

A parallel randomized controlled trial examining the effects of rhythmic sensory stimulation on fibromyalgia symptoms

Thenille Braun Janzen¹, Denise Paneduro², Abdullah Mosabbir³, Larry Picard², Allan Gordon², LeeR. Bartel^{3*}

1 Music and Health Research Collaboratory, Faculty of Music, University of Toronto, Toronto, Ontario,

Canada.

2 Wasser Pain Management Centre, Sinai Health System, Toronto, Ontario, Canada.

3 Faculty of Music, University of Toronto, Toronto, Ontario, Canada.

Extended Abstract

ABSTRACT

This study is a double-blind, two-arm parallel randomized controlled trial that investigated the effects of 40Hz rhythmic sensory stimulation (RSS) on fibromyalgia and associated symptoms. Two distinct treatment parameters were tested: 1) a single frequency stimulation (40Hz) of vibrotactile stimulus, and 2) stimulation of random and intermittent complex wave gamma-range vibrotactile stimulation. Study participants included fibromyalgia patients who were instructed to use a portable device generating vibrotactile stimulation for 30 minutes, five days per week, over five weeks, concomitant with usual care. Fibromyalgia symptoms, pain severity and interference, depression symptoms, quality of life and sleep quality were assessed at baseline and post-intervention. Results indicated that there were statistically significant changes from baseline to post-treatment in measures of fibromyalgia symptom severity, pain interference, depression, and sleep quality. Treatment outcomes did not differ significantly between groups. These findings suggest that vibrotactile rhythmic sensory stimulation in the gamma range may improve fibromyalgia symptoms and ease associated comorbidities. These preliminary findings warrant further investigations into the effects of rhythmic sensory stimulation on chronic pain conditions.

1. INTRODUCTION

Fibromyalgia (FM) is characterized by chronic widespread pain for which no cause can be identified (e.g., tissue damage or inflammation) [1]. Common symptoms include chronic fatigue, sleep disturbance, reduction in physical functioning, and psychological complications such as anxiety and depression [1]. Unfortunately conventional pharmacological treatments for FM have shown modest or short-lived results and intolerable side effects [2,3]. Non-pharmacological therapies have thus become an integral component of a multi-disciplinary treatment approach to FM that must be investigated and validated [4,5]. Previous exploratory studies have demonstrated an improvement of FM symptoms after treatment with gamma-range (30-120Hz) RSS [6–8]. However, most studies investigating the effects of RSS have used widely differing parameters of stimulation in relation to frequencies, stimuli waveforms, temporal pattern, and application protocols. The present study investigated the effects of two different parameters of gamma frequency vibrotactile RSS on fibromyalgia symptoms. A double-blind, two-arm parallel randomized controlled trial was designed including two groups: 1) a FM group that received continuous sine wave single-frequency stimulation (40 Hz) and 2) a FM group that received random and intermittent complex wave gamma-range RSS with peaks at 33 Hz and 45 Hz.

2. MATERIALS AND METHODS

Participants were outpatients aged 18-70 years of age, with a formal diagnosis of FM (Table 1). Participants were instructed to use a portable device (Sound Oasis VTS-1000) generating vibrotactile stimulation for 30 minutes, five days per week, over five weeks, concomitant with usual care. Outcome measures were collected before and after the treatment period.

Table 1: Demographic characteristics of participants at baseline.

	Group 1 (n=25)	Group 2 (n=25)	Total (n=50)
Age (years)	50 ± 12.18	50 ± 12.27	50 ± 12.27
Disease duration (years)	8 ± 7.3	7.9 ± 7.1	7.9 ± 7.1
FIQ total score (0 – 100)	70 ± 17	63 ± 15	67 ± 16
Sex (M/F)	23/2	23/2	46/4
Medication for pain (Y/N)	21/4	21/4	42/8
Self-reported comorbidity n (%)			
Anxiety	4 (16%)	4 (16%)	8 (16%)
Depression	8 (32%)	1 (4%)	9 (18%)
Chronic Fatigue Syndrome	2 (8%)	5 (20%)	7 (14%)
Temporomandibular joint disorder	2 (8%)	2 (8%)	4 (8%)
Chron's disease, colitis	4 (16%)	3 (12%)	7 (14%)

Values are expressed as mean ± standard deviation. Group 1: continuous 40 Hz vibrotactile rhythmic sensory stimuli; Group 2: intermittent gamma frequency rhythmic sensory vibrotactile stimuli. All participants were informed of the study design and the randomization procedure, and no suggestion was made about the superiority of either treatment. All procedures were approved by the Mount Sinai Hospital Research Ethics Board (15-0140-E) and the Office of Research Ethics at the University of Toronto (31916) and registered at ClinicalTrials.Gov (NCT02493348).

3. RESULTS

A total of 50 patients were enrolled, of which 38 completed the study (22 in Group 1, and 16 in Group 2). FM symptoms, depression severity, and sleep quality improved significantly among patients in both groups (Table 2).

Table 2. Change in outcome measures from baseline to post-intervention by treatment groups.

	Group 1 (n=25)		Group 2 (n=25)	
	Baseline	Post- Intervention	Baseline	Post- Intervention
FIQ	70 ± 17	57 ± 27 ^(M,**)	63 ± 14	56 ± 20 ^(M,*)
BPI – Pain Interference	7 ± 2	6.38 ± 2	6.15 ± 2	5.02 ± 2 ^(M,**)
BPI – Pain Severity	6.4 ± 1.5	5.8 ± 2	6 ± 1.75	5.5 ± 2
PHQ-9	16.5 ± 6.11	13.7 ± 7.45 ^(M,*)	12.6 ± 4.61	11 ± 5.14 ^(M,*)

QLES-Q	37.42 ± 20	43.50 ± 23	43.85 ± 14	47 ± 15
PSQI	14.68 ± 2.9	12.96 ± 3.6	12.68 ± 3.8	11.60 ± 4.2 ^(M,*)

Values are expressed as mean ± standard deviation. Results are based upon intention-to-treat analyses.

M = main effect of Time; I = Time by Group Interaction

* p < 0.05 ; ** p < 0.005.

FIQ, Revised Fibromyalgia Impact Questionnaire; BPI, Brief Pain Inventory; PHQ-9, Patient Health Questionnaire-9; QLES-Q, Quality of Life Enjoyment and Satisfaction; PSQI, Pittsburgh Sleep Quality Index.

4. CONCLUSION

This study investigated the effects of gamma-frequency rhythmic sensory stimulation on FM symptoms. Our findings suggested that there were significant changes from baseline in measures of fibromyalgia symptoms, pain interference levels, depression severity, and sleep quality. The improvements in symptom severity however did not differ significantly between both groups, suggesting that both settings of RSS parameters were enough to produce a meaningful effect on FM symptoms. Follow up studies involving controlled groups should be conducted. Further research is needed to confirm the present results and as well as identifying a potential mechanisms underlying clinical responses to rhythmic sensory stimulation.

5. REFERENCES

1. Clauw, D.J. Fibromyalgia: A clinical review. *JAMA - J. Am. Med. Assoc.* 2014, *311*, 1547–1555.
2. Robinson, R.L.; Jones, M.L. In search of pharmacoeconomic evaluations for fibromyalgia treatments: A review. *Expert Opin. Pharmacother.* 2006, *7*, 1027–1039.
3. Lautenschläger, J. Present state of medication therapy in fibromyalgia syndrome. In *Proceedings of the Scandinavian Journal of Rheumatology, Supplement*; Taylor and Francis A.S., 2000; Vol. 29, pp. 32–36.
4. Baranowsky, J.; Klose, P.; Musial, F.; Haeuser, W.; Dobos, G.; Langhorst, J. Qualitative systemic review of randomized controlled trials on complementary and alternative medicine treatments in fibromyalgia. *Rheumatol. Int.* 2009, *30*, 1–21.
5. Wahner-Roedler, D.L.; Elkin, P.L.; Vincent, A.; Thompson, J.M.; Oh, T.H.; Loehrer, L.L.; Mandrekar, J.N.; Bauer, B.A. Use of complementary and alternative medical therapies by patients referred to a fibromyalgia treatment program at a Tertiary Care Center. *Mayo Clin. Proc.* 2005, *80*, 55–60.
6. Weber, A.; Werneck, L.; Paiva, E.; Gans, P. Effects of music in combination with vibration in acupuncture points on the treatment of fibromyalgia. *J. Altern. Complement. Med.* **2015**, *21*, 77–82.
7. Chesky, K.S.; Jon Russell, I.; Lopez, Y.; Kondraske, G. V. Fibromyalgia tender point pain: A double-blind, placebo-controlled pilot study of music vibration using the music vibration table(tm). *J. Musculoskelet. Pain* **1997**, *5*, 33–52.
8. Naghdi, L.; Ahonen, H.; Macario, P.; Bartel, L. The effect of low-frequency sound

stimulation on patients with fibromyalgia: a clinical study. *Pain Res. Manag.* **2015**, *20*, e21-7.