Effects of *Panax ginseng* on Quality of Life

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OBJECTIVE: To assess the time-dependent effects of *Panax ginseng* on health-related quality of life (HRQOL) by use of a general health status questionnaire.

METHODS: Subjects were randomized in a double-blind manner to *P. ginseng* 200 mg/d (n = 15) or placebo (n = 15) for 8 weeks. The Short Form-36 Health Survey version 2 (SF-36v2), a validated general health status questionnaire, was used to assess HRQOL at baseline and at 4 and 8 weeks. HRQOL between the groups was compared by use of repeated-measures analysis of covariance. A p value <0.05 was considered statistically significant.

RESULTS: There were no significant differences in baseline demographics and SF-36v2 scores between the groups. After 4 weeks of therapy, higher scores in social functioning (*P. ginseng* 54.9 ± 4.6 vs. placebo 49.2 ± 6.5; p = 0.014), mental health (*P. ginseng* 52.2 ± 7.7 vs. placebo 47.2 ± 7.3; p = 0.075), and the mental component summary (*P. ginseng* 51.3 ± 7.4 vs. placebo 44.3 ± 8.3; p = 0.019) scales were observed in patients randomized to *P. ginseng;* these differences did not persist to the 8-week time point. The incidence of adverse effects was 33% in the *P. ginseng* group compared with 17% in the placebo group (p = 0.40). Subjects given *P. ginseng* (58%) were more likely to state that they received active therapy than subjects given placebo (17%; p < 0.05).

CONCLUSIONS: *P. ginseng* improves aspects of mental health and social functioning after 4 weeks of therapy, although these differences attenuate with continued use.

KEY WORDS: ginseng, health-related quality of life, Short-Form 36.

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The use of herbal remedies increased by 380% from 1990 to 1997 in the US, resulting in >$5 billion in annual sales.[1,2] In a recent survey, the most commonly used herbal product was ginseng, with 31% of respondents reporting usage during the previous 12 months.[3] Moreover, expenditures on ginseng are substantial; >$86 million was spent in 1997 by US consumers.[4]

Promotional claims for *Panax ginseng* include maintenance of natural energy, improved mental and physical abilities, and an overall feeling of well-being.[5] Moreover, in a recent survey,[3] 54% of ginseng users took the product to promote general health and well-being, 43% to increase stamina and performance, and 18% to improve mood. It is important to scientifically evaluate the effect of ginseng on quality of life because it is being marketed to improve general health.

Several studies have measured the effect of *P. ginseng* on health-related quality of life (HRQOL).[6-12] However, each of these studies had limitations, including use of nonvalidated questionnaires,[7] symptom score ratings,[6] or psychological questionnaires alone.[8,10] Some studies were specifically conducted in postmenopausal women,[11,12] elderly patients with memory problems,[9] or patients with diabetes.[6] It is not known whether these findings would be applicable to individuals without these conditions. Moreover, many of the studies have examined the effect of combined ginseng with a multivitamin and have not examined the effects of ginseng alone.[7-9] Therefore, we conducted a study to evaluate the effect of *P. ginseng* on HRQOL in a young adult population, using a validated general health status questionnaire in a controlled clinical study.

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Methods

STUDY DESIGN

The effect of *P. ginseng* on HRQOL was assessed in a randomized, double-blind, placebo-controlled study. Subjects were recruited by placing advertisements at the University of Connecticut and in the university's newspaper, *The Daily Campus*. Subjects were eligible for study entry if they were ≥18 years old and were excluded if they were taking anticoagulants; had an adverse reaction to any ginseng extract (*Panax*, American, or Siberian) or lactose; had a personal history of alcohol or drug abuse; were pregnant or planning to become pregnant; were nursing; had a baseline diastolic blood pressure >85 or <60 mm Hg; had any history of renal, hepatic, or autoimmune dysfunction; had a history of ventricular or supraventricular arrhythmias; or did not provide informed consent.[4] Subjects were randomized by use of a random-number table. The study was blinded from patients by matching placebo, and investigators were unaware of treatment assignment until the end of the study. The study was approved by the institutional review board of the University of Connecticut.

Subjects abstained from any ginseng-containing products for a week before the study was initiated to ensure an adequate washout period.[13] They were then randomized to *P. ginseng* 200 mg (Ginsana[5]) or matching placebo (lactose-filled gelatin capsules) with a full glass of water before 1000 hours for 8 weeks.

HRQOL was assessed at baseline and at 4 and 8 weeks. A reminder note was given to each participant for the follow-up visit. In addition, subjects were E-mailed 1 week prior to the follow-up appointment. If they did not respond to the E-mail, the subject was contacted by telephone 1 day before the scheduled visit.

HRQOL ASSESSMENT

The Short Form-36 Health Survey version 2 (SF-36v2), a valid, reliable general health status instrument, was used to assess the effect of *P. ginseng* on HRQOL.[14] It is particularly suited to the assessment of relatively minor changes in HRQOL in healthy populations and takes only 10 minutes to complete.[14-17] The SF-36v2 is the updated version of the original SF-36. Changes from the original version include format modification, wording revisions, and changes in the number of response choices, which resulted in greater reliability, validity, and readability.[14] SF-36v2 consists of 36 questions that address 8 scales or domains: physical functioning, mental health, role limitations due to physical health, pain, social functioning, role limitations due to emotional problems, vitality, and general health perceptions. Physical and mental health summary measures may also be calculated. Scores range from 0 to 100, with higher values indicating better function. Each of the domains are then normed or adjusted to a US population mean of 50 ± 10 to allow for easy comparison of scores. The normed scores are reported in the article. A blinded investigator scored the SF-36v2 according to the instructions of the authors.[14]

At the end of the 8-week treatment period, subjects were asked 3 questions: (1) which therapy they believed they were taking, (2) whether they felt any differently during treatment, and (3) whether they experienced any adverse effects.

STATISTICAL ANALYSIS

Intention-to-treat analysis was used. χ^2 Analysis was used to compare nominal data (Fisher's exact test if any cell <5), and continuous data were compared by use of Student's *t*-test. Repeated-measured analysis of covariance with 1 between-condition (experimental condition – *P. ginseng* or placebo) and 1 within-subject factor (time) was used to compare differences in HRQOL scores at baseline and at 4 and 8 weeks. Baseline data were used as constant covariants. A p value <0.05 was considered statistically significant.

Missing data were analyzed by use of Little's missing-completely-at-random test,[18] which showed that the subjects lost to follow-up were unrelated to patients' HRQOL (p = 0.81). Because the data were missing at random, an expectation-maximization algorithm for the repeated-measures model was used to impute missing data.[19] Statistical analysis was conducted with use of SPSS version 10.0 (SPSS, Chicago).

Because the SF-36v2 does not have published sample size calculations, the original SF-36 was used to establish the number of subjects required for the study. A sample size of 15 in each group was needed to determine a 20-point difference (on a scale of 0–100) in 6 of the 8 domains: physical functioning, social functioning, general health, mental health, bodily pain, and vitality with an $\alpha = 0.05$ and $\beta = 0.2$.[17]

Results

Thirty subjects were recruited and were randomly assigned to *P. ginseng* 200 mg (n = 15) or placebo (n = 15). One subject in the active treatment group dropped out of the study within the first few weeks because of nausea and vomiting. Three subjects in each group did not return for the 8-week follow-up appointment. This was most likely because of scheduling problems from the onset of the summer vacation at the university and was probably not treatment-related.

Subject demographics are summarized in Table 1. There were no statistically significant differences between the 2 groups in age, gender, weight, ethnic background, or smoking status.

A comparison of SF-36v2 scores in subjects taking *P. ginseng* and placebo at baseline and at 4 and 8 weeks is provided in Table 2. At baseline, there were no significant differences between treatment groups in SF-36v2 scores. At 4 weeks, social functioning was significantly higher in the *P. ginseng* group compared with those given placebo (p = 0.014). In addition, a trend toward a higher mental health score (p = 0.075) was seen at the 4-week time point in subjects assigned to *P. ginseng*. Moreover, the mental component summary score was significantly higher in the *P. ginseng* group at 4 weeks than that in the control group (p = 0.019). None of these differences persisted to the 8-week evaluation. No other significant differences between the groups were detected at the 4- and 8-week time points. When missing data points were not imputed, the results were unchanged.

Table 3 summarizes the responses to the questions asked at the end of the study. The *P. ginseng* group was

Table 1. Baseline Subject Demographics

Parameter	Ginseng[a] n (%)	Placebo[a] n (%)	p Value
Age (y)	21.9 ± 2.4[b]	21.3 ± 2.9[b]	0.59
Gender			
male	9 (60)	4 (27)	0.14
female	6 (40)	11 (73)	
Ethnic background			
white	13 (87)	12 (80)	0.60
Asian	2 (13)	3 (20)	
Weight (kg)	69.8 ± 13.2[b]	65.2 ± 10.3[b]	0.30
Smoker			
yes	2 (13)	1 (7)	0.83
no	12 (80)	13 (87)	
occasionally	1 (7)	1 (7)	

[a]n = 15.
[b]Mean ± SD.

more likely to state that they felt they received ginseng (58% vs. 17%; $p < 0.05$) and to report feeling differently during the study (58% vs. 8%; $p = 0.03$). The incidence of adverse events was similar between the 2 groups (*P. ginseng* 33% vs. placebo 17%; $p = 0.40$). There was 1 report of each of the following adverse effects among patients assigned to *P. ginseng*: nausea/vomiting, insomnia, rebound irritability, and headache. The subject who experienced nausea and vomiting withdrew from the study, whereas other adverse effects in the treatment group were either tolerable or diminished with time. Adverse effects reported in the placebo group were heartburn (n = 1) and sleeplessness (n = 1). Both subjects remained in the study.

Discussion

To our knowledge, this is the first study to evaluate the effects of *P. ginseng* on HRQOL using the SF-36v2. Our study was able to overcome many of the limitations of previous studies.[6-12] We used a validated general health status instrument rather than symptom score ratings[6] or psychological questionnaires.[8,10] Because claims for "an overall feeling of healthy well-being" have been made, we believed that it was important to assess overall HRQOL rather than to focus on psychological measures alone.[5] We found significantly higher scores in the active group in the social functioning and mental component summary scales after 4 weeks of therapy, although these differences were no longer evident at 8 weeks. We also observed a trend toward improvement in mental health scores. Additionally, subjects randomized to *P. ginseng* were significantly more likely to state that they felt differently during treatment and were more likely to believe that they received ginseng than the placebo group.

To evaluate the clinical significance of these changes, we calculated the effect size (change in time within a group divided by the SD) to facilitate a distribution-based interpretation.[20] Effect sizes of 0.2, 0.5, and 0.8 are considered small, moderate, and large effect sizes, respectively. The effect sizes calculated for the social functioning, mental health, and mental component summary scales exceeded 0.2 (0.38, 0.30, and 0.30, respectively). This implies that the change in scores in the social functioning, mental health, and mental component summary scales after 4 weeks of *P. ginseng* are at least minimally clinically significant.

To date, there has been equivocal evidence that *P. ginseng* improves HRQOL.[6-12] In a recent survey,[3] only a third of ginseng users perceived the product to be effective. In elderly patients with memory problems,[9] *P. ginseng* plus a multivitamin did not improve HRQOL as measured by the Life Satisfaction in the Elderly Scale after 9 months of therapy. In 2 additional studies,[8,10] *P. ginseng* had no effect

Table 3. Responses to Questions Asked at the End of the Treatment Period

Parameter	Ginseng[a] n (%)	Placebo[a] n (%)	p Value
Which treatment do you believe you received?			
ginseng	7 (58)	2 (17)	0.05
placebo	5 (42)	10 (83)	
Did you feel any differently during the study?			
yes	7 (58)	1 (8)	0.03
no	5 (42)	10 (83)	
not really	0 (0)	1 (8)	
Did you experience any adverse effects?			
yes	4[b] (33)	2[c] (17)	0.40

[a]n = 12.
[b]Headache, insomnia, rebound irritability, and nausea/vomiting.
[c]Sleeplessness and heartburn.

Table 2. Mean (± SD) SF-36 Normed Scores at Baseline and at 4 and 8 Weeks[a]

	Ginseng			Placebo		
Scale	Baseline (n = 15)	Week 4 (n = 14)	Week 8 (n = 12)	Baseline (n = 15)	Week 4 (n = 15)	Week 8 (n = 12)
Physical functioning	55.6 ± 4.9	55.7 ± 5.1	55.7 ± 4.4	54.5 ± 3.5	55.5 ± 2.3	55.5 ± 2.4
Role physical	54.7 ± 2.6	52.3 ± 7.1	53.3 ± 5.2	52.6 ± 6.3	53.4 ± 4.5	54.0 ± 3.4
Bodily pain	55.6 ± 7.3	57.2 ± 6.5	56.4 ± 6.0	57.1 ± 5.6	56.4 ± 5.9	58.3 ± 4.2
General health	52.7 ± 8.0	53.2 ± 5.6	53.2 ± 7.5	54.7 ± 4.8	55.9 ± 4.5	56.4 ± 4.4
Vitality	51.1 ± 8.6	54.1 ± 6.8	55.8 ± 4.8	49.2 ± 10.2	49.8 ± 10.3	53.7 ± 7.1
Social functioning	53.2 ± 4.5	54.9 ± 4.6[b]	54.4 ± 4.5	50.7 ± 7.4	49.2 ± 6.5	51.4 ± 5.2
Role emotional	49.9 ± 8.6	50.6 ± 8.6	48.1 ± 8.2	46.6 ± 9.4	46.0 ± 6.6	47.8 ± 7.5
Mental health	50.6 ± 5.3	52.2 ± 7.7[c]	52.3 ± 5.2	48.3 ± 7.0	47.2 ± 7.3	51.7 ± 7.3
Physical component score	56.4 ± 5.6	55.8 ± 4.8	56.4 ± 4.7	57.3 ± 4.4	58.4 ± 3.6	58.1 ± 2.4
Mental component score	48.9 ± 8.0	51.3 ± 7.4[d]	50.5 ± 6.0	45.6 ± 9.2	44.3 ± 8.3	48.4 ± 7.7

SF-36 = Short Form-36 Health Survey; v2 = version 2.
[a]Based on SF-36v2 using 1998 SF-36 US population-based norms with a mean of 50. All comparisons vs. placebo.
[b]$p = 0.014$.
[c]$p = 0.075$.
[d]$p = 0.019$.

on psychological well-being after 8–12 weeks. However, alertness, relaxation, and appetite, measured on a visual analog scale, improved significantly compared with placebo at the end of 12 weeks.[8] In another study,[7] HRQOL improved after 8 and 12 weeks of *P. ginseng* ($p < 0.001$). However, an unvalidated 11-item questionnaire was used to assess HRQOL.

In patients with type 2 diabetes mellitus, 100 mg of ginseng (unknown type) increased psychophysical performance, mood, vigor, and well-being ($p < 0.01$), whereas physical activity improved with the 200-mg ginseng dose only ($p < 0.05$) when a linear analog scale was used after 8 weeks.[6] Two recent studies[11,12] in symptomatic postmenopausal women showed significant benefit with ginseng on depression, well-being, general health, and anxiety after 1–2 months. However, in 1 of the studies, when HRQOL was measured by the women's health questionnaire and symptoms on a visual analog scale, no improvement with *P. ginseng* was observed.[11]

Moreover, in a systematic review of clinical trials with ginseng, the evidence for improved physical performance was equivocal.[21] This is corroborated by the lack of effect on the physical functioning, role functioning, and physical component summary scales observed in our study.

Our findings showed that some aspects of HRQOL improve early during the course of therapy, but these differences dissipated with time. Caffeine, a substance that, like ginseng, is used to increase alertness and energy, has been shown to improve physical and mental performance.[22] However, tolerance to the effects of caffeine develops after 7–18 days.[23,24] In chronic caffeine users, abrupt discontinuation leads to headache, tiredness, fatigue, and mood disturbance.[25,26] It is thought that continued caffeine use is driven by relief of withdrawal.[27] Whether a similar pattern of improvement in physical and mental functioning occurs with ginseng, followed by tolerance and relief of withdrawal symptoms with chronic use, is not known but warrants further investigation.

There were several limitations to our study. Because we enrolled only 30 subjects, small changes in other HRQOL domains may have been more difficult to demonstrate. The study lacked sufficient power; however, this pilot study will enable us to calculate an adequate sample size for a future trial. Furthermore, we used healthy young adults in a university setting; our findings may not be applicable in other populations. The general health status instrument we selected did not assess changes in sleep, an adverse effect observed in the study, or libido, which may have been affected by *P. ginseng*. We only asked the students to abstain from ginseng-containing products; other concurrent herbals were not addressed. We also did not address adherence in the subjects. Because we did not measure HRQOL until week 4 of the study, any changes that may have occurred at an earlier time point may have been missed. Also, we did not question subjects about adverse effects until the 8-week time point, although one self-reported adverse event was shown early in the course of therapy.

Summary

We found that *P. ginseng* 200 mg/d improved social functioning and mental component summary scores after 4 weeks of therapy, but these differences did not persist with continued use. Caution should be taken in interpretation because of the small sample size and the young population studied. Future studies should examine the effect of *P. ginseng* on HRQOL using a larger sample size, measure the effects at earlier time points, and investigate the effects of ginseng withdrawal.

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EXTRACTO

OBJETIVO: Evaluar los efectos dependientes de tiempo de *Panax ginseng* en la calidad de vida relacionada a salud (HRQOL, por sus siglas en inglés) mediante la administración de un cuestionario que mide estado de salud general.

MÉTODOS: Las personas que participaron en el estudio fueron asignadas aleatoriamente usando el método doble-ciego a un grupo que recibió 200 mg de *P. ginseng* (n = 15) o a un grupo que recibió placebo (n = 15) diariamente por 8 semanas. El cuestionario Short Form-36 version 2 (SF-36v2), un cuestionario validado que mide el estado de salud general de una persona, fue administrado al comenzar el estudio, a las 4 y a las 8 semanas subsiguientes para determinar el HRQOL. La calidad de vida fue comparada entre grupos usando el método estadístico de análisis de covarianza de mediciones repetidas. Se consideraron como estadísticamente significativos los valores-p menores de 0.5.

RESULTADOS: Las puntuaciones en el SF-36v2 y la información demográfica de los participantes no fue significativamente diferente entre los 2 grupos al comenzar el estudio. Después de 4 semanas en la terapia, el promedio de las puntuaciones fue más alto para el grupo que recibió *P. ginseng* que el grupo que recibió placebo en funcionamiento social (*P. ginseng* 54.9 ± 4.6 vs. placebo 49.2 ± 6.5; p = 0.014), salud mental (*P. ginseng* 52.2 ± 7.7 vs. placebo 47.2 ± 7.3; p = 0.075) y el resumen del componente mental (*P. ginseng* 51.3 ± 7.4 vs. placebo 44.3 ± 8.3; p = 0.019). Estas diferencias no se mantuvieron al finalizar las 8 semanas de tratamiento. La incidencia de efectos secundarios fue 33% en el grupo de *P. ginseng* y 17% en el grupo placebo (p = 0.40). Las personas que recibieron *P. ginseng* (58%) expresaron con mayor frecuencia que habian recibido un tratamiento activo que las personas en el grupo placebo (17%; p < 0.05).

CONCLUSIONES: El *P. ginseng* mejora aspectos de la salud mental y el funcionamiento social después de 4 semanas de tratamiento pero este efecto disminuye con el uso continuo.

Homero A Monsanto

RÉSUMÉ

OBJECTIF: Évaluer l'effet du *Panax ginseng* sur la qualité de vie (QoL) à l'aide d'un questionnaire non-spécifique.

DEVIS EXPÉRIMENTAL: Une étude prospective à double insu a été conduite chez 30 individus. Les sujets ont reçu soit une dose quotidienne de 200 mg de *P. ginseng* (n = 15), soit un placebo (n = 15) pendant 8 semaines. La répartition des traitements s'est effectuée de façon aléatoire. La version no. 2 du questionnaire Short Form-36 (SF-36v2), un questionnaire non-spécifique largement validé, a été utilisée pour mesurer la QoL au départ, ainsi qu'après 4 et 8 semaines de traitement. Les groupes ont ensuite été comparés par analyse de co-variance pour mesures répétées. Une valeur de p de 0.05 a été déterminée a priori comme statistiquement significative.

RÉSULTATS: Les groupes étaient similaires au départ quant aux paramètres démographiques et aux valeurs de QoL. Après 4 semaines de thérapie, des valeurs plus élevées ont été observées sur deux des échelles dans le groupe recevant le *P. ginseng*, soit le fonctionnement social (*P. ginseng* 54.9 ± 4.6 vs. placebo 49.2 ± 6.5; p = 0.014) et la santé mentale (*P. ginseng* 52.2 ± 7.7 vs. placebo 47.2 ± 7.3; p = 0.075). Une différence similaire a aussi été observée pour le score agrégé de la composante mentale (*P. ginseng* 51.3 ± 7.4 vs. placebo 44.3 ± 8.3; p = 0.019). Ces différences n'étaient plus présentes à la fin de l'étude, soit après 8 semaines de traitement. L'incidence des effets secondaires était de 33% dans le groupe recevant du *P. ginseng* et de 17% dans le groupe recevant du placebo group (p = 0.40). Une plus grande proportion de sujets recevant du *P. ginseng* (58%) avait l'impression de recevoir le produit actif en comparaison à ceux recevant du placebo (17%; p < 0.05).

CONCLUSIONS: Le *P. ginseng* améliore certains aspects reliés à la santé mentale et au fonctionnement social après 4 semaines de traitement, cependant ces différences s'atténuent lorsque le traitement est prolongé.

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