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Author contributions

The different contributions of the team are described in more detail below:

Conceptualization: JMB, CTV; **Methodology:** DHG, CTV; **Software:** JMB; **Validation:** IBDF, ECM; **Formal analysis:** JMB, CGG; **Investigation:** IBDF, ECM; **Resources:** IBDF, ECM; **Data curation:** DHG, CGG; **Writing – Original draft:** CGG, CTV; **Writing – Review & Editing:** JMB, DHG; **Visualization:** DHG, CTV; **Supervision:** JMB; **Project administration:** JMB, DHG.

Dose-response of talus mobilizations in weight bearing ankle dorsiflexion ROM of the older adults with limited ankle mobility: A randomized controlled trial

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ABSTRACT

Background: Although manual therapy is an effective technique for increasing ankle range of motion, the dose-response required is unclear.

Objective: To find out what number of sessions of talus mobilizations will induce a detectable change in weight bearing ankle dorsiflexion range of motion of older adults with limited ankle mobility.

Design: Four-arm randomized clinical trial.

Setting: Community-dwelling.

Methods: 62 older adults; aged over 60; with ankle dorsiflexion ROM below 35 degrees. Four groups received from one to four treatment sessions. Each session consisted of 3 mobilizations of 30 seconds, with of the talus in anteroposterior glide, with a rest of 30 seconds. Grade IV mobilizations were applied to target the accessory movement of the ankle up to the resistance offered by periarticular tissues. The Lunge test was used to measure weight bearing ankle dorsiflexion.

Results: The four groups increased their ankle mobility after one session, but two sessions were needed to overcome the established 4.7 degrees' threshold, regardless of group. Only those participants who received four sessions maintained the improvements for 8 weeks.

Conclusions: Two sessions of talus mobilizations are effective in improving weight bearing ankle dorsiflexion ROM. It will be necessary to deliver four sessions of treatment if these improvements are to be maintained for at least 8 weeks.

Clinical trial registration number: XXX

Keywords: ankle joint, dose-response, older adult, talus mobilizations.

Implications for practice

- Manual therapy is effective in improving the weight bearing range of movement of the ankle in the older adult, but the number of ideal treatment sessions has not been studied.
- Two sessions of talus mobilizations improve weight bearing ankle dorsiflexion ROM of the older adult with limited ankle mobility.
- This is the first study to analyse the dose-response of talus mobilizations in the older adult.

INTRODUCTION

Articular mobilization techniques have been applied to treat diverse affections. The approach can help to increase joint range of motion (ROM) and improve outcomes such as functional capacity [1,2]. When applied to the ankle joint, the treatment can improve ROM, and induce benefits on balance and functional performance in patients with stroke [3,4], or improve postural control and ROM in people with ankle instability [5,6].

It is well established that ankle function decreases with ageing, since there is a general tendency toward a loss of mobility and strength, and soft tissue stiffness [7,8]. For such reason, previous studies conducted with older adults put their efforts on evaluating whether articular mobilizations could increase the ankle ROM [9,10]. Some of them also evaluated whether the likely improvement in ankle mobility could in turn have an impact on balance [11–14], since the ankle is known to play a key role on postural control, and helps to develop movement strategies [15,16]. However, a fundamental aspect when establishing a treatment has not yet been clarified: the number of sessions needed for ankle mobilizations to improve the ankle ROM, being effective in clinical terms. Indeed, a very variable number of sessions were suggested by the studies conducted in older adults, which ranged from 1 to 12 [9–14]. This led to findings that were inconclusive, since the studies found from positive to non-existent benefits.

Given the above factors, this trial sought to determine the dose-response (number of sessions) of treatment (talus mobilizations) needed to induce a minimal detectable change in weight bearing ankle dorsiflexion range of motion of older adults presenting with limited ankle mobility.

METHODS

Study design

This was a four-arm, randomized clinical trial conducted between October and December 2020 (clinicaltrials.gov id. XXX). The study design adhered to the ethical recommendations set in Helsinki and successive updates, and was approved by the Ethics Committee of the University of XXX (no. XXX). The participants were recruited from a socio-cultural association of old people in Valencia. All participants signed a consent form. Then, participants were randomly allocated to one of the four groups. Random allocation sequence was generated with the Matlab® software. Allocation was concealed by using sealed and opaque envelopes that were sequentially numbered. An information brochure explaining the possible interventions was provided before agreeing to participate, what precluded blinding participants. Outcomes were assessed at baseline, immediately after each session of treatment, and 8 weeks after the last session for each group (short- and mid-term effect).

Participants

The threshold below which ankle mobility is considered to be limited has not been strictly defined in the literature. Overall it is agreed that weight bearing ankle dorsiflexion ROM should be over 35 degrees. Considering normative values, this study set that a threshold of 35 degrees [17–19]. On that basis, potential participants were screened for eligibility by a member of the team. Eligible participants were community-dwelling older adults; aged over 60; and presenting with limited weight bearing ankle dorsiflexion ROM, either in the right or left limb (i.e. < 35 degrees) [20]. Potential participants with lower limb injury in the three months prior to the study; or diagnosed condition than may influence mobility assessments (i.e. severe osteoarthritis, neurological condition, vestibular affection) were excluded. One member of the team, who was not informed about participant assignment, implemented the assessments; however, blinding of outcome assessor was not ensured due to study design (i.e., some

participants had to be assessed a different number of times depending on group assignment). The participants were treated by the same physiotherapist, who had more than 15 years of experience.

Interventions

The four groups received the same treatment with an increasing number of sessions: group G1=1 session; group G2=2 sessions, G3=3 sessions and G4=4 sessions of treatment. Sessions were held twice a week, with a separation of 2-3 days between them. Each session consisted of 3 mobilizations of 30 seconds, with of the talus in anteroposterior glide, with a rest of 30 seconds between mobilizations [21,22]. According to Green *et al*. [21], a grade III and IV according to Maitland favors viscoelastic tissue adaptation, inducing gains in the ankle dorsiflexion movement. Those higher grades are used to stretch the joint capsule and passive tissues whish support and stabilize the joint so increase range of movement. For this, we used grade IV mobilizations, to target the accessory movement of the ankle up to the resistance offered by periarticular tissues [22,23]. The treatment was administered with the participant lying supine, with a wedge under the knees to reduce stress. Mobilizations were performed with a bimanual grip, making direct compression on the talus.

Outcomes

We sought to determine the number of sessions of experimental intervention needed to induce a minimal detectable change. A baseline change over 4.7 degrees in the Lunge test was the minimum threshold considered as a detectable change [24]. According to this, we determined the number of sessions. The Lunge was used to assess weight bearing ankle dorsiflexion ROM by measuring the maximum tilt of the tibia that the participant could perform while standing and bearing the weight on the limb. To do this, the participants were asked to face the wall and then move one leg forward the distance of one step. Subsequently, they were

asked to try to bring the flexed knee towards the wall without lifting the heel off the ground. A Baseline® Digital Inclinometer (Fabrication Enterprises Inc.) was used to assess this outcome [24].

Sample size

A priori sample size estimation needed to adequately power the trial was implemented. An *F*-test of repeated measures, between factors, was performed considering four groups, f = 0.4, and α=0.05, and β = 0.2, to obtain a power over 0.8. A total of n = 48 participants were needed. An assumed 20% sample loss resulted in an estimated of 60 participants. Calculations were performed using the G*Power3.1 software tool [25].

Statistical analysis

Data were analyzed using the SPSS software version 24.0 (IBM Corp., Armonk, NY, USA) licensed by University of XXX. Descriptive statistics were used to present data as means and standard deviations. The normality of the distribution for the quantitative variables was verified using the Shapiro-Wilk test. *F*-tests were used to assess between-group baseline differences. As aforementioned, a baseline progression in the Lunge test over 4.7 degrees was considered minimally important [24]. This value was used to determine the dose-response of the intervention. In addition, it was also verified whether any of the four groups maintained this improvement in the medium term.

RESULTS

Figure 1 shows the flow of participants throughout the trial. All of the 62 participants who were screened, matched the eligibility criteria and were randomized. All of them completed the treatment scheduled. The demographic characteristics of the participants of the four groups and the baseline values of the Lunge test are presented in Table 1. No between-

group baseline differences in demographic and clinical outcomes were observed. The compliance was 100%.

Please, insert Figures 1 here.

Please, insert Table 1 here.

Table 2 presents Lunge test results. Overall, four groups significantly increased their ankle mobility after one session (p<0,001), but two sessions were needed for a minimal detectable change of 4.7 degrees in ankle mobility (Figure 2). The third and fourth session increased joint range to a greater extent, albeit moderately. Regarding detraining, all groups showed a loss in joint ROM 8 weeks after the last session. The decrease was significant in groups one and two. However, only those participants who received four sessions maintained the improvement above 4.7 degrees (G4 = 5.2; SD 3.3 degrees; p<0,001).

Please, insert Table 2 here.
Please, insert Figure 2 here.

DISCUSSION

The findings of this study support that one session of ankle mobilizations induces significant changes in ankle mobility, whereas two sessions are effective in improving weight bearing ankle dorsiflexion over 4.7 degrees in the participating older adults who presented a ROM below 35 degrees. The results also suggested that four sessions of treatment are needed to maintain ankle ROM gains for at least 8 weeks.

Overall, joint mobilization techniques are considered effective to increase joint mobility and restore functional limitations [10,12]. However, the treatment dose needed to induce a detectable change had not been studied yet [23]. Our study suggests that one session of treatment will increase ROM; but we speculate whether this increase may not be enough to

have a clinical impact on the general functionality of the older adult. This could explain that some of the studies that delivered one session of ankle and foot mobilizations and evaluated the effects of on balance found either positive or non-existent changes [14,26]. And that, on the contrary, when a greater number of sessions were applied -varying from 4 to 12-, the effects were generally positive [9–12,27].

Analyzing baseline changes, the greatest relative ROM increase occurred after the first session. However, the ROM kept improving in a slight upward trend throughout the treatment. Similar studies oriented to younger populations did not find great improvements with just one session [22,23]. However, our findings are similar to those of a previous study with similar treatment and population [9]; consistently, such study suggested that one session of treatment would induce the greatest ROM increase, and that successive sessions would induce small but also positive gains. Despite this, not all the results were consistent, since an important change was induced after just one, not two sessions in such study. We speculate and discuss the possible reasons: the treatment protocol was coincident, but the mean age of our study sample was lower, and although in both cases participants presented with limited ankle mobility, the baseline ROM in this study was higher than that of Hernández-Guillen and Blasco's [9]. Whether a subject with a greater limitation could have a greater ROM gain with a single session would need further investigation.

The results also suggested a tendency for the effects of the intervention to diminish or even be lost over time (our follow up was up to 8 weeks). Even when the baseline gains were similar among those who received between 2 and 4 sessions, detraining effect was considerably less with 4 sessions. This finding was already suggested by other authors, who stated that when a certain number of sessions is applied, the effects could be maintained in time, both in the case of six sessions of ankle mobilization [9], and when the mobilizations were combined with exercise [11].

This is the first study to analyze the dose-response of talus mobilizations in the target population. The Lunge test, used to measure weight bearing ankle dorsiflexion, it is a validated and highly reliable test that has made it possible to record the evolution of outcomes [17,24]. Also, provides practical value to the findings, because 1) most basic daily activities are performed under loading conditions such as gait, climbing stairs, and sitting down and standing up, while 2) a positive association between ankle mobility and functional performance is established [28]. Having said that, some other previous studies estimated passive and active ankle mobility without bearing weight, what may bias possible comparisons [10–12,26].

There are also limitations. Participants were healthy community-dwelling older adults, and thus, Grade IV intensity could be applied without pain. To assess subjects with pathology would be also of interest. The therapist experience was over 15 years, so further research would be needed to understand the magnitude of effects when the treatment is delivered by less experienced interventors. Finally, it would be interesting to compare the effects of this protocol in different age ranges within the older adult population, and / or differentiating by the degree of mobility limitation presented, since as discussed, our results seem to suggest that these factors could predispose the number of sessions needed to achieve a detectable improvement.

CONCLUSION

This study supports that two sessions of talus mobilizations produce a detectable change in weight bearing ankle dorsiflexion ROM. In addition, that four sessions of treatment are needed if the improvements are to be maintained for at least 8 weeks. Future investigations are needed to determine whether the degree of mobility limitation presented by a subject and their age could be additional factors to consider when scheduling a treatment.

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Conflict of interests

The authors declare that there is no conflict of interest.

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TABLES

Table 1. Baseline characteristics of the participants.

	Group G1	**Group G2**	**Group G3**	**Group G4**	***P*-value**
n	16	16	15	15	
Women (n, %)	13 (81.2%)	13 (81.2%)	12 (80.0%)	10 (66.7%)	-
Age (years)	72.8 (6.9)	68.5 (5.8)	66.2 (4,2)	70.1 (7.5)	0.156
Height (cm)	161.2 (6.7)	162.4 (6.7)	162.9 (5.6)	163.9 (6.8)	0.237
Weight (kg)	72.9 (14.1)	66.6 (9.3)	68.4 (11.7)	67.2 (9.7)	0.238
Lunge test (degrees)	27.8 (5.0)	27.9 (3.9)	27.8 (5.6)	26.9 (4.0)	0.932

Table 2. Weight bearing ankle dorsiflexion range of motion Mean (SD) values.

	S_1	**S_1-BL**	***p-value***	**-**	**-**
G1	32.2 (4.6)	4.4 (3.0)	<0.001	-	-
G2	32.4 (2.8)	4.5 (3.2)	<0.001	-	-
G3	31.7 (5.1)	3.8 (3.1)	<0.001	-	-
G4	31.2 (4.0)	4.2 (2.3)	<0.001	-	-
	S_2	**S_2-BL**	***p-value***	**S_2-S_1**	***p-value***
G1	-	-	-	-	-
G2	32.5 (4.2)	4.7 (2.8)	<0.001	0.2 (3.6)	0.849
G3	32.6 (6.0)	4.8 (3.2)	<0.001	0.9 (1.9)	0.089
G4	31.8 (4.5)	4.9 (2.6)	<0.001	0.6 (2.2)	0.306
	S_3	**S_3-BL**	***p-value***	**S_3-S_2**	***p-value***
G1	-	-	-	-	-
G2	-	-	-	-	-
G3	32.7 (5.0)	4.8 (3.2)	<0.001	0.9 (1.2)	0.873
G4	32.0 (4.3)	5.1 (3.6)	<0.001	0.2 (2.1)	0.66
	S_4	**S_4-BL**	***p-value***	**S_4-S_3**	
G1	-	-	-	-	-
G2	-	-	-	-	-
G3	-	-	-	-	-
G4	32.7 (2.9)	5.8 (2.9)	<0.001	0.7 (1.9)	0.196
	F-up (8w)	**F-up (8w)-BL**	***p-value***	**F-up - S_L (8w)**	***p-value***
G1	29.1 (5.7)	1.3 (1.3)	0.001	-3.1 (3.7)	0.004
G2	29.9 (4.1)	2.0 (2.1)	0.001	-2.6 (3.1)	0.005
G3	31.7 (4.9)	3.8 (1.6)	<0.001	-1.0 (3.5)	0.268
G4	32.2 (4.3)	5.2 (3.4)	<0.001	-0.5 (2.0)	0.294

Si = number of treatment sessions ranging from 1 to 4; S_L=last treatment session

F-up (8w): Follow up assessment 8 weeks after the last treatment session

FIGURE LEGENDS

Figure 1. Design and flow of participants through the trial.

Figure 2. The figure shows the effects of one to four sessions of treatment. Mean baseline changes and the minimally detectable threshold (4.7 degrees) are plotted per group. MDC: Minimal detectable change.

FIGURES

Figure 1

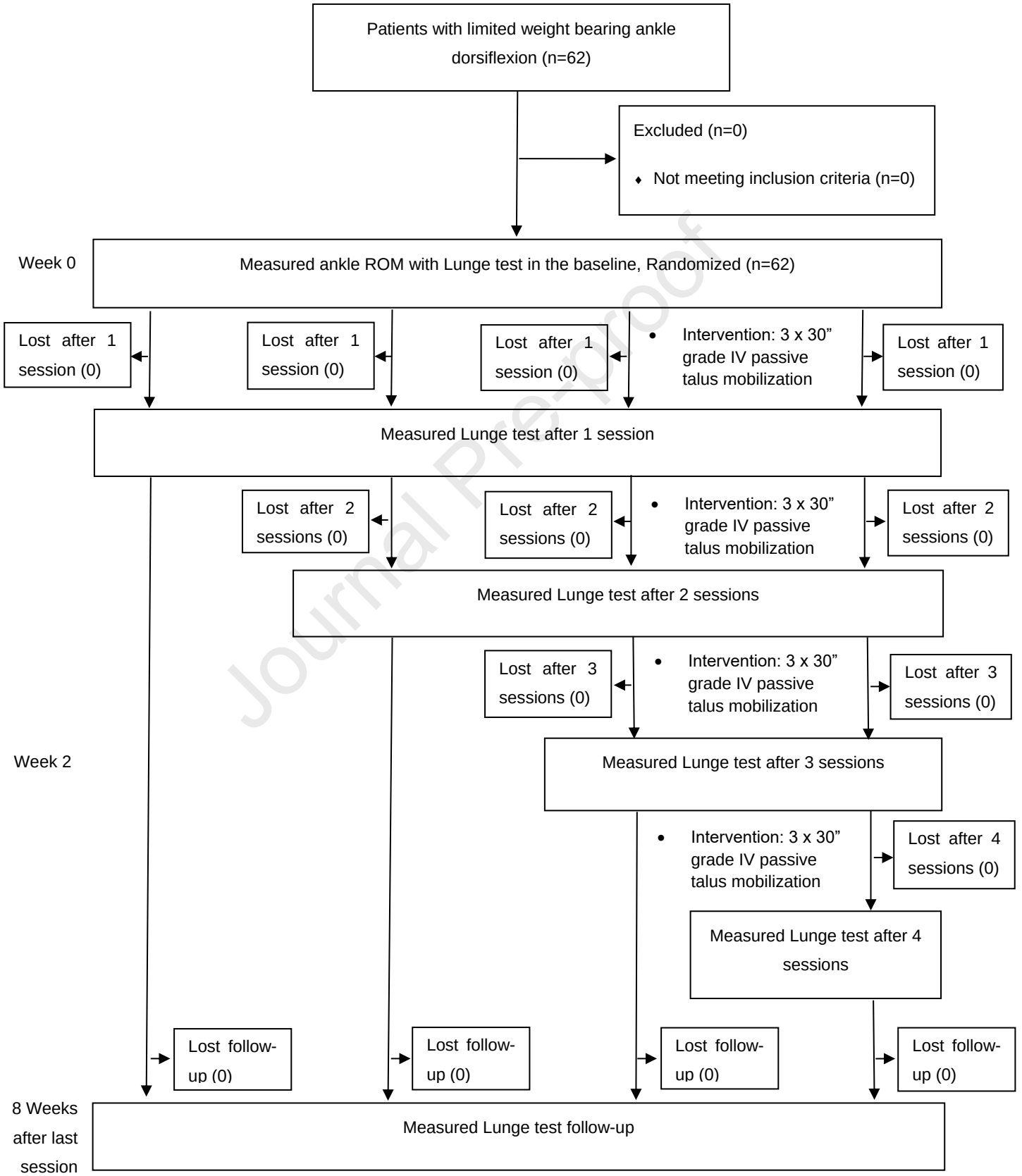
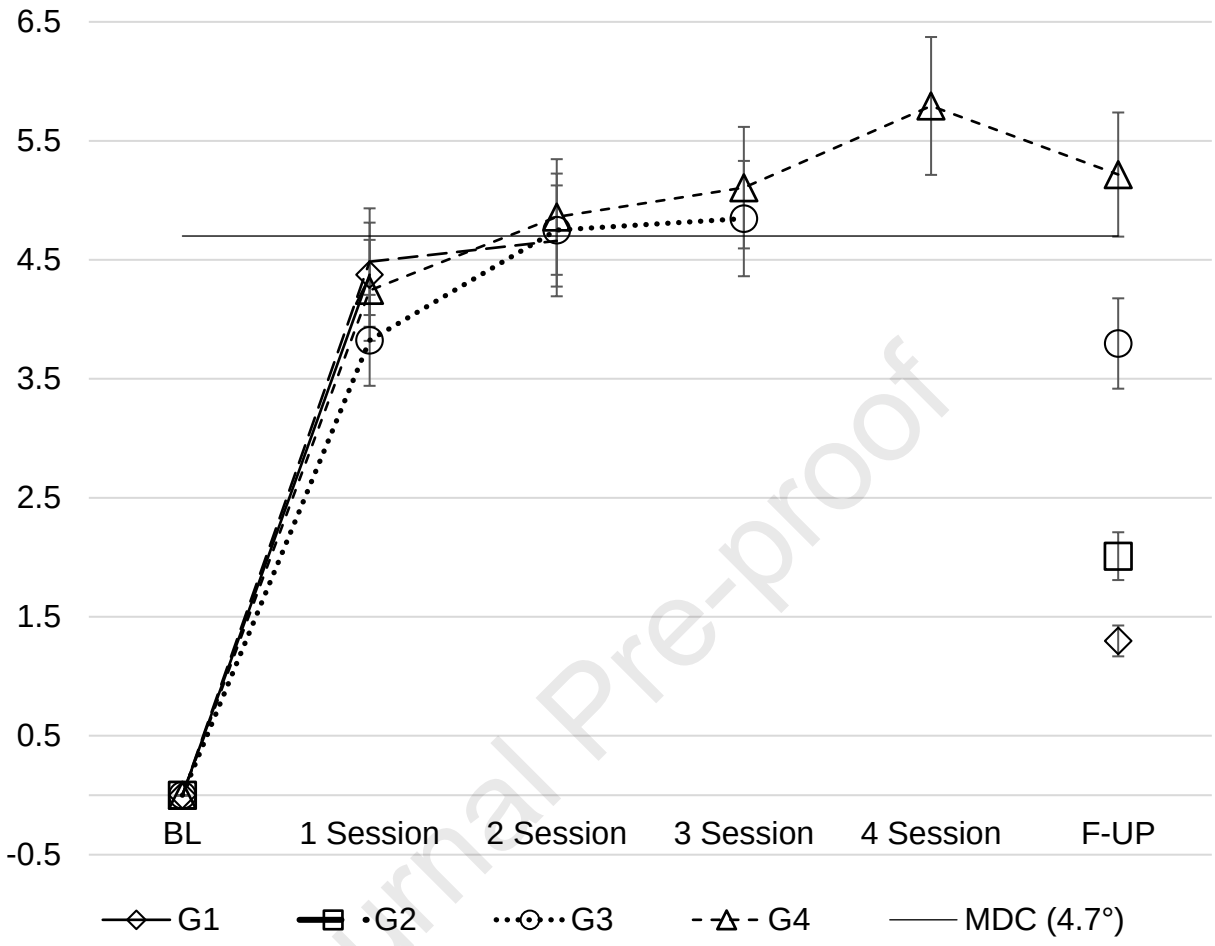


Figure 2



Implications for practice

- Manual therapy is effective in improving the weight bearing range of movement of the ankle in the older adult, but the number of ideal treatment sessions has not been studied.
- Two sessions of talus mobilizations improve weight bearing ankle dorsiflexion ROM of the older adult with limited ankle mobility.
- This is the first study to analyse the dose-response of talus mobilizations in the older adult.

Conflicts of interest

None.

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Ethical approval details

This study was approved by the Human Research Ethic Committee of the Universitat de Valencia (1230807).