

**Title:** Coplanar Arrangement Of Shortwave Diathermy Is The Most Efficient In Skin Temperature Change: A Randomized Controlled Trial.

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## **Study Protocol with Statistical Analysis Plan:**

### Study Design

A randomized crossover trial. Using a website (<http://www.randomization.com>), an independent researcher randomly allocated the subjects in three groups with a ratio of 1:1:1 and block sizes of 18. Then, concealed allocation results in sequentially numbered, opaque, sealed envelopes, and placed it in an agreed location. Another researcher opened the envelopes only before the first intervention, in the presence of the subject. Each group differs regarding arrangement application order, as follows: group A) coplanar, contraplanar and longitudinal; group B) contraplanar, coplanar and longitudinal; group C) longitudinal, coplanar and contraplanar.

The same researcher that captured the thermographic images color-coded the results, which were given to a blinded researcher for data analyses, who returned it afterwards for decoding. The researchers were kept blinded to the process in which they did not participate, and the subjects to the intensity indicator monitor.

### Participants

Young health male university students, reached through social media, volunteered to participate in the study. Eligible subjects were those that consent in abstain from physical activity at least 24 hours prior to the intervention day, and in avoid caffeine, alcohol, and food intake at least one hour prior to the intervention. Subjects who injured the thigh region in the three months before the study, had circulatory history, cardiac pacemakers, metal implants or external fixation<sup>6</sup>, and self-reported current smoking would be excluded.

### Interventions

Each subject attended to three sessions with a washout period of at least 24 hours. In order to stabilize body temperature, subjects laid in a relaxed prone position on a wooden stretcher, under instruction to refrain from touching the left thigh over the 20 minutes of acclimatization. Then, the previous determined capacitive technic arrangement of SWD was applied for 20 minutes.

The SWD device we used was Diatermede II (Carci® 4022, São Paulo, SP, Brazil), on continuous mode, with a frequency of 27.12 MHz. Which was delivered by means of two pad electrodes (17x12 cm) surrounded by felt and positioned over 1 cm<sup>6</sup> of toweling. On coplanar arrangement, the electrodes were as far apart as the cross-sectional diameter of the pad electrode (Figure 1). We controlled the intensity based on a referred warm heat perception by the subject. The device was calibrated prior to data acquisition.

We measured the temperature in three time points, first: before the application (baseline), after acclimatization period, second: immediately after each application, and third: each minute over 25 minutes after electrodes removal. We maintained room temperature between 23 °C and 25 °C, with a mean humidity of 64% throughout the study. The room had no source of infrared radiation or airflow.

Previously to acclimatization period we had marked each 6 cm over 36 cm from the base of the patella towards the anterior superior iliac spine. We collected skin temperature under the electrode (at the centre of the proximal electrode), and at the thigh centre (6 cm from the proximal electrode's edge). Thus, on coplanar and longitudinal arrangement at 18 cm and 30 cm marks, and on contraplanar arrangement at 12 cm and 24 cm marks (Figure 2).

Outcomes Measures

The primary endpoint was to determine the most efficient arrangement of capacitive technic with respect to temperature change over the 25 minutes after application, which was measured in Celsius (°C) on the anterior aspect of the left thigh.

To collect skin temperature we used an SC325 infrared thermography camera (A325sc; FLIR Systems, Antennvägen 6, PO Box 7376 SE-187 66 Täby, SWEDEN), positioned vertically 1 m from the thigh. The camera was calibrated prior to data acquisition. Manufacturers' specifications defined an accuracy of +/- 2%, and emissivity of 0.01 to 1. We analyzed the thermographic images (320 x 240 pixels) using ResearchIR software, version 4.40.1.6 (Copyright © 2016 FLIR Systems, FLIR Systems, Inc., 27700 SW Parkway Avenue, Wilsonville, OR 97070 USA).

#### Statistical Analysis

We used descriptive statistics to summarize data, computing means and standard deviations (SDs) for the primary endpoint, and the Shapiro-Wilk test for checking data normality. To compare the arrangements we conducted a repeated measures analysis of variance (ANOVA) and Bonferroni post-hoc tests. The  $\alpha$  level was set at  $<.05$ . Effect size was calculated through partial eta squared and correlated using Cohen index (.1 to .3 as small, .3 to .5 as medium, and over .5 as large). In order to summarize the data we conducted 5-minute interval analysis. SPSS software (version 20; IBM Corp, Armonk, NY) was used for analyzes.