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# Glutalytic Clinical Trial for Normal Consumption of Gluten Containing Foods

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\*Running title: Glutalytic Clinical Trial

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## Background

Gluten sensitivity and the incidence of Celiac disease are ever increasing. The aim was to measure the effectiveness of an enzyme based dietary supplement on the reduction of symptoms encountered upon the consumption of gluten.

## Results

The data showed a statistically significant improvement when compared to the placebo group in the following categories: pain, bloating, emptying of bowels, hunger pains, rumbling of stomach, lower energy levels, headaches, and food cravings. There was no statistically significant improvement in the following symptoms: comfort, nausea, and loss of appetite.

## Conclusion

Overall, the dietary supplement, Glutalytic, reduced many of the symptoms that are encountered upon the consumption of gluten.

## Introduction

Gluten is the most important protein component of several grains, most notably wheat, rye, and barley. These grains are the basis for a range of flour and wheat derived products consumed throughout the world. In some individuals, gluten components cause significant gastrointestinal distress and other symptoms. Non-Celiac gluten sensitivity is a syndrome characterized by gastrointestinal and extraintestinal symptoms occurring within a few hours to days after the ingestion of gluten and rapidly improving after gluten withdrawal. Celiac disease, on the other hand, is classified as a genetically linked autoimmune disorder that damages the lining of the small intestine and prevents it from absorbing parts of food that are important for staying healthy. The damage is due to a reaction to eating gluten, which is found in wheat, barley, rye, and possibly oats.[1-3]

Non-Celiac gluten sensitivity and Celiac disease appear to be different due to epidemiologic and pathogenetic aspects. Although non-Celiac gluten

sensitivity prevalence is still poorly defined in society, it is thought to be more frequent than Celiac disease. The Center of Celiac Research estimates that approximately six percent of the U.S. population suffers from gluten sensitivity, while the prevalence of Celiac disease is approximately one percent of the population in developed and developing countries. Due to the ever increasing prevalence of gluten sensitivity and Celiac disease, there is ongoing research on the subject. There is currently no cure or treatment outside of a gluten free diet. [2,4]

The purpose of this double-blind, randomized, placebo controlled study is to determine if a dietary supplement, namely Glutalytic, included with a normal diet results in reduced symptoms of gluten intolerance in a standard population, as compared to the placebo group. For those who are gluten sensitive, the hope is to enable them to lead a normal life without any food restrictions by incorporating the dietary supplement into their daily regimen. The dietary supplement should aid in the breakdown of the gluten complex to help minimize the symptoms.

For those diagnosed with Celiac disease, the goal is to minimize the risk of persistent or recurring symptoms due to contamination through the crossover effect, thus giving the individuals peace of mind when eating away from home.

## Methods

*Questionnaire Design* - The questionnaire used in this clinical was a modified version of the Internal Review Board (IRB) approved, Celiac disease-specific symptom index which was developed and validated by Daniel A. Leffler and his colleagues. The questionnaire was modified to account for non-celiac gluten sensitivity instead of narrowing only on Celiac sensitivity, and was designed to cover a spectrum of symptoms that could occur upon the ingestion of gluten. [1]

*Clinical Design* - This survey was administered to the entire group of individuals prior to beginning the supplement regimen. In conjunction with the

questionnaire, questions regarding the participants' demographics were also completed. The participants were not asked to change their diets in any way.

The clinical was designed for twenty individuals and the data presented represents the eleven participants who achieved full completion of the clinical. Individuals proceeded to ingest a dosage of the placebo or Glutalytic with every meal for a week. During this time, the participants maintained a meal log of everything they ingested. After seven days, the participants completed the questionnaire.

## Results

Sample frequency was calculated using Microsoft Excel 2010 (Table 1, 2, 3) and samples were analyzed using IBM SPSS Statistics for the Wilcoxon Signed-rank test and descriptive statistics (Table 2, 3). The level of significance ( $\alpha$ ) was chosen to be 5%. Initially

frequencies of responses were calculated, followed by the Wilcoxon Signed-rank test in order to see if there was any improvement on a question by question basis between subjects.

The results of the initial questionnaire were tallied and converted into percentages to be used as a control against the data gathered during the placebo time as well as the dietary supplement regimen. This data is exhibited in Table 1.

To examine the placebo effect, the raw data gathered at the end of week two were converted into percentages. This can be viewed in Table 2.

To determine the effectiveness of the dietary supplement, Glutalytic, the raw data was transformed into percentages and displayed in Table 3.

### Before Regimen

Question	None of the time	A little of the time	Some of the time	Most of the time	All of the time
1. Have you been bothered by pain or discomfort in the upper abdomen or the pit of the stomach during the past 4 weeks?	18%	55%	27%	0%	0%
2. Have you been bothered by nausea during the past 4 weeks?	82%	9%	9%	0%	0%
3. Have you been bothered by rumbling in your stomach during the past 4 weeks?	0%	45%	55%	0%	0%
4. Has your stomach felt bloated during the past 4 weeks?	0%	55%	36%	9%	0%
5. When going on the toilet, have you had the sensation of not completely emptying your bowels during the past 4 weeks?	27%	45%	18%	9%	0%
6. Have you been bothered by hunger pains during the past 4 weeks?	9%	64%	27%	0%	0%
7. Have you been bothered by low energy during the past 4 weeks?	9%	27%	64%	0%	0%
8. Have you been bothered by headaches during the past 4 weeks?	36%	36%	18%	9%	0%
9. Have you had food cravings in the last 4 weeks?	18%	36%	9%	36%	0%
10. Have you had a loss of appetite during the past 4 weeks?	36%	64%	0%	0%	0%
Question	Excellent	Good	Fair	Poor	Terrible
11. Overall, how is your health?	18%	82%	0%	0%	0%
Question	Excellent	Good	Fair	Poor	Terrible
12. How much more physical pain have you had during the past 4 weeks?	55%	36%	9%	0%	0%
Question	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
13. I am comfortable	18%	73%	9%	0%	0%
14. I am as healthy as anybody I know	55%	27%	18%	0%	0%

**Table 1**

Frequency of answers to questionnaire given before both placebo and Glutalytic.

### After Placebo

Question	None of the time	A little of the time	Some of the time	Most of the time	All of the time
1. Have you been bothered by pain or discomfort in the upper abdomen or the pit of the stomach during the past 4 weeks?	27%	18%	55%	0%	0%
2. Have you been bothered by nausea during the past 4 weeks?	55%	27%	18%	0%	0%
3. Have you been bothered by rumbling in your stomach during the past 4 weeks?	18%	64%	18%	0%	0%
4. Has your stomach felt bloated during the past 4 weeks?	0%	73%	9%	18%	0%
5. When going on the toilet, have you had the sensation of not completely emptying your bowels during the past 4 weeks?	55%	18%	18%	9%	0%
6. Have you been bothered by hunger pains during the past 4 weeks?	55%	36%	9%	0%	0%
7. Have you been bothered by low energy during the past 4 weeks?	9%	27%	64%	0%	0%
8. Have you been bothered by headaches during the past 4 weeks?	55%	36%	0%	9%	0%
9. Have you had food cravings in the last 4 weeks?	18%	18%	55%	9%	0%
10. Have you had a loss of appetite during the past 4 weeks?	73%	27%	0%	0%	0%
Question	Excellent	Good	Fair	Poor	Terrible
11. Overall, how is your health?	18%	82%	0%	0%	0%
Question	Excellent	Good	Fair	Poor	Terrible
12. How much more physical pain have you had during the past 4 weeks?	9%	91%	0%	0%	0%
Question	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
13. I am comfortable	9%	82%	9%	0%	0%
14. I am as healthy as anybody I know	18%	73%	9%	0%	0%

**Table 2**  
Frequency of questionnaire response after placebo was given.

### After Glutalytic Regimen

Question	None of the time	A little of the time	Some of the time	Most of the time	All of the time
1. Have you been bothered by pain or discomfort in the upper abdomen or the pit of the stomach during the past 4 weeks?	36%	64%	0%	0%	0%
2. Have you been bothered by nausea during the past 4 weeks?	91%	9%	0%	0%	0%
3. Have you been bothered by rumbling in your stomach during the past 4 weeks?	45%	45%	9%	0%	0%
4. Has your stomach felt bloated during the past 4 weeks?	18%	73%	9%	0%	0%
5. When going on the toilet, have you had the sensation of not completely emptying your bowels during the past 4 weeks?	64%	36%	0%	0%	0%
6. Have you been bothered by hunger pains during the past 4 weeks?	73%	27%	0%	0%	0%
7. Have you been bothered by low energy during the past 4 weeks?	36%	45%	18%	0%	0%
8. Have you been bothered by headaches during the past 4 weeks?	64%	27%	9%	0%	0%
9. Have you had food cravings in the last 4 weeks?	36%	55%	0%	9%	0%
10. Have you had a loss of appetite during the past 4 weeks?	64%	18%	18%	0%	0%
Question	Excellent	Good	Fair	Poor	Terrible
11. Overall, how is your health?	64%	27%	9%	0%	0%
Question	Excellent	Good	Fair	Poor	Terrible
12. How much more physical pain have you had during the past 4 weeks?	64%	36%	0%	0%	0%
Question	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
13. I am comfortable	36%	55%	9%	0%	0%
14. I am as healthy as anybody I know	45%	45%	9%	0%	0%

**Table 3**  
Frequency of questionnaire response after regimen was given. Frequencies which differed from the “before-regimen questionnaire” statistically ( $p < 0.05$ ) are indicated via \*. Questions which additionally did not differ between the pre-regimen and placebo group are indicated with\*\*.

## Discussion

As was expected, the highest frequency of symptoms occurred prior to the clinical, then there was a slight placebo effect vs. the initial results and compared to the Glutalytic results. When Glutalytic was administered, the participants exhibited the least amount of symptoms (Figure 1). The frequency, and severity of all of the symptoms were reduced when Glutalytic was administered.

While there were numerous symptoms that were reduced by Glutalytic, many were also reduced by the placebo; for the purposes of this study only those symptoms that were reduced by Glutalytic, while not being reduced by the placebo will be examined. These symptoms included pain in the upper abdomen, feeling bloated, trouble emptying bowls, and food cravings (Table 3).

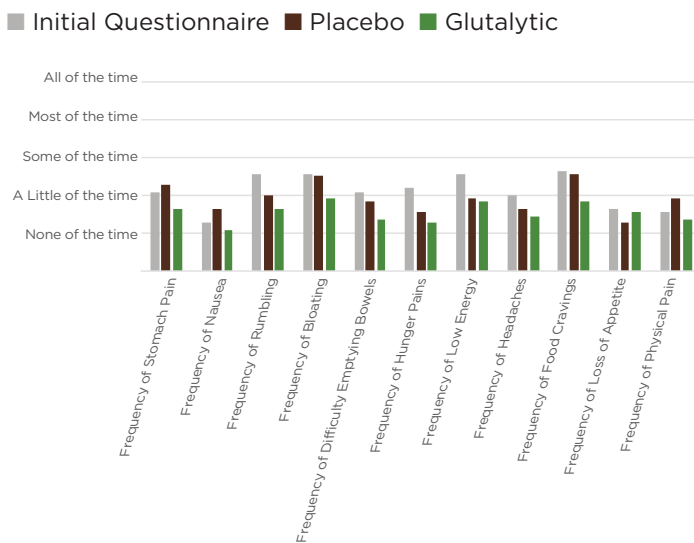
Symptoms that were reduced by both the placebo and Glutalytic included: rumbling of the

stomach, hunger pains, lower energy levels, and headaches. The comparison of the placebo effect to Glutalytic can be seen in Figure 2. Overall the dietary supplement reduced many of the symptoms including: pain in the abdominal area, rumbling of the stomach, feeling bloated, trouble emptying bowels, hunger pains, lower energy levels, headaches and food cravings.

Although it was not statistically significant, the placebo group saw an increase in pain compared to the pre-regimen. The pain anomaly cannot be explained without further investigation.

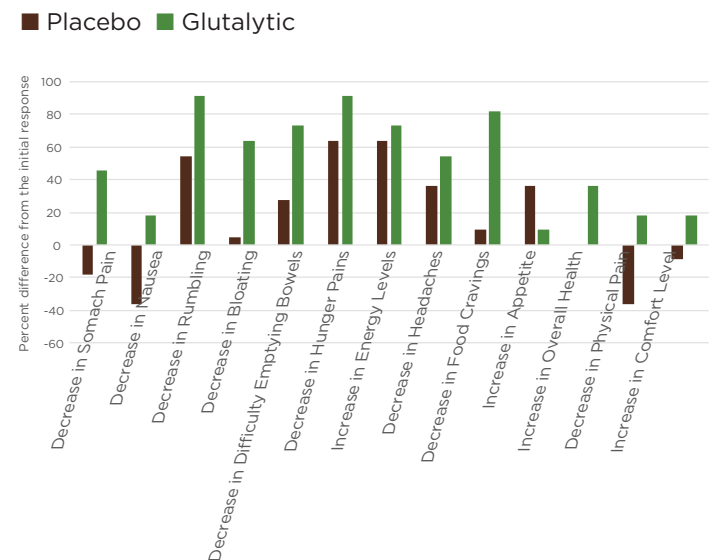
It can be concluded that while Glutalytic cannot completely diminish the symptoms associated with gluten sensitivity, it can reduce the frequency and severity.

## Direct Comparison of the Three Questionnaires



**Figure 1.** Direct Comparison of the Three Questionnaires

## Changes from the Initial Questionnaire



**Figure 2.** Changes from the Initial Questionnaire to the Placebo and Glutalytic

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