2 weeks daily five times a week, music group (50) which has received music therapy at home, 65 participants have got no treatment. Outcomes measures: systolic and diastolic blood pressure, heart and breathing rate, skin temperature, fingertip-floor distance, joint mobility failures, mood scale, VAS pain scale, 5-point Likert’s well-being scale and cognitive failures questionnaire (CFQ). Safety was assessed for effects on the cardiopulmonary system and the side effects. The statistical analysis of the data was performed by using the SPSS21 software package.

Results: after the 2 weeks in geothermal group reduced blood pressure, heart and breathing rate (p<0.001); pain (p<0.001), skin temperature (p<0.05), improved spine (p <0.05) and joint mobility (p <0.001), general well-being (p<0.001), mood (p<0.001) and cognitive functions (p=0.001) were observed. In the music therapy group reduced breathing rate (p<0.01), pain (p<0.05) and improved general well-being (p<0.01) were observed. Adverse events were rare in both groups. No significant changes were observed in the control group.

Conclusions: the balneotherapy using very high salinity geothermal waters has multiple health-enhancing effects and is safe for seamen.
mined by the million of years geochemical erosion; many elements are of the geological origin because of decay (of uranium, torus and potassium) and melting processes (9). Due to high temperature and salinity geothermal waters serves people in the industry and for strengthening health during bathing procedures (10). The geothermal resources such as hot springs and geothermal water take an important place in the health and wellness sectors (8). Hot geothermal springs for balneotherapy are mainly used in China, US, Turkey, Czech Republic, Slovakia, Germany, Hungary, Italy, Japan, Poland, Spain, Switzerland, Russia, Iceland, Chile, Bulgaria, Greece, Serbia, Brasil, India, Argentina, Iran, Guatemala (10,11). Lithuania compared to neighboring countries has favourable geothermal conditions in western part in particular (8). The geothermal water extracted from the drills compared to the natural is used recently for balneotherapy (Iceland, Romania, Poland and etc), so there is not enough research on the effect and safety of such type of water for human body especially with very high salinity waters. Researchers have mostly used the water of 0.6-31.9 g/l salinity, excluding trials in the Dead Sea (340 g/l salinity).

The main aims of the research were to evaluate the impact of new origin very high salinity geothermal water bath for reinforcing comprehensive health of seamen and explore the safety profile of very high mineralization thermal water with possibility to find efficient measure to enhance wellbeing of representatives of stress-related occupation. To our knowledge, there were no trials made in Lithuania or in another country with such concentration of water usage.

**Material and methods**

This research was conducted in observance of the rules of good clinical practice. Its protocol was approved by the regional Research Ethics Committee (BE-2-31). The research was carried out at rehabilitation center of Klaipėda Seamen’s Health Care Center based in Klaipeda, during September-November, 2012. Lithuania. Male working seamen aged 25-64 years, working at sea for more than 5 years, after returning from the sea after long-term journey. The sample size and the power of the study were calculated with IBM SPSS Sample Power Release 3.0.1. All subjects were recruited and examined by trained GP independent of the spa setting. The patients completed the balneotherapy and music therapy treatments as outpatients, with no change in their daily routine or work attendance. All subjects were informed about the purpose, conditions and course of the study prior to inclusion and signed participants’ agreement. The patients were excluded from the study with the following conditions: acute pain, acute organic neurological deficit, neoplastic or inflammatory lesion, decompensated cardiovascular disease, uncontrolled or unstable metabolic disorders, acute febrilic infections, cutaneous suppuration, decompensated neurosis, participants who received any kind of physiotherapy during 3 month period prior to the study.

The patients were randomly divided into three groups: geothermal water, music therapy and control (no treatment). Randomization was performed by the individual who was not involved in the implementation of the study. The randomization was simple, with generation of random numbers. The professional performing the statistical analysis was aware of the randomization. Primary end-points of our study were effect on physical and psychological condition, secondary- safety profile.

The geothermal group was treated with the natural warm geothermal water of 34.6 °C and pH 6.07, from well „Geoterma2P“(1135 m deep, Lower Devon layer). The chemical composition of water is shown in table 1.

The subjects underwent fifteen minutes balneotherapy sessions every day for two weeks. The patients were monitored continuously during the treatment sessions. The study protocol required participants to attend at least 60% of treatments, minimum of 6 balneotherapy sessions.

The music therapy procedures were performed at home with Peter Huebner Medical Resonance Therapy Music (RRR 932 General Stress) which is used for medical purposes (12). Participants were trained on the procedure: 20

| Table 1. The mineral composition of geothermal mineral water |
|-----------------|------------------|
| **Element**     | **Concentration, mg/L** |
| Cl⁻             | 66.930           |
| Na⁺             | 27.580           |
| Ca²⁺            | 8.990            |
| Mg²⁺            | 2.630            |
| SO₄²⁻           | 1.330            |
| K⁺              | 690              |
| HCO₃⁻           | 74               |
| Fe total        | 12,14            |
| B               | 6,501            |
| Si⁴⁺            | 4,886            |
| Li⁺             | 1,200            |
| F⁻              | 0,91             |
| Mn²⁺            | 0,501            |
| Cu²⁺            | 0,167            |
| Zn²⁺            | 0,062            |
| Total solute content | 108.224        |
minutes sitting or lying down, with closed eyes, most ideally with earphones, to avoid disturbances from outside.

Before and after each bath status of participants were assessed by measuring systolic and diastolic blood pressure, heart rate (with automatic blood pressure monitor Micro life), breathing rate, axillar skin temperature (non-contact thermometer Medisana), fingertip-floor distance (cm with ruler), participants were interviewed about pain (10 cm visual analogue scale, VAS) and general well-being according Likert 5 point scale.

Participants of music therapy group were given self-monitoring protocols: the general feeling, systolic and diastolic blood pressure and heart rate before and after procedure, changes in the sensation.

Baseline and post-2 week therapy assessments were performed by GP. Before and after the course of procedures each participant by evaluated by the GP on general condition, complains, blood pressure, heart and breathing rate, mobility of joints (shoulder, knee, hip) with goniometer and fingertip-floor distance (cm) were measured. Psychoneurological condition was assessed with Cardiff University mood scale (1) and cognitive failure questionnaire (CFQ) (13).

Statistical analysis of the data was performed by using
the SPSS21 software package. Working seamen background, demographic variables and their balneotherapy and music therapy treatments as outpatients were examined using descriptive analysis (mean, standard deviation, range, percentages and frequencies). After testing for normality, we used the settings of parametric and nonparametric criteria, the Student's t, ANOVA with Bonferroni test for multiple comparison, and Mann–Whitney and Kruskal–Wallis tests to compare two or more groups. The categorical variables were compared using the chi-square (χ²) and z tests for the comparison of the proportions between the groups. P-values less than 0.05 were interpreted as statistically significant.

**Results**

The recruitment of patients began in September 2012 and the research was started in the middle of November 2012. 65 participants were in the geothermal water group, 55 completed more than 60% of the therapy course (drop-out of 8 because of work demands and personal reasons and 2 because of flu). 35 out of 50 participants came to final assessment (drop-out because of personal reasons). From the 65 control group participants return for the final control visit 50 (drop-out both 15 because of work demands and personal reasons). Demographic and baseline clinical characteristics of participants are shown in table 2. All groups were similar in demographic data, BMI, basic health self-assessment, stress and fatigue experience and intensity. Participants in geothermal group differ in more morbidity, less drug usage, higher frequency of pain, lack of sleep.

The effect of interventions on cardiopulmonary function and temperature. Change of systolic and
Figure 3. The changes on well-being in research groups before and after treatment according 5-point Likert’s scale.
seen in functional parameters: reduced systolic and diastolic blood pressure, heart and breathing rate, skin temperature while in music therapy significantly only breathing rate was reduced. No significant changes have been noticed in control group (Table 3).

The effect on musculoskeletal system. After each procedure there were significant positive changes observed in fingertip-floor distance after each balneotherapy procedure p<0.001-0.007 (Fig. 3), in separate cases lowering of distance exceeds 14 cm, reduction mean was 3.2 cm (SD 5.0) (95% CI 0.94 to 5.5, p=0.008). At the end of treatment fingertip-floor distance has been lowered by 2 cm (65%).

In music and control groups the fingertip-floor distance has not significantly increased (p= 0.921 and 0.472). ANOVA between groups is p<0.001.

There were positive changes after the balneotherapy in shoulder, knee, and hip joints motion range. Joint mobility failures in degrees before treatment were 10.0 (SN 7.7) vs 3.8 (SN 4.3) after treatment, mean change was 6.2 (95%CI 5.11 to 7.3), p<0.001).

The effect on overall condition. The feeling of pain was reduced significantly after 60% of procedures in geothermal water group (p=0.049–<0.001).

In comparison 2 weeks of the geothermal therapy with the baseline has showed significant improvement in pain (VAS reduction mean difference 1.69 (95% CI 0.43 to 0.84), p<0.001 and -2.9 (95%CI -5.3 to -0.52), p=0.018 respectively). No statistically significant differences were seen in music (mean difference 0.1, CI -0.8 to 1.1, p=0.757) and control group (mean difference 0.1, CI -0.5 to 0.7, p=0.73). The effect on pain between all groups was significant (ANOVA F5,292 = 2.6, p=0.026).

The positive effect on overall wellbeing after 2 weeks was significant in comparison with baseline in both geothermal (mean difference -0.52, p=0.001) and music groups (mean difference -0.34, p= 0.006). The control group does not show a better effect (p=0.683) (Figure 3). The difference between all groups was significant ANOVA F5,292 = 7.4, p<0.001.

The effect on mood and cognitive function. Mood scales analysis: 15 of 18 different manifestations of mood were positively changed in the geothermal group. In comparison between baseline and therapy mood states are shown in table 4.

The significant reduction in a stress-related mood condition was noticed in geothermal group (mean difference 16.8 (95%CI 11.1 to 22.5, p<0.001). No significant changes were seen in music (p=0.082) and control group (p=0.636). Fatigue-related mood was reduced also in geothermal group (mean difference 10.6 (95% CI 5.7 to 15.5, p<0.001), in music group the effect was not significant (p= 0.287) as in control group (p=0.903). The difference between the groups was statistically significant: for stress-related mood ANOVA F7,732 =6.9, p<0.001, for fatigue-related mood ANOVA F7,732 = 4.1, p<0.001.

Statistically significant positive mental differences in the average before and after balneotherapy treatment were found in a half (12 of 25) investigated possible cognitive processes abnormalities (p<0.05). There was only one statistically significant difference in the musical group (p=0.043). The comparison of results of all the study groups in overall cognitive failure is shown in table 5.

During the balneotherapy procedures the participants actively expressed better feelings (in descending order) on pain, sleep, energy, fatigue, muscle relaxation, body flexibility, mood, anxiety, endurance, cough, skin, extremities melting, venous state, abrasions healing, constipation; music therapy group members noticed better in (in descending order): anxiety, relaxation, energy, mood, fatigue, sleep, pain, dyspnoe and concentration.

It has been reported no serious treatment-related adverse event.

Only one participant in geothermal group was exacerbation of psoriasis on the legs (1.5 %). The patients were not treated and stayed at the study. Three participants reported skin redness and itching (4.6 %). In the musicotherapy group one participant reported headache (3%) and one annoyance due to dislike of music 3% (1).

Discussion
Our research confirms that seafaring is physically and mentally challenging occupation.

| Table 5. The changes in general cognitive failures (CFQ) after 2 weeks in all study groups |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
|                                | Geothermal group N=55 | Musical group N=35 | Control group N=50 |                                |
|                                | Mean, (SD) | Mean, (95%CI), p | Mean, (SD) | Mean, (95%CI), p | Mean, (SD) | Mean, (95%CI), p | ANOVA |
| Before                         | 31.3 (11.4) | 6.7 (2.7 to 10.7) | 26.6 (13.6) | 3.7 (-2.0 to 9.4) | 26.0 (9.5) | -1.3 (-4.7 to 2.1) | F7,720 = 7.5, p<0.001 |
| After                          | 24.5 (10.4) | 0.001 | 22.9 (9.8) | 0.202 | 27.3 (7.4) | 0.446 | <0.001 |
Seamen encounter big stress and fatigue levels, big morbidity with cardiovascular, nervous and gastrointestinal diseases, bad habits with smoking, alcohol use and no rehabilitation with doctors follow-up; that is why they need to find effective rehabilitation measures to improve quality of life.

The aim of this research was to assess the safety and effects of balneotherapy with very high salinity geothermal water in seafarers for cardiovascular, musculoskeletal system and well-being. Based on the results presented here, geothermal water treatment was more effective and statistically significant in several subjective and objective outcome parameters compared with the musical and control groups. Overall, research has shown the positive parameters indicated a tendency for positive cardiopulmonary and muscular skeleton effects, improved well-being and mood changes in geothermal water therapy group. IT an analysis demonstrated the advantage of the thermal group over music and controls. Our research is different in mineralization and the origin of mineral water. We have used extremely high salinity water of 108 g/l although some papers note about possible adverse events if water is more than 80 g/l TDS and most often they are diluted to less concentrations. Our research has demonstrated the safety of this type of water for general working population.

During the last decades a lot of attention was paid to the exploration of balneotherapy impact mechanisms, developed theoretical formulas and models the flow of minerals through the skin, carrying trials in vitro and in vivo for materials assess roads and metabolism to determine their safety and efficacy (14-16). The combined effects of balneotherapy results in a beneficial impact which has been observed in rheumatic diseases, depression, psoriasis, chronic/allergic rhinosinusitis, blood pressure, chronic obstructive pulmonary disease (17).

This research complements the previous reports on cardiovascular system that balneotherapy can reduce the blood pressure and the heart rate. Cimbiz et al (2005) argued, that after balneotherapy procedures compared to control there were assessed statistically significant improvement in hemo-dinamic indicators (blood pressure, heart work, pulmonary function) (18). Paguorelas et al (2011) concludes balneotherapy has an effect on heart diseases (19). Kapetanovic et al trial (2013) showed that balneotherapy does not affect people with mild hypertension and has not significant changes of blood pressure (20). Becker BE and the other scientists has revealed hydrotherapy effects on lowering blood pressure (12 mmHg in systolic and 26 mmHg in diastolic) (21). After the procedure of mineral bath for pilots in China (2012) scientists found that balneotherapy improves left ventricular pumping function and pilots physical capacity (p<0.05) (22). The highest mineral water mineralization has The Dead sea water. 85 original clinical studies have been made. The reviews has showed that water has an effectiveness on skin, inflammatory and non-inflammatory rheumatic, bowel, ischemic heart diseases, heart failure and other diseases (23).

The analgesic effect of thermal water is well known. Cimbiz et al (2005), Bender T et al (2005) found out that the balneotherapy could be used for various origins of pain, post-traumatic conditions with no harm to hemodynamics. Verhagen (2008) in Cochrane review has given to balneotherapy silver level evidence compared with no treatment for pain, quality of life and usage of analgesics (7). The effect on the back pain and better spinal mobility has been recently proven by Kulish A, Kesiktas N, Tefner IK (24). Falagas et al (2009) in metanalysis confirmed biggest effect of balneotherapy on pain (25).

The balneotherapy affects autonomic nervous system with the lowering influence of nervous system. This leads to relaxation, stress and anxiety reduction, improvement of cognitive functions (Ohtsuka, 2002; Eskandari, 2002; Lane, 2008; Thayer, 2002,2005; Ziegelstein, 2007). The effect on the level of serotonin and SERT receptors could work on depression and mood (26). The balneotherapy has shown the effectiveness for psychoemotional well-being, mental activity (27), mood with light dementia (28), tension, angry, fatigue, depression, activity, energy mood manifestations (Li Xiu, 2012) (29).

A wide range of hydrotherapy procedures as preventive measures are popular in many countries and Lithuania. Previous studies has addressed balneotherapy mostly to specific diseases and with minor mineralization of waters. Our study was the first to observe both cardiopulmonary and psycho neurological effects with high salinity geothermal waters. More studies of high salinity geothermal waters are needed with more participants, standardized methodology, double-blinded, with longer follow-up.

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Competing interests
None declared.

Conclusions
1. The balneotherapy using geothermal water from artificial resources has a comprehensive positive effect on...
physical and mental seamen health state: the reduction of blood pressure, heart, breathing rates, pain and fatigue; it improves the mood, cognitive function and joint mobility.

2. The geothermal water treatment is more effective for seamen health than the music or no treatment at all.

3. The balneotherapy with very high salinity geothermal water has good safety profile.

4. Geothermal water baths could be an efficient and cost-effective measure for rehabilitation of physical and mental health of seamen or representatives of other occupations.

Conflict of interest
The authors declare that there is no conflict of interests regarding the publication of this paper.

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BALNEOTERAPIJOS GEOTERMINIU VANDENIU VANDENIU
RYŠYS SU JŪRININKŲ SVEIKATA: RANDOMIZUOTAS
KONTROLIUOJAMAS TYRIMAS
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Raktažodžiai: balneoterapija, geoterminis vanduo, jūrininkų sveikata.
Santrauka
Tyrimo tikslas: įvertinti ypač didelės mineralizacijos geoterminio vandens poveikį visapusiškam jūrininkų sveikatos stiprinimui ir ištirti jo saugumą. Method. 180 jūrininkų buvo randomizuoti į tris grupes: geoterminę (65), kuriai skirtos 2 savaičių 108 g/l mineralizacijos geoterminio vandens vonios penkiskart savaitėje kasdien, muzikos grupę (50), kuriai skirta muzikos terapija namuose, ir kontrolinę (65), negavusią jokio gydymo. Tyrimo metu matuotos sistolinės ir diastolinės kraujospūdžio, širdies susitraukimų ir kvėpavimo dažnis, odos temperatūra, pirmųjų-grindų atstumas, sąnarių judrumas, skausmo (VAS), bendros savijautos (5-balu pagal Likert’ą) ir nuotaikos skalės bei pažintinių nesėkmių klausimynas (CFQ). Saugumas vertintas poveikiumi širdies ir kvėpavimo sistemoms ir pašalinių poveikų dažniu. Statistinė duomenų analizė naudotas SPSS 21 programinės įrangos paketas.

Rezultatai: po 2 gydymo savaičių geoterminės grupės dažnai sumažėjo kraujo spaudimas, širdies susitraukimų ir kvėpavimo dažnis (p<0.001), skausmo intensyvumas (p<0.001), odos temperatūra (p<0.05), pagerėjo stuburo (p<0.05) ir sąnarių judrumas (p<0.001), bendra savijauta (p<0.001), nuotaika (p<0.001) ir pažintinės funkcijos (p=0.001). Muzikos terapijos grupėje sumažėjo kvėpavimo dažnis (p<0.01) ir pagerėjo bendra savijauta (p<0.01). Pašalinių poveikiai abiejose grupėse buvo reti. Kontrolinėje grupėje reikšmingi pokyčiai nestebėti. Išvados: balneoterapija didelės mineralizacijos geoterminio vandens turi daugybinių sveikatą gerinančių poveikį ir yra saugi.

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