

# Oral Supplementation of Dragon Power® Polygonatum had Beneficial Effects on Testosterone's Relationship with Cardiorespiratory Fitness and Erection: a Double-Blind, Placebo-Controlled Study

Bo-Han Wu <sup>1</sup>, Yung-Kai Lin <sup>2</sup>, Yung-Hsiang Lin <sup>3</sup>, Chi-Fu Chiang <sup>3\*</sup>

<sup>1</sup> Department of Recreational Sport & Health Promotion, National Pingtung University of Science and Technology, Pingtung, Taiwan.

<sup>2</sup> Institute of Food Safety and Risk Management, National Taiwan Ocean University, Keelung, Taiwan. Department of Food Science, National Taiwan Ocean University, Keelung, Taiwan. Graduate Institute of Biomedical Engineering, National Chung Hsing University, Taichung, Taiwan.

<sup>3</sup> Research & Design Center, TCI CO., Ltd., Taipei, Taiwan.

\*Corresponding author: Chi-Fu Chiang, Research & Design Center, TCI CO., Ltd., Taipei, Taiwan.

Received date: December 13, 2023; Accepted date: December 20, 2023; Published date: January 05, 2024

**Citation:** Bo-Han Wu, Yung-Kai Lin, Yung-Hsiang Lin, Chi-Fu Chiang, (2024), Oral Supplementation of Dragon Power® Polygonatum had Beneficial Effects on Testosterone's Relationship with Cardiorespiratory Fitness and Erection: a Double-Blind, Placebo-Controlled Study, *J. Nutrition and Food Processing*, 7(1); DOI:10.31579/2637-8914/200

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## Abstract:

As age increases, the concentration of testosterone (male hormone) in the body gradually decreases, causing various aging conditions, such as physical strength. Among them, the Chinese herbal medicine Polygonatum kingianum (PK) can very well improve physical strength and resist fatigue. The purpose of this study is to explore whether PK can increase testosterone's relationship with cardiorespiratory fitness and erection. Subjects were randomly assigned to either the placebo group (n=25) or the PK group (n=25). Subjects were required to ingest 50 mL of the test product daily for a duration of 4 weeks. Cardiorespiratory endurance and blood biochemical values were analyzed at week 0, week 2, and week 4. After the subjects took it for 4 weeks, the results showed that PK extract drink increased testosterone 14% compared to the placebo group, and without any side effects on liver and kidney function. After taking PK extract drink for 2 and 4 weeks, the cardiorespiratory endurance index was significantly improved by 3.7% and 6.2%, and phosphodiesterase 5 (PDE5) expression was significantly decreased by 23.3% and 28.9% compared to placebo group. PK extract drink increased testosterone and was harmless to humans, and improved physical strength, erectile function.

**Key words:** cardiorespiratory endurance; chinese herbal medicine; erection, polygonatum kingianum; testosterone

## Introduction

In recent years, male health has become a prominent and important topic in the field of wellness. With the accelerating pace of modern life, issues related to male health are increasingly receiving attention. More and more men are beginning to care about how to maintain their physical and mental well-being to overcome the various pressures of life. Testosterone, also known as the primary sex hormone, is predominantly produced in the testes in males and in the ovaries in females [1]. It plays a crucial role in physiological processes in both males and females, although its levels are typically higher in males [2]. Testosterone secretion in men is highest between the ages of 15 and 30, but after the peak period, as testicular function declines, the concentration of testosterone in the blood decreases at a rate of 1 to 2% per year [3]. At the age of 40, men may suffer from various aging phenomena due to insufficient testosterone concentration [3]. Some studies had indicated that testosterone plays a crucial role in

muscle growth and strength. It facilitates protein synthesis, aiding in muscle development and growth [4]. Elevated levels of testosterone can enhance muscular endurance, enabling men to perform exceptionally well in physical activities and exercise [5]. Testosterone also demonstrates a positive association with heart health. It helps maintain normal cardiac function, including regulating heart contractions and rhythms [6]. Adequate supplementation of testosterone can prevent the onset of heart disease and cardiovascular conditions [7]. Additionally, it contributes to maintaining vascular elasticity and health, thereby supporting proper blood circulation [8]. Testosterone also contributes to improving cardiorespiratory fitness (the body's ability to acquire sufficient oxygen through exercise), which is essential for prolonged or high-intensity physical exertion [9]. However, with age, testosterone levels gradually decline, which can lead to a range of health issues [10].

Polygonati Rhizoma, first recorded in “MingYi BieLu” written by Hongjing Tao of the Liang Dynasty in China, has been a TCMs and nutritious food for over 2000 years [11]. Polygonatum kingianum Coll. Et Hemsl., Polygonatum sibiricum Red. And Polygonatum cyrtoneura Hua are depicted in Chinese Pharmacopoeia (2020 edition) as legal sources of Polygonati Rhizoma [12]. Polygonati Rhizoma is a deficiency-nourishing Chinese herbal medicine utilized as both medicine and food [13]. In traditional Chinese medicine, Polygonatum kingianum (PK) is an important genuine-medicinal-materials cultivated in Yunnan, China, and is used by the Bai, Wa, and Zhuang nationalities as a traditional medicine for enhancing immunity, anti-fatigue, and anti-aging [13,14]. Moreover, the active ingredients of PK include saponins, flavonoids, and polysaccharides [15]. PK is considered a traditional Chinese herbal medicine that provides positive support for male reproductive health. It is used to enhance sperm quality and vitality [16]. PK is believed to have the ability to replenish physical strength and increase vitality, aiding in combating fatigue and boosting energy levels. However, there is currently limited clinical research on the effects of PK on testosterone levels and cardiorespiratory fitness in males.

The PK extract used in this trial was from TCI Co., Ltd. The main purpose is to explore the effects of PK extract drink on cardiopulmonary fitness, blood total testosterone and metabolic indicators in male subjects.

## Materials and Methods

### Preparation of Polygonatum kingianum extract

The extract of Polygonatum kingianum was prepared using a solution. The process began with 100g of P. kingianum being combined with 2000g of deionized water. This mixture was then heated to 90°C to facilitate extraction. Following this, the solution was filtered and subsequently concentrated. The final yield of the P. kingianum extract was 800g [17].

### Clinical trial design

The study was registered in clinicaltrials.gov (No. NCT05877677), and was performed under a protocol approved by the Antai Medical Care Cooperation Antai- Tian-Sheng Memorial Hospital Institutional Review Board (Approval Number: 23-027-A), and was conducted according to the code of ethics on human experimentation established by the Declaration of Helsinki (1964) and its amendments. Written informed consent was obtained from all participants after a full explanation of the study. A double-blinded, placebo-controlled, randomized study was conducted. The subjects were randomly assigned to two groups, with 25 subjects in each group. The number of subjects is calculated according to <https://clincalc.com/Stats/SampleSize.aspx>. Subjects need to take 50 mL of the test product after breakfast every day for 4 weeks. Blood chemistry (AST, ALT, BUN, Creatinine, total cholesterol, LDL-C, HDL-C, triglycerides, testosterone, NO, PDE5 gene) and cardiorespiratory

endurance tests were collected at week 0, week 2, and week 4 of the study. The age of the subjects was  $40.7 \pm 4.9$  years old. Inclusion criteria: Healthy male aged 30-60 years old. The exclusion criteria included: i) heart, liver, kidneys, endocrine and other organs (such as hypertension, diabetes, renal dysfunction and heart-related diseases) and mental patients; ii) who have undergone surgery within 6 months or have lower limb injuries; iii) who are allergic to Polygonatum kingianum extract; iv) in other clinical trials related to anti-fatigue within 4 weeks of the trial. During the clinical trial, the subjects did not change their lifestyle and eating habits, and did not engage in high-intensity exercise 48 hours before each experiment [18].

### Supplement formulation

Polygonatum kingianum group: containing Dragon Power® Polygonatum kingianum extract 6g, sucralose, citric acid, water. Placebo group: containing sucralose, citric acid, water. Subjects need to take 50 mL of the test product after breakfast every day for 4 weeks. The placebo, Polygonatum kingianum group were packaged in the same appearance, shape, and size.

### Three-minute step test

The subject performed a 3-minute step-climbing test. The subject used a 35cm step-climbing step to continuously perform a 3-minute step-climbing test. After the test, the subjects collected data from 1 minute to 1 minute and 30 seconds, and from 2 minutes to 2 minutes and 30 seconds, three minutes to three minutes and thirty seconds, three thirty seconds of pulse count, and the heart rate recovery ability is used to calculate the cardiorespiratory endurance index of the subject. The calculation formula is as follows: cardiorespiratory endurance index = exercise duration (seconds)\*100/ (sum of three pulses) \*2 [19].

### Statistical analysis

The comparison of measurement results were analyzed by Analysis of covariance (ANCOVA) followed by SPSS statistical software, as  $p < 0.05$  was considered statistical significance.

## Results

### Polygonatum Kingianum increased testosterone and is harmless to humans

Figure 1 showed the enrollment process of a clinical trial. Table 1 showed the results of the biochemical analysis. The markers of liver and kidney function and blood lipids were not significantly changed. Testosterone significantly increased 14% in PK group after 4 weeks of taking the subjects compared to the placebo group (Figure 2A). These results showed PK extract drink increased testosterone in male without causing any side effects on liver and kidney function.

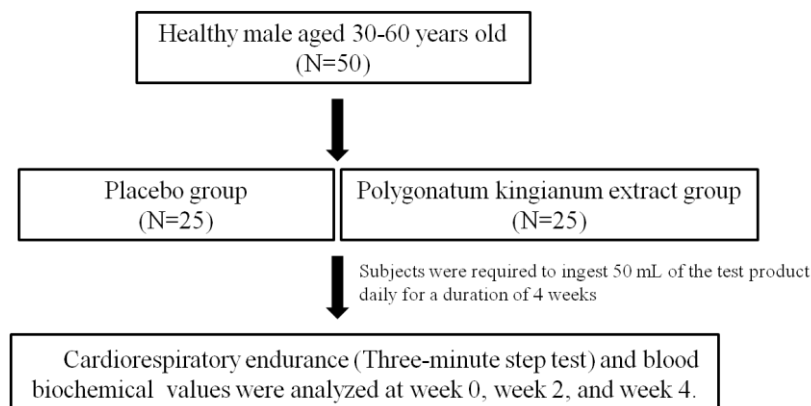
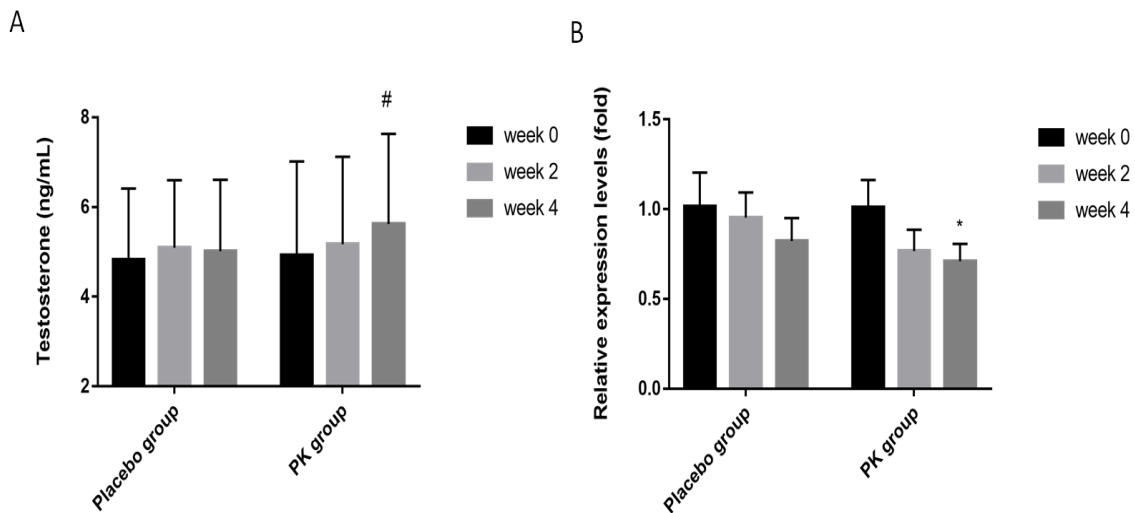


Figure 1: Clinical trial flow chart.



**Figure 2:** Polygonatum Kingianum increased testosterone and decreased PDE5 gene. Subjects were randomly assigned to either the placebo group (n=25) or the PK group (n=25). Subjects were required to ingest 50 mL of the test product daily for a duration of 4 weeks. (A) testosterone. (B) PDE5, erection suppressor gene, were analyzed at week 0, week 2, and week 4. \*, compared with baseline (week 0) (\*, p < 0.05). #, compared with placebo group (#, p < 0.05).

Items	Group	week 0	week 2	F value	week 4	F value
GOT	placebo group	22.6±5.4	21.1±5.2	0.493	22.7±3.9	0.611
	PK group	23.1±7.9	24.3±15.0		23.8±8.5	
GPT	placebo group	25.9±10.6	24.1±9.8	1.385	26.1±11.6	0.67
	PK group	29.1±19.5	26.6±13.4		28.1±21.7	
BUN	placebo group	14.8±2.5	14.7±2.8	0.315	14.3±3.2	0.914
	PK group	15.6±3.9	15.2±3.6		15.2±3.3	
CRE	placebo group	0.99±0.14	0.97±0.14	2.539	0.98±0.16	1.253
	PK group	0.97±0.14	1.01±0.17		1.01±0.17	
TG	placebo group	139.7±72.9	116.9±54.1	0.963	128.5±62.5	0.094
	PK group	143.5±71.9	128.1±60.4		124.7±57.7	
ChoL	placebo group	195.5±27.4	193.9±25.1	3.09	195.6±27.9	0.24
	PK group	202.3±31.3	202.2±28.4		197.8±29.4	
HDL-C	placebo group	59.2±22.3	59.4±22.2	0.629	54.9±17.5	0.629
	PK group	52.6±12.7	52.0±11.6		53.0±11.8	
LDL-C	placebo group	122.5±23.6	122.5±22.1	1.916	126.6±24.7	0.925
	PK group	131.3±25.8	134.8±23.6		131.7±25.4	
Testosterone	placebo group	4.82±1.59	5.09±1.51	0.104	5.02±1.59	4.796*
	PK group	4.93±2.09	5.17±1.95		5.62±2.01	
NO	placebo group	89.63±53.58	78.41±50.40	0.001	84.70±41.33	0.35
	PK group	82.52±59.79	78.37±36.97		78.56±31.28	

GOT: Glutamic Oxaloacetic Transaminase ; GPT: Glutamic Pyruvic Transaminase ; BUN: Blood urea nitrogen  
 CRE: Creatinine ; TG: Triglyceride ; ChoL: Cholesterol ; HDL-C: High density lipoprotein ; LDL-C: Low density lipoprotein ; NO: Nitric oxide  
 Significantly different from the placebo: \*, p < 0.05.

**Table 1:** Subjects' blood biochemical values (N=50)

**Polygonatum Kingianum improved physical strength.**

Next, to explore whether taking PK extract drink can increase cardiorespiratory fitness. A three-minute step test was used for analysis, and the subject's cardiorespiratory endurance index was calculated based on heart rate recovery ability. **Table 2** showed that after taking PK extract

drink for 2 and 4 weeks, the cardiorespiratory endurance index can be significantly improved by 3.7% and 6.2%, and the effects are significantly better than the placebo group. These results showed that taking PK extract drink can help improve physical strength.

Items	Group	week 0	week 2	F value	week 4	F value
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physical index	placebo group	698.8±123.8	716.5±133.0	10.039*	710.7±121.9	6.057*
	PK group	640.8±99.3	664.3±104.0		680.4±117.0	
total pulse rate	placebo group	132.6±22.6	126.7±25.3	8.071*	124±25.1	5.396*
	PK group	143.6±21.4	139.4±19.2		138.6±20.5	

Significantly different from the placebo: \*,  $p < 0.05$ .

**Table 2:** Subject cardiorespiratory endurance by three-minute step test (N=50)

### Polygonatum Kingianum improved erectile function.

Phosphodiesterase 5 Inhibitors (PDE5Is) are now widely used in the management of erectile dysfunction. Inhibiting the PDE5 gene can relax the smooth muscle of the penile corpus cavernosum and dilate blood vessels, improving erectile function. After taking PK extract drink for 2 and 4 weeks, the PDE5 expression can be significantly decreased by 23.3% and 28.9% compared to placebo group (Figure. 2B). These results showed that taking PK extract drink can help improve erectile function.

### Discussion

This study is the first clinical trial to prove that taking PK extract drink can increase physical strength. PK extract drink can significantly increase the testosterone concentration, physical index and total pulse number during the recovery period after exercise, all of which were significantly different from the placebo group. Therefore, this study confirms that short-term intake of PK extract drink can significantly improve cardiorespiratory fitness and erectile function.

PK is a plant characterized by its dual utility in both medicinal and dietary contexts. In addition to its therapeutic and health-promoting properties, it is utilized as a vegetable, seasoning, and ingredient in beverages [20]. The tuberous roots of this plant are notably abundant in starch content, rendering them suitable as a staple food source [20]. Furthermore, the plant exhibits ornamental characteristics, further augmenting its overall value in various applications. Phytochemical and pharmacological studies have shown that PK contains a variety of chemical components, including Polygonatum sibiricum polysaccharides (PSP), steroidal saponins, flavonoids, phenols, alkaloids, and lignin [21-23]. Polygonatum sibiricum has many biological activities, such as anti-tumor, hypoglycemic, hypolipidemic, anti-aging, antiviral, anti-inflammatory, and other effects [24]. The study indicated that Polygonatum sibiricum brought the testicular weight close to the normal range, increased sperm survival rate, reduced sperm abnormality rate, elevated testosterone levels, lowered reactive oxygen species (ROS), and inhibited testicular cell apoptosis through the thioredoxin-interacting protein (TXNIP)-nucleotide-binding oligomerization domain-like receptor protein 3 (NLRP3)-Caspase-1 signaling pathway. Consistent with our results, PK extract drink increased testosterone [22].

Saponins and flavonoids are the primary bioactive compounds in PK responsible for its anti-hypoxic effects [13,25]. The ability of PK to counteract hypoxia may be attributed to its capacity to effectively neutralize surplus free radicals, uphold the functionality of antioxidant enzymes, and impede oxidative stress stemming from lipid peroxidation [13,26]. These findings provide valuable insights into the potential of PK as a potential source of health products aimed at avoiding hypoxia or regulating cardiopulmonary function. The treatment of rats with Polygonatum alte-lobatum Hayata prolonged endurance time to fatigue, increased total antioxidant capacity, superoxide dismutase (SOD) activity, and reduced blood lactate [27]. Polygonatum cyrtonea polysaccharide (PCP) prolonged the exhaustive swimming time of mice when compared with normal control group [28]. Meanwhile, PCP decreased serum levels of lactic acid (LA), blood uric nitrogen (BUN), superoxide dismutase (SOD), glutathione peroxidase (GSH-Px) and malondialdehyde (MDA), and increased the contents of liver glycogen, muscle glycogen and muscle ATP [29]. These results revealed that PCP had good anti-fatigue ability. Polygonatum sibiricum extract increased the activity of secondary messengers of cellular aerobic capacity, such as

AMPK and p38 [30]. These secondary messengers stimulated the increase in the synthesis of cell mitochondria and antioxidant enzymes, which may have indirectly improved aerobic capacity [31]. Consistent with our results, in the three-minute step test, PK extract drink can help improve cardiorespiratory endurance index, suggesting anti-fatigue effect.

Numerous herbal remedies have been utilized in traditional medicine to address erectile dysfunction [32]. The study has demonstrated that certain traditional formulations, incorporating extracts from plants like Ginkgo biloba L. and Vitis vinifera L., are recognized as inhibitors of the PDE5 enzyme [33]. Furthermore, experimental studies have substantiated the efficacy of various herbs, including Polygonatum verticillatum, in enhancing sexual activity in animal models [34]. Polygonati Rhizoma was used in treating sexual dysfunction, lung trouble. Polygonatum verticillatum leaf aqueous extract possesses aphrodisiac property [34]. Phosphodiesterases (PDEs) are a group of functionally diverse enzymes found in various organs and tissues throughout the body [35]. Among these, PDE5 has garnered significant attention, primarily due to the introduction and widespread use of the selective PDE5 inhibitor, as an oral treatment for erectile dysfunction [36]. PDE5 plays a crucial role in regulating the contractile tone of vascular and trabecular smooth muscle through the enzymatic degradation of cyclic 3',5'-guanosine monophosphate (cGMP), a vital second messenger [37]. Nitric oxide (NO) affects erection by activating adenylyl cyclase and increasing cAMP concentration [38]. Consistent with our results, PK extract drink decreased PDE5. However there is no significant change in NO, suggesting PK extract drink mainly by increasing cGMP. The anti-aging gene Sirtuin 1 is critical for cardiovascular function, muscle function, testosterone synthesis and Sirtuin 1 activation improve erectile function. Exercise activates Sirtuin 1 pathways and PK may contain critical Sirtuin 1 activators that increase testosterone concentrations [39-41]. The limitations of this study include: 1. This product was only studied on a specific ethnic group - males; 2. There were few test items for cardiorespiratory fitness; 3. Erection only observed gene expression and refers to subject feedback, and did not analyze erectile function. ;4. The mechanism by which PK increased testosterone needs more research to verify ; 5. The recommended dose for this test was 6g of PK extract. Although there was no toxicity to liver and kidney functions, more animal toxicology was needed to verify the highest and safest dose.

### Conclusion

The PK extract drink increased testosterone about 14%, and without any side effects on liver and kidney function. And the cardiorespiratory endurance index was significantly improved about 6.2%, and PDE5 expression was significantly decreased about 28.9% compared to placebo group. It was recommended that PK extract drink can be used as an effective nutritional supplement.

### Conflict of interest

The authors declare that they have no conflict of interest

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