

Short-term CellSentials Supplementation Significantly Improves the Quality of Life Metrics of Essentials Users

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Summary

Nutrition and supplementation play a broad role in human health. Many aspects of health are known to vary depending on gender and age, such as blood glucose and cholesterol (McPherson, Healy et al. 1978). This same observation can be extended to nutrition where males and females of different ages may benefit differently from supplementation, due to underlying physiological differences. An understanding of which health markers vary by supplementation and the underlying cause of these associations may allow further tailoring of supplementation to associate needs. In the present study we revisit our 2015 CellSentials® premarketing safety evaluation to identify general areas of health that are improved by CellSentials® supplementation as well as understand how observed improvements may be different based on gender and age. This study consisted of quality of life metrics collected from Essentials® users before and after one month of CellSentials® supplementation. Quality of life metrics were collected using the medical outcomes study short form (SF-36). This form is widely used for quality of life assessment in general populations and health intervention evaluations (Hemingway, Stafford et al. 1997, Soleymanian, Kokabeh et al. 2017) and assesses mental and physical health using self-reported metrics (Ware and Sherbourne 1992, Ware 2000).

We observed that one month of CellSentials® supplementation significantly increased quality of life scores in 3 of the 8 metrics tested [mental health, vitality (energy), bodily pain]. These changes were more pronounced in females, however similar trends were observed in males. Moreover, older males reported a greater improvement in vitality (energy), while older females reported a greater reduction in bodily pain. Our study demonstrates that the Essentials® upgrade (CellSentials®) significantly increased specific aspects of human health after just one month of use. Additionally, we highlight gender and age variations with supplementation that provide new avenues for research into personalized nutrition. Further studies based on the presented results will allow additional personalization of USANA products enabling them to better nourish, protect, and renew individualized aspects of associate health.

Results and Discussion

Essentials® supplementation users show improved quality of life measures relative to the US population.

The median SF-36 value improvements of overall mental and physical health for Essentials® users relative to the US average were calculated. We observed that the average health scores for Essentials® supplement users were higher than that of the average for the US population, an increase of 3.3% for overall mental health and 6.3% for overall physical health (Figure 1), **suggesting that Essentials® supplementation may improve measured mental and physical health aspects relative to the US population.**

CellSentials® supplementation significantly improved reported mental health and vitality scores and reduced reported instances of bodily pain

Four areas of mental health and the overall assessment of mental health were tested for significant improvements between Essentials® users at baseline and after 28 days of CellSentials® supplementation ($P > 0.01$; Figure 1). The overall assessment of mental health showed significant improvement ($P = 0.0023$; 2.21% improvement; Figure 1) as well as two specific areas of overall mental health, mental health ($P = 1.15 \times 10^{-4}$; 2.47% improvement) and vitality (energy; $P = 0.0064$; 1.81% improvement; Figure 1).

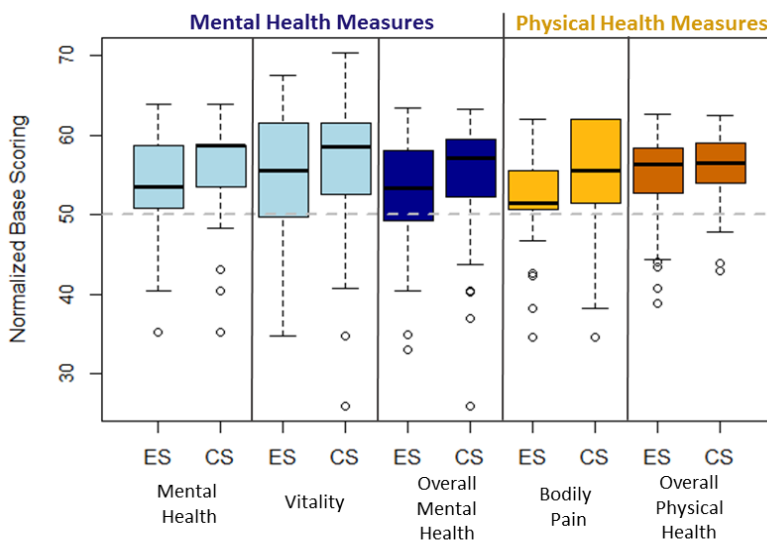


Figure 1. One month of CellSentials® supplementation improved multiple aspects of health. Boxplot showing SF-36 scores for health measures that were significantly improved after one month of CellSentials® supplementation (CS), as well as the SF-36 score for overall mental (dark blue) and physical (dark orange) health. Significance was measured by change in mean value between Essentials® (ES) and CS (horizontal black lines). US population mean is shown as a grey horizontal dashed line.

Four areas of physical health and the overall assessment of physical health were tested for significant improvements before and after CellSentials® supplementation. Only physical pain was significantly improved ($P = 7.73 \times 10^{-4}$; 2.48% improvement; Figure 1). General health was trending toward improvement ($P = 0.031$; 1.28% improvement; data not shown) however did not meet the corrected significance threshold ($P < 0.01$). **This analysis highlights specific areas of health where CellSentials® supplementation may confer added benefit over Essentials® supplementation.**

CellSentials®-related health improvements are more pronounced in females

Health areas that were significantly improved by CellSentials® supplementation were analyzed for gender differences. In all 3 areas, females showed a stronger effect. The median percent improvements in females were 2.98 ($P = 6.12 \times 10^{-4}$), 2.42 ($P = 0.021$), and 2.33 ($P = 0.026$) for mental health, vitality (energy) and bodily pain, respectively. Among males, the median percent improvements were 1.65 ($P = 0.051$), 0.84 ($P = 0.062$), and 2.01 ($P = 0.030$), respectively. Because the increased number of females may contribute to the stronger effects observed we subset the female data to the same size as the males [N=27] and calculated the median percent improvement for this smaller subset. The observed group median percent improvement for this female subset were nearly identical to the larger dataset and still larger than that observed in males, 3.00, 2.42, and 2.60 for mental health, vitality (energy) and bodily pain, respectively. **This suggests that although improvements were observed in both genders, females may benefit more in tested areas than males.**

CellSentials®-related health improvements are different among individuals of varying age and gender

Health areas that were significantly improved by CellSentials® supplementation were analyzed for associations with age separately in males and females. Increasing age was significantly correlated with the amount of reduction in bodily pain reported, among females ($P = 0.025$; Figure 2 left) but not males ($P = 0.93$; data not shown). Increasing age was significantly associated with the amount of increased vitality (energy) in males ($P = 0.034$; Figure 2 right) but not females ($P = 0.64$; data not shown). Overall, we demonstrated interactions between age and gender on the amount of observed effect from supplementation. **These interactions highlight health areas where the positive effects of supplementation may vary depending on age or gender and provide direction into areas and where further study may improve USANA products through increased personalization.**

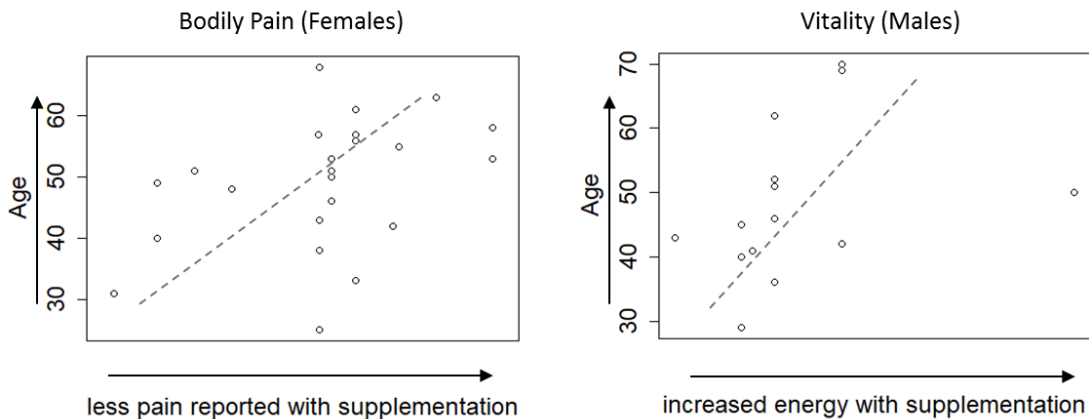


Figure 2. Males and females may benefit differently from CellSentials® supplementation.

Scatterplot showing the correlation between reported bodily pain and age among females (left) and reported vitality (energy) among males (right). Older females reported a larger reduction in bodily pain after supplementation, while older males reported a larger increase in vitality.

Materials and Methods

Medical outcomes study short form (SF-36)

The SF36v2 Health survey was developed to be a brief, broad measure of various aspects of human health. That encompass two major health areas, mental and physical health. Mental health assessment is comprised of 4 health domains: i) mental health which assesses the amount of anxiety, depression, loss of behavioral control and psychological well-being, ii) role-emotional which assesses mental health related role limitations, iii) social functioning which assesses the effects of social activity on physical or emotional health, iv) vitality which assesses amount of energy and fatigue. Physical health assessment is comprised of 4 health domains as well: i) physical functioning which assesses ability to perform daily tasks as well as more strenuous exercise, ii) role-physical which assesses the extend of role limitations due to physical health issues, iii) general health which assesses individual's perceptions of overall health, and iv) bodily pain which assesses the intensity of bodily pain and the extent to which it interferes with daily activity. Across all categories low scoring is indicative of negative effects i.e. increased pain or reduced physical function.

SF-36 data collection and processing

This study was a premarketing safety evaluation. One hundred and twenty-seven individuals were recruited through the United States and Canada with the help of USANA associate physicians. Each volunteer completed the SF-36 survey before and after taking CellSentials® for four weeks. Ninety-six individuals completed the 4-week evaluation. Twenty-six individuals were excluded from further analysis due to one or more of the following criterion: i) reported illness during the study, ii) lack of Essentials® supplementation for 3 months before the study, iii) did not provide

ethnicity information. The final study population for analysis consisted of 45 Caucasian, 14 Hispanic, and 11 Asian subjects that reported using Essentials® for 3 months immediately preceding the study. There were 27 males and 43 females with mean ages of 49 [29-70] and 49 [25-68].

Statistical Analyses

Rv3.3.3 was used for all analyses. SF-36 scores were normalized to the US population (Ware 2000). Differences between baseline Essentials® and one month CellSentials® supplementation were assessed using a paired Wilcoxon rank sum test for Mental Health, Vitality, General Health, Bodily Pain, and Role Physical parameters as well as the Mental Health and Physical summary parameters. Role Emotional, Social Functioning, and Physical Functioning were assessed using the non-parametric test for censored data found in the R package EnvStats. A p-value of 0.01 was required for significance in mental and physical health parameters to account for testing 4 aspects of physical or mental health as well as the overall score.

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