

# PILOT STUDY RESEARCH SUMMARY

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# RESEARCH INGREDIENTS, DESIGN, AND METHODS

## STUDY SUBJECTS

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There were a total of 50 patients consisting of men and women between the ages of 29 and 84 with Type I or Type II Diabetes. 25 patients received the ingredients and 25 patients received a placebo. All patients were randomized.

Investigators and personnel were blinded to assure accuracy.

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

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



**50**

patients

ages between

**29-84**

**25**

received placebo

## STUDY DESIGN

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**Objective:** To determine efficacy of a liquid herbal formula

**Overview:** This pilot study was a 3-month (90 day) trial.

Many companies do their own “in house” studies and many times those results can be incorrect, misleading, or skewed. This research on the ingredients was done by a 3rd party, independent, FDA-approved, regulated pilot facility meeting all the highest standards for studying prescription and non-prescription medications. Other studies conducted by this facility:

1. Adventis - Hypertension
2. Novaris-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

This trial has Internal Review Board (IRB) approval to guarantee all patients’ rights are protected and research studies are implemented and conducted in accordance with FDA guidelines.

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

Dr. David J. Miller and staff monitored all patients’ symptoms.



## METHODS

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### Important Scale

- Included 0% to 100% improvement to be checked weekly for the 12-week trial period.
- All patient-scoring systems were performed with the the 3rd party pilot research team to assure accuracy and to limit patient bias, thereby allowing this design study to be statistically significant.

### Statistical Plan Reference 17 – 20

Standard randomization was performed to ensure proper randomization.

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

Baseline characteristics were compared using the Mantel-Haenszel chi-square test except for small cell sizes, where the Fisher's exact test was employed, for categorical parameters and the two-sample t-test for continuous parameters. Statistical significance was set at five percent (or 0.05).

Outcomes of both the tools were analyzed using nonparametric procedures, such as the Wilcoxon Rank sum tests and two-group t-tests for the means of the various questions for the two groups. Statistical significance was established that a trend will be between 0.05 1 and 0.10 while true significance will be defined as equal to or less than 0.05.

Subscales for the SF-36 were calculated according to Ware's manuals and compared using tests for means.

**The improvements of health benefits increased from week 4 to week 12 of the pilot study.**



# RESEARCH INGREDIENTS, DESIGN, AND METHODS

## Impact on Quality of Life:



### **INCREASE IN ENERGY:**

Week 1-4 of pilot study - There was a 30% improvement in energy.  
Week 5-12 of pilot study - Overall patients noted a 60% improvement.



### **IMPROVEMENT IN MENTAL ALERTNESS:**

Week 1-4 - There was a 20% improvement in alertness.  
Week 5-12 - Overall patients noted a 60% improvement.



### **IMPROVED LIBIDO:**

Week 1-4 - There was a 20% improvement in libido.  
Week 5-12 - Overall patients noted a 50% improvement.



### **ENHANCEMENT IN MOOD:**

Week 1-4 - There was a 50% improvement in mood.  
Week 5-12 - Overall patients noted a 65% improvement.



### **IMPROVEMENT IN SLEEP:**

Week 1-4 - There was a 30% improvement in sleep.  
Week 5-12 - Overall patients noted a 60% improvement.



### **DIETARY HABITS:**

Week 1-4 - There was a 20% improvement in diet.  
Week 5-12 - Overall patients noted a 50% improvement.



### **OVERALL FEELING OF WELL-BEING:**

Week 1-4 - There was a 50% improvement in overall well-being.  
Week 5-12 - Overall patients noted a 75% improvement.



### **IMPROVED BLOOD GLUCOSE LEVELS:**

Within the 12 week period - provided support for healthy glucose metabolism (up to 50%)



### **IMMUNE FUNCTION SUPPORT:**

Within the 12 week period – provided support for healthy immune function (up to 30%)



### **BLOOD LIPIDS IMPROVEMENT:**

Within the 12 week period - Provided nutritive support for healthy blood lipid levels (up to 25%)

Based on the above findings contained in this study, the ingredients were shown to have a positive impact on many quality of life issues.

## SUMMARY

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Based on the above subjective and objective findings contained in this study, the formula has been shown to have a positive impact on Type I and II Diabetes (can be used with insulin and oral hypoglycemics) in reducing blood sugar levels. Also, there are the positive affects on patients suffering from hypercholesterolemia (can be used with cholesterol lowering medications), therefore, the improvement noted in the study would warrant the formula ss a first line product, as an all natural agent. The formula enhances the body's immunity, which demonstrates a whole host of anti-aging benefits, disease fighting and prevention properties. CRP levels are now accepted by mainstream medicine to be the most accurate predictor of cardiovascular disease. The formula has demonstrated that this inflammatory protein can be managed in a natural manner, thus decreasing the risk of cardiovascular disease and improving cardiovascular health.





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