



OBJECTIVES

To conduct a randomized controlled double-blind clinical trial, to assess the efficacy of three different doses of BoNT-A intramuscular injections and possible adverse effects of this treatment in patients with persistent masticatory myofascial pain; in order to establish a treatment protocol



- 100 volunteers
- 18 – 45 years
- Myofascial pain
- Contraceptive use
- Pain ≥ a 3m
- Previous treatments

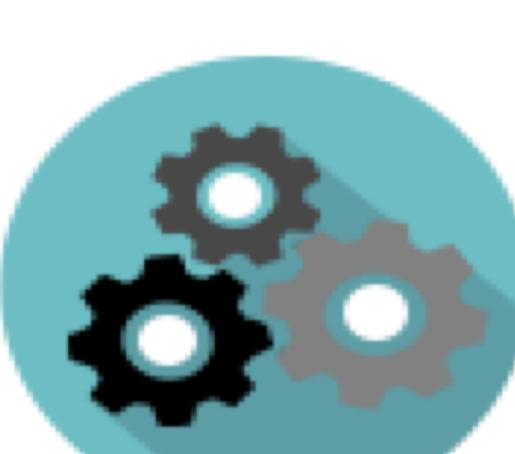
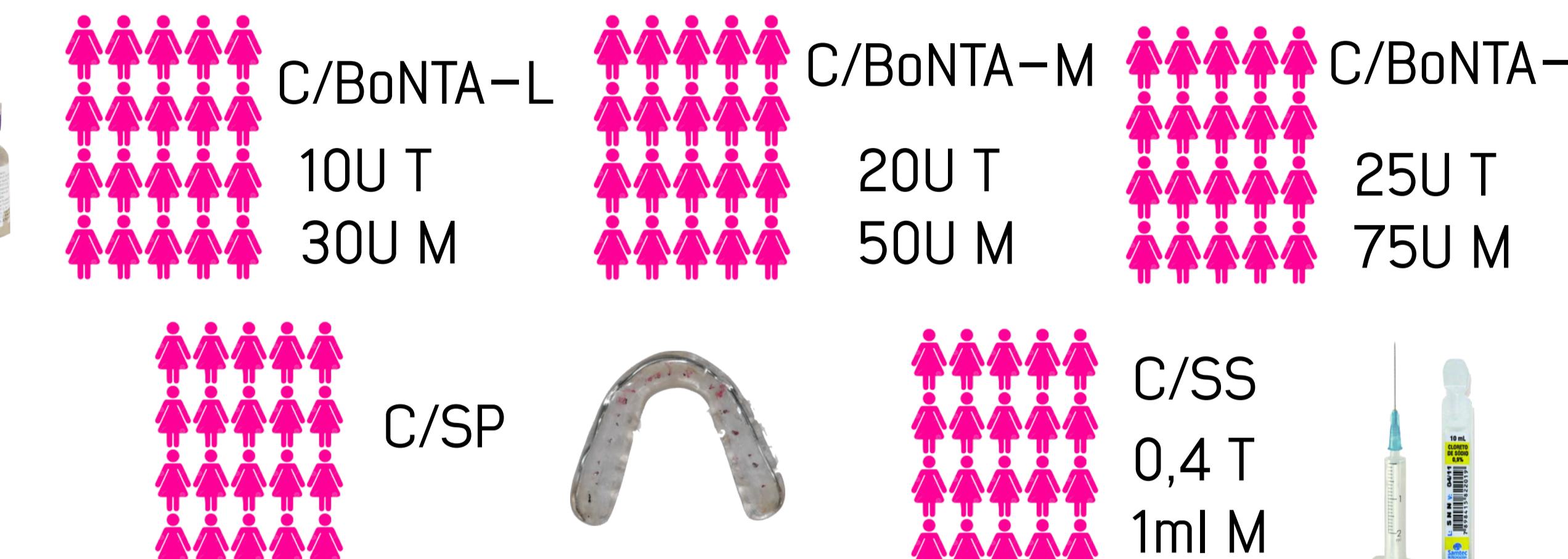
Randomization



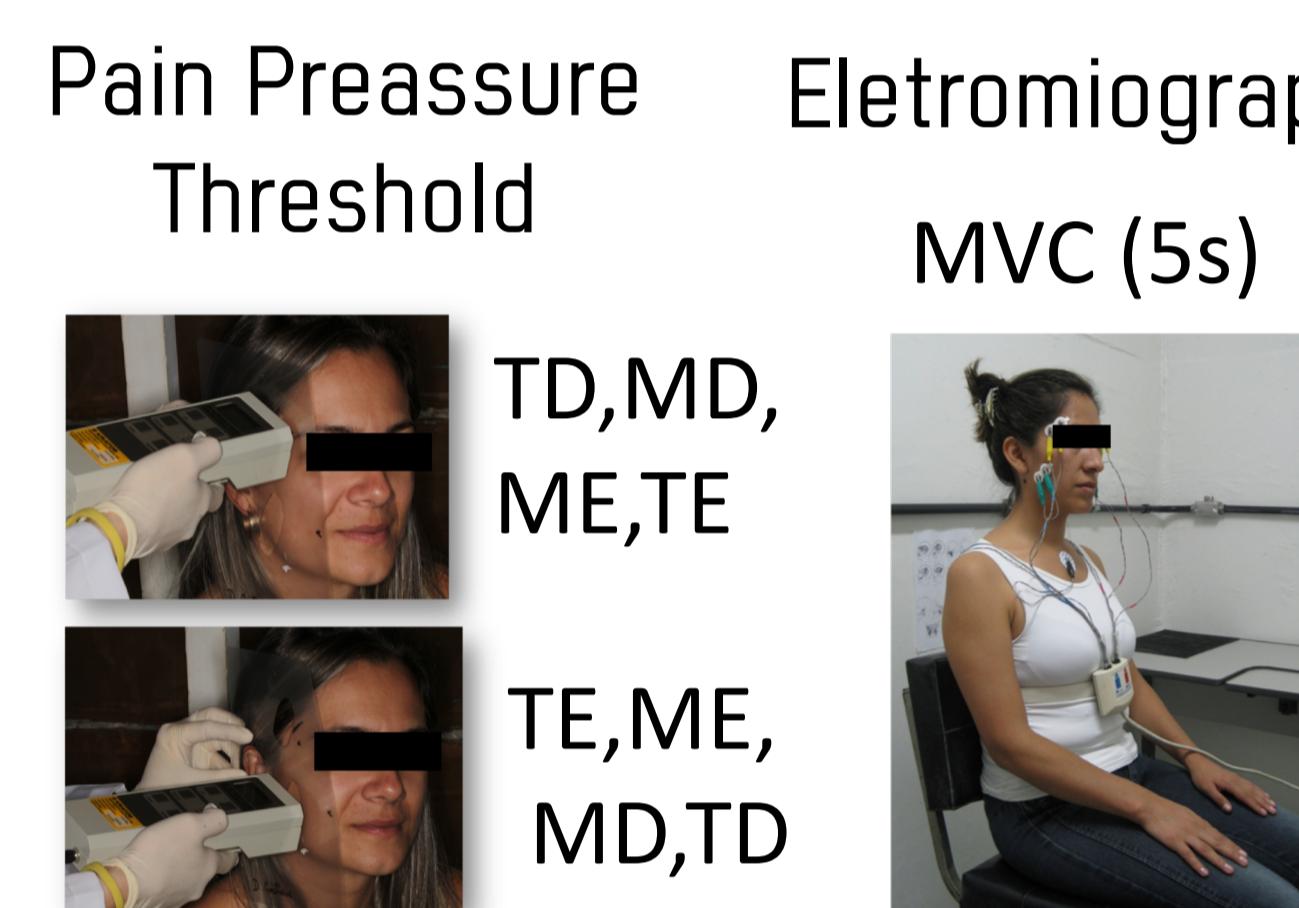
Ultrasonography



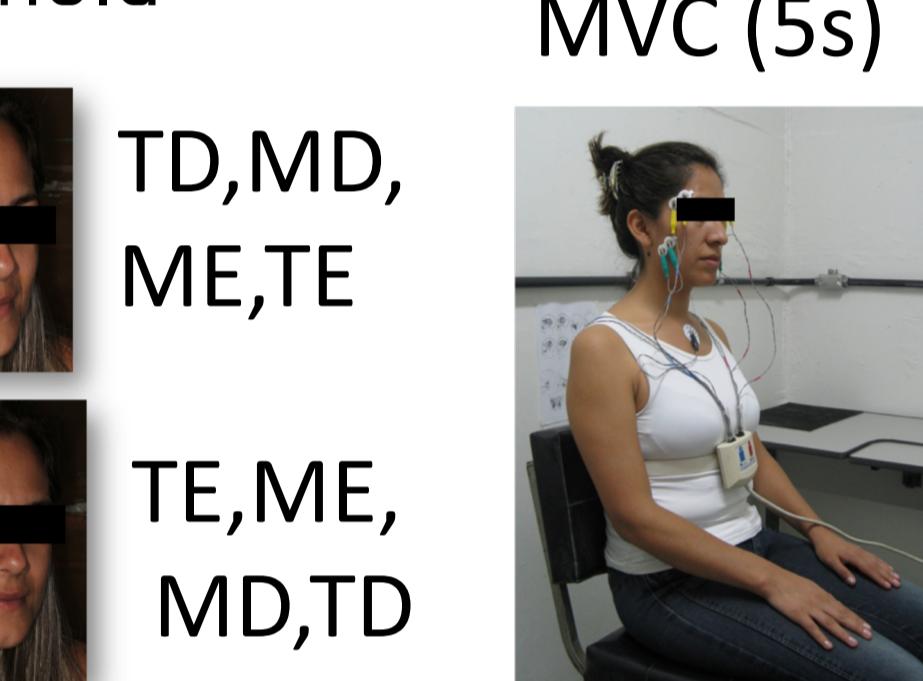
5 groups



METHODS

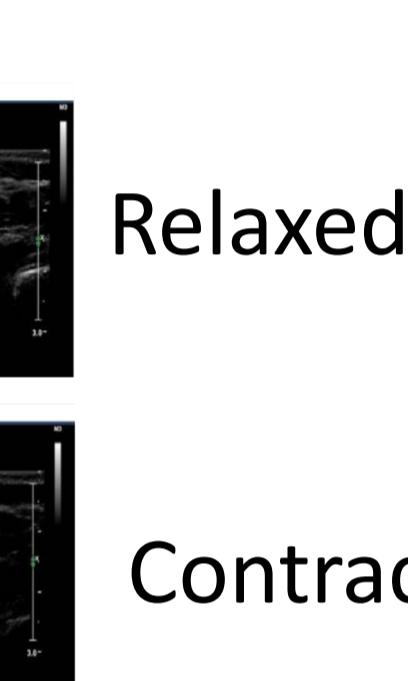


Pain Pressure Threshold



Eletromiography

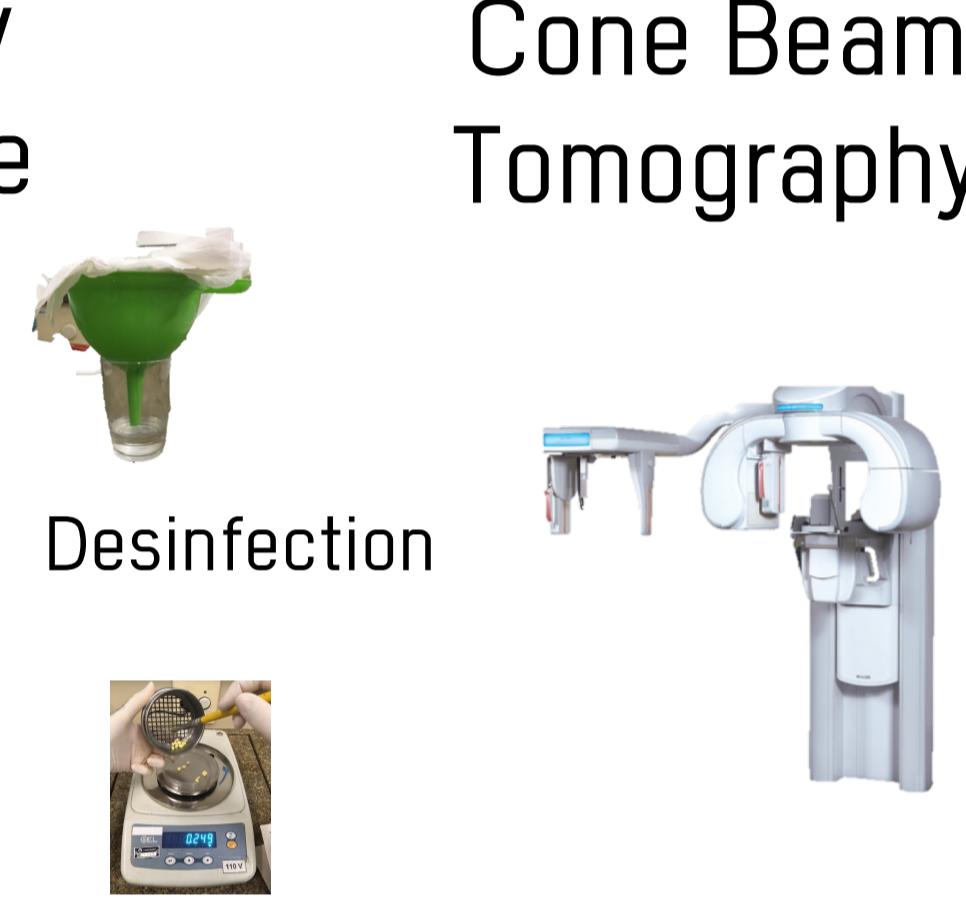
MVC (5s)



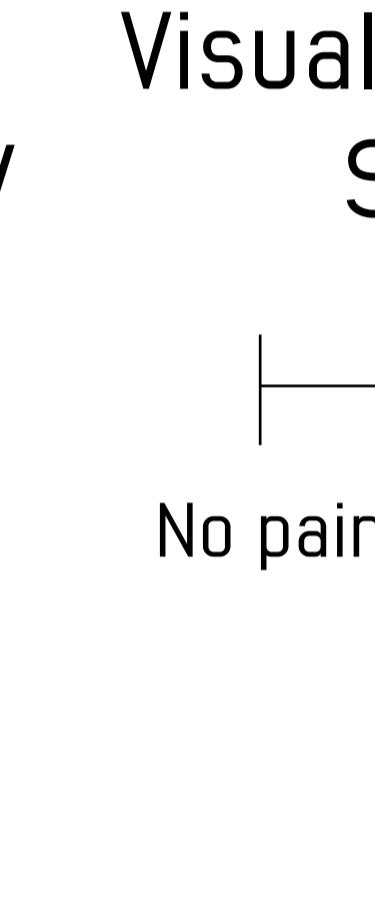
Ultrasonography



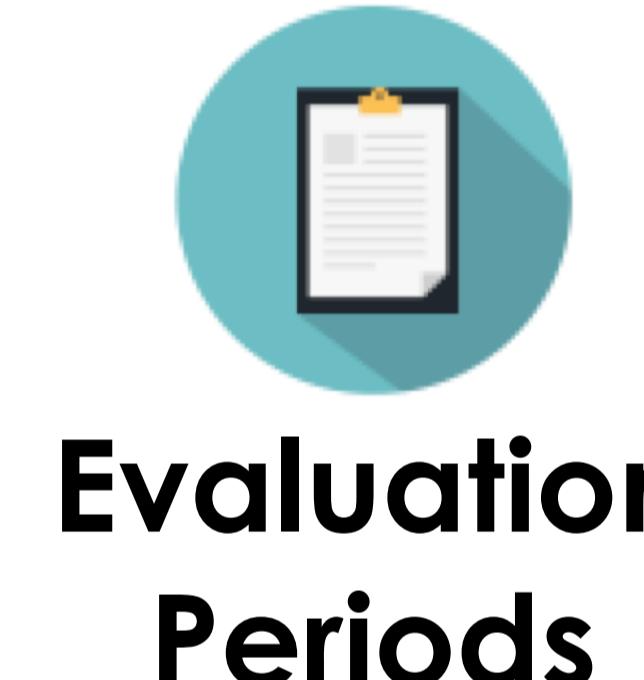
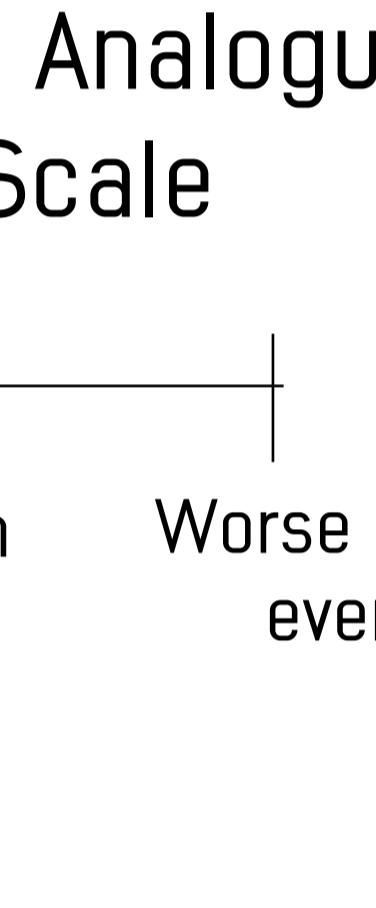
Masticatory Performance



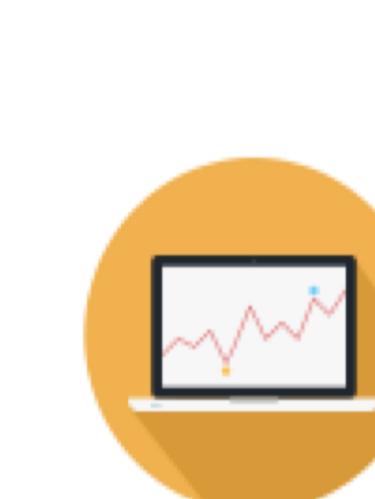
Cone Beam Tomography



Visual Analogue Scale



7, 14, 21, 28,
90 and 180 days



Linear mixed model test was used for comparisons between groups and evaluation periods ($p<0.05$).



RESULTS

Figure 1. Visual Analogue Scale scores among groups in different experimental periods

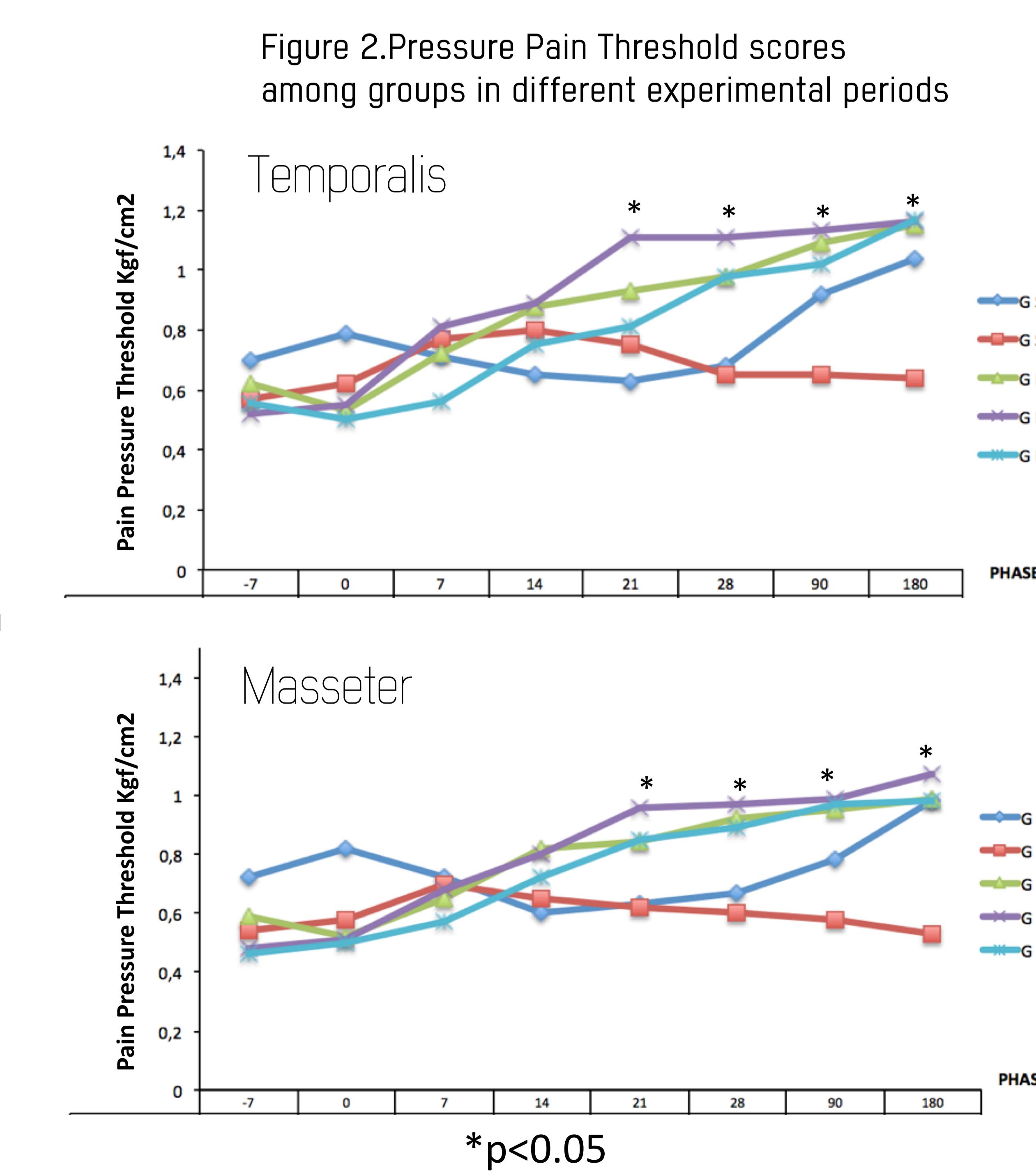
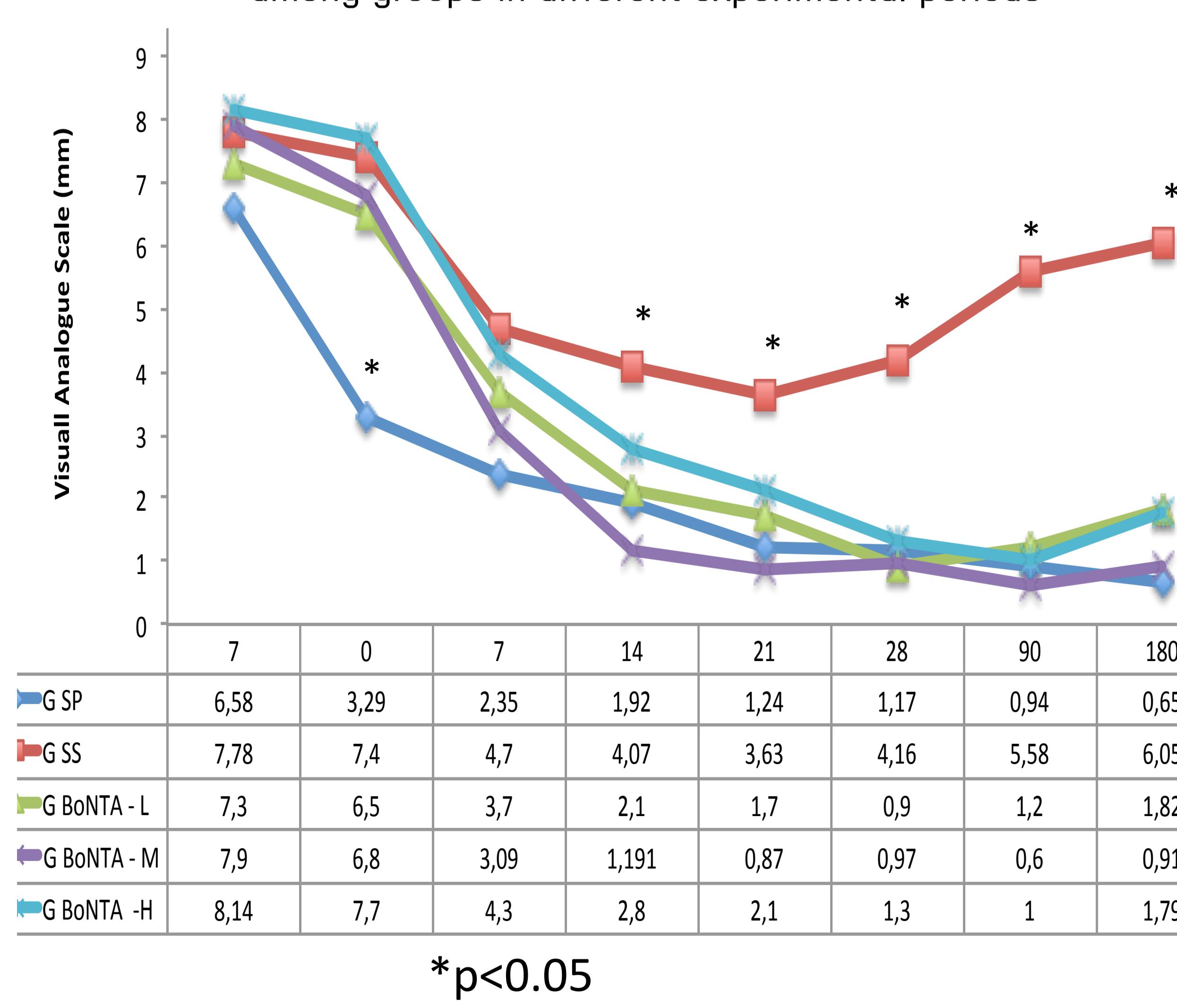


Figure 3. Root Mean Square scores in maximum muscle contraction condition among groups in different periods

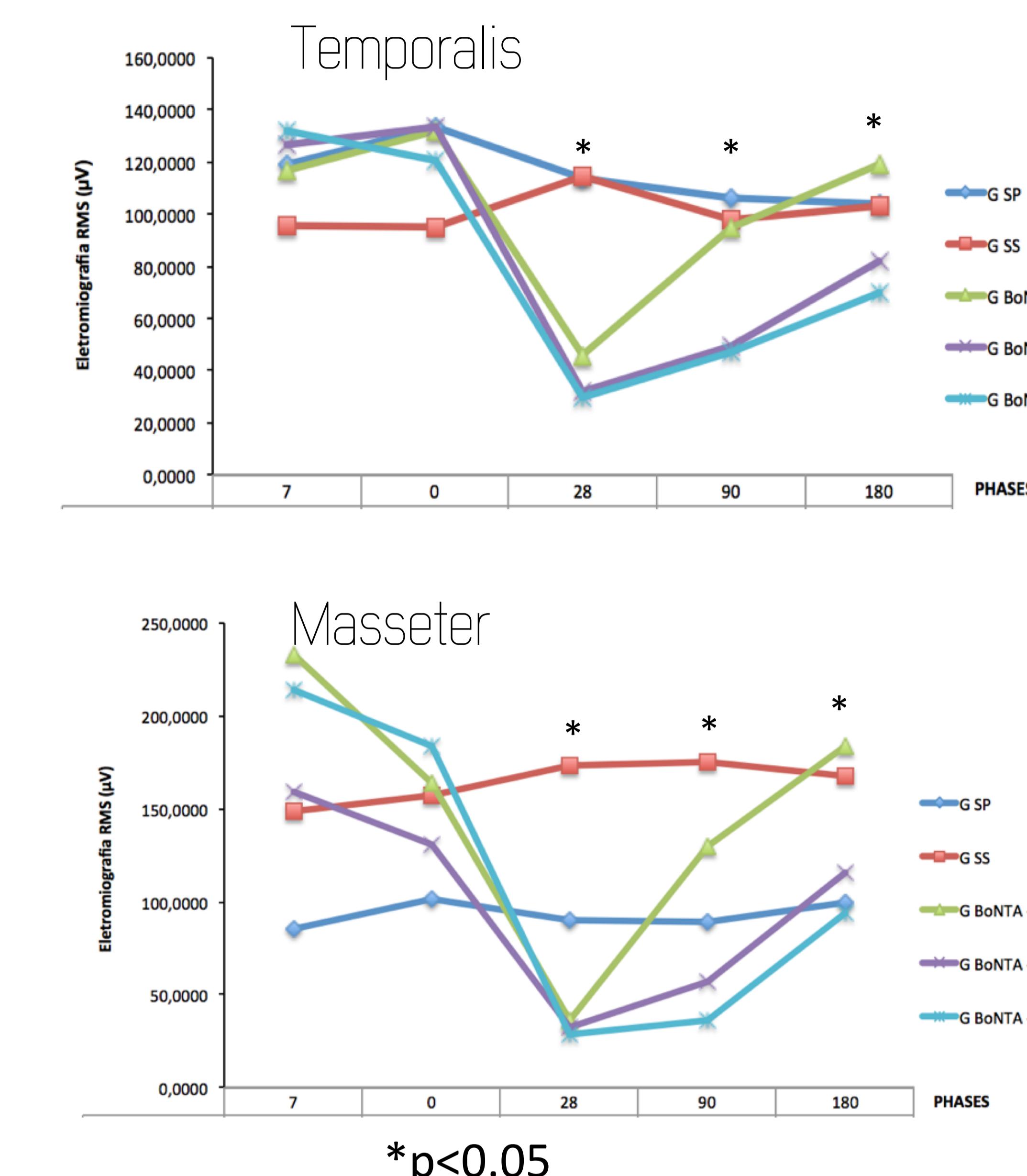


Table 1. Mean and standard deviation of muscle thickness evaluated in different periods

M	T	SS	BoNTA-L	BoNTA-M	BoNTA-H
CONTRACTED					
0	2,45 (1,05) Aa	2,32 (0,71) Aa	2,13 (0,88) aA	1,89 (0,82) Aa	
RT 30	2,45 (1,27) Aa	1,70 (0,65) ABb	1,40 (0,55) Bb	1,54 (0,71) Ba	
90	2,57 (1,51) Aa	1,70 (0,59) ABb	1,47 (0,62) Bb	1,41 (0,43) Ba	
0	11,70 (1,88) Aa	12,37 (1,75) Aa	11,90 (1,55) Aa	12,34 (1,68) Aa	
RM 30	12,04 (2,11) Aa	11,75 (1,47) ABb	9,88 (1,83) Bb	10,44 (1,26) Ba	
90	12,09 (1,79) Aa	11,6 (1,70) ABb	10,49 (1,72) Bb	11,38 (1,67) Ba	
0	11,51 (1,80) Aa	12,83 (1,44) Aa	12,52 (1,71) Aa	12,39 (1,91) Aa	
LM 30	11,72 (1,81) Aa	12,08 (2,11) Aa	11,10 (1,77) Ab	10,91 (1,56) Ab	
90	11,76 (1,68) Aa	12,01 (1,67) Aa	11,28 (1,64) Ab	11,22 (1,49) Aab	
0	2,49 (0,99) Aa	2,57 (0,80) Aa	2,26 (0,84) Aa	2,03 (0,57) Aa	
LT 30	2,44 (0,97) Aa	1,68 (0,62) ABb	1,50 (0,54) Bb	1,59 (0,66) Bab	
90	2,58 (0,97) Aa	1,65 (0,64) Bb	1,42 (0,63) Bb	1,41 (0,51) Bb	

Uppercase in horizontal represent differences groups
Lowercase in vertical denote differences among evaluation periods

Table 2. Mean and standard deviation of the comminuted median particle sizes (mm) according to period and concentration groups

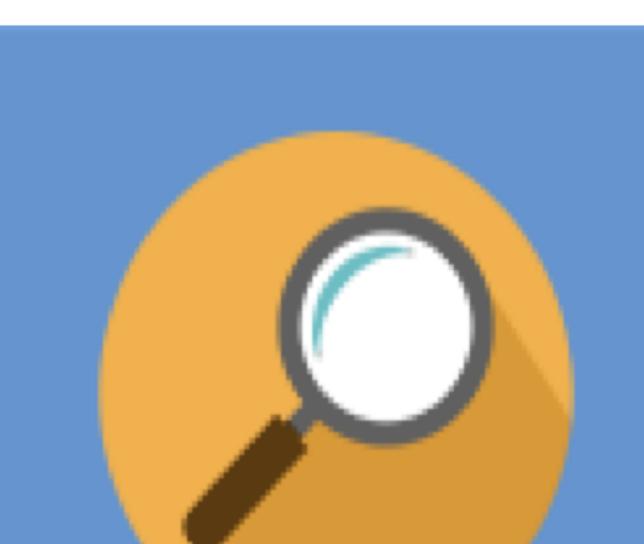
Groups	Baseline	Period				
		7 D	14 D	21D	28D	90D
BoNT-A						
High	5.9±0.8 Bab	6.4±0.6 Aab	6.6±0.5 Aa	6.7±0.6 Aab	6.4±0.7 Aa	6.1±0.7 ABab
Medium	5.9±0.9 Bab	6.8±0.5 Aa	6.9±0.6 Aa	6.8±0.7 Aa	6.6±0.6 ABA	6.3±0.8 Ba
Low	5.5±0.9 Bb	6.1±0.7 Ab	6.1±0.6 Ab	6.1±0.8 Abc	6.2±0.4 Aa	5.5±0.7 Bb
SS	6.2±0.7 Aa	5.8±0.7 Ac	5.8±0.8 Ab	5.7±0.9 Ac	5.7±0.9 Ab	5.1±1.1 Bc
BoNTA						
High	5.9±0.8 Bab	6.4±0.6 Aab	6.6±0.5 Aa	6.7±0.6 Aab	6.4±0.7 Aa	6.1±0.7 ABab
Medium	5.9±0.9 Bab	6.8±0.5 Aa	6.9±0.6 Aa	6.8±0.7 Aa	6.6±0.6 ABA	6.3±0.8 Ba
Low	5.5±0.9 Bb	6.1±0.7 Ab	6.1±0.6 Ab	6.1±0.8 Abc	6.2±0.4 Aa	5.5±0.7 Bb
SS	6.2±0.7 Aa	5.8±0.7 Ac	5.8±0.8 Ab	5.7±0.9 Ac	5.7±0.9 Ab	5.0±1.1 Bb

Different uppercase letters in horizontal represent differences among evaluation periods
Different lowercase letters in vertical denote differences among groups

Table 3. Median of coronoid apophysis bone volume evaluated in different periods

Periods	Right				Left			
	SS	BoNTA-L	BoNTA-M	BoNTA-H	SS	BoNTA-L	BoNTA-M	BoNTA-H
217.2aA	213.6aA	195.6aA	207.9aA	185.7aA	243.6aA	156.4aB	232.8aA	
(±77)	(±122.3)	(±118)	(±108.7)	(±25.5)	(±184.3)	(±76.2)	(±86.4)	
210.9aA	194aA	164.3aA	189.2bA	171.3aA	236.3aA	158.5aA	195.1bA	
(±50.6)	(±213.8)	(±135.9)	(±93.8)	(±61.1)	(±195.4)	(±54)	(±105.1)	

Different lowercase in vertical represent significant differences among evaluation periods
Different uppercase in horizontal represent significant differences among groups



CONCLUSIONS

BoNT-A is an effective therapy to control persistent masticatory myofascial pain; however due to the evident side effects on muscle contraction, masticatory performance, muscle thickness and in mandibular volume bone, which are not reported from conservative treatments, we suggest that low doses of BoNT-A could be indicated in patients that not get substantial pain relief from conservative treatments.

SUPPORT:

FAPESP 2014/1586