INCLUSION/EXCLUSION CRITERIA FOR

FIBROMYAGLIA CASE STUDY

STUDY DONE BY DR. ANTHONY BERARDINO

INCLUSIONS

	being female
	age between 30 and 55 years
	have an ovulatory cycle
	height between 59” and 70”, body mass between 110lbs and 176lbs, and BMI in the range of > or = to 40 lbs/m^2
	present a diagnosis of fibromyalgia made by a medical doctor
	not having diabetes mellitus and uncontrolled blood pressure
	not having psychiatric illness or having malignant tumors
	is not pregnant
	not to be hypersensitive to light
	cognitive level enough to understand the procedures and follow the guidelines
	has symptoms of fibromyalgia longer than 3 months

EXCLUSIONS

	not attend for more than two consecutive sessions
	at any time and for any reason expressing an intention to leave the study
	Arthritis, Chronic Fatigue Syndrome, Lupus, Autoimmune Diseases
	cognitive changes
	people who perform some exercise
	having a pacemaker
	persons under the age of 30 and more than 55 years
	had symptoms of fibromyalgia less than 3 months
	no serious mental health illness such as dementia or schizophrenia; psychiatric hospitalization in the last 2 years
	no developmental disability/cognitive impairment that prelude adequate comprehension of informed consent form, and/or ability to complete case report forms
	no litigation/disability benefits involvement related in any way to the parameters of the study
	has not participated in any form of research over the prior 30 days

AVAILABILITY

	meet 3x/week for 4 weeks
	$50 deposit due at the time of your first visit*
	attend preprocedural visit
	attend postprocedural visit
	keep a Daily Diary provided to you

ADDITIONAL INFORMATION

Pre-Procedure Assessment Phase: during the one-week period before the procedure begins, subjects will take place in a 7-day pain management stabilization phase. It will include taking note of the medication(s) and treatment(s)/therap(ies) that the subject is using at the time of entry. The investigator will then review the list with the subject and instruct that only what is listed be used/applied during the 1-week stabilization phase.
Procedure Phase: It will last four weeks, with treatment sessions being performed 3 times weekly with approximately 48 hours between each session. Treatment times have a minimum of 6 minutes and a maximum of 36 minutes. All painful regions as reported will be treated. The subject will be expected to keep a Daily Diary provided to them for the 28 days of the procedure phase. It will include the medication(s)/therap(ies) used for pain and non-pain management and any adverse events that the subject believes to be happening as a result of treatment.
Post-Procedure Phase: The subject will be required to keep a Daily Diary provided to them for the 28-day post-procedure phase. It will include the medication(s)/therap(ies) used for pain and non-pain management.

***the $50 paid at the first visit will be fully refundable after the conclusion of the study. Failure to comply with study parameters will result in removal from the study and no refund.**