Is Osteopathic Manipulative Treatment effective in Migraine?

Preliminary Report of a Randomized Controlled Trial conducted at the Hospital of Ancona (Marche, Italy) in the period between march 2010 and march 2011.

International Congress of Osteopathic Medicine. Florence –Italy 6/9 April 2011

Epidemiological data

- MIGRAINE is classified at the 19th place by the World Health Organization in the ranking of the disabling disease. [1]
- It is a common disorder that affects about 6% of men and 18% of women [2]
- On average 88 hours of work are lost each year by those suffering from migraine. [3]
- In the U.S. in 1998 were spent $ 13 billion for care and in 2002 was $ 19 billion in lost productivity, missed. [4]
- In Europe there is the higher percentage of migraineurs in the whole World 5

1 Mathers CD, Stein C, Fat DM et al., Global Burden of Disease 2000: version 2, methods and results. World Health Organization, 2002

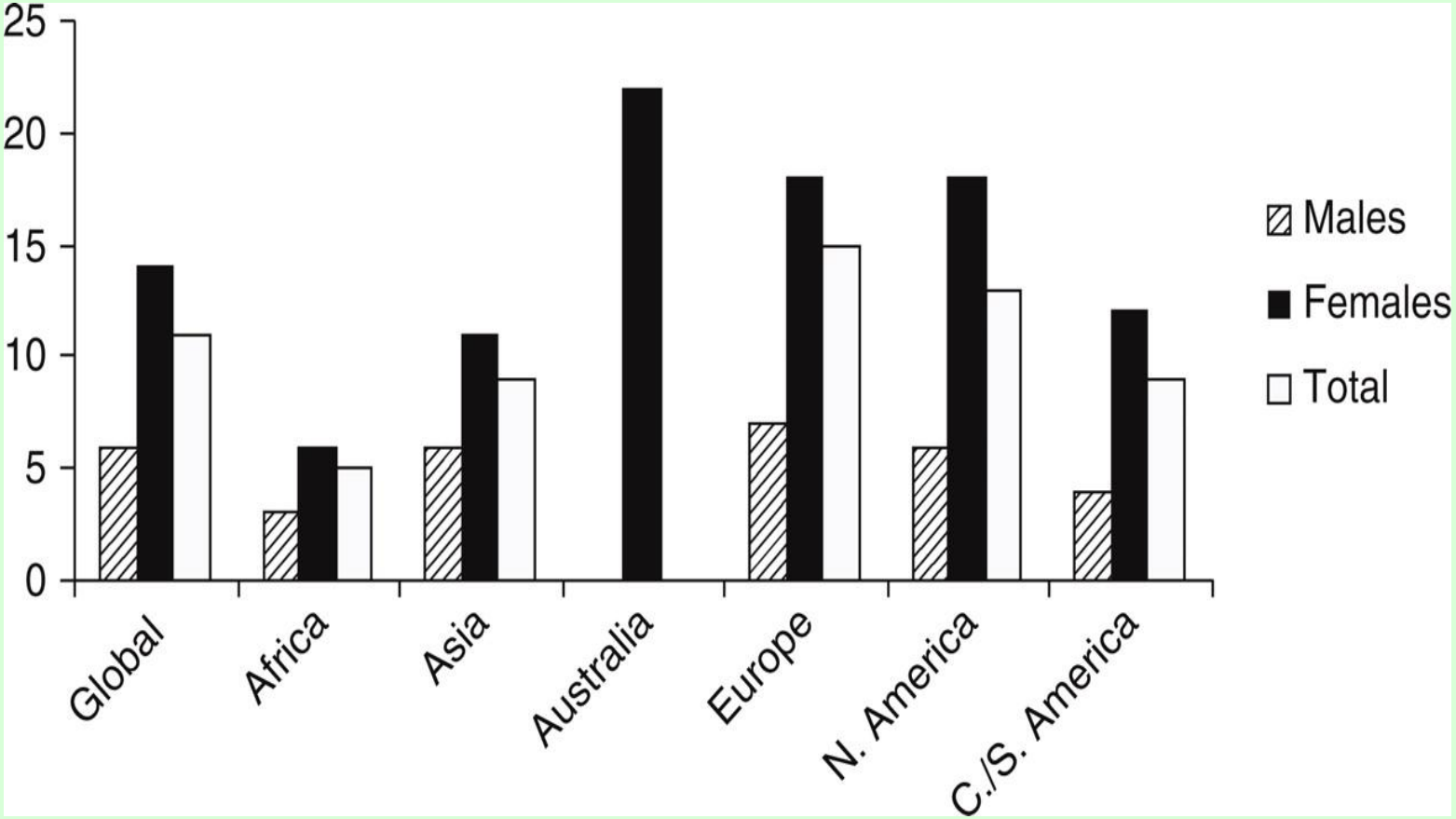
2 lLipton RB, Scher AI, Kolodner K, Liberman J, Steiner TJ, Stewart WF. Migraine in the United States: epidemiology and patterns of health care use. *Neurology*. 2002;58(6): 885-894

3 Stewart WF, Wood GC, Razzaghi H, Reed ML, Lipton RB. Work impact of migraine headaches. *J Occup Environ Med*. 2008;50(7)736-745.

4 WF, Ricci JA, Chee E, Morganstein D. Lost productive work time costs from health conditions in the United States: results from the Ameri- can Productivity Audit. *J Occup Environ Med*. 2003;45(12):1234-1246.

5 Stovner L et al. Cephalalgia 2007;27:193-210

Figure 3 Prevalence of current migraine in adults for the different continents.



Stovner L et al. Cephalalgia 2007;27:193-210

The aim of This Study is to determine the efficacy of the OMT on a sample of 105 subjects affected by migraine evaluated by the HIT-6 questionnaire.

The study was carried out in the Department of Neurology of the United Hospitals of Ancona in the period March 2010-summer 2011. All patients male and feminine admitted in the unit with a diagnosis of migraine are according with International Headache Society criteria were considered eligible for the study.

Exclusion criteria

Patients with secondary forms of headache, chronic illness, psychiatric illness, post-menopausal women, aged under 18 and over 60 years old were excluded from the study.

According to the sample size calculation using an effect size of 5 points between groups and 35 within groups with a power of 90% and an alfα equal to 0.05, 105 patients entered in the study and were randomly divided in three groups:

1) OMT only

2) Drugs (triptans) only

3) Sham therapy

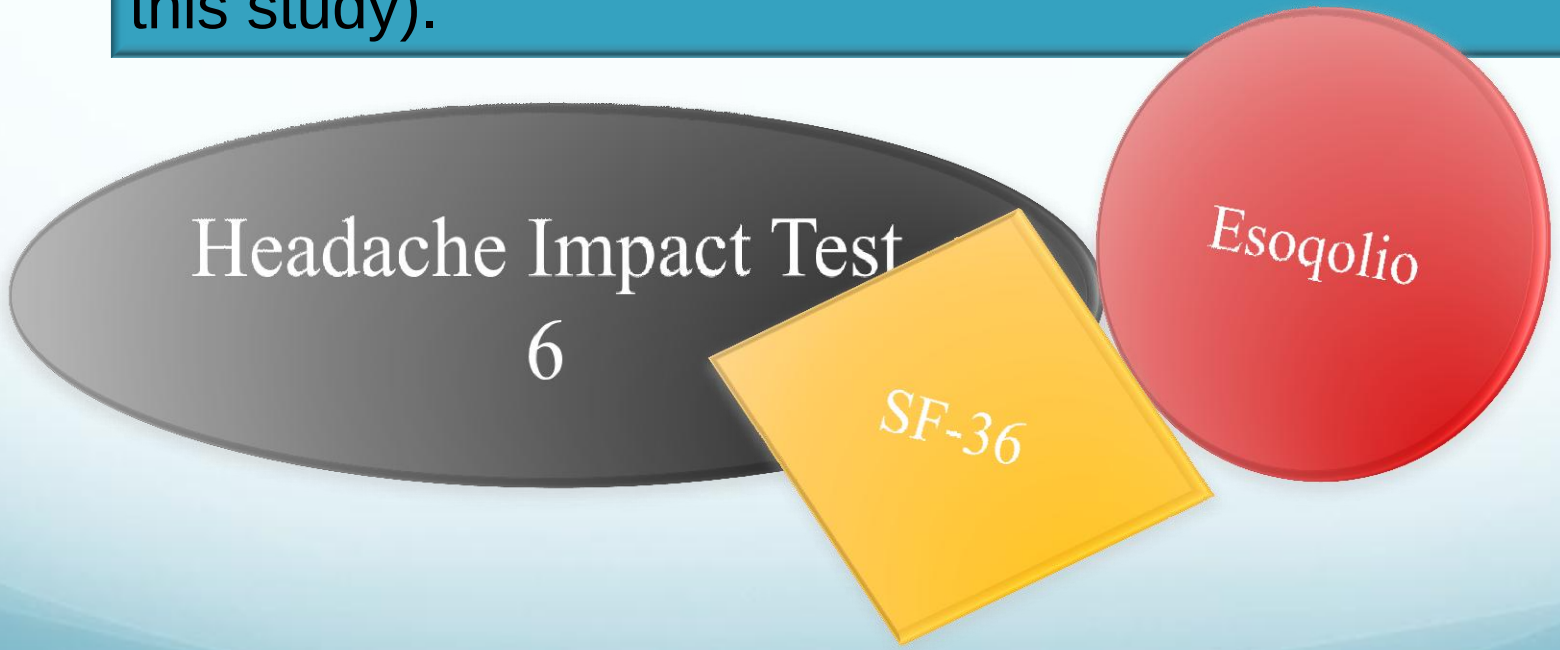
All patients were followed up for 8 treatments in 6 month.

Randomization of Operators

Carried out by a researcher of EBOM, operators osteopaths were divided randomly into 3 groups with a:

1) OMT Osteopaths treaters
2) Sham Group Therapy
3) Evaluators

At the baseline Patients were referred by the coordinators of the study to the compilation of a sociodemographic questionnaire (esoqolio) and two paper models on the HIT-6 and the SF-36v2 (respectively the primary and secondary outcome of this study).



The group of evaluators provided for the collection of data of somatic dysfunction of patients suitable for the study using Johnston's Tests with the first two levels of specificity. This was performed on all patients in the study at the baseline and at the follow-up after 26 weeks.

OMT

Summary of the tecniques:

- Craniosacral Therapy
- Fascial Techniques
- Muscle Energy Techniques
- B.L.T.

Treatment Plan

Week 1	**I treatment**		**Week 14**	**VI treatment**
Week 2	**II treatment**			
Week 4	**III treatment**			
			Week 18	**VII treatment**
Week 6	**IV treatment**			
			Week 22	**VIII treatment**
Week 10	**V treatment**			
			Week 26	**Follow Up**

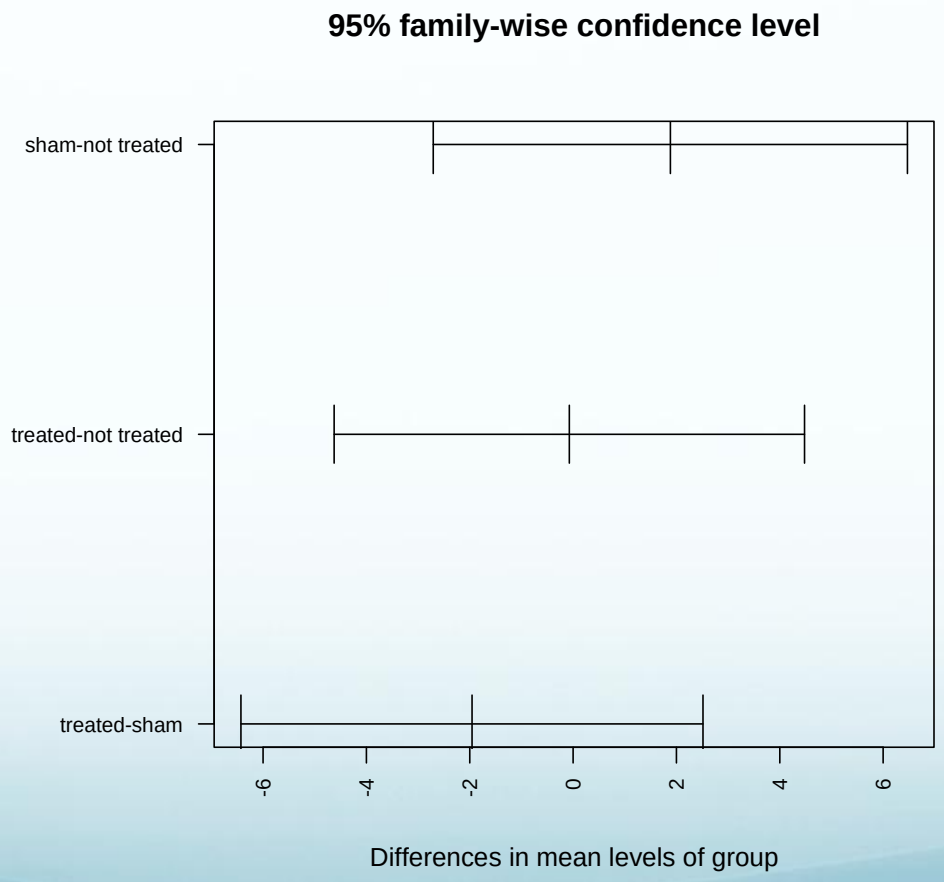
Results:

Results presented are based on a smaller sample (N=50) since the study is still running.
At baseline, no difference in mean between the three groups in term of socio-demographic characteristics, severity of migraine and quality of life.

	WEIGHT				SEX
	Diff	lwr	upr	p	p
S-NT	-0.26	-8.77	8.24	0.99	
T-NT	-4.39	-12.72	3.92	0.42	
T-S	-4.13	-12.12	3.86	0.43	
Overall				0.34	0.89

	HIT-6				AGE			
	Diff	lwr	upr	p	Diff	lwr	upr	p
S-NT	1.88	-2.70	6.47	0.59	5.63	-0.51	11.78	0.07
T-NT	-0.07	-4.62	4.47	0.99	0.81	-5.19	6.83	0.94
T-S	-1.95	-6.42	2.51	0.55	-4.81	-10.59	0.95	0.12
Overall				0.50				0.05

Results at the baseline HIT-6



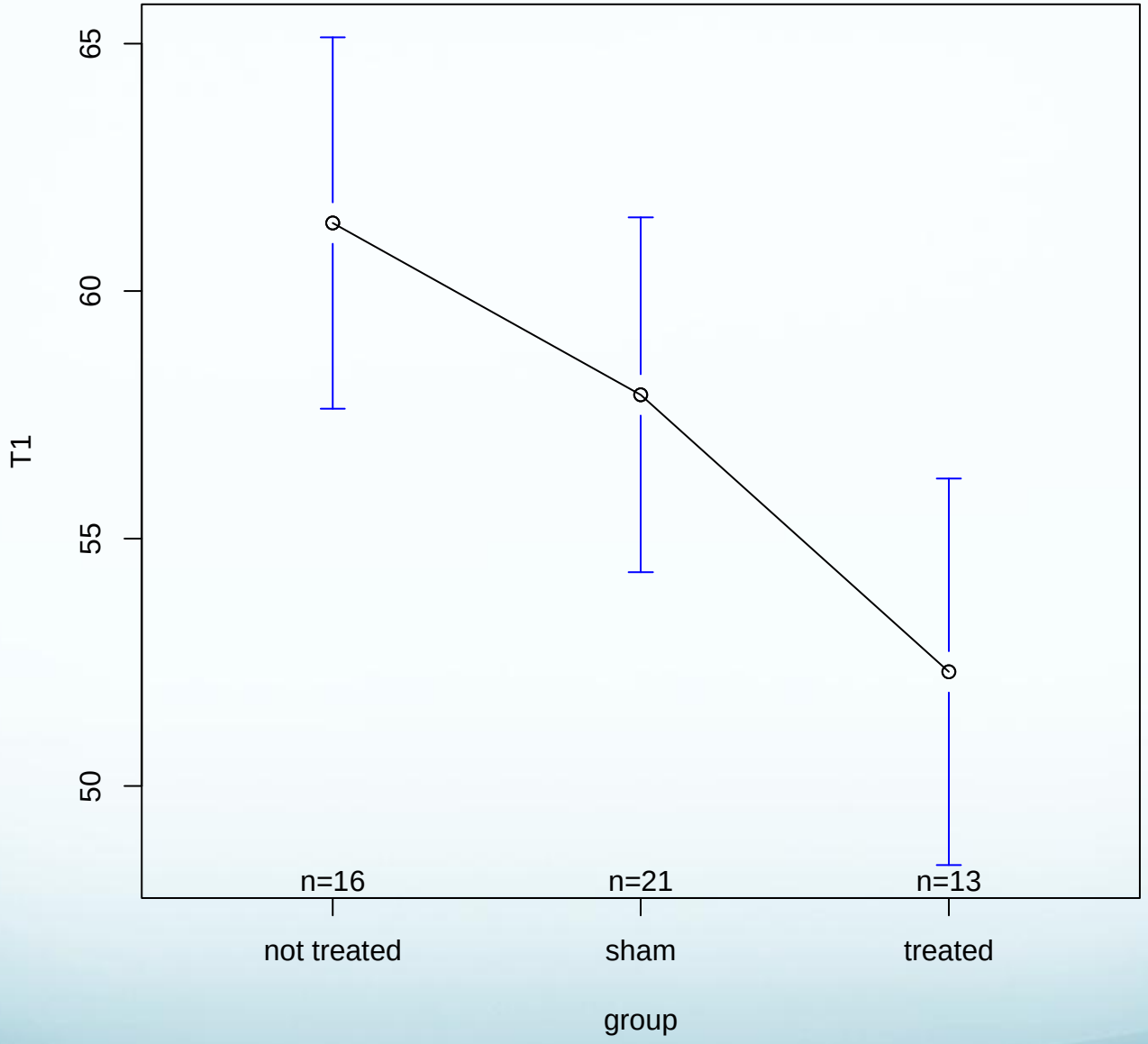
At the end of the follow-up ANOVA showed a statistically significant difference on the primary outcome between the three groups : F (2,47) =5.61, p= .006.

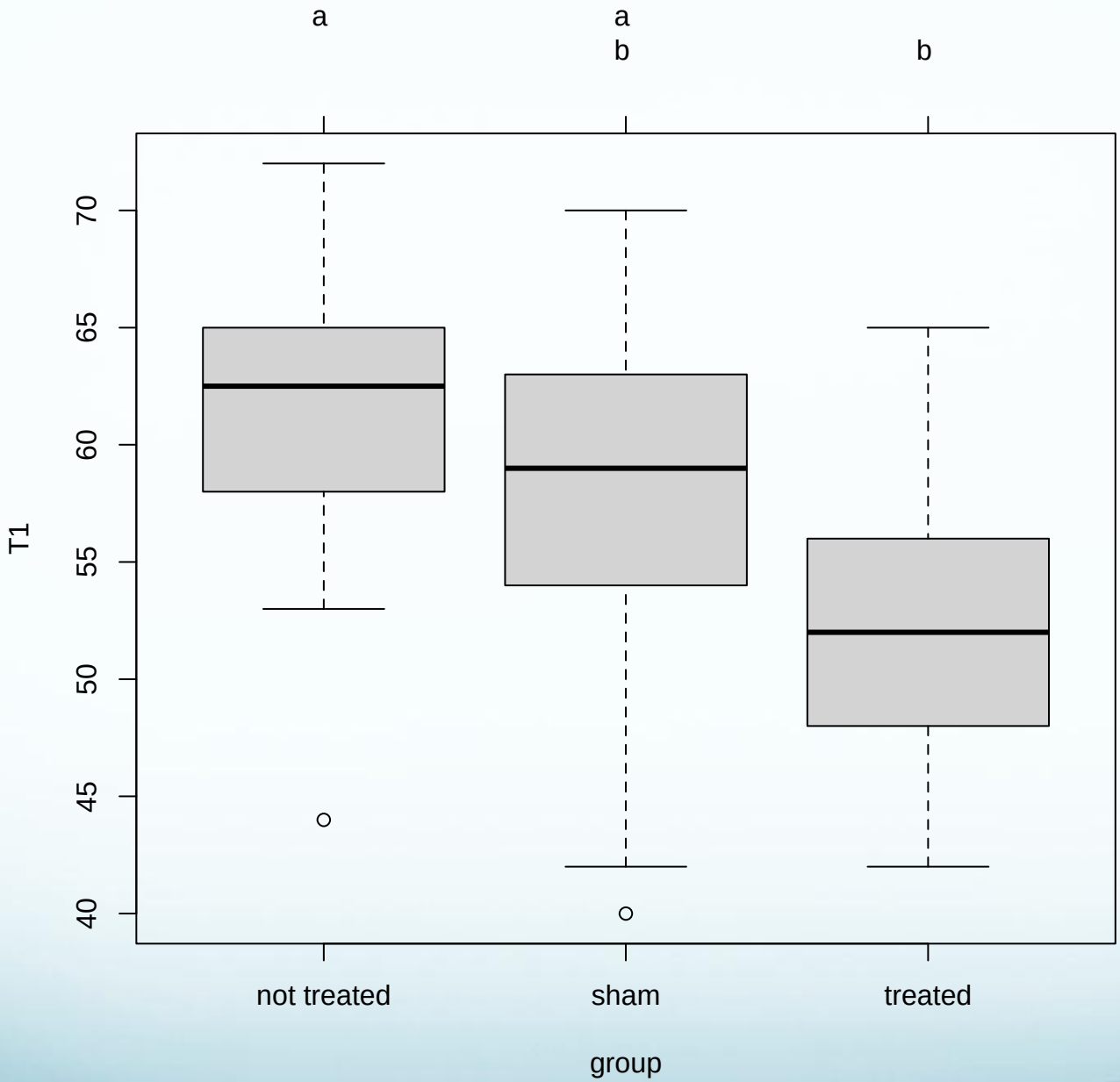
Tukey post-hoc comparisons of the three groups indicate:

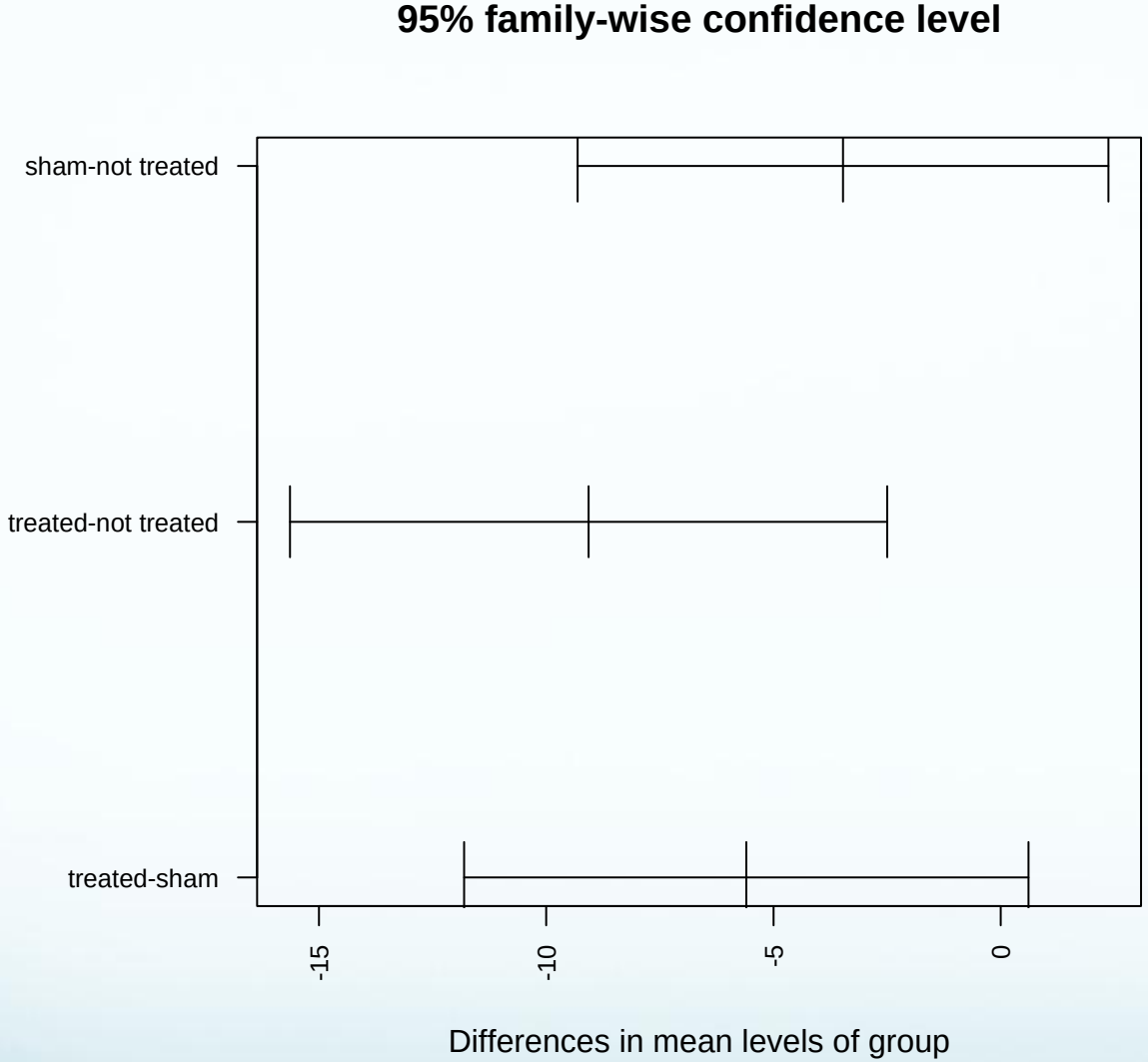
- that sham was not statistically different from drug group (M= -3.47, 95% CI [-9.31, 2.37], p= .33)

- OMT was statistically different from drug group (M = -9.07, 95% CI [-15.64,-2.50], p= .004)

- OMT was almost statistically significant from sham group (M = -5.60, 95% CI [-11.81, -0.61], p= .08).


T1
65
60
55
50
n=16
n=21
n=13
not treated
sham
treated
group


a
a
b
b
T1
70
65
60
55
50
45
40
not treated
sham
treated
group


95% family-wise confidence level
sham-not treated
treated-not treated
treated-sham
-15
-10
-5
0
Differences in mean levels of group

Conclusion

This preliminary data, even though not completed, showed a significant difference between OMT group and the others two, suggesting that the OMT can be considered an efficient procedure in the management of patients with migraine.

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Thanks for your kind attention