Clay body wrap with microcurrent: Effects in central adiposity

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ABSTRACT

Introduction: Increased fat mass is becoming more prevalent in women and its accumulation in the abdominal region can lead to numerous health risks such as diabetes *mellitus*. The clay body wrap using compounds such as green clay, green tea and magnesium sulfate, in addition to microcurrent, may reduce abdominal fat mass and minimize or prevent numerous health problems.

Objective: This study aims at measuring the influence of the clay body wrap with microcurrent and aerobic exercise on abdominal fat.

Methods: Nineteen female patients, randomized into intervention (n = 10) and control (n = 9) groups, were evaluated using ultrasound for visceral and subcutaneous abdominal fat, calipers and abdominal region perimeter for subcutaneous fat and bioimpedance for weight, fat mass percentage and muscular mass. During 10 sessions (5 weeks, twice a week) both groups performed aerobic exercise in a cycloergometer and a clay body wrap with microcurrent was applied to the intervention group.

Results: When comparing both groups after 5 weeks of protocol, there was a significant decrease in the subcutane- ous fat around left anterior superior iliac spine in the intervention group (ρ = 0.026 for a confidence interval 95%). When comparing initial and final abdominal fat in the intervention group, measured by ultrasound (subcutaneous and visceral fat) and by skinfold (subcutaneous fat), we detected a significant abdominal fat reduction.

Conclusion: This study demonstrated that the clay body wrap used with microcurrent and aerobic exercise can have a positive effect on central fat reduction.

Keywords: Central adiposity, Body wrap, Microcurrent, Green clay, Physical exercise

1. Introduction

Evidence shows that nutritional modifications combined with sedentary lifestyle have contributed to the accumulation of body fat (McMichael et al., 2007). Adipocyte metabolism is regulated by sympathetic nervous system and hormones such as catecholamines, leading to lipolysis which consists on triglyceride breakdown (Pénicaud et al., 2000).

According to Westphal (2008) fat location is more related with side effects than its quantity. Even though the gynoid pattern is the most common in women, genetic and hormonal disorders may be associated with the accumulation of abdominal fat (Freedland, 2004; Ibrahim, 2009). Increased central adiposity, particularly deep subcutaneous and visceral, increases the risk and has a role on multiple diseases such as diabetes *mellitus*, dyslipidemia and hypertension (Freedland, 2004; Goodpaster et al., 2005; Ibrahim, 2009).

One of the physical therapy procedures used in clinical practice to reduce abdominal fat is the clay body wrap with microcurrent. It is composed by green clay (with calcium and aluminum as components), green tea and magnesium sulfate, impregnated in a bandage whose com- pressive effect enhances fluid drainage from the abdominal region through the superficial lymphatic system (Standring, 2008).

Green tea has beneficial effects in reducing fat and body weight, given its ability to increase fat oxidation, leading to mature fat cells' apoptosis, inhibition of adipogenesis and inhibition of differentiation of preadipocytes. Its action occurs by the mechanism shown in Fig. 1. Green tea topical application enables the retention of some com- pounds in the adipose tissue without easily reaching the systemic route (Belo et al., 2009; Heinrich et al., 2004).

Another body wrap component is magnesium sulfate, which can positively influence lipolysis once the magnesium absorbed by adipocytes allows hormone-sensitive lipase's activity facilitating triglyceride break- down (Rayssiguier et al., 1990).

Green clay is composed of several elements capable of inducing lipolysis and it is also a low cost, easily accessible material. In addition to magnesium, calcium is another green clay component. An increase in extracellular calcium concentration leads to an augmented enzymatic activity and promotes a reduction of calcitriol, leading to lipolysis (Soma et al., 2003; Zemel et al., 2005). In fact, for Laudánska et al. (2002) human skin appears to be permeable to Ca^{2+} and Mg^{2+} ions, suggesting the possibility of skin penetration by these two components. Moreover, the aluminum present in clay exerts its action only in the presence of certain

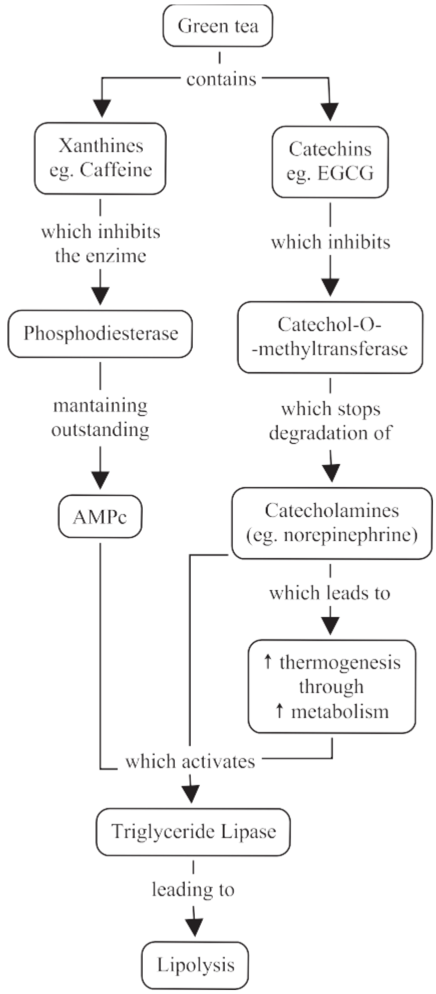

Fig. 1. Green tea's physiological action mechanism on lipolysis.
Adapted from Lin et al. (2005), Maki et al. (2009), and Rains et al. (2011).

lipolysis enzymes, modifying them and promoting the enzyme-substraterecognition (Corvis et al., 2007; Rumberger et al., 2004).

Microcurrent (electrolipophoresis) helps triglyceride degradation by increasing blood flow and metabolism, provoking changes in cell membrane polarity and activating triglyceride lipase and hormone- sensitive lipase enzymes (Curtis et al., 2010; Kirsch, 2002; Puhar et al., 2011). Therefore, this study aims at measuring the influence of the clay body wrap with microcurrent and aerobic exercise on central adiposity reduction.

2. Methods

2.1. Sample

The sample of this controlled trial was composed by 20 volun- teers selected by inclusion criteria such as being a faculty female student, with a body mass index ranging from normal (18.5– 24,99) to pre-obese (25–29.9) (WHO, 2006) and taking oral con- traceptives. Those who practiced regular physical activity or had it as a contraindication were diagnosed with a pathology that could influence lipid metabolism, smoked or consumed alcohol regular-ly, and those who presented any contra indications to microcurrent (Kirsch, 2002) were excluded. Volunteers were divided randomly intothe intervention group (IG) and the control group (CG).

2.2. Instruments

Before measurements, a pilot study was conducted in order to analyze intra-rater reliability, using intraclass correlation (ICC 3.1) and standard error of measurement (SEM). A rigid tape in centimeters was used to measure abdominal perimeter (SEM = 0.1 cm; ICC = 0.99). Skinfold measurements were performed using Harpenden® analog calipers (SEM = 0.2 mm; ICC = 0.96). Bioimpedance Tanita BC-545 InnerScan™ was used to calculate the percentage of total and trunk fat, weight and muscle mass. Echograph Toshiba Medical Systems, with a 7.5 MHz frequency probe was chosen to measure subcutaneous and visceral abdominal fat (SEM = 0.3 mm; ICC = 0.97). Food frequency questionnaire (FFQ) was implemented in order to see whether the participants maintained their eating habits throughout the protocol (Cronbach's α[1] = 0.70). This questionnaire assesses eating habitsbased on the diet over a specified period of time (1 week in this study). It has9 sections (related with different kinds of food and drink) classifiedby the portion size, which allows for an estimate of the total calories ingested per day. During sessions, beyond monitoring heart rate (Polar® heart monitors), the intensity of aerobic exercise was controlled using Borg Scale.[2] A cycloergometer was used for aerobic exercise and the Enraf Nonius® model 692 Sonopuls® device was used to deliver microcurrent.

2.3. Materials

The materials used for the clay body wrap were as follows: green clay; green tea *ElivaPura* lot 01MAT 177103S (xanthines and catechins); magnesium sulfate; distilled water; ethanol and bandages. The green clay, from *Seara* lot 69 0013 and collected in Portugal, presented the following chemical composition in %: SiO_2 (27.8); CaO (25.5); Al_2O_3 (11.2); MgO (4.6); Fe_2O_3 (2.3); K_2O (1.57); TiO_2 (0.37); Na_2O (0.05);
and loss on ignition (26.0). Clay is ground and sieved and used without any further purification. It belongs to the smectite group, commercialized for external therapeuticuse.

2.4. Procedures

Both groups were assessed initially and after 5 weeks of interven- tion. Intervention was performed twice a week, with a total of 10 sessions.

Ultrasound was used to measure subcutaneous and visceral abdominal fat. The former was calculated using 4 areas: between xiphoid apophysis and navel, below navel and above left and right anterior superior iliac spine (ASIS). The latter was measured only in one area, between xiphoid apophysis and navel. Waist perimetermeasurements were done in four areas: the narrowest perimeter between the last rib and the iliac crests, the point immediately above the iliac crests, the most prominent abdominal point and at trochanter level. A waist–hip ratio was calculated by dividing the narrowest perim- eter between the last rib and the iliac crests by the trochanter level pe- rimeter. Skinfold measurements with a caliper, to analyze superficial fat, were performed using triceps, suprailiac, thigh and abdominal skinfolds. Some of these were also used to estimate body fat percentage
[body fat's % = 1.1470292 − 0.0009376 ∗ (X3) +[3] 0.0000030 ∗ (X3) ∗

2 − 0.0001156 ∗ (X4) − 0.0005839 ∗ (X5)] (Eston and Reilly, 2009).

[1] Cronbach's alpha is a coefficient of internal consistency that shows how closely re-lated a set of items are as a group. For comparing groups, α values of 0.7 to 0.8 are regarded as satisfactory (Bland and Altman, 1997).

[2] The Borg Scale is a subjective index that is used to assess a patient's degree of ex-haustion or reaction to activities. In practice, the patient indicates the level of exhaus- tion and the extent of any dyspnea or chest pain experienced during activity on a scale from 6 to 20 (Vogels et al., 2003).

[3] Jackson and Pollock's formula, where X3 = sum of triceps, suprailiac and thigh skinfolds in millimeters, X4 = age in years, X5 = circumference at trochanter level in centimeters (Eston and Reilly, 2009).

Afterwards each participant was evaluated with the bioimpedance device to measure percentage of total and trunk fat, weight and muscle mass. At last, FFQ was self-applied. Participants were asked to keep their eating habits and to maintain their usual physical activity constant during the study.

Intervention protocol in IG began with a vigorous massage during 5 min, with an alcoholic extract of green tea (96% ethanol) macerated for 5 days. Combination of ethyl alcohol with green tea provides a good extraction of the tea components (Bajerskaa et al., 2011). In addi- tion, ethanol promotes the mechanical removal of contaminants and dissolves lipids in the lipid membrane, increasing the permeability of the skin (Goates and Knuton, 1994). The massage was followed by the application of a solution of 33.79 g of green clay combined with
18.56 g of magnesium sulfate (proportion in volume of 6 measures of green clay for 4 measures of sulfate) dissolved in 16.67 ml of distilled water. Then a low elasticity bandage soaked in an infusion of 3.12 g of green tea, 6.94 g of magnesium sulfate (1 measure, in volume) and
0.5 l of water was applied with increased pressure from the center to the periphery. The intervention protocol ended with microcurrent in the abdominal region with electrodes in a parallel position, intensity below the sensitivity threshold and a maximum of 1 mA, frequencies of 25 Hz and 10 Hz (15 min each to prevent desensitization of adipocytes)and change in polarity every second (Curtis et al., 2010; Kirsch, 2002).

The protocol also included 30 min of aerobic moderate-intensity ex- ercise (50%) using Karvonen's formula,[4] performed on a cycloergometer simultaneously with the clay body wrap (Vogels et al., 2003). Borg Scale (moderate intensity = 13–14) was applied (O'Donovan et al., 2010).

Control group only performed aerobic moderate-intensity exercise, following the same principles as the intervention group.

2.5. *Ethics*

Authorization was requested to the institution where the study occurred. The Declaration of Helsinki was signed by all participants. The control group was invited to undertake the intervention protocol at the end of the research study.

Food frequency questionnaire application required the authoriza- tion from the author of the Portuguese version.

2.6. *Statistics*

Predictive analytics software (PASW® Statistics) version 18 was used for the statistical analysis, with a significance level of 5% (ρ b 0.05). Central tendency measures, median and interquartile deviation were used. All severe outliers were excluded. Given the small size of the sample, non-parametric tests were applied (Rosner, 2006). A new variable was calculated using differences between initial and final results in each group. Mann–Whitney test[5] was used to compare this variable between groups. The Wilcoxon test[6] was used to compare the initial and final moments in each group. Effect size was calculated
using Cohen's d [(final moment mean intervention group − final moment mean control group) / both groups' final standard deviation)]
(Cook, 2008).

[4] Karvonen's formula is used to derive training heart rate (HR). The calculation was made as follows: HR during training = HR in the resting state + (0.50 × HR reserve), where HR reserve = HR maximum − HR resting state (Vogels et al., 2003).

[5] The Mann–Whitney test (or Wilcoxon rank-sum test) is a nonparametric that can be used to test the null hypothesis that two independent samples came from the same population. It is applied when is not assumed that the data came from a normal distri-
bution and the sample size is less than 30 (Rosner, 2006).

[6] The Wilcoxon signed-rank test is the nonparametric version of a paired samples *t*- test and it is used to compare two related samples when they cannot be assumed to be normally distributed and their size is less than 30 (Rosner, 2006).

3. Results

The sample (n = 19) was characterized by the variables described in Table 1.

Characterization variables showed no significant differences between groups suggesting that both groups were comparable. When comparing intervention group (IG) and control group (CG) after 10 sessions of intervention there was a significant decrease in subcutane- ous fat measure, confirmed by ultrasound on the left ASIS (Table 2). Al- though there were no other statistically significant results when IG was compared with CG after 10 sessions, when calculating the intervention ef- fect size (using Cohen's *d*), a moderate effect size strength was found re- garding above navel subcutaneous fat (0.53), below navel subcutaneous fat (0.64) and waist perimeter (0.51). Even though no significant differ-ence was found above navel, a large intervention effect size strength was encountered for visceral fat (0.84).

When comparing the groups' results in the two moments it was observed that the IG had a more significant improvement after 10 sessions of intervention than the CG. IG's greater improvements could be confirmed by ultrasound results, with a significant decrease in sub- cutaneous and visceral fat above navel and subcutaneous fat below navel. Nevertheless, an improvement in subcutaneous fat was found on the left ASIS. More significant improvement could be seen in the IG comparing skinfold results at the beginning and after the intervention protocol, with a significant decrease in all measured skinfolds after 10 sessions and a decrease in fat percentage. Perimeter measure- ments decreased significantly in final moment in the IG, except for the perimeter above the iliac crest (Table 3 and Fig. 2). Bioimpedance IG values were not influenced by the intervention protocol except for the percentage of body fat that decreased significantly (p b 0.05) (Table 3 and Fig. 2).

Aerobic exercise was revealed as important in reducing central adiposity, as the control group's percentage of total fat, subcutaneous fat below navel, abdominal vertical skinfold, body fat percentage and waist and most salient abdominal point perimeter measures decreased significantly (Table 3).

4. Discussion

After 10 sessions of intervention, IG significantly decreased subcuta- neous fat tissue, confirmed by ultrasound on the left ASIS, when com- pared with the CG. This decrease can be due to the clay body wrap action throughout physiological principles of its different components. Regarding green tea, evidence shows that catechins' and xanthines' ability to penetrate the skin has a direct effect on fat reduction (Belo et al., 2009; Rawlings, 2006). Although green tea's exact degree of penetra- tion is not well understood, it crosses all skin layers and when combined with ethanol and microcurrent its penetration is further increased (Rains et al., 2011).

On the other hand, clay mineral properties such as adsorption seem to be sufficient enough to be effective on lipolysis (Carretero, 2002).

Table 1
Sample (n = 19) characterization in both groups at initial moment.

Variable	Group	Median	Interquartile deviation	Maximum	Minimum
Age (years)	Intervention	20	1.13	23	19
	Control	21	1	23	18
Height (m)	Intervention	1.62	0.04	1.54	1.69
	Control	1.67	0.05	1.75	1.55
Weight (kg)	Intervention	56.9	4.57	66.9	49.5
	Control	56	2.5	62.6	51.1
BMI (kg/m^2)	Intervention	20.8	1.58	28.2	19.3
	Control	20.4	0.29	23.4	19.5
FFQ (kcal/day)	Intervention	1989.5	100.76	2056.3	1747.3
	Control	1569	280.25	2942.9	1059.9

Table 2
Median and interquartile deviation values of the variable difference for all studied variables. Mann–Whitney test statistic (U-value) and ρ value of control (n = 9) and intervention group (n = 10) comparison, after 10 intervention sessions.

	Variable	Group	Median	Interquartile deviation	U-value	ρ
Bioimpedance	Weight (kg)	Intervention	−0.2	0.59	41	NS
		Control	−0.2	0.55		
	Total fat %	Intervention	−1.5	0.79	39	NS
		Control	−1.3	1.35		
	Trunk fat%	Intervention	−1.6	1.28	32	NS
		Control	−2.1	2.15		
	Muscle mass (kg)	Intervention	0.5	0.54	41	NS
		Control	0.5	0.88		
Ultrasound (mm)	Subcutaneous fat above navel	Intervention	−1.8	1.58	35	NS
		Control	−0.9	1.08		
	Visceral fat above navel	Intervention	−1.7	1.35	36.5	NS
		Control	−0.8	1.7		
	Below navel	Intervention	−2.5	1.49	42.5	NS
		Control	−3.0	1.53		
	Right ASIS	Intervention	−0.8	1	37	NS
		Control	−0.7	0.43		
	Left ASIS	Intervention	−0.9	0.66	17	0.026
		Control	0.1	0.45		
Skinfold measurement (mm)	Suprailiac	Intervention	−0.2	0.17	30	NS
		Control	−0.1	0.1		
	Abdominal vertical	Intervention	−0.1	0.15	40.5	NS
		Control	−0.1	0.05		
	Abdominal horizontal	Intervention	−0.1	0.17	36	NS
		Control	−0.1	0.08		
	Body fat %	Intervention	−1.8	1.32	40	NS
		Control	−1.9	1.19		
Circumference measurement (cm)	Waist	Intervention	−2	0.72	29	NS
		Control	−0.9	0.90		
	Above iliac crests	Intervention	0.1	0.50	30	NS
		Control	1.8	1.1		
	Most salient abdominal point	Intervention	−0.8	0.80	36	NS
		Control	−0.5	0.38		
	Waist–hip ratio	Intervention	−0.01	0.01	23	NS
		Control	0	0.01		

$\rho \leq 0.05$.
NS — not significant.
ASIS = anterior superior iliac spine.

Regarding the paper of calcium, Zemel et al. (2005) and Soma et al. (2003) found that extracellular calcium contributes to the activation of enzymes such as triglyceride lipase (responsible for lipolysis), and to the reduction of compounds such as 1,25-dihydroxyvitamin D (calcitriol), which act on adipocytes by promoting calcium influx. Intracellular calci- um can stimulate lipogenesis and suppress lipolysis. This way, calcium from body wrap can promote lipolysis and fat tissue reduction by its actions on triglyceride lipase and by decreasing calcitriol, and con- sequently intracellular calcium, limiting its effects on adipocytes. Magnesium effects were studied by Rayssiguier et al. (1990), who advo- cated that its entrance into the adipocyte would increase lipolysis. Moreover, microcurrent could also contribute for IG fat reduction by increasing ATP and by its sympathetic nervous system action suggesting that it leads to lipolysis' activation (Kirsch, 2002; Puhar et al., 2011).

Despite the small sample, the statistical results revealed a moderate intervention effect size on the above navel subcutaneous fat, below navel subcutaneous fat and waist perimeter, as well as a large interven- tion effect size strength found for above navel visceral fat.

Comparing initial and final assessment moments in IG, there was a significant decrease in visceral fat above navel that can be explained by the use of the clay body wrap. In fact, aerobic exercise as well as microcurrent promote fat acid consumption, especially from sub- cutaneous adipose tissue (Boucher et al., 2008; Horowitz, 2003). Vis- ceral fat reduction can be due to the clay body wrap compounds, given that they reinforce the effects of aerobic exercise, enhancing li- polysis in the whole abdominal area, even in deeper places where ex- ercise alone do not revealed a reduction of fat mass.

Intervention group revealed a decrease in all measured skinfolds and in fat percentage, revealing a reduction of the fat layer. According to this and taking into account the other results, it appears that joining the different constituents of the body wrap does not interfere with its intervention in lipolysis. As Nafisi et al. (2002) reported, the xanthines in aqueous solution have limited interaction with calcium and magnesium, not influencing their skin penetration. Even according to Monajemi and Ebrahimi (2004), who report some connection between xanthines and potassium, the intended effects do not seem to be affected because potassium is not a lipolysis enhancer and it is present in a small concentration in clay.

The small sample size, which can be seen as a limitation, was due to the fact that the present study's inclusion and exclusion criteria were restricted to avoid biases by non-controllable variables. Also, such a prolonged protocol requires great collaboration from the participants. Even though, this study's sample is larger than the ones in other studies with identic purposes (Komatsu et al., 2003).

It is also important to mention that some elements of green clay other than calcium and magnesium cross the skin. Compounds such as silica and titanium can reach the epidermis and sometimes the dermis. However, they cannot reach circulation (Boonen et al., 2011; Miquel-Jeanjean et al., 2012). Other ions, such as aluminum and potas- sium, were detected in blood or urine after topical application (Flarend et al., 2001; Shani et al., 1985). However, no systemic risk was attribut- ed to the use of potassium. The aluminum applied was not harmful to health because, according to Flarend et al. (2001), only 0.012% of alumi- num penetrates the skin; EMA (2010) recommend a maximum dose of

Table 3
Both groups' initial and final moments median and interquartile deviation values of all studied variables using Wilcoxon test statistic (Z-value) and ρ value.

		Variable	Initial moment		Final moment		Z-value	ρ IM → FM
			Median	IQD	Median	IQD		
Bioimpedance	IG	Weight (kg)	56.9	4.56	56.4	4.76	−0.61	NS
		Total fat %	24.7	5.69	24.7	5.64	−2.25	0.02
		Trunk fat %	20.0	7.29	21.4	7.36	−1.48	NS
		Muscle mass (kg)	40.9	1.24	41.4	0.98	−1.69	NS
	CG	Weight (kg)	56.0	2.50	56.0	2.68	−1.10	NS
		Total fat %	25.1	3.45	23.8	3.83	−2.10	0.04
		Trunk fat %	20.2	4.80	18.3	5.63	−1.96	NS
		Muscle mass (kg)	40.0	1.08	41.1	0.85	−1.25	NS
Ultrasound (mm)	IG	Subcutaneous fat above navel	13.7	4.13	11.5	4.06	−2.29	0.02
		Visceral fat above navel	8.9	3.35	6.2	2.36	−2.60	0.006
		Below navel	23.7	7.48	22.7	7.39	−2.70	0.004
		Right ASIS	8.6	3.39	9.0	2.70	−1.89	NS
		Left ASIS	8.0	3.54	8.3	3.43	−2.30	0.02
	CG	Subcutaneous fat above navel	11.0	1.43	10.1	1.00	−1.84	NS
		Visceral fat above navel	5.8	2.53	4.2	1.98	−1.90	NS
		Below navel	18.0	3.65	15.2	2.60	−2.52	0.008
		Right ASIS	5.6	1.83	5.0	1.68	−1.19	NS
		Left ASIS	5.6	1.48	5.3	1.18	−0.77	NS
Skinfold measurement (mm)	IG	Suprailiac	18.6	1.65	17.8	0.92	−1.99	0.04
		Abdominal vertical	17.1	1.26	15.9	1.97	−2.09	0.04
		Abdominal horizontal	16.4	0.90	16.3	1.55	−1.99	0.04
		Body fat %	29.4	2.26	27.0	1.65	−2.70	0.004
	CG	Suprailiac	17.9	1.70	17.4	1.83	−1.30	NS
		Abdominal vertical	16.8	0.67	15.6	0.92	−2.55	0.008
		Abdominal horizontal	15.7	0.95	15.5	0.58	−1.60	NS
		Body fat %	28.3	1.95	27.5	1.20	−2.55	0.008
Circumference measurement (cm)	IG	Waist	71.3	4.26	69.3	4.41	−2.60	0.006
		Above iliac crests	74.7	6.43	75.0	6.98	−0.66	NS
		The most salient abdominal point	82.7	4.84	81.3	4.92	−2.60	0.006
		Waist-hip ratio	0.76	0.04	0.73	0.03	−2.29	0.02
	CG	Waist	69.3	3.37	69.0	3.60	−2.67	0.004
		Above iliac crests	73.6	2.03	75.0	2.93	−2.07	0.04
		The most salient abdominal point	82.5	1.98	81.2	2.00	−2.55	0.008
		Waist-hip ratio	0.70	0.05	0.69	0.05	−0.42	NS

$\rho \leq 0.05$.
NS — not significant.
IG = intervention group and CG = control group.
I Moment/IM = initial moment; F Moment/FM = final moment. IQD = interquartile deviation.

1.25 mg aluminum/person and only 14.53% of this was applied; JEFCA (2006)stipulated a weekly dose of 1 mg/kg and the amount applied in this study, twice a week, from a sample medium weight of 56.9 kg corresponds to 0.64% of this dose. The aforementioned magnesium also is not toxic (Saris et al., 2000). Although calcium may have systemic effects, given the limited amount applied and short duration of this study, it does not seem likely to lead to a health risk (Tateo and Summa, 2007).

Further studies are proposed to assess the most active compound of the wrap therapy on central adiposity reduction, as well as the best proportions to use. Studies using larger samples are also necessary in order to reinforce our conclusions.

5. Conclusion

This study demonstrates that the clay body wrap with microcurrent and aerobic exercise plays a role in abdominal subcutaneous and visceral fat reduction. Physical therapy is important not only in reducing abdominal fat but also in preventing the development of related diseases and promoting health.

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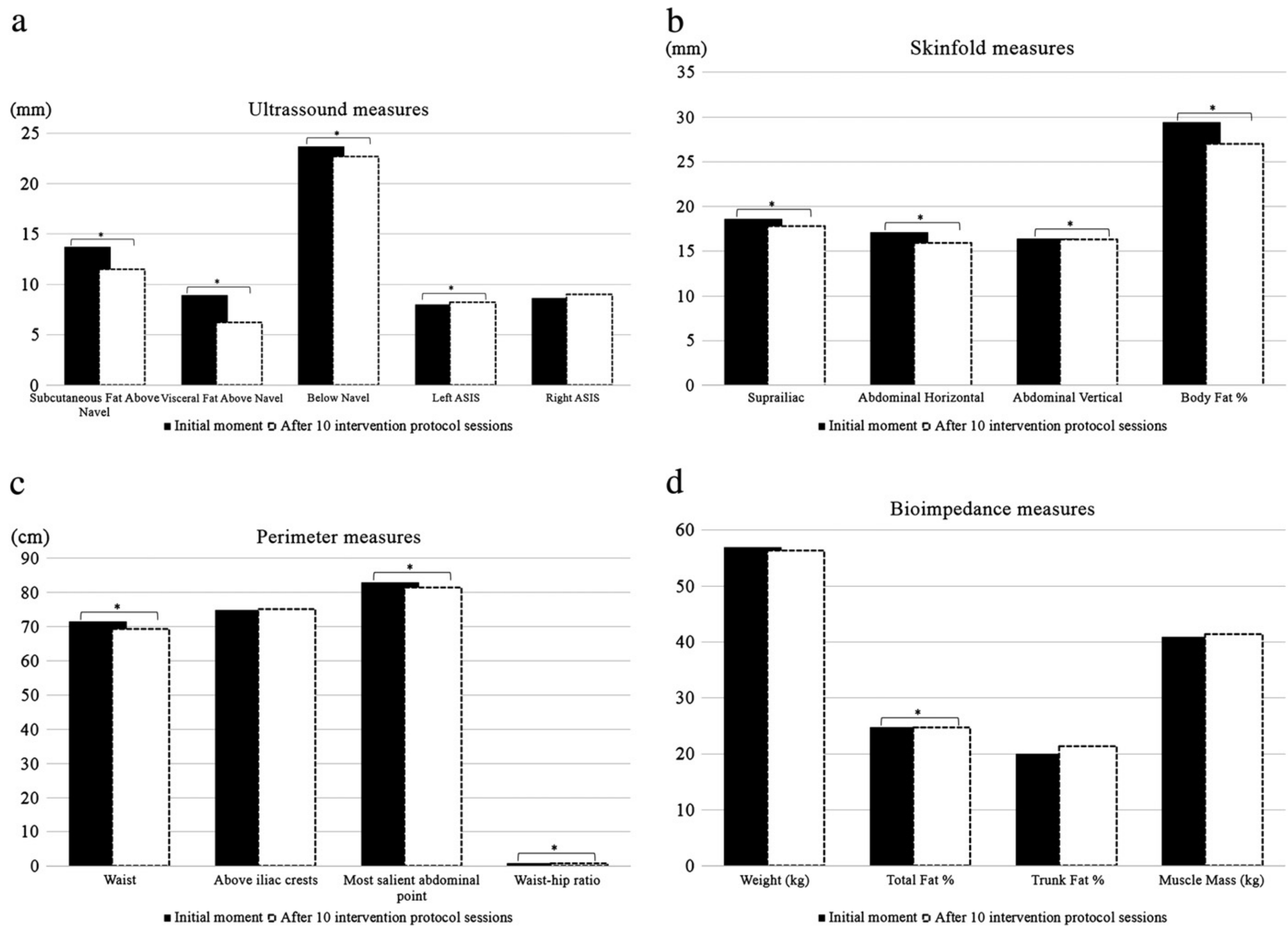

Fig. 2. a, b, c & d — IG results after 10 intervention protocol sessions (*: p b 0.05).

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