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Myofascial points treatment with focused extracorporeal shock waves (f-ESW) for plantar fasciitis: an open label randomized clinical trial.

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Abstract:

Background: Plantar fasciitis (PF) is a common cause of heel pain. Among the several conservative treatment options, Extracorporeal Shock Wave Therapy (ESWT) is considered the standard treatment. However, recent studies suggest that PF may be sustained by a myofascial impairment proximal to the pain area with a biomechanical disequilibrium of the entire limb and pelvis**. Aim of the study:** By combining the concepts of Fascial Manipulation and ESWT, the purpose of this study was to evaluate the effectiveness of the ESWT on myofascial points in a sample of subjects with PF. **Study design**: open label randomized controlled clinical trial. **Setting:** outpatient clinic. **Methods and population:** Patients with PF were randomly assigned to an Experimental treatment Group (EG), treated with focused ESWT on myofascial points, and a Control Group (CG), treated with the focused ESWT traditional approach on the medial calcaneal tubercle. Every patient underwent a 3-session program and follow-up after 1 and 4 months. Outcome measures included the Foot and Ankle Outcome Score (FAOS) and the Italian Foot Functional Index (17-iFFI). **Results:** Thirty patients were enrolled in the study. Four patients of the CG dropped out the study, therefore twenty-six patients were included in the final analysis. Improvement in 17-iFFI and FAOS scores was observed in both groups starting from the third treatment and confirmed at the 1-month and 4-month follow-ups, with earlier improvement in the score values observed in the EG.

Conclusions: ESWT on myofascial points could provide an interesting alternative with better outcomes in terms of time needed for recovery compared to traditional ESWT for the conservative management of PF.

Keywords: Plantar fasciitis, fascia, ESWT, rehabilitation, myofascial trigger points, fascial manipulation

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1. Introduction

Plantar fasciitis (PF) is a chronic, musculoskeletal condition, and it represents the most common cause of knife-like pain, typically at the enthesis of the fascia, at the medial plantar area of the heel (medial calcaneal tuberculum region) [1,2]. PF is often related to specific athletic and work activities, although it can also occur in sedentary subjects, especially if overweight. Major prevalence occurs among people between 40 and 70 years old; however, this condition can affect adults of all ages[3].

Although it is known as an inflammatory condition, recent studies have demonstrated a prevalence of degenerative changes in plantar aponeurosis. The damage of collagen fibres seems to be due to repetitive microtears at the calcaneal enthesis by biomechanical overuse, often because of prolonged standing or running. This hypothesis is confirmed by histological studies that show fibre degeneration and disorientation, angiofibroblastic hyperplasia and calcifications with minimal or no evidence of inflammation[4]. Therefore, even though the term “fasciitis” is universally used, this condition has an origin that is mechanically degenerative rather than inflammatory, since continuing biomechanical stress overloads the plantar fascia with microfailures and abnormal repair processes.

The plantar fascia, also called the plantar aponeurosis, is a strong connective structure composed of three bundles (medial, central and lateral) arising from the medial calcaneal tubercle. It helps to maintain the longitudinal arch of the foot and acts as a “shock absorber”. It is continuous with the Achilles tendon [5–7], thus contributing to better distribute the tendon’s tension, allowing the transmission of forces from the hind to the forefoot and vice versa[8]. Previous studies have demonstrated the existence of an anatomical connection between plantar fascia and the paratenon of the Achilles tendon: it is a fascial sheet that slides over the calcaneal bone[9]. Aging produces a continued reduction in fibres connecting the Achilles tendon to the plantar fascia: if an infant has a strong, thick portion of tissue connecting the two structures, in the elderly, a partial loss of this connective tissue has been observed.

Although clinical examination is usually sufficient to make a diagnosis, imaging can be extremely helpful in achieving an precise diagnosis, excluding other causes of heel pain and assessing response to treatment.

The symptoms usually start as intermittent medial plantar heel pain after a long period of rest (typically with the first steps in the morning) or after a long walk. The pain often decreases after further walking but can return with continued weight bearing. The classical signs of PF include sharp, stabbing pain upon palpation of the plantar fascia insertion at the medial calcaneal tuberosity and along the plantar fascia [1]; pain at the Windlass test; pes planus or cavus deformity; a limitation in active ankle dorsiflexion < 10° from the neutral position (retraction or tension in the Achilles tendon). A thorough gait analysis often reveals an antalgic claudication with an increase of contralateral stance time and an asymmetry in step length due to the pain at the heel of the affected foot. However, it is important to exclude other causes of heel pain: calcaneal stress fractures, bone edema, plantar fascia rupture, among others.

Plain radiography provides a widespread instrumental exam to evaluate subjects complaining of heel pain. Although it often represents the first-choice imaging modality, it does not provide direct information about plantar aponeurosis. However, radiographs can show abnormalities related to PF such as cortical irregularities and/or sclerosis of the calcaneal bone, calcifications into the PF and calcaneal spurs.

Ultrasonographic evaluation of the plantar fascia represents a non-invasive, cost-effective, rapid, easily accessible, real-time exam. Moreover, it is a useful tool for guiding injection procedures. Typical sonographic findings are detectable in subjects with clinical signs of plantar fasciitis and include loss of fibrillar pattern and decrease in echogenicity, increase in thickness of the PF at the calcaneal insertion over 4 mm, calcifications within the fascia and/or in perifascial tissues, PF or perifascial hyperemia upon Doppler examination [10].

Magnetic Resonance Imaging (MRI) provides a second level instrumental exam, showing plantar fascial thickening, usually fusiform and localised at the medial calcaneal insertion of the fascia[11]; intrafascial areas of intermediate signal on T1-wighted images; intrafascial (at the proximal aspect of the fascia) and perifascial edema in T2-weighted images [12].

Conservative treatment options for PF include rest, weight loss, non-steroidal anti-inflammatory drugs, physical therapies (ultrasound therapy, low-energy and high-energy laser therapy), plantar fascia and calf muscle stretching exercises [2,13,14]. If symptoms persist, second-option treatment is usually local corticosteroid injections. However, despite providing a good effect in terms of pain reduction, corticosteroids have proven to damage the fascial tissue, thus increasing the risk of further degeneration and eventual rupture [15,16]. To avoid this complication, different regenerative injection therapies (prolotherapy, Platelet Rich Plasma – PRP) have been proposed [17–20].

Extracorporeal Shock Wave Therapy (ESWT) is a treatment recommendation for patients with chronic PF recalcitrant to other conservative treatments. Previous studies have reported variable success rates in terms of pain reduction, from 55% to 88%, compared to placebo, in short or medium periods and [21–24] recurrence rates up to 20% [25]. Several studies have reported best results with the application of focused ESWT for regenerative effects mediated by neo-vascularisation, growth factor release and collagen remodelling [26–28]. Over the last years, myofascial tissue, especially myofascial trigger points, have come increasingly into focus for ESWT, based on the concept of the fascia as a continuum causing proximal tension, which could generate symptoms in distal regions, such as the plantar fascia [29–33].

This protocol was found to be effective even though it does not consider treatment of the medial insertion of the plantar fascia [32,34]. This supports the hypothesis that heel pain may be an epiphenomenon of a global impairment instead of a local problem and that ESWT may be effective on the myofascial tissue as well. Although the literature shows extremely heterogeneous treatment protocols regarding the application of focused ESWT in terms of Energy Flux Density (EFD), number and frequency of sessions, most of the protocols usually applied in the treatment of plantar fasciitis focus on the plantar aponeurosis alone and do not consider the tensile forces in the entire limb. This approach could lead to a short-lived result with a variable rate of recurrence [35,36] likely due to unsolved proximal impairment.

Usually, the physical exam reveals a point of maximum tenderness close to the origin of the plantar fascia; therefore many in many approaches, shockwaves are applied in the medial insertion of the plantar fascia at the level of the heel, which is not always the primary cause of the pathology. It is necessary to take a global approach that analyses in detail all the components that have influence on the plantar fascia. Therefore, through an open label randomized controlled clinical trial, our intent was to evaluate the efficacy of ESWT on myofascial points, combining the concepts of fascial manipulation and treatment based on focal shock waves and compare this treatment to the single point focused ESWT approach.

2. Materials and Methods

Patients and treatment protocol

From April 2019 to February 2020, we enrolled patients attending our outpatient clinic with chronic severe heel pain due to recalcitrant plantar fasciitis not responsive to other conservative treatments. The study design was an open label randomized controlled clinical trial. The inclusion criteria were ≥ 18 years of age, the presence of heel pain ≥ 3 months duration unresponsive to first-choice conservative treatments (non-steroidal anti-inflammatory and/or other analgesic drugs, exercise program, insoles), specialist diagnosis of plantar fasciitis confirmed by clinical examination, pain intensity ≥ 5 at the Visual Analog Scale (VAS).

The exclusion criteria were previous ankle/foot fracture or surgery, previous ankle/foot infections, neurological deficits of the lower limbs, diagnosis or suspect of fibromyalgia, local steroid injection within the previous 3 months, diabetes mellitus, vascular diseases.

Patients were randomized by using the RAND function of Microsoft Excel into 2 Extracorporeal Shock Wave Treatment (ESWT) groups: the Experimental treatment Group (EG), 11 patients, and the Control Group (CG), 19 patients. In each group, 3 sessions of treatment were administered, one per week. A Duolith SD1 T-Top device (STORZ Medical) was used. The CONSORT flow diagram of the study is shown in Figure 1.

The study was conducted in accordance with the principles of the Declaration of Helsinki [37]. Approval to perform the study was obtained from the local Ethics Committee (protocol number 61902). The present study has been registered on ClinicalTrials.gov (ID number: NCT05090059). All participants signed the informed consent form prior to taking part in the study.

Experimental Group (EG). Subjects were treated by the global lower limbs myofascial point approach [11]. Before every session, a motor physical examination and a palpatory examination on myofascial points of the lower limbs and pelvis were performed, according to the standard approach of Fascial Manipulation® (FM) by Stecco. For each session, after selecting 3 or 4 myofascial points based on Fascial Manipulation principles, 1500 shocks of focused shockwaves (5 Hz, 0.05-0.167 mJ/mm^2, according to the patient's pain threshold) per point were administered (Figure 2). The choice of treatment parameters was based on the observation that this amount of energy is the minimum needed to loosen the densification of the myofascial point; in addition, for this amount of energy, adverse effects are extremely rare. At the end of the treatment of every single myofascial point, we evaluated if the shocks had been successful in terms of loosening densification and, if not, we completed the treatment manually until myofascial point release was obtained.

Control Group (CG). Subjects underwent focused ESWT on the area of the painful heel on the medial calcaneal tubercle after palpatory identification of the point of maximal heel tenderness. The patients received 2000 shocks with a 0.20-0.32 mJ/mm^2 (according to the patient's threshold) with a 5 Hz frequency delivered over one single spot. Four patients of the CG dropped out the study (1 after the second treatment, 3 after the third treatment).

Outcome measures

All patients were assessed using the 17-Italian Foot Function Index (17-iFFI) and the Foot and Ankle Outcome Scale (FAOS). Patients were asked to complete the questionnaires before every session; their answers were related to pain and functional limitation of ankle and foot during the previous 7 days.

17-iFFI is a validated Italian shortened version of the Italian Foot Functional Index (FFI). [38,39] It consists of 17 items divided into 3 subscales: pain (5 items), disability (9 items) and limitation of activity (3 items). The items were rated on a Visual Analogue Scale (VAS), from 0 to 10. The answers lie between "no pain" and "worst pain imaginable" (pain), "no difficulty" and "so difficult as to be unable" (disability), and "none of the time" and "all of the time" (limitations). A score is calculated for every subgroup of items, and the final score is then calculated by adding the subscale scores and dividing the result by 170. The final percentage score is between 0% (best outcome) and 100% (worst outcome).

FAOS has been largely used to evaluate the efficacy of many proposed conservative or mini-invasive treatments for plantar fasciitis [40,41,42], including focal ESWT. [43] It consists of 42 items. It is a self-administered questionnaire that contains five subscales: pain (9 items), other symptoms (7 items), function in activities of daily living (17 items), function in sports and recreation (5 items) and foot-and-ankle related quality of life (4 items). It is designed to measure the patient's subjective perception of pain and functionality during daily life in the previous 7 days. The questions are made to be answered with qualitative terms (None, Mild, Moderate, Severe, Extreme) or temporal terms (Never, Rarely, Sometimes, Often, Always) corresponding to a numeric value from 0 to 4. The score for each subdomain as well as the total FAOS is then calculated and normalised to a 0–100 scale, where 0% is the worst outcome and 100% the best outcome. Finally, a global percentage score, from 0% (worst outcome) to 100% (best outcome), is given. We used an on-line calculator to obtain the subscale scores and the final score [44].

Patients completed the questionnaires before the beginning of the treatment (T1). Then the assessment was repeated before every following treatment session (T2-T3), and the answers were related to pain and functional limitation of the last 7 days. Then they completed the questionnaires during the follow-up evaluations after 1 (T4) and 4 months (T5) from the last treatment session. The choice of a 4-month follow-up was based on previous studies showing a minimum of a 3-month follow-up period as a good cut-off to evaluate the efficacy of ESW therapy in managing plantar fasciitis [45]. If the patient suffered from bilateral plantar fasciitis, questionnaires were completed with the characteristics of the most symptomatic foot, according to the patient's subjective sensitivity.

Statistical Analysis

The a priori power analysis was conducted using the software G*Power 3.1.9.7 for Windows. The minimum sample size required for the mixed-model analysis applied on the changes at the different time-points (T2, T3, T4 and T5), considering the main and interaction effects, was computed in order to capture a small effect size as defined by Cohen. Parameters were selected as follows: an alpha error probability of 0.05, a power of 0.8 and a weak correlation among measures at the different time-points. The minimum sample size varied from 14 to 28 subjects

Patient characteristics were summarised with mean and standard deviation, median and interquartile range for quantitative variables, with count and percentage in each category in the case of qualitative variables. Normality was checked graphically with a Q-Q plot and with a Shapiro-Wilk test. Comparison between the two groups was conducted with a Student's t test or a Wilcoxon rank sum test depending on the normality of the quantitative variables. Fisher's exact test was used for qualitative variables.

The statistical analysis of FAOS and FFI during the follow-up visits was performed considering the change between each session and T1 (T-T1). Mixed-model analysis was applied on the change at T2, T3, T4 and T5 considering the following factors in the model: treatment group, time and the interaction treatment over time, and an autoregressive of the first order covariance matrix. In the case of a statistically significant interaction ($p < 0.10$), the treatment's difference was estimated at each time with the least squares mean of the change and a 95% confidence interval (CI). P-values and CIs were adjusted with Bonferroni's method to consider multiple comparisons. The same analysis was conducted adjusting for patient's gender since the distribution between the two treatment groups was statistically different.

The statistical significance was considered for p value < 0.05 if not otherwise stated. Data analysis was performed with SAS 9.4 (SAS Institute Inc., Cary, NC, USA).

3. Results

Thirty patients were included in the study; demographic characteristics are summarised in Table 1. Four patients of the CG dropped out the study (1 after the second treatment, 3 after the third treatment, Figure 1). Therefore, twenty-six patients were included in the final analysis. The EG group was younger, although the difference was not statistically significant (mean EG = 54.7 vs CG = 59.3, $p = 0.35$) and with lower female prevalence (EG = 45.5% vs CG = 84.2%, $p = 0.042$). Baseline values of FAOS (median EG = 68 vs CG = 69, $p = 0.36$) and FFI (mean EG = 54.2 vs CG = 48.4, $p = 0.41$) were comparable in the two groups.

17-iFFI. The 17-iFFI decreased significantly during the sessions (time effect $p < 0.0001$) from baseline (Figure 3a, Figure 4a, Table 2), and the decrease was in favour of the EG group (treatment group effect $p = 0.0016$), though not with the same intensity over time (interaction effect $p = 0.0926$). The treatment difference was statistically significant at all sessions except in T2. The analysis conducted adjusting for gender gave approximately the same results (data not shown).

FAOS. FAOS change from baseline (Figure 3b, Figure 4b, Table 3) increased significantly during time (time effect $p < 0.0001$), and the increase was in favour of the EG group (treatment group effect $p = 0.0072$), though the difference was not the same over time (interaction effect $p = 0.0143$). The two groups differed significantly but not in the T2 session. The analysis conducted adjusting for gender gave approximately the same results (data not shown).

4. Discussion

In the present study, we applied ESWT in the altered myofascial points of the lower limb according to the fascial manipulation method instead of in the area of pain. The rationale was to consider the myofascial continuity throughout the whole body. The lower limb's fascial system should be considered as a unique entity that covers the limb as a glove, connected proximally with the pelvis fasciae through epimysial expansions of the abdominis muscle fascia and the gluteal ones, and distally with the plantar fascia through the so-called "Achilles-calcaneal system" [46].

Hujing et al. found the fascial system to be responsible for the transmission of at least 30% of the mechanical forces in the musculoskeletal system due to myofascial expansion connecting muscle and epimysial fasciae [47]. We hypothesised that plantar fasciitis might be the result of altered force transmission along the myofascial system causing stress in the ending segments of the body. Thus, a myofascial impairment in the proximal districts of the lower limbs and pelvis may affect the mechanical load in the feet and may have a role in the pathogenesis of plantar fasciitis. It could also explain the high prevalence of proximal radiation of the pain associated with the plantar pain found in these patients.

Supporting our hypothesis, previous studies reported that ESWT application in the gastrocnemius-soleus trigger points improves plantar fasciitis symptoms[34] and that patients with hamstring tightness were about 8.7 times as likely to experience plantar fasciitis [48]. There is also evidence that associating ESWT to stretching exercises could be more effective than the ESWT alone [32,49].

In this study, we recorded results consistent with the literature for the application of ESWT in the medial insertion of plantar fascia [50]. We achieved similar to better results in terms of foot pain, disability and time needed for recovery with the release of proximal myofascial points using the fascial manipulation method.

Furthermore, a stimulating impulse applied in the inflamed zone can worsen the symptoms in the short term (no improvement was found at the end of the treatment for TG, time T3), and pain relief occurs after months, probably due to the time needed by the biological process to restore the physiological state of the tissue and the resolution of inflammation. In contrast, we found rapid improvement on both scales for the EG already in the second session (T2), although this data was not statistically significant. This result was maintained both in short-term (1 month, T4) and medium-term (4 months, T5) follow-up, with statistical significance. These findings are likely related to the restoration of correct gliding in the fascial system, thus solving the biomechanical impairment. It is likely that the tightness of proximal muscular structures, such as hamstrings, could be transmitted to more distal structures through the fascia cruris. By solving the proximal contracture, the gliding of the whole "fascia cruris-Achilles tendon's paratenon-plantar fascia" wrap around the myotendinous structures could be restored, thus explaining the short-term improvement in foot pain and function.

The global approach using myofascial points does not exclude focused treatment. It could be used as the first step in the treatment of plantar fasciitis to rapidly reduce pain. This proposal is related to the fact that problems regarding proximal structures could generate impairment in the distal areas of the lower limb leading to inflammation and degeneration of plantar fascia sustained by usage and overload. As a second step of the therapy, when inflammation decreases, ESWT focused on the calcaneal insertion of the plantar fascia may be included in order to prevent worsening pain and assist the regenerative process on the collagenic structure of the fascia.

The present study has several limitations. First, the sample size was limited; therefore, it would be difficult to generalise our results to a larger population. Second, the number of participants included in the analysis for each group is different. Third, the follow-up period was relatively short, thus not allowing an investigation of the recurrence rate of heel pain and functional impairment. Further studies with a bigger sample size and a longer follow-up period are needed. Another limit could be the different number of shocks given in the two groups: the myofascial protocol included 1500 shocks for each myofascial point (3-4 points for session) versus 2000 shocks for the standard focused ESTW. However, although the number of shocks was unequal, the total amount of energy was distributed in multiple areas, minimising the risk of adverse reactions.

In conclusion, treatment of the myofascial points with ESWT in subjects suffering from plantar fasciitis could be an effective treatment option. It fosters the hypothesis that a global biomechanical re-equilibrium of the body would be necessary to completely solve the pathology.

5. Conclusions

Plantar fasciitis may be sustained by a myofascial impairment proximal to the pain area that ends in a biomechanical disequilibrium of the entire limb and pelvis. Consistent with the literature, ESWT was found to be an effective treatment option for the pathology by using the standard application in the medial calcaneal insertion of the plantar fascia as well as in the myofascial points. In this study, we registered better results in terms of pain reduction and time needed for recovery for the myofascial group compared with the standard protocol. This may be due to the release of myofascial tension along the whole limb.

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Tables

Table 1: Patient characteristics at baseline. EG: Experimental Group. CG: Control Group. SD: Standard Deviation. FAOS: Foot and Ankle Outcome Score. FFI: Foot Functional Index

N = 30	*EG (n = 11)*	*CG (n = 15)*	*P Value*
Age (years)			
Mean (SD)	54.7 (13.7)	59.3 (12.2)	0.3505
Median (Range)	55.0 (23.0 – 78.0)	57.0 (36.0 – 82.0)	
Sex			
F	5 (45.5%)	16 (84.2%)	0.0419
M	6 (54.5%)	3 (15.8%)	
FAOS			
Mean (SD)	59.4 (17.5)	63.8 (20.0)	
Median (Range)	68.0 (29.0 – 80.0)	69.0 (17.0 – 93.0)	0.3647
FFI			
Mean (SD)	54.2 (20.6)	48.4 (16.4)	0.4061
Median (Range)	52.0 (26.0 – 85.0)	46.0 (18.0 – 74.0)	

	EG (n = 11)	CG (n = 15)	EG vs CG	
	Mean (sd)	**Mean (sd)**	**Adjusted Least Squares Mean (95% CI)**	**Adjusted p-value**
T2	- 10.5 (12.6)	-6.6 (11.6)	-3.9 (-20.0; 12.1)	1.0000
T3	-21.8 (23.0)	-2.9 (8.5)	-18.9 (-35.0; -2.9)	0.0138
T4	-36.1 (24.2)	-15.41 (12.1)	-20.7 (-37.3; -4.1)	0.0084
T5	-40.5 (26.8)	-20.5 (14.6)	-19.9 (-36.7; -3.2)	0.0128

Table 2: Mean (standard deviation) values of the 17-iFFI score expressed as difference from the baseline value (17-iFFI score in T1), adjusted least squares mean (95% confidence interval) and p-

values for the comparison EG versus CG. EG: Experimental Group. CG: Control Group. Sd: standard deviation. CI: Confidence Interval.

	EG (n = 11)	CG (n = 15)	EG vs TG	
	Mean (sd)	**Mean (sd)**	**Adjusted Least Squares Mean (95% CI)**	**Adjusted p-value**
T2	6.5 (16.7)	3.9 (4.9)	2.7 (-9.2; 14.5)	1.0000
T3	15.4 (14.8)	0.7 (8.8)	14.6 (2.8; 26.5)	0.0091
T4	23.1 (14.1)	10.5 (10)	12.8 (0.7; 25.0)	0.0341
T5	26.9 (18.5)	12.9 (11.4)	14.2 (1.9; 26.5)	0.0163

Table 3: Mean (standard deviation) values of the FAOS score expressed as difference from the baseline value (FAOS score in T1), adjusted least squares mean (95% confidence interval) and p-

values for the comparison EG versus CG. EG: Experimental Group. CG: Control Group. Sd: standard deviation. CI: Confidence Interval.

Figure Legend

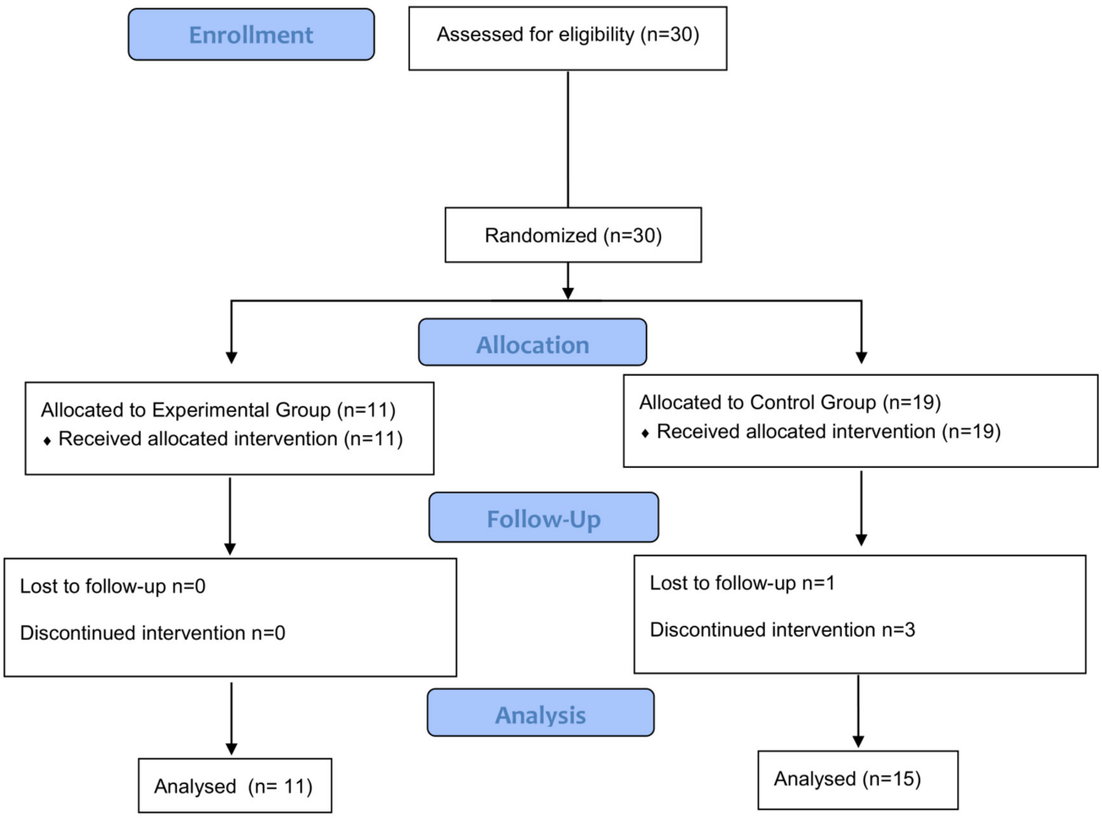
Figure 1. CONSORT flow diagram of the study.

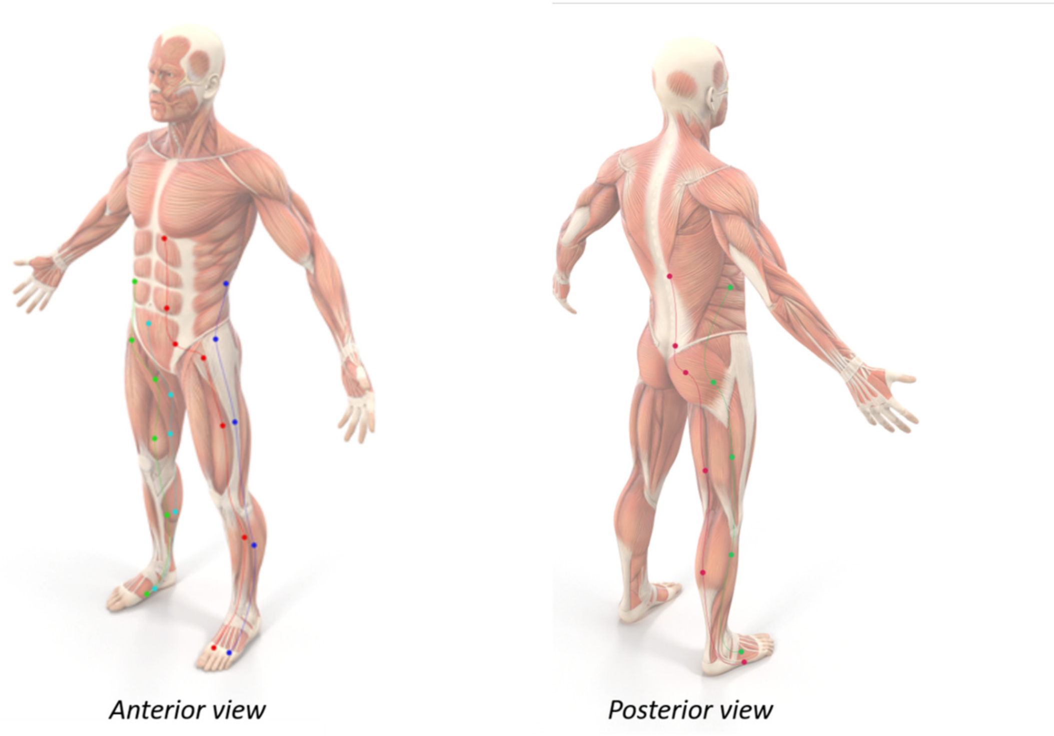
Figure 2. Graphic representation of the treated points in the Experimental treatment Group (EG) during the first (red), second (green) and third (blue) session.

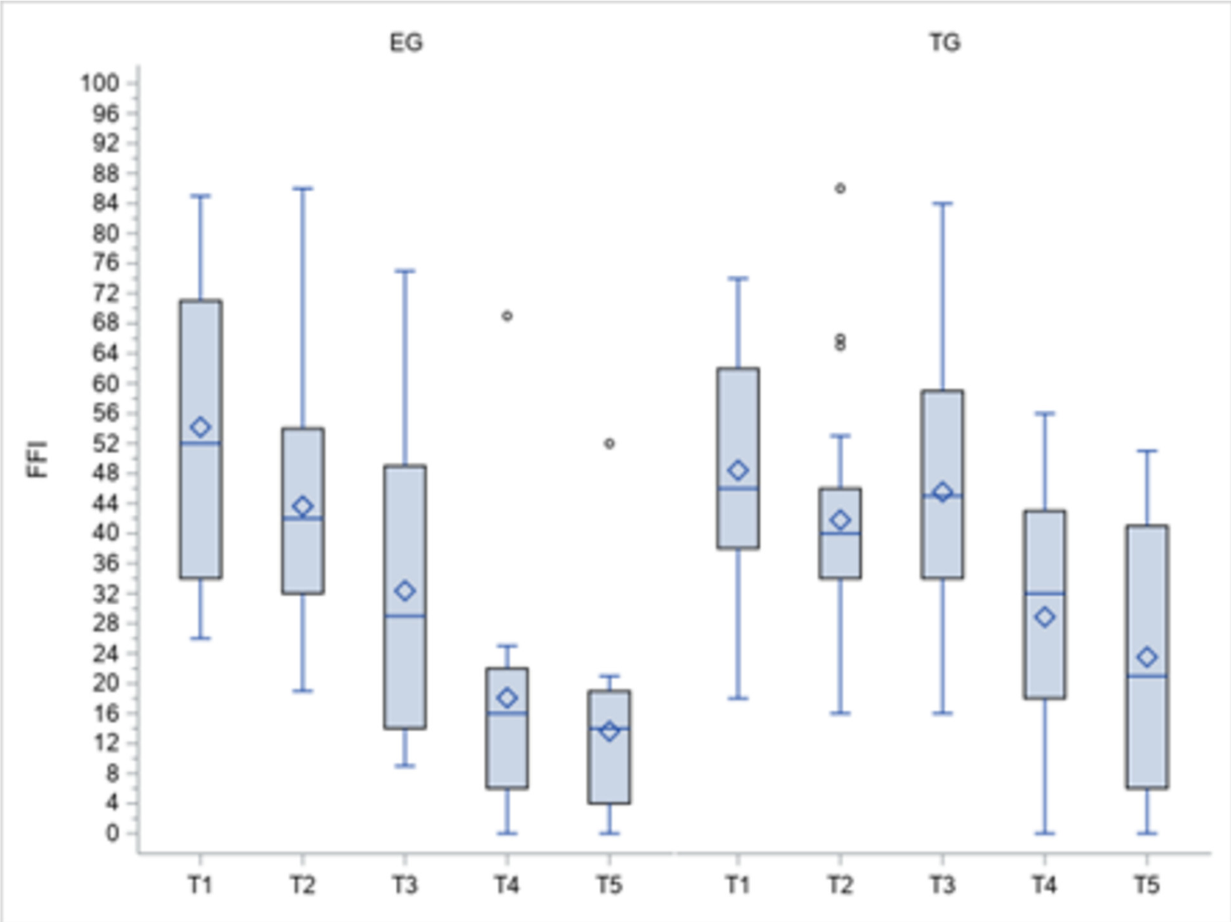
Fig. 3 The lower and upper fences of the box represent the 1st and 3rd quartile, the bisecting line the median, the diamond the mean. The upper whisker is the largest datum smaller than 1.5×interquartile range above the 3rd and the lower whisker is the datum larger than 1.5×interquartile range below the 1st quartile. **Figure 3a**: Box plot of 17-iFFI score distribution at session T1, T2, T3, T4 and T5. 17-iFFI: 17-Italian Foot Functional Index. **Figure 3b**: Box plot of FAOS score distribution at session T1, T2, T3, T4 and T5. FAOS: Foot and Ankle Outcome Score.

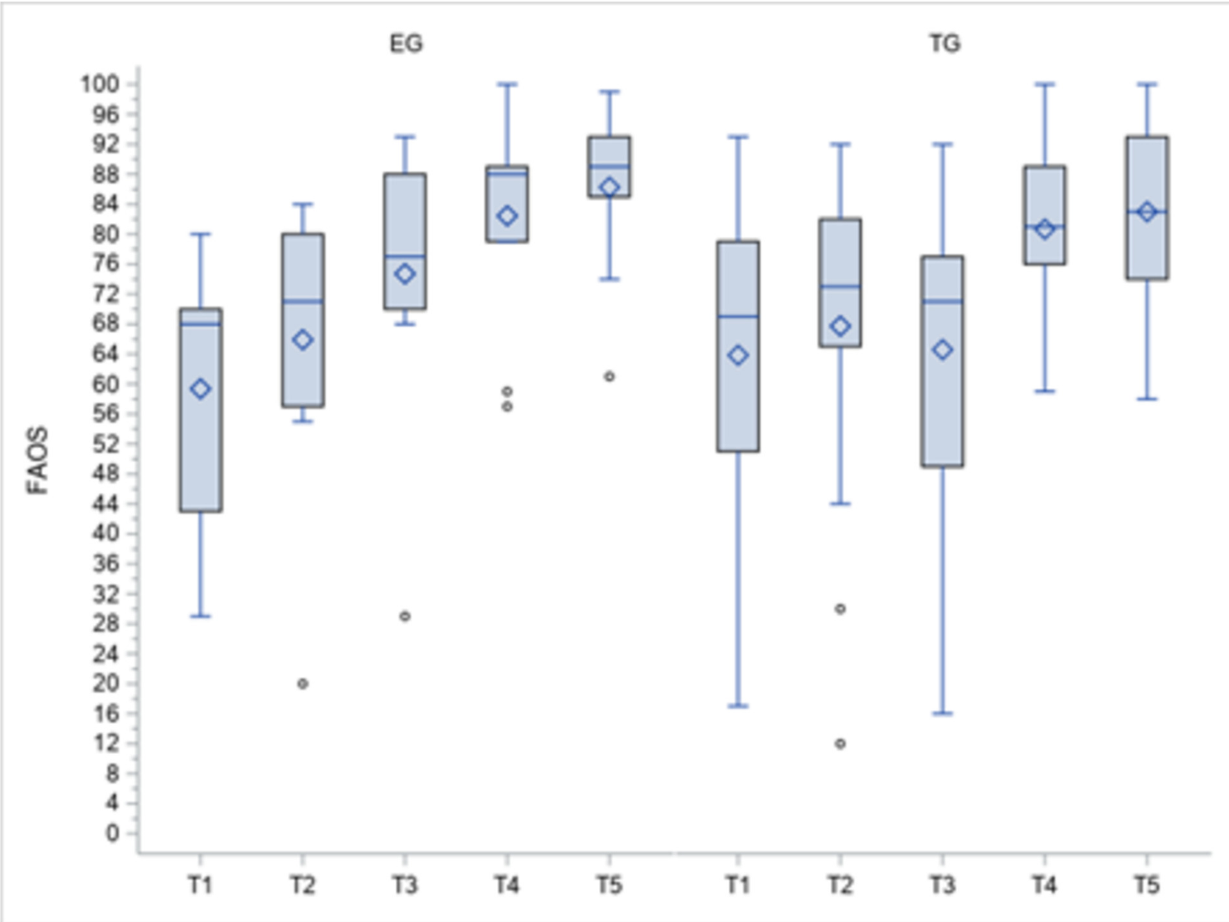
Figure 4a: Least Squares Mean Estimates of the absolute variation of the 17-iFFI score in T2, T3, T4 and T5 with respect to the baseline (T1). 17-iFFI: 17-Italian Foot Functional Index.

Figure 4b: Least Squares Mean Estimates of the absolute variation of the FAOS score in T2, T3, T4 and T5 with respect to the baseline (T1). FAOS: Foot and Ankle Outcome Score.


Enrollment
Assessed for eligibility (n=30)
Randomized (n=30)
Allocation
Allocated to Experimental Group (n=11)
♦ Received allocated intervention (n=11)
Allocated to Control Group (n=19)
♦ Received allocated intervention (n=19)
Follow-Up
Lost to follow-up n=0
Discontinued intervention n=0
Lost to follow-up n=1
Discontinued intervention n=3
Analysis
Analysed (n= 11)
Analysed (n=15)


Anterior view
Posterior view


EG
TG
FFI
100
96
92
88
84
80
76
72
68
64
60
56
52
48
44
40
36
32
28
24
20
16
12
8
4
0
T1
T2
T3
T4
T5
T1
T2
T3
T4
T5



EG
TG
FAOS
100
96
92
88
84
80
76
72
68
64
60
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52
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44
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32
28
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20
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T1
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T3
T4
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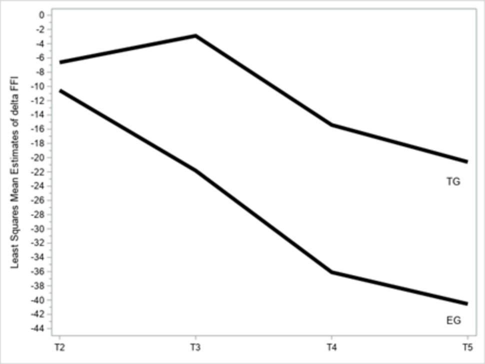
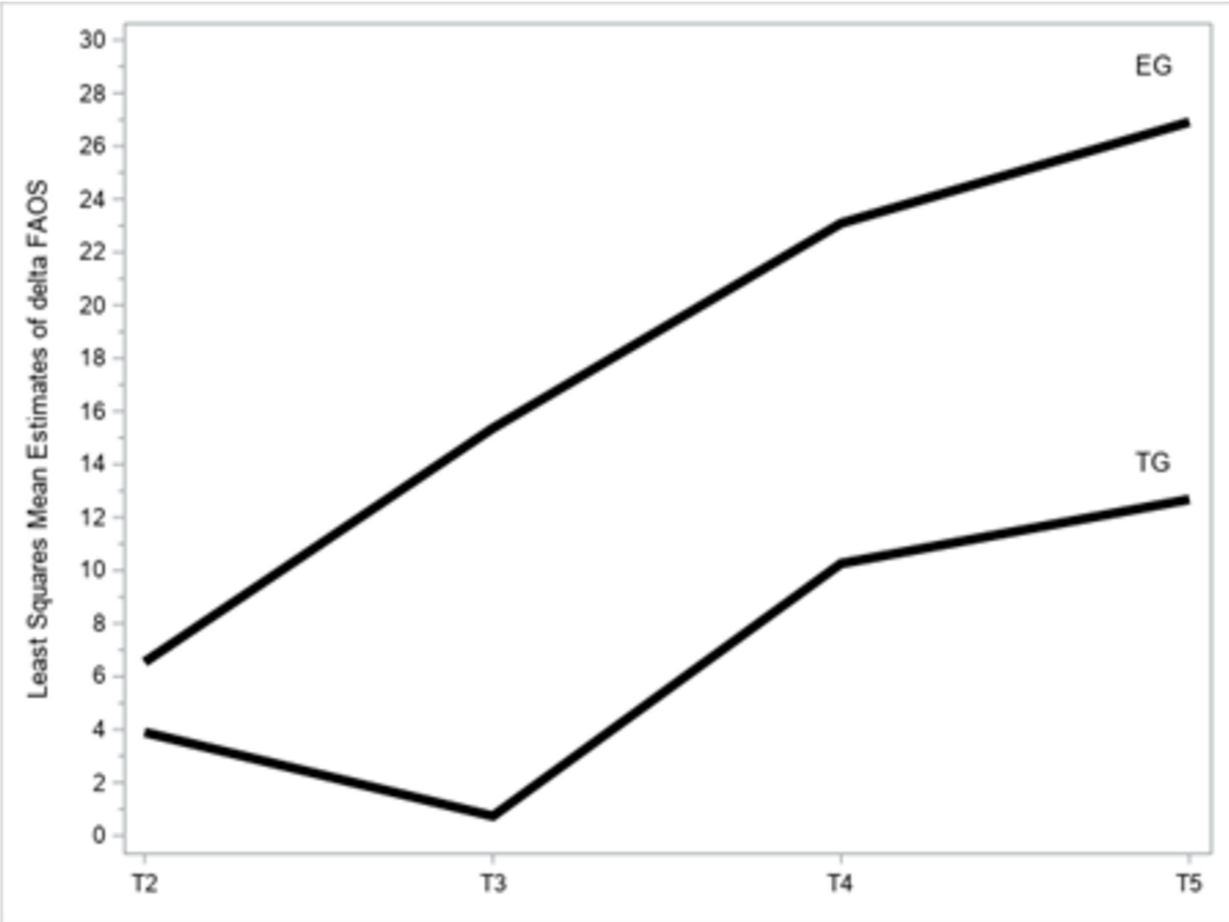

Least Squares Mean Estimates of delta FFI
0
-2
-4
-6
-8
-10
-12
-14
-16
-18
-20
-22
-24
-26
-28
-30
-32
-34
-36
-38
-40
-42
-44
TG
EG
T2
T3
T4
T5



Least Squares Mean Estimates of delta FAOS
0
2
4
6
8
10
12
14
16
18
20
22
24
26
28
30
EG
TG
T2
T3
T4
T5