Disease Management Program to Help Patients with Chronic Pain Study

Purpose

Often individuals with chronic pain feel powerless and stop being active and proactive; they let pain rule their lives. The purpose of this study is to see if a comprehensive disease management program can empower patients to take make permanent lifestyle changes to decrease or alleviate chronic pain.

We were also interested to see if the Creative Visualization (CV) component addressed the psychological needs of patients. Participants optimistic and motivation toward the change is a key for success and ability to sleep for 6+ hours.

Condition	Intervention
Chronic Pain	Nutritional: Daily Supplementation (Douglas Labs) Behavioral: CV delivered via Dr. Patrick Porter's Personal Achievement Device (15 patients) Behavioral: Online-Delivered Cognitive Behavioral Therapy (HeLP - Health eLifestyle Program[1]) Behavioral: Telephone Delivered Accountability and Education Control Intervention
Enrollment:	30
Study Start Date:	July 2008
Completion Date:	September 2008

Patient Demographics and Methods

The study group comprised of patients drawn from a clinical trial conducted at **American Pain and Wellness**. Patients are chronic pain sufferers and long-term patients. The clinical trial lasted for a 12-week period.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both

Criteria

Inclusion Criteria:

- Definitive diagnosis of chronic pain confirmed by participants' primary care physicians
- Average pain intensity in the past month of greater than 3 on 0-10 numeric rating scale;

- Pain is either worse or started since the onset of the disability;
- Pain of at least six months duration, with pain reportedly present greater than or equal to half of the days in the past six months;
- Reads and speaks English;
- Must be able to communicate over the phone (i.e., must be verbal);
- Age 18 years or older

Exclusion Criteria:

- Cognitive impairment defined as one or more errors on the Six-Item screener (Callahan et al., 2002).
- Current or previous participation in a CBT intervention (e.g., psychotherapy, relaxation training, hypnosis, biofeedback) for pain or other psychological disorder such as a mood disorder, anxiety disorder, or substance abuse (obtained via self-report)

Study Type: Interventional

Study Design: Treatment, Randomized, Single Blind (Outcomes Assessor), Parallel Assignment, Efficacy Study

Primary Outcome Measures:

- Average pain intensity in the past week [Time Frame: Four times in a 7-day period Pre-Treatment, Mid-Treatment, Post-Treatment, and 3, 6 and 12 months post-randomization.]
- Adherence to behavior modification program

Secondary Outcome Measures:

- Affect of CV on self confidence, sleep
- Affects of nutritional supplementation
- Increased Energy

Treatment Protocol

Group 1: Treatment Protocol was directed by their physical and employed patient office visits, Internet based behavior modification program, daily educational emails, and bi-weekly phone consultation with Certified Lifestyle Coach.

Group 2: Treatment Protocol was at the directed by their physical and employed patient office visits, Internet based behavior modification program, daily educational emails, and bi-weekly phone consultation with Certified Lifestyle Coach. In addition, this group received Dr. Porter's portable achievement devise.

Results

Here they received daily emails and weekly trainings from HeLP. They were required to fill out their own "Lifestyle Journal" where they recorded exactly what they ate, how they took their supplements, and how they exercised. Their journal was automatically graded and reviewed by their own personal lifestyle coach. They took their high-quality nutritional supplements throughout the 12 weeks of the clinical trial.

During the clinical trial, participants avoided all sugar, flour, bread, cereals, rice, pasta, and potatoes. They also began a modest aerobic exercise program for 30 minutes 5 times per week.

They all commented on how easy the program was and how great they felt. In fact, all 25 participants were able to do all three aspects of the Healthy for Life Program at least 80% of the time.

Here are the results of this clinical trial:

- Their weight decreased an average of 13 pounds
- Their BMI (Body Mass Index) decreased 2.2 points
- They lost an average of 2 ½ inches from their waist (all the weight loss was from their abdomen)
- Their systolic blood pressure dropped an average of 10 points
- Their diastolic blood pressure dropped an average of 6 points
- Their total cholesterol decreased an average of 17%
- Their LDL or bad cholesterol decreased an average of 20%
- Their Triglyceride levels dropped an average of 27%
- Their insulin sensitivity index increased an average of 12%
- Their blood insulin levels dropped an amazing 40%
- Their C-Reactive Protein (a measure of inflammation in the body) decreased an average of 12%

Group 1: Five out of 15 participants dropped out for various reasons, with three purchasing supplements for the clinic monthly.

Group 2: No dropouts. This group gained additional benefits from the portable achievement device: fell asleep faster and slept longer (average 6 hours) and felt less stress about change.

[1] Healthy eLifestyle Program (HeLP) Clinical Trial Results: Western International Review Board (IRB) Clinical Study under FDA Guidelines