



Attain[®]
GC CONTROL[™]
Natural Blood Sugar Support Supplement



Metabolic Syndrome with Prediabetic Factors
*Clinical Study Summary Concerning the Efficacy
of the GC Control[™] Natural Blood Sugar
Support Supplement*



Metabolic Syndrome with Prediabetic Factors

Study Concerning the Efficacy of the GC Control™ Natural Blood Sugar Support Supplement

Background:

Researchers worldwide have noticed an alarming rise in the cluster of medical risk factors known as “metabolic syndrome.” A National Health Statistics report from 2009 put the number of U.S. citizens who met the criteria for metabolic syndrome at 34% of the adult population. The most indicative symptoms are central obesity (apple-shaped body) and insulin resistance. Other factors are elevated blood pressure, high triglyceride levels, low HDL levels, aging, and lack of exercise. The more of these factors exhibited, the greater the risk for the development of serious ailments—including heart disease (53% greater risk) and stroke (76% greater risk). The likelihood of developing diabetes is increased fivefold for those who develop metabolic syndrome, and the Centers for Disease Control and Prevention (CDC) reports one in nine U.S. residents aged 20 years or older suffered from diabetes in 2010. On a global basis, the World Health Organization (WHO) warns that deaths from diabetes will double in the next 25 years. While diabetes has traditionally been thought of as a genetic malady, research shows that type 2 diabetes (which comprises 90% of diabetic cases worldwide) is largely influenced by nutritionally poor diets and lack of exercise. According to the WHO, “Healthy diet, regular physical activity, maintaining a normal body weight, and avoiding tobacco use can prevent or delay the onset of type 2 diabetes.” This statement is echoed by the Mayo Clinic, where patients are advised to make “aggressive lifestyle changes” that can affect metabolic syndrome factors and bring about positive changes in personal health. Since metabolic syndrome has been shown to foreshadow serious diseases, prevention and control efforts at the metabolic syndrome level could have a positive effect on future health outcomes for many patients.

Purpose:

This study tested the efficacy of a low-glycemic, low-carbohydrate nutritional supplement containing patent-pending mineral delivery technology and a proprietary blend of natural blood sugar support ingredients. The supplement shake is designed to promote healthy blood glucose metabolism and support normal insulin response. Researchers sought to determine whether the product could be beneficial to those who have developed metabolic syndrome with prediabetic factors.

Methods:

Blood chemistries and scored questionnaire data were established as a baseline for the prediabetic participants in a 56-day study. The tests were repeated on days 28, 42, and 56. Results were then compared and evaluated for statistical significance.

Results:

Statistical significance was shown for the change in both A1C and serum glucose levels. Insulin level reduction was also determined to be statistically significant. Scored questionnaire data showed above-average improvement in key categories, including a 53.53% reduction in fatigue intensity, compared to baseline.

Conclusions:

Those who wish to take measures to maintain proper blood sugar support health, may realize benefits from the regular use of the formulation tested. Optimal results would be realized when the tested nutritional product (GC Control™ Natural Blood Sugar Support Supplement) is included as part of an overall regimen of sound dietary habits and positive lifestyle changes.

» Results

Scored data showed above-average improvement in key categories...

» Introduction

... more than one-third of U.S. adults already exhibit fasting blood glucose levels in the prediabetic range.

» Introduction

... individual choices and actions can prove significant in determining whether or not one will become afflicted with metabolic syndrome, prediabetes, or Type 2 diabetes.

Introduction

Metabolic syndrome and prediabetes have reached epidemic proportions in recent years, and the forecast is troublesome. While not a disease, metabolic syndrome is a condition that includes a series of risk factors that precede diabetes. The CDC predicts as many as one-third of adults in the U.S. could contract diabetes by 2050. Furthermore, says the CDC, more than one-third of U.S. adults already exhibit fasting blood glucose levels in the prediabetic range.

On the global stage, the International Diabetes Foundation says that metabolic syndrome and diabetes are “driving the cardiovascular diseases (CVD) epidemic” and that the factors contributing to the increase—things like an aging population, the tendency towards a sedentary lifestyle, and diets high in calories and refined carbohydrates—are not “country-specific.” A meta-study, published in 2006, combined the results of 21 independent studies and found that those afflicted with metabolic syndrome exhibited a 35% greater incidence of mortality from all causes, and a 74% greater incidence of mortality from cardiovascular disease when compared to subjects without metabolic syndrome.

The good news is that individual choices and actions can prove significant in determining whether or not one will become afflicted with metabolic syndrome, prediabetes, or more serious health concerns. While it is believed some patients are genetically predisposed and will develop serious health problems regardless of preventative measures, the World Health Organization argues that lifestyle and dietary changes can delay the onset of type 2 diabetes. The CDC estimates that 90% of adults with diabetes could have prevented it.

The Melaleuca nutritional research team conducted extensive studies, leading them to determine that a specially formulated nutritional shake supplement—one designed specifically to support healthy blood glucose metabolism and insulin response—could be a valuable help to those individuals seeking to improve their health and provide nutritional and natural blood sugar support supplementation.



Criteria for evaluation

Primary efficacy evaluation

- To support and optimize blood glucose metabolism in subjects with prediabetic A1C levels by evaluating blood chemistry results. (The A1C measures the average “free blood glucose” level over the past three months. It’s a good indication of how well the body is able to properly metabolize blood sugar.)
- To improve subject’s energy levels, fatigue levels, and factors associated with satiety and appetite control using a scored questionnaire.

Methods

After protocol approval by the Institutional Review Board, male and female subjects between 18 and 45 years of age were prescreened to meet the inclusion and exclusion criteria. A sample population of prediabetics, sufficient to establish a statistically valid confidence interval, was selected to participate in the study. Subjects with an A1C range of 5.5%–6.4% were eligible for the study. For each subject, the study concluded after 56 days from enrollment and included 4 follow-ups. Informed consent from each participant was obtained before being administered the investigational supplement.

On Day 0 (baseline), medical history and physical examinations were performed on all subjects. Blood collections were performed at time points 0 (baseline), 90, and 150 minutes on Day 0. All fasted subjects received the test article immediately after time point 0 (baseline) and before time point 30 minutes. All study participants continued a 56-day treatment. Subsequent blood chemistries were performed on all subjects on Days 28, 42, and 56 at time point 0 minutes, to be tested for the selected biomarkers.

Scored questionnaires, consisting of a psychometric response scale, were used to measure subjective data on Day 0 (baseline). All subjects completed subsequent scored questionnaires on days 28, 42, and 56 to assess subjective levels of energy and satiety.

The test articles for this study were supplied with GC Control™ Natural Blood Sugar Support Supplement, which was labeled as “6OP78546.” The subjects received the GC Control™ Natural Blood Sugar Support Supplement twice a day (powder pouches).

Statistical Methods

- The study group was analyzed in two phases: acute (0, 90, and 150 min.) and extended treatment (days 0, 28, 42, and 56) respectively
- All statistical analyses were performed using GraphPad 5.0
- Global Analysis was performed using an unpaired *t* test
- Results of the analysis were expressed as Mean \pm standard error
- Scored questionnaire results were expressed as relative frequencies (percentage) and showed as Mean \pm standard error

Results

Unpaired *t* Test

GC Control™ 60P78546 showed the following results, when comparing baseline (Day 0) to end point (Day 56):

- A statistically significant reduction ($p=0.00003$) in A1C levels
- A statistically significant reduction ($p=0.00005$) in serum glucose levels
- A statistically significant reduction ($p=0.0067$) of insulin levels
- HOMA levels were reduced, but not in the range of statistically significant ($p=0.3540$)

Variable	Baseline (MEAN \pm SE)	Day 56 (MEAN \pm SE)	Improvement (%)	Normal Ranges
HbA1C	5.859 \pm 0.054	5.566 \pm 0.054	5.00	4.6–5.4 mg/dl
Glucose	102.6 \pm 1.63	94.24 \pm 1.55	8.14	70–100 mg/dL
Insulin	53.7 \pm 2.48	45.06 \pm 1.80	16.08	2.6–24.9 μ g/mL
HOMA	4.18 \pm 0.40	3.67 \pm 0.36	12.16	1–4

Figure 1. Unpaired *t* test results.

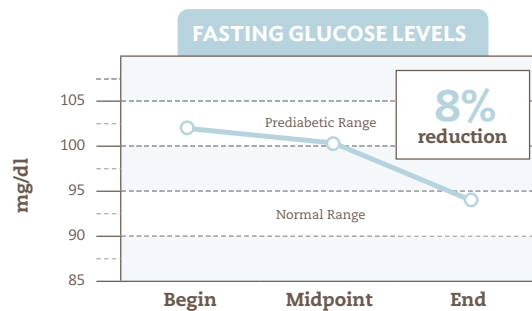


Figure 2. Participants using GC Control reported an 8% decrease in fasting glucose levels over the course of the study.

Scored Questionnaire Results

The following scored questionnaire ratings were used to measure energy:

- Current intensity of energy
- Current intensity of fatigue

The following scored questionnaire ratings were used to measure satiety:

- Current degree of hunger
- Current assessment of how much one could eat

Each scored questionnaire consisted of 100 mm horizontal lines with extreme sensations anchored at the ends of the lines. The subjects completed the scored questionnaire by placing a vertical slash on the line corresponding to their sensation.

Energy scored questionnaire evaluation results (Day 0 compared to Day 56)

- A 9.68% increase in energy intensity
- A 53.53% decrease in fatigue intensity

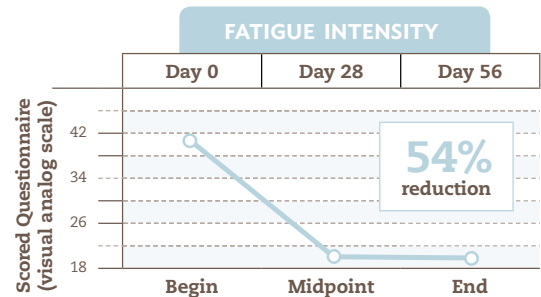


Figure 3. Over the course of the study, participants using GC Control™ reported a 54% decrease in fatigue.

Satiety scored questionnaire evaluation results (Day 0 compared to Day 56)

- A 36.52% decrease in appetite intensity
- A reduction of 28.53% for “How much can you eat?”

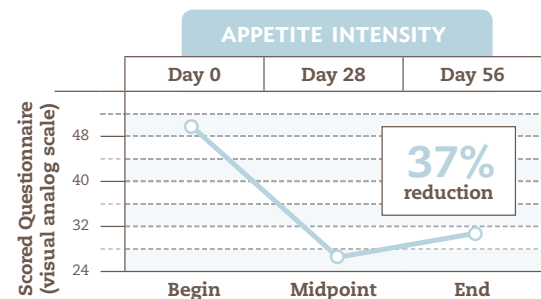


Figure 4. Participants using GC Control also reported a 37% decrease in appetite intensity over the course of the study.

» Discussion

There is an increasing risk for people who exhibit the symptoms of metabolic syndrome... to develop prediabetes or type 2 diabetes.

» Conclusions

It is suggested that Attain® GC Control™ Natural Blood Sugar Support Supplement be incorporated into a healthy lifestyle to maintain the efficient metabolism of glucose and insulin.

Discussion

There is an increasing risk for people who exhibit the symptoms of metabolic syndrome—including elevated blood pressure, central obesity, cholesterol levels out of the desired range, and insulin resistance—to develop prediabetes and other potential health complications.

A1C levels of 5.6% or below are considered normal. A1C levels of 6.5% or greater are indicative of diabetes. A1C levels greater than 5.6% but less than 6.5% are in the range of prediabetes—and this is the area where preventative measures may be most effective.

GC Control™ is a nutritionally balanced, low-glycemic natural blood sugar support supplement that's high in protein and high in fiber. It achieves the displayed results by using a proprietary blend of patent-pending and specialized natural ingredients combined at a specific balance and exacting concentration. Those ingredients include chromium (as chromium amino acid oligofructose complex), super-concentrated cinnamon bark extract, Korean red ginseng root extract, mulberry fruit leaf extract, green tea leaf extract, and sweet potato extract—all of which have additional human clinical studies backing their blood sugar support properties.

Conclusions

Using the test product, a study was completed by a nationally recognized clinical research company to determine the validity and efficacy of the GC Control™ Natural Blood Sugar Support Supplement. The study used IRB approval, with male and female subjects between 18 and 45 years of age with prediabetic factors of high glucose spikes in the last 90 days (A1C). The tests were a 56-day protocol, with measurements at Days 0, 28, 45, and 56. Blood work and scored questionnaires were completed on each test day.

Results were significant for the following factors:

- Reduction in fasting glucose levels (>8%)
- Reduction in glucose spikes (>5%)
- Reduction in insulin levels (>16%)
- Decrease in fatigue (>54%)
- Decrease in appetite (>37%)

In conclusion, study participants saw significant changes in the key areas related to healthy blood

sugar support. Those who implement diet and lifestyle changes may effectively manage metabolic syndrome and prediabetic factors. It is suggested that GC Control™ Natural Blood Sugar Support Supplement be incorporated into a healthy lifestyle to maintain the efficient metabolism of glucose and insulin.

Further studies should be conducted to confirm these findings.

Reference List

- 1 <http://www.cdc.gov/nchs/data/nhsr/nhsr013.pdf>
- 2 <http://www.ncbi.nlm.nih.gov/pubmed/17000207>
- 3 <http://www.nhlbi.nih.gov/health/health-topics/topics/ms/>
- 4 <http://apps.nccd.cdc.gov/DDTSTRS/FactSheet.aspx>
- 5 <http://www.who.int/mediacentre/factsheets/fs312/en/>
- 6 <http://www.mayoclinic.com/health/metabolic%20syndrome/DS00522>
- 7 <http://www.cdc.gov/diabetes/pubs/factsheet11.htm>
- 8 <http://www.ncbi.nlm.nih.gov/pubmed/17000207>
- 9 Tuomilehto J, Lindstrom J, Eriksson JG, et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance.
- 10 <http://www.diabetes.org/diabetes-basics/prevention/pre-diabetes/pre-diabetes-faqs.html>

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