

Clinical Trial ID:

NCT00000422

Title:

Tailored Treatments of Fibromyalgia

Summary:

This study will evaluate the effects of matching treatments to people with fibromyalgia

syndrome (FMS) on the basis of their psychosocial and behavioral characteristics. We will

look at how patients respond to a rehabilitation program that includes physical therapy

and information about fibromyalgia. We will combine this program with psychological

treatments that are either matched or mismatched to the way patients cope with and adapt

to symptoms of FMS. The second aim of our study is to better understand how different FMS

symptoms may vary together and how these symptoms change as a result of treatment in a

person's natural environment. People with FMS and healthy people of the same ages will

record their moods, thoughts, symptoms, activities, and fatigue levels three times a day

for 2 weeks. Participants will use palm-top computers to record these "real-time"

assessments. This approach will permit people to rate how they feel at a particular time rather than looking back in time.

Detailed Description:

Fibromyalgia syndrome (FMS) is a prevalent, chronic musculoskeletal pain disorder.

Despite extensive study, researchers do not understand well the etiology and pathophysiologic mechanisms of FMS, and have not shown any treatment to be universally effective. We propose that FMS is a complex disorder involving multiple factors, both physical and psychosocial-behavioral.

In our previous research, we demonstrated that FMS patients are heterogeneous in the psychosocial-behavioral axis and can be classified into three distinct subgroups on the basis of their psychosocial adaptation to symptoms. In this study we will extend our previous research and attempt to match treatments to patients' psychosocial-behavioral characteristics. Specifically, we will test the efficacy of uniquely tailored treatment for each psychosocial subgroup.

We will treat three groups of FMS patients with one of three treatment

protocols

involving standard physical therapy and varying psychological treatments. A total of 312

FMS patients will undergo six half-day interdisciplinary treatment sessions consisting of

psychological treatments and physical therapy emphasizing aerobic conditioning, pacing,

and body mechanics. All protocols include a standardized physical therapy and either

cognitive-behavioral pain management therapy, interpersonal skill training, or supportive

counseling.

In addition to the treatment outcome study, we will prospectively assess various symptoms

of FMS in the patients' natural habitats to better understand covariations of FMS

symptoms. Patients will do repeated daily monitoring using a palm-top computer

(ecological momentary assessment), which will permit us to evaluate process ratings

compared to retrospective reports.

Overall, the results of these studies should establish the benefit of matching treatments

to patient characteristics and enhance our understanding of the roles of

cognitive-affective-behavioral adaptation by people with FMS.

Eligibility Criteria:

Inclusion Criteria:

- **Female**
- **Able to visit Seattle based clinic 9 times**
- **Meet ACR criteria for FMS**

Exclusion Criteria:

- **Pregnancy**
- **Exercise contraindicated by physician due to other medical conditions**
- **Significant psychopathology**
- **Do not meet FMS criteria**
- **Cardiac problems**

Gender:

Female

Minimum Age:

21 Years

Maximum Age:

65 Years

Phase:

Phase 2/Phase 3

Conditions:

- Fibromyalgia

Interventions:

- Cognitive-behavioral psychotherapy and physical exercise

Locations:

- University of Washington, Seattle, Washington