

TITLE Participant Reported Improvement in Cellulite by Vari-pad
Apparel and Objective Measurements – a “First Use”
Pilot Study.

Authors: Melissa J Kiely BSc (Hons) (ORCID: 0000-0002-8663-6127)
Ashleigh Poulsen
Simon D Muschamp (ORCID: 0000-0002-5077-6312)
Chloe Sallis (ORCID:0000-0002-9600-1408)
Mark S Whiteley MS FRCS(Gen) (ORCID: 0000-0001-6727-6245)

Institution: The Whiteley Clinic, Stirling House, Stirling Road, Guildford,
Surrey, GU2 7RF

Correspondence: Prof M S Whiteley MS FRCS(Gen), The Whitely Clinic, 1
Stirling House, Stirling Road, Guildford, Surrey, GU2 7RF
Email: mark@thewhiteleyclinic.co.uk
Tel: +44 (0) 330 0581850
Fax: +44 (0) 1483 477194

Article type: Original Article

Short title: Participant Reported Improvement in Cellulite by Vari-pad
Apparel

Word Count: 2046

NCT number: NCT05748678

ABSTRACT

Background:

Cellulite affects 80-90% of post-pubertal females and, although cosmetic, has proven adverse psychological effects. A new compression garment with patented “vari-pad” technology has been developed, aiming to stimulate lymphatic return from the buttocks and thighs. The primary aim of this small pilot study was to assess participant satisfaction after using this garment in the short term and secondarily, to look for any objective improvements.

Methods:

18 female participants (mean 47.5y, range 26-60) completed the study. There were 2 weeks of “stabilisation”, 4 weeks of wearing the garment, and 2 weeks of further assessment. With the initial assessment, there were 9 visits for each participant. At each visit, weight, participant satisfaction (0-10), 3D images (Canfield, USA) and transcutaneous water content (LymphScanner, Delfin Technologies, Finland) were recorded.

Results:

There was no significant weight change in any of the participants during the trial period. After 4 weeks of wearing the garment there was a significant improvement in participant satisfaction of their cellulite ($n=15$, $p=0.0036$) with a mean improvement of 18.5%. 3D image analysis of dimple volume showed no significant change in buttock cellulite, a significant decrease in left thigh cellulite ($n=17$, $p=0.0123$), but not on the right ($p=14$, $p=0.6890$). There was a significant decrease of localised water ($n=36$, $p=0.0041$)

Conclusion:

The vari-padded compression garment produced a significant improvement in participant satisfaction after just 4 weeks of treatment. Objective measurements failed to show a significant

difference in cellulite on the buttocks but showed a significant improvement in the thighs by analysis of both dimple volumes and reduced transcutaneous water measurements. Further study is suggested to demonstrate if longer timeframes for use of the apparel will lead to further significant improvement in the appearance of cellulite.

INTRODUCTION

Cellulite is a multifactorial condition, which has been described as “aesthetically disturbing”,¹ and “one of the most intolerable aesthetic imperfections” due to the skin phenotype closely resembling an orange peel with dimpling and denting of the skin.^{2,3} Although present in 80-90% of post pubertal women, predominantly the subcutaneous tissue around the thighs, buttocks, and hips, a previous study has showed that up to 98% of females are concerned about cellulite, and that it decreases their self-esteem.^{4,5}

Whilst the pathophysiology of cellulite remains unknown due to its complex nature, it is thought the dermis and subcutaneous tissue are implicated.² However, it has not yet been determined if the effects of these are independent or mutually exclusive. It is thought to be due to an amalgamation of genetics, hormones, diet, and lifestyle, with numerous other factors that trigger or intensify the appearance of cellulite. It has also been identified that cellulite formation accelerates during adolescence, pregnancy and in women around the menopausal age.¹

There have been many interventions proposed to treat cellulite such as the topical agents methylxanthines and retinoids, lasers, radiofrequency heating, acoustic waves, subcision of the dimpled areas, collagenase clostridium histolyticum injection, dermal fillers, cryolipolysis, shockwave therapy and high-intensity focused ultrasound.^{3,4}

A study by Augusto *et. al* used a garment made with synthetic fibres embedded with ceramic nanoparticles and identified a reduction in body measurements with this protocol.⁶ They suggested that this product produced a progressive drainage effect, and therefore may suggest compression therapy could reduce the appearance of cellulite due to it's a stimulating of effective lymph drainage.

The vari-pad apparel has been designed to reduce the appearance of cellulite and has two main components. The first and simpler of the two, is a compression garment worn as a pair of shorts over the buttocks and upper thighs. The second component, which is unique, is the incorporation of

patented variable height ink-polymer pads on the inner surface of the garment. It is suggested that these cause local areas of variable increased pressure when the garment is worn, with the aim to stimulate lymphatic and tissue fluid movement locally as the patient moves. These pads are of varying sizes and have been arranged so as to stimulate the movement of lymph and tissue fluid towards the major lymph nodes in the groin.

In view of the very high levels of concern that women have with regards cellulite, this study was performed to assess participant satisfaction and experience in a small group of women with cellulite wearing novel, padded apparel. In addition, we sought to assess any objective improvements that might be found in the short term.

PARTICIPANTS & METHODS

Participants were recruited onto the study via social media. A total of 23 female participants were selected, based on the inclusion criteria, and written informed consent was obtained from each participant. As per the HRA decision tool (<https://www.hra-decisiontools.org.uk/ethics/>), ethical consideration was not required. However, this trial was registered as a clinical study (<https://clinicaltrials.gov/>) - NCT05748678.

One participant was excluded from the study due to pregnancy, with 4 others lost to follow up. Eighteen females completed the study, mean age 47.5 years (range 26-60 years).

Participants were graded on their cellulite from week 1 on the study according to Table 1. Using this scale there were 3 participants with grade 1 cellulite, 7 with grade 2, and 8 with grade 3.

Participants visited weekly over a period of 9 weeks:

- Weeks 1 and 2 – Stabilisation period. Participant wore their regular undergarments.
- Weeks 3 to 7 - Participants wearing the padded compression underwear.
- Weeks 8 and 9 - participants resumed wearing their regular undergarments.

At the initial assessment, participants were weighed, their height measured, BMI calculated, and they were asked to complete a visual analogue score from 0-10, signifying how they regarded their cellulite from 0-10 each week (0 being no cellulite at all and 10 being the worst that they could imagine).

Patients were also asked to keep their exercise regimes constant throughout the study.

Each participant then had 3-dimensional photographs taken using the Vectra H2 imaging system (Canfield, New Jersey, USA) of 4 specific areas: left and right buttocks and left and right thighs. These photos were then independently analysed at weeks 1, 3, 5, 7 and 9 to calculate the total volume of dimpling in each location.

Each week, a weight measurement was repeated alongside a localised transcutaneous water content measurement using LymphScanner (Delfin Technologies, Finland) in each of the 4 areas.

Due to position changes in images or incomplete data, some participants' data had to be excluded for a specific location, and therefore "n" will be stated for each due to its variation.

Statistical analysis of data produced was performed using GraphPad Prism 9.4.1 for Windows (San Diego, California, USA). A Repeated Measures One-way ANOVA followed by post-hoc Tukey's multiple comparisons test was used, with statistical significance being recognised with a p value below 0.05.

RESULTS

Participant Satisfaction:

Three patients failed to mark their VAS score clearly, making the analysis of these 3 records impossible and these were excluded. Of the remaining participants, there was a significant improvement in participant satisfaction as to their own assessment of their cellulite after 4 weeks of wearing the trial garment (n=15, p=0.0036) – see Figure 1. This was maintained at the second post-compression visit. The mean improvement in satisfaction rate using the visual analogue scale was 18.5%.

Furthermore, when the individual scores are mapped (Figure 2) it can be observed that almost all participants saw an improvement in the week following removal of the garment.

Weight

To ensure that any improvement was not due to weight loss, the participant's weight was measured at each appointment. One patient did not wish to be weighed each time and her data was excluded from this analysis. There was no significant weight change in the participants throughout the study period (n=17, p=0.3154) – see Figure 3.

Volume of dimpling on skin's surface by 3D imaging

All images were transmitted to Canfield (USA) for independent analysis of volume. Unfortunately, many of the images were unsuitable for analysis, most commonly because the participants had indentations on the skin from underwear or clothing. In both the left and right buttock, participants showed no statistical change in volume (left: n=12, p=0.6162, right: n=11, p=0.6644) over the 9 weeks. When the data from both was combined, there was also no significance (n=23, p=0.9323).

In the left thigh, there was a significant decrease in the volume of dimpling observed over time ($n=17$, $p=0.0123$) – see Figure 4, with Tukey's multiple comparison showing a significant decrease between weeks 1 and 7 ($p=0.0023$), the last week of wearing the garment. It is interesting however, that the right thigh showed no similar significant change in dimple volume throughout the study ($n=14$, $p=0.6890$) - see Figure 5.

When the data for both thighs are combined, they also show no significance with Tukey's multiple comparison, although it is very close to significance ($n=31$, $p=0.0514$) – see Figure 6. However, there was a significant difference between the first week where the participant was wearing their own underwear, and the final week of wearing the compression apparel (week 7, $n=31$, $p=0.0214$) see Figure 6.

Percentage of water content

In the left and right buttock, there was no significant change in the percentage of water content over the 9 weeks (Left: $n=18$, $p=0.3725$; Right: $n=18$, $p=0.7411$). Combining the data for both buttocks also showed no significant change ($n=36$, $p=0.1903$) – see Figure 7.

The left thigh showed a tendency to reduced water content, but failed to reach significance ($n=18$, $p=0.3452$), but the right thigh showed a significant decrease in the percentage of localised water content between weeks 1 and 6, and weeks 1 and 7 ($n=18$, $p=0.0070$), the final two weeks of wearing the apparel. Combining the data from both thighs, there was a significant decrease of localised water throughout the study ($n=36$, $p=0.0041$) – see Figure 8.

DISCUSSION

Although cellulite is an aesthetic condition with no known adverse impact on health, it does have a profound psychological impact on those women suffering from it, many of whom go to extraordinary lengths to try to improve it.⁷ As the majority of post-pubertal females have cellulite to a greater or lesser extent, it would seem sensible to prioritise the subjective feelings of the participants undergoing the treatment rather than rely on whether any objective test is capable of noting an improvement.

Hence in this study, we concentrated on the patient satisfaction as the primary outcome, with objective assessments as secondary outcome.

It should be noted that many of the participants had indentations from both the treatment garments as well as other underwear or tight clothes when they came in for reviews. Although they were asked to remove the treatment garments 2 hours before the appointment, this was not always done. Even when it was, tight underwear or clothes could still cause indentations on the skin. As such, although the most obvious cases were discarded before analysis with 3D photography, such indentations might explain why there was no significant improvement in participant satisfaction at the assessment for each of the 4 weeks of wearing the garment. However, we found a significant improvement in participant satisfaction at the assessment one week after completion of wearing the apparel, that was maintained until the second post-treatment week assessment in most subjects.

Patient comments were not collected as part of the process and so have not been recorded in this report. However, most of the comments were centred around the comfort of wearing the garment and the smoothness of the skin by the end of the 4 weeks of wearing it.

Objectively, the 3D camera system was able to identify a reduction in the volume of the dimples in the cellulite on the thighs, although no change could be noted on the buttocks. Simplistically this might suggest that the garment does not improve cellulite on the buttocks. However, the garment

was only worn for 4 weeks in this short study, and, generally, the subcutaneous fat is a thinner layer on the thigh than the buttocks. In addition, the quadriceps muscles in the thigh have a more rigid tone throughout the day than the gluteus muscles of the buttock, giving a better “base” for the compression garment to compress the sub-cutaneous tissue against, especially during movement.

The difference of objective results by 3D imaging was also mirrored by the difference found in water content of the tissues as measured using a transcutaneous method by the Lymphscanner.

Although participant satisfaction is subjective and hence could be a possible “placebo effect”, the “spaghetti plot” of individual responses shows that 11 out of the 15 (73%) reported an improvement one week after wearing the garment with 3 reporting a minor decrease and one no difference.

The main limitations of this study are the relatively small number of participants, and the very short time of wearing the trial garment. As this was a “first use” pilot study for this new garment, the numbers of participants were kept low as if there was no advantage found in this small number, then further study or development would need to be questioned. Furthermore, the short time of treatment was chosen as although we would expect a more significant improvement with longer treatment, an early improvement would help those using the product see an advantage within a reasonable time of starting to use it.

However, the small number of participants did prevent sub-group analysis, such as the response of treatment to patients with different grades of cellulite, and the effect of HRT or other medications on the outcome.

Having found these positive findings in a small group of participants in the short term, we aim to perform larger studies, involving more participants and using the garment for longer, to assess the maximum benefit that can be obtained, and which sort of participants would see the best improvements.

In conclusion, in a “first use” pilot study of the vari-padded compression garment in a small number of patients, we found a significant improvement in participant satisfaction after 4 weeks of using the garment for 8 hours in every 24. Objective measurements showed a significant difference in cellulite on the thighs by 3D photographic image analysis of dimple volumes and reduced transcutaneous water measurements in both. Larger studies with more participants and usage of the apparel are warranted.

References

1. Zerini I, Sisti A, Cuomo R, Ciappi S, Russo F, Brandi C, et al. Cellulite treatment: a comprehensive literature review. *J Cosmet Dermatol*. 2015 Sep;14(3):224–40.
2. Arora G, Patil A, Hooshanginezhad Z, Fritz K, Salavastru C, Kassir M, et al. Cellulite: Presentation and management. *J Cosmet Dermatol*. 2022 Apr 14;21(4):1393–401.
3. Sadick N. Treatment for cellulite. *Int J Womens Dermatol*. 2019 Feb;5(1):68–72.
4. Alizadeh Z, Halabchi F, Mazaheri R, Abolhasani M, Tabesh M. Review of the Mechanisms and Effects of Noninvasive Body Contouring Devices on Cellulite and Subcutaneous Fat. *Int J Endocrinol Metab*. 2016 Jul 3;14(4).
5. Tokarska K, Tokarski S, Woźniacka A, Sysa-Jędrzejowska A, Bogaczewicz J. Cellulite: a cosmetic or systemic issue? Contemporary views on the etiopathogenesis of cellulite. *Advances in Dermatology and Allergology*. 2018;35(5):442–6.
6. Conrado LAL, Munin E. Reduction in body measurements after use of a garment made with synthetic fibers embedded with ceramic nanoparticles. *J Cosmet Dermatol*. 2011 Mar;10(1):30–5.
7. Bass LS, Hibler BP, Khalifian S, Shridharani SM, Klivanov OM, Moradi A. Cellulite Pathophysiology and Psychosocial Implications. *Dermatol Surg*. 2023 Apr 1;49(4S):S2–S7.

LEGENDS

- Table 1: Clinical grading scale for cellulite.
- Figure 1: Participant satisfaction with their assessment of their own cellulite.
- Figure 2: “Spaghetti plot” showing how each participant’s satisfaction with their assessment of their own cellulite varied between visits (assessments at end of treatment weeks = weeks 3-7).
- Figure 3: Mean weight showing no change in weight of the participants over the time of the study.
- Figure 4: Graph showing the change in volume of dimples of the left thigh as measured by 3D photographic assessment (* and ** = significant difference at $P < 0.05$).
- Figure 5: Graph showing the change in volume of dimples of the right thigh as measured by 3D photographic assessment.
- Figure 6: Graph showing the change in volume of dimples of the both thighs as measured by 3D photographic assessment (* = significant difference at $P < 0.05$).
- Figure 7: Assessment of transcutaneous water content of both buttocks over the course of the study.
- Figure 8: Assessment of transcutaneous water content of both thighs over the course of the study (* and ** = significant difference at $P < 0.05$).

Table 1:

| Grading Scale | Description |
|---------------|--|
| 0 | No alteration to the skin surface |
| 1 | Skin is smooth whilst subject is standing/lying, but alterations can be seen by pinching the skin or by muscle contraction |
| 2 | 'Orange-peel' or mattress appearance is evident upon standing without the use of any manipulation (pinching or muscle contraction) |
| 3 | Alterations seen in grade two presented together with raised areas and nodules |

Figure 1:

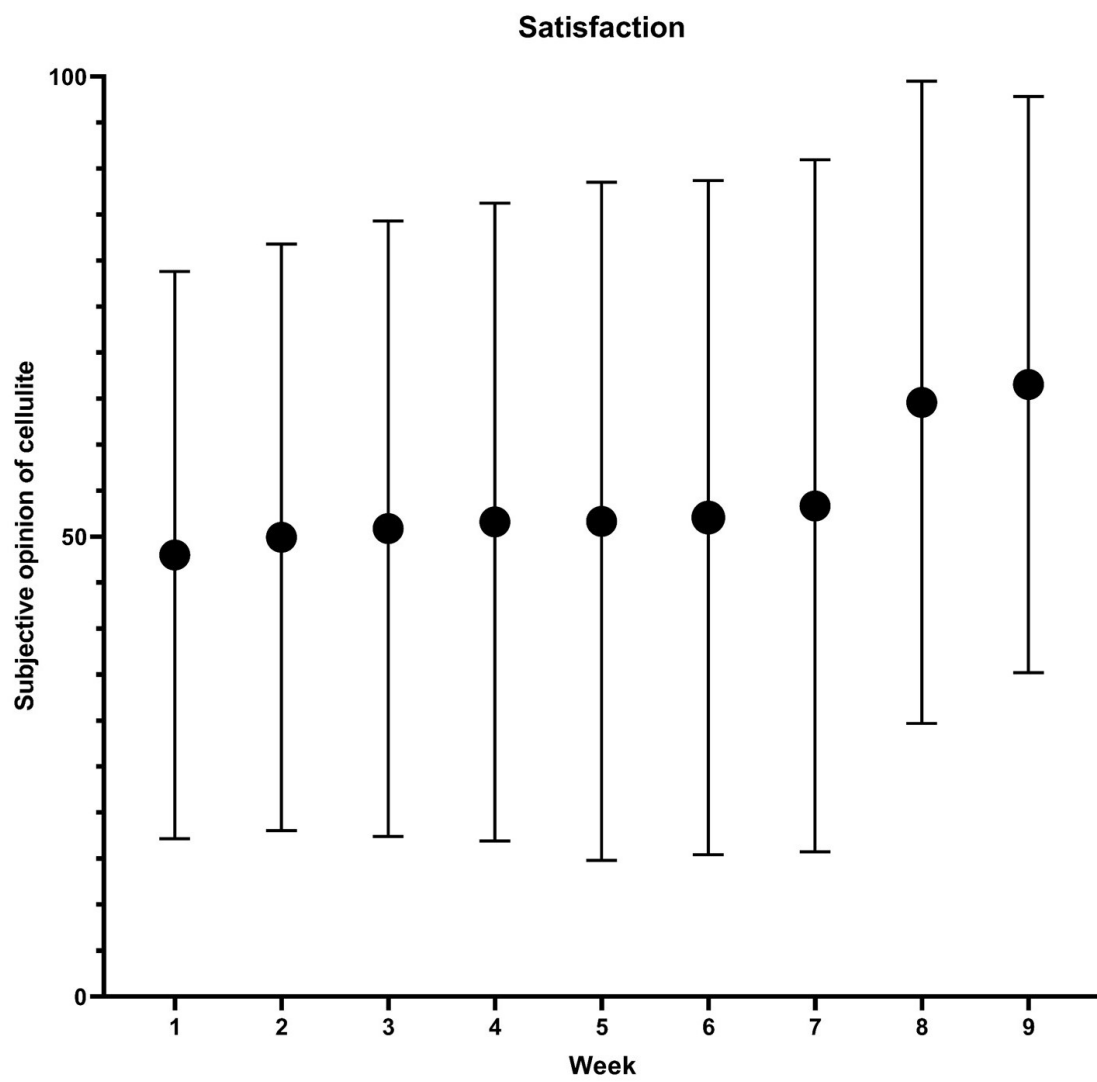


Figure 2:

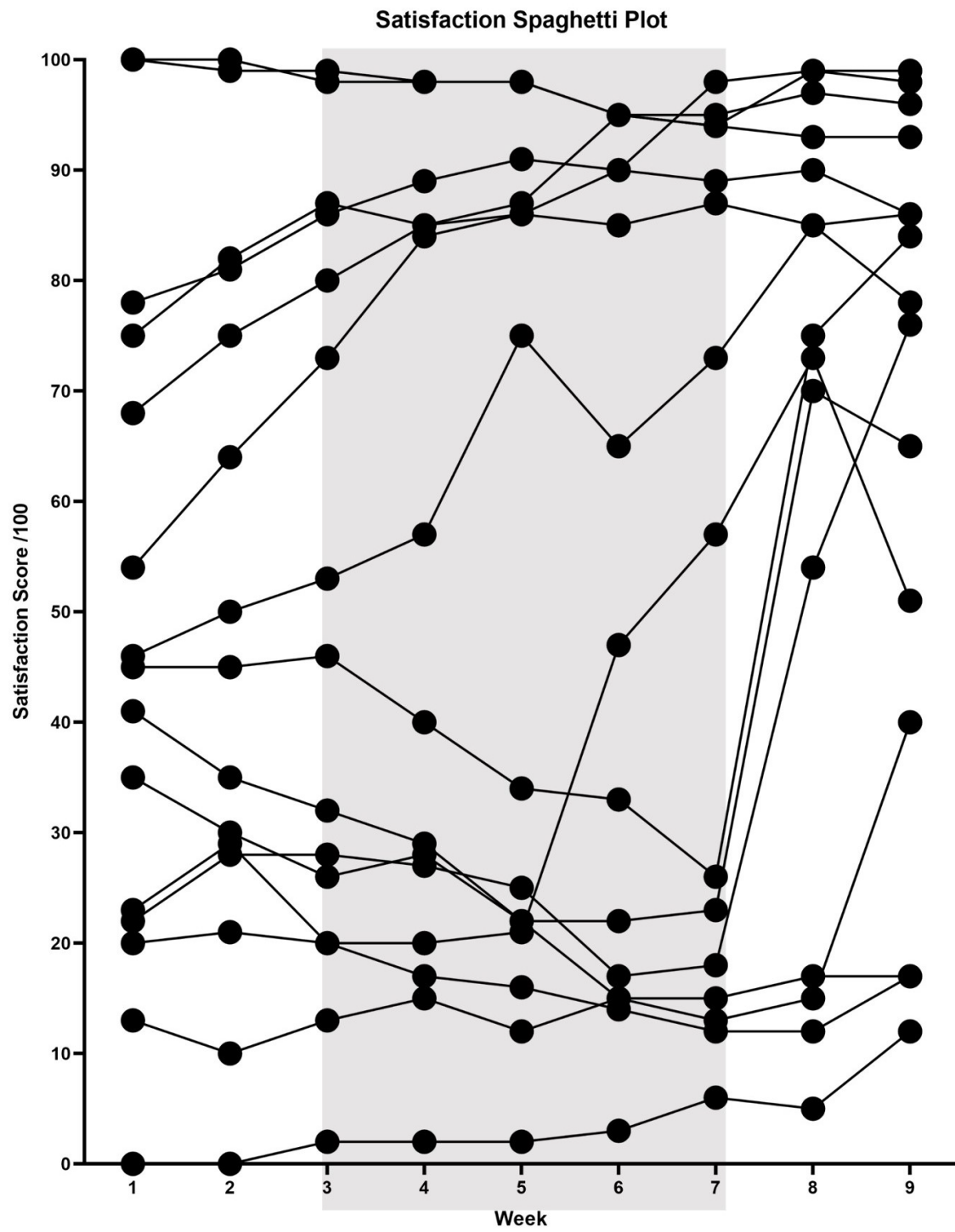


Figure 3:

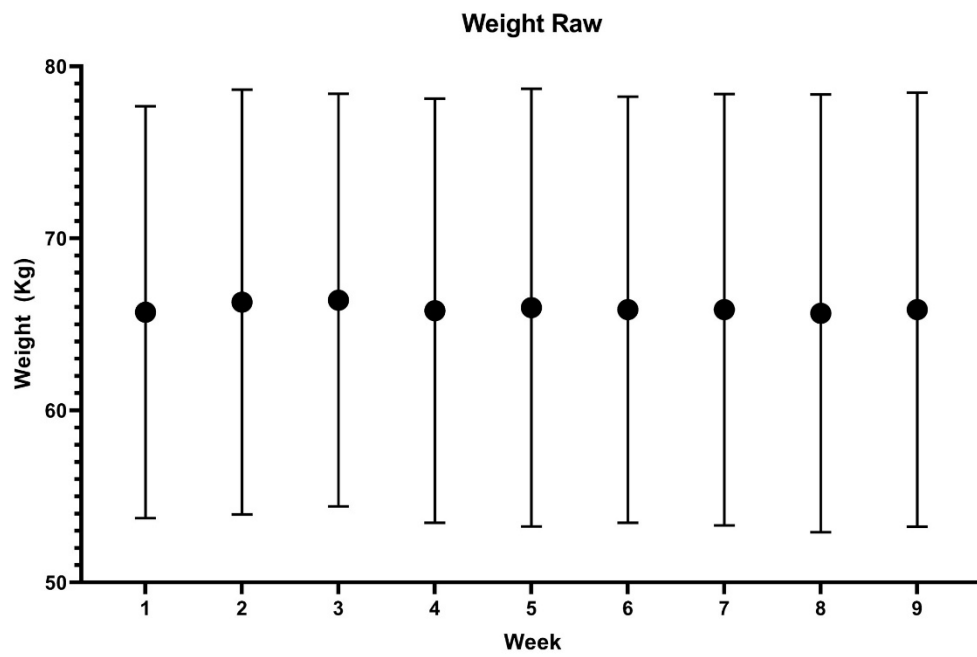


Figure 4:

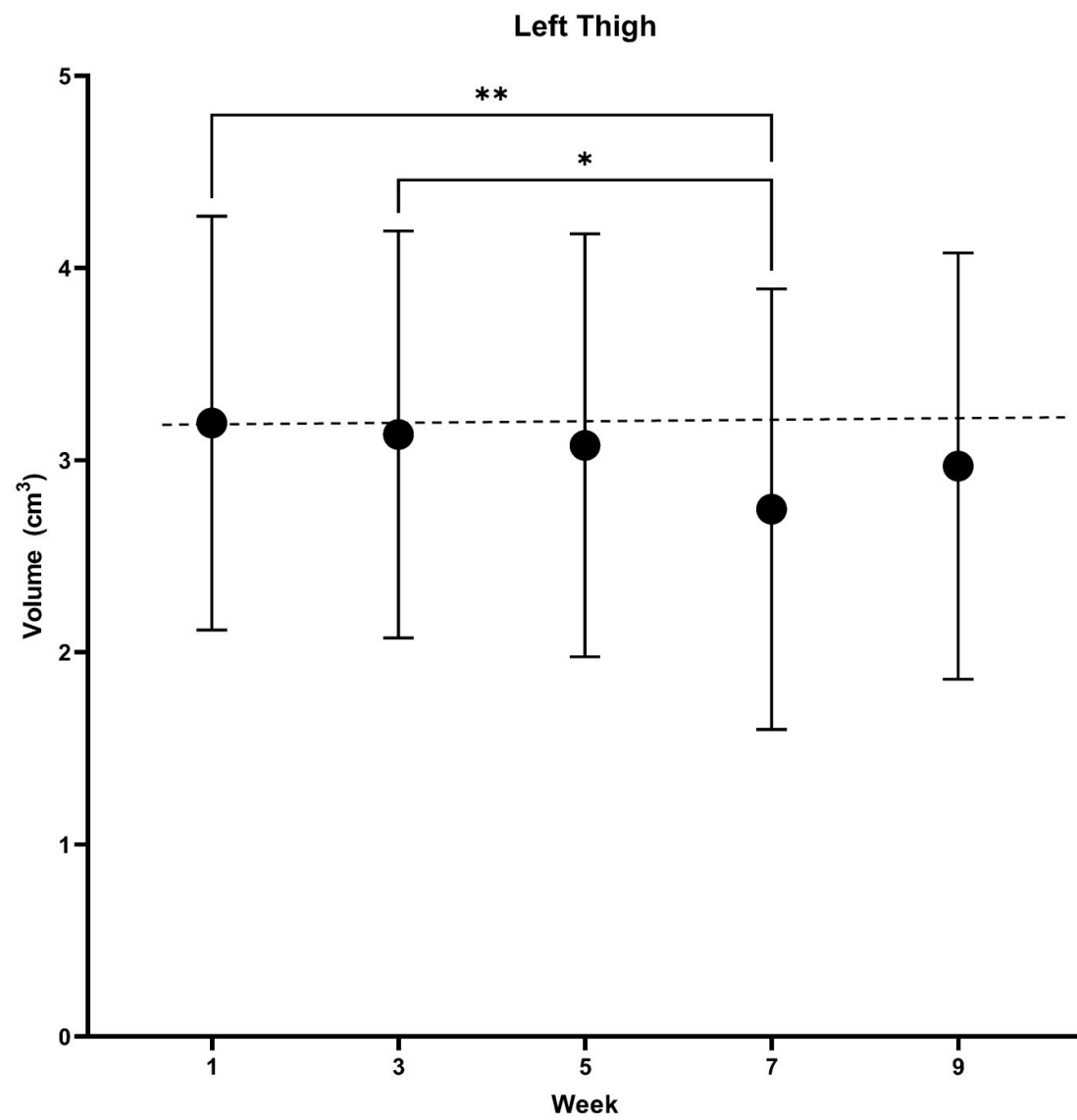


Figure 5:

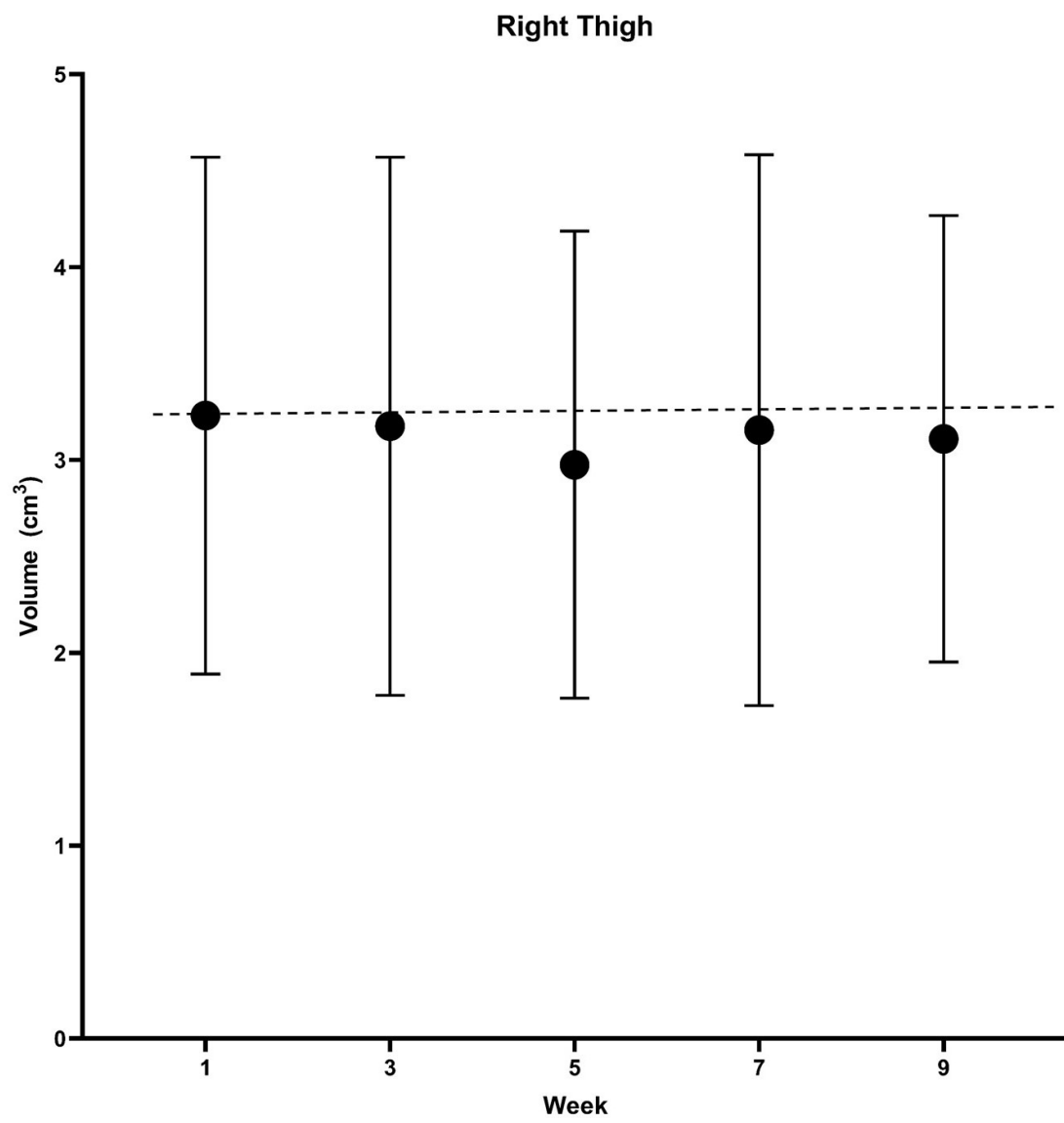


Figure 6:

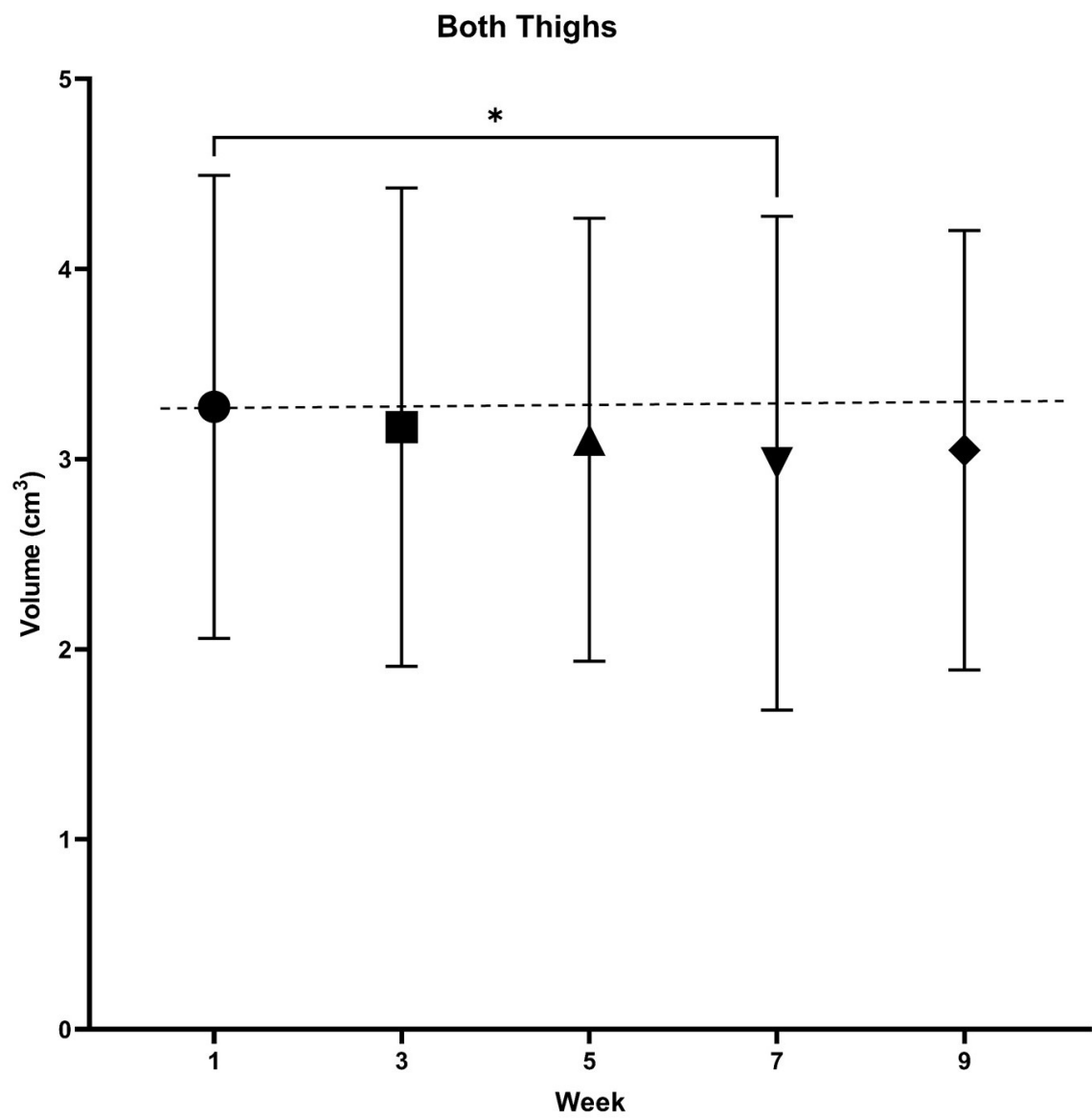


Figure 7:

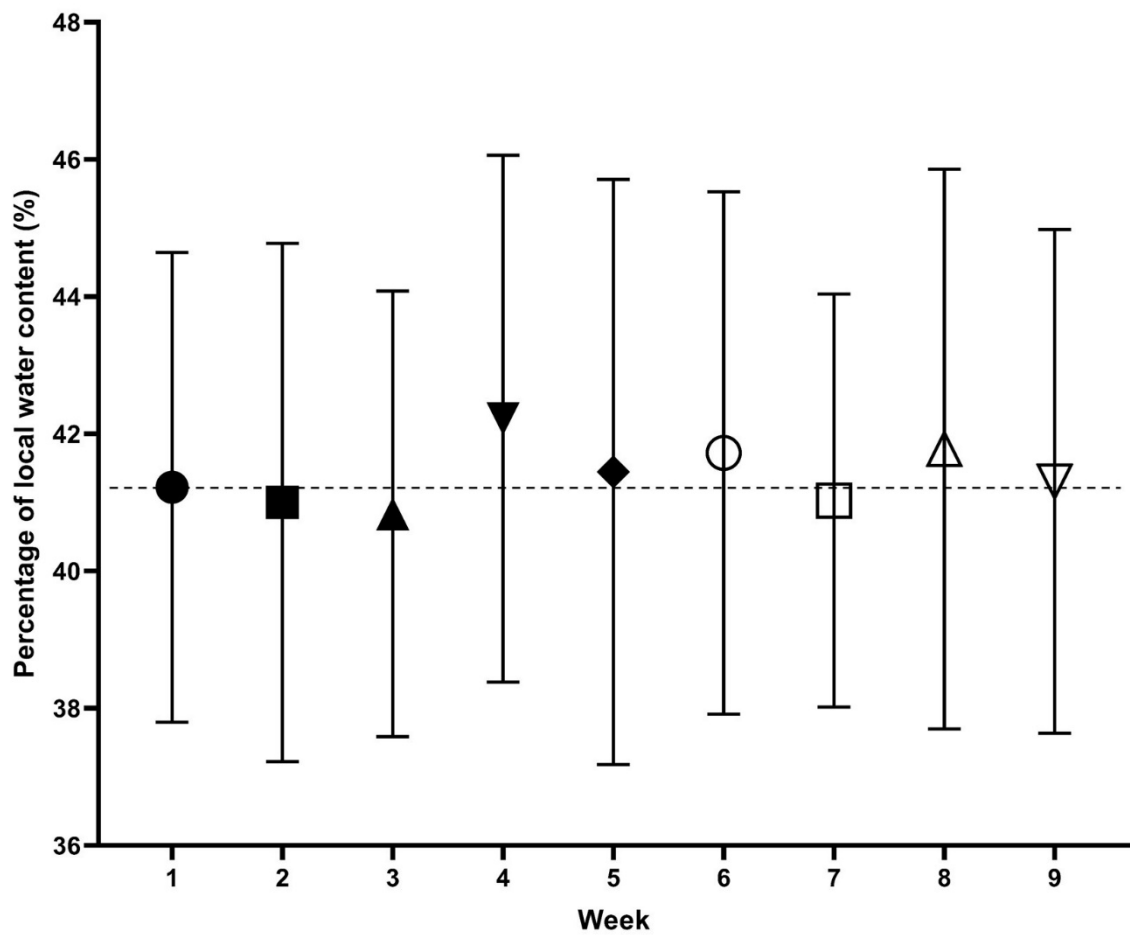


Figure 8:

