



UNIVERSITÀ DEGLI STUDI DI SIENA
DIPARTIMENTO DI MEDICINA CLINICA E SCIENZE IMMUNOLOGICHE
Sezione di REUMATOLOGIA
Coordinatore Prof. Roberto Marcolongo

*Scuola di Specializzazione in
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Efficacy of CELLFOOD (Deutrosulfazyme) in patients diagnosed with Fibromyalgia

Clinical Study Introduction

Fibromyalgia syndrome (FMS) is a chronic pathology characterized by widespread muscular and skeletal pain, by chronic fatigue and axial stiffness, by sleep disorder, and by tender points located in specific soft tissue and/or muscular/skeletal areas with a variety of accompanying clinical symptoms (e.g.: Asthenia, Paraesthesia, Allodynia, Cefalea.)

The diagnosis is based on a characteristic anamnesis, on the evaluation of at least 11 of 18 tender points after palpation according to the ACR principles of 1990 and on haematic, chemical and radiographic (x-ray) exams.

Fibromyalgia typically affects middle aged men and women between the ages of 30 and 55. Fibromyalgia is more prevalent in women and the outline can be primary or secondary to other chronic pathologies. Etiopathogenesis is not still clear, but probably it presents a multi-factorial nature. In fact, neurological, neuroendocrine, psychiatric, muscular, inflammatory and genetic factors are involved.

Non REM sleep troubles are common among Fibromyalgia patients and this can explain the constant asthenia upon awaking that progressively increases during the day. Some authors maintain that there is a compromise of the central and peripheral nervous system.

CELLFOOD is a nutritional supplement in a colloidal solution based on oxygen, trace minerals, amino acids and enzymes. It emanates H⁺ ions (used for metabolic normalization



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of the acidosis) and O⁻ ions that react with oxygen free radicals, and leads to the forming of molecular bio-available oxygen.

CELLFOOD causes the elimination of oxygen free radicals, the conservation of a scavenger, produces rising oxygen and provides optimal cellular nutrition.

For this reason, it is used by athletes to reduce the sense of fatigue and to improve athletic performance. The clinical goal of this study is to evaluate the efficacy of CELLFOOD in the treatment of patients suffering from Fibromyalgia who did not respond to conventional therapies.

Materials and Methods

Thirty (30) patients suffering from Fibromyalgia who did not respond to conventional therapies were recruited. Before the beginning of the treatment (day 0), all patients were subjected to mechanical pain diagnostic measurements, and a subjective evaluation of critical tender points - compiled on the Fibromyalgia Impact Questionnaire (FIQ). Twenty-one (21) patients were treated with CELLFOOD (according to the dosage suggested by NuScience Corporation) and nine (9) patients with a placebo (single blind). The protocol foresaw a control of all the above mentioned parameters 3 months before the consumption of CELLFOOD (day 30, and day 90). One month after the beginning, the patients were contacted by phone and a brief interview was conducted to evaluate the effectiveness of the treatment as well as the VAS on tender points (day 30).

Results

The following parameters as evaluated in the clinical study, showed significant improvement: VAS on actual pain (graph 1), the semi-quantitative evaluation of actual pain



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(graph 2), working fatigue and/or daily activity fatigue during the last week (graph 6) and the count of tender points (graph 7). The other parameters of Fibromyalgia Impact Questionnaire (FIQ) showed improvement as well, without reaching statistical significance. None of patients experienced adverse effects connected with the products.

Conclusions

After analyzing the clinical data, it is noted that after twelve (12) weeks of treatment with CELLFOOD (Deutrosulfazyme), there was a marked clinical improvement of Fibromyalgia's symptomatology both on a subjective level (VAS) and on an objective level (tender point count) on treated patients. The patients' tolerability was optimal and consequently the completion ratio was high (none of patients withdrew from the study). In conclusion, this new therapeutic approach could effectively provide an important contribution in the treatment of patients afflicted with Fibromyalgia syndrome; both from chronic pain and from chronic fatigue symptoms associated with FMS, therefore reducing the need to explore more complex pharmacological solutions. Furthermore, since the product dosage was restricted to the manufacturers suggestion, further investigation using larger dosages for a longer period of time is suggested in order to better evaluate the efficacy of the product.



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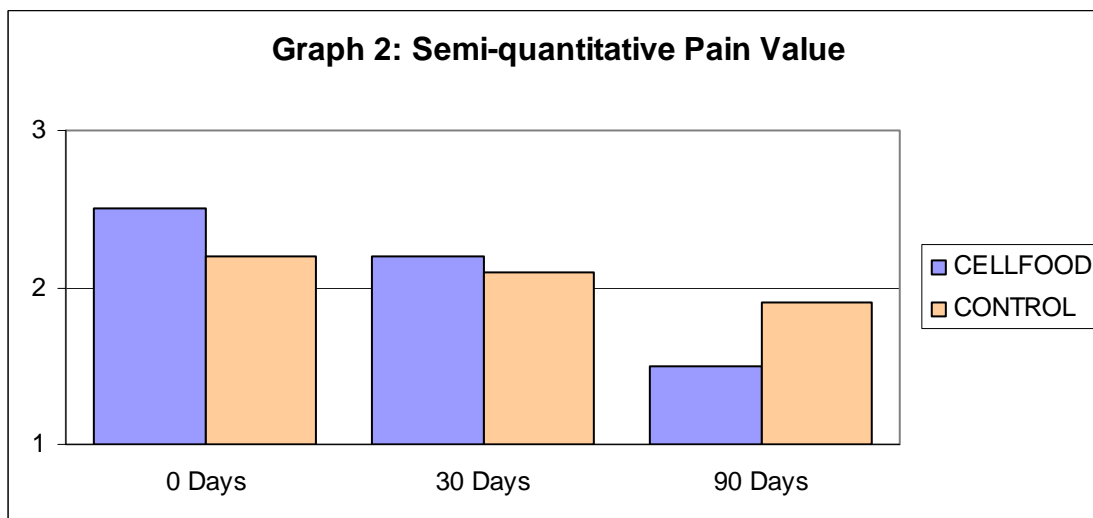
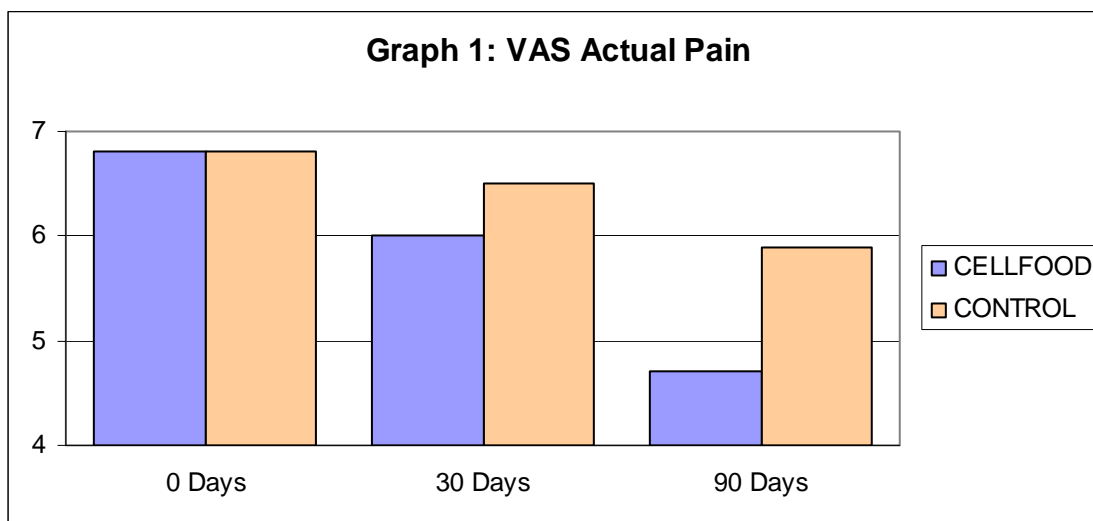
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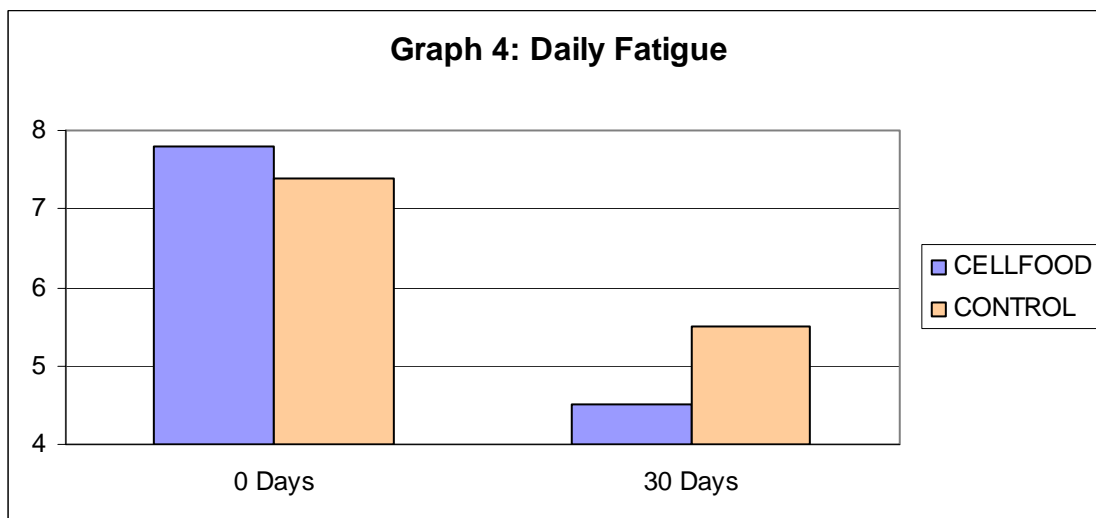
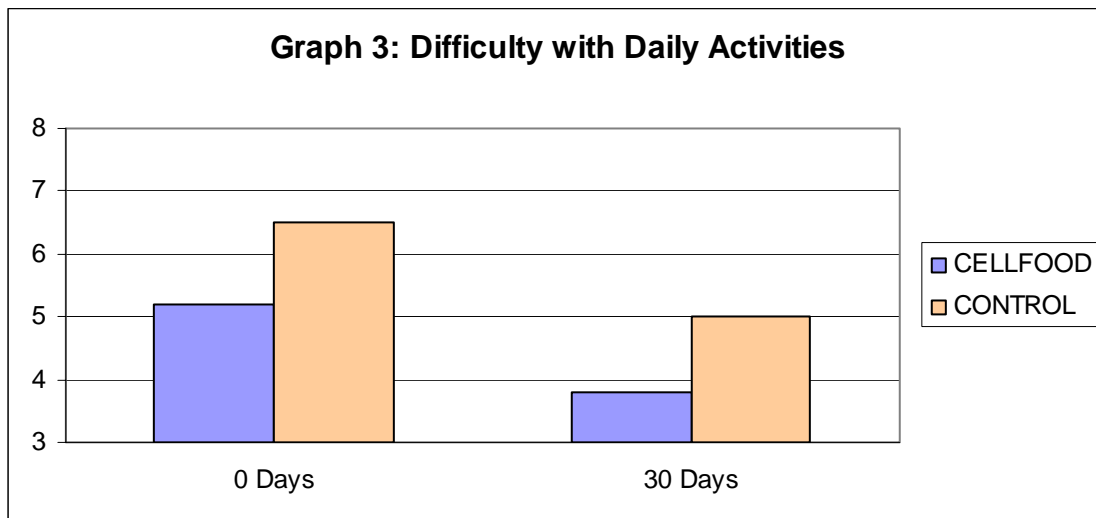
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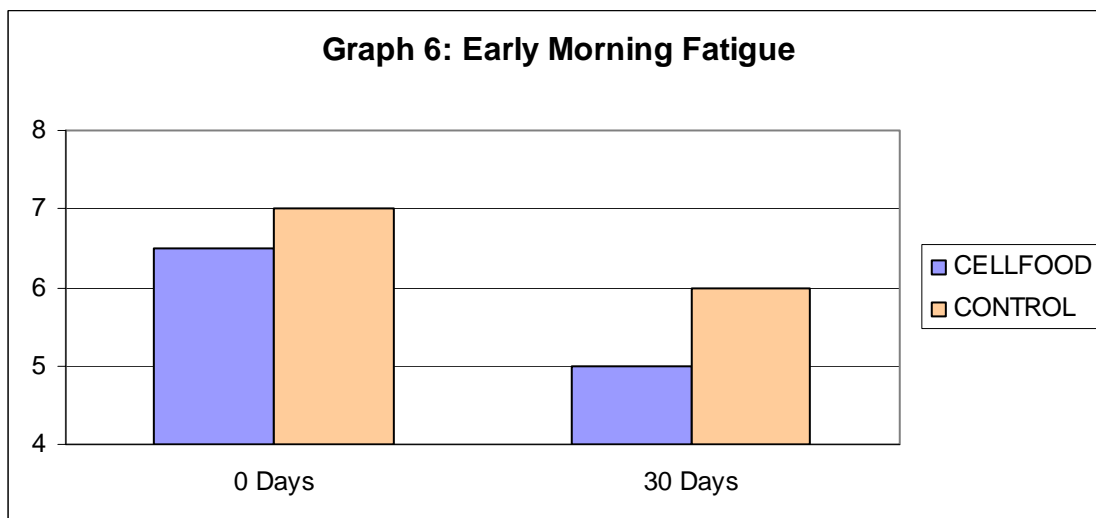
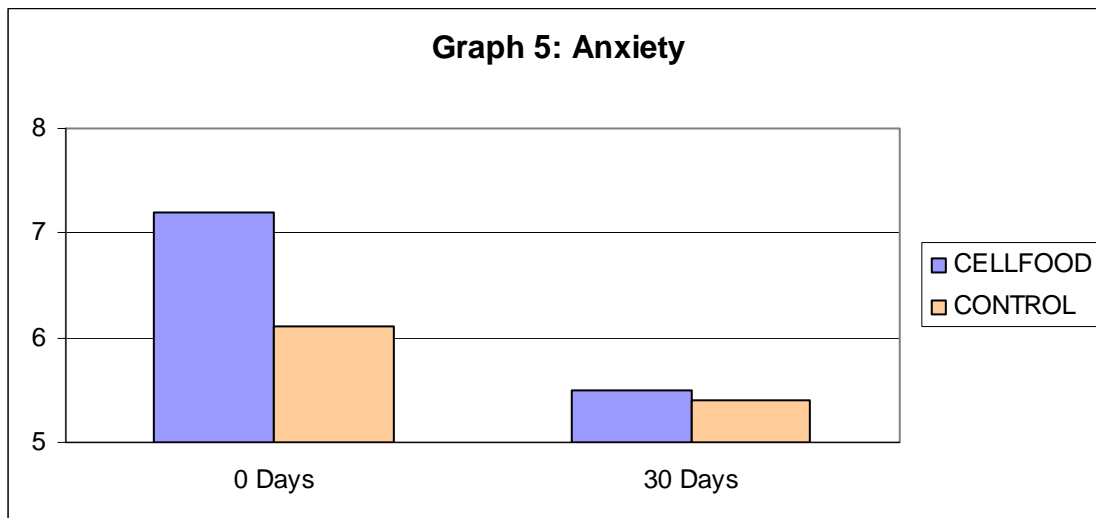
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