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ORIGINAL ARTICLE

Extracorporeal Shockwave Therapy Versus Graston Instrument Assisted Soft-Tissue

Mobilization in Chronic Plantar Heel Pain: A Randomized Controlled Trial

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BACKGROUND: Although there are studies showing that extracorporeal shockwave therapy (ESWT) and instrument-assisted soft-tissue mobilization (IASTM) methods are effective in chronic plantar heel pain (CPHP) treatment, there is a need for studies comparing these techniques. Our goal is to compare the effectiveness of ESWT vs IASTM using Graston Technique® (GT®) instruments in addition to stretching exercises (SEs) in CPHP.

METHODS: Sixty-nine patients were randomly assigned to 3 groups as ESWT+SEs (Gr I), GT®+SEs (Gr II) and SEs (CG) (ratio 1:1:1). SEs program twice/day, for 8-week was standard for all. Gr I received low intensity ESWT while in Gr II, GT® was the selected method. Visual analog scale (VAS) (for initial step and activity pain); foot function index (FFI); short form-12 (SF-12), and Tampa Scale were used at pretreatment, posttreatment and follow-ups (8-week and 6-month).

RESULTS: VAS and FFI scores improved in the posttreatment and follow-ups in all ($p < .00$) While effect sizes in Gr I and Gr II were greater than CG in initial step pain at posttreatment and 8-

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week-follow-up, Gr II had highest effect size at 6-month-follow-up. The mean SF-12 scores in Gr I and Gr II showed improvement on the posttreatment assessment. Furthermore, Gr II showed significant improvements in FFI scores compared to other groups in 6-month-follow-up ($F=6.33$, $p=.003$). **CONCLUSIONS:** Even though ESWT+SEs and GT[®]+SEs interventions seem to have similar effects on initial step pain at posttreatment and 8-week-follow-up; GT[®]+SEs was found most effective for improving functional status at 6-month in the management of CPHP.

Plantar heel pain (PHP)/plantar fasciitis usually presents as a chronic condition, which is considered as degeneration in the proximal plantar aponeurosis with microtears due to repeated tension in the plantar fascia ^{origo}¹⁻³. The main complaint of chronic plantar heel pain (CPHP) is the initial step pain felt prominently in the medial side of the heel. Typically, pain subsides after some steps but may worsen after prolonged load bearing activities³. CPHP has a remarkable negative impact on foot-specific and general health-related quality of life⁴. Additionally kinesiophobia associates with poorer foot function⁵.

Vast majority of PHP patients respond to non-surgical treatments with several modalities^{6,7}. In the literature, there is a consensus that ESWT, manual therapy and SEs are safe and effective^{8,9} with level of evidence A^{3,9}.

Low-energy ESWT applications cause microtrauma in the damaged tissue producing localized hyperemia through sound waves⁸. According to stated in sytematic review by Sun et al (2020); ESWT might be related with improvements in soft tissue healing, reduction of

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calcification, inhibition of pain receptors, inhibition of pain receptors, or denervation to achieve pain relief and neovascularization¹⁰. In the treatment of PHP, studies have indicated that ESWT is an effective^{3,9-11} and reliable treatment method^{9,12}. It has also been stated that there is a need for multi-centered, well-designed, higher quality randomized controlled studies with sufficient number of participants¹⁰.

As a manual therapy method, instrument-assisted soft tissue mobilization (IASTM) treatment had been reported to be effective against pain and secondary disability due to pain in musculoskeletal diseases¹³. Graston Technique® (GT®) applies longitudinal pressure along the tissue fibers through specially designed instruments creating micro traumas in the damaged areas, scar tissue destruction and adhesion loosening. Additionally, collagen synthesis and connective tissue remodeling are stimulated¹³⁻¹⁶. Studies revealing effectiveness of GT® in CPHP are usually case studies with no controls and evidence levels are low^{6,17}.

In CPHP management, several research studies compare ESWT, myofascial release and other methods^{9,18-20}. To the best of our knowledge, there is no study comparing the effectiveness of ESWT and GT® interventions. Hence, our aim was to compare the effectiveness of ESWT and GT® interventions combined with SEs in CPHP on pain, functional status, quality of life and kinesiophobia.

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METHODS

Study Design

A prospective, double-blind, randomized, controlled trial was performed at the Yeditepe University Orthopedics and Traumatology Clinic and Bahçesehir University Faculty of Health Sciences Physiotherapy and Rehabilitation Laboratory between December 2018 and March 2020 in accordance with the Declaration of Helsinki. This study was approved by Medipol University Non-Interventional Clinical Research Ethics Committee numbered 10840098-604.01.01-E.15417. All participants were informed about the interventions and the potential adverse effects and signed the informed consent form.

The participants who fulfilled the criteria were randomized to 1 of the 3 parallel groups. Group I (Gr I) received ESWT and SEs (n=23), Group II (Gr II) managed by GT® and SEs (n=23). Group III (Gr III) received SEs and served as control (CG) (n=23). The program of “Research Randomizer”, which as an online randomization web service, (<https://www.randomizer.org/>) was utilized for distribution of the groups. Simple randomization procedures (computerized random numbers) were conducted, and sequentially numbered index cards with the random assignment were prepared by an investigator with no clinical involvement in the study. The index cards were folded and placed in sealed, opaque envelopes. Then, the investigator opened each envelope and assigned the participants to their groups. The interventions were performed by the same physical therapist (GT® by P.P., ESWT by E.T.Ç.) and the outcome measures were

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administered by another therapist (D.K.C.). As the interventionists were aware of the allocated arm, the outcome assessor was blinded to the allocation procedure.

Participants

The study included 88 feet of 69 patients with CPHP (average age 47 years; ranging 22 to 65; female:28, male:38). Inclusion criteria were aged 18-60, symptomatic for at least 3 months, with a history of initial step pain 5 and more (VAS), still symptomatic after at least 3 nonsurgical treatments (including NSAID drug use and cortisone injection). Patients with history of foot surgery, stress fracture, tarsal tunnel syndrome, infection, neurological problems, tumorous conditions, coagulation disorder and pregnancy were excluded.

Outcome Measures

A senior orthopedic surgeon (U.S.) evaluated all participants initially. A predetermined structured questionnaire (age, gender, height, weight, symptom duration, sociodemographic conditions, presence of chronic diseases, and previous foot surgery) was completed through face-to-face interviews by the same investigator (U.S.). Outcome measures were completed in the pretreatment, posttreatment (4-week) and the 8-week follow-ups (face to face) while 6-month follow-up assessment was performed by telephone interview by the same blinded assessor (D.K.C.). Only FFI scores and initial step pain status were evaluated at 6-month follow-

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up. The primary outcome was VAS-initial step pain. Secondary outcomes were VAS-activity pain, foot function index (FFI), short form-12 (SF-12) and Tampa Scale for Kinesiophobia.

The Visual Analog Scale (VAS): For initial and activity pain, the patients marked on a scale of 0 (indicating no pain) to 100 mm (most severe). The marked point was measured with a millimeter ruler²¹. The minimal clinical significance was found 1.3 centimeters mm for chronic conditions²².

Foot Function Index (FFI): The FFI is a self-assessment scale consisting of 23 items measuring the impact of foot disorders in terms of pain, disability, and activity limitation. The higher the score, the worse the individual's condition. It has been shown that the Turkish version of the FFI used in our study is sensitive to changes, and valid and reliable²³. The following minimal important differences were found for Foot Function Index: 12 for pain, 7 for disability and 7 for Total Foot Function Index²⁴.

Short-Form 12 (SF-12): The questionnaire consists of 12 statements, organized into various subscales including physical and mental domains. The total score ranges from 0 to 100, with higher scores indicating better status²⁵.

Tampa Scale for Kinesiophobia (TSK): Kinesiophobia was evaluated using the TSK. The TSK is a 17-item questionnaire that evaluates a person's fear of movement and/or (re)injury. The total score ranges from 17 to 68, with higher scores indicating higher degrees of kinesiophobia. In

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2011, the scale was translated into Turkish, and a test-retest reliability study was conducted by Yilmaz O. et al²⁶.

Interventions

Patient Education Program

The patient education program was provided to inform about CPHP, (including symptoms and complications) and to give instructions through E.T.Ç. before randomization. The exercise programs were introduced as “hands on” instruction (calf and plantar fascia specific stretching exercises) initially by E.T.Ç.²⁷

Stretching Exercises (SEs) Protocol

The SEs for plantar fascia, gastrocnemius, and soleus were assigned to all groups as part of their home program twice a day (7 days/week). For each region, SEs were performed with three repetitions and intermittently and 30 seconds holding time were preferred in their program. Self-stretching plantar fascia exercises: These exercises were performed by placing the affected leg crosswise on the contralateral leg in the seated position. Patients held the base of their toes with one hand and dorsiflexed the distal metatarsophalangeal joints until they felt tension in the arch of their foot²⁷⁻²⁹.

Self-stretching of the calf muscles: While patients were standing, they leaned against the wall with their affected leg behind. While the knee was flexed, the soleus muscle is stretched,

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and while the knee is extended, the gastrocnemius muscle is stretched. During the exercises, attention was paid to keep the heel on the floor^{27,30}.

Extracorporeal Shock Wave Therapy (ESWT) Protocol

While the patient in prone position, ankle was supported with cylindrical pillow. Low dose ESWT was applied to painful areas in the plantar fascia and tuber calcanei once a week for 4 weeks with the BTL L-6000 SWT device (United Kingdom) with an application dose of 10 Hz, 2.5 bar, 2000 shock wave³¹.

Graston Technique® (GT®) Protocol

The technique was applied by a GT® certified therapist with 13 years of experience in orthopedic rehabilitation. The plantar fascia and gastrosoleus muscles were treated with GT® instruments twice a week for 4 weeks. The GT® instruments and mobilization techniques to be used were determined according to the GT® manual and the applied protocol was demonstrated in table 1³². Before the intervention, superficial heat was applied for 10 minutes with a hot pack to plantar fascia and gastrosoleus muscles. After GT treatment was completed, participants performed SEs in the clinic to ensure collagen reorganization as suggested by the protocol³³.

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Sample size

Power analysis of the study was with 80% reliability, alpha level of 0.05, minimal clinical significance of 1.3 centimeters²², standard deviation of 0.5 as 21 patients per group and 63 patients in total by using G-power 3.1.9.7 software (Universität Kiel, Kiel, Germany).

Considering the 10% drop out rate, the number of patients required for recruitment was calculated to be 69.

Statistical Analysis

Statistical Package for Social Science (SPSS) version 20.0 for Windows software (SPSS, Inc., Chicago, IL, USA) was preferred. The Kolmogorov–Smirnov test was performed to assess the distribution of the data. Differences between the groups in baseline characteristics (age, BMI, and symptom duration) were assessed through independent samples t-test and Chi-squared test (gender). Changes in the mean (95% CI) variable scores within the groups were assessed through paired samples t-test. Repeated measures analysis of variance (rANOVA) was conducted in time (pretreatment, posttreatment, and follow-up) as a within-subject variable, and with group (Gr I, Gr II or CG) as a between-subjects variable to analyze the effect of the interventions on the primary and secondary outcomes. The effect sizes (ES) were determined, as suggested by Kazis et al., dividing the changes in mean baseline and follow-up scores by the baseline standard deviation³³. The ES of 0.2, 0.5, and 0.8 were considered small, moderate, and

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large, respectively. The significance level was set at $p < 0.05$. Once the differences between the mean scores were determined, the least significant difference (LSD) post-hoc test was used with a Bonferroni correction. Depending on the repetition of the outcome measures, significance was accepted as $p = .05/3 = .016$ or $p = .05/4 = .0125$.

RESULTS

Twentythree in the Gr I (29 feet), 23 in the Gr II group (29 feet), and 20 in the CG (29 feet), a total of 66 participants completed the study. Three participants dropped out in CG. At baseline, all groups were homogenous in terms of demographics and symptom duration ($p > 0.05$) (Table 2). Twentyone patients in Gr I (27 feet), 21 in Gr II (29 feet) and 18 in CG (23 feet) participated in the 6-month follow-up interview. A flow diagram of the study was shown in Figure 1.

All groups demonstrated statistically significant improvement in VAS-initial step pain, VAS-activity pain and FFI scores from the baseline to the posttreatment ($P < .000$ for all groups) and from the baseline to the 8-week ($P < .000$ for all) (Table 3) and 6-month follow-up ($P < .000$ for all) (Table 4) (Figure 2,3). The overall group-by-time interaction for rANOVA was not significant for the VAS-initial step ($F = 1.00$, $P = .372$ for the posttreatment, $F = 1.87$, $P = .161$ for the follow-up) and VAS-activity ($F = 2.79$, $P = .067$ for the posttreatment $F = 1.26$, $P = .288$ for the 8-week follow-up (Table 3), $F = 2.20$, $P = .117$ for the 6-month follow-up (Table 4). According to the ES calculation, while both Gr I and Gr II were more effective than CG in VAS-initial step pain at posttreatment

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(ES= 2.61, 2.47 and 1.07 respectively) and at 8-week follow-up (2.55, 2.39 and 1.17 respectively), ESWT+SEs was most effective in VAS-activity pain at posttreatment and 8th week. Effect sizes of all groups were similar in terms of FFI at posttreatment and 8-weeks. At 6-month follow up, effect size of G II was found as highest in VAS-initial step pain.

The overall group-by-time interaction for rANOVA was significant for FFI from the baseline to the posttreatment ($F=3.15$, $P=.048$) and baseline to 6-month follow-up ($F=6.33$, $P=.003$). The mean difference in the FFI in the Gr II and CG from baseline to after the treatment was -17.90 ± 17.85 and -15.83 ± 8.61 respectively, in favor of Gr II ($P=.048$), after the LSD test P value was .016. However, after LSD test, p value was calculated as .002 between Gr I and Gr II, .007 between Gr II and CG in favour of Gr II for 6-month follow-up.

While SF-12 physical score improved in the posttreatment in Gr I and Gr II ($P=.048$ and $P=.013$, respectively), statistically significant improvement was observed in Gr II and CG compared to the pretreatment at the 8th week evaluation ($P=.027$ for both). Looking at the ES values, all treatment groups had a small effect on the posttreatment (ES=0.22, 0.24, 0.27 respectively), and 8-week recovery (ES for Gr I =0.24; ES for Gr II =0.35) except for CG, where improvement at 8-week was moderately effective (ES= 0.50). While statistically significant improvement in SF-12 mental score was observed only in CG in the posttreatment ($P=.04$), the ES was medium (ES=0.69). In the 8-week results, statistically significant improvement was observed in Gr II and CG ($P=.005$ and $P=.04$), the ES were small for Gr I (ES=0.21), and medium

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for the other groups (ES=0.59 and 0.53 respectively). No significant improvement was observed in kinesiophobia scores in any of the groups (Table 3) at posttreatment and 8-week.

DISCUSSION

This randomized controlled study compares the ESWT vs GT[®] interventions in CPHP management. Our findings revealed remarkable improvements in pain relief and functional outcomes in all groups. However, the ES for initial step pain in Gr I and Gr II was better than CG in posttreatment and follow-up. For activity pain, ESWT+SEs (Gr I) seemed to be the most effective. Though the mean score of FFI statistically improved in all, none of them was superior to the others. There was also no statistically significant difference between the mean kinesiophobia scores of the groups during the post and follow-up.

SEs have been reported as an effective, safe, and early applied method with the highest level of evidence in PHP treatment⁹. In PHP/PF clinical practice guideline, clinicians recommended a plantar fascia–specific and gastrocnemius/soleus SEs programs to reduce pain level in the short term (1 week- 4 months)³. Kamonseki et al. found that SEs is directly associated with functional status in patients with PF³⁰. According to our results, the mean pain status (initial step & activity) and FFI level improved in CG, which is consistent with the literature. Although only the physical score of SF-12 increased during the follow-up period, statistically significant improvements were seen in the mental score of SF-12 both in

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posttreatment and follow-up in CG. Though, it is well known that SEs are effective for CPHP patients, ESWT+SEs and GT[®]+SEs had superior ES in pain level compared to the only SEs. Thus, considering the higher ES value for pain level, we may suggest the combined therapies especially for CPHP patients to reduce the pain intensity level for initial step and activity. ESWT is another treatment option, which is frequently recommended in the literature. Rompe et al. compared the effects of ESWT, and those of ESWT+SEs on pain (initial step pain, worst pain and FFI pain subscale) and function (FFI sum score). In the study, one group only received ESWT (n=73) once a week for three weeks while the others participated to ESWT and plantar fascia specific SEs (n=79). All patients were assessed at baseline, second, fourth- and twenty-fourth-month follow-up. According to this study, the FFI sum score had significant improvement in ESWT+SEs than only ESWT group (P<.001). The group that performed ESWT and SEs outperformed the other group in all evaluations. The treatment efficacy continued at the 4-month, but no difference was observed between the two groups at the 24-month²⁹. In contrast to the study by Rompe et al, our results indicated that ESWT+SEs combination was found to be more effective than only SEs in reducing initial step and activity pain. Still there was no difference between the groups in terms of functional status. To the best of our knowledge, there is no study investigating quality of life and kinesiophobia scores in the literature. In the present study, while ESWT+SEs had a remarkable improvement in SF-12 physical scores, this effect did not last until the follow-up with no change in the kinesiophobia score.

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Manual therapy includes joint mobilization or soft tissue mobilization (deep tissue massage or myofascial release (MFR)). In the literature, myofascial release performed on the calf and plantar fascia has been found to be effective in the treatment^{27,36,37}. IASTM treatment performed in combination with SEs has been recommended both to increase the flexibility of the plantar fascia and to provide collagen reorganization¹⁷. Studies using IASTM for PF are limited to case studies^{17,38}, a case series⁶ and a pilot study carried out with a small number³⁷. Results of these studies showed improvement in pain and function^{6,17,38}. Since IASTM was not performed alone in any of these studies and there were no control groups, it was not possible to evaluate the contribution of IASTM to the treatment. In a feasibility study examining the effectiveness of IASTM treatment using GT[®] in PHP, a group that was given stretching and strengthening exercises and a home program (n=6) was compared with the group (n=5) on which GT[®] was performed in addition to these exercises. After 8 sessions of treatment (2 sessions x 4 weeks) and follow-up after 90 days, clinically important changes in the IASTM group and moderate-to-large between-group ES suggested that further research is warranted to determine whether these trends are meaningful³⁹. The results of our study are in line with the literature in that pain, function, and quality of life physical scores improved in the posttreatment and the follow-up in the Gr II. In our study the ES of the Gr II group was much higher in the VAS-initial step compared to the CG group while there was no difference in effect size values in VAS-activity and FFI scores. SF-12 physical scores improved in the posttreatment

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and the follow-up, while no change was observed in kinesiophobia score. Additionally, FFI scores were better at 6 months in the Gr II compared to Gr I, CG.

Considering these findings, we believe that attempts to further optimize nonoperative treatment modalities in patients with CPHP are warranted. Furthermore, the number of randomized controlled studies with blind assessors is limited, and there are few studies that compared combined conservative management protocols which are common in clinical practice. To our knowledge, the present study is the first prospective randomized controlled study comparing 3 methods of nonoperative treatment for CPHP by evaluating pain level, functional capacity and kinesiophobia. As far as we know this is the first study in which GT[®] intervention was conducted having sufficient number of patients and a randomized controlled research with 6-month follow-up. We considered that the GT[®] intervention and SEs lasting 4-week have potential effect to improve on FFI scores 6-month comparing to pretreatment assessment. Our study contributes to the literature in these aspects.

There are a few limitations in our study. First, the changes in body weight were not monitored in the study. Second, physical activity status of the cases was not evaluated by using an objective methodology. High body mass index and restricted activity level may have a relationship with functional status. Further studies are needed to monitor these risk factors influencing the outcomes after the treatment. We think that it is important for future studies to expand patient education programs by taking other risk factors into account and via long-term

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follow-up. In the present study, we have reached our calculated sample size. If the number of cases increases, the consistency of the outcomes in the ESWT+SEs and GT®+SEs groups may be identified better compared to SEs.

CONCLUSIONS

The results of the study showed that all treatment protocols (ESWT+SEs and GT®+SEs and SEs) have similar effects on functional capacity and pain level in short term. It was observed that the effectiveness of ESWT and GT® treatments on initial step pain and the efficiency of ESWT treatment on activity pain created the highest improvement in short term. Additionally, we believe that the management strategies in PHP which must lead to improvements in functional capacity, quality of life and kinesiophobia as well as pain level can be considered as satisfactory. As a conclusion, we suggest using of GT® combined with SEs protocol for management of CPHP due to effectiveness on pain relief and on functional status for long term effect in the light of the findings. Further studies with larger sample size, long-term follow-up, and monitoring risk factors (BMI, physical activity level e.g.) will provide a more tailored management strategy.

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Conflict of Interest: None reported.

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Table 1. Graston technique® application protocol

Region	Instrument	Technique	Period
Calf	GT 5	Sweep	1 minute
Local lesions	GT 2	Strum	1 minute
Achilles tendon	GT 2	Frame	1 minute
Plantar fascia	GT 2	Sweep	1 minute
Between Metatarsal bones	GT 6	Swivel-Frame	1 minute

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Table 2. Baseline variables: Demographics, Outcome Measures Selected Physical Impairments

		Group I (ESWT+SEs) (n=23, feet=29)		Group II (GT®+SEs) (n=23, feet=29)		CG (SEs) (n=20, feet=23)		P
		Mean ± SD n-%	Median	Mean ± SD n-%	Median	Mean ± SD n-%	Median	
	Age (year)	47.26±9.76	49	49±12.17	51	43.60±13.65	41.5	.328*
Gender	Female	7	30.40%	9	39.10%	12	60.00%	.136#
	Male	16	69.60%	14	60.90%	8	40.00%	
	BMI (kg/cm²)	28.93±4.12	28.69	28.30±3.81	29.23	28.40±5.04	27.52	.871*
	Symptom duration (month)	29.57±37.45	12	40.57±36.08	36	23.45±14.03	22	.204*

Abbreviations: BMI, Body Mass Index, CG: Control Group.

**One way ANOVA, #Chi Square Test*

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Table 3. Comparison of pain intensity, foot function index, quality of life and kinesiophobia between groups

Assessment	pretreat	posttreat	P*	rANOVA					follow-up (8-week)	P*	rANOVA				
	Mean (SD)	Mean (SD)		Effect size	F	P**	LSD		Mean (SD)		Effect size	F	P**	LSD	
							Gr.	P***						Gr.	P***
Pain Intensity (cm)															
VAS-Initial Step															
Gr I (ESWT+SEs) (n=23, f=29)	7.80 (1.49)	3.91 (2.60)	<.001	2.61	1.00	.372	-	-	4.00 (2.54)	<.001	2.55	1.87	.161	-	-
Gr II (GT®+SEs) (n=23, f=29)	7.71 (1.65)	3.62 (2.40)	<.001	2.47					3.76 (2.29)	<.001	2.39				
CG (SEs) (n=20, f=23)	7.22 (1.73)	5.36 (1.75)	<.001	1.07					5.18 (2.45)	<.001	1.17				
VAS-Activity															

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Gr I (ESWT+SEs) (n=23, f=29)	8.13 (1.68)	4.50 (2.53)	<.001	2.16						4.00 (2.78)	<.001	2.45				
Gr II (GT®+SEs) (n=23, f=29)	7.12 (2.53)	4.58 (2.42)	<.001	1.03	2.79	.067	-	-		3.45 (2.18)	<.001	1.45	1.26	.288	-	-
CG (SEs) (n=20, f=23)	6.53 (1.98)	3.81 (1.65)	<.001	1.37						3.83 (2.43)	<.001	1.36				
Foot Function Index																
Gr I (ESWT+SEs) (n=23, f=29)	50.63 (16.81)	35.26 (18.31)	<.001	0.91			1-2	.435		33.54 (20.82)	<.001	1.01				
Gr II (GT®+SEs) (n=23, f=29)	48.60 (18.82)	30.69 (18.76)	<.001	0.95	3.15	.048	1-3	.092		28.93 (17.26)	<.001	1.04	2.75	.07	-	-
CG (SEs) (n=20, f=23)	58.24 (16.84)	42.41 (16.87)	<.001	0.94			2-3	.016		37.71 (20.48)	<.001	1.21				
Quality of Life																
PCS-12																
Gr I (ESWT+SEs) (n=23, f=29)	38.73 (11.65)	41.38 (9.66)	.048	0.22			-	-		41.55 (9.17)	.068	0.24			-	-

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Gr II (GT®+SEs) (n=23, f=29)	40.35 (10.87)	42.98 (10.35)	.013	0.24						44.26 (9.74)	.027	0.35				
CG (SEs) (n=20, f=23)	36.48 (8.36)	38.77 (9.00)	.118	0.27	1.23	.29				40.67 (10.14)	.027	0.50	1.27	.28		
MCS-12																
Gr I (ESWT+SEs) (n=23, f=29)	46.00 (10.10)	45.64 (11.41)	.882	0.03						48.18 (9.28)	.199	0.21				
Gr II (GT®+SEs) (n=23, f=29)	45.59 (9.72)	46.51 (10.16)	.586	0.09	.12	.88	-	-		51.35 (11.19)	.005	0.59	.49	.61	-	-
CG (SEs) (n=20, f=23)	42.07 (8.31)	47.87 (9.54)	.004	0.69						46.50 (12.17)	.045	0.53				
Kinesiophobia																
TSK																
Gr I (ESWT+SEs) (n=23, f=29)	41.89 (4.10)	40.82 (3.93)	.288	0.26			-	-		41.10 (5.45)	.330	0.19			-	-

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Gr II (GT®+SEs) (n=23, f=29)	42.00 (5.00)	41.37 (5.72)	.309	0.12	.35	.70			40.89 (5.00)	.123	0.22	.27	.75		
CG (SEs) (n=20, f=23)	42.80 (4.70)	41.34 (5.29)	.106	0.31					42.15 (5.32)	.362	0.13				

Abbreviations: cm, centimeter; LSD, least significant difference; Gr, Group; f, feet; MCS, Mental Component Score; PCS, Physical Component Score; SD, standard deviation; TSK, Tampa Scale for Kinesiophobia, VAS, Visual Analogue Scale, CG: Control Group.

*Paired sample t-test; significance level set at <.05.

Repeated measures analysis of variance (rANOVA); significance level set at <.05. * Significance was accepted as $P^{**}=.05/3=.016$.

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Table 4: Comparison initial step pain between groups at 6-month.

Assessment	pre treat.	post treat.	P*	rANOVA				follow-up (8-week)	P*	rANOVA				follow-up (6-month)	P*	rANOVA				
	Mean (SD)	Mean (SD)		F	P**	LSD		Mean (SD)		F	P**	LSD		Mean (SD)		Effect size	F	P**	LSD	
						Gr	P**					Gr	P**						Gr	P***
VAS-Initial Step (cm)																				
Gr I (ESWT+SEs) (n=21, f=27)	7.75 (1.53)	4.01 (2.64)	<.001					4.18 (2.51)	<.001					3.48 (2.63)	<.001	2.79				
Gr II (GT®+SEs) (n=21, f=29)	7.71 (1.65)	3.62 (2.40)	<.001	.52	.593	-	-	3.76 (2.29)	<.001	.22	.796	-	-	2.06 (2.26)	<.001	3.42	2.20	.117	-	
CG (SEs) (n=18, f=23)	7.08 (1.57)	5.19 (1.66)	<.001					4.99 (2.45)	<.001					2.78 (2.41)	<.001	2.73				
Foot Function Index																				

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Gr I (ESWT+SEs) (n=21, f=27)	52.03 (15.77)	36.34 (18.14)	<.00 I					35.00 (20.69)	<.00 I					35.17 (24.20)	<.00 I	1.06			1- 2	.00 2
Gr II (GT®+SEs) (n=21, f=29)	48.60 (18.82)	30.69 (18.76)	<.00 I	1.9 7	.14 5	-	-	28.93 (17.26)	<.00 I	.49 3	.61 3	-	-	13.15 (12.95)	<.00 I	1.88	6.3 3	.00 3	1- 3	.73 6
CG (SEs) (n=18, f=23)	56.55 (17.18)	40.14 (16.33)	<.00 I					34.97 (19.86)	<.00 I					27.84 (21.63)	<.00 I	1.67			2- 3	.00 7

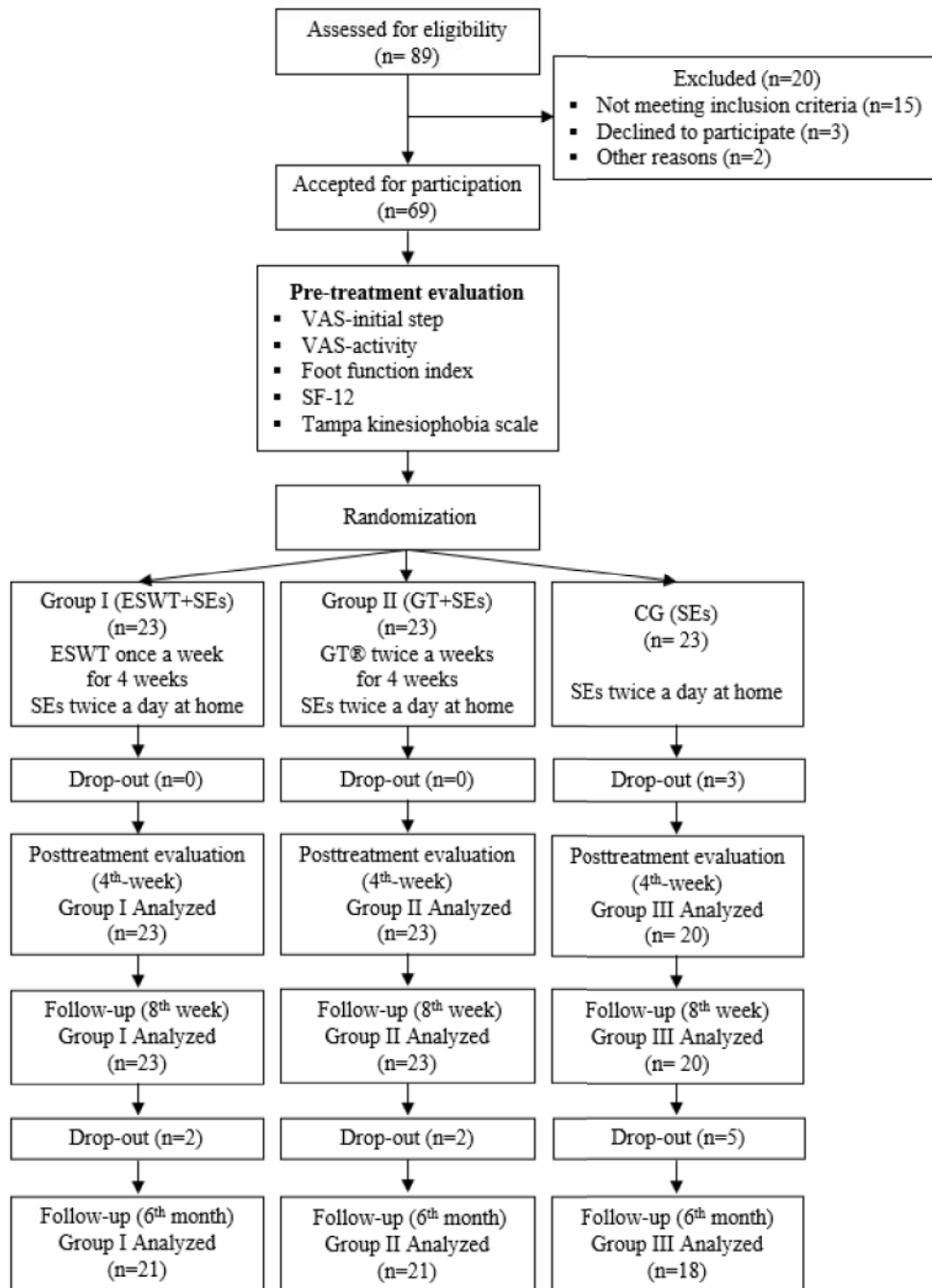
Abbreviations: pretreat, pretreatment; postreat., posttreatment; LSD, least significant difference; SD, standard deviation; VAS, Visual Analogue Scale, cm, centimeter; Gr, Group; f, feet; CG, Control Group.

*Paired sample t-test; significance level set at <.05.

Repeated measures analysis of variance (rANOVA); significance level set at <.05. * Significance was accepted as P**=.05/4=.0125.

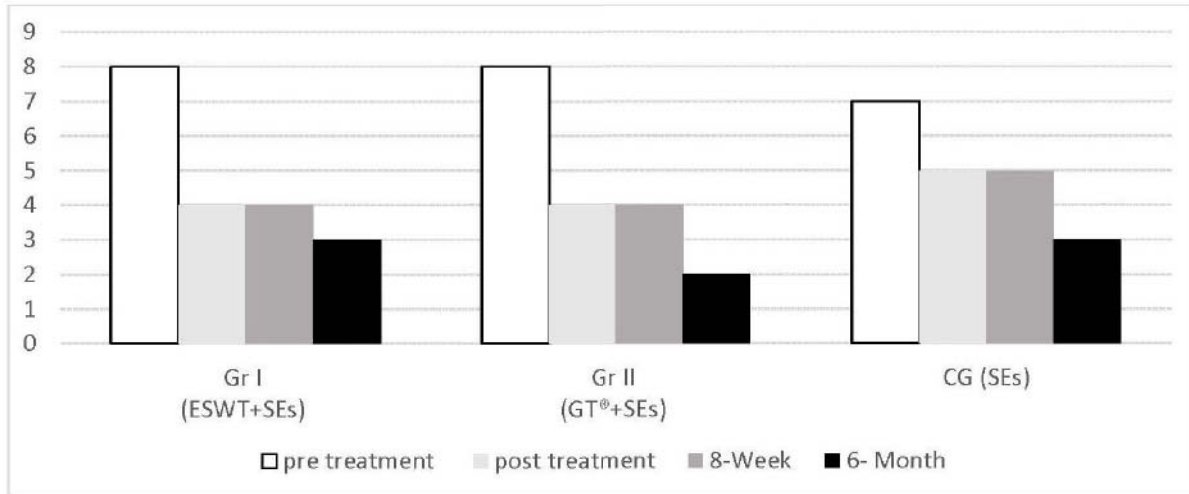
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Figure 1. Flow diagram of the study



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Figure 2: Comparison initial step pain between groups at 6-month



Visual Analogue Scale (VAS)-Initial Step (cm)

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Figure 3: Comparison foot function index between groups at 6-month

