

# Effects of a novel dietary supplement on physical and mental function in middle-aged adults: A double-blind, randomized, placebo-controlled trial

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## ABSTRACT #1076.8

Aging is characterized by a gradual loss in physical and mental function starting at 30-40 years of age. The purpose of this study was to compare a novel combination of *Cordyceps sinensis*, pomegranate extract, and *Panax ginseng* (TRT) to control (CNTL) formula regarding physical, mental, and sexual desire. Healthy males and female subjects (n=116) were recruited to participate in a prospective, double-blind, randomized, placebo-controlled trial that lasted 60 days. Subjects were randomized into a control (n= 56; CNTL) or treatment (n= 60; TRT) groups and stratified by age and gender. Mental (MCS) and physical (PCS) wellbeing were measured by validated questionnaires. Other measurements included blood chemistry measurements, skin carotenoid concentrations, and adverse events. There were n=48 in CNTL and n=47 in TRT groups that completed the study. No differences were detected in the mean scores for (PCS=CNTL;-0.47, TRT;-0.08) or (MCS=CNTL;0.32, TRT;-1.98) and sexual desire between groups nor between age. There was a strong trend towards higher skin carotenoid concentrations in the TRT group (P=0.052). There was no difference between groups for adverse events or blood chemistry. The TRT formulation appears to be safe. We were unable to detect differences in physical, mental, and sexual desire as seen in animal studies presumably because this population was so healthy and didn't show an age related decline. There was an interesting finding that subjects consuming the TRT formulation experienced a trend towards higher skin carotenoid concentrations and warrants further investigation in a population which has age-related decline in physical, mental, sexual decline, or experiencing greater oxidative stress. Research was supported by Nu Skin Enterprises, Provo, Utah

## INTRODUCTION

Aging is characterized by a gradual loss of various functions starting at 30 to 40 years of age and affecting most body systems in a variable but predictable pattern. Physical fitness (muscular strength, aerobic capacity, and muscular flexibility) usually wanes with age, which partly explains concomitant increases in body fat percentage and losses in lean tissue mass. Sexual desire declines with advancing age in both males and females.

Not only does aging negatively affect physical function, but the mental effects of aging similarly worsen with time. Cognitive impairment and memory deterioration are more prevalent among the middle-aged population than among the young. Overall, the process of aging ultimately decreases quality of life across several domains including physical, mental, and sexual.

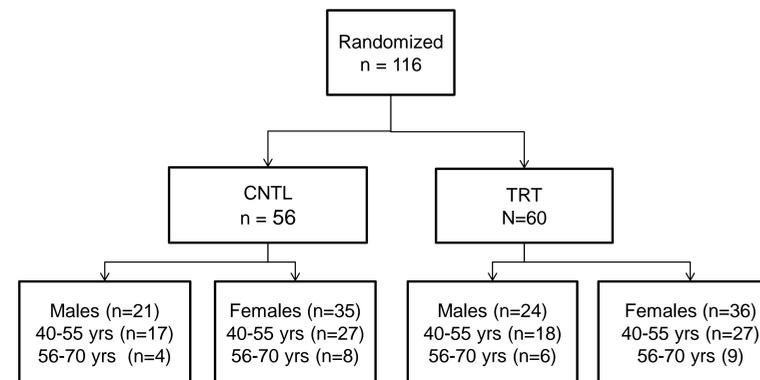
We have identified several natural ingredients and extracts that have potential to influence mental and physical functions. *Panax ginseng* (PG) is a traditional medicine in Asian countries that has been used for its tonic effect and possible curative and restorative properties. Ginseng is now used by millions of people worldwide unfortunately, clinical trials on the health benefits of ginseng have historically been plagued by small sample size, various concentrations and preparations, and lack of adequate control groups. We have noted that a traditionally used fungus, *Cordyceps sinensis* (CS), can influence physical performance and change gene expression profile of muscles to a more youthful expression. Pomegranate (*Punis granatum*) has a long history of cultivation and use as a nutritious food and traditional medicine. Analytical characterization of the bioactive components of pomegranate fruit extract (PX) has revealed active constituents, mainly ellagitannins and phenolic acids. Other phytochemicals in pomegranate include polyphenols, catechins, gallocatechins, and anthocyanins such as prodelpinidins, delphinidin, cyanidin, and pelargonidin. We have incorporated these ingredients into rodent diets and tested the formula's effects in murine models and have found increased endurance, memory, and sexual function as compared to control diets.

Given the promising animal results, the excellent safety profile, and the complementary mechanisms of action of *Panax ginseng*, *Cordyceps sinensis*, and pomegranate, we tested a proprietary blend of PG, CS, PX (Treatment-TRT) vs control--CNTL (similar in appearance) to determine changes in physical/mental function, skin carotenoids, as well as safety as measured by adverse events and changes in laboratory values in healthy, middle-aged adults.

## Design, Subjects, and Methods

- Prospective, randomized, placebo-controlled, double-blind, multicenter trial (Tucson, AZ, Houston, TX, and Minneapolis, MN)
- Healthy, middle-aged adults Males and Females (n=116)
  - Subjects stratified by age group (40-55 or 56-70 years) and gender
- Conducted over 8 weeks with TRT or CNTL supplementation
  - Changes in physical and mental function
    - Physical component summary (PCS) and mental component summary (MCS) scores from standardized questionnaire, SF-36
    - Sexual desire questions from Medical Outcomes Study (MOS) Sexual Problems Score
  - Comprehensive laboratory tests and vital signs
  - Adverse events
  - Skin carotenoid scores (BioPhotonic Scanner, Nu Skin Enterprises, Provo, UT)
- Study was approved by an Institutional Review Board (IRB) and listed on clinicaltrials.gov (# NCT01155076)

## Randomization and Subjects Completing Study



Randomization	Study Product		p-value*
	CNTL n = 56	Group B n = 60	
Early withdrawal	8 (14.3%)	13 (21.7%)	0.3743
Reason:			
Death	0	0	
Investigator decision	0	0	
Subject withdrew	4	3	
Lost to follow-up	1	7	
Other	3	3	

## RESULTS

Table 1. Subject compliance

Variable	Product Group		p-value
	CNTL	TRT	
Percent taken, all subjects			
Mean	88.21	83.16	0.053*
SD	10.40	14.62	
Minimum	42.50	42.50	
Maximum	98.33	95.83	
Percent taken, males 40-55			
Mean	86.67	78.94	0.225†
SD	13.01	17.98	
Minimum	44.17	43.61	
Maximum	98.33	93.33	
Percent taken, males 56-70			
Mean	92.22	91.67	0.866†
SD	5.09	1.67	
Minimum	86.67	90.00	
Maximum	96.67	93.33	
Percent taken, females 40-55			
Mean	87.84	85.97	0.555†
SD	10.93	10.56	
Minimum	42.50	47.50	
Maximum	95.00	95.00	
Percent taken, females 56-70			
Mean	90.49	77.96	0.101†
SD	3.30	19.95	
Minimum	86.11	42.50	
Maximum	95.00	95.83	

\*CNTL vs. TRT, ANOVA with age group and sex as covariates  
† Unpaired t-test

Table 2. Physical (PCS), Mental (MCS), and Sexual Desire Score from baseline and 8 weeks

	Study Product						p-value*
	CNTL			TRT			
	Day 0	Day 56	Change	Day 0	Day 56	Change	
PCS							
Mean	56.49	57.05	0.53	56.66	57.94	1.18	0.457
SEM	0.501	0.473	0.479	0.603	0.534	0.667	
MCS							
Mean	56.34	56.37	0.28	54.23	56.67	2.15	0.105
SEM	0.844	0.863	0.592	0.918	0.944	1.020	
Sexual Desire Score							
Mean	78.97	80.78	1.78	78.14	79.60	2.85	0.640
SEM	2.47	3.01	1.34	2.17	2.53	1.66	
Skin Carotenoid Score							
Mean	23147	23126.0	-969.7	24858.8	25875.2	1018.9	0.052
SEM	1614.5	1396.2	735.6	1154.5	1478.4	701.7	

\*Change, CNTL vs. TRT, ANOVA with age group and sex as covariates

## SUMMARY/ CONCLUSIONS/RECOMMENDATION

- Products were safe and well tolerated (no differences in adverse events, changes in laboratory values, or vital signs)
- Strong trend towards higher skin carotenoid concentrations in the TRT group (p=0.052)
- No differences in physical, mental, and sexual desire as seen in animal studies presumably because this population was so healthy and didn't show an age related decline
- TRT group compliance was lower and so may have influenced ability to detect differences
- May need to study effects of blend longer
- TRT group experienced a trend towards higher skin carotenoid concentrations and warrants further investigation since product did not contain carotenoids and may indicate improved antioxidant status.
- Recommend further study of novel formulation in population experiencing decline of physical and mental vitality.