

# Green medicinal clay in the treatment of the unspecified lumbar pain: clinical trial

*Argila medicinal verde no tratamento da dor lombar inespecífica: ensaio clínico*

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## ABSTRACT

**BACKGROUND AND OBJECTIVES:** Lower back pain is one of the musculoskeletal diseases with the highest incidence all over the world. In approximately 85% of the cases it is classified as unspecified, which means that it has no evident cause. With that in mind, geotherapy is a non-invasive technique that allows control over the lower back pain. The goal of this study was to evaluate the results of geotherapy on the relief of the unspecified lower back pain.

**METHODS:** Semi-experimental quantitative clinical trial, comparing before and after states, including 26 participants who received four applications of green clay cataplasm on the lower back region with an interval of seven days. The pain intensities before and after the interventions were evaluated by a visual analog scale and an Oswestry Disability Index questionnaire. For the data analysis, the Kolmogorov-Smirnov and *t* Student methods were used, with a significance level of 5% ( $p < 0.05$ ).

**RESULTS:** There was significant statistics that showed lower back pain relief with the cataplasm mode geotherapy using green clay, reaching  $p = 0.0001$  in the visual analog scale.

**CONCLUSION:** The geotherapy with green clay applied on the lower back region of the body was effective on diminishing of the unspecified chronic lower back pain.

**Keywords:** Chronic pain, Complementary therapies, Low back pain.

## RESUMO

**JUSTIFICATIVA E OBJETIVOS:** A dor lombar é uma das doenças musculoesqueléticas de alta incidência em todo o mundo. Aproximadamente em 85% dos casos ela é classificada como inespecífica, significando que não tem uma causa evidente. Diante disso, a geoterapia é uma técnica não invasiva que possibilita controle da dor lombar. O objetivo deste estudo foi avaliar os resultados da geoterapia no alívio da dor lombar inespecífica.

**MÉTODOS:** Ensaio clínico, semi-experimental, do tipo antes e depois, de natureza quantitativa, que incluiu 26 participantes que receberam quatro sessões de cataplasma de argila verde na região lombar com intervalo de sete dias. A intensidade da dor antes e depois das intervenções foi avaliada pela escala analógica visual e questionário *Oswestry Disability Index*. Para análise dos dados foram utilizados os testes: Kolmogorov-Smirnov e *t* de Student, com nível de significância de 5% ( $p < 0,05$ ).

**RESULTADOS:** Houve significância estatística com a geoterapia na modalidade cataplasma lombar com argila verde no alívio da dor lombar, obtendo-se  $p = 0,0001$  para a escala analógica visual.

**CONCLUSÃO:** A geoterapia com argila verde aplicada na região lombar foi efetiva na redução da intensidade da dor lombar crônica inespecífica.

**Descritores:** Dor crônica, Dor lombar, Terapias complementares.

## INTRODUCTION

Unspecified back pain (BP) is defined as pain or dysfunction with no specific or clear cause, reaching 85% of BP occurrences<sup>1</sup>. It's a multidimensional phenomenon, encompassing physical and emotional suffering, functional disability and restriction of social participation, due to organic, psychological and social factors. Several guidelines have pointed to the importance of biopsychosocial treatment, because it contributes to the relief of the patient's pain<sup>2</sup>.

In this regard, non invasive lumbar cataplasm geotherapy using green clay was chosen. This modality is indicated for the improvement of vascularization, oxygenation and local tissue nutrition, offering pain relief<sup>3</sup>.

Geotherapy, geo – earth, clay; therapy – treatment, a practice that uses medicinal clay as an intervention method, is a healing integrative therapy, based on the biophotonics, bioelectricity, piezoelectric and mineralizing theories, which acts on all aspects of the individual, resulting in a state of balance, relaxation and harmony, favoring health. Green clay is applied in cases of imbalance and in cases of chronic diseases and/or pain,

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such as joint pain, resulting from chronic inflammatory processes, as well as in BP and cervical pain, for its analgesic, anti-inflammatory, balancing properties as well as helping homeostasis<sup>3</sup>. According to the Ministry of Health, geotherapy is a simple practice, with a well-defined, safe, non-invasive history. It's effective in clinical studies and can be used in inflammatory processes, injuries, healing, lesions and in osteomuscular diseases<sup>3</sup>. This therapy was included in the *Política Nacional de Prática Integrativas e Complementares* (PNPIC) by ordinance number 702 of March 21, 2018<sup>4</sup>. The objective of the present study was to evaluate the results of geotherapy in the relief of non-specific BP.

**METHODS**

A quantitative, exploratory clinical trial, with longitudinal temporality, comparing before and after, which includes students and collaborators of *Universidade do Sul de Santa Catarina* (UNISUL). The sample is non probabilistic, recruited from the university by the means of flyers and Facebook and Instagram social networks. Thirty individuals were included and allocated in one treatment group. After the second session, four participants were excluded for not attending to the next appointments, so the study was concluded with 26 participants, from February to March 2019 (Figure 1).

The inclusion criteria were: to be a student and/or collaborator of UNISUL or to be on the waiting list of the School Clinic; to have BP; to be between 18 and 59 years old. The exclusion criteria were: to have a skin lesion in the place where the clay would be applied; to use topical drugs in the place where the clay would be applied; to use opioids. The study is in accordance with the Declaration of Helsinki of the

World Medical Association and respected the Resolution 466/12 of the National Health Council<sup>5</sup>, which determines the Guidelines and Regulatory Standards for Research in an experimental unit involving human beings, meeting the requirements of the Free and Informed Consent Term (FICT). There were 4 sessions of green clay application and pain intensity assessment by the visual analog scale (VAS), and in the first and last sessions the data collection instruments were filled. In the first session, the participant filled out the questionnaire for sociodemographic characteristics survey and the ODI questionnaire for BP evaluation. Afterwards, the patient was placed on a stretcher in ventral decubitus position, clothes and adornments were removed, and the skin was prepared for the application of the clay with gentle exfoliation performed three times, using warm wet gauze at T12 to the sacral region. The green clay, at a tepid temperature, 2 cm thick, was placed on the gauze moistened with a spatula from T12 to the sacral region, which was covered with paper towel. Sheet was covering the entire body of the individual. After 40 minutes, the gauze and the clay residues were removed with moist gauze and cotton and the area was dried with paper towels. The second and third sessions occurred respectively 7 and 14 days later, following the same procedure, but the clay remained in the body for 40 minutes. The fourth and last sessions took place 7 days after the third session, and after applying the clay for 40 minutes, the participant filled out the socio-demographic questionnaire and the ODI questionnaire. The research was performed at the UNISUL School Clinic of Naturology, under approval of the Research Ethics Committee number 3.101.272 and CAAE 0455218.6.0000.5369.

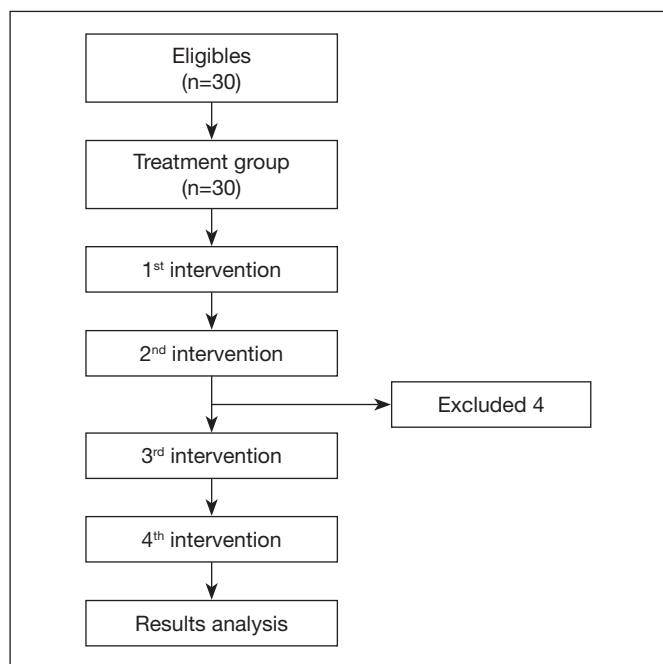
**Statistical analysis**

Mean and median pain intensity were calculated and for the ODI questionnaire the GraphPad Prism (version 4) was used. The data were tested for normality using the Kolmogorov-Smirnov test and submitted to the Student's t test with a significance level of 5% (p<0.05).

**RESULTS**

There were 19 female and 7 male volunteers, aged between 19 and 55. Regarding the use of analgesics, 88.46% of the participants declared not to use it and 11.54% used only when necessary (during the research they didn't use it). From the participants, 7.69% declared to have between 3 and 5 hours of sleep, 69.23% declared to have between 5 and 7 hours, and 23.08% declared to have between 8 and 10 hours. Regarding the most frequent position on their day, 88.46% claimed to remain seated. The style and quality of life characteristics of the group stands out in the information raised by the sociodemographic questionnaire, which made it possible to raise the information that 61.54% practiced physical activity and 42.31% said they worked 6 to 8h a day.

There was a significant decrease in pain after the first session, with mean pain before application of 4.54±2.319 and after 1.81±2.350, with statistical significance (p=0.0001).



**Figure 1.** Flow diagram of participants during each stage of the research

In the second session the mean pain before application was  $4.42 \pm 2.120$  and after  $1.46 \pm 1.985$ , with statistical significance ( $p=0.0001$ ). In the third session the mean pain before application was  $3.04 \pm 2.200$  and after  $1.12 \pm 1.862$ , with statistical significance ( $p=0.0001$ ). In the fourth session the mean was  $2.62 \pm 2.844$  and after  $0.73 \pm 1.845$ , with statistical significance ( $p=0.0001$ ). Regarding the mediate effects, the mean pain before application in the first session was  $4.54 \pm 2.319$  and after application in the last session was  $0.73 \pm 1.845$ , with significance level ( $p=0.0001$ ).

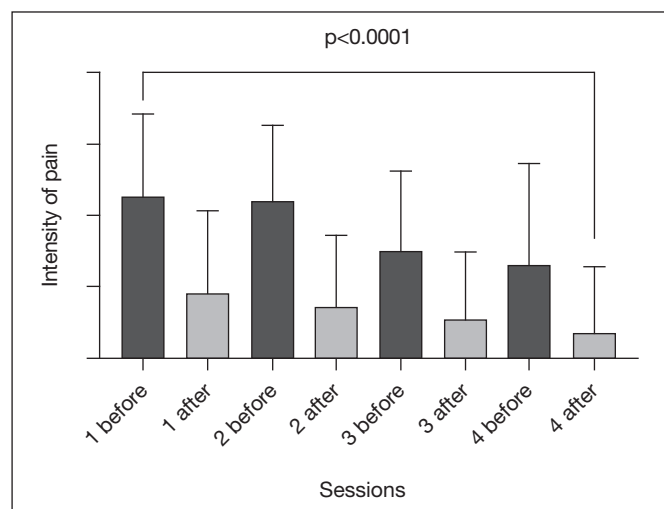


Figure 2. Pain intensity evaluated by the visual analog scale

In regards to the ODI questionnaire, the initial mean pain was  $41.23 \pm 12.160$  and the final mean was  $33.31 \pm 7.918$ , corresponding to the statistical significance level  $p=0.001$  (Figure 3).

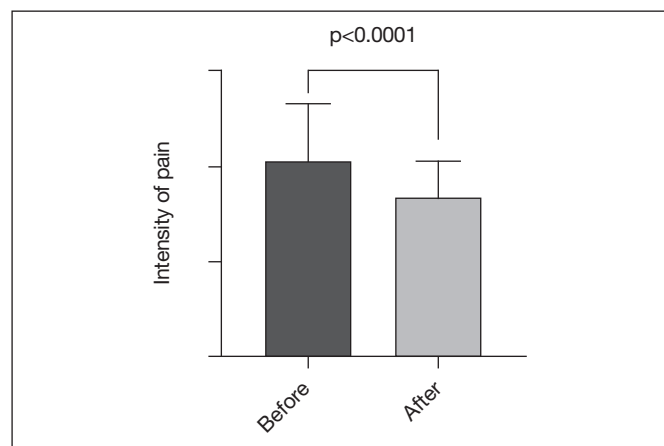


Figure 3. Intensity of pain by the Oswestry Disability Index questionnaire

## DISCUSSION

The results showed that the application of green medicinal clay in the lumbar area contributed significantly to the relief of the unspecified BP, in an immediate and mediate manner. A relevant aspect refers to the theories that underpin geotherapy, in which there is a relationship of ionic or radionic exchange

through which free electrons, present in minerals, translate the therapeutic properties of the clay. Therefore, within the physical-chemical properties, the energy potential of geotherapy is based on the piezoelectric effect, caused by crystalline structures of  $Si^{4+}$  free silica and clay minerals<sup>3</sup>. The friction of the clay crystalline structures, induced by proper handling, generates electrical charge by piezoelectric effect and activates the vibrational system, in charge of stimulating the skin and maintaining the energetic action. In turn, the mineralizing theory, a result of the varieties and concentrations of elements, ensured by the radioactive and intrinsic properties, can perform ion exchange between the clay and the skin<sup>3</sup>.

The chemical components found in green clay are: sodium oxide, zinc, potassium monoxide, aluminum oxide, magnesium, manganese, copper, aluminum, silicon, molybdenum, titanium oxide, lithium, sodium and potassium, ensuring analgesic, anti-inflammatory, decongestant and healing property<sup>3-11</sup>. The study<sup>6</sup>, which performed chemical analysis of several clays, found that green clay presents the greatest diversity of elements, including iron oxide, related to magnesium, calcium, potassium, manganese, aluminum, phosphorus and silicon. The data showed that 88.46% of the participants remained seated most of the day. A study<sup>7</sup> conducted with 52 individuals who worked seated showed that 83% had BP, which allows us to infer that this position can trigger the pain, since when the sitting position is maintained for a long period, it can generate some muscle and joint deficit, interfering in the mobility, flexibility and exhaustion of the spine's posterior muscles, which can interfere with its alignment and stability. When seated, the individual may be in an inadequate position for a prolonged period without lumbar and forearm support, in addition to anterior torso flexion, which intensifies the pressure on the intervertebral discs by more than 70%, increasing the likelihood of pain<sup>7</sup>. By decreasing inflammatory processes and osteomuscular lesions, geotherapy provided pain relief<sup>2</sup>.

A study conducted with university students showed that 66% reported pain in the lumbar region and the sitting posture for a long period during class was a variable that may be related to the presence of muscle imbalances and pain, especially in the spine<sup>8</sup>. 61.54% of participants reported doing physical activities, which allows us to infer that the practice of physical activity does not contribute to the relief of the BP. However, the reason for the physical activity was not evaluated, and it could have been performed for pain relief or, also, that the pain itself could be due to the practice of physical activity. A study involving data from the 2013 *Pesquisa Nacional de Saúde* (PNS - National Health Research) found that intense physical activity in the workplace and at home, in both sexes, is not beneficial to health, since it increases muscle and joint overload, in addition to fatigue, which can lead to osteomuscular problems<sup>9</sup>.

On the contrary, another research done with physiotherapy students assessed that 60,5% of the participants did not practice physical exercises and, from those, 60,9% presented BP – suggesting that the practice of physical activities could be a factor of prevention, since it helps to strengthen the muscles<sup>10</sup>.

Chronic lumbar pain restricts daily activities and also creates anxiety due to the sensation of unproductivity, disability and the reduction of independence. These restrictions, truly disturb adults in the economic active age, since they result in reduction of functional working capacity and execution of daily activities, influencing on quality of life<sup>8</sup>. Such problem leads to high demand for health services, consequently generating high social costs, decreased productivity, absence from work and, as a result, costs on welfare<sup>9,11</sup>.

Since most individuals in this research did not use analgesics, it is possible to infer that clay may have contributed to BP relief. A study conducted in a patient with second-degree burns used gray medical clay as a form of treatment and provided relief from pain and burning, in addition to assisting in the inflammatory process of burning<sup>12</sup>. Considering that 42.31% of the studied individuals worked six to eight hours a day, it is possible to infer as a possible cause of pain the length of working hours. A study that analyzed the prevalence of musculoskeletal pain in nursing professionals found that those who had a weekly workload between 30 and 42 hours had greater pain complaints, especially in the lower part of the spine<sup>13</sup>. Yet another research with physiotherapy and psychology academics showed that 80.7% had back pain and remained seated, eventually in an inadequate manner, for long hours, which may have contributed to the development of pain<sup>14</sup>. Another study designed to analyze the relationship between sleep disorders and the occurrence of chronic non-communicable diseases, found that 31.4% suffered from altered sleep and lower back pain<sup>15</sup>. In the same line of research, a study carried out in Korea showed that the presence of muscular pain was significantly greater in those who slept for 5 to 7 hours, concluding that the duration of sleep, short or long, is associated with musculoskeletal pain, especially in the lumbar area<sup>16</sup>. The results of this research showed geotherapy as an alternative in the prevention and treatment of lower back pain, with the advantage of being painless and non-invasive, acting on the individual's emotions<sup>3</sup>. Green clay therefore has an effect on osteomuscular pain, besides promoting muscle relaxation and helping to reduce tension caused by stress or physical discomfort<sup>3</sup>. The results of this research showed that green clay geotherapy is an alternative for the prevention and treatment of lower back pain, acting on the individual's emotional aspects, promoting muscle relaxation and helping to reduce tension caused by stress and physical discomfort, with the advantage of being painless and non-invasive<sup>6</sup>. Among the non-pharmacological therapies for BP relief, geotherapy showed significant results in pain reduction when compared to other studies<sup>17-19</sup>.

It is essential to conduct more studies with a larger sample and control group, a limiting factor of this study, in order to assess the possibility that the placebo effect did influence or not the results obtained.

## CONCLUSION

Geotherapy with green clay applied to the lumbar area was effective in the reduction of the unspecified lumbar pain intensity.

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