

**CINNERGEN <sup>TM</sup>**

A Randomized Double Blind Phase I Clinical Study Designed

To Determine Efficacy of Cinnergen<sup>TM</sup>

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Principal Investigator with the following companies:

|                                 |                      |                        |          |
|---------------------------------|----------------------|------------------------|----------|
| Abbott Laboratories<br>Wellcome | Marion Laboratories  | Sandoz                 | Glaxo    |
| Sankyo/Upjohn<br>America        | Reed & Carnick       | Lorex                  | Takeda   |
| Kal-Chemie                      | Schering             | G. D. Seric & Co.      | Novartis |
| Ciba-Geigy<br>Marion Roussel    | Merck, Sharp & Dohme | Whitehall Laboratories | Hoechst  |
| Hoffmah/LaRoche<br>Holdings     | Pfizer               | Chiesi Pharmaceuticals | TAP      |
| Eli Lilly<br>Medica             | 3M Pharmaceuticals   | Lederle                | Asta     |
| Parke-Davis<br>Zeneca           | Smith Kline          | Rhone-Poulenc Rorer    | Astra    |
| Glaxo<br>Collaborative          | ICI Pharmaceuticals  | Bristol Myers Squibb   | Genomics |
| McNeil<br>McNeil                | Searle               | Bayer Pharmaceuticals  | Ortho-   |
| Wyeth Ayerst                    | Schwartz-Pharma      | Johnson & Johnson      | Aventis  |

## Background:

The purpose of this study was to determine Cinnergen's™ efficacy in a controlled Phase I study. Upon completion of the case study on Cinnergen™, it was shown to have a positive effect on lowering blood sugar in a Type II Diabetic.

- To determine the effects of Cinnergen™ on Type I and Type II Diabetics with regard to lowering and regulating blood sugar levels.
- All 50 patients completed a survey questionnaire upon completion of the study regarding Quality of Life Issues.

## Research Design and Methods:

### Study Subjects

There were a total of 50 randomized patients consisting of men and women between the ages of 29 and 84 with Type I Diabetes or Type II Diabetes. During the study, Twenty-five (25) patients received Cinnergen™ and twenty-five (25) patients received a placebo.

The investigator and all personnel involved in the study were blinded to assure accuracy.

Patients signed an informed consent. All results are based upon patient's compliance and completion of the study.

All 50 patients were current patients of Pennsbury Family Medical Centers.

Patients who complete the study were given the option of continuing on Cinnergen™ for an additional 3 months free of charge. After the three (3) months, patients may continue on Cinnergen™ for a nominal fee.

## Study Design

This study is a double blind phase 1, 3-month (90 day) trial performed at Bucks County Clinical Research by principal investigator Dr. David J. Miller and staff.

Please see curriculum vitae of Dr. David J. Miller, DO, FAAP, Richard M. Goldfarb, MD, FACS, and brochure of Bucks County Clinical Research as a center of

MD, FACS, and brochure of Bucks County Clinical Research as a center of excellence and innovation in clinical research by visiting the website at [www.bccrinc.com](http://www.bccrinc.com).

Bucks County Clinical Research is an FDA-approved and regulated clinical facility, which meets the highest standards for studying prescription and non-prescription medications. Current on-going studies include:

1. Adventis - Hypertension
2. Novartis-Value – Hypertension
3. Novartis-Navigator – Hypotension and Diabetes
4. Novartis-Select – Elderly Systolic Hypertension
5. Pfizer at Goal – Lipitor
6. Pfizer-Azithromycin – four indications pharyngitis, CAP, bronchitis and pneumonia
7. Glaxo-Smith Kline – COPD
8. Glaxo-Smith Kline – Hypertension, Diabetes
9. Ortho-McNeil – Bronchitis

BCCR guarantees all patients' rights will be protected and research studies will be implemented and conducted in accordance with FDA guidelines.

Patients were instructed to orally ingest 1 ounce (1 capful) of Cinnergen™ in the morning. Cinnergen™ was to be taken with or without food. Patients were instructed keep product refrigerated after opening.

Patient selection was not based on race, color, or socio-economic status.

Dr. David J. Miller and staff of BCCR monitored all patients. A list of each patient's medications and supplements with dosages were given to Dr. Miller and staff prior to commencement of this study. Patients were instructed to maintain a list of all medications, supplements and their dosages that they were currently using and kept track of any additions or deletions of medications, or any changes in dosages. This included all Diabetes medication during the 12-week study.

## Summary of Ingredients

We have summarized the known uses and mechanisms of action, and any known side effects for the herbs used in the formulation of Cinnergen™.

**Kelp:** A sea vegetable, which acts as a source of several important minerals including iodine, potassium, magnesium, calcium, and iron. It is also an excellent source of several trace minerals, all of which are easily absorbed because they occur in food form. Kelp has traditionally been used to improve metabolism because of its positive effect on the thyroid, and also acts as a general alkalizer. Kelp contains alginic acid, a substance which helps to soothe the GI tract. Excessive intake of kelp may interfere with proper thyroid function. Kelp intake should be kept low during pregnancy.

**Cinnamon:** A valued spice that has been prized since biblical times, Cinnamon provides several novel compounds to assist health including terpenoids like eugenol and cinnamaldehyde. Cinnamon is both anti-viral and antibacterial and is good for infections including fungal, urinary tract, and tooth decay. It improves digestion and the eugenol has anesthetic potential for treating pain. One specific compound, methyl hydroxychalcone polymer (MHCP) has been tested and shown to be able to lower blood sugar in two ways. It both enhances the action of insulin increasing its effectiveness up to twenty times, and can mimic insulin in the event that insulin is severely deficient and absent as in the case of Type 1 diabetics. Some people may be allergic to cinnamon, but the pure oil is more likely to cause reactions and should be avoided if known allergies exist. Excess use can cause mouth sores. Excess Cinnamon should be avoided during pregnancy.

**Blueberry Leaf:** The leaves of the blueberry plant have long been a remedy for balancing blood sugars. They are well known in the Caucasus Mountains for centuries for this purpose. Blueberry leaves contain a substance called chlorogenic acid, also found in certain types of coffee beans, which acts on specific enzymes to alter glucose metabolism in a favorable way. The net result is a decrease in glucose absorption from the gut, a slowing of glycogen conversion to glucose, and an increase in glucose metabolism. Blueberry's leaves also have anti-oxidant benefits and are safe to use on a regular basis.

**Oat Seed:** Oats have been a staple food of many cultures for centuries. They are high in protein, fiber, and nutrients. When taken in extract form, Oat Seed is an excellent restorative remedy. It has been traditionally used to fight both mental and physical fatigue, and is a natural nervine. As a whole food, Oats and Oat Seed are non-toxic and safe to use daily.

**Cranberry:** Cranberry was first eaten due to its tangy taste appeal, and was

supposedly eaten at the first Thanksgiving dinner by the pilgrims. It is an excellent source of Vitamin C as well as proanthocyanidins, a powerful anti-oxidant. Because of this, Cranberries are of benefit to overall health including blood vessels, vision, and the cardiovascular system. Of particular interest is the fact that the anthocyanidins have been shown to have an antiadherence action for cells in the urinary tract. That is they can prevent bacteria (E. coli) from clinging to cells lining the walls of the bladder thereby decreasing the occurrence and severity of UTI's. Cranberry concentrate is generally considered safe, even during pregnancy. It should not be used as a substitute for antibiotics during a urinary tract infection.

**Aloe Vera Juice:** Aloe originally came from Africa and has historically been used for many of the same conditions and benefits it is used for today. Typically the latex part of the plant is used as a natural laxative, which is beneficial when used temporarily to correct constipation. The aloe juice when processed apart from the inner latex of the aloe has a multitude of nutrients and possesses anti-inflammatory action and is famous for its wound healing ability. It is also thought to be helpful for ulcers. Placebo controlled studies have demonstrated aloe's ability to lower blood sugar. While the latex portion of aloe can be habit forming as a laxative, the juice is generally safe for daily use.

**Ginger:** One of the most versatile and beneficial herbal spices, Ginger has been used in Chinese medicine for over 2,500 years and is also well known in Ayurvedic healing. The volatile oils in Ginger are responsible for many of its effects, however more than 600 compounds have been found in Ginger. It is beneficial and well known for relieving nausea and motion sickness, and will also improve overall digestion. Ginger has anti-inflammatory and anti-bacterial ability. For circulation, Ginger has been shown to decrease the viscosity of blood. In animal studies, Ginger has reduced blood sugar. Ginger is generally safe when used as directed, but may cause heartburn in sensitive people. If there is a history of gallstones, caution is advised before using Ginger. It is considered safe to use for nausea during pregnancy for short periods of time. Ginger use should be stopped prior to surgery.

**Irish Moss:** This common plant is found in cooler regions of North America as well as Europe, and Asia. It is an overall nutritive food and has good demulcent properties. This makes it ideal for both respiratory problems and excessive acid in the digestive system. Excessive doses over long periods of time may cause gastrointestinal or liver problems.

**Green Tea:** Tea is the second most consumed beverage in the world and has been part of Chinese medicine for over 4,000 years. Green Tea is not fermented and therefore the active constituents remain more active. Green Tea is a strong source of polyphenols which have numerous benefits. The polyphenols are very strong antioxidants which favorably influence cardiovascular health, immunity. The phenol, EGCG (epigallocatechin gallate), has been shown to increase energy expenditure making it a good metabolic enhancer. Green tea also contains certain amino acids

making it a good metabolic enhancer. Green tea also contains certain amino acids which have stress relieving properties. Green tea is safe and non-toxic, however excessive consumption may lead to heartburn.

**Enzymes:** DIGEZYME is a multi-enzyme complex consisting mainly of amylase (starch hydrolyzing enzyme), protease (protein hydrolyzing enzyme) and lipase (fat hydrolyzing enzyme). In addition to these, it also contains cellulase (that hydrolyzes cellulose) and lactase (that hydrolyzes lactose). The enzymes in this complex are of microbial origin (fungal amylase, lipase, lactase, cellulase; and a bacterial neutral protease). Supplemental enzymes accomplish many things including:

- Ø Reduce toxic load generated by undigested food materials
- Ø Support digestive health
- Ø Support healthy immune functions
- Ø Facilitate restful sleep
- Ø Support mental capabilities
- Ø Help maintain healthy body composition
- Ø Help maintain skin health and texture

**Acerola Berry:** Grown in abundance in parts of South America, acerola is consumed there like orange juice in the US. Acerola is a general nutritive that can act as an anti-inflammatory, astringent, anti-pyretic, liver cleanser, and is beneficial for anemia, and diabetes. Oranges provide 500 to 4,000 parts per million (ppm) of vitamin C, or ascorbic acid, whereas acerola has been found in tests to provide ascorbic acid in a range of 16,000 to 172,000 ppm. Acerola also provides twice as much magnesium, pantothenic acid, and potassium as oranges. It also contains vitamin A (4,300 to 12,500 IU/100 g, compared to approximately 11,000 IU for raw carrots) and thiamine, riboflavin, and niacin in concentrations comparable to those in other fruits. Large doses may cause diarrhea. There is some indication that individuals with latex allergies may be sensitive to acerola.

**Sugar Sea Beet:** Found growing in Europe, North Africa and Asia, as far as India, and is found in muddy maritime marshes in many parts of England, Sugar Sea Beet is an excellent source of nutrients, and starchy gums. The nutrients can help energize the body in a balanced manner. It is eaten to help build the quality of red blood cells and also acts to cleanse the liver and gall bladder. There are no contra-indications to eating Sugar Sea Beet.

**Black Cherry:** An extremely popular and desirable fruit eaten worldwide, cherries are high in a number of phytochemicals, including: anthocyanins (pigments responsible for the red and blue colors of fruits and vegetables), which may have anticancer properties based on their antioxidant activities that defend cells against harmful carcinogens); and quercetin, a so-called flavonoid, which is an antioxidant and may have both anticancer potential as well as anti-inflammatory and antihistaminic properties. It is this anti-inflammatory activity that has made cherries (specifically cherry juice) of interest to people who suffer from gout. Cherries are excellent to help cleanse the system, particularly the liver, and can help neutralize excess systemic acids. Other than people who are specifically allergic to cherries, there is no safety concern with cherries.

## Methods

### Important Scale:

- § Determine fasting blood sugar levels at day 0, day 30, day 60 and completion of study day 90.
- § Measure Hemoglobin A1C at the beginning and completion of study.
- § All patient-scoring systems were performed with the Bucks County Clinical Research team to assure accuracy, thereby allowing this design study to be statistically significant.
- § Patients were required to continue to monitor their own blood sugar levels and report readings daily during the 90 day study.

### Primary Outcomes:

#### Laboratory Data:

- § Fasting Blood Glucose
- § Hemoglobin A1C

### Secondary Outcome – Exit Survey-Quality of Life Issues:

Rating Scale: 5 = excellent

4 = very good

3 = good

2 = poor

1 = very poor

0 = no change

Quality of Life Issues:

- § Convenience of use
- § Taste
- § Energy level
- § Aid in Sleep Habits
- § Mental Alertness
- § Mood
- § Libido
- § Dietary Habits
- § Decrease in Illness
- § Overall Feeling of Well-being

The Nottingham Health Profile (NHP)

The NHP is classified as a generic measure for the assessment of health-related quality of life (QoL). It has been extensively tested in Britain and Sweden with regard to reliability and validity.

## Short-Form Health Survey Questionnaire (SF-36)

We also used John Ware's SF-36 Quality of Life questionnaire to reflect general medical and psychological well being. The SF-36 is an established tool that has been used in many published research articles and will be useful in this context

### Testing Frames:

A complete set of risk factors were collected at baseline on all patients during the screening component. This includes a complete medical history, behavioral (smoking) and associated matters.

The laboratory testing of Hemoglobin A1C will be done on day 0 and on day 90.

### Statistical Plan:

Standard randomization will be performed to ensure proper randomization.

All data was entered into a Microsoft Excel database, while all statistical analyses were performed using the PC version of Statistical Analysis System.

## Evaluation of Efficacy

The study was designed to measure the decrease in blood sugar levels, Hemoglobin A1C and the stabilization of blood sugar levels.

The exit survey was attached to indicate diabetic patients' associated quality of life issues concerning the product.

### Diabetes Mellitus:

Worldwide Diabetes Mellitus (DM) is an epidemic. In the United States approximately 13 million people have been diagnosed with Diabetes Mellitus and another six to eight million are thought to have the disease and are undiagnosed. Additionally, slightly less than 800,000 new cases are diagnosed each year.

Additionally, slightly less than 600,000 new cases are diagnosed each year.

The disease is divided into two major groups, Type I adolescent onset and Insulin-Dependent Diabetes Mellitus (IDDM), and Type II usually adult onset and primarily Non-Insulin Dependent Diabetes Mellitus (NIDDM). The later (Type II) is treated with oral medications, diet and exercise. Type II DM is far more prevalent, making up approximately 90% of all cases.

Diabetes affects minorities in a disproportionate ratio – some estimates as high as 50% - in the Native-American, African-American, Hispanic American and Asian American populations.

The National Institute of Health (NIH) and other government agencies estimate that complications, the vast majority arising from nerve damage (Neuropathy), cost the American taxpayer over \$105 billion per year. These complications are the leading cause of kidney disease, blindness and amputations.

What is Diabetes? Diabetes Mellitus is a group of diseases characterized by high levels of blood glucose resulting from defects in insulin secretion, insulin action, or both. Diabetes can be associated with serious complications and premature death, but people with Diabetes can take measures to reduce the likelihood of such occurrences.

Prevalence of Diabetes:

Diagnosed: 16 million people

Undiagnosed: 6 to 8 million people

Newly diagnosed per year: 798,000

Rate of increase from 1990 to 2000: 49%

Expected increase by 2050: 165%

Incidence of Diabetes Related Deaths: Studies have found death rates to be twice as high among middle-aged people with Diabetes as among middle-aged people without Diabetes. Based on death certificate data, Diabetes contributed to 193,140 deaths in 2004. Diabetes was the seventh leading cause of death listed on U.S. death certificates in 2004. Diabetes is believed to be under-reported on death certificates, both as a condition and as a cause of death.

## Types of Diabetes:

**Type I Diabetes:** Type I Diabetes was previously called Insulin-Dependent Diabetes Mellitus (IDDM) or juvenile-onset Diabetes. Type I Diabetes may account for 5 to 10 percent of all diagnosed cases of Diabetes. Risk factors are less well defined for Type I Diabetes than for Type II Diabetes. Autoimmune, genetic, and environmental factors are involved in the development of Type I Diabetes.

**Type II Diabetes:** Type II Diabetes was previously called non-insulin dependent Diabetes Mellitus (NIDDM) or adult-onset Diabetes. Type II Diabetes may account for about 90 to 95 percent of all diagnosed cases of Diabetes. Risk factors for Type II Diabetes include older age, obesity, family history of Diabetes, prior history of Gestational Diabetes, impaired glucose tolerance, physical inactivity, and race/ethnicity. African Americans, Hispanic/Latino Americans, American Indians, and some Asian Americans and Pacific Islanders are at particularly high risk for Type II Diabetes.

**Gestational Diabetes:** Gestational Diabetes develops in 2 to 5 percent of all pregnancies but disappears when the pregnancy is ended. Gestational Diabetes occurs more frequently in African Americans, Hispanic/ Latino Americans, American Indians, and persons with a family history of Diabetes. Obesity is also associated with higher risk. Women who have had Gestational Diabetes are at increased risk for later developing Type II Diabetes. Some studies report that nearly 40 percent of women with a history of Gestational Diabetes developed Diabetes.

**Mature Onset Diabetes of the Young (MODY):** A relatively new phenomena, early age onset of Type II Diabetes or MODY has health officials concerned that the diets of American children are promoting the occurrence of Diabetes in teenagers. This information and the condition known as Pre-Diabetes may indicate expansion of an already existent epidemic.

**Pre-Diabetes:** It is estimated that 30 million Americans are currently at risk for developing Type II Diabetes. This has been labeled as Pre-Diabetes by the medical community and is diagnosed by the incidence of Impaired Glucose Tolerance or IGT.

**Other Specific Types:** Other Specific Types of Diabetes may result from specific genetic syndromes, surgery, drugs, malnutrition, infections, and other illnesses. Such types of Diabetes may account for 1 to 2 percent of all diagnosed cases of Diabetes.

## Complications of Diabetes: (Statistics from the National Institutes of Health (NIH), Washington D.C.)

**Heart Disease:** Heart Disease is the leading cause of Diabetes-related deaths. Adults with Diabetes have heart disease death rates approximately 2 to 4 higher than those of adults without Diabetes. **Stroke:** The risk of stroke is 2 to 4 higher in people with Diabetes.

**High Blood Pressure:** An estimated 60 to 65 percent of people with Diabetes have high blood pressure.

**Blindness:** Diabetes is the leading cause of new cases of blindness in adults 20 to 74 years old. Diabetic retinopathy causes from 12,000 to 24,000 new cases of blindness each year.

**Dry Skin:** Poor circulation and neuropathy are common among Diabetes sufferers.

**Kidney Disease:** Diabetes is the leading cause of end-stage renal disease, accounting for about 40 percent of new cases. In 2004, approximately 28,000 people with Diabetes developed end-stage renal disease and a total of 98,872 people with Diabetes underwent dialysis or kidney transplantation.

**Nervous System Disease:** Approximately 60 to 70 percent of people with Diabetes have mild to severe forms of nervous system damage (which often includes impaired sensation or pain in the feet or hands, slowed digestion of food in the stomach, carpal tunnel syndrome, and other nerve problems. Severe forms of diabetic nerve disease are a major contributing cause of lower extremity amputations.

**Amputations:** More than half of lower limb amputations in the United States occur among people with Diabetes. From 2002 to 2004, about 67,000 amputations were performed each year among people with Diabetes.

**Dental Disease:** Periodontal disease (a type of gum disease that can lead to tooth loss) occurs with greater frequency and severity among people with Diabetes. Periodontal disease has been reported to occur among 30 percent of people age 19 years or older with Type I Diabetes.

**Pregnancy Complications:** The rate of major congenital malformations in babies born to women with pre-existing Diabetes varies from 0 to 5 percent among women who receive preconception care, to 10 percent among women who do not receive preconception care. Between 3 and 5 percent of pregnancies among women with Diabetes result in death of the newborn, the

rate for women who do not have Diabetes is 1.5 percent.

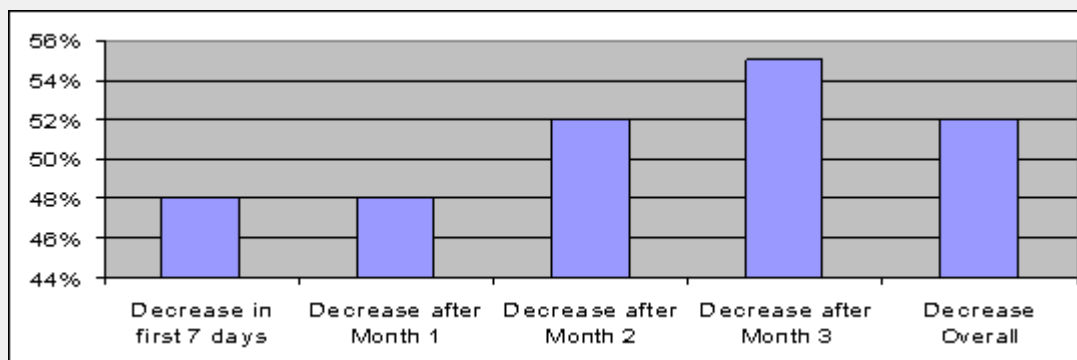
### Side Effects:

Patients were pre-screened for any allergy to cherries, blueberries and cranberries and all 62 patients reported no allergies to the above. Of the 50 patients that completed the study, less than 5% reported mild nausea during the first week on Cinnergen™. All symptoms completely resolved and did not interfere with the use of Cinnergen™ to complete the study.

### Results:

62 patients were originally enrolled in the study. 12 of those patients were either non-compliant and/or had associated medical problems that would not allow them to complete the study. The associated medical problems were not the result of taking Cinnergen™. The following results are based on the 50 patients that completed the study.

### Decrease in Blood Sugar on Patient's using Cinnergen™



48% of patients using Cinnergen™ had a decrease in their blood sugar in the first 7 days with the average drop of 12%

48% of patients using Cinnergen™ had a decrease in their blood sugar after month 1

with the average drop of 22%

with the average drop of 22%

2

52% of patients using Cinnergen™ had a decrease in their blood sugar after month

with the average drop of 24%

3

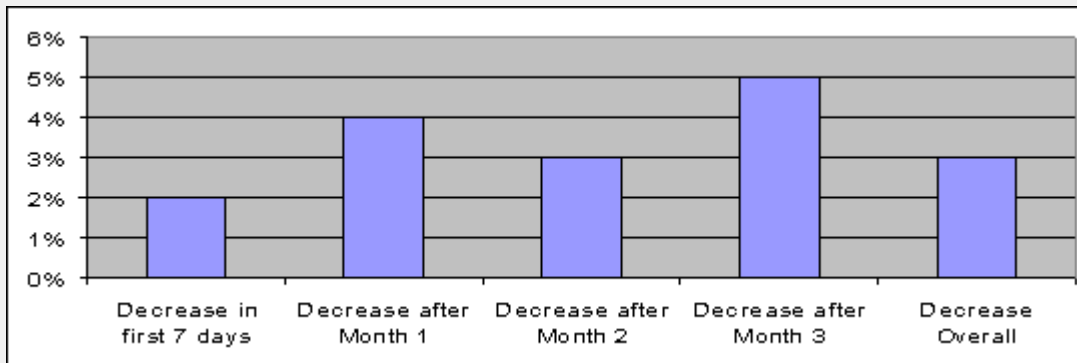
55% of patients using Cinnergen™ had a decrease in their blood sugar after month

with the average drop of 22%

52% of patients using Cinnergen™ had a decrease in their blood sugar overall

with the average drop of 17%

### Decrease in Blood Sugar on Patient's using Placebo



2% of patients using Placebo had a decrease in their blood sugar in the first 7 days

with the average drop of 1%

4 % of patients using Placebo had a decrease in their blood sugar after month 1

with the average drop of 2%

3% of patients using Placebo had a decrease in their blood sugar after month 2

with the average drop of 2%

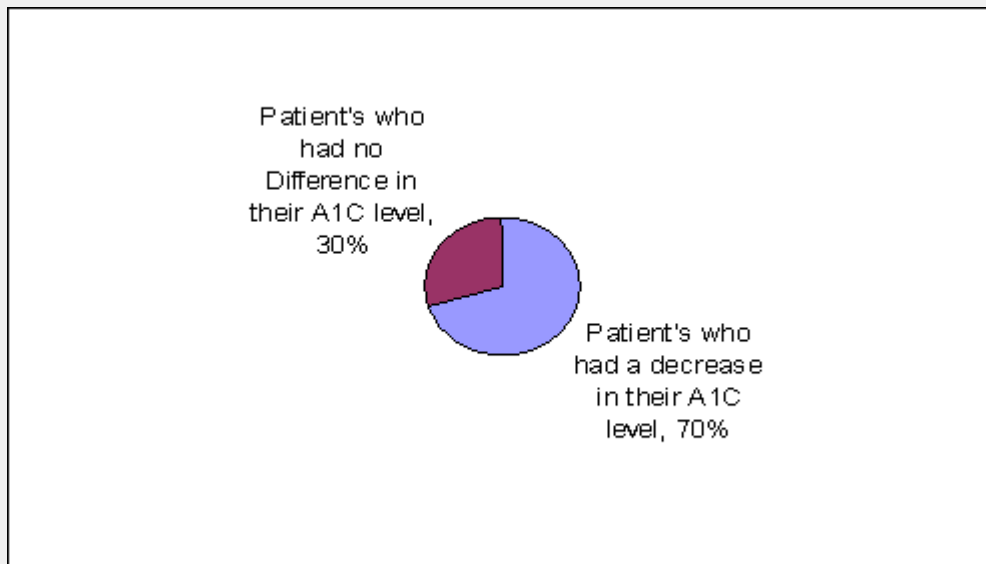
5% of patients using Placebo had a decrease in their blood sugar after month 3

with the average drop of 2%

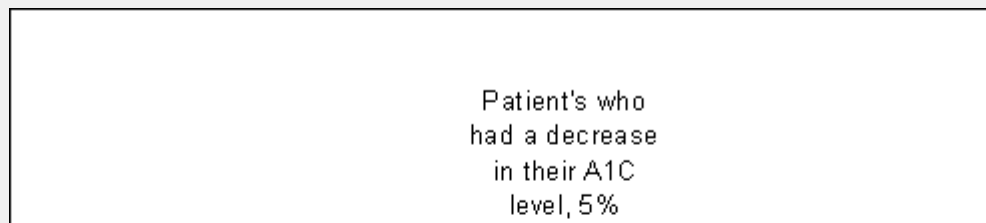
3% of patients using Placebo had a decrease in their blood sugar overall

with the average drop of 1%

### Decrease in Hemoglobin A1C levels for Patient's on Cinnergen™



### Decrease in Hemoglobin A1C for Patient's on Placebo

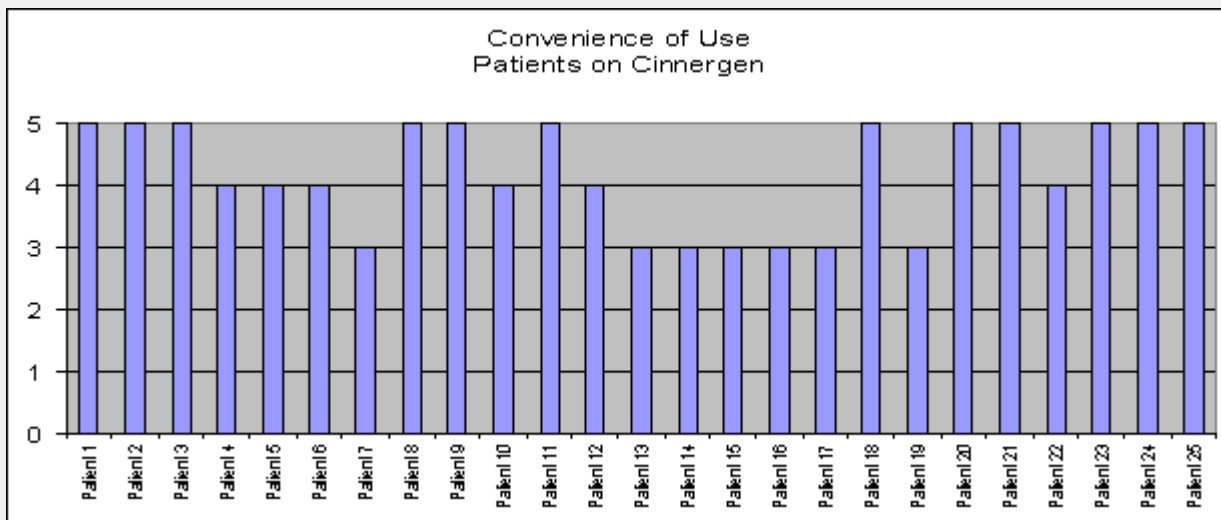




Patient's who  
had no  
Difference in  
their A1C level,  
95%

### Quality of Life Issues- Rating Scale

5 = Excellent      2 = Poor  
4 = Very Good      1 = Very Poor  
3 = Good      0 = No Change

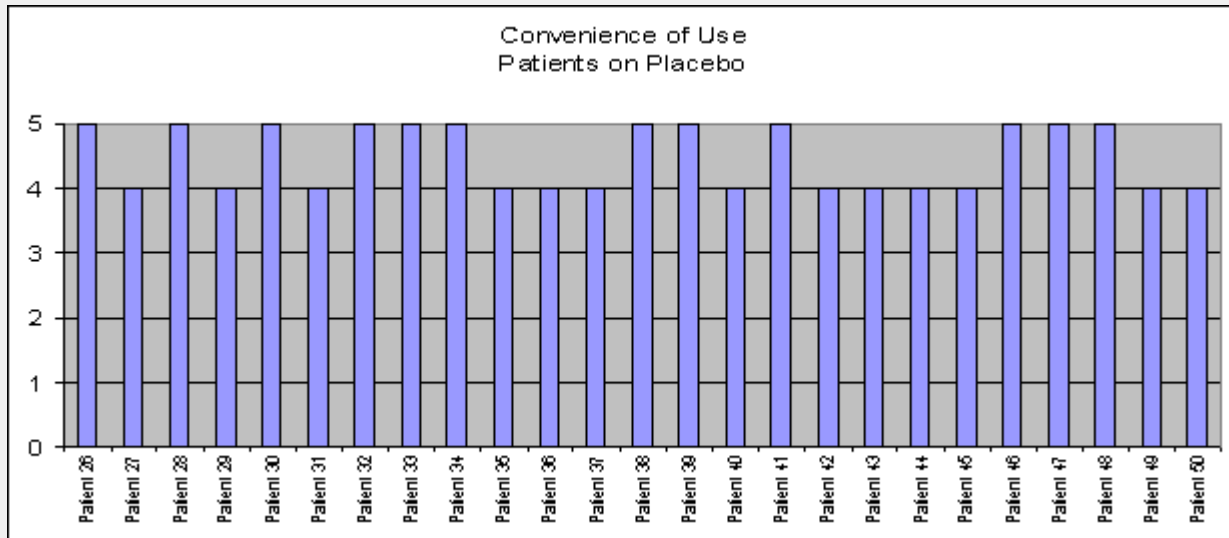


Convenience of Use for patients on Cinnergren™:

48% Excellent

24% Very Good

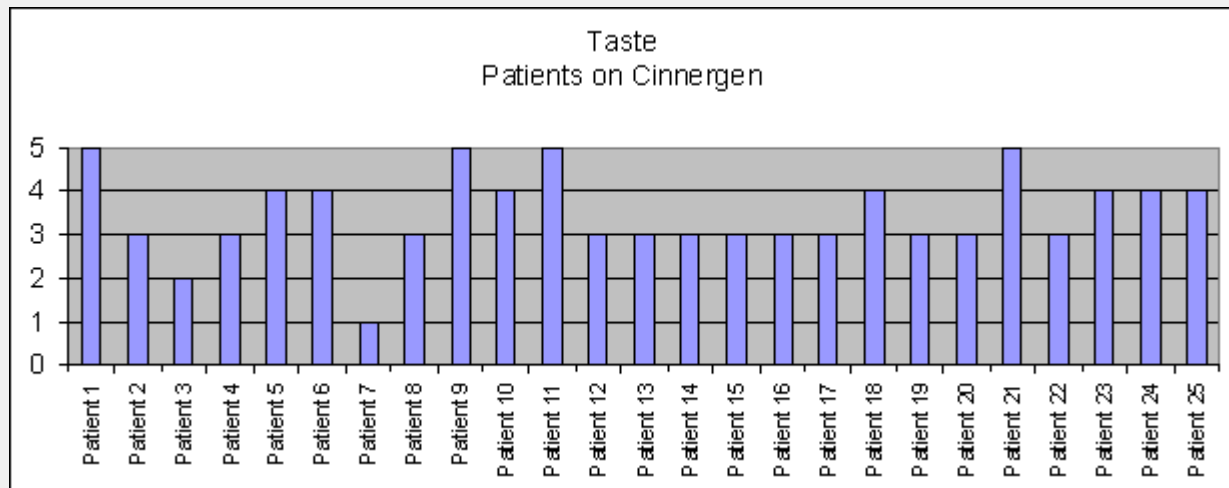
28% Good



Convenience of Use for patients on Placebo:

48% Excellent

52% Very Good



Taste for patients on Cinneger™:

Taste for patients on Cinnergen™.

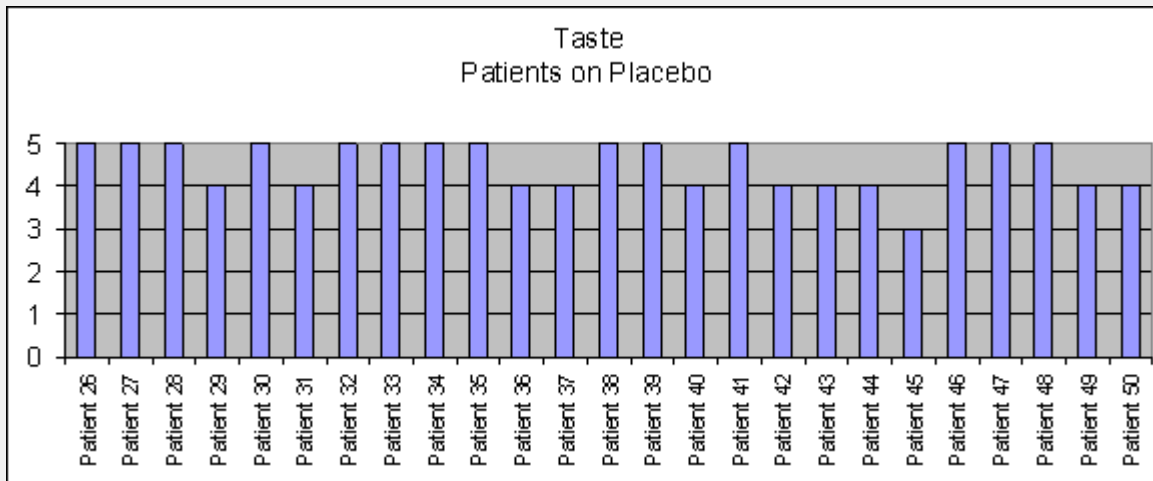
16% Excellent

4% Poor

28% Very Good

4% Very Poor

48% Good

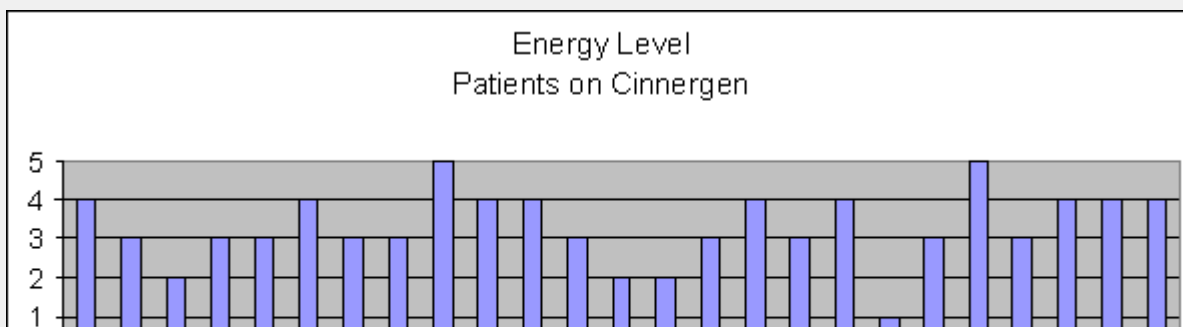


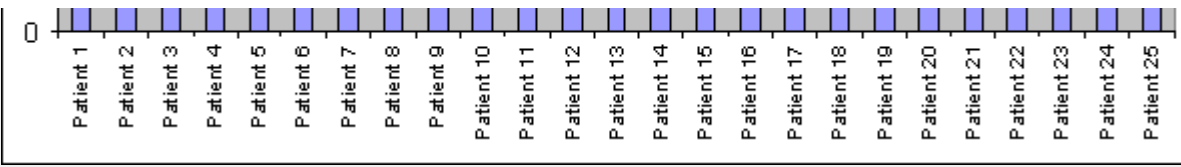
Taste for patients on Placebo:

56% Excellent

40% Very Good

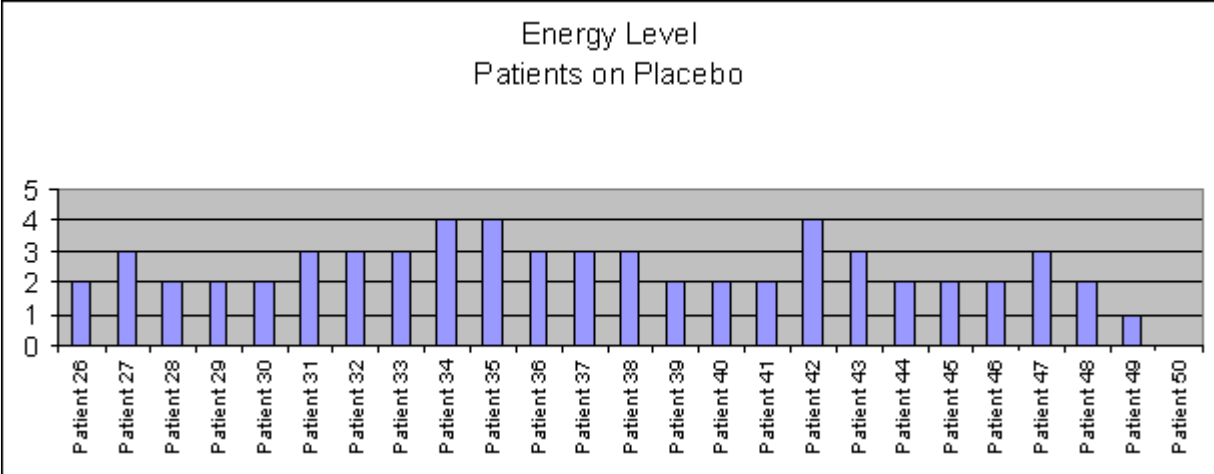
4% Good





Energy Level for patients on Cinnergen™:

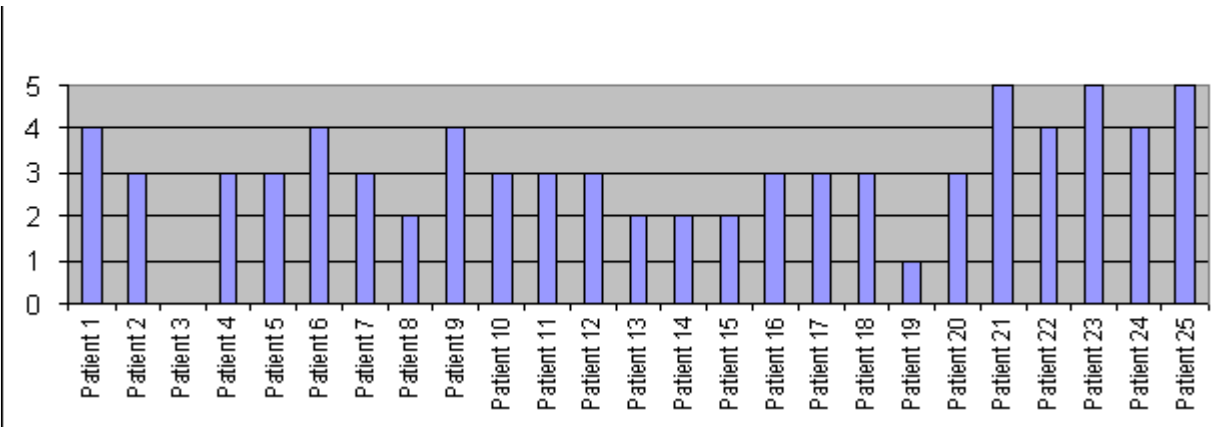
8% Excellent      12% Poor  
 36% Very Good      4% Very Poor  
 40% Good



Energy Level for patients on Placebo:

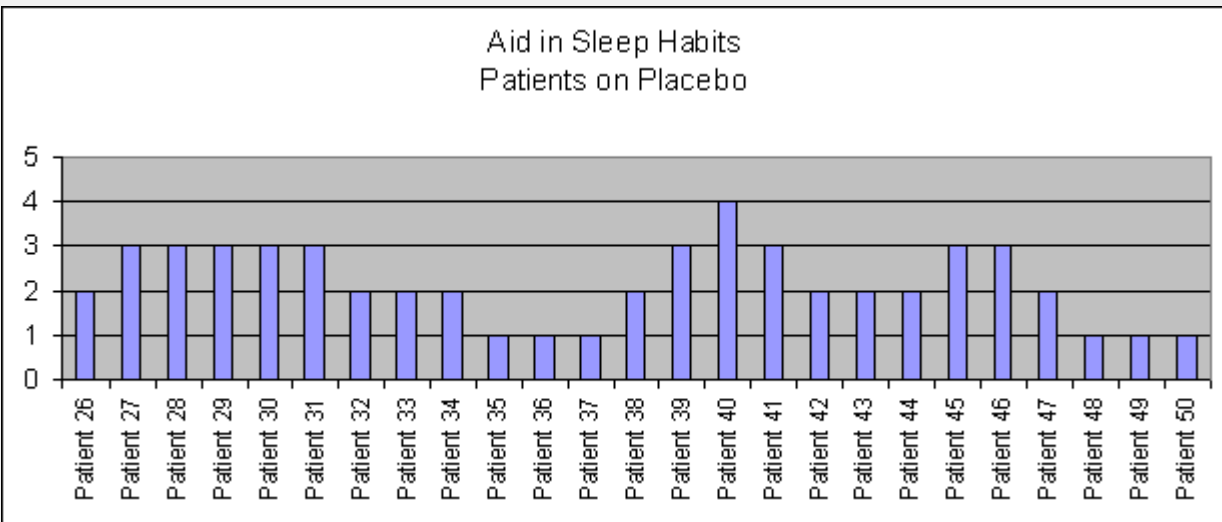
12% Very Good      4% Very Poor  
 36% Good      4% No Change  
 44% Poor

Aid in Sleep Habits  
 Patients on Cinnergen



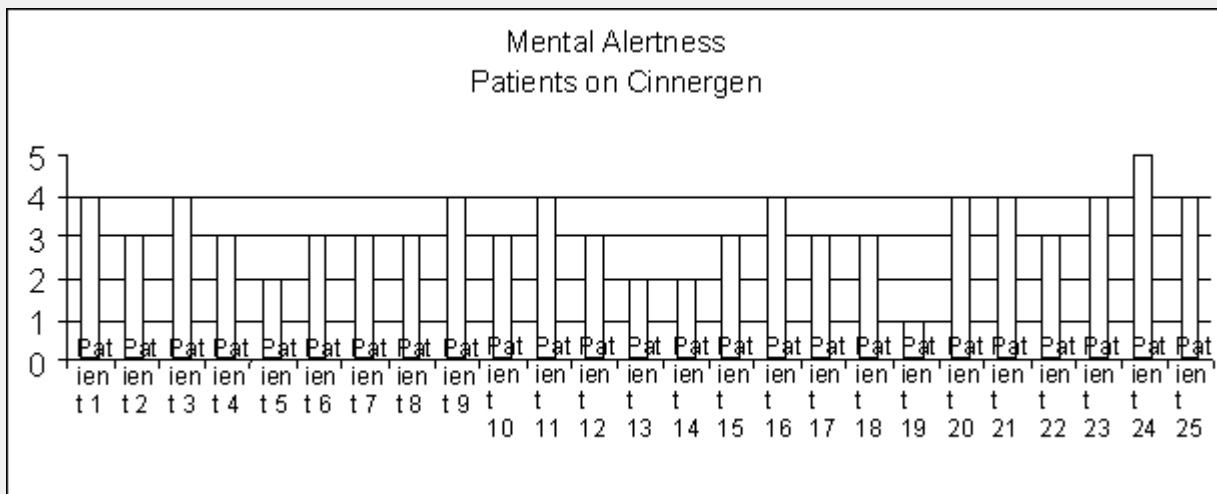
Aid in Sleep Habits for patients on CinnergenTM:

12% Excellent      16% Poor  
 20% Very Good    4% Very Poor  
 44% Good        4% No Change



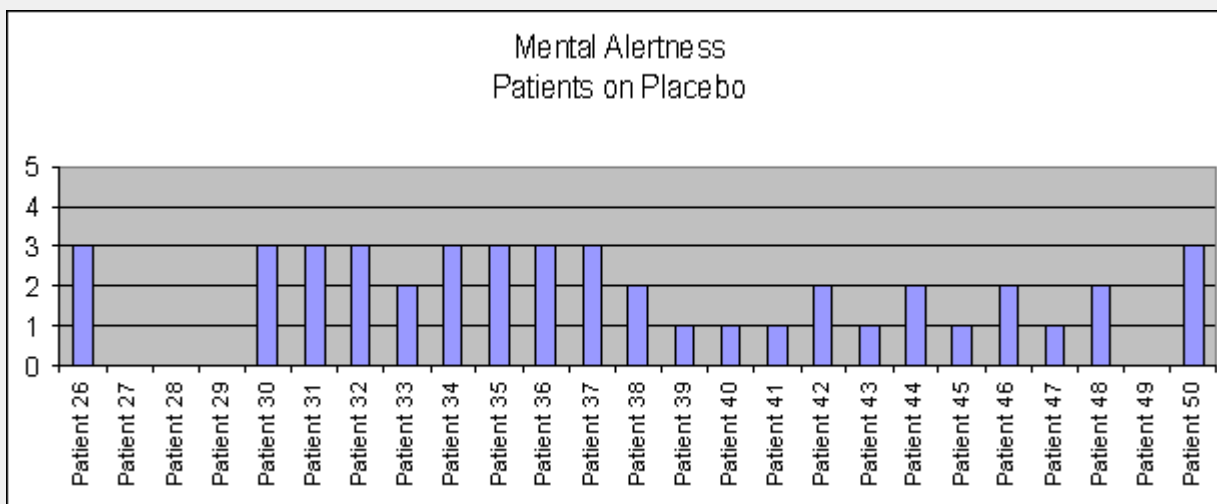
Aid in Sleep Habits for patients on Placebo:

4% Very Good      24% Very Poor  
 36% Good  
 36% Poor



Mental Alertness for patients on Cinnergen™:

4% Excellent      12% Poor  
 36% Very Good      4% Very Poor  
 44% Good

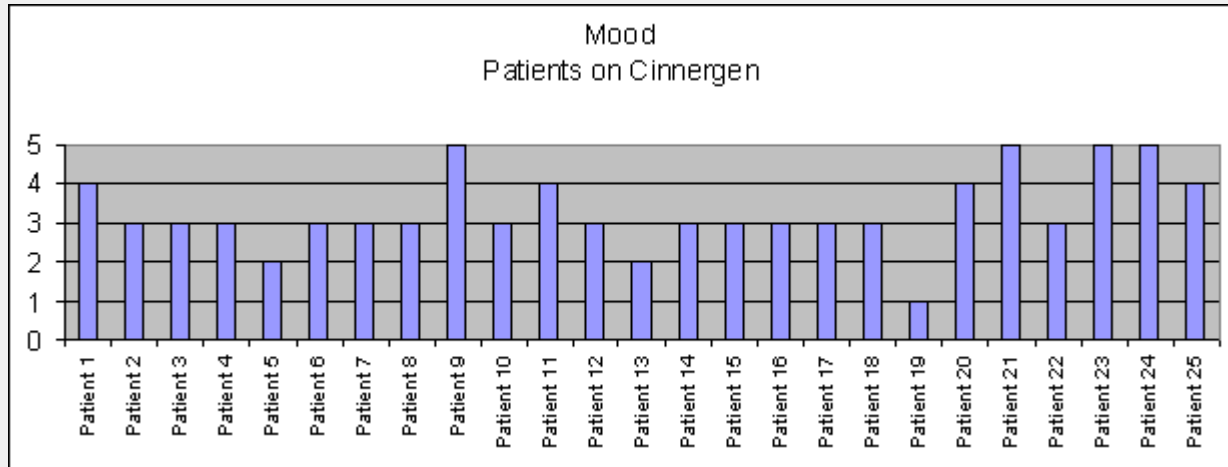


Mental Alertness for patients on Placebo:

36% Good 4% No Change

24% Poor

24% Very Poor

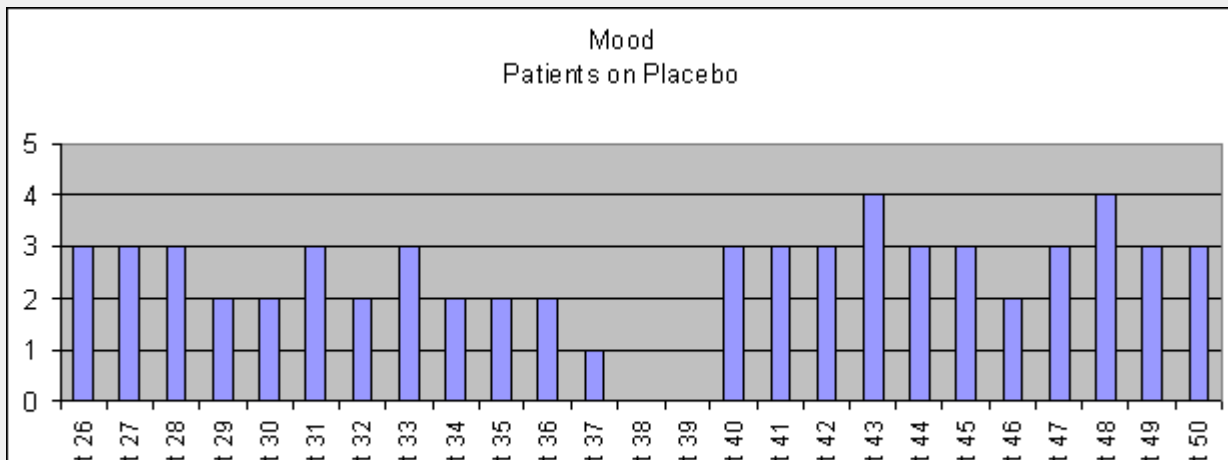


Mood for patients on Cinnergen™:

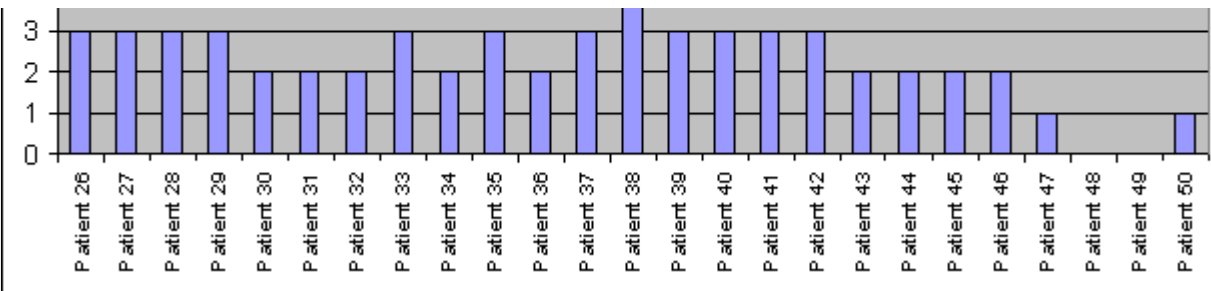
16% Excellent 8% Poor

16% Very Good 4% Very Poor

56% Good





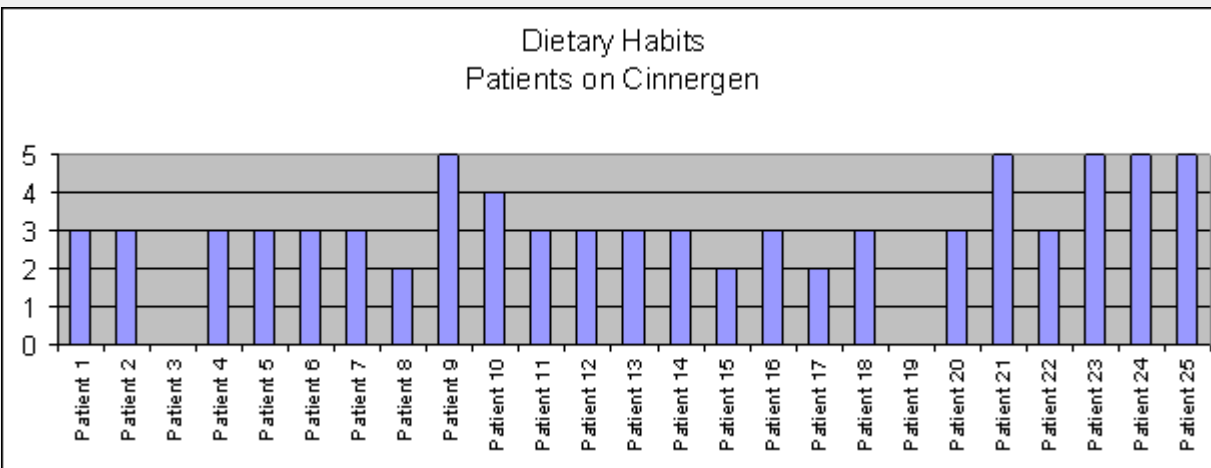


Libido for patients on Placebo:

4% Very Good      8% Very Poor

44% Good      8% No Change

36% Poor

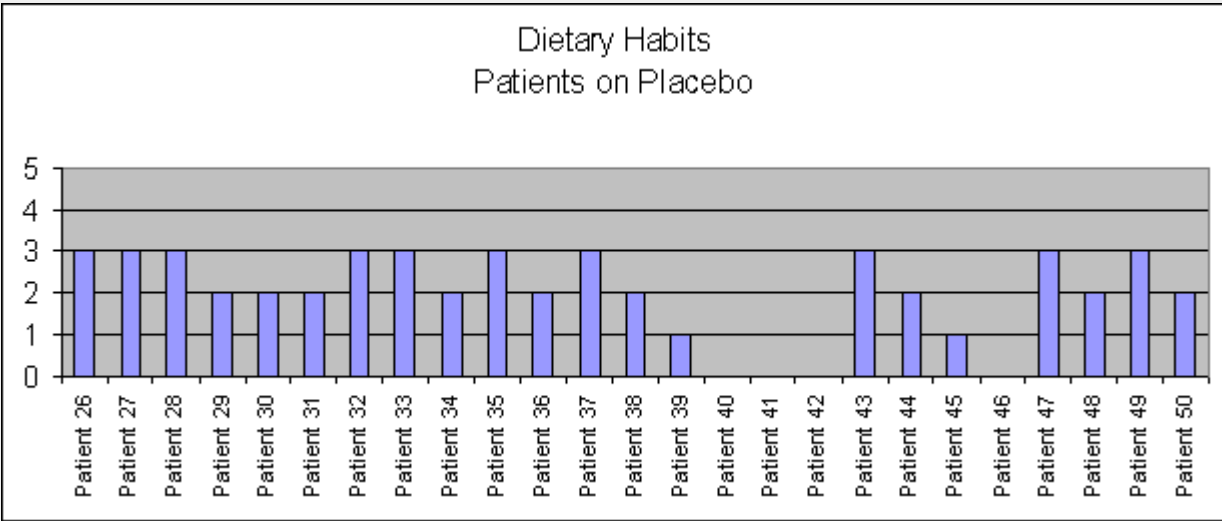


Dietary Habits for patients on Cinnergen™

20% Excellent      12% Poor

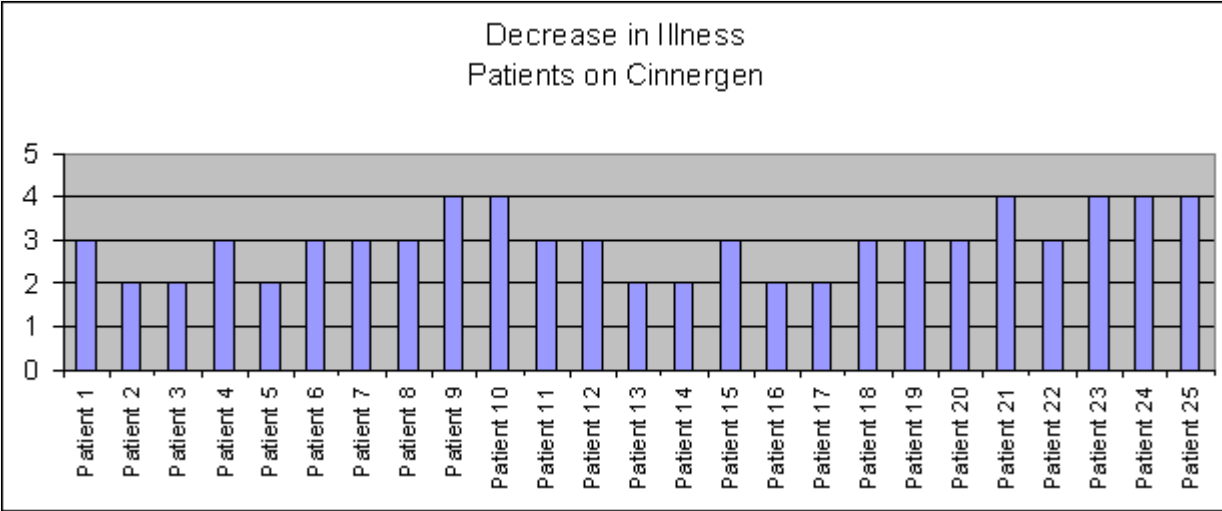
4% Very Good      8% No Change

56% Good



Dietary Habits for patients on Placebo:

- 40% Good    16% No Change
- 36% Poor
- 8% Very Poor

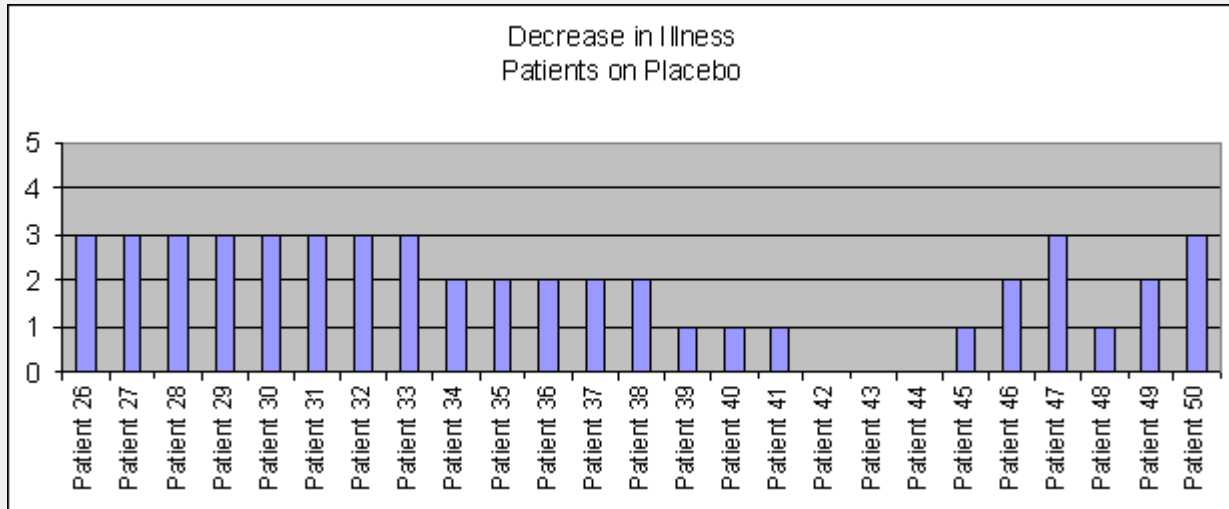


Decrease in Illness for patients on Cinnergen™:

24% Very Good

48% Good

28% Poor

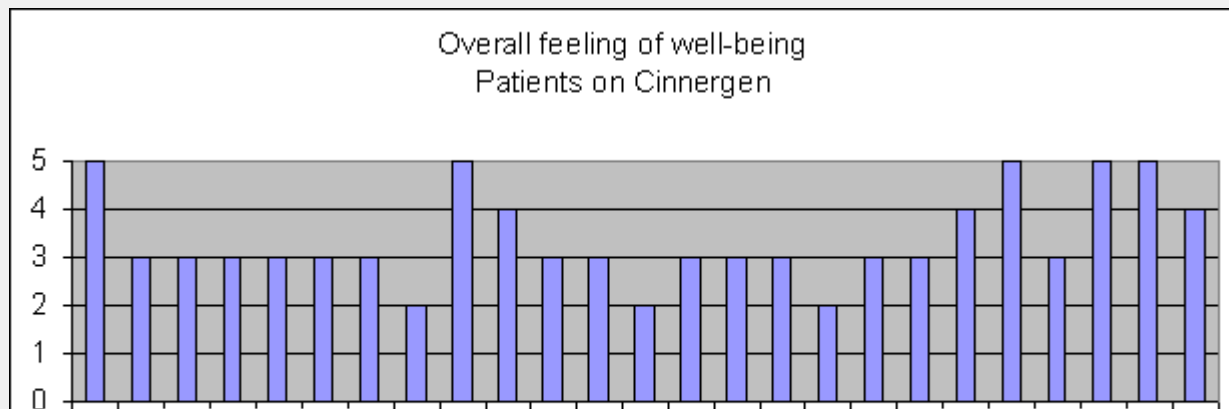


Decrease in Illness for patients on Placebo:

40% Good 12% No Change

28% Poor

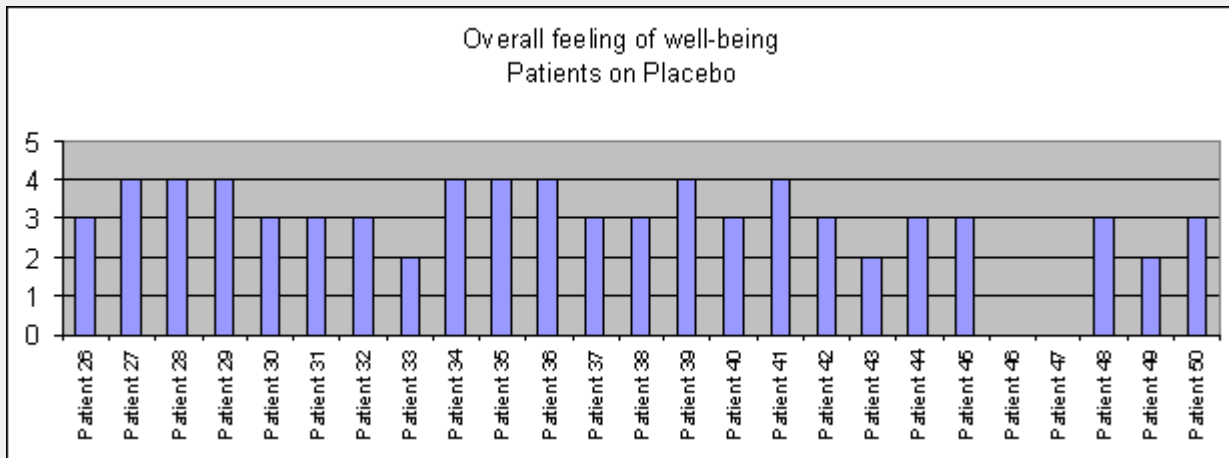
20% Very Poor



Patient 1  
 Patient 2  
 Patient 3  
 Patient 4  
 Patient 5  
 Patient 6  
 Patient 7  
 Patient 8  
 Patient 9  
 Patient 10  
 Patient 11  
 Patient 12  
 Patient 13  
 Patient 14  
 Patient 15  
 Patient 16  
 Patient 17  
 Patient 18  
 Patient 19  
 Patient 20  
 Patient 21  
 Patient 22  
 Patient 23  
 Patient 24  
 Patient 25

Overall Feeling of Well-being for patients on Cinnergen™:

20% Excellent      12% Poor  
 12% Very Good  
 56% Good



Overall feeling of Well-being for patients on Placebo:

32% Very Good      8% No Change  
 48% Good  
 12% Poor

Discussion:

The various types of Diabetes remain a major health concern in the United States and abroad. With this rampant rate of increase in Diabetes, we must address the associated medical conditions it causes, which clearly affect patient's lifestyles and their morbidity and mortality rate. Diabetes management is addressed by the health care community with proper diet and exercise as well as prescription medications, when diet and exercise alone do not control their circulating glucose levels. The

when diet and exercise alone do not control their circulating glucose levels. The results tabulated above clearly address the diabetic patient with a safer, less expensive addition and/or alternative to managing Diabetes Mellitus. The impressive results indicated that the use of Cinnergén™ on a daily basis would allow 52% of the patients taking 1 ounce of Cinnergén™ a day, to have their blood sugars well controlled by Cinnergén™ alone. We strongly recommend that the diabetic patients continue to follow proper diabetic nutritional guidelines as well a daily exercise program. The remaining 48% of the patients would be able to decrease the amount of prescribed diabetic medications in order to properly control their Diabetes.

There are two powerful reasons that blood sugar control is important, the diabetic patient will feel better and it will prevent or delay the start of diabetes complications. All diabetics are instructed to keep tight controls on their blood sugar levels with home testing devices. An additional monitoring device that has and remains the main stay on blood glucose sugar control levels is called Hemoglobin A1C. The Hemoglobin A1C level will measure the true control of their blood sugar and will account for the variations of their blood sugar levels on a daily basis. This most important test has allowed the medical profession to accurately recommend additions and deletions to diabetic management. The Hemoglobin A1C is a good resource to use along with their daily blood sugar checks, for the best possible control. The results of the Cinnergén™ patients' (non-placebo) were exceptional with a 70% improvement in the Hemoglobin A1C levels.

The Quality of Life Issues also present a much added benefit to the use of Cinnergén™. The convenience of use, taste, energy level, aid in sleep habits, mental alertness, mood, libido, dietary habits, decrease in illness, and overall feeling of well-being clearly show the results of greater than 75% benefit in the above mentioned categories. This alone would make it beneficial for the diabetic patients to add Cinnergén™ to their daily regimen.

The authors recommend when adding Cinnergén™ to their diabetic management, that the patients continue to have their blood sugar levels monitored, Hemoglobin A1C levels measured and follow a proper diabetic diet as well as exercising daily. It is therefore concluded that all patients, pre-diabetic or diabetic will benefit from the use of Cinnergén™ on a daily basis.

#### References:

- 1 Blumenthal M, et al. ed. The Complete German Commission E Monographs:

Therapeutic Guide to Herbal Medicine. Trans. J. Klein, Boston, MA: American Botanical Council, 1998

- 2 Newall CA, Anderson LA Philpson JD. Herbal Medicine: A Guide for Healthcare Professionals. London, UK: The Pharmaceutical Press, 1996
- 3 Foster S, Tyler VE. Tyler's Honest Herbal: A Sensible Guide to the Use of Herbs and Related Remedies. 3rd ed, Binghamton, NY: Haworth Herbal Press, 1993
- 4 American Pharmaceutical Association. Handbook of Non-prescriptive Drugs. 11th ed. Washington, D.C.: American Pharmaceutical Association, 1996.
- 5 Wichtl MW. Herbal Drugs and Phytopharmaceuticals. Ed, N.M. Bisset. Stuttgart: Medpharm GmbH Scientific Publishers, 1994
- 6 Balch, J.F., and P.A. Balch. Prescription for Nutritional Healing: A Practical A to Z Reference to Drug-Free Remedies Using Vitamins, Minerals, Herbs and Food Supplements. 2nd ed. Garden City Park, NY: Avery Publishing Group, 1997
- 7 Mayell M. Off-the-Shelf Natural Health: How to Use Herbs and Nutrients to Stay Well. New York: Bantam Books, 1995
- 8 Tyler, V.E., The Honest Herbal. Binghamton, NY: Haworth Press/Pharmaceutical Products Press, 1993.
- 9 Leung, A.Y., and S. Foster. Encyclopedia of Common Natural Drugs & Cosmetics. 2nd ed. New York: John Wiley & Sons, 1996
- 10 The Review of Natural Products by Facts and Comparison: St. Louis, MO: Wolters Kluwer Co, 1999
- 11 Schulz V, Hansel R, Tyler, VE. Rational Phytotherapy: A Physician's Guide to Herbal Medicine. Trans. Terry C Telger. 3rd ed. Berlin, Germany: Springer, 1998.
- 12 Gruenwald J, et. Al. PDR for Herbal Medicines. 1st ed. Montvale NJ: Medical Economics Company, Inc., 1998
- 13 Duke, JA CRC Handbook of Medicinal Herbs. Boca Raton, FL: CR Press, 1985

- 14 Heinerman, J. Heinerman's Encyclopedia of Healing Herbs and Spices. West Nyack, NY: Parker Publishing Co., 1996
- 15 Lawrence Review of Natural Products. St. Louis: Facts and Comparisons, July, 1990
- 16 Mindell E. Earl Mindell's Herb Bible. New York's Simon & Schuster/Fireside, 1992.
- 17 Clinical Trials  
Meinert, Curtis  
Oxford University Press Various Sections
- 18 Practical Statistics for Medical Research  
Altman, Douglas G.  
Chapman and Hall, London 1993 pp 181-191 & 232-250
- 19 Medical Uses of Statistics, Second Edition  
Edited by: John C. Bailar III and Frederick Mosteller  
NEJM Books (New England Journal of Medicine)  
Boston, MASS 1992 Chapter 10:P Values
- 20 Bouchet C. et al  
Section of quality-of-life measures for a prevention trial: a psychometric analysis.  
Control Clinical Trials: 2000 Feb; 21 (1): 30-43
- 21 American Diabetes Association web site
- 22 American Association for Clinical Chemistry web site
- 23 Medscape for Physicians web site
- 24 American Heart Association web site

