TOA-FREE CAT'S CLAW

Pentacyclic Alkaloid-Chemotype Uncaria tomentosa

Compiled APRIL 2003

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The British Naturopathic Journal
The quarterly journal for Naturopaths

Original article

"As the several case studies illustrate, TOA-Free Cat's Claw has proven in our clinic to be a safe natural remedy with a wide range of therapeutic efficacy. To date our patients continue to show remarkable clinical improvement"– John Kule MD.

TOA-Free Cat's Claw in the Primary Care Setting

John Kule MD reports that 98 per cent of patients being treated with a rare Peruvian medicinal plant show clinical improvement

Introduction

RECENT advances in the chemical analysis of Cat's Claw have shed new light on its use as a natural therapeutic agent. Specifically, it has been found that the clinical efficacy increases as the pentacyclic oxindole alkaloid (POA) fraction increases and as the tetracyclic oxindole alkaloid (TOA) content decreases respectively. TOA-Free Cat's Claw (*Uncaria tomentosa*) is a rare form of Cat's Claw that has been found to be 100 per cent TOA free. It is a wild-crafted product of a unique Peruvian rain forest microclimate that so far has been found to be most effective in its most minimally processed form. At a TOA-Free Cat's Claw Conference, held May 10, 2002 in Florida, Brian Lamb, a medical herbalist from Scotland, reported that 100 percent of the terminally ill patients he is treating with TOA-Free Cat's Claw are showing remarkable clinical improvement; an historical review of the scientific literature on *Uncaria tomentosa* was presented by Jerry Schlesser ND, DC, CNS; and Professor Henk Oswald MD, PhD, expounded on his experience of the use of TOA-Free Cat's Claw in the treatment of cancer. Michael Coyle demonstrated TOA-Free Cat's Claw's use as an antimicrobial agent. This paper explores the use of TOA-Free Cat's Claw in the primary care setting.

Integrative health care

All patients were seen and treated at the East Aiken Health Center in Aiken, South Carolina. The background of the patient population is diverse. Aiken is located in rural South Carolina, but has long been a winter training centre for thoroughbred and standard bred racehorses. Fall, winter, and spring also see an influx of hunter/jumpers, three-day eventers and polo players, and golfers. Local industry includes the Savannah River Nuclear Site, so the town has an unusually large engineering and managerial class. The East Aiken Health Center is an integrative health care clinic. General and family medicine are practiced, as well as several modalities of alternative medicine. The local hospital supplies most of our standard diagnostic testing with more specialized testing available at the Medical College of Georgia located in Augusta, Georgia, about 30 miles distance. In-house, we use an extended history and physical, scalar technology, applied kinesiology, and live cell microscopy. In the future we would like to add on heart rate variability and biological ionization testing.

Dosing

The dosing schedule used in all cases, unless otherwise stated, was three 600mg per oral capsules of TOA-Free Cat's Claw twice a day for 10 days. Thereafter dosage was decreased to two 600mg capsules twice a day. TOA-Free Cat's Claw was taken on an empty stomach, by itself. Other supplementation (vitamins/minerals) was taken with meals.

Concurrent usage of other herbs was discouraged as it was felt that other herbs might contain alkaloids with a blocking effect similar to the tetracyclic oxindole alkaloids (TOAs). Beginning in March, 2002, and continuing to date, more than 60 patients have been treated with TOA-Free Cat's Claw.

Conditions treated include:

.Chronic Fatigue
.Fibromyalgia
.Status Post Cerebrovascular Accident
.Chronic Back Pain
.Status Post Breast Cancer
.Diabetes
.Hypertension
.Irritable Bowel
.Candidiasis
.Hypothyroid
.Menopausal Syndrome
.Pre Menstrual Syndrome
.Peptic Ulcer Disease
.Gastritis
.Rheumatoid Arthritis
.Arthritis
.Schizophrenia
.Asthma
.Lyme's Disease
.Benign Prostatic Hypertrophy

Cases

Of the total of 60 patients, only one has so far failed to show clinical improvement. Several case studies have been selected, and are presented, hopefully to illustrate the amazing scope of illnesses that are being successfully treated with TOA-Free Cat's Claw at our clinic.

Case #1. BK, 48-year-old white male, recently diagnosed with incipient cirrhosis of the liver. Patient has a history of light alcoholic consumption but at time of exam was under much personal and professional stress and was experiencing acute flare up of Epstein Barr, herpes simplex, and systemic yeast. Physical findings were significant for fatigue, weight loss, pale appearance, decreased urinary stream, and moderately tender liver of normal size. This patient began TOA-Free Cat's Claw one capsule twice a day and then moved up to two capsules twice a day. He was also placed on a yeast-free diet, and AA supplementation: severe nocturnal cramping was alleviated with calcium supplementation and a multivitamin/mineral supplement. The patient experienced almost immediate increase energy, increased sense of well-being, and increased mental clarity. A mild diuretic effect was well tolerated as the urinary stream normalized within three to five days. The patient also experienced several healing crises which included liver tenderness, bowel inflammation at several sites haemorrhoidal and fissure inflammation followed by normalisation. The patient continues to improve on one per oral twice a day.

Case #2. PE, 53-year-old white female diabetic education nurse. The patient has a long history of rheumatoid arthritis as well as insulin dependent diabetes mellitus, and also hormone replacement therapy with synthetic estrogen alone since hysterectomy in 1979. The patient expressed a desire for more natural treatment alternatives at first her visit. Other medications included Celebrex, Claritin D, Nasonex, and prednisone as needed in acute arthritic flare-ups. The patient was changed to Natural TriEstPro. The Celebrex, Claritin, and Nasonex were discontinued and TOA-Free Cat's Claw begun at three capsules twice a day. Despite the patient's initial scepticism, she has been well with no acute flare-ups. A mild decrease in fasting blood sugars has also been noted. The patient continues to do well on two capsules twice a day.

Case #3. KW, 33-year-old white female with a history of severe asthma beginning after a bout of pneumonia as a seven-yearold. The patient has had multiple hospital admissions, with increasing severity and frequency of asthma attacks occurring the last few years. Her last hospitalisation also almost required the use of intubation/respirator, and did require intravenous corticosteroid. The patient is taking Depoprovera IM every month, Proventil inhaler every day, Flovent inhaler twice a day, and Serovent inhaler twice a day. On physical exam, there was marked SOB and abundant wheezing in all lung fields. Live cell microscopy revealed severe rouleaux. The patient was begun on TOA-Free Cat's Claw three capsules twice a day with marked improvement noted within three days. There have been no further hospital admissions to date, and the patient is back to work.

Case #4. AS, 56 year-old-white female with a history of schizophrenia, cholecystitis/cholelithiasis (surgery has been recommended on several occasions), renal lithiasis, and poorly controlled hypertension. Surgeries included hysterectomy and bladder tack. The patient had been noncompliant with medications (anti-hypertension and anti-psychotic), noncompliant with dietary restrictions (a hot fudge sundae occasioned her last gall bladder colic), and is obese. The patient was voluntarily restricted to home. On at least one occasion in the past, the patient had to be admitted for psychiatric care. Live cell testing revealed marked spicules, liver congestion, and marked lymphatic congestion. Prior to beginning TOA-Free Cat's Claw, the patient's mental condition was deteriorating with auditory and visual hallucinations, and increasing threats of physical harm directed toward her husband (actually directed

toward "Raymond", but her husband's name is "Bill."). Within one week of beginning TOA-Free Cat's Claw the patient's mental condition remarkably stabilised. The patient was able to leave home and shop for the first time in three years, and also became more compliant with taking medications, It was felt that IM B_ would further improve the patient's condition but she would not tolerate the injections. The patient remains stable on TOA-Free Cat's Claw and anti-hypertension (Diovan) medication alone.

Case #5. PK, 56-year-old white female, who since 1998 has suffered neuralgia-like pain and burning sensations in the oral mucosa. Also night sweats, chronic muscle and joint pain, fatigue, short-term memory loss, and visual blurring ("seems my eyeglasses are dirty when they are clean.") Occult dental infection was corrected with oral surgery and a combination of oral penicillin and clindamycin. Symptomatic relief lasted several weeks after which the dental/oral facial neuralgia returned. The patient subsequently was diagnosed with Lyme's disease by fluorescing antibody. Colloidal silver (MSP) was initiated along with homoeopathic Ledum, resulting in partial relief of symptoms. TOA-Free Cat's Claw was added to the above regimen and increased the patient's symptomatic relief to approximately 95 per cent.

Case #6. FC, 75-year-old white male, with a long history of chronic fatigue syndrome and fibromyalgia, and depression. Chronic worsening symptoms of fatigue, muscle soreness, and cognitive loss ("I just can't think clearly") had rendered the patient almost housebound. Domestic support is minimal as the patient is married to a sedentary chain smoker little interested in her own health problems and who ridicules the patient's search for health in the alternative medical field. The patient also suffers insomnia, which could more rightly be described as a loss of circadian rhythm as the patient is unable to fall asleep at night, then chronically is unable to awaken in the mornings. The patient takes Xanax, cytomel, Allegra, Humulin R and N. Treatment with Nutri-Spec diphasic supplementation designed to help restore a more normal diurnal rhythm met with limited success. The addition of TOA-Free Cat's Claw resulted in a marked improvement in the patient's energy level, sense of well-being, increased daily activity, and improved cognitive functioning.

Case #7. JM, 75-year-old white male, with a long-standing history of anaemia. The patient was successfully treated with whole food combinations of iron and chlorophyll (Standard Process Ferrofood and Chlorophyll Complex). The patient then began to experience gastrointestinal distress and then had several episodes of rectal bleeding, determined on physical exam not to be of haemorrhoidal origin. The patient was scheduled for upper and lower gastrointestinal endoscopy which was delayed for one month due to hospital backlog. TOA-Free Cat's Claw was begun one 600mg capsule twice a day then increased to two per oral twice a day. The patient experienced one more episode of gastrointestinal bleeding while taking TOA-Free Cat's Claw, then a cessation of symptoms. At the time of endoscopy, no upper or lower gastrointestinal lesion could be identified. The patient continues to show clinical improvement.

Summary

In these cases and others, what we have consistently noted so far can be summarised as the following: positive clinical findings:

- *Increased energy*. This in particular has been gratifying when used with chronic fatigue syndrome, fibromyalgia, and depression.
- *Sense of wellbeing/lifting of brain fog*. Current studies are underway but this finding appears to be related to the anticoagulant properties of TOA-Free Cat's Claw. Those patients suffering from chronic cold hand and feet seem to make the most gain here. Also to be explored would be a positive effect on infertility, especially when coupled with Peruvian Maca.
- *Decreased inflammation*. Here there might be a transient exacerbation of symptoms, then a marked improvement. The only patient in our clinic who has not shown improvement was one who stopped the TOA-Free Cat's Claw when her symptoms worsened. There was no way to get this patient to understand the concept of a healing crisis.
- *Decreasing blood pressure*. Almost all of our hypertension patients have been able to lower their dosage of anti-hypertension medication. None has been able to discontinue the antihypertension medication altogether, at least at this point in time.
- *Decreasing blood sugar*. All our diabetic patients have had mild lowering of fasting blood sugars (about 10 to 20 points.)
- *Increased diuresis*. All of the patients have experienced a mild diuretic effect.

Adverse clinical findings

These include:
_ Lower extremity cramping. This is easily alleviated when present by either/or calcium supplementation and a good multivitamin/mineral combination.
_ Several patients have experienced healing crises. In fact, individual patients have experienced multiple "mini-crises" with continued use of TOA-Free Cat's Claw. No patient has required hospitalisation while on TOA-Free Cat's Claw.
_ One patient experienced a severe immediate gastritis. The dose was lowered to 250mg each day instead of a normal starting dose of 1800mg twice a day. Within two weeks the maximum dose was tolerated. Gastrointestinal complaints have resolved. This patient's presenting complaint was chronic migraine headache. No change has been noted yet in the severity or frequency of the headaches.
_ Skin rash. Several of the patients experienced transient photosensitive skin rashes, none requiring any treatment other than time. In our clinic, 12 patients have had adverse effects of one or all of the above.

Conclusion
As the several case studies illustrate, TOA-Free Cat's Claw has proven in our clinic to be a safe natural remedy with a wide range of therapeutic efficacy. To date our patients continue to show remarkable clinical improvement. As our experience and confidence with the use of TOA-Free Cat's Claw grows, we are applying TOA-Free Cat's Claw to an expanding list of clinical illnesses.

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Randomized Double Blind Trial of an Extract from the Pentacyclic Alkaloid-Chemotype of Uncaria tomentosa for the Treatment of Rheumatoid Arthritis

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ABSTRACT. ***Objective.*** To evaluate safety and critical efficacy of a plant extract from the pentacyclic chemotype of Uncaria tomentosa (UT) in patients with active rheumatoid arthritis (RA).

M*ethods*. Forty patients undergoing sulfasalazine or hydroxychloroquine treatment were enrolled in a randomized 52 week, 2 phase study. During the first phase (24 weeks, double blind, placebo controlled), patients were treated with UT extract or placebo. In the second phase (28 weeks) all patients received the plant extract.

R*esults*. Twenty-four weeks of treatment with the UT extract resulted in a reduction of the number of painful joints compared to placebo (by 53.2% vs. 24.1%; p=0.044). Patients receiving the UT extract only during the second phase experienced a reduction in the number of painful (p=0.003) and swollen joints (p=0.007) and the Ritchie Index (p=0.004) compared to the values after 24 weeks of placebo. Only minor effects were observed.

Conclusion. This small preliminary study demonstrates relative safety and modest benefit to the tender joint count of a highly purified extract from the pentacyclic chemotype of UT in patients with active RA taking sulfasalazine or hydroxychloroquine. (J Rheumatol 2002;29:678-81)

Key Indexing Terms:
RHEUMATOID ARTHRITIS **UNCARIA TOMENTOSA**
CLINICAL TRIAL **COMPLEMENTARY MEDICINE**

Uncaria tomentosa (Willd.) DC. is a giant vine of the Rubiaceae family, Cinchonoidae subfamily, growing in the rain forest of Peru. Because of its curved thorns, this vine, together with 16 other different species of plants, has also been called "uña de gato" in Spanish and "cat's claw" in English. Scientific and commercial interest in Uncaria tomentosa (UT) was aroused by reports of miraculous cures of diseases like arthritis, cancer, asthma, stomach ulcers, inflammation of the urinary tract, abscesses, and disorders of wound healing.

Attempts to extract potentially therapeutic components from this plant led to the discovery of 2 chemotypes of UT with a different pattern of tetracyclic (TOA) or pentacyclic oxindole alkaloids (POA)[1]. Quinovic acid glycosides, sterols, epicatechine, and other ubiquitous components were found in both chemotypes. The POA were found to have immune modulatory effects. Besides enhancing phagocytosis, as reported for other plant derived immune modulators[2], POA were shown to inhibit proliferation of highly activated lymphocytes while stimulating proliferation of resting or weakly activated lymphocytes. These effects were antagonistically inhibited by TOA[3].

UT derived preparations are already used as complementary medication, without, however, sufficient clinical evidence of safety and efficacy. We initiated a randomized, double blind, placebo controlled study to evaluate the effects of a well characterized and standardized TOA-free UT extract in patients with active rheumatoid arthritis (RA) treated with sulfasalazine or hydroxychloroquine.

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Supported by Immodal, Austria.

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Submitted April 23,2001; revision accepted October 18, 2001.

MATERIALS AND METHODS

Patients. Forty patients aged 20 years or more who fulfilled the American College of Rheumatology criteria for RA[4] with Steinbrocker functional class II or III[5] were enrolled in the study. Disease was considered active when 3 of the following 4 criteria were fulfilled: $\geq$ 6 painful joints, $\geq$ 3 swollen joints, morning stiffness

> 30 min. erythrocyte sedimentation rate (ESR)>25 mm/h, or C-reactive protein (CRP) > 20.0 mg/I. All patients had been treated with sulfasalazine or hydroxychloroquine for a period of at least 6 months; in the 6 week prior to enrollment in the study, patients had to take stable doses of these drugs. Nonsteroidal anti-inflammatory drugs (NSAID) and prednisolone up to 10 mg/day or its equivalent were permitted.

Patients with coexisting hematologic, renal, hepatic, cardiovascular, neurologic, or psychological diseases were excluded. Chronic infection or a neoplastic event in the medical history were considered reasons for exclusions. Patients with a history of alcohol or drug abuse and those with known poor compliance were excluded. In the 4 weeks before and during the course of the study, patients were not permitted to have intraarticular, intramuscular, and soft tissue steroid injections. Pregnant women and nursing mothers were not enrolled in the study. The study was approved by the local ethics commission and written informed consent was obtained from all patients.

Study design. The study was carried out in 2 phases at the Rheumatological Outpatient Unit of Innsbruck University Hospital. In the first phase of 24 weeks, the study was designed to be randomized, double blind, and placebo controlled. During this period, patients received one capsule of the plant extract or placebo 3 times daily while continuing their antirheumatic therapy. In the second phase, all patients received the plant extract.

Clinical assessment, was always performed by the same investigator (EM) at the beginning of the study and at 4, 8, 16, 24, 36 and 52 weeks thereafter. The number of swollen (out of 66) and painful joints (out of 68) and the Ritchie Index[6] were determined, and patients were asked to assess pain and disease activity with a visual analog scale (VAS). Morning stiffness was measured on a 5 step scale (0= no morning stiffness, 1 = < 30 min, 2= 30-60 min., 3= 1-2 h, 4= 2-4 h, 5=>4 h). At the start of the study, at 24 weeks thereafter, and at the end of the study, patients' functional capacity was determined with the Health Assessment Questionnaire (HAQ)[7]. Safety was monitored by physical examination, blood pressure, pulse rate, and body temperature and body weight measurements. Laboratory studies included ESR, CRP, rheumatoid factor (RF), antinuclear antibodies, complete blood count, and hepatic and renal variables.

Study medication. Krallendorn® capsules (Immodal Pharmaka GMbH. Volders, Tyrol, Austria) contained 20 mg of an aqueous acid-extracted dry extract of Radix Uncariae tomentosae (Willd.) DC. mod. pent., with 14.7 mg/g POA and no TOA. Lactose 130 mg and ascorbic acid 200 mg per capsule were used as filler. With the exception of the active ingredient, the placebo had the same ingredients.

Statistical analysis. An intent-to-treat analysis was performed. Descriptive statistics included mean values with standard deviations. For comparison of dependent variables at different times the nonparametric Wilcoxon and the Friedman test were used; the Mann-Whitney test was applied for comparison between the UT extract and placebo group. A p value < 0.05 was considered significant. Statistical calculations were performed with SPSS version 9.0.

RESULTS

Demographic data. Patients' characteristics are presented in Table 1. There was no statistical difference between the 2 groups with regard to sex, duration of disease, medication, intake of corticosteroids, and clinical and laboratory values, with the exception of CRP (higher values in the placebo group).

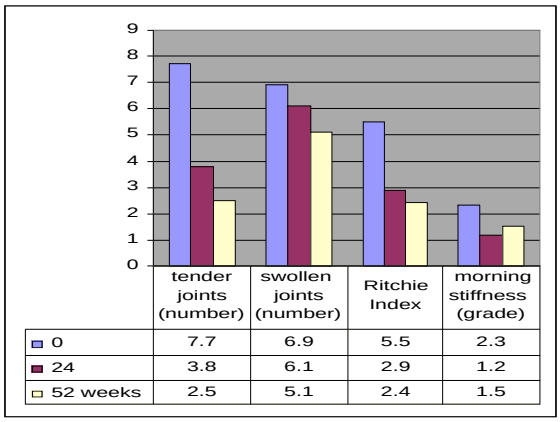
Out of 40 subjects, 19 were randomized to the placebo and 21 to the UT extract group. During the study, one patient from each group dropped out because of adverse events, and one patient from the plant extract withdrew after one month of treatment with the UT extract because of inefficacy of the drug.

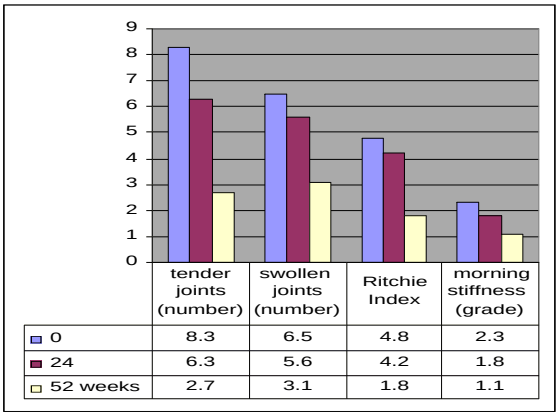
Clinical efficacy. Phase 1 (UT extract or placebo). Comparison of the 2 groups at the end of the first phase of study showed that patients in the plant extract group had fewer painful joints than those of the placebo group (reduction by 53.2 vs 24.1%; p=0.044). No differences were observed between the 2 groups for the other variables.

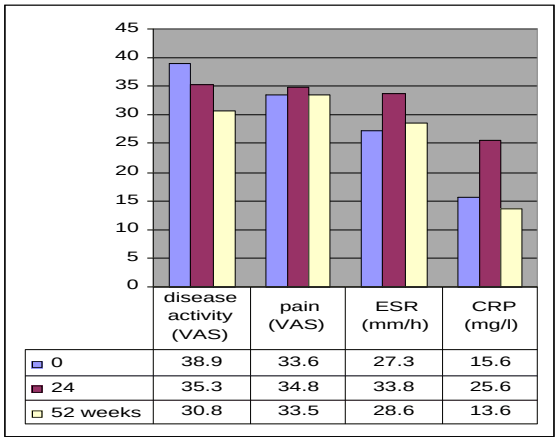
In patients given the plant extract there was a reduction in the number of tender joints (p-0.001), Ritchie Index (p=0.002), and duration of morning stiffness (p=0.002) after 24 weeks compared to the

Table 1. Patient demographics at study entry.

	UT Extract n=21	Placebo Group, N=19
Age, mean ± SD, yrs	53.1 ± 13.4	54.9 ± 13.5
Female/male	20/1	15/4
Disease duration, mean ± SD, yrs	6.1 ± 5.7	7.9 ± 8.3
Tender joints, mean ± SD	7.9 ± 3.0	8.4 ± 4.4
Swolen joints, mean ± SD	7.0 ± 4.2	6.3 ± 2.8
Morning stiffness, mean grade	2.3	23
ESR, mm/l h, mean ± SD	27.3 ± 19.4	30.1 ± 19.7
CRP, mg/l, mean ± SD	15.6 ± 16.9	28.1 ± 25.3
RF poitive	10	8
Sulfasalazine/hydroxychloroquine	18/3	17/2
Patients taking prednisolone	7	8







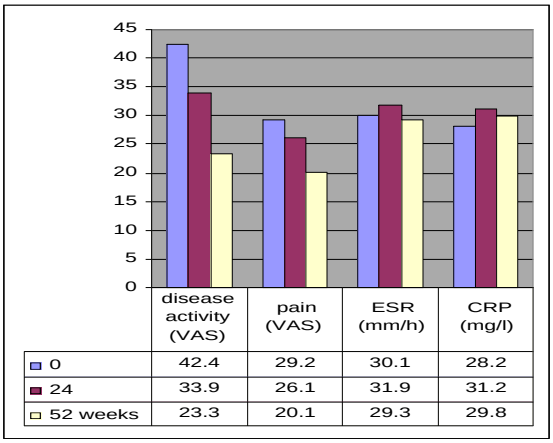


Table 1. Mean outcome measures at 0, 24 and 52 weeks after onset of treatment with UT extract.

Table 2. Mean outcome measures at 0, 24, and 52 weeks in patients receiving placebo from Week 0 to Week 24 and treatment with UT extract from Week 24 to 52.

baseline valued, whereas in the placebo patients the number of tender joints, Ritchie Index, and duration of morning stiffness were not significantly reduced (Figures 1 and 2). No changes were detected for the number of swollen joints, patient assessment of disease activity, subjective assessment of pain, and the laboratory variables except for an increase in the level of RF in the placebo group ($p=0.041$).

Phase 2 (UT extract). Further intake of the UT extract resulted in a reduced number of tender joints ($p < 0.001$), Ritchie Index ($p = 0.001$), and duration of morning stiffness ($p = 0.004$) compared with the baseline values at Week 0 (Figure 1). No changes were found for the other clinical variables and the laboratory values.

In patients who received the plant extract only during the second phase, there was a reduction in the number of painful joints ($p = 0.003$), number of swollen joints ($p = 0.007$), and Ritchie Index ($p = 0.004$) compared to the values observed at the end of their placebo treatment (Figure 2). There was a decrease in the intensity of pain and disease activity as assessed by the patients and the duration of morning stiffness; none of these changes, however, reached statistical significance. Among the laboratory values there was a reduction in the RF from 135 to 32; this too, along with the other laboratory measures, was not statistically significant.

There was no change of the HAQ in either group compared to baseline values or the end of the first phase.

Table 2. Adverse events. Relation to treatment: 1 = definitely not, 2 = probably not, 3 = possibly, 4 = probably, 5 = definitely

	UT Extract		Placebo	
	No. of Patients	Relation to Treatment	No. of Patients	Relation to Treatment
Dyspepsia	2	2;2	2	2;4
Respiratory infection	2	2;3	1	2
Dermatitis	0	--	2	2;3
Pruritus	2	2;2	0	--
Conjunctivitis	1	2	1	2
Influenza	1	2	1	2
Gastritis	1	2	1	3
Herpes zoster	1	2	1	2
Urinary tract infection	1	2	0	--
Fatigue	1	2	0	--
Diarrhea	0	--	1	4
Headache	0	--	1	2
Toothache	0	--	1	2

Safety. During the first phase, adverse events occurred in 12 patients of each group (Table 2). One patient taking the UT extract withdrew from the study owing to gastritis and one patient from the placebo group because of diarrhea. In the second phase, 7 other side effects were seen, none that could be clearly attributed to the drug intake. No major side effects were seen in the active and the placebo group.

DISCUSSION

An increasing number of patients with RA are skeptical about conventional antirheumatic medication. It has been reported that up to 40% of rheumatology patients visit a complementary medicine practitioner in the course of their disease[8]. Failure of orthodox drugs to bring sufficient relief of symptoms and concern about potential side effects are the main reasons patients turn to complementary approaches[9].

Many patients believe that plant derived drugs have less side effects, but at least some efficacy. Thus extracts from a variety of plants are widely used by patients with rheumatic diseases, although the efficacy of the majority of these preparations has not been substantiated with adequate evidence. In addition, some herbal therapies were reported to have clinically relevant side effects. Taking these facts into consideration there is a demand for research on the efficacy and safety of this kind of complementary medicine[10-12].

Selected plants of Uncaria tomentosa have a long tradition in the Ashaninka Indians of Peru as a remedy for rheumatic diseases[1]. *In vitro*, a UT plant extract containing POA revealed an immunomodulatory effect, which is antagonistically inhibited by TOA[3]. An alkaloid-free extract from UT was shown to enhance DNA repair[13]. Another UT extract containing POA has been reported to inhibit production of tumor necrosis factor-_ and to have antioxidative effects[14]. Information on the clinical efficacy of UT in patients with rheumatic diseases, however, is quite sparse.

This study demonstrates that a TOA-free extract from the pentacyclic chemotype of UT, in combination with sulfasalazine or hydroxychloroquine, has some favorable clinical effect on RA disease. At the end of the placebo controlled phase of the study, the number of painful joints was reduced in patients treated with the UT extract compared to the placebo group, whereas the number of swollen joints, the Ritchie Index, and morning stiffness were not affected. Followup of patients treated over a total period of 52 weeks revealed continuing clinical improvement, with a reduction in the number of tender joints, the Ritchie Index, and morning stiffness compared to baseline. These results suggest that this TOA-free extract from the pentacyclic chemotype of UT has a clinically relevant adjunctive therapeutic potential when combined with conventional disease modifying drugs, corticosteroids, and NSAID. The daily dosage of 60 mg of an aqueous acid-extracted dry TOA-free extract of UT can be considered well tolerated and safe. There were no side effects clearly attributable to the UT extract and both the number and quality of the side effects of the UT extract were comparable to placebo. Whether and to what extent variations in the doses applied lead to changes in toleration and efficacy needs to be examined in larger placebo controlled double blind trials.

The TOA-free extract from the pentacyclic chemotype of UT administered in this study represents a purified and well defined agent containing a defined and standardized content of POA, whereas many other herbal products lack a clear specification of their ingredients. Indeed, most cat's claw products available in health food stores vary in quality and quantity of their content[15,16]. Both the total alkaloid amount and the percentage of pentacyclic alkaloids vary over a wide range in the undefined UT extracts. Even different batches of the same product may show considerable variations of ingredients[16].

From the phytochemical standpoint plant species are not homogenous sources of raw material. There is variation in components in many plant species depending on external factors like climate or light, whereas heredity may cause the development of different chemotypes, as in UT. In view of these circumstances, high standards of manufacturing and quality control in the production of herbal drugs are necessary to provide herbal remedies with a clear specification of their ingredients. Although there is evidence for the safety and efficacy of some herbal therapies, this kind of treatment can only be accepted for treatment of rheumatic disease when the specific preparation offers a well defined and standardized medication shown to be effective and safe in adequate controlled clinical trials.

Concerning TOA-free extract from the pentacyclic chemotype of Uncaria tomentosa, on the basis of its relative safety and modest benefit to the tender joint count compared to placebo shown in this small preliminary study, a larger longer placebo controlled double blind trial is recommended.

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Lechitel Weekly, Sofia, Bulgaria, April 2003

Why TOA-Free Cat's Claw Successfully Treats Over 100 Diseases

Atanas Tzonkov
Herbalist and Healer, Editor in Chief of "Lechitel" Weekly
and Director of "Lechitel" Health Center

Despite the widespread belief that no remedy can treat more than a couple of diseases, the truth is entirely different. Even in conventional medicamental medicine, there are drugs - for instance corticosteroids or non-steroidal anti-inflammatory drugs - that do treat or positively influence a large number of "diseases" or clinical symptoms. Additionally many antibiotics, in spite of their apparent or relative specificity, successfully treat quite a large number of different bacterial infections.

Just as the treatment range of antibiotics is relatively wide, this is also true of many of the of the so-called natural remedies: herbs, bee products, fruit and vegetable extracts, as well as, fish and other animal extracts. Such a "cure-all" nature is also associated with authentic natural mumio, propolis and royal jelly. According to many Japanese authors, these remedies may be used to treat 82 different conditions. There are many others alternative treatments noted for their unquestionably wide-ranging therapeutical impact: psychotherapy, music therapy, hydrotherapy, cryotherapy, yoga, acupuncture, acupressure, etc.

By mentioning the most powerful medicinal and natural remedies, I aim to emphasize that none of them can match TOA-Free Cat's Claw. TOA-Free Cat's Claw outrivaled everything known in therapy on at least several criteria: safety, power and speed of action, or efficacy. It has a healing range unseen so far. These claims and conclusions do not rely on existing publications on TOA-Free Cat's Claw but on my own practice as a healer. My files include thousands of patients: **lung cancer** cases exceed 100, the **Helicobacter pylori infections** – 400, **hypertension** sufferers – 700, **MS** patients – 50, and dozens of patients with **diabetes**, **lupus erythematosus**, **bronchial asthma**, **polycystic kidney disease**, etc. My files encompass more than 100 different diseases defined according to the generally accepted classifications in conventional, academic medicine, but we shall return to this question later.

Here are just a few particular illustrations proving that TOA-Free Cat's Claw can both favorably influence the symptoms and eliminate the causes for a huge number of diseases, some of which are even known to date in official medicine as incurable.

1. S.B., 68, teacher. Suffering from **BRONCHIAL ASTHMA** – for 36 years now. The diagnosis was determined at the University Hospital in Pleven and confirmed by the National Laboratory at the Institute of Infectious and Parasitic Diseases in Sofia. Treatment included nophilin, clemastin, antibiotics, syrups, salbutamol. Proven **allergy** to dust mites, bird down and plumage, various perfumes and pollen from a large number of herbs and flowers. Patient was subjected to desensitization from 1969 to 1980. The severe **cough** subsided but the **difficult breathing** persisted, as well as the **rapid fatigue**. The use of Becloforte and Ventolin inhalers caused **dermatitis** (rashes and itching).

After a 3-month use of TOA-Free Cat's Claw 600 mg in a 2 x 1 dosage with a cup of Rooibos tea half an hour before meals the difficult inhaling and exhaling disappeared. So did the rashes and the itching. The inhaler and all the previously taken medicines were rendered unnecessary and their use was discontinued. This lasting effect has persisted for 9 months already. The patient responded to the results of her treatment with TOA-Free Cat's Claw by saying, "I've been born again!"

2. P.T., 80, former school principal. Diagnosis: **PROSTATE CANCER**, ascertained at the Alexandrovska Hospital in Sofia. Symptoms: **pain in the groin and genitals, difficult urinating, muscle spasms in the leg, noisy breathing (swishing, wheezing), ulcer, colitis, gastritis, gastrointestinal complaints (pain, heartburn, flatulence, rumbling in the bowels, eructation, constipation)**. After various fruitless conventional treatments on Dec 16th 2002 the patient was examined in the Lechitel Health Center laboratory with diagnostic tests of Hoffman-LaRoche. The results: a) PSA – 8.6, WITH REFERENCE VALUES AT UP TO 4; b) CHLAMYDIA TRACHOMATIS – 1:32.

After taking TOA-Free Cat's Claw and Rooibos tea by a special scheme for one month, on Feb 17th 2003 the control laboratory tests showed the following results: a) PSA – 2.73; b) CHLAMYDIA TRACHOMATIS – NEGATIVE.

The patient reported that the gastrointestinal complaints have vanished almost completely, as well as the muscle spasms in the legs, the noisy breathing, pains and difficult urinating. He keeps on taking a maintenance dosage of TOA-Free Cat's Claw and Rooibos tea.

3. P.R., 53, engineer. **PAPILLARY CARCINOMA OF THE THYROID**, with lymph-node metastases. Histologically diagnosed at the National Specialty Hospital for Active Oncological Treatment in Sofia in 1997. Complete **surgery and radiotherapy** in 1997 and 1998. Constantly increasing levels of the thyroglobulin (TG), its value in March 2002 being 81.39. On Sept 3rd 2001 the X-ray scans show multiple **metastases in both lungs**. The tests are positive for *Helicobacter pylori* and *Chlamydia trachomatis* (1:512). The complex treatment with TOA-Free Cat's Claw 600 mg by a flexible scheme and chemotherapy for a year and a half achieved the following results: Chlamydia infection eliminated, thyroglobulin reduced from 81.39 (March 2002) to 51.46 (June 27th 2002), the reference values being 1.4-14.78, Helicobacter pylori deactivated. The patient is doing very well.

4. _.V., 56, journalist. **BLADDER CARCINOMA**. Diagnosed at five of the leading hospitals in the country, including the National Specialty Hospital of Oncology, Sofia. Accompanying conditions and symptoms: **hydronephrosis, calculous holecystitis, colitis, urinary blood, blood-spitting, permanent fever 38°C, hemoglobin – 50, SR (sedimentation rate) – 55, fatigue, albuminuria, decubitus…** Date: June 22nd 2002.

After a several month therapy with antibiotics, alcozin and herbs the patient's condition not only failed to improve but continued to deteriorate. The oncologists restrained from surgery and radiotherapy; some of them believed the patient should be operated without delay.

After including TOA-Free Cat's Claw and 3 more products in the therapy, **on the sixth day**: 1. The patient **was strong enough** to make a full day round of laboratories tests and doctors' visits. 2. The **pain** was overcome. 3. The **body temperature** returned to normal. 4. **SR fell from 55 to 27.5** and only traces remained from the **protein in the urine**. 5. The **hemoglobin** rose from 50 to 70. 6. The **bleeding** stopped.

After 4-month, not quite consistent treatment with TOA-Free Cat's Claw **the tumor shrank by more than 60%**. Unfortunately, due to reasons independent of us, we were unable to continue and follow up the patient's treatment.

5. C.T., 55. The patient complains of repulsion to all kind of food, stomach aches, nausea, vomiting. Gastroscopy and biopsy at three different hospitals have confirmed the presence of **Helicobacter pylori** in the gastric mucosa. The patient has undergone two courses of antibiotics, including Helicocin, without obtaining the desired medicinal effect. She suffered serious weight loss and was fed intravenously. Helicobacter pylori was not eliminated.

The patient came to see me three months after these unsuccessful therapies. The serological testing of peripheral blood confirmed the presence of Helicobacter pylori. **Her blood pressure was 170/110.** After a 1-month treatment using only TOA-Free Cat's Claw 120 mg, (1 capsule in the morning half an hour before breakfast with a cup of Rooibos tea), the patient noted an increase in both her appetite and her strength, the aches were fading and the nausea and vomiting had stopped. The follow-up testing for Helicobacter pylori obtained a negative result. The patient's blood pressure was 120/80.

6. J.I., 80, teacher. The patient had undergone **BREAST CANCER** surgery 15 years ago. She contacted me in the spring of 2001 when she had the following conditions and symptoms: **bilateral chronic pyelonephritis, chronic gastroduodenitis, hypertension, insomnia, conjunctivitis, vertigo, allergies, rhinitis, tracheitis, rheumatic pains, parodontitis, itching over the whole body, fatty infiltration of the liver.** The patient had been unsuccessfully treated with non-steroidal anti-inflammatory drugs, antibiotics, etc.

The blood sugar level was slightly elevated, as well as the total cholesterol and triglycerides. The tumor markers (CA 15-3) varied from 19 (Nov 4th 2000) to 52 (June 28th 2001). The sedimentation rate (SR) was above the norm – from 20 to 60 (between January and October 2002).

I appointed tests for the detection of Chlamydia and Helicobacter pylori. The results were: ***Helicobacter pylori*** – positive (240), ***Chlamydia trachomatis*** – positive (1:512).

After prolonged treatment, mainly with TOA-Free Cat's Claw 600 mg by a complex scheme, and several other natural products, the following results were achieved:

First, all disease symptoms faded away.

Second, some of the paraclinical readings move in the upper range but most of the time are within the norm (glucose, lipids, liver enzymes).

Third, some other readings have still not completely returned to normal (the tumor marker CA 15-3 and SR).

Fourth, the rheumatic marker AST was brought down from 1:264 (March 28th 2002) to 1:16 (Oct 30th 2002).

Fifth, Chlamydia trachomatis levels were reduced from 1:512 (May 9th 2001) to zero (April 22nd 2002). The patient was unable to make the test earlier…

Sixth, Helicobacter pylori (positive) was reduced from 240 (on May 9th 2001) to 90 (positive) on April 22nd 2002.

Seventh, the patient feels very lively, energetic and has no complaints.

But let's go back to the question: Why is TOA-Free Cat's Claw capable of successfully treating more than 100 diseases?

To answer that question we need to realize and admit that the time has come to radically reform orthodox medicine. It is more and more apparent that its theoretical principles, as well as its practice, has become not only unproductive and inefficient but harmful to patients.

First of all, today's predominantly medicamental medicine treats millions of people but ***cannot cure*** a single hypertension patient, asthmatic or a patient suffering from rheumatoid polyarthritis, multiple sclerosis (MS), polycystic disease or skin conditions like vitiligo, psoriasis, lupus erythematosus, etc., etc. What does that mean – that medical science and practice are on the wrong path, have taken the wrong direction and don't understand the essence of the problem they're striving to overcome.

Second, conventional medicine today is mainly attempting to treat the symptoms; it is a symptomatic kind of medicine and therefore fruitless, unproductive and inefficient. And it

is impossible for it to be otherwise since medical science is unable to identify what or which are the factors causing cancer, asthma, diabetes, MS, arthritis, etc. The majority of pathological mechanisms are still undeciphered and for that reason a successful treatment program can rarely be applied.

Third, when I say that TOA-Free Cat's Claw can successfully treat more than 100 diseases, I feel to a large extent embarrassed and uncomfortable – not because it isn't true but because it's not true that what medicine still treats as nosological units, diagnoses or diseases are really such. Examples? In my opinion conditions as gastritis, colitis, ulcer, Crohn's disease, ulcerous colitis, IBS and the like are theoretical fiction, terminological crutches for the helpless conventional therapies. Over 95 percent of gastrointestinal disorders and diseases are actually caused by two types of infection – Helicobacter pylori and Chlamydia trachomatis. Once we eliminate these, of course with the help of TOA-Free Cat's Claw, the above mentioned "diagnoses" disappear too. Identical examples are the conditions of the motor and skeletal system: arthritis, arthrosis, Bechterev's disease, cervical arthrosis, gonarthrosis, omarthrosis, coxarthrosis, radiculitis, etc.

Fourth, TOA-Free Cat's Claw gives the unprejudiced, free-minded people the chance to understand the pressing necessity for a new approach to the illness and the patient, a new approach to health. First of all the patient should be diagnosed in depth and width according to all achievements of modern medicine. The diagnostic methods should be systematically applied for controlling the treatment process. The treatment should be complex, non-invasive, agreeable, efficient and with no side effects. This can only be accomplished by TOA-Free Cat's Claw.

Fifth, TOA-Free Cat's Claw is not only able to cure many kinds of diseases still regarded by conventional medicine as untreatable, but also *a whole bouquet of other conditions or symptoms in a patient* . Notably, these conditions are increasingly common among the elderly. In such cases, doctors are forced to prescribe more and more synthetic medicines to offset the negative consequences of some allegedly lifesaving or irreplaceable remedies (as the non-steroidal anti-inflammatory drugs, corticosteroids, antibiotics or cytostatics). The patient can only break out of this vicious circle of drugs with TOA-Free Cat's Claw. It replaces, substitutes, makes unnecessary all the commonly used antirheumatic, anti-inflammatory, anticancer, antiviral drugs. TOA-Free Cat's Claw has all these characteristics and many more that no synthetic drug remedy possesses.

Sixth, TOA-Free Cat's Claw treats the patient's whole body and not just the specific disease or symptoms. Scientific medicine and other remedies of the so-called natural, tender, popular, alternative medicine talks about radical, pathoetiological, definitive treatment. TOA-Free Cat's Claw doesn't talk about it – it does it. If I'm offering something new, it is the OPTIMAL MEDICINE. That means reasonable, optimal, effective combined use of all the efficient tools for diagnosing, treatment and prevention, irrespective of whether they come from the certified or popular medicine. This is not in the interest of the pharmaceutical giants but it is in the interest of every ordinary man, every honest citizen and taxpayer.

Seventh, TOA-Free Cat's Claw is the masterpiece of medicine. It is the key to the future of medicine – truly humane, worthy of Homo sapiens, compatible with reason and conscience. TOA-Free Cat's Claw opens the door for new, still unknown or not sufficiently appreciated herbs and other health gifts of Nature. As long as medicine doesn't cut the umbilical cord connecting it with Nature, it will continue to care successfully for human health and strengthen it.

Professor Henk Oswald, M.D., Ph.D.

- Director, Complementary Medicine Clinic, Amsterdam, Netherlands
- Director and Principal, Meditest International, Amsterdam, Netherlands
- Professor, Metabolic Chemistry, Universities at Jakarta and Colombo
- Board Member of IRENATH (International Institute for Research and Development on Natural and Holistic Therapies)
- Member, International Academy of Natural Health Science
- Chairman, Foundation "Nutrition and Science"

Dr. Henk Oswald is a prominent pioneer in the fields of natural health and metabolic chemistry. During the course of a distinguished medical career that has spanned more than forty years, he has received over 70 awards and honors in recognition of his significant contributions. Included among these is the prestigious Albert Schweitzer Award for Medicine, and knighthood in the Knights of Malta.

Dr. Oswald was the first in Europe to utilize the HLB blood test and later the first to use live blood analysis. In 1980, he participated in research that detected the connection between intestinal microorganisms and diseases in other organs. He is frequently invited to be the key speaker at seminars all over the world on the subject of the early detection of cancer and other degenerative diseases.

Nutritional Evaluation Utilizing Dark Field Microscopy

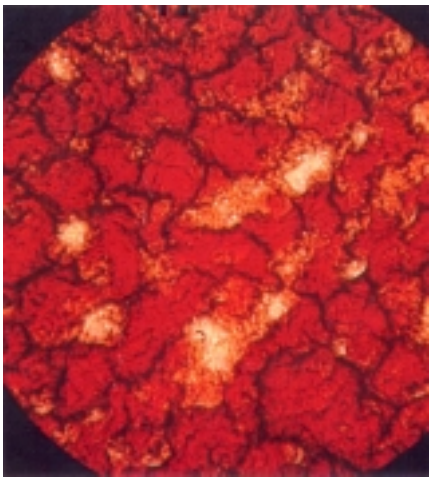
The pictures on the following pages indicate the power and benefits of TOA-Free Cat's Claw (600 mg.). The "Before Treatment" photographs are of damaged blood cells due to free radical attack. The "After Treatment" photographs show cells after treatment with only TOA-Free Cat's Claw (600 mg.).

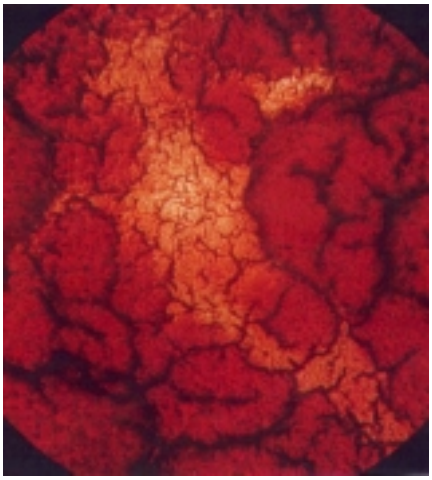
Note how the attack of free radicals has damaged the cells. The formerly healthy cells have lost their integrity. This is indicated by their clumping together and fuzzy appearance. The free radicals have opened the way to fungal development and other micro-organic invaders. Because of free radical damage, the cell has an inability to process nutrients.

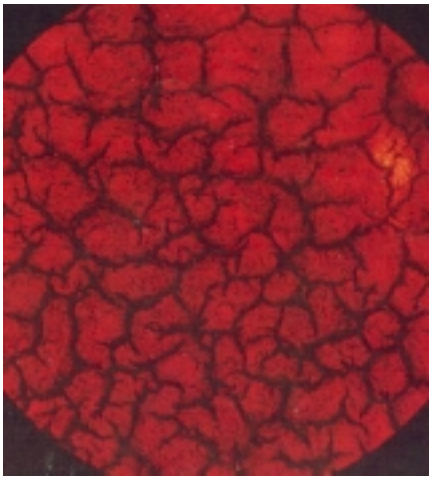
In the photographs of cells receiving treatment, you will note the cells have regained their independence and the damaged areas are minimized. This is indicated by the lack of yellowish white discoloration, increased clarity, and greater cell integrity.

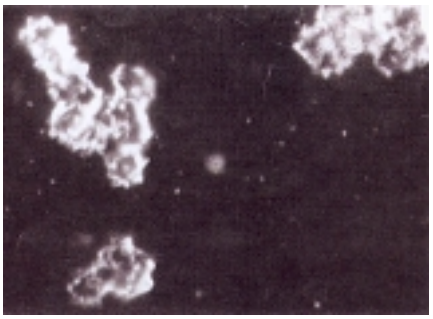
As you can see, in an amazingly short time period, TOA-Free Cat's Claw (600 mg.) succeeded in restoring health to the individuals' blood cells.

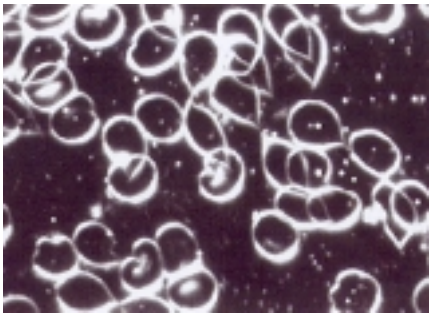
Rheumatoid Arthritis Patient Treated with TOA-Free Cat's Claw (600 mg.)

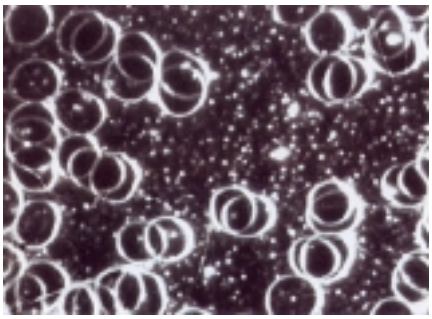










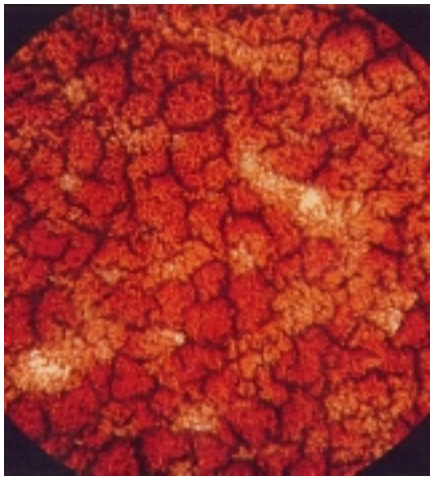


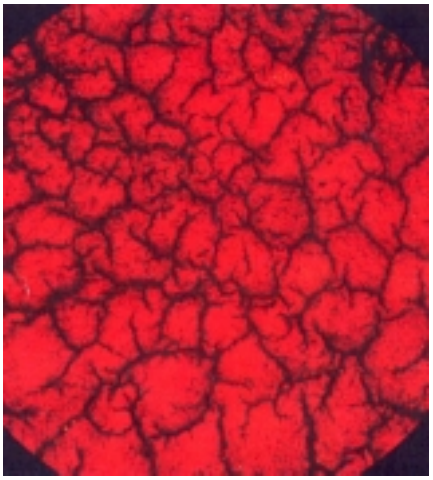
Patient with rheumatoid arthritis in much pain, on a regimen of four daily painkillers and cortisone. The patient is put on a regimen of one TOA-Free Cat's Claw (600 mg.) four times daily.

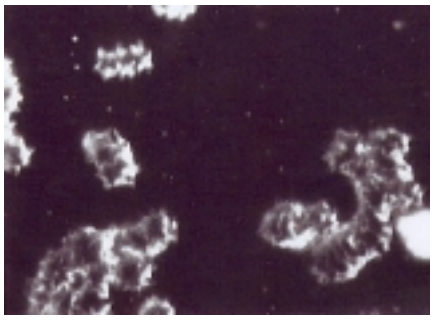
The top photograph shows fewer white spots. The bottom photograph shows the cells less attached, but with free radical damage and oxidation. TOA-Free Cat's Claw (600 mg.) has anti-oxidant properties and is a free radical scavenger, but it cannot be used in combination with cortisone, so the cortisone is discontinued. The patient continues on a regimen of two painkillers and three TOA-Free Cat's Claw (600 mg.) daily.

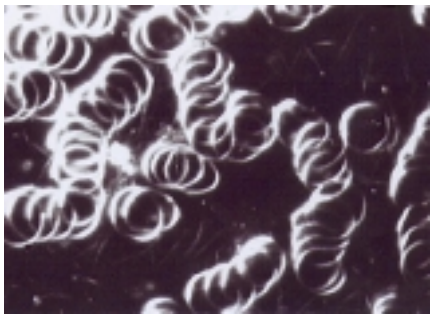
Three months later the white spots are almost eliminated (top) and no cell deformation is evident in the red cells (bottom). In addition, the somatids are plentiful and the plasma is clean. After six months of TOA-Free Cat's Claw (600 mg.) the patient feels fine, can walk without crutches and is experiencing almost no pain. After one year, the patient is put on a maintenance dose of one TOA-Free Cat's Claw (600 mg.) daily.

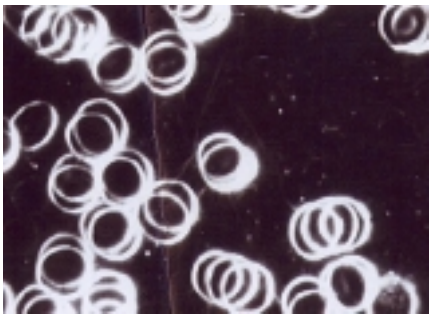
Arthritis Patient Treated with TOA-Free Cat's Claw (600 mg.)









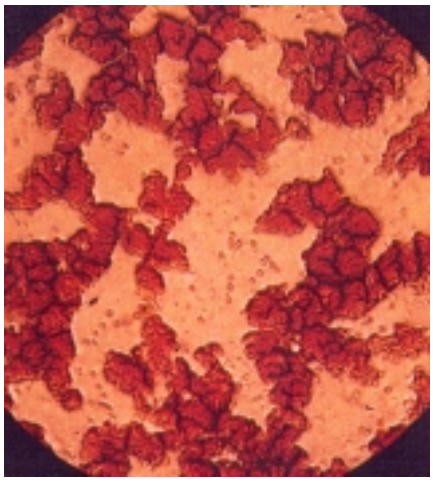


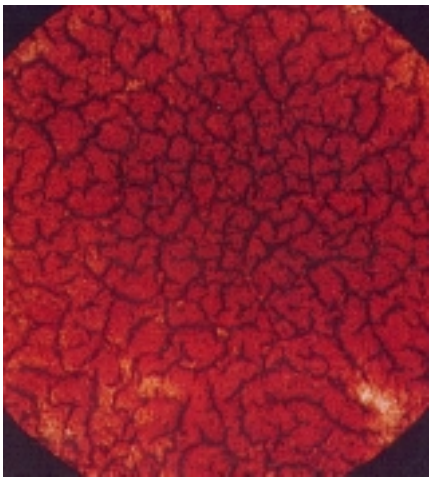
The above two photographs are typical pictures of arthritis. The patient, who has experienced five years of pain, was put on a regimen of two TOA-Free Cat's Claw (600 mg.) twice daily for four weeks, then one TOA-Free Cat's Claw (600 mg.) three times daily until the next appointment.

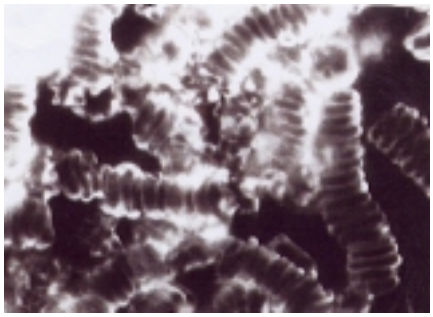
These two photographs show the same patient after eight weeks of treatment, with the top photograph showing fewer white spots, and the bottom photograph showing the red blood cells less attached to one another.

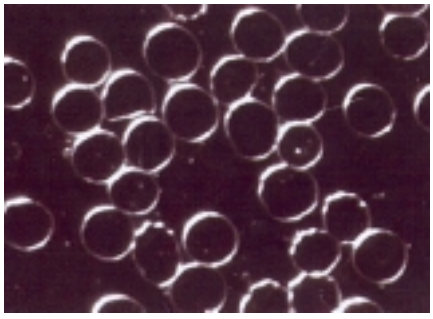
The above photographs show "back to normal" blood. In the bottom photograph, the separation of the red blood cells is clear, along with clean plasma and plentiful somatids. The patient was put on a maintenance dosage of two TOA-Free Cat's Claw (600 mg.) once a day.

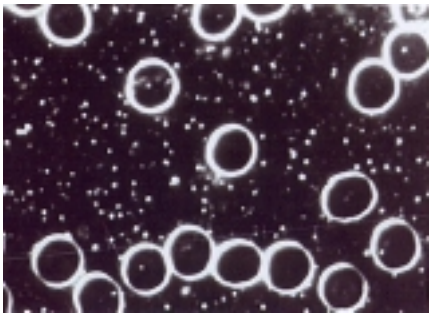
Colon Cancer Patient Treated with TOA-Free Cat's Claw (600 mg.)











The white spots present on the top picture indicate colon cancer on a post-operative patient. The bottom photograph shows the red cells attached to one another and the presence of parasites. Patient is started on regimen of two TOA-Free Cat's Claw (600 mg.) three times a day for three weeks, then two times a day for the next several months.

Three months later there are fewer white spots (top), and the cells are more detached and with fewer lines (bottom). The hospital is postponing chemotherapy. The patient will continue with two TOA-Free Cat's Claw (600 mg.) twice daily.

Five months later there are no large white spots (top), and the blood is back to normal with many somatids, indicating an improved immune system. The patient feels fine and is back to work. Maintenance dosage: two TOA-Free Cat's Claw (600 mg.) once a day.

Pilot Study of Pentacyclic Alkaloid-Chemotype of Uncaria tomentosa for the Treatment of Lyme Disease

December 28, 2002 – March 22, 2003

Presented at The International Symposium for Natural Treatment of Intracellular Micro Organisms (March 29, 2003) Munich, Germany

Principal Investigators

- William Lee Cowden, M.D.
- Luis Romero M.D., Ph.D.
- Joan Vandergriff, N.D. - Nutritional Consultant
- Hamid Moayad, D.O. - Lyme Literate Physician
- Svetlana Ivanova, M.D., Ph.D.

Report by Dr. William Lee Cowden, M.D.

- Cardiologist
- Internist
- Private Practice for 25 years
- Specializing in Integrative Medicine
- Co-Author of Alternative Medicine Definitive Guide to Cancer
- Co-Author of Longevity- An Alternative Medicine Definitive Guide

Pre Study Anecdotal Observations

- 58 patients referred from Hamid Moayad, D.O.
- 25 – 50% Overall Symptom Improvement over 2 – 3 months

Case Study

16 year old Male

- Flu- Jan. 2002
- Emotional stress
- 30 lb. weight loss
- CBC & Health Panel basically normal except SGOT= 95 and high CMV antibodies
- Aug. 30 2002- IGM= 1.8
- Jan. 13, 2003- Borrelia- IGM= 0.7

Summary of Pilot Study

- 28 patients started study
- 14 patients (control group) continued using conventional therapy during study and failed to improve. Some patients worsened.
- 14 patients (experimental group) received alternative treatment, 13 completed study (1 dropped out due to cancer surgery) and all improved subjectively and objectively.

Methods Used

- Evaluating Biological Terrain
- Refract Meter – Sugar
- pH Strips – Saliva and Urine
- Conductivity Meter – Mineral Congestion
- Kinesiological Analysis
- Iridology
- Dark field Microscopy
- Blood Type Diet

Multisystem Protocol for Lyme Disease

- Blood Type Diet
- Enzymes with meals
- Enzymes between meals
- Vitamins- Minerals
- TOA-Free Cat's Claw
- Laser Detoxification
- Light beam generator
- Skin Brushing
- Bath Detoxification
- Laughter
- Prayer
- Emotional Release

History of Lyme Disease

Lyme disease was first recognized in the United States in 1975, following a mysterious outbreak of juvenile rheumatoid arthritis near the community of Lyme, Connecticut. The rural location of the Lyme outbreak and the onset of illness during summer and early fall suggested that the transmission of the disease was by an arthropod vector.

In 1982, the etiologic agent of Lyme disease was discovered by Willy Burgdorfer. Burgdorfer isolated spirochetes belonging to the genus Borrelia from the mid-guts of Ixodes ticks. He showed that these spirochetes reacted with immune serum from patients that had been diagnosed with Lyme disease. Consequently, the lyme spirochete resembling the syphilis spirochete was given the name Borrelia burgdorferi.

Besides ticks, Lyme can be transmitted by fleas, mosquitoes, mites, human-to-human contact, blood transfusions, gnats and unpasteurized milk.

Number of Cases

The United States Center for Disease Control (CDC) reports that there have been less than 180,000 confirmed cases of Lyme disease since 1980. Nick Harris, Ph.D., Director of the International Lyme and Associated Diseases Society (ILADS), states "Lyme is grossly under-reported. In the U.S., we probably have about 200,000 cases per year."

Dan Kinderlehrer, M.D., stated on the *Today Show* (June 10, 2002) that the actual number of cases may be closer to 100 times more (18 million cases) than what the CDC reports.

Joanne Whitaker, M.D., who specializes in advanced testing methods for Lyme, suspects that the great majority of people in the U.S. are infected with Borrelia burgdorferi.

There are very few symptoms where one shouldn't consider Lyme, especially given that a quarter of the U.S. population may be affected. It is estimated that Lyme Disease may be a contributing factor in more than 50% of chronically ill people.

Frequently Misdiagnosed

Katrina Tang, M.D., HM.D., Medical Director of the Century Wel1ness Clinic in Reno, Nevada, states that Lyme Disease eludes many doctors because of its ability to mimic many other diseases. According to an informal study conducted by the American Lyme Disease Alliance (ALDA), most patients diagnosed with Chronic Fatigue Syndrome (CFS) are actually suffering from Lyme Disease. In a study of 31 patients diagnosed with CFS, 28 patients, or 90.3%, were found to be ill as a result of Lyme.

Dr. Paul Fink, past president of the American Psychiatric Association, has acknowledged that Lyme disease can contribute to every psychiatric disorder in the Diagnostic Symptoms Manual IV (DSM-IV). This manual is used to diagnose psychiatric conditions such as attention deficit disorder (ADD), antisocial personality, panic attacks, anorexia nervosa, autism and Aspergers syndrome (a form of autism).

Lyme Disease has often been misdiagnosed as various allergic conditions, Alzheimer's, Attention Deficit Disorder (ADD), Autism, Chronic Candidiasis, Chronic Fatigue Syndrome, Crohn's Disease, Epstein Barr, Fibromyalgia, Guillain-Barré Syndrome, Headaches (severe), Hypothyroidism, Irritable Bowel Syndrome, Juvenile Rheumatoid Arthritis, Lou Gehrig's Disease (ALS), Lupus, Opthalmolgical Disorders, Parkinson's Disease, Pseudo tumor Cerebra, Rheumatoid Arthritis, Temporomandibular Joint (TMJ), Trigeminal Neuralgia and Multiple Sclerosis. Additionally, Lyme Disease has been misdiagnosed as a neuro-psychiatric problem such as Bipolar Disorder and Schizophrenia.

Stages of Lyme Disease

- Stage I - Bull's eye rash (25%), flu-like symptoms (Antibiotics effective at this stage)
- Stage 2 - Muscle aches, fatigue, joint pain, " migratory arthritis", loss of appetite
- Stage 3 - Severe neurological symptoms, profound fatigue, memory loss, severe pain.

Stage One (Early Infection)

A distinctive, expanding red rash that usually develops at the site of the tick bite and is accompanied by flu-like symptoms often characterizes the early stage of Lyme Disease. Spirochetes can be isolated from the leading edge of the rash. However, it is important to remember that in 20-40% of the cases no rash is ever observed. Also, not all rashes that occur at the site of a tick bite are due to Lyme Disease (an allergic red reaction to tick saliva often occurs at the site of a tick bite even in the absence of spirochetes).

Stage Two (Dissemination Stage)

- Occurs days to weeks following infection.
- At this stage the spirochetes spread hematogenously to additional body tissues.
- One or more of the following symptoms and signs may be noted:
    - fatigue
    - chills and fever
    - headache
    - muscle and joint pain
    - swollen lymph nodes
    - secondary annular skin lesions

Stage Three (Persistent Infection)

Some symptoms and signs of Lyme Disease may not appear until weeks, months, or years after a tick bite or other exposure to Lyme.

Common clinical manifestations at this stage may include migratory pain to joints, tendons and muscles, cardiac involvement and neurological symptoms.

Arthritis is most likely to appear as brief bouts of pain and swelling, in one or more large joints, especially the knees.

Nervous system abnormalities can include numbness, pain, Bell's palsy (paralysis of the facial muscles, usually on one side), and meningitis (fever, stiff neck, and severe headache).

Microbial Co-Infections in Lyme Disease

- Borrelia
- Babesia
- Ehrlichia
- Bartonella
- Mycoplasma
- Viruses

Symptoms in 13 Pilot Study Participants

	Before Study	End of Study	Improvement %
Fatigue	13/13	12/13	92.3
Stomach Pain	10/13	10/13	100
Joint Pain	8/13	7/8	87.5
Memory Problems	9/13	8/9	88.9
Muscle Pain	7/13	7/7	100
Visual Disturbances	5/13	4/5	80
Emotional Instability	5/13	4/5	80
Peripheral Neuropathy	5/13	5/5	100
Insomnia	4/13	3/4	75

Herxheimer Reaction

The die-off of toxin-producing organisms in the body releases toxins which may cause a patient to feel temporarily worse before feeling better. This "healing crisis" was first identified by the German physician Karl Herxheimer and is known as the "Herxheimer Reaction".

Case Study 1 - J.M.

35 year old Caucasian male on disability with blood type A, bowel inflammation, carbohydrate intolerance, insomnia

Before Treatment:

- Weight loss from 155 to 98lbs. during course of 3 years
- Health Panel shows no abnormalities
- 50 specialists consulted (Including Mayo Clinic)
- Lyme specialist said no treatment would help.

After treatment:

- Insomnia completely overcome
- Joint pain - 50% improved
- Energy- 90% improved
- Renewed hope for the future
- Family and friends notice dramatic difference in patients overall well–being.

Case Study 2 - D.M.

50 year old Caucasian female with blood type O, Peripheral Neuropathy, pain in muscles and tissue

Before Treatment:
- Methadone Sulfate - 20 mg. 4-5 times/day
- Oxycontin - as needed
- Pain in legs and feet
- Constipation
- Sugar 4.0, Saliva pH 7.0, Urine 5.0, Conductivity 10

After Treatment:
- Norco, only one twice daily
- Pain reduction 90%
- Bowel movement twice daily
- Sugar 0.5, Saliva 6.5, urine 6.0-7.0, conductivity 6

Case Study 3 – M.G.

46 year old Caucasian female with blood type O, extreme fatigue, joint and muscle pain

Before Treatment:
- Major anxiety and depression
- 3-5 days without bowel movement
- Major emotional stress
- On disability because of joint pain

After Treatment:
- CBC Blood test normal
- Can do full day of work without problem
- No constipation
- Less brain fog
- Pain reduction- 50%
- Dealing with daily stresses well

M.G. "This is the first day in years that I have been able to get up out of bed and go about my normal activities."

Case Study 4 – C.F.

18 year old Caucasian female with Blood Type O, extreme weakness and fatigue, acute Pancretitis, Appendicitis, and anaphylactic food reactions

Before Treatment:

- Completely dependent on family
- Walked with walker
- Sick since age 3
- No social life

After Treatment:

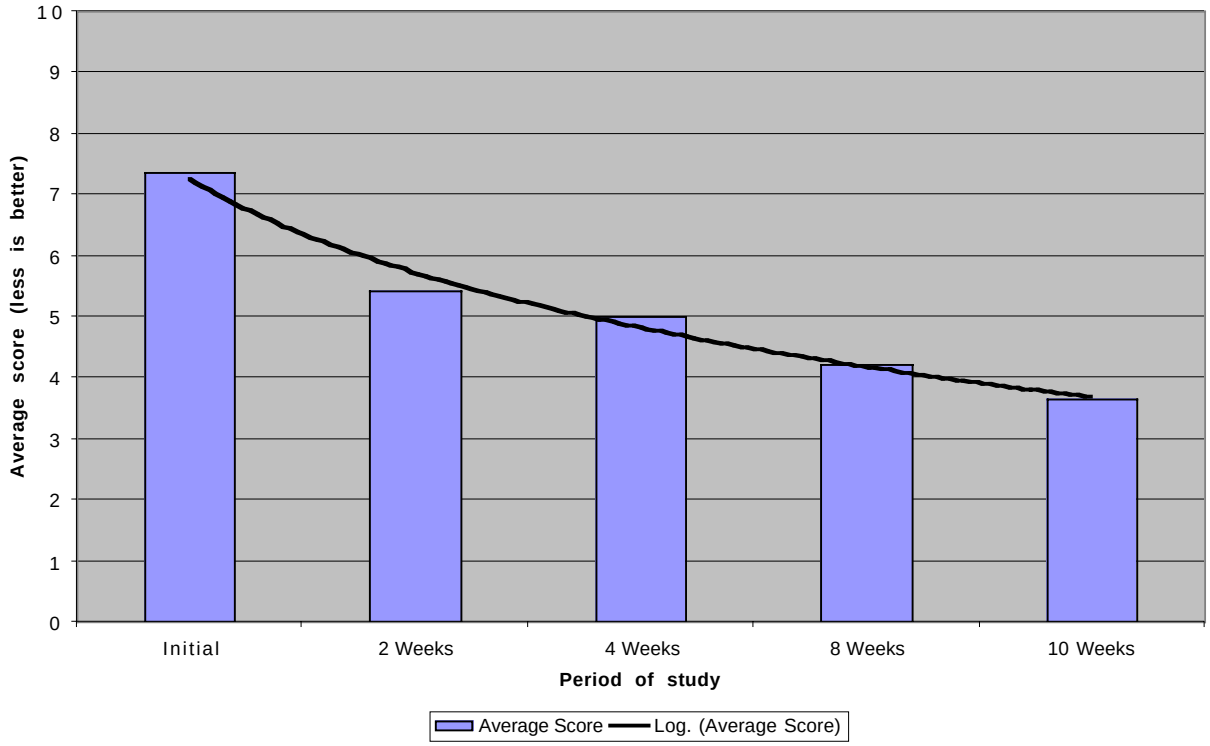
- Takes care of herself
- Walks without walker
- Going on dates
- 50- 75% improvement

C.W., *"This study has made an incredible impact on my life, health and well-being. I came into this program on a walker and I was completely dependent on my family for everything."*

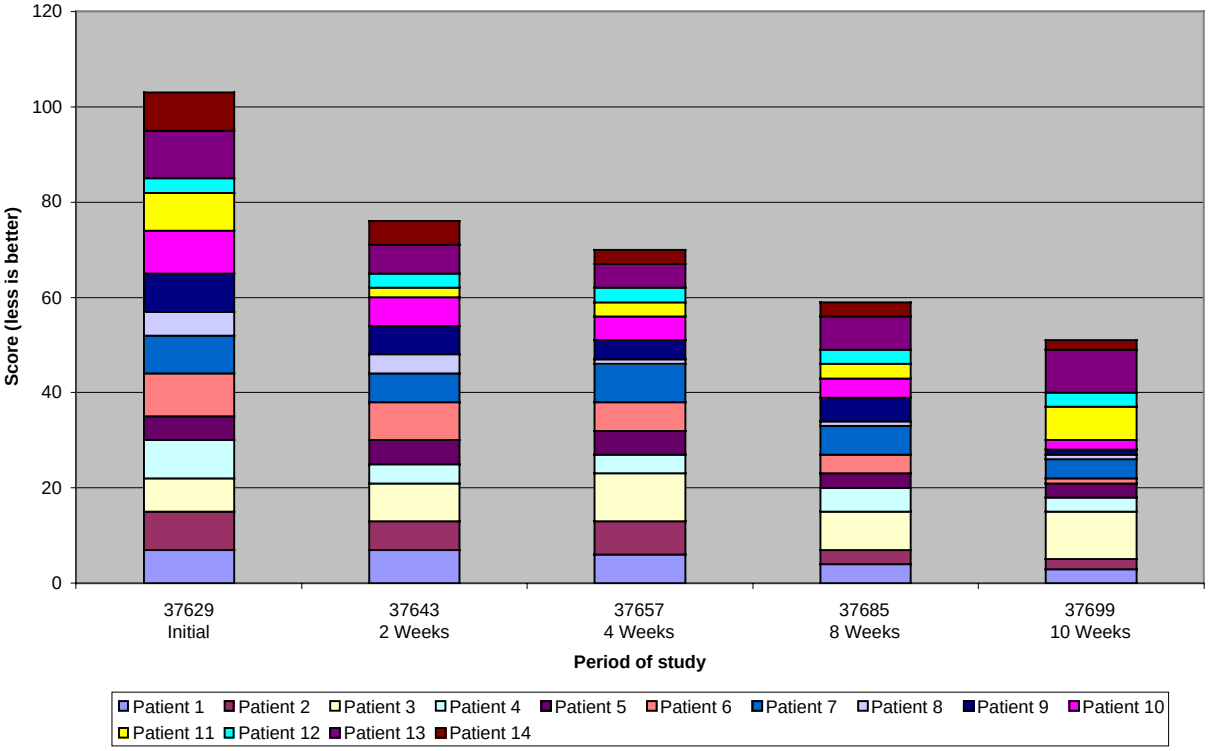
Impact of the Study – Patient's Perspective

T.H. *"I just wish all Lyme Diseases suffers were able to access this kind of treatment; Maybe…Someday"*
J.M. *"I've tried a few things at a time that had some limited benefits. I think what made this treatment work was that it simultaneously addressed all my problems and it was so comprehensive."*
K.U. "*I feel better than I have in 25 years."*
D.M. *"I am doing things that I haven't been able to do in years."*
T.G. *"It wasn't easy, but it was worth it."*

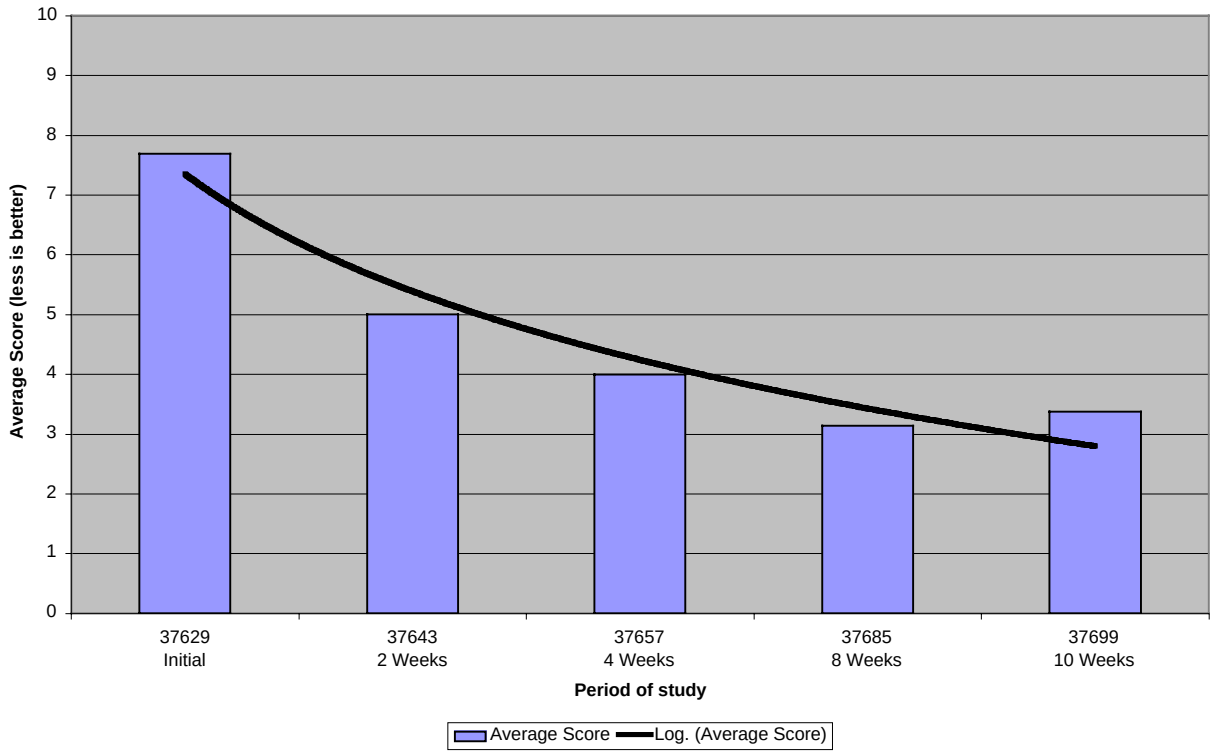
Fatigue Self-Assessment (Experimental Group)



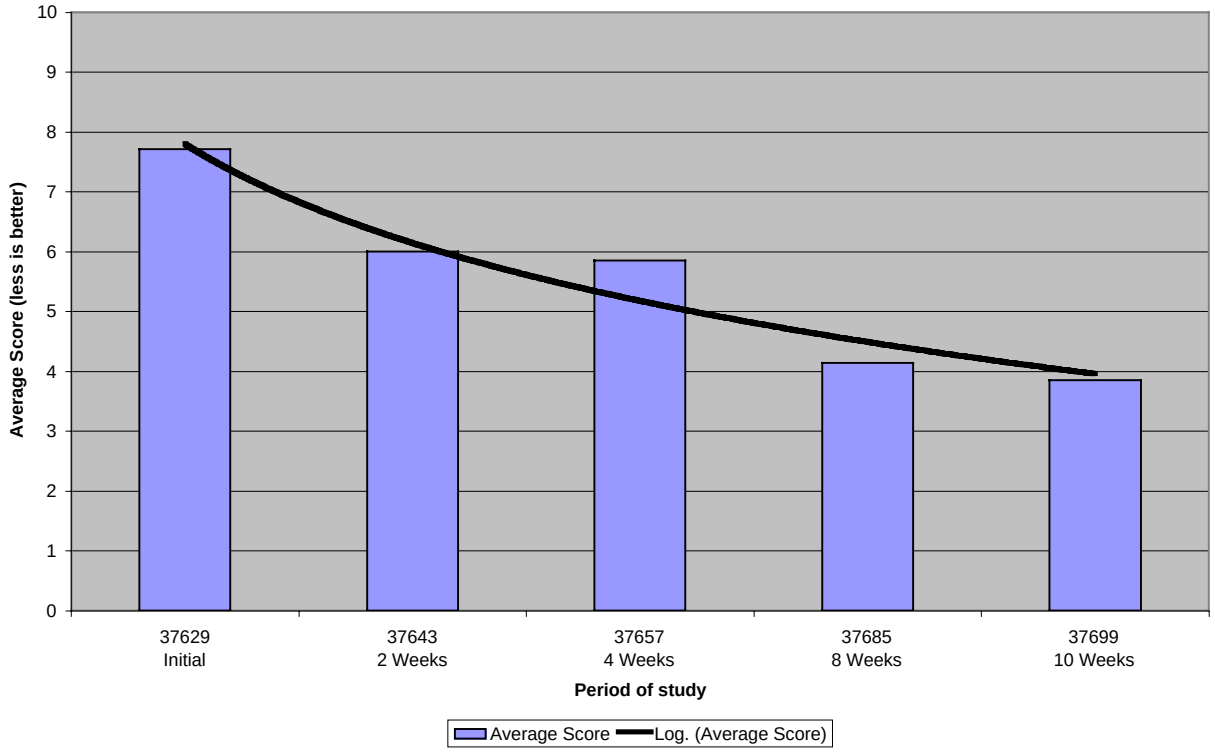
Total Patient Fatigue Self-Assessment



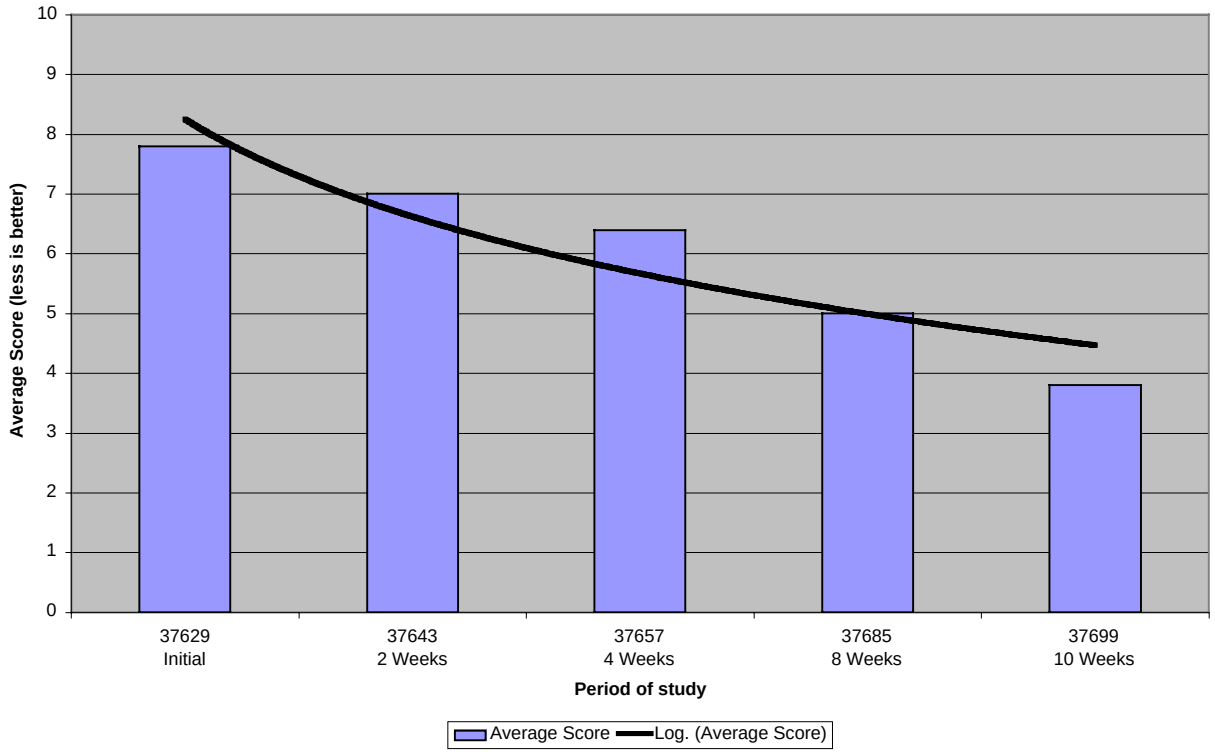
Joint Pain Self-Assessment



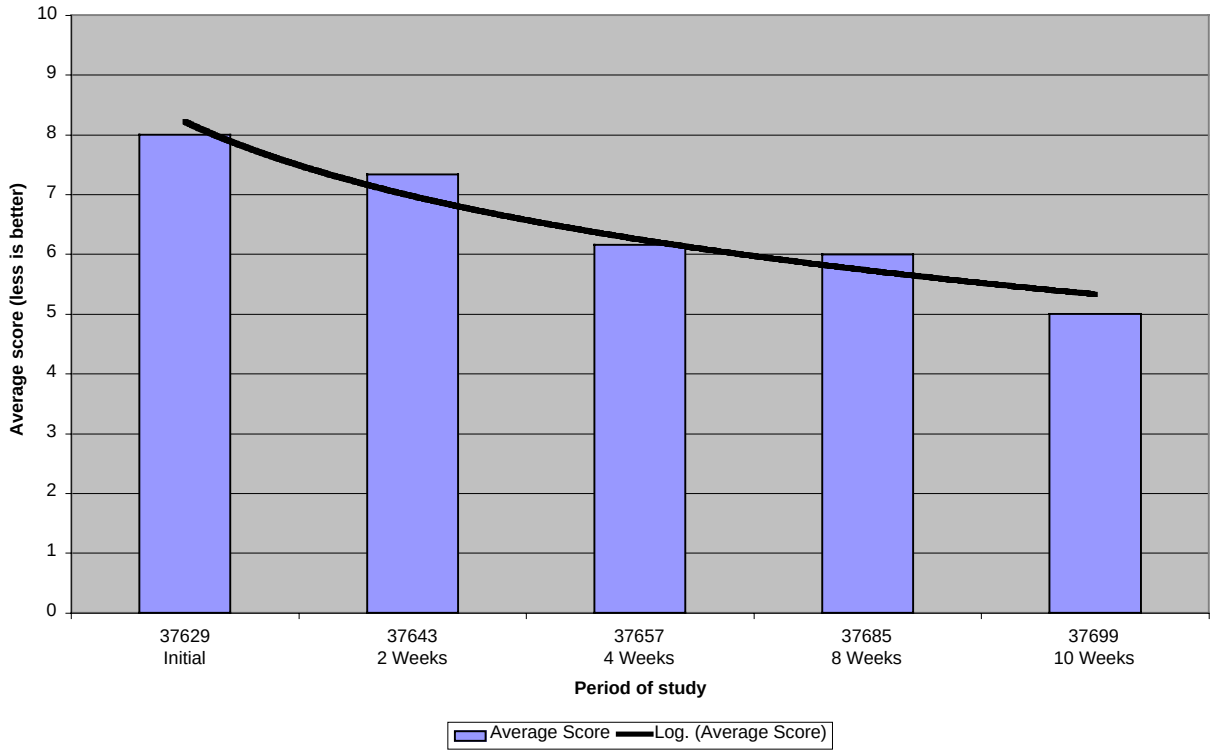
Muscle Pain Self-Assessment



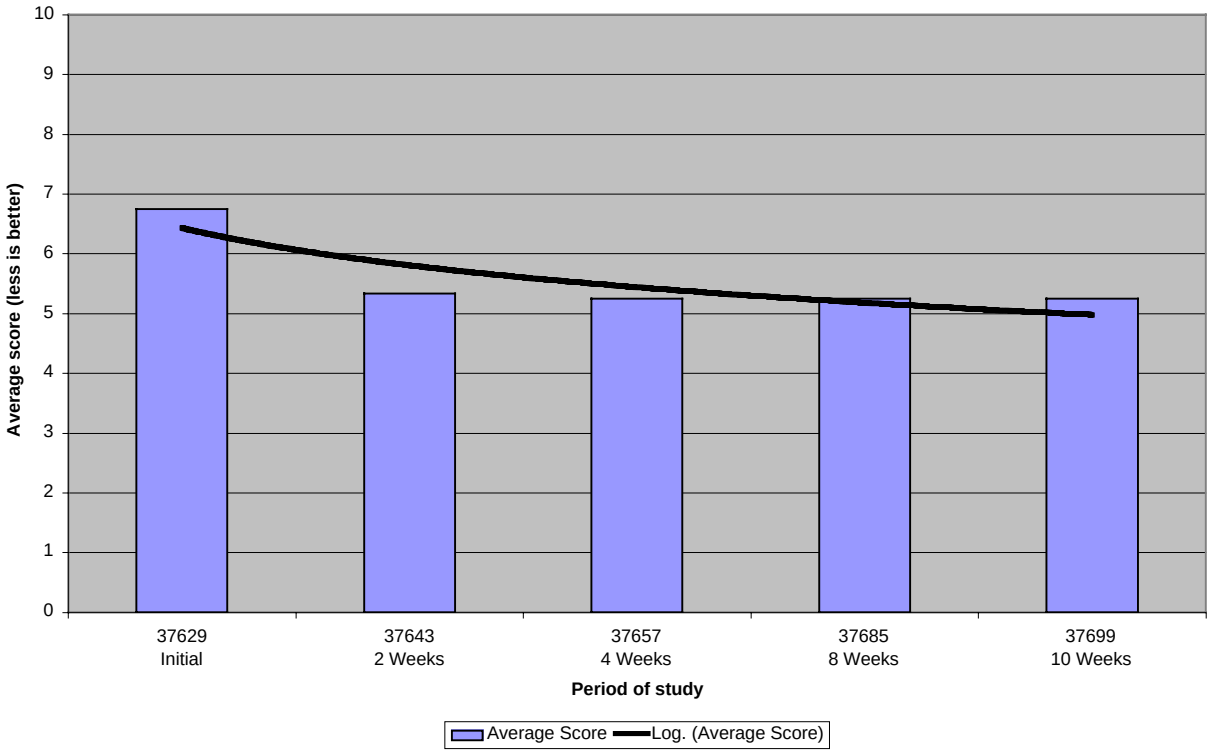
Memory Impairment Self-Assessment



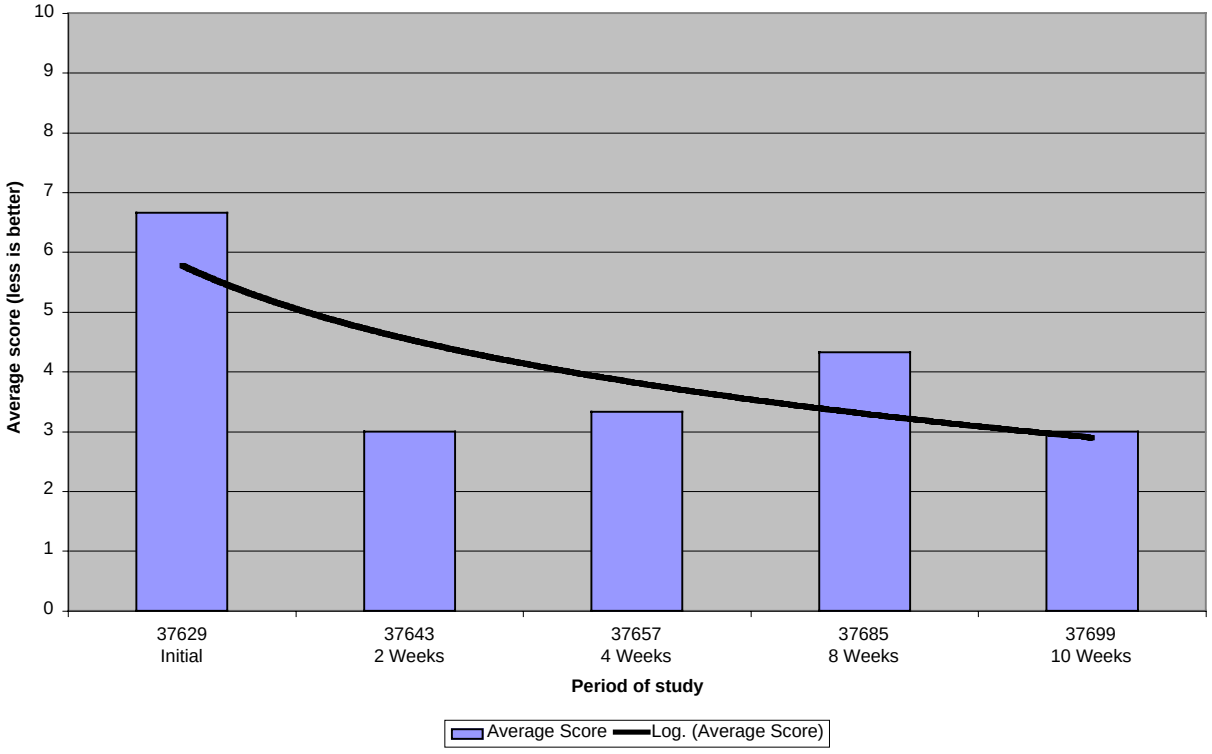
Concentration and Thinking Impairment Self-Assessment



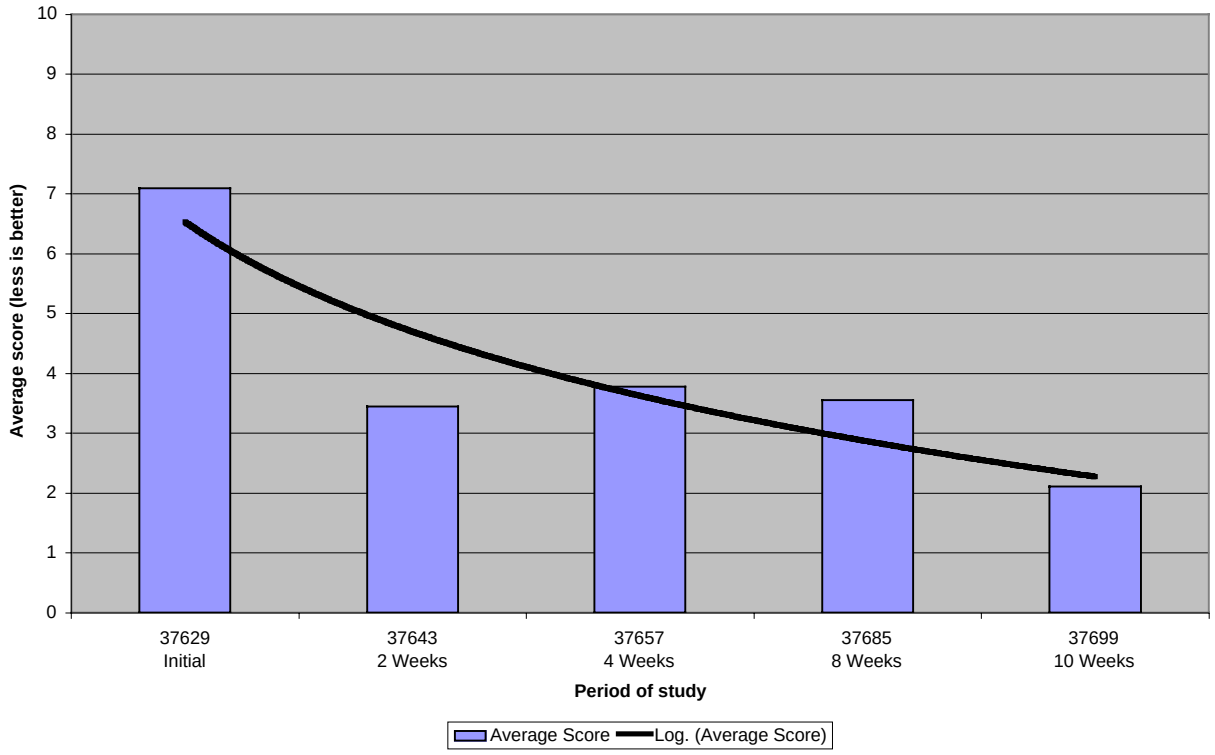
Cognitive Dysfunction Self-Assessment



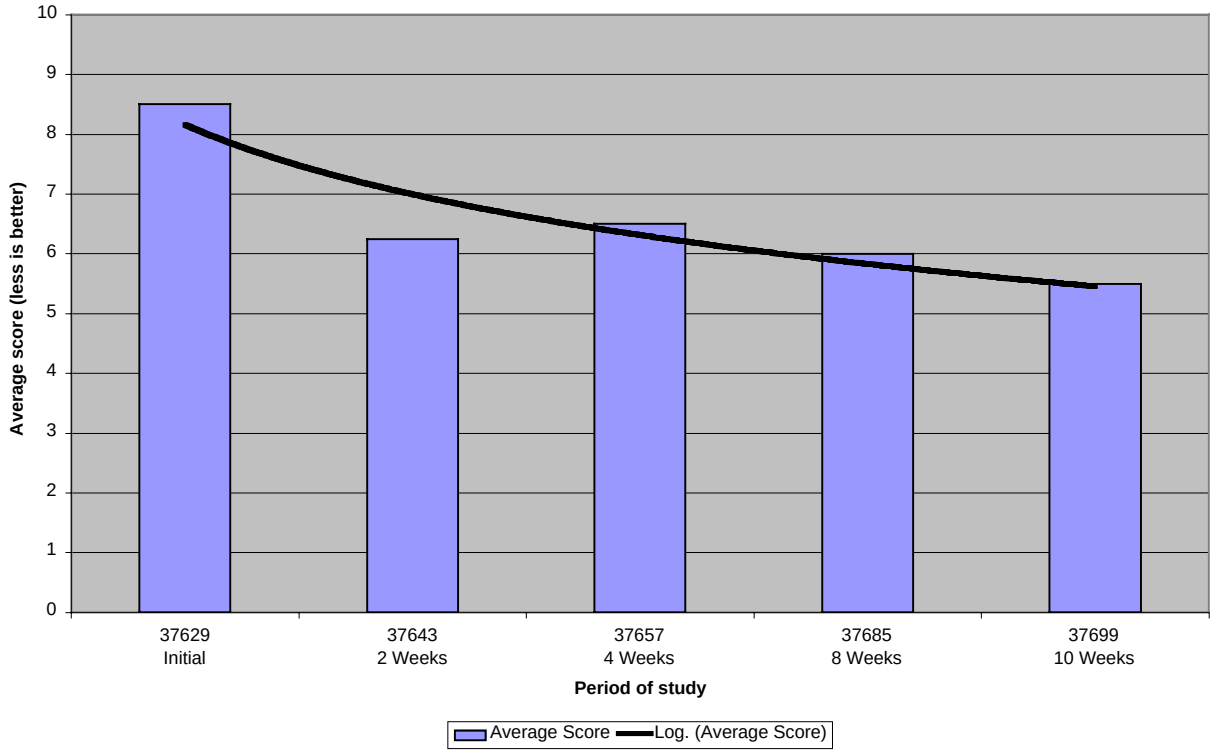
Stomach Pain Self-Assessment



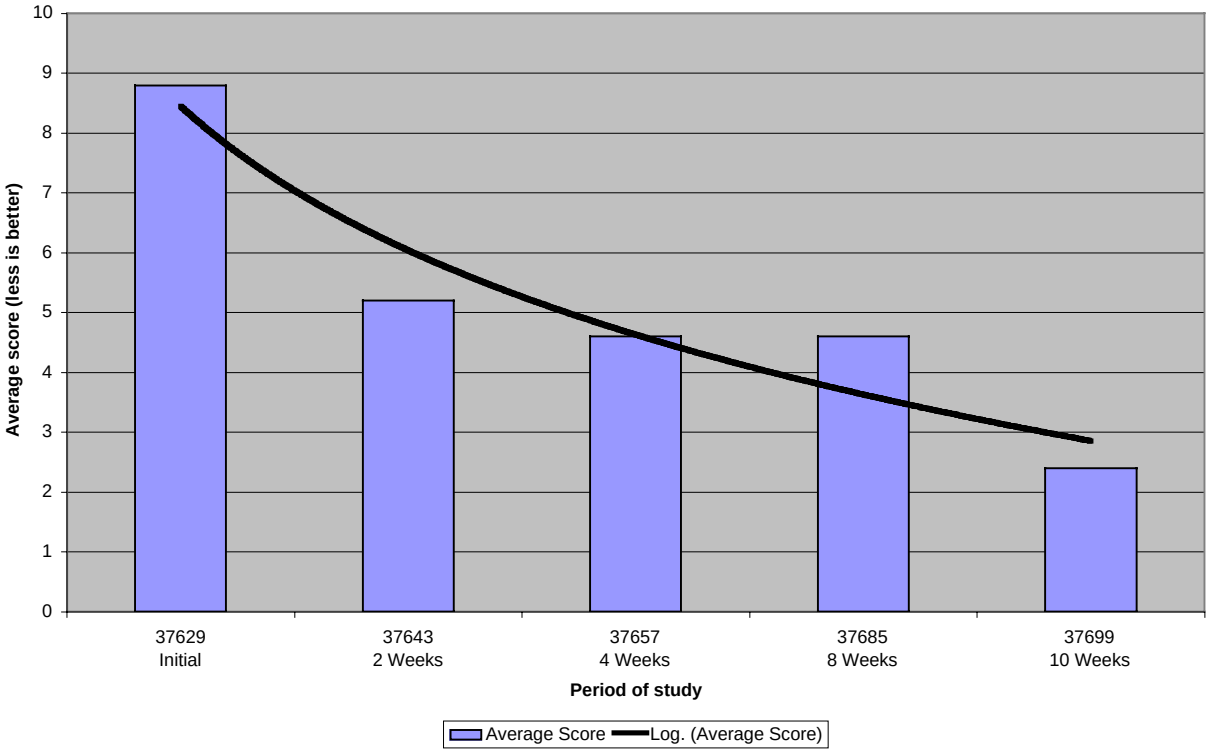
Digestive Disturbances Self-Assessment



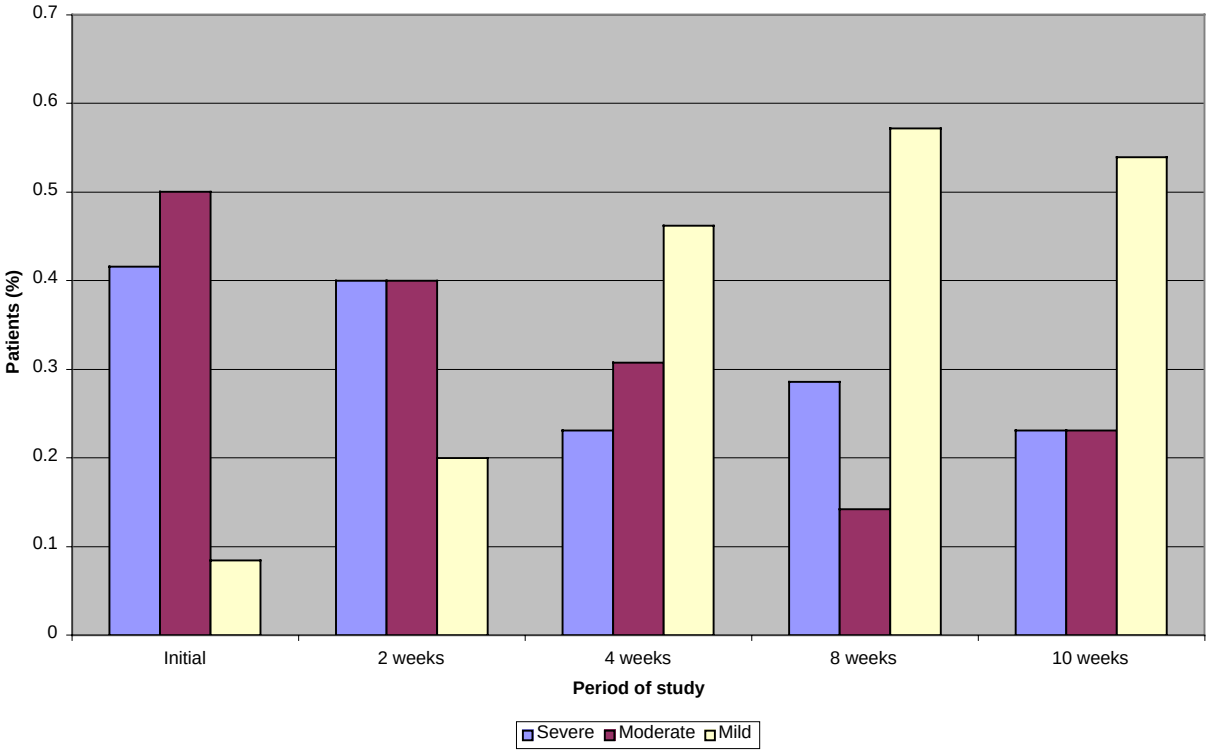
Limbic Encephalitis Symptoms



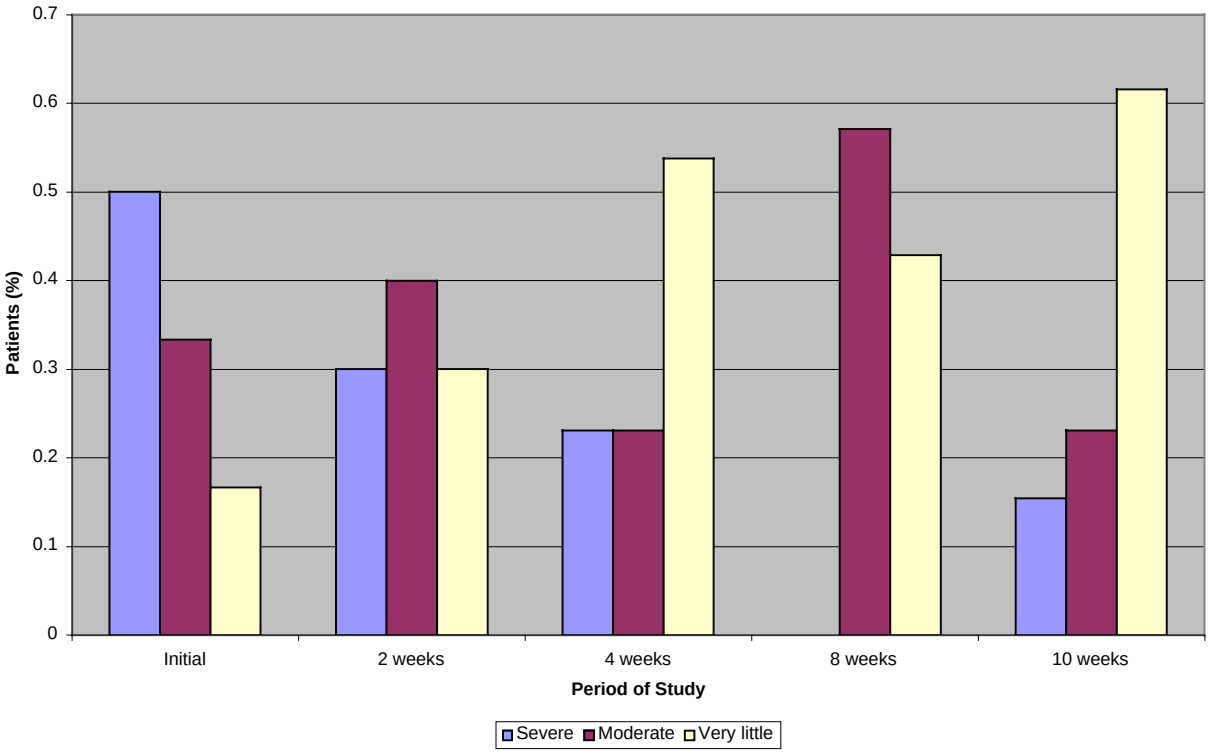
Peripheral Neuropathy Symptoms



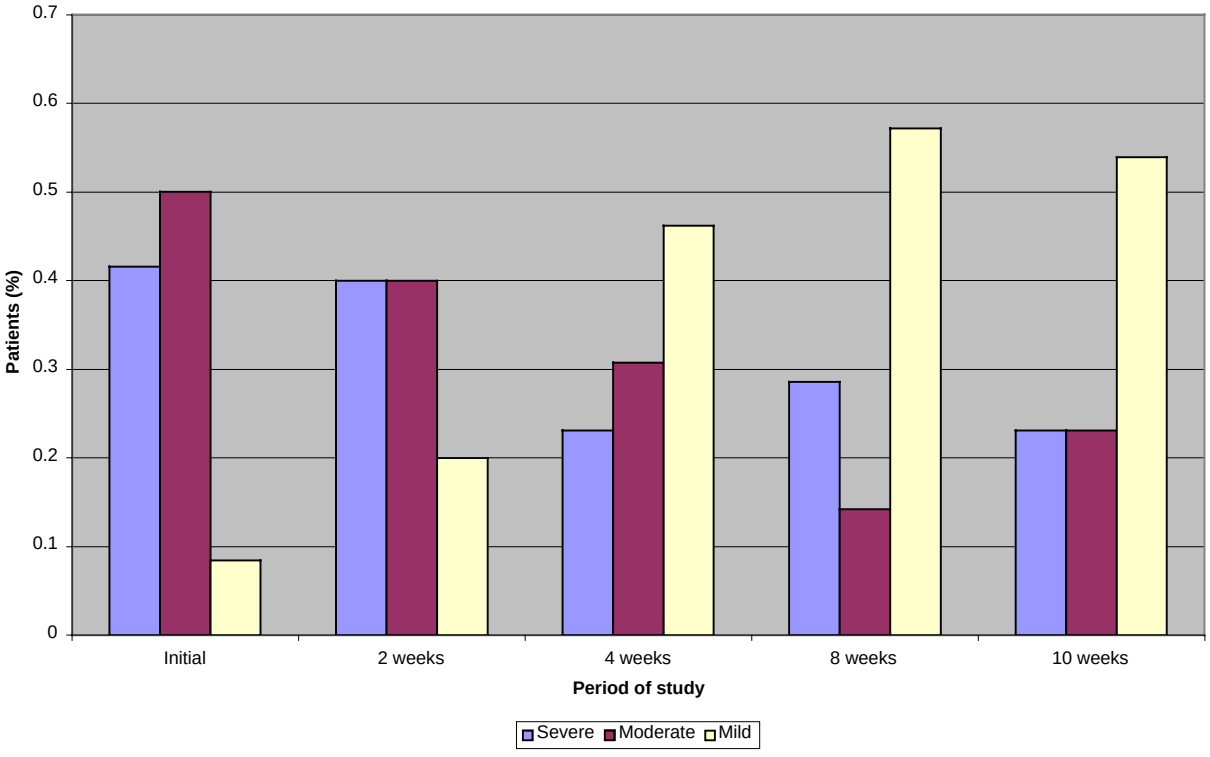
Patients' Bodily Pain



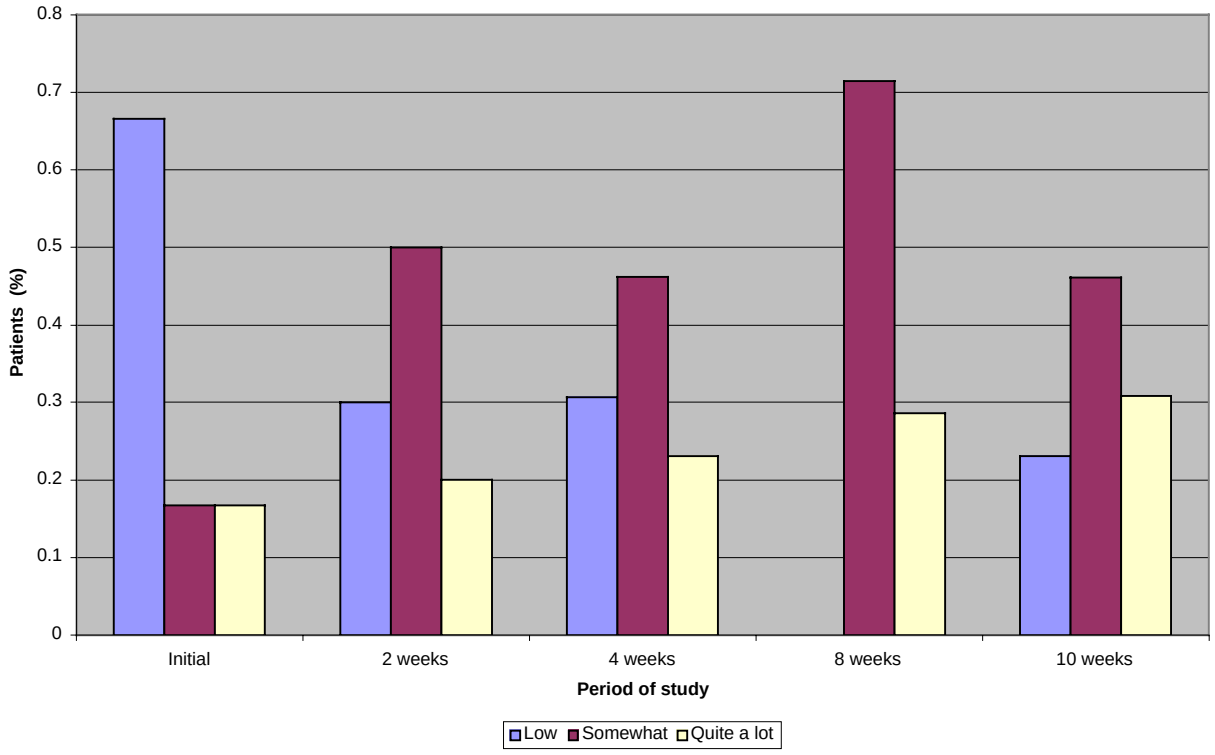
Impact of Physical Health on Usual Daily Activities



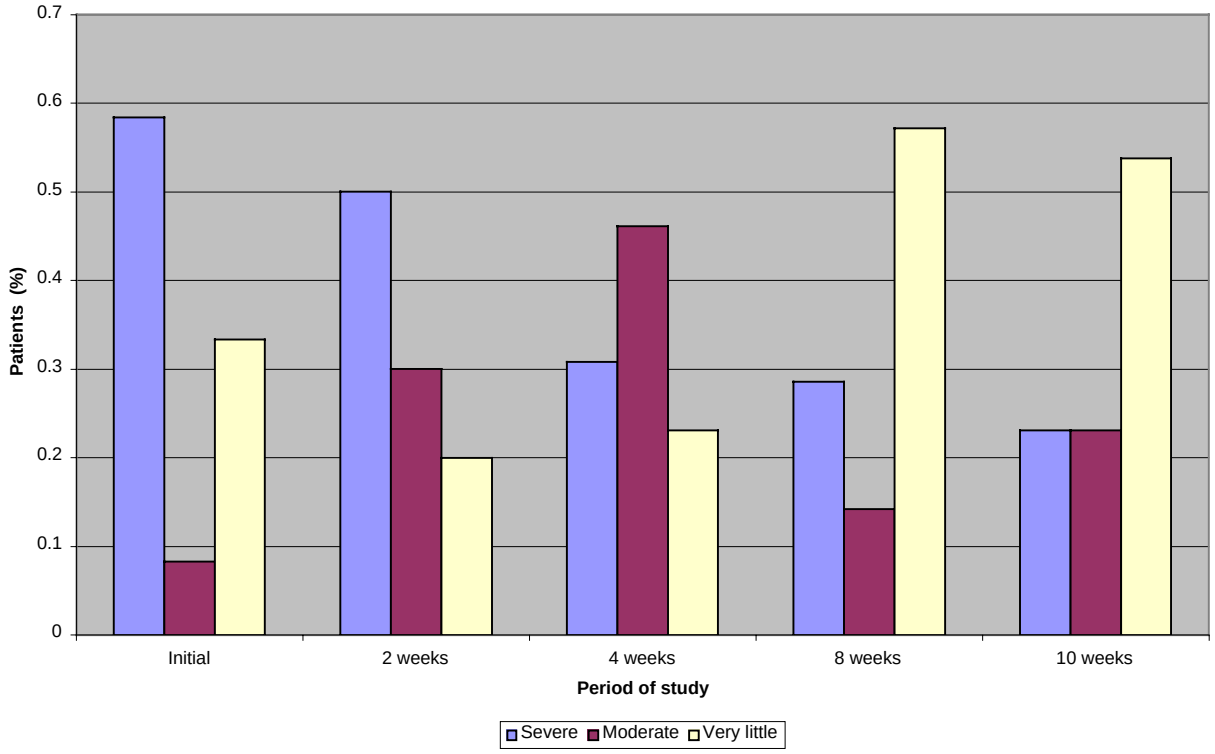
Patients' Bodily Pain in the Past 4 Weeks



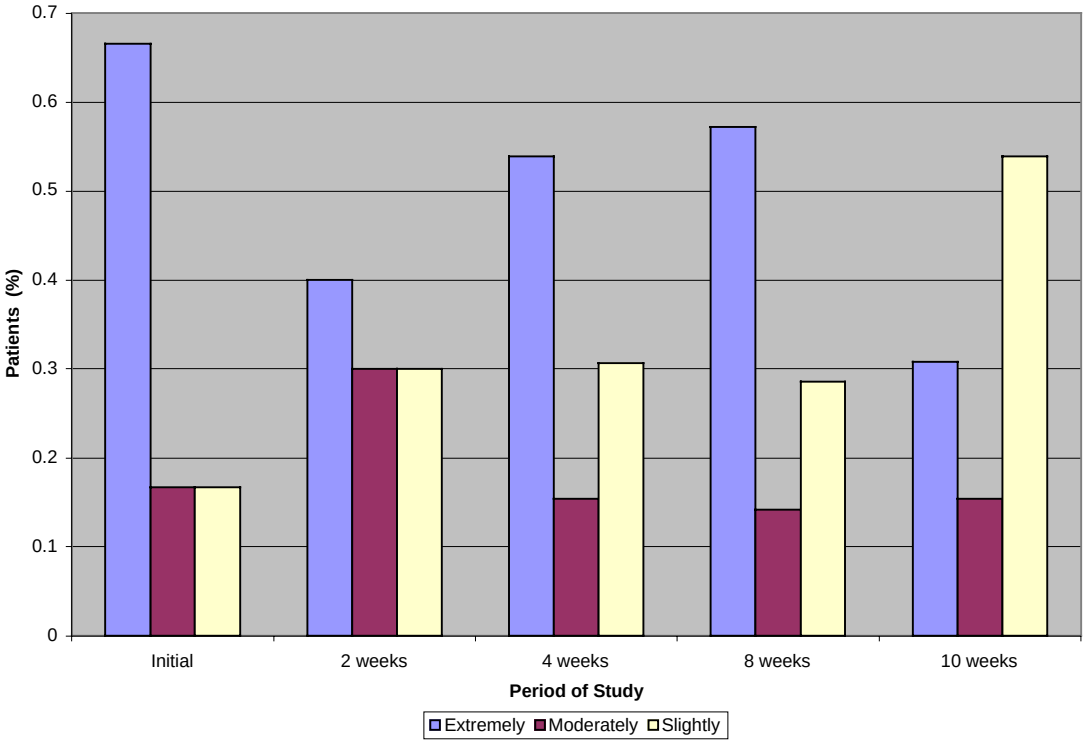
Patients' Energy Level



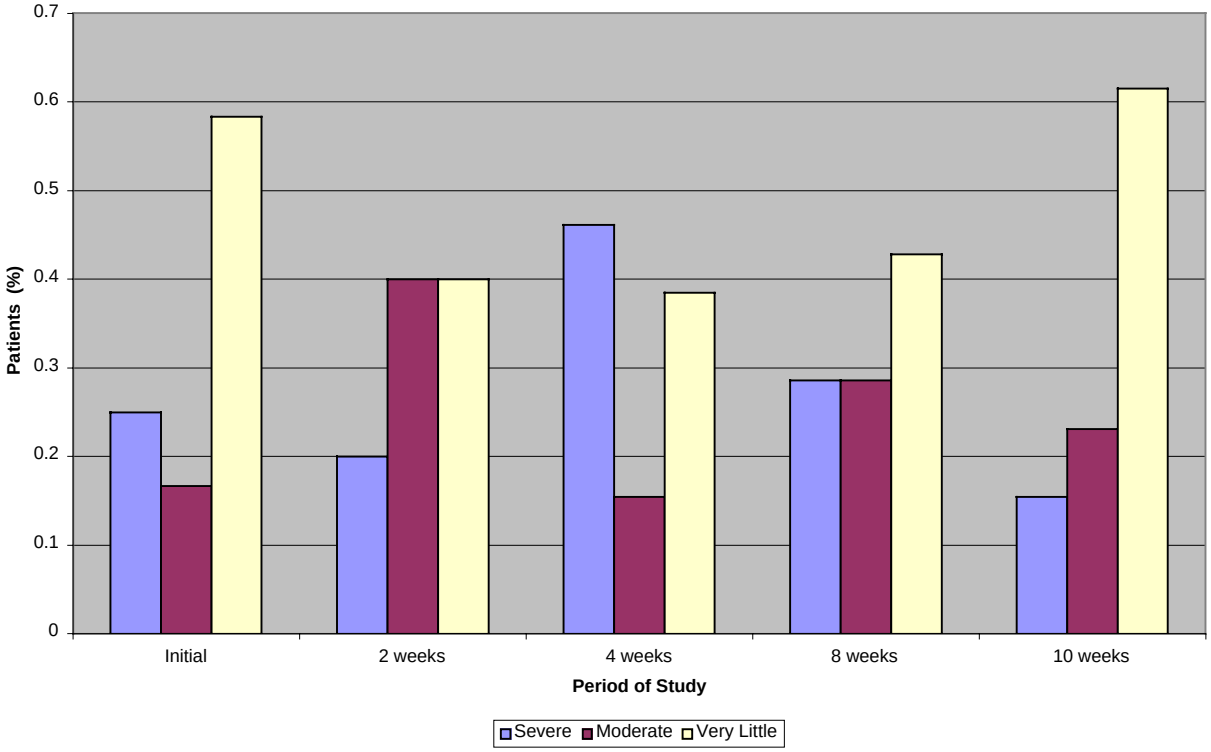
Impact of Patients' Emotional Problems on Their Social Activities



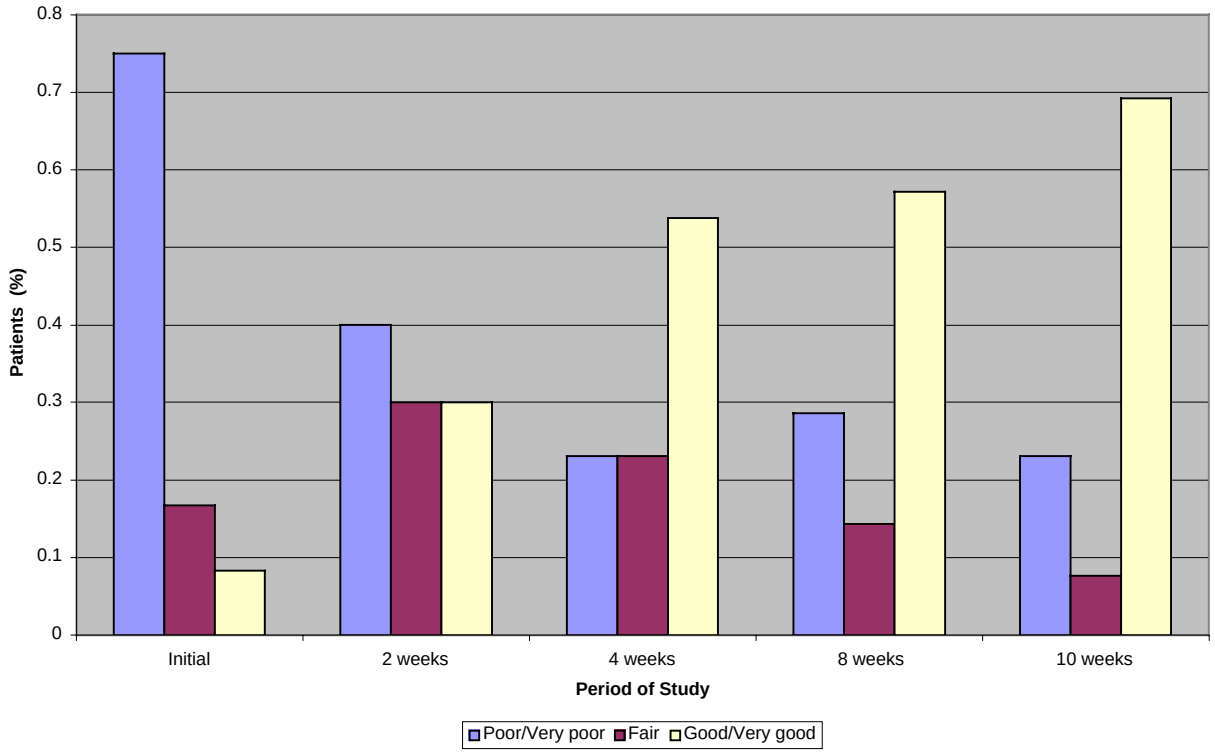
The Severity of Patients' Emotional Problems (Anxiety, Depression, Irritation)



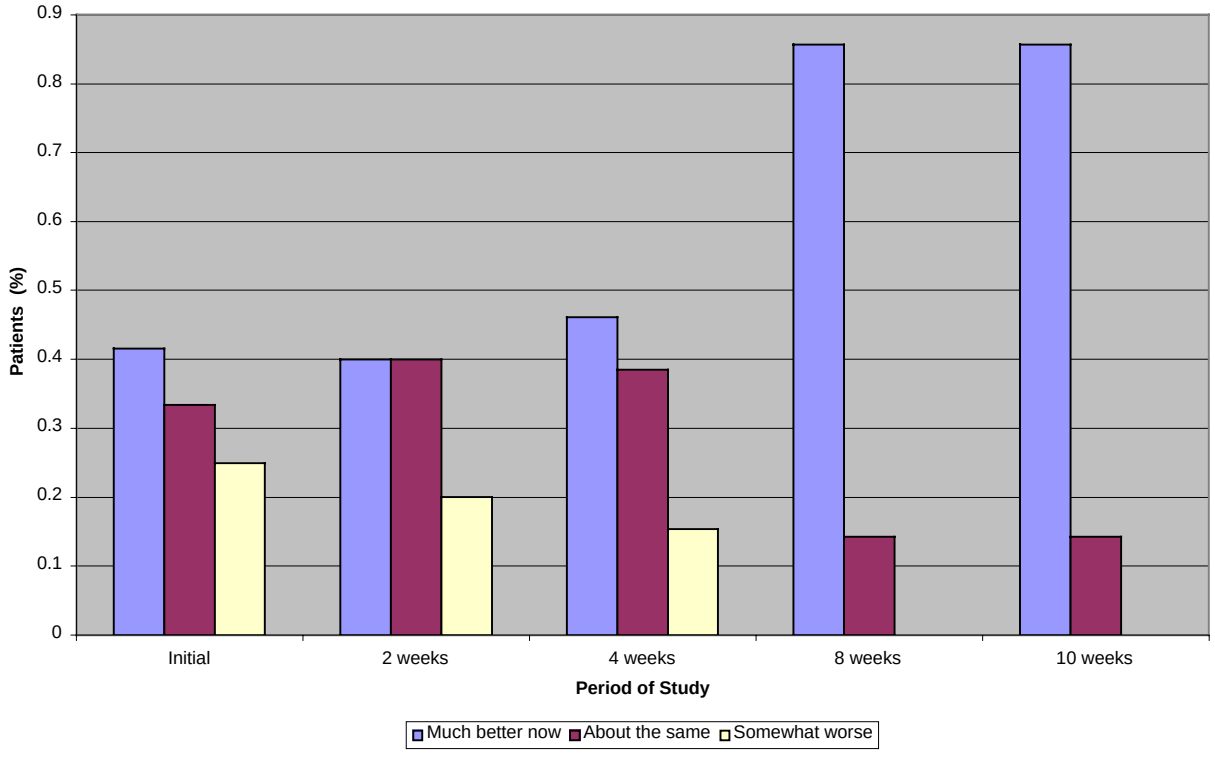
Impact of Patients' Emotional Problems on Their Daily Activities



Patients' Overall Health in the Past 4 Weeks



Patients's Health in General Now, Compared with 1 Year Ago



Impact of Patients' Physical Health on Their Daily Work