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ORIGINAL CONTRIBUTION

Effect of shock wave therapy associated with aerobic exercise on cellulite: A randomized controlled trial

Sara Troia PT[1] | Ana Maria Moreira PT[1] | Daniela Pisco PT[1] | Andreia Noites PhD, MSc, PT[1,2] | Ana Luisa Vale PT[1] | Paulo Carvalho PhD, MSc, PT[1,2] | Rui Vilarinho MSc, PT[1,2]

[1]Department of Physiotherapy, School of Health, Polytechnic Institute of Porto, Porto, Portugal

[2]Center for Rehabilitation Research (CIR) – Human Movement System (Re) habilitation, Polytechnic Institute of Porto, Porto, Portugal

Correspondence
Andreia Noites, School of Health, Polytechnic Institute of Porto, Porto, Portugal.
Email: arn@ess.ipp.pt

Abstract

Background: Cellulite is a multifactor and controversial condition. Several methods have been explored to reduce it, not always with favorable results. Shock Wave Therapy has been shown to be effective, but the results of its association with an Aerobic Exercise Program are unknown.

Aims: To verify whether Shock Wave Therapy in association with an Aerobic Exercise Program reduces the degree of severity of Cellulite in the gluteal region and in the ⅓ of the proximal posterior of the thigh.

Methods: Forty-five healthy women, aged from 18 to 32, randomly assigned, considering the severity degree in the Cellulite Severity Scale and the level of physical activity, in three groups: two experimental and one control group. The control group performed the evaluations. The experimental group 1 performed an Aerobic Exercise Program, and the experimental group 2 associated this program with a Radial Shock Wave Therapy protocol. The experimental groups completed six interventions within 3 weeks. In addition, the degree of severity in the Cellulite Severity Scale, height, body composition, skin temperature, and subcutaneous adipose tissue thickness were assessed. One-way ANOVA test and Kruskal-Wallis were used to obtain the results, with level of significance of 0.05.

Results: Forty-two women completed the study. There was a significant reduction in the severity of Cellulite between experimental group 2 and group 1 ($P = 0.032$), and from group 2 to the control group ($P = 0.042$).

Conclusion: The association of Shock Wave Therapy and Aerobic Exercise was shown to be effective in reducing the severity of cellulite.

KEYWORDS

adiposity, cellulite, extracorporeal shock wave therapy, physical therapy modalities, shock wave therapy

Clinical trials: NCT03986983.

1 | INTRODUCTION

Cellulite, also known as Gynoid Lipodystrophy, affects about 90% of postpubertal women, being almost nonexistent in men. However, its prevalence is not completely defined.[1] It is considered a subcutaneous tissue disorder, with structural and biochemical components that change skin topography and it is visible in the form of bulges and depressions, located mainly in the lower limbs and in the femoral gluteus region.[2-5] This degenerative condition has a complex and multifactor etiology, which is not fully understood so far, although it can be explained by three theories (hormonal, morphological and vascular).[2,4,6]

According to the hormonal theory, women have about 20% more adipocytes, which is thought to be estrogen-related, a fact that may contribute to the severity of cellulite.[5,7] The morphological characteristics of these cells predispose them to herniation, also described in the theory of morphological alterations of the subcutaneous adipose tissue.

This second theory is the one most described in the literature and is related to the interlobular connective tissue septa that interconnect subcutaneous adipose lobes. These septa are thin and have perpendicular projections in women, which favors the deposition of subcutaneous adipose tissue and its expansion to the surface of the dermis.[2,8]

According to the third theory, the microcirculation deficit and the reduction of subcutaneous adipose tissue lymphatic drainage leads to a greater predisposition of microedema in subcutaneous fat layers and, consequently, to subcutaneous adipose tissue thickening, leading to changes in the skin surface.[2,4]

Several risk factors that contribute to the severity of cellulite are such as, a high fat diet, physical inactivity, smoking and drinking habits, pregnancy and postpartum period.[9]

In this sense, even though it is an esthetic problem, the intervention in this condition is necessary and all etiological factors must be considered. In order to do that, some therapeutic options have been outlined to reduce its severity. The therapies available include Vaccum therapy, Lymphatic Drainage, High Intensity Focused Ultrasound, and thermal therapies such as, Cryolipolysis, Low Intensity Laser and Radiofrequency.[1] However, the results of these techniques in the treatment of cellulite are controversial and scarce, often presenting uncomfortable long sessions for the patient.[1]

The influence of Shock wave Therapy (SWT) on the reduction of cellulite severity has been studied, showing beneficial results. SWT is a safe and effective approach through short sessions.[10] It consists of the application of acoustic waves (production of a pulse of high pressure), induced in a short time, generating mechanical pressure waves in the tissues, which promotes cavitation phenomena, forming gas bubbles in the intervened fluids. This leads to increased cell diffusion, increased membrane permeability, and cytoskeletal lesions which lead to adipocyte lipolysis and/ or apoptosis.[7,11,12] In addition, it promotes increased blood flow in the region and cellular metabolism, as well as stimulation of lymphatic drainage and self-regeneration processes.[3,7,11-13] Also, SWT promotes skin elasticity, as it enhances neocollagen and elastin production by the stimulation of fibroblastos.[4,7,10,11,13,14]

Several studies have verified the isolated effectiveness of SWT in reducing the severity of cellulite. Knobloch et al. associated this with an exercise program. Nevertheless, none verified the effect of SWT associated with an Aerobic Exercise Program (AEP). Physiologically, this type of exercise makes the intervention safer for participants due to the oxidation of fatty acids.[15] In this sense, as there are no studies that present results of the association of an AEP with SWT in reducing the degree of severity of cellulite, more studies should be carried out.

Thus, the present study has as its main objective to analyze the effect of six SWT sessions in association with an AEP on the degree of severity of cellulite in the gluteal region and in the ⅓ of the proximal posterior of the thigh. Secondary objectives are to analyze the effect of six SWT sessions in association with a AEP on the hip, gluteal, and proximal thigh perimeter, on the microcirculation of the gluteal region and in the ⅓ of the proximal posterior of the thigh, and on the thickness of subcutaneous adipose tissue.

2 | METHODS

2.1 | Study design

This study is classified as clinical trial, cross-sectional, randomized, controlled and blinding by the evaluators, presenting three groups with 14 women in each group - Control Group (CG) that performed the evaluations, Experimental Group 1 (EG1) that performed an Aerobic Exercise Program and Experimental Group 2 (EG2) that associated this program with a Radial Shock Wave Therapy protocol - with an allocation ratio of 1:1: 1. It is a single center study, taking into account the CONSORT criteria.[16]

The study was approved by the Ethics Committee of Health School of the Polytechnic Institute of Porto (ESS-P.Porto), (registration No. 1499/2019). All participants were duly informed about the research project (rationale, procedures and associated risks). The informed consent form, according to the Declaration of Helsinki, was signed by the non-opposing participants. The anonymity and confidentiality of participants at all stages of the study were also ensured. Upon completion of the study, EG2 participants were given the opportunity to perform SWT on the left lower limb. This study is registered in clinical trials with the number NCT03986983.

2.2 | Sample selection and inclusion criteria

The target population was female students from the Health School of the Polytechnic Institute of Porto (ESS-P.Porto), aged between 18 and 35, who volunteered to participate in the study.

Inclusion criteria were individuals with moderate (score between 6 and 10) and severe (score between 11 and 15) cellulite in the gluteal region and in the ⅓ of the proximal posterior of the thigh region,

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TABLE 1 Cellulite Severity Scale (CSS)

	0	1	2	3	SCORE
Number of evident depressions	None/no depressions	A small amount: 1-4 depressions are visible	A moderate amount: 5-9 depressions are visible	A large amount: 10 or more depressions are visible	
Depth of depressions	No depressions	Superficial depressions	Medium depth depressions	Deep depressions	
Morphological appearance of skin surface alterations	No raised areas	'Orange peel' appearance	'Cottage cheese' appearance	'Mattress' appearance	
Grade of laxity, flaccidity or sagging skin	Absence of laxity, flaccidity, or sagging skin	Slight draped appearance	Moderate draped appearance	Severe draped appearance	
Classification scale by Nürnberger and Müller	Zero grade	First grade	Second grade	Third grade	
				TOTAL SCORE:	

according to the Cellulite Severity Scale (CSS) (Table 1). Exclusion criteria were unstable body mass in the last 3 months, but a variation less than or equal to 2 kg was considered acceptable; Low Body Mass Index (BMI), BMI < 18.5, or individuals suffering from obesity, BMI > 30; dieting to lose weight in the last 3 months or at the beginning of the study; dietary restrictions; altered hormone treatment in the last 6 months; pregnant or postpartum individuals for a period inferior to 1 year; individuals with metabolic, hematological, renal, dermatological (in the region under study), cardiovascular, respiratory, digestive and orthopedic (that prevented the exercise) dysfunctions; individuals with pacemaker, infection or tumor in the region under consideration; individuals subjected to any kind of intervention for the treatment of cellulite in the past 3 months; medication (corticosteroids and non-steroidal anti-inflammatory drugs), and athletes of high competition.[17,18]

2.3 | Instruments

2.3.1 | Sample selection, characterization, and satisfaction questionnaires

A questionnaire was developed to verify compliance with the necessary criteria for participation in the study and to collect sociodemographic data.

To determine the participants physical activity level, the International Physical Activity Questionnaire (IPAQ) - short version was used. This allowed measuring the duration, type, frequency and intensity of physical activity of the participant in the last 7 days. Craig et al[19] validated it for the Portuguese population, with concurrent validity of 0.49 and reproducibility coefficient of 0.83.

To assess the characteristics of participants' food intake in the last 12 months, the Food Frequency Questionnaire (FFQ) was used. This questionnaire allowed us to identify consumption patterns and is validated for the Portuguese population with average values of correlations with food records of daily rates of 0.54. The reproducibility of the questionnaire has a mean correlation value of 0.57 for the 22 nutrients.[20]

In order to verify satisfaction with the results of the intervention, a satisfaction questionnaire was prepared by the authors based on the questionnaire made by Schlaudraff et al.[21] The questionnaire consisted of two questions "Can I see improvements in the learning of cellulite in the intervention área?" and "Am I satisfied with the results of the intervention I performed?", to which the patient could answer from 0 ("I totally disagree") to 5 ("strongly agree"). This questionnaire was sent by e-mail to EG1 and EG2 participants after the intervention cycle.

2.3.2 | Cellulite Severity Scale (CSS)

Cellulite Severity Scale evaluated the degree of severity of cellulite, quantifying five clinical and morphological variables, namely

TABLE 2 Intraobserver reliability values obtained in the pilot study

	Intraclass Correlation (ICC)
Cellulite Severity Scale (CSS)	0.973
Waist circumference (cm)	0.971
Hip Perimeter (cm)	0.990
Maximum temperature (thermography) (C)	0.977
Minimum temperature (thermography) (C)	0.979
Subcutaneous adipose thickness without contraction (mm)	0.998
Subcutaneous adipose thickness with contraction (mm)	0.996

the number of evident depressions, the depth of depressions, the morphological aspect of the skin surface, the degree of sagging and the degree of cellulite obtained on the Nürnberger and Müller scale.[22] The final score ranges from 1 to 15, from 1 to 5 corresponding to mild severity, 6 to 10 moderate, and 11 to 15 severe.[18] For the evaluation we used photographic records of the gluteal region and posterior proximal thigh. A CANON® brand EOS 600D camera with 18 megapixel resolution and ISO sensitivity from 100 to 6400 was used.

2.3.3 | Scale and measuring tape

To determine body mass and percentage of total fat mass, the Tanita model BC-545 Inner Scan TM (Body Composition Monitor) scale was used, with a maximum capacity of 150 kg and an accuracy of 0.1 kg for each kg. Correlation coefficient with dual energy radiological absorptiometry (DEXA) varied between 0.88 and 0.89.

Measurement of height was performed using a seca® 206 tape - mechanical measuring tape. This inelastic and flexible tape has an accuracy of 1 mm and 0-220 cm measuring scale.

Having collected these data, the BMI (Body Mass/Height2 (kg/m^2)) was subsequently calculated in the Excel database used to record the participants' data.

2.3.4 | Thermography

Thermography was used to assess skin surface temperature, which shows changes in blood flow and vascularization, as skin and subcutaneous temperature depend on the vascular input of the considered site. The FLIR® E6 series thermal imager was used, with a resolution of 160 × 120 pixel and thermal sensitivity < 0.06°C.

2.3.5 | Ultrasound

To measure the thickness of subcutaneous adipose tissue, the ViamoTM ultrasound model built by Toshiba Medical Systems Corporation was used with a 7.5 Hz wave frequency probe.

2.4 | Procedures

2.4.1 | Pilot study

A pilot test and retest study was conducted in which six volunteers, who met the eligibility criteria and did not participate in the final study, were informally invited. This study included the application of the sample selection and characterization questionnaire, the photographic record according to the CSS, the evaluation of height and body composition (body mass, height, percentage of total fat mass and BMI), thermography, and ultrasound evaluation. It was performed at ESS-P.Porto in June 2019.

The pilot study aimed at training procedures, and to assess the intraobserver reliability of ultrasound, thermography and CSS, and interobserver reliability of ultrasound. The retest was performed after 7 days (interval short enough not to allow changes in subjects, but long enough to prevent the evaluator's memorization). Table 1 and Table 2 show that there was an excellent Intraclass Correlation Index (ICC) for the mentioned measures.

2.4.2 | Sample selection

The target population was invited via posters and social networks to participate in the study. Individuals who met the eligibility criteria were invited orally to participate in this study after a brief explanation and signing the informed consent.

Each participant was assigned a numeric code to randomize each group. The distribution of participants was stratified by physical activity level, attributed by the IPAQ scale score, and the degree of severity of cellulite according to CSS. The code and respective scale scores were written on paper. Thus, the participants were divided homogeneously and randomly by group. The investigators responsible for the evaluations were unaware of the participants' allocation.

2.4.3 | Sample characterization

The sample selection and characterization questionnaire was completed in the first evaluation. The researcher in charge asked the

questions and the data were entered directly into a computer without internet connection, ensuring the protection of the participants' data. IPAQ was self-administered at baseline. The FFQ was delivered in paper, so that participants could fill it in at home. The results obtained in the FFQ were processed through the Food Processor Plus program.

Regarding eating habits and physical activity, participants were asked to maintain them throughout the study.

The satisfaction questionnaire was sent by e-mail to EG1 and EG2 participants after the intervention cycle ended.

2.5 | Data collection

All data collection procedures were performed in the same room at ESS-P.Porto, facilities and the temperature and light conditions were unchanged at both times of evaluation. Each participant wore disposable underwear and stood in an upright position, looking straight ahead, with their upper limbs crossed over the abdominal region and their legs at hip width, barefoot, on a sheet of A3 paper (where the support base was drawn and used during the evaluation moments). The first evaluation (M0) was performed before the intervention cycle and the last one (M1), 24 hours after the last intervention in the two EG, and 3 weeks after the first evaluation of the CG. In the first, the photographic recording of the gluteal and thigh regions was performed, as well as the assessment of body composition and anthropometric measurements, thermography and ultrasound. At M1, the same measurements were repeated.

2.5.1 | Cellulite severity rating

Cellulite Severity Scale numerical results were considered in order to assign a score to each participant. This was carried out by a blind panel of experts, consisting of three teachers from the ESS-P.Porto, X Physiotherapy department, through the photographic record, done in the frontal and sagittal plane, with and without muscle contraction. Moreover, the photographic record was also performed with the participant in prone position, in the frontal plane, with and without muscle contraction. The camera was positioned at a fixed distance of approximately 1.20 m and at a variable height, according to the participant's characteristics, using a tripod, with the camera base aligned with the coccyx base. A CANON® brand camera (model EOS 600D) was used, and a manual mode with ISO 800 was selected. Photographs were set against a black backdrop and were always taken in the same place with the same luminous characteristics without natural light.

2.5.2 | Assessment of body composition and height

In order to obtain the body mass value and fat mass percentage, the participants remained barefoot on the TANITA scale, grasping the hand electrodes parallel to the floor, looking straight ahead, with upper limbs along the body, ensuring always the conditions determined by the TANITA company.

For height measurement, two measurements were performed and their mean was calculated. In order to perform the height measurement, the tape measure was fixed to the wall. The participant was barefoot, with heels, buttocks, shoulder blades, and occipital bone close to the wall, keeping their feet at hip width. This measurement was performed at the end of the expiratory phase to tidal volume in apnea. [23]

2.5.3 | Skin surface temperature rating

The photographs were set against a black backdrop. The maximum and minimum temperature data were collected through FLIR Tools software.

2.5.4 | Subcutaneous adipose tissue thickness assessment

Measurement of subcutaneous adipose tissue thickness was performed at the midpoint between the coccyx end and the right great trochanter, with and without muscle contraction, using the aforementioned measuring tape. The thickness was determined directly by the "frozen" images on the screen. Two measurements were taken and their average was considered.

2.5.5 | Calculating Training Heart Rate (THR) and effort perception

For each participant, the theoretical maximum heart rate (HR max = 220 - Age) was previously determined. Rest HR was obtained after a 5-minute rest in the sitting position using a heart rate monitor. Then, using the Karvonen Equation, the THR (THR = Rest HR + Intensity (HR max - Rest HR)) was calculated using 40% intensity.[23] The Borg Scale was explained to the participants who were asked to maintain a moderate intensity (10-11) during training.[23,24] This scale ranges from 6 to 20, with six being an extremely light exercise and 20 a maximal effort. It has very high correlation values with HR (0.80-0.90).

2.6 | Intervention protocol

The intervention protocol was applied in July 2019 at ESS-P.Porto. At each session, participants allocated to EG2 underwent a Radial SWT protocol at the level of the gluteal region and in the ⅓ of the proximal posterior of the thigh, followed by the AEP. EG1 performed the same AEP. The CG was not subjected to any intervention. The six intervention sessions took place at a minimum interval of 24 and a maximum of 72 hours. Two weekly sessions were held, concluding a 3-week intervention cycle.

2.6.1 | Shock Wave Therapy (SWT) protocol

To perform SWT, the BTL®-6000 SWT Easy device with pressure up to four bars, 1-15 Hz frequency and 20mm multifocal transmitter, was used. The following parameters were selected: 3.5 bar pressure, 15 Hz frequency and 3000 pulses for 3 minutes. The participants remained in the prone position and ultrasound gel was used as contact medium. SWT was applied to the gluteal area (delimited by the buttock groove, posterosuperior iliac spine and great trochanter) and on the right in the ⅓ of the proximal posterior of the thigh, in the horizontal and then vertical direction.

2.6.2 | Aerobic Exercise Program (AEP)

The AEP, lasting 30 minutes, was performed using a 20 cm step, immediately after the end of the SWT protocol. Before starting, a heart rate monitor (Polar H10 ± 1 beats per minute), as reliable as the electrocardiogram for HR (0.981-0.998 correlation), was placed in the participant, who was positioned facing the step. They were asked to go up and down the step, starting the movement with their dominant lower limb, and could alternate the member whenever they wanted to. The participant was asked to maintain a proper posture, with relaxed shoulders, forward-looking stance, and torso in an upright position. The participant was also asked to adequately ventilate to avoid apnea during exercise. It was set at what sound rate each participant reached the THR and level 10 or 11 of the Borg scale, and this rhythm was adapted throughout the exercise, ensuring a moderate intensity during the exercise.

2.7 | Statistic

Statistical Package for Social Sciences (SPSS) version 25 software (IBM, Chicago) was used for statistical analysis and interpretation of the data at a significance level of 0.05.

So as to assess the normality of the variables under study, the Shapiro-Wilk test was used. The homogeneity of the variances was also verified. Descriptive statistics were performed using measures of central tendency (mean and median) and dispersion (SD and interquartile deviation). To compare the results between groups, one-way ANOVA and Kruskal-Wallis tests were used. In order to analyze the results between moments, the t test for paired samples and Wilcoxon's were used.

3 | RESULTS

3.1 | Calculation of the number of participants required

The G-Power 3.0.10 (Universität Düsseldorf) Software was used to calculate the number of participants required in each group, for a power of 95% and $\alpha = 0.05$. This calculation was based on a similar article, in which the CSS scale value was evaluated.[6] An effect size of 1.43 was determined and a minimum of 14 participants in each group was necessary, based on the values of the referred study.[6]

3.2 | Sample characterization

When contacted, 45 participants agreed to participate in this study, however, one participant from each group gave up due to impossibility to continue the sessions. In this sense, 42 participants completed the study, performing the two assessment moments and 28 completed the six intervention sessions (Figure 1).

The cycle of interventions ran from July 1st to July 19th 2019. The initial evaluation was performed from June 25th to 27th, and the final evaluation from July 23rd to 26th (when the study was concluded). No adverse events were reported during this study.

In Table 3, it is possible to verify that the groups did not present significant differences among themselves. The sample had a median of eight points in the CSS which corresponds to a "moderate" grade in all groups. Each group contained three participants classified as "severe" severity of cellulite and the rest as "moderate".

Regarding the IPAQ, most subjects had a "moderate" level of physical activity practice (10 in CG; nine in EG1 and nine in EG2), six participants had "low" level (two participants in each group), and 11 "high" level (three in CG, four in EG1, and four in EG2). It is also important to mention that five participants had smoking habits (two in CG and three in EG2).

3.3 | Effects of the intervention

Table 4 shows the results of each group between moments and among groups. After three participants gave up, the groups remained without significant differences in the variables under study, for an n = 14 in M0. Thus, they could still be compared.

Between M0 and M1, the CSS score showed a significant reduction in EG2 ($P = 0.001$). Among groups, the difference in CSS score was significant in the difference variable, with a greater reduction in the degree of severity of cellulite in EG2 compared to CG and EG2 compared to EG1 (EG2 > CG $P < 0.001$; EG2 > EG1 $P = 0.032$), as it is possible to observe in Figure 2. In EG2, the two participants classified as "severe" changed to "moderate".

Body mass and fat percentage did not show significant differences between moments or among groups. Regarding the higher skin surface temperature, there were no significant differences.

Finally, in the thickness values of subcutaneous adipose tissue, there was no significant change between moments or among groups (Table 5).

4 | DISCUSSION

With the aim to analyze the effect of performing six SWT sessions in association with an AEP, on the degree of severity of cellulite in the

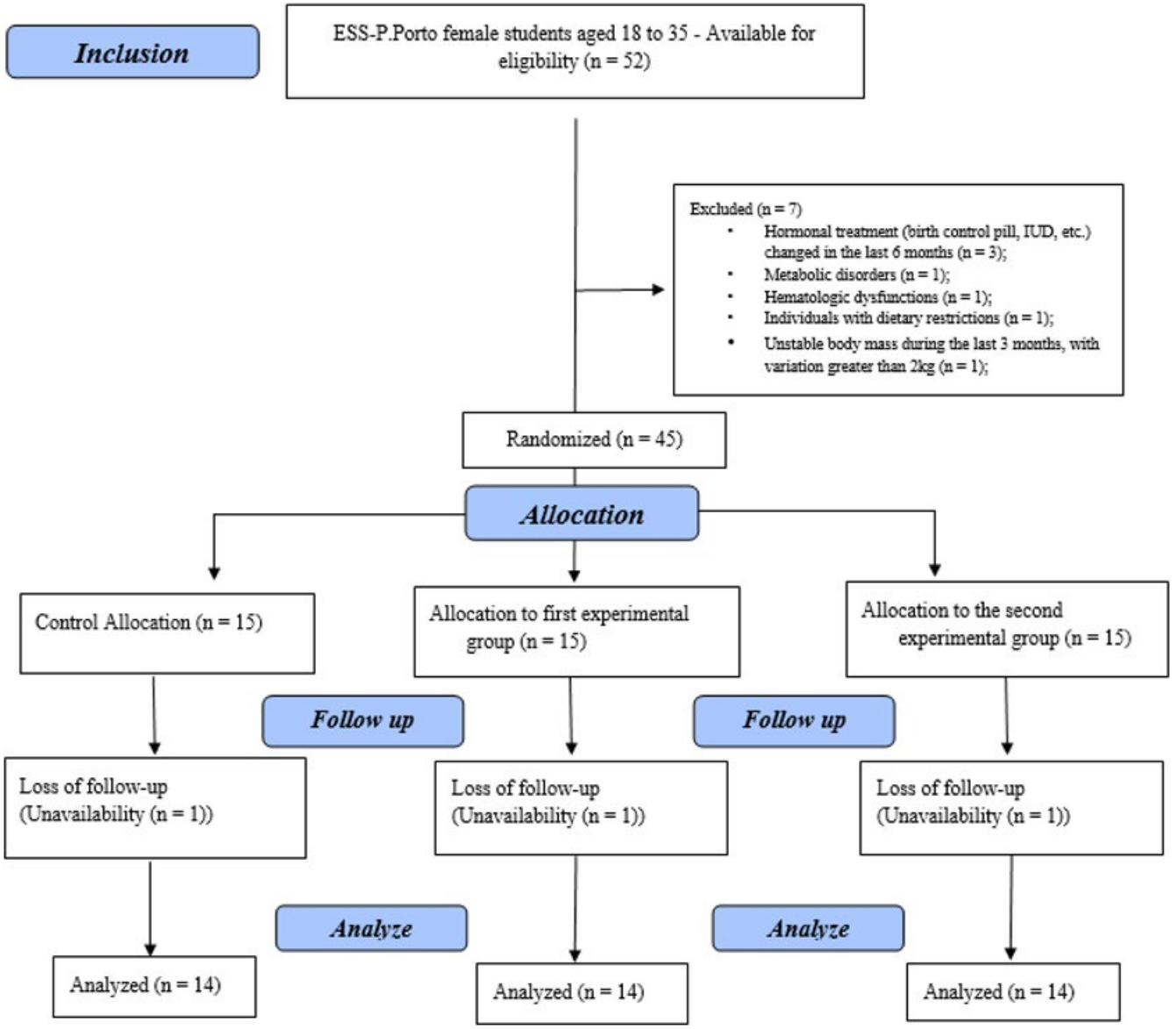

FIGURE 1 Sample constitution diagram

TABLE 3 Interobserver reliability values obtained in the pilot study

	Intraclass Correlation (ICC)
Subcutaneous adipose thickness without contraction (mm)	0.988
Subcutaneous adipose thickness with contraction (mm)	0.975

gluteal and posterior proximal thigh region, specific parameters of SWT and of the AEP were selected.

There are two types of SWT, which differ in magnitude and depth of penetration. The Focused SWT reaches deeper layers by higher pressure, whereas the Radial SWT does not reach a deep penetration. Although in the case of cellulite, the depth reached is sufficient and the divergence of the wave can cover a larger area. Moreover, it is more tolerable by patients. Thus, in the present study we used Radial SWT (also called Acoustic SWT).[21]

The parameters were based on those presented by Adatto et al,[2] Knobloch et al,[3] and Hexsel et al.[6] These authors performed an average of six treatment sessions, twice a week, with 2000-3000 impulses per session, at 2.6-4.6 bar of intensity, and frequency of 15 Hz. The results of these studies reflect that SWT could be used to reduce the severity of cellulite. Knobloch et al[6] further added that the outcome of SWT in combination with gluteus muscle strength training is superior to placebo treatment associated with an equal exercise program in "moderate" to "severe" cellulite degrees.

TABLE 4 Mean/median and SD/interquartis of the characterization variables of the general sample and between groups and *P* value intergroups

	Sample n = 45	GE1 n = 15	GE2 n = 15	GC n = 15	*P* value
Age (y)	21.00[1.00]	21.00[0.63]	21.50[0.63]	21.00[1.12]	0.383[a]
Height (m)	1.63 ± 0.05	1.62 ± 0.06	1.61 ± 0.04	1.65 ± 0.05	0.132
BMI (kg/m^2)	22.97[2.09]	23.01[1.47]	25.18[3.30]	22.13[1.64]	0.139[a]
Waist/hip ratio	0.77 ± 0.04	0.77 ± 0.36	0.77 ± 0.05	0.77 ± 0.44	0.931[b]
Calories (Kcal)	2288.58 ± 657.92	2197.61 ± 640.40	2349.69 ± 796.81	2318 ± 549.15	0.807[b]
Carbohydrates (g)	261.04 ± 75.93	258.83 ± 34.20	269.75 ± 88.09	254.55 ± 68.66	0.858[b]
Total Fat (g)	94.13 ± 32.49	88.65 ± 34.20	94.24 ± 34.56	88.65 ± 34.20	0.668[b]
Sugars (g)	116.72 ± 41.35	115.30 ± 47.42	122.71 ± 39.32	112.14 ± 39.00	0.780[b]

Note: Mean ± SD; Median [Interquartile Deviation]; *P* value: intergroup.

[a]Value obtained through the Kruskal-Wallis test.

[b]Value obtained through the one-way ANOVA.

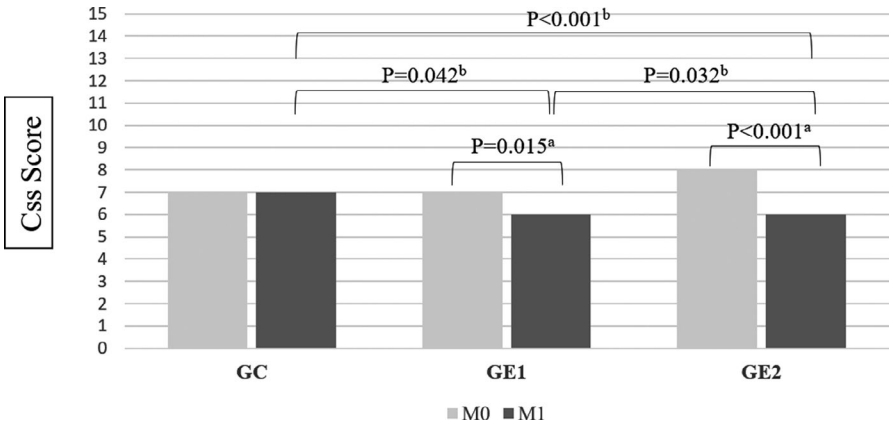

FIGURE 2 Graph representing the result obtained in the CSS score.

Therefore, after SWT, the combination of AEP may be advantageous since the increase in subcutaneous adipose tissue may be related to the increase in severity in cellulite. Accordingly, the interlobular septa of connective tissue of the dermis interconnect with the subcutaneous adipose lobes, and these thin septa with perpendicular projections favor the deposition of adipose tissue. Its expansion to the surface of the dermis leads to the appearance of bulges and depressions, so the more adipose tissue there is, the greater the appearance of cellulite. In addition, it is safer for the individual as it enhances the metabolism of fatty acids because during exercise, fatty acids are transported to skeletal muscle, and oxidized in the mitochondria, being an important mucular energy source.[15]

The exercise modality was selected to be more specific in the recruitment of gluteofemoral activity. It is further added that this region has a lower lipolytic activity than the abdominal.[25] The results of this study demonstrate that between M0 and M1, the CSS score decreased in the EG2. After the intervention, it was possible to verify that the EG2 presented a decrease in the severity of cellulite compared to EG1 and CG.

These results show that the combination of SWT and AEP is significantly effective in reducing the degree of severity of cellulite. This can be explained by the direct and indirect effects of SWT on tissues. The direct effect results of the energy transferred to the target tissues, while the indirect is the result of the creation of cavitation bubbles in these tissues. Both are hypothesized to produce a biological response in the adipocyte, promoting increased cell membrane permeability, cytoskeleton lesions, mitochondrial, endoplasmic reticulum, and nuclear membrane alterations, which may lead to lipolysis and/or apoptosis.[7,21] This phenomenon enhances the reduction of tension in the connection of interlobular connective tissue septa with subcutaneous adipose tissue lobes, causing less skin stretching.[2,8]

In the extracellular matrix of the skin, it induces the formation of neocolagen and neoelastine, increases blood circulation, temperature and local metabolism, inducing self-regeneration processes in the tissue. In addition, SWT stimulates lymphatic drainage.[4,11] In sum, all these processes can decrease the severity of cellulite.[3,7,10-13]

Hence, the results obtained are in agreement with the study by Adatto et al[2] in which they evaluated the skin roughness, the volume of depressions, the volume of elevations, and the elasticity of the skin. They found a significant decrease in the amount of roughness, depressions, elevations and elasticity of the skin.[2] Regarding

TABLE 5 Mean/median and SD/interquartile of the variables under study. Intragroup (between M0 and M1) and intergroup (in M0, M1 and in the difference variable) *P* values

		GE1		GE2		GC		*P* value intergrup		
		M0 n = 14	M1 n = 14	M0 n = 14	M1 n = 14	M0 n = 14	M1 n = 14	M0	M1	M1-M0
Score on Cellulite Severity Scale	*P* value[a]	7.0 [0.8] **0.015**	6.0 [1.0]	8.0 [1.1] **0.001**	6.0 [1.1]	7.0 [2.1] 0.584	7.0 [2.1]	0.530[b]	0.316[b]	**< 0.001**[b] GE2 > GC (< 0.001) GE2 > GE1 (0.032)
Body Mass (Kg)	*P* value[a]	60.30 [4.73] 0.278	60.40 [4.64]	65.60 [9.93] 0.068	65.55 [10.06]	62.45[3.88] 0.119	62.00 [3.69]	0.248[b]	0.363[b]	0.943[b]
Fat mass percentage (%)	*P* value[d]	28.11 ± 1.13 0.078	27.54 ± 1.10	29.21 ± 2.28 0.661	29.50 ± 2.24	28.44 ± 1.24 0.117	27.91 ± 1.29	0.892[c]	0.665[c]	0.324[c]
Highest temperature buttock level and ⅓ of the proximal posterior of the thigh (°C)	*P* value[d]	33.72 ± 0.29 0.345	34.14 ± 0.29	34.75 ± 0.42 0.387	34.38 ± 0.25	34.04 ± 0.94 0.405	34.34 ± 0.30	0.109[c]	0.817[c]	0.329[c]
Lower temperature buttock level and ⅓ of the proximal posterior of the thigh (°C)	*P* value[d]	27.97 ± 0.33 **0.024**	28.76 ± 0.25	28.26 ± 0.39 0.475	28.54 ± 0.27	27.73 ± 0.47 0.157	28.36 ± 0.30	0.657[c]	0.559[c]	0.598[c]
Adipose tissue thickness without contraction (mm)	*P* value[d]	35.28 ± 1.11 0.698	35.11 ± 0.88	34.16 ± 1.50 0.172	35.03 ± 1.57	33.24 ± 2.51 0.156	34.25 ± 12.88	0.727[c]	0.919[c]	0.294[c]
Adipose tissue thickness with contraction (mm)	*P* value[d]	42.12 ± 1.40 0.214	43.02 ± 1.31	41.79 ± 2.18 0.465	42.36 ± 1.92	39.22 ± 2.89 0.128	40.45 ± 2.88	0.609[c]	0.679[c]	0.820[c]

Note: Mean ± SD; Median [Interquartile Deviation]; M1-M0: difference variable; *P* value.

[a]Value obtained through the Wilcoxon test.

[b]Value obtained through the Kruskal-Wallis test.

[c]Value obtained through the one-way ANOVA.

[d]Value obtained through the T test for paired samples.

Knobloch et al[3] and Hexsel et al[6] significant improvements in the severity degree of cellulite assessed by CSS were found.

With regard to the lower temperature, only the EG1 showed a significant increase, which can be justified by the fact that exercise promotes the increase of the local microcirculation.[2,8] The fact that in EG2 this change has not been verified may be associated with the effect of SWT on the extracellular matrix, which induces the formation of neocolagen and neoelastine, leading to an increase in dermis thickness. This phenomenon may justify that even with increased local microcirculation, the temperature may not be as perceptible to the skin surface.[4,11] These results are in agreement with the study by Schlaudraff et al,[21] where participants were treated unilaterally with SWT with similar parameters, not showing a significant reduction in the surface temperature of the skin assessed by contact thermography.

There were no significant differences in the thickness of subcutaneous adipose tissue between moments or among groups, which is not in accordance with what Hexsel et al[3] observed. They seem to find a significant decrease of this parameter, however, in this study Focused SWT was used. Thus, it may be pertinent to verify in a future study the effects of Focused SWT, since these reach greater penetration associated with a phenomenon of convergence of the mechanical wave, which can lead to a change in the thickness of the adipose tissue, associated with an AEP.

Relating to limitations of the present study, we can identify the fact that the CSS scale is a subjective scale, however, it was used by a group of highly experienced experts in the area. Furthermore, the evaluations were performed at different times of the day, influenced by the availability of each participant. In addition, there was no control of the menstrual cycle phase at the time of assessment, as hormonal changes may influence some of the parameters evaluated. It was also not possible to control the eating, smoking, drinking and physical activity habits during the study. It is further noted that there was no blindness of the participant as the SWT device does not withstand a minimal intensity without effects. In future studies, we recommend that there should be control in relation to the factors mentioned above.

Finally, regarding the methods, it would be pertinent to verify the long-term effect of the intervention performed as the results were reached immediately after the intervention. It would be relevant to see how long the results effectively last.

5 | CONCLUSION

It was concluded that six SWT sessions in association with the performance of an AEP had an effect in the reduction in the degree of severity of cellulite in the gluteus and in the ⅓ of the proximal posterior of the thigh. Although the isolated AEP did not show such a significant effectiveness as the one above, they were also meaningful.

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CONFLICT OF INTEREST

The authors report no conflicts of interest.

AUTHOR CONTRIBUTION

All the authors have contributed substantially to the manuscript and approved the final submission.

DATA AVAILABILITY STATEMENT

Data available on request from the authors. This study was registered at ClinicalTrials.gov (NCT03986983).

ORCID

Andreia Noites https://orcid.org/0000-0002-2590-962X

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