# Effect of Chlamydomonas Reinhardtii Powder on Blood Glucose and Immune Function: A Randomized Clinical Trial

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**Abstract:** *To analyze the effect of Chlamydomonas reinhardtii powder on blood glucose and immune function, 113 subjects were included with impaired glucose regulation (IGR),randomly divided into control group and observation group, 56 cases in control group and 57 cases in observation group. The control group was given placebo, and the observation group was given Chlamydomonas reinhardtii powder. Compare with the changes of fasting plasma glucose (FPG), 2-h postprandial blood glucose (2hPG) and immune function indexes between the two groups. After 90 days of treatment, Results indicated that the FPG and 2hPG levels in the observation group were lower than those before treatment (P < 0.01),and the 2hPG level was lower than that in the control group (P < 0.01). The scores of overall feeling, psychological feeling,physical feeling and comprehensive evaluation in the observation group significantly increased than those before treatment (P<0.01). Compared with the control group , the changes in the four scores were statistically significant. Chlamydomonas reinhardtii powder can help maintain the healthy level of blood sugar and improve the body's immune level.*

**Keywords:** *Chlamydomonas reinhardtii powder, Impaired glucose regulation (IGR), Blood glucose, Immunity function*

## 1. Introduction

Impaired glucose regulation (IGR) refers to higher fasting and postprandial blood glucose than normal, resulting in impaired glucose metabolic regulation [1]. Studies have shown that IGR can cause cardiovascular physiological changes and increase the incidence of hematological and metabolic diseases [2]. 8% to 11% of people with IGR develop diabetes [3]. Impaired glucose regulation IGR occurs in one quarter of patients with coronary heart disease [4]. Blood sugar value is closely related to diet structure, exercise degree and living habits [5]. Proper diet, proper exercise and healthy lifestyle can help control blood sugar. Diabetes is a lifelong disease, and the damage to the body is accumulated year by year, and the risk of complications of diabetes is gradually increasing. Years of experience in the treatment of diabetes have shown that relying solely on hypoglycemic drugs cannot achieve a stable and lasting effect [6]. People are exploring ways to control blood sugar levels through daily diet to intervene in the development of the disease. In this study, the effects of Chlamydomonas reinhardtii powder on blood glucose and immune function in people with glucose impairment were analyzed, and now it is reported as follows.

## 2. Materials and Methods

### 2.1. Test compound

Chlamydomonas reinhardtii powder used in this study were provided by the Shanxi Touyun Co.Ltd(China) in the form of green powder. Chlamydomonas reinhardtii powder (batch number: 20220511) is produced and provided by Shanxi Touyun Biotechnology Co., Ltd. Sample properties: powder, tinned, shelf life:24 months. The placebo was 100% maltodextrin.

### 2.2. Inclusion criteria

Refer to the evaluation document of health food function of the State Food and Drug Administration:evaluation method of auxiliary hypoglycemic function in Annex 3 of the State Food and Drug Administration (2012) No.107.

**Inclusion criteria were as follows**:

- Age 18-65 years old;

- IGR was defined as fasting plasma glucose (FPG) ≥ 5.6 (100 mg/dl) and < 7.0 mmol/L (126 mg/dl), and/or 2-h postprandial blood glucose (2hPG) ≥ 7.8 mmol/L (140 mg/dl) and < 11.1 mmol/L (200 mg/dl) .

- Informed consent is signed by all study participants.

**Exclusion criteria were as follows**:

- Pregnant or lactating women;

- who are allergic to the test sample;

- Impaired liver and renal function;

- Those who did not meet the inclusion criteria, did not take the test sample as prescribed, or had incomplete data that affected the observation results.

### 2.3. Study design

A 90-days, double-blind, randomized [1:1] and parallel clinical trial was conducted. Once enrolled, subjects were assigned to one of the two groups, with one receiving placebo and the other Chlamydomonas reinhardtii powder. There are no less than 50 subjects in each group.

Subjects were instructed to take 3-6g powder with warm water twice daily.

Participants reported to the research center two times during the 90-days intervention study: at baseline (D0) and at the end of the intervention period (D90).

### 2.4. Observation index

- FPG and 2hPG were used as reference standards for blood glucose control.

- Immune function was assessed using the SF-36 health questionnaire. The questionnaire is divided into four aspects: overall feeling, psychological feeling, physiological feeling and comprehensive evaluation. The scores of each aspect and the whole questionnaire should be considered in the scoring. The effects of the samples before and after the trial were evaluated by the method of combining the scores of each aspect and the overall scores.

### 2.5. Statistical Analysis

All statistical analyses were performed using spss software. All data are presented as mean ± standard deviations (SD) for variables .Data were analyzed at the $P<0.05$ level of significance.

## 3. Result and analysis

### 3.1. Volunteers recruitment

After pre-inclusion, 113 volunteers were engaged in the trial. All volunteers met the exclusion criteria and the inclusion criteria initially.  57 individuals  were assigned to the observation group. 56 participants were participated in placebo groups. During the trial, eight subjects dropped out for reasons unrelated to the product. The proportion of shedding subjects was less than 20% (Table 1).

*Table 1: loss rate.*

| group | enrollment case | number of people who drop out | valid case | drop out rate% |
|---|---|---|---|---|
| observation group | 57 | 4 | 53 | 7.0% |
| control group | 56 | 4 | 52 | 7.1% |

### 3.2. Baseline data

A total of 105 subjects completed the study protocol. Eligible candidates contain 31 males, 74 females. The observation group consisted of 53 individuals, including 14 males and 39 females. The placebo group consisted of 52 subjects, including 17 males and 35 females. Table 2 shows that there was no statistical difference in baseline data between the two groups ($P > 0.05$).

*Table 2: Baseline data($\bar{x} \pm SD$).*

| | observation group(n=53) | control group(n=52) |
|---|---|---|
| gender(mal/female) | 14/39 | 17/35 |
| age | 61.72±7.64 | 60.58±6.87 |
| FPG(mmol/L) | 6.10±0.96 | 6.06±1.03 |
| 2hPG(mmol/L) | 9.01±2.22 | 9.00±1.73 |
| overall feeling | 22.66±3.09 | 22.37±3.27 |
| psychological feeling | 22.19±3.73 | 21.90±4.14 |
| physical feeling | 20.21±2.22 | 20.37±3.09 |
| comprehensive evaluation | 65.06±7.77 | 64.63±9.27 |

### 3.3. FPG and 2hPG

*Table 3: Comparison of blood glucose control level between two groups($\bar{x} \pm SD$).*

| | observation group (n=53) | | | placebo group(n=52) | |
|---|---|---|---|---|---|
| | before trial | after trial | | before trial | after trial |
| FPG | 6.10±0.96 | 5.98±0.91** | | 6.06±1.03 | 6.13±1.08 |
| 2hPG | 9.01±2.22 | 8.04±1.68**## | | 9.00±1.73 | 9.12±1.84 |

Self comparison** $P < 0.01$, Comparison between groups ## $P < 0.01$

Before the trial, there were no significant difference in FPG and 2hPG between two groups ($P > 0.05$). After the trial, the FPG and 2hPG levels in the observation group were lower than those before treatment ($P < 0.01$).The 2hPG level in the observation group was lower than that in the control group ($P < 0.01$) (Table 3).

### 3.4. Immunity syndromes

*Table 4: Health questionnaire (SF-36) ($\bar{x} \pm SD$).*

| | observation group(n=53) | | Control group(n=52) | |
|---|---|---|---|---|
| | before trial | after trial | before trial | after trial |
| overall feeling | 22.66±3.09 | 23.40±2.82**## | 22.37±3.27 | 21.87±2.96 |
| psychological feeling | 22.19±3.73 | 23.19±2.82**# | 21.90±4.14 | 21.77±3.35 |
| physical feeling | 20.21±2.22 | 22.32±2.77**## | 20.37±3.09 | 20.81±2.48 |
| comprehensive evaluation | 65.06±7.77 | 68.91±6.87**## | 64.63±9.27 | 64.44±8.07 |

Self comparison** $P < 0.01$, Comparison between groups## $P < 0.01$, # $P < 0.05$

After 90 days of treatment, the result indicated that the scores of overall feeling, physical feeling, comprehensive evaluation in the observation group were higher than those of the control group ($P < 0.01$), and the scores of psychological feeling also significantly increased($P < 0.05$). The changes in the four scores were statistically significant.

In the observation group, the scores of overall feeling, physical feeling, psychological feeling, comprehensive evaluation are higher than those before the trial ($P < 0.01$). There was a steady increase in comprehensive evaluation, from an average of 65.06 at baseline to 68.97 at the end of the 3-month supplement period.

Before and after the trial, there were no statistically significant differences in overall feeling, physical

feeling, psychological feeling, comprehensive evaluation in the control group ($P>0.05$) (Table 4).

## 4. Discussion

IGR, also known as Prediabetes, is a state between normal glucose tolerance (NGT) and diabetes mellitus (DM), including impaired fasting glucose (IFG) and(or) impaired glucose tolerance(IGT). The clinical symptoms are not obvious or asymptomatic, and the main characteristics are abnormal blood glucose by laboratory examination, including FPG, 2hPG, glycated hemoglobin, etc. Studies have shown that the damage of macrovessels and microvessels has occurred in the IGR stage, involving many organs such as heart, kidney and retina.

In recent years, the incidence of diabetes has been increasing, and it has become a major problem affecting the health of people all over the world. IGR is the only way for normal blood sugar to develop into diabetes, About 70% of patients with impaired glucose tolerance will progress to diabetes[7], and several large IGR studies have shown that pre-diabetes can be reversed with intervention[8] ,so effective prevention and management of IGR is very necessary and of great significance.

Chlamydomonas reinhardtii powder is a kind of seaweed powder. It is made from Marine natural seaweed through fermentation, purification and fine processing. It is rich in polysaccharides, protein, cellulose, vitamins, potassium, iron, calcium, phosphorus, iodine, selenium, cobalt and other trace elements. This study analyzed the effects of Chlamydomonas reinhardtii powder on blood glucose and immune function of impaired glucose regulation individuals and indicated that after 90 days of treatment, the FPG and 2hPG levels in the observation group were lower than those before treatment ($P<0.01$).The 2hPG level in the observation group was lower than that in the control group ($P<0.01$). These results indicate that Chlamydomonas reinhardtii powder can assist in lowering blood glucose. Lampropoulou et al.[9] found that patients with type 2 diabetes had more immune function abnormal. This study indicated that after 90 days of treatment, the scores of overall feeling, physical feeling, comprehensive evaluation in the observation group were higher than those of the control group  ($P<0.01$),and the scores of psychological feeling  also significantly increased($P<0.05$). The changes in the four scores were statistically significant.  These results indicated that Chlamydomonas reinhardtii powder could improve the immune function of patients

In conclusion, Chlamydomonas reinhardtii powder can help maintain the healthy level of blood sugar and improve the body's immune level.

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