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Original Research

Sport injury prevention in individuals with chronic ankle instability: Fascial Manipulation® versus control group: A randomized controlled trial

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Abstract

Chronic ankle instability (CAI) is one of the most common syndrome that occurs following an initial ankle sprain. Sprains are often correlated with recurrent sprains, loss of range of motion (ROM) and deficits in proprioception and postural control. The objectives were to evaluate the effectiveness of Fascial Manipulation® (FM) as a preventative measure in semi-professional athletes with CAI, and monitor symptomatology, equilibrium and ROM of the injured ankle.

A single-blinded randomized controlled trial was conducted in the rehabilitation department of a medical centre. Twenty-nine semi-professional male footballers were recruited. Nine subjects, with no previous symptomatology, were assigned to a baseline group, twenty symptomatic subjects were randomized into either study or control group. All three groups followed a specific training program. The control group followed normal training protocols and received standard medical care. The study group received an additional three FM treatment sessions.

Symptomatology, ROM outcomes were recorded for all players at baseline, before each treatment for the treatment group, and at 1, 3, and 6 months follow-ups. At one year, an additional follow-up on was performed via phone.

Four severe ankle traumas and one mild ankle trauma were reported in the control group during the trial period. The 6 months outcomes in the study group showed statistically significant improvements. The 1-year follow-up reported the absence of any reported trauma in the study group.

FM was effective in improving ROM, and symptomatology in footballers with CAI. FM intervention was effective in preventing injury in the study sample.

Keywords: Fascial Manipulation; Sport injury; Prevention

1 Introduction

The United States of America National Collegiate Athletic Association (NCAA) injury surveillance system reviewed the type of injuries resulting from the practice of fifteen sports with ankle sprains being the most frequent type of injury (Gerber et al., 1998; Hootman et al., 2007; Beynnon et al., 2001). The activities associated with a high risk of ankle injury included team sports played on a field in open air or indoors where play involved contacts, jumps and directional changes (Janssen, 2016; Attenborough et al., 2014). The highest rate of sprains occurs in football (soccer) with a calculated 61% mean of players affected (Fong et al., 2007; Ekstrand and Tropp, 1990; Walls et al., 2016). Nineteen percent of ankle injuries are recurrent with 61% of footballers presenting with more than one distortion (Arnason et al., 2004; Kofotolis et al., 2007; Putukian et al., 1996; Kofotolis et al., 2007, 2007). This type of injury is responsible for a substantial number of days of absence from sporting activities (Bahr and Reeser, 2003; Fernandez et al., 2007). Around one third of the total costs related to sports injuries are caused by ankle trauma (Verhagen et al., 2000) with the ankle being the most commonly injured area of the body (Fong et al., 2007; Ekstrand and Tropp, 1990). In the Netherlands, it is estimated that 1.5 million acute sports injuries occur each year in a sporting population of 7,950,000 athletes (Schmikli et al., 2009) (Schmikli et al., 2009). In another study, a total of 120,000 ankle sprains were registered of which 43,000 (36%) required medical treatment for an estimate annual cost of €43,200,000 (Verhagen et al., 2005) highlighting the financial burden of this condition on healthcare systems worldwide.

There is strong evidence that, following an initial ankle sprain, athletes are at doubled risk of incurring another sprain especially during the first year post trauma (Fernandez et al., 2007; Bahr and Bahr, 1997; Ekstrand and Tropp, 1990; Milgrom et al., 1991; Verhagen 2004). Even though the acute symptoms of a sprain resolve rapidly, between 20 and 50% of patients report persistent problems such as pain and instability (Ekstrand and Tropp, 1990; Guillo et al., 2013). Gerber et al. (1998) state that between 30 and 40% of patients with a history of ankle sprain report recurrent sprains or residual symptoms of instability (Verhagen et al., 1995; Schaap et al., 1989). A Cochrane review states that up to 20% of individuals will develop chronic ankle instability (CAI) secondary to an initial sprain (De Vries et al., 2011). The symptoms more commonly encountered with CAI include: sensation of the ankle “giving way” (Trevino et al., 1994; Konradsen et al., 2002; Liu and Jason, 1994; Tropp, 2002), mechanical instability (Konradsen et al., 2002; Tropp, 2002; Eiff et al., 1994; Hintermann, 1999), pain and swelling (Liu and Jason, 1994; Hintermann, 1999; Ng and De, 2007; Freeman et al., 1965), loss of strength (Kaminski and Hartsell, 2002), recurrent sprains (Konradsen et al., 2002; Hintermann, 1999; Garn and Newton, 1988; Vaes et al., 2001; Löfvenberg et al., 1994), functional instability (Eiff et al., 1994; Fong et al., 2007), sense of insecurity when running or walking and/or the presence of pain sometimes also not associated with traumatic episodes (Monaghan et al., 2006).

Prevention plays an important role in the field of sports. The literature supports prevention as the best treatment in high-level CAI athletes even though there is no defined gold standard (Janssen, 2016). Neuromuscular training was effective in the short term for CAI but the long-term effects of this intervention remain unclear (deVries et al., 2011). The lack of a gold standard can be noted in the contrasting advice given by two recent guidelines. Martin (2013) indicated that clinicians should include the following procedures: manual therapy aimed at increasing dorsiflexion of the ankle, proprioception and weight-bearing exercises in patients recovering from a lateral sprain. On the other hand, Roosen (2013) did not recommend manual therapy in the treatment of acute ankle sprain due to very low levels of evidence and weak strength of recommendations. However, both guidelines support, with moderate levels of evidence, therapeutic exercises that are commonly administered through rehabilitation protocols aimed at increasing proprioception through balance board, ankle discs, and wobble boards. Athlete compliance when executing the rehabilitation protocols is of primary importance to ensure effectiveness of intervention (Janssen, 2016). The average time required to implement preventative interventions varies from 20 to 30 min with repetitions three times weekly or daily for around nine weeks (Barengo et al., 2014). However, recovery times often do not align with the competitive needs of athletes in need of a short-term recovery. This highlights the need to investigate treatment approaches with faster recovery times, and more efficient therapeutic protocols, meeting the demands of patients on training programs or following a regular sporting activity. A recent study show how Fascial Manipulation® (FM) can shorten rehabilitation times (Branchini et al., 2015). A 2011 study demonstrated that FM, with a focused treatment over the retinacula, improved stabilometrical platform values at three and six months follow-up and improve clinical outcomes in patients with CAI (Stecco et al., 2011). For this reason, it was decided to design a single blind randomized controlled trial to evaluate whether three treatment sessions with FM had an impact on the clinical outcomes of CAI in semi-professional footballers and if this approach changed the natural course of the condition especially for the incidence of injury post-treatment.

2 Materials and methods

2.1 Study design

A single blinded randomized controlled trial consisting of three groups: study (SG), control (CG) and baseline (BG) was designed. Randomization into the SG and CG was performed only for eligible subjects with CAI. The BG was used as a comparative to SG and CG for the outcomes of the trial. Each subject signed the informed consent to participate in the trial that was approved by the Ethics Committee of the University of Padova (2965P 19, August 2013) and followed the principles of the Helsinki's declaration. The trial registration number issued by ClinicalTrials.gov was PADOVA_08072013. Within this trial, a previous study was conducted to evaluate the quality of the connective tissue around the ankle in young athletes and a control group via ultrasonography (Stecco et al., 2015).

2.2 Participants

Thirty-two semi-professional male athletes from three Italian football teams were recruited from April to June 2015. The participants were recruited after the approval of each team's coach. Out of the thirty-two subjects, twenty-nine completed the trial, three were not recruited for organizational reasons, and two were lost at follow-up. The twenty subjects meeting the inclusion criteria and presenting symptoms attributed to CAI were randomized. A

further nine subjects referring no previous symptomatology in the lower limbs were recruited and assigned to the BG. All twenty-nine participants were active semiprofessional athletes performing three workouts of at least 2 h per week. To recruit the semi-professional foot ballers, the athletes were individually interviewed after the approval of the team's coach. The study included only males with a mean age of 29 years old (± 8.58), a mean weight of 76 kg (± 12) and a mean height of 179 cm (± 6.6).

All subjects followed a training program over four weeks in complete autonomy at their respective training centers. The program was the standardized annual training protocol used at the start of the sports season that all the three football clubs followed. The workout had a duration of about 120 min divided in 45 min dedicated to running, 55 min for specific activities for athletic movement, including kicking, jumping, exercises using Freeman tables and exercises to increase muscle strength: 25 min for muscle stretching activities of posterior chain, quadriceps femoris muscle and adductors muscles.

2.3 Inclusion and exclusion criteria

The score on the activities of daily living (ADL) of the “Foot and Ankle Ability Measure” (FAAM-I) ([Martin, 2005](#)) was used as an inclusion criterion. The questionnaire was administered during the initial consultation to recruit a sample of subjects presenting functional limitations to the ankle-foot region. The other inclusion criteria for the study and control group were: history of traumatic ankle sprain (unilateral or bilateral) in the last 5 years with more than one week of prognosis and a score lower than 84 points on the FAAM-I questionnaire of ADL. Exclusion criteria were: concurrent orthopedic or neurological pathology, history of fractures in the last 3 years, surgical intervention in the lower limbs and changes in pharmacological therapy in the last 4 weeks. Subjects were excluded from the study at the time of injury and no more data were collected from participants after the injury. However, the relevant data collected up to the injury were included in the analyses.

For the BG, the inclusion criteria were: no previous history of ankle disorders in the previous 5 years, with maximal score obtainable (84 points) on the ADL of the FAAM-I questionnaire. This group had the same exclusion criteria as the SG and the CG. The interruption criteria for the trial included decision of the subject to withdraw from the trial, any additional physiotherapeutic intervention to those initially intended and starting or changing any pharmaceutical therapy during the trial period.

2.4 Randomization and blinding

At baseline (T0), the twenty participants with CAI were randomized in the SG or CG by a physiotherapist (PT) (PT A, with more than 5 years' experience in FM) through a multiplicative congruential generator of Lehmer. After randomization, the SG and CG had ten subjects each, the baseline group had nine subjects. All subjects were evaluated by a physiotherapist (PT B, with one-year experience in FM and in his last year of physiotherapy school) who was blinded to the subjects' group allocation. The blinding of PT B was ensured through clinic procedures: upon arrival the subjects were directed to PT B who evaluated all the participants at T0 and at all other contact times. After completing the evaluation, PT B sent the subjects back to reception. The receptionist, who was aware of treatment allocation, directed the subjects to either the treatment room if the subject was part of the SG or fixed the following appointment if the participant was randomized in the CG. The treatment was carried out by PT C (with one-year experience in FM and in his last year of physiotherapy school) in a different treatment room to avoid unblinding of PT B. Additionally, PT B and PT C agreed that no exchange of information should occurred between themselves during the length of the trial.

2.5 Intervention

Each subject in the treatment group received three sessions lasting 45 min each during the pre-seasonal training time. Treatment was provided by the same physiotherapist (PT C) at weekly intervals over three weeks. The technique involves deep friction over specific points mapped by Luigi Stecco named Centre of Coordination (CC) and Centre of Fusion (CF) ([Stecco and Stecco, 2004](#)). Thirty percent of muscle fibers merge in the surrounding connective tissue through myofascial expansions and do not reach the tendon of that muscle ([Huijing and Baan, 2008](#)). It has been recognized that synergic muscles are belong to the same fascial lodge ([Stecco et al., 2015](#)). Hence the myofascial expansions from synergic muscles activation would traction the same fascial sheath. It is hypothesized that the mechanical traction of the myofascial expansions resulting from the activation of synergic muscles creates a convergent force over a specific location of the fascia corresponding to the CC and CF.

The FM treatment modality has commonalities with other techniques using deep friction manipulation. Whilst the treatment modality can be compared to other techniques, the reasoning process for the choice of point to be treated presents major differences. The points are selected after a specific assessment process involving clinical history taking, a clinical examination of specific movements as well as palpatory verifications ([Day et al., 2012](#); [Pintucci et al., 2017](#)). During the clinical history, segments of dysfunction are identified with an emphasis on the chronology to allow for the development of a treatment hypothesis based on the current symptomatology of patients and previous musculoskeletal events, which may be causing compensations. The selection of points to treat is guided by the assessment chart (FM chart) ([Pintucci et al., 2017](#)). The choice of point is based on the information collected through the chart, movement verifications, patient pain rate and radiation and subjective presence of “densification” by the clinician to limit the overall clinician's subjectivity in the decision process. The treatment must be performed over specific areas (CCs and CFs) that are anatomically safe and do not overlie major superficial nerves and veins. Additional guidance for point selection includes avoiding the patients' excessively painful areas where inflammation, lesions or even fractures could be present and absolute contraindications as thrombosis, phlebitis, skin lesions and fever ([Stecco and Day, 2010](#)). The manipulation of these specific points aims at restoring the gliding of the underling tissue layers

(Cowman et al., 2015). It is hypothesized that the long-lasting effect of FM (Branchini et al., 2015; Ćosić et al 2014; Pratelli et al., 2015; Stecco et al., 2014; Guarda-Nardini et al., 2012; Picelli et al., 2011) is mostly due to the rationality of the selection of the points rather than the manipulation itself.

In this trial, it was decided to limit the selection of treated CCs and CFs to the lower limbs only (below the iliac crest) and the contralateral pelvis. If both lower limbs were injured, the most symptomatic side was treated. Despite this approach limiting the potential of the method, it was considered to adequately focus treatment options and increase reproducibility of this study's findings.

2.6 Outcome measures

Outcomes were measured at baseline (one or two days before starting the pre-seasonal training), before each treatment and at follow-up at 1, 3, 6 months. In addition, a phone interview was conducted at 1-year follow-up where all subjects were asked the total number and location of ankle sprains suffered over the last year. The range of motion (ROM) was measured using a universal goniometer with two arms, according to the methodology reported by Boone et al., in 1978. The CAI symptoms of the athletes were measured with the FAAM-I scale validated in Italian (Martin, 2005). This outcome measure is composed of 29 items divided into two subscales: the subscale of ADL including 21 items and the subscale of sport including 8 items. The maximal possible functional level is 84 points for ADL and 32 points for the "SPORT" module. At the end of the questionnaire the patient is asked to indicate for each module the relative percentage of functional capabilities with 0% being total incapacity and 100% being the state prior injury.

2.7 Statistical analysis

Data were collected in excel sheet database. The software SPSS Statistic 22 was used for analysis. Statistical analyses were performed to evaluate differences between groups at each measuring time (mean \pm SD). Statistical significance was reached for p values $<$.05. Descriptive statistics were used to examine the differences in outcome measures between groups. Inferential statistics were used to investigate the homogeneity of groups at baseline. Repeated measure analysis of variance (ANOVA) was conducted to evaluate the null hypothesis. The Bonferroni post hoc test, for follow-up comparisons, was performed to evaluate pairwise differences.

2.8 Power calculations

A power analysis was conducted before the study to determine the appropriate sample size. The α level was set a priori at $P = .05$, and power was set at 80%. Effect size was estimated at 1.23, which was calculated based on previous strength literature of incidence of CAI (Docherty et al., 1998; Holme et al., 1999). The result of the power analysis indicated that 11 participants per group would provide sufficient power.

3 Results

The study included only males with a mean age of 29 years old (± 8.58), a mean weight of 76 Kg (± 12) and a mean height of 179 cm (± 6.6). Fig. 1 illustrates the flow chart of the subjects in this trial.

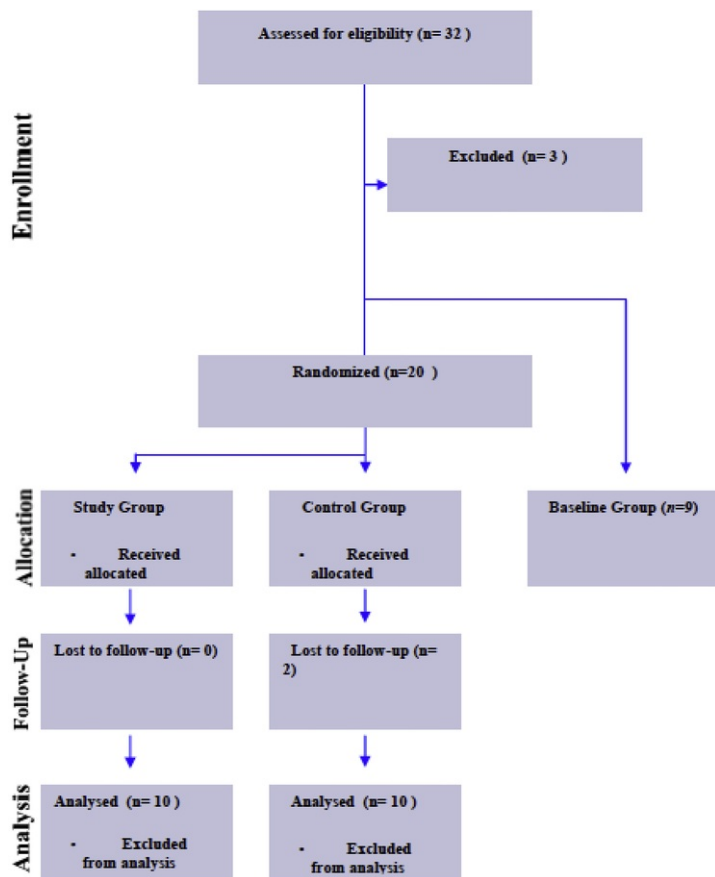


Fig. 1 Flow chart of the subjects.

alt-text: Fig. 1

The SG and CG were homogeneous at baseline for basic characteristics: age, weight, number of ankle sprain in the last five years and in FAAM-I ADL score (see [Table 1](#)).

Table 1 Baseline values for measured outcomes. $\alpha = * < 0.05$; $** < 0.001$; $*** < 0.0001$; SG: study group; CG: control group; SD: standard deviation.

alt-text: Table 1

Variable	Mean (S.D.)	Mean (S.D.)	Mean (S.D.)	Test Fisher Snedecor		
	SG	CG	BG	SG/CG	CG/BG	BG/SG
Age (<i>n</i>)	28.4 ± 10	30.4 ± 6.72	28 ± 8.8	.58	.44	.73
Weight (<i>Kg</i>)	75.8 ± 15.3	76.55 ± 7.37	75.4 ± 7.7	.07	.89	.07
Height (<i>cm</i>)	177.4 ± 7.5	179.6 ± 6.11	179.8 ± 5.8	.001	.001	.48
Dominant foot (<i>n</i>)						
Right	9	9	6			

Left	1	1	3			
Ankle sprain (<i>n</i>)	3.2 ± 2.2	2.1 ± 2.2	0.4 ± 0.5	.42	.73	.19
Side of symptoms (<i>n</i>)						
Right	9	8	6			
Left	1	2	3			
Ankle sprain in last five years (<i>n</i>)				.39	.81	
Yes	10	10	0			
No	0	0	9			
FAAM-I ADL (<i>n</i>)	75.2 ± 5.6	75.1 ± 9.7	84 ± 0.0	.12		

α = * < 0.05; ** < 0.001 *** < 0.0001 SG: study group; CG: control group; BG: baseline group S.D. = standard deviation; FAAM-I: Foot and Ankle Ability Measure, ADL subscale and SPORT subscale.

However, the basic characteristics were not homogeneous at baseline between SG/CG and CG/BG for the height of the subjects ($p < .005$).

Five injuries were reported during the length of this trial and all of them occurred in the CG. One injury was mild and resolved with six days of rest, hence this subject was not excluded from the trial. Four were classified as severe injuries that required medical and physiotherapy interventions (Stubbe et al., 2015). Table 2 reports the number of points, mean and standard deviation treated for each subject.

Table 2 Number of point treated for every patients of SG. SG: study group; SD: standard deviation.

alt-text: Table 2

Participants SG	Points Treated			
	T0	T1	T2	Mean ± SD
1	5	9	9	7.7 ± 2.3
2	6	10	13	9.7 ± 3.5
3	5	8	9	7.3 ± 2.1
4	7	10	8	8.3 ± 1.5
5	6	8	9	7.7 ± 1.5
6	7	11	8	8.7 ± 2.1
7	7	8	7	7.3 ± 0.6
8	8	10	11	9.7 ± 1.5
9	5	8	10	7.7 ± 2.5
10	7	12	9	9.3 ± 2.5
				8.3 ± 0.8

SG: study group; T0: first treatment; T1: second treatment; T3: third treatment.

Table 3 report the statistical analysis for each outcomes within group. An ANOVA was conducted to evaluate the null hypothesis for changes in subjects' ROM and symptoms (FAAM) when measured at baseline and follow-up. Mauchly's test indicated that the assumption of sphericity had been violated, therefore degrees of freedom were corrected using Greehouse-Geisser (epsilon was <.75), as recommended by Girden in 1992. Follow-up comparisons, Bonferroni post hoc test, indicated that pairwise difference was significant (see Table 3) for the SG in most of the ROM values after 1, 2, 3 treatments as well as at 3, 6 months follow-up of ROM and at 1 year phone interview.

Table 3 Repeated Measures ANOVA for scale FAAM-I and range of motion. $\alpha = * < 0.05$; $** < 0.01$ $*** < 0.001$ SG: study group; CG: control group; BG: baseline group T0: beginning; T1: one week; T3: two week; T4: one month; T5: six month; FAAM-I: Foot and Ankle Ability Measure, ADL subscale and SPORT subscale.

alt-text: Table 3

Variable			Greenhouse-Geisser			Post hoc tests using Bonferroni Correction														
						T0/T1			T0/T2			T0/T3			T0/T4			T0/T5		
			Between-subjects	Within-subjects	SG/CG	Between-subjects	Within-subjects	SG/CG	Between-subjects	Within-subjects	SG/CG	Between-subjects	Within-subjects	SG/CG	Between-subjects	Within-subjects	SG/CG	Between-subjects	Within-subjects	SG/CG
Dorsiflexion (°)	Active	R	.004**	.407	.079	.99	.99	.99	.123	.99	.99	.33	.99	.99	.055	.99	.369	.277	.99	.99
		L	.002**	.749	.006**	.99	.99	.841	.031	.99	.334	.061	.99	.092	.351	.99	.088	.99	.99	.99
	Passive	R	.001***	.490	.001***	.042	.99	.028	.001***	.99	.003**	.004**	.99	.003*	.001***	.99	.001***	.001***	.99	.001***
		L	.001***	.449	.001***	.027	.99	.001***	.011*	.99	.003**	.011*	.99	.001***	.017*	.99	.021*	.017*	.99	.017*
Plantar flexion (°)	Active	R	.003**	.520	.002**	.007	.99	.604	.001***	.99	.003**	.002**	.99	.006**	.005**	.99	.138	.022*	.99	.594
		L	.013	.371	.525	.99	.99	.99	.267	.99	.99	.117	.99	.99	.295	.99	.99	.316	.99	.99
	Passive	R	.001***	.490	.001***	.094	.99	.202	.001***	.99	.001***	.029*	.99	.008**	.013*	.99	.075	.056	.99	.105
		L	.013	.449	.685	.99	.99	.99	.267	.99	.99	.117	.99	.99	.295	.99	.99	.316	.99	.99
Passive Pronation (°)	R	.001***	.178	.001***	.99	.99	.549	.258	.99	.258	.097	.976	.009**	.006**	.99	.001***	.006**	.705	.001***	
	L	.001***	.061	.001***	.041	.815	.002**	.021*	.250	.001***	.034*	.99	.005*	.070	.99	.009**	.070	.99	.01*	
Passive Supination (°)	R	.008**	.212	.002**	.056	.545	.002**	.039*	.99	.023*	.038*	.99	.007**	.496	.99	.388	.198	.99	.263	
	L	.001***	.640	.002**	.132	.99	.431	.010	.99	.054	.027*	.99	.019*	.01*	.99	.015*	.047*	.99	.081	
Passive Adduction (°)	R	.003**	.644	.003**	.358	.99	.323	.101	.99	.097	.077	.99	.033*	.364	.99	.343	.198	.99	.291	
	L	.001***	.575	.002**	.99	.99	.99	.019*	.99	.112	.084	.99	.126	.114	.99	.157	.117	.99	.310	
Passive Abduction (°)	R	.001***	.272	.001***	.507	.99	.99	.033*	.99	.064	.013*	.99	.015*	.014*	.99	.019*	.067	.99	.111	
	L	.031	.575	.038	.99	.99	.99	.585	.99	.654	.944	.99	.475	.99	.99	.538	.99	.99	.505	
FAAM-I ADL (n)			.023	.330	.750	.585	.99	.99	.926	.99	.99	.439	.930	.99	.374	.99	.99	.356	.876	.99
Self-assessment ADL (%)			.066	.779	.251	.814	.99	.99	.399	.99	.99	.567	.99	.99	.761	.99	.99	.703	.99	.99
FAAM-I SPORT (n)			.001***	.136	.099	.079	.19	.99	.016*	.680	.99	.23	.810	.99	.013*	.99	.99	.008**	.99	.99
Self-assessment SPORT (%)			.001***	.627	.064	.079	.99	.99	.016*	.99	.693	.023*	.99	.695	.013*	.99	.99	.008**	.99	.975

Statistical significance was achieved and maintained at evaluation times and up to the 6 months' follow-up for the following specific ROM directions: right passive dorsiflexion; left passive pronation. Right active plantarflexion reach the statistical difference at T0-T2 and T0-T3; while right passive pronation reach the statistical difference at T0-T3, T0-T4 and T0-T5. Right passive supination reach the statistical significant difference at T0-T1, T0-T2 and T0-T3 and T0-T3 and T0-T4 on the left side. Right passive abduction was statistical significant different at T0-T3 and T0-T4.

The between groups analysis for ROM and FAAM-I scale at T1, T2, T3, T4, T5, in the SG achieved statistical significance at evaluation time and up to the 6 months' follow-up for the passive dorsiflexion both right and left, active right and left plantarflexion. The FAAM-I SPORT reported a significant statistical improvement in all the evaluation except the T0-T1, while the self-assessment SPORT reach the statistical significance at T0-T2 and T0-T3.

4 Discussion

This is the first randomized controlled trial evaluating the effectiveness of FM as a preventative measure in the semiprofessional athlete with CAI. The results obtained in this trial are otherwise similar to those currently reported in the literature (Stecco et al., 2011) and the prevalence of altered CCs and CFs being present in subjects with a history of ankle sprains (Kalichman et al., 2016).

The five traumatic events of subjects randomized in the CG had an impact on data analysis. Four subjects exited the trial following severe trauma that prevented them from continuing competitive activities and required medical and physiotherapy treatments. Because the clinical conditions of these subjects were not compatible with the inclusion criteria of this trial, they were excluded from further analysis. A fifth subject, even though suffering from an ankle sprain, proceeded in the trial since the injury was mild, resolved within one week, and since no medical or physiotherapy interventions were necessary. This highlights the other ramifications of injury prevention including athletes missing the entire season leading to increased costs related to injury and loss of competitive play (Krist et al., 2013).

In this trial, 50% of the subjects in the control group (5 over 10) manifested mild or severe trauma requiring the interruption of competitive activities from a minimum of 6 days up to a maximum of the entire season. On the opposite, the subjects on the SG did not report any traumatic events, which allowed them to play for the entire season with increased physical abilities as reported in the follow up evaluations. For this reason, the null hypothesis was rejected and the data of this small trial support the hypothesis that this treatment could be effective in preventing injuries in semi-professional players.

The FAAM-I scale was a useful instrument in assessing the symptoms and functional abilities of the subjects of this study presenting with CAI. The intragroup analysis showed that SG reached a statistically significant improvement throughout the trial at each evaluation for most modules and at the 6-months follow-up. However, at T1 the module SPORT FAAM-I of the CG showed statistically significant worsening. From this study's data it could be hypothesized, with adequate caution considering the small sample size, that the pre-seasonal training program used after a rest period could have initially worsened the ankle parameter of the subjects. The athletes undergoing FM treatment had an opposite trend to CG. These footballers reporting an increase in functional ratings and showed significant improvement after one treatment.

The intergroup analysis reached statistical significance for several components of range of motion and was highly significant in passive right dorsiflexion where the majority of the players had CAI (see Table 4).

Table 4 Descriptive and Inferential statistics (intergroup) of ROM and FAAM. SG: study group; CG: control group; BG: baseline group T0: beginning; T1: one week; T3: two week; T4: one month; T5: six month; FAAM-I: Foot and Ankle Ability Measure, ADL subscale and SPORT subscale.

alt-text: Table 4

Time rilevation			Test F di Fisher-Snedecor				Wilcoxon-Mann Whytney [ranksum-test]								
			T0				T3			T4			T5		
Variable			Mean (S.D.) SG	Mean (S.D.) CG	Mean (S.D.) BG	p SG/CG	Mean (S.D.) SG	Mean (S.D.) CG	P value	Mean (S.D.) SG	Mean (S.D.) SG	P value	Mean (S.D.) SG	Mean (S.D.) CG	P value
Dorsiflexion (°)	Active	R	15.8 ± 2.7	17 ± 3.09	20 ± 4.74	.69	19.30 ± 3.47	16.44 ± 3.68	.0784	19.60 ± 2.50	16.67 ± 3.84	.1351	18.90 ± 1.66	15.5 ± 3.30	.0196
		L	15.9 ± 3.25	16.10 ± 4.33	20.89 ± 3.59	.40	20.70 ± 3.02	16.44 ± 4.19	.0247	19.40 ± 2.88	16.78 ± 3.67	.1483	18.50 ± 1.84	16 ± 3.66	.1301
	Passive	R	11.2 ± 3.52	13.5 ± 2.68	16.78 ± 2.86	.43	18.40 ± 2.95	15.67 ± 3.20	.046	19.20 ± 2.74	15.67 ± 3.20	.0189	18.70 ± 1.89	15.5 ± 3.30	.0299
		L	12.7 ± 3.8	14.20 ± 3.16	17.44 ± 5.48	.59	20.00 ± 2.36	16.22 ± 4.02	.012	19.10 ± 1.66	15.89 ± 3.44	.0245	18.90 ± 1.91	15.13 ± 3.14	.0099
Plantar flexion (°)	Active	R	33.2 ± 5.88	38.6 ± 6.57	41.11 ± 9.2	.75	43.50 ± 6.26	39.44 ± 3.91	.0786	42.00 ± 6.75	38.89 ± 5.46	.3297	40.50 ± 6.43	37.88 ± 4.52	.3961
		L	34 ± 11.1	43.5 ± 8.51	44.44 ± 8.46	.44	43.00 ± 4.83	38.89 ± 4.86	.1184	42.50 ± 6.77	39.44 ± 5.83	.3253	41.50 ± 6.69	38.13 ± 5.30	.3177
	Passive	R	34.5 ± 6.43	37.4 ± 6.98	38.33 ± 9.68	.81	42.50 ± 5.40	38.89 ± 4.17	.0632	42.00 ± 6.75	37.22 ± 5.07	.1292	41.00 ± 7.38	38.5 ± 4.41	.2791
		L	36.3 ± 7.01	42.7 ± 8.92	41.11 ± 8.58	.48	42.00 ± 3.50	38.33 ± 5	.1209	41.00 ± 6.15	38.33 ± 5.59	.3292	41.00 ± 6.15	39.13 ± 4.97	.4597
Passive Pronation (°)	R	18.9 ± 7.19	20.5 ± 5.99	21.11 ± 7.41	.59	30.50 ± 6.43	27.56 ± 5	.1776	31.00 ± 5.16	26.67 ± 6.12	.1157	30.10 ± 5.61	27.5 ± 5.35	.5151	
	L	18.9 ± 8.44	22 ± 6.75	23.89 ± 7.82	.52	30.50 ± 4.97	27.56 ± 5.48	.2234	29.50 ± 4.38	27.56 ± 5.48	.4262	29.30 ± 4.40	28.13 ± 4.58	.6323	
Passive Supination (°)	R	23.8 ± 8.01	25.7 ± 4.76	29.44 ± 7.26	.14	34.50 ± 3.69	28.56 ± 4.61	.0123	31.50 ± 3.37	27.78 ± 4.41	.0878	31.50 ± 2.42	27.5 ± 3.78	.0362	
	L	24.3 ± 5.72	25.8 ± 5.22	25.56 ± 8.82	.79	33.50 ± 3.37	30 ± 5.59	.1832	33.50 ± 5.80	30 ± 6.12	.2798	32.30 ± 5.01	29.38 ± 6.23	.3474	
Passive Adduction (°)	R	20.7 ± 7.26	22.2 ± 8.92	22.22 ± 10.03	.55	31.00 ± 3.94	25.56 ± 6.82	.0683	28.00 ± 4.22	24.44 ± 6.82	.248	27.80 ± 4.16	24.63 ± 5.95	.3268	

	L	21.6 ± 5.85	22 ± 7.15	24.44 ± 7.75	.56	29.00 ± 4.59	23.89 ± 6.97	.0991	28.00 ± 4.22	23.56 ± 5.92	.1082	27.10 ± 3.31	24 ± 5.55	.2346
Passive Abduction (°)	R	22.8 ± 7.27	26.7 ± 3.8	26.11 ± 6.01	.07	34.50 ± 2.84	29.44 ± 6.35	.0644	33.00 ± 3.50	31.11 ± 6.51	.6582	30.50 ± 2.84	30.88 ± 6.24	.6027
	L	25.5 ± 5.99	26 ± 3.94	26.67 ± 7.07	.23	30.50 ± 3.69	29.78 ± 7.10	.8985	29.00 ± 3.16	30.22 ± 5.04	.3431	29.3 ± 3.71	29 ± 4.57	.8425
FAAM-I ADL (n)		75.2 ± 5.61	75.1 ± 9.72	84 ± 0	.12	81.00 ± 2.83	72.33 ± 8.03	.0135	80.50 ± 2.42	70.44 ± 0.19	.0403	80.10 ± 2.69	71.50 ± 7.46	.0106
Self-assessment ADL (%)		84.3 ± 16.38	85 ± 11.30	100 ± 0	.28	95.30 ± 6.73	83.89 ± 10.54	.0176	94.00 ± 6.15	84.44 ± 11.58	.043	93.50 ± 6.26	83.75 ± 8.35	.0118
FAAM-I SPORT (n)		22.7 ± 5.36	28.1 ± 4.12	32 ± 0	.45	29.60 ± 2.27	25.33 ± 5.36	.1216	29.40 ± 2.80	25.56 ± 5.36	.1579	29.00 ± 2.83	26 ± 4.24	.1471
Self-assessment SPORT (%)		78 ± 13.98	80.5 ± 20.34	100 ± 0	.28	92.00 ± 7.53	82.22 ± 12.28	.0677	90.70 ± 7.99	83.33 ± 11.73	.1498	91.00 ± 8.10	85 ± 8.86	.1182

The literature reports dorsiflexion as a key parameter for evaluating the improvement of ankle joint range of motion (Pope et al., 1998). It is also interesting to note that athletes in the BG, who reported a maximal score on the questionnaire, did not necessarily report better ROM compared the randomized athletes at intake (see Table 4).

The above results may be supported by recent studies on the ankle retinacula and the deep fascia. These are codified and defined as richly innervated structures of connective tissue that are also dedicated to force transmission, motor coordination and proprioception (Stecco et al., 2011). The improvement observed in the SG may be ascribed to the treatment of the fascial tissue not only in the symptomatic area, but also in the entire lower limb and contralateral pelvis. This is supported by Kondersen (2002) explaining how the sequelae of a traumatic event in the lower limb does not remain circumscribed to the affected side, but can generate disorders expanding on the contralateral side. Indeed 85% of subjects with CAI present with deficits that are clinically observable and reproducible in the opposite limb. For this reason, and by applying the guidelines of the FM method, it was decided to also treat the contralateral pelvis, even if asymptomatic, with the aim of restoring normal biomechanics and preventing the occurrence of future symptoms. This trial showed effectiveness of FM in decreasing rigidity and increasing ankle ROM (Cowman et al., 2015). FM intervention is based upon the principle of restoring gliding of the fascial plane and increasing joint ROM. This is obtained by normalizing the activation threshold of the mechanoreceptors located in the fascial tissue. Further studies are necessary to confirm this hypothesis and to reinforce the findings of this study considering the rather small sample size.

4.1 Limitations

This trial presents several limitations including lack of double blinding, small sample size in the three groups with ten participants in the study and control groups and nine participants in the baseline group. The analysis of the data did not respect the intention to treat.

5 Conclusion

The results suggest that FM is a valid approach in improving ROM and symptoms in the semi-professional athlete, suffering from CAI, suggesting that participation in the study group increase performance level. This trial indicates that this therapy could be considered for effective prevention of ankle injuries during the entire football season as well as for decreasing costs and loss of competitive play in athletes. Three treatment sessions of 45 min showed long-term improvements maintained at the 6 months' follow-up and prevented the interruption of sports activities at one year.

Data availability

Yes.

Consent

All the participant of the study subscribed a written consent to participate at the study.

Author contributions

Simone Brandolini, Giacomo Lugaresi, Antonio Santagata, collect all the data from the participants. Andrea Ermolao, Marco Ermolao, Aurélie Marchand, Antonio Stecco designed the study, evaluated the data and wrote the manuscript.

Competing interests

The authors Simone Brandolini, Giacomo Lugaresi, Andrea Ermolao, Marco Ermolao declare that there is no conflict of interest regarding the publication of this manuscript. Antonio Stecco, Aurélie Marie Marchand and

Antonio Santagata are members of the Fascial Manipulation Association. The Association is non-profit, with the objective of promoting and supporting research in the field of pain relief in general and in the field of anatomy and physiopathology of the fasciae.

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