Functional Foods and Quality of Life: A Prospective Study

Kate Bauer, Vasuki Wijendran, Charles Marsland and Stacey J Bell[*]

[*]*110 Woodland Street, Reno, NV 89523, USA.*

ABSTRACT

Consuming nutrient-dense foods have been shown to reduce the risk of cardiovascular disease, type 2 diabetes, all-cause mortality, and obesity. These conditions also reduce quality of life. Paradoxically, the diet consumed by most Americans is nutrient-poor and rich in salt, sugar and saturated fats, which increases the risk of these chronic conditions and worsens quality of life. Functional foods have been proposed to correct the poor diet. We have previously shown in two retrospective studies that individuals, who consumed one functional food that is nutrient-rich, portion-controlled, easy-to-prepare meal daily, experienced improvement in quality of life indicators. The purpose of this prospective study was to assess the effect of consuming one of the same nutrient-dense, functional food daily over two months.

21 subjects started the study (mean age was 43 ± 16 years; 29% male) and six withdrew for reasons unrelated to the foods used in the study. Participants received the functional foods and nutritional coaching to assist with compliance at no charge. Subjects submitted weekly data collection forms electronically; measurements included body weight, waist circumference, and quality of life indicators using a scale of one to five with five being the best. In addition, the percentage of individuals showing improvement after two months from this prospective study were compared to retrospectively obtained data obtained at month 2, 6 and 12.

During the 2 month period, subjects consumed about six functional foods weekly. Body weight and waist circumference readings were unchanged. Using the rating scale of one to five, the most improved quality of life indicators (>20%) were for passion, sleeping better, more energy, and having fewer food cravings. The next tiers (10-20% improvement) were for having a better diet quality, nicer appearance, and feeling fuller. Comparison between these prospectively obtained data and those obtained retrospectively revealed a steady improvement (i.e., percentage of individuals who improved) between two months and one year in several quality of life indicators: general feeling of wellbeing (33% to 100%); feeling full (40% to 97%); energy (60% to 84%); mood (33% to 73%); and diet quality (53% to 89%).

This study supports a role for inclusion of one nutrient-dense, healthy functional food daily to improve quality of life. The benefits are noticeable after two months and improve over time.

Keywords: Functional foods, Nutrient-dense foods, Diet quality, Diet and quality of life, Nutrient-dense foods

INTRODUCTION

Nutritional scientists nearly unanimously agree that a poor diet is associated with an increased risk of common chronic conditions like type diabetes and cardiovascular disease, which cause premature mortality [1-4]. These conditions worsen quality of life such as feeling a lack of energy, having constant hunger, and being unable to sleep. The proposed diet for optimal health includes mainly whole foods like vegetables, fruit, nuts, whole grains; and low intakes of red and processed meats, sugar, saturated fats and sodium [5-7].

Despite the overwhelming evidence of what constitutes a healthy diet, compliance with one is poor and most Americans over-consume what should be limited (e.g. salt, sugar and saturated fats) and under-consume the aforementioned healthy foods [8]. The poor diet is mainly from ultra-processed and addictive foods, thus disallowing

someone to lose weight and reduce disease risk [9]. Admittedly, these ultra-processed foods are less expensive, tastier, have a long shelf life (i.e., will not spoil like the recommended healthy foods) and are easier to prepare than those that have been shown to reduce disease risk.

New strategies are welcome to correct poor eating habits and

Corresponding author: Stacey J Bell, D.Sc., RDN, Nutrient Chief Science Officer, Nutrient,110 Woodland Street, Reno, NV 89523, USA, Tel: (617) 999-6150; E-mail: stacey.bell@nutrientfoods.com

functional foods have been proposed as a solution. Functional foods are foods enhanced with bioactive ingredients and have demonstrated health benefits [10]. They usually have demonstrated beneficial physiological effects in the prevention, management, and/or treatment of chronic disease that is beyond basic nutrition. Functional foods can come from conventional foods or from the addition of a bioactive constituent in conventional food like vitamins and minerals. Thus, the best option to improve the diet may be a healthy, nutrient-dense functional food that is low in salt, sugar and saturated fats and is tasty, easy-to-prepare and inexpensive.

We have shown that nutrient-dense, functional foods that meet these healthy food criteria produce medically significant weight loss and promote significant lowering of blood pressure and blood glucose [11-14]. Use of these same nutrient-dense functional foods in a healthy population also conveyed other benefits. In two retrospective studies of current customers (http://nutrientfoods.com), consuming one nutrient-dense functional food daily improved many quality of life indicators [15,16]. Participants reported changes in quality of life indicators after two months, six months, and one year. More than 80% of the subjects at all-time points reported experiencing: more energy, fewer mid-day crashes, eating better and fullness and satisfaction. More than 75% reported improvement in feeling stronger, having more focus and being in overall better health.

The purpose of this prospective study is to confirm these retrospectively obtained quality of life findings. Participants will provide data about changes in quality of life indicators and agree to consume one of the same nutrient-dense, portion-controlled functional foods daily for two months.

MATERIALS AND METHODS

This is a prospective, single-armed study with recruitment of individuals aged 21 years and older, who agreed to consume one healthy, portion-controlled, easy-to-prepare nutrient-dense functional food daily for eight weeks. Participants received the foods and nutritional coaching to assist with compliance at no charge. Subjects completed weekly data collection forms and submitted them electronically.

Subjects

Individuals, who failed to meet entry criteria for other studies (https://nutrientfoods.com/pages/unmatched-live-clinicals), were recruited to participate in this study. If they had a chronic condition, it needed to be well controlled. No one could be pregnant, lactating, or considering getting pregnant and all were naïve to consuming the nutrient-dense foods used in the study.

Dietary intervention

Each day for eight weeks, participants were provided one nutrient-dense functional food of their choosing from an array including shakes, bars, hot and cold cereals, and hot meals like noodles and cheese and Pad Thai (http://nutrientfoods.com). Foods were portion-controlled and easy-to-prepare; most required just the addition of hot water. Each functional food contained 25% of the Daily Value (DV) or more for every vitamin, mineral, except sodium and chloride; and 25% of the Adequate Intakes (AI) or more for omega-3 fatty acids. All foods were relatively low in total sugar and saturated fats.

Measurements

Subjects provided weekly weights, and monthly measurements of waist circumference. Disease risk for cardiovascular disease (CVD), hypertension, and type 2 diabetes was determined using body mass index (BMI) and waist circumference. Waist circumference measurements are abnormally high if they are greater than 102 cm for men and 88 cm for women.

Participants completed weekly, self-reported quality of life indicators for these ten questions: how they generally felt, satiety, food cravings, moodiness, energy level, gastrointestinal symptoms, sleep, appearance (i.e., hair, skin and nails), diet quality and passion. Ratings were made using a scale of one (the worst) to five (the best). The percentage change was then calculated by: the mean at week 8 – the mean at baseline/baseline × 100.

In order to compare these prospectively obtained quality of life data with those obtained retrospectively at 2, 6 and 12 months, the prospective data are presented differently. In the two retrospective studies, the quality of life indicators were presented as the percentage of participants reporting improvement by saying Yes (i.e., the number of subjects stating improvement for each quality of life indicator/the total number of subjects answering the question × 100) [15,16]. For these prospectively obtained quality of life data, determination of percentage of participants who improved was calculated by: the number of subjects recording a higher quality of life indicator, using the scale of one to five, at week 8 than baseline/total number of subjects answering the question × 100. If baseline data were not available, the responses at week 4 were used instead.

STATISTICS

Data are expressed as means ± standard deviation (S.D.).

RESULTS

Twenty-one subjects were enrolled in the study and six withdrew; three stopped communicating at baseline, one was hospitalized at week 1 for an unrelated issue, one became pregnant at week 2 and one stopped communicating at week 4. Of the initial group (29% male), the average age was 43 ± 16 years **(Table 1)**. Five reported having no co-morbidities, five had arthritis and six had hypertension.

Table 1. Baseline demographics.

Attributes	Baseline information
Co-morbidities (some subjects had more than one)	-5 none -5 arthritis -6 hypertension -2 hypercholesterolemia -2 type 2 diabetes
Mean body weight (kg)	91 ± 37
Waist circumference at risk	2/6 men>102 cm; 12/15 women>88 cm
Body mass index (kg/m^2)	30 ± 11
Classification of body weight*	8 Normal 4 Overweight 6 Obese Class I 1 Obese Class II 2 Obese Class III
Disease risk classification for cardiovascular disease, hypertension and type 2 diabetes based on body mass index and waist circumference*	Eight at no risk Two at increased risk Two at high risk Seven at very high risk Two at extremely high risk

[17]

The subjects consumed an average 6 ± 1 functional foods weekly with everyone eating at least five of the seven. Three participants did not exercise during the study; and seven met the American Heart Associate recommendation of least 150 minutes weekly (https://www.heart.org/en/healthy-living/fitness). Exercises used included: Barre, volleyball, tennis, pickle ball, biking, hiking, resistance training and walking.

Anthropometry

Using baseline BMIs, eight participants were normal weight, four were overweight and nine were classified as obese (17) **(Table 1)**. Abnormal waist circumferences were present in 2/6 men and 12/15 women. Baseline disease risk for CVD, hypertension and type 2 diabetes was: eight had no risk, two had increased risk, two had high risk, seven had very high and two had extremely high risk.

Body weight and BMI did not change appreciably over the eight weeks **(Table 2)**. Seven subjects lost weight; most lost

1 or 2 kg, but one participant lost 10 kg. Four subjects gained 2-4 kg and four had no change. The participant who lost the most weight also experienced a 3-unit decline in BMI. Three others increased BMI 1 unit and another three decreased BMI by 1 unit.

Women had greater reductions in waist circumference than men **(Table 2)**. Mean change in waist circumference decreased from 95 ± 9 cm to 85 ± 16 cm after 8 weeks. Men's waist circumferences increased over the same time from 101 ± 32 cm to 103 ± 30 cm. The three participants with the biggest decreases in waist circumference measurements were all female (decreases of 16, 28 and 30 cm). Three other subjects had smaller reductions in waist circumferences; two women experienced reductions of 6 and 8 cm, and one man by 5 cm. According to BMI and waist circumference readings at the end of the study, three participants lowered their risk for CVD, hypertension, and type 2 diabetes (data not shown). One woman experienced an increased risk by starting with no risk and going to increased risk, because of a 2 kg weight gain despite having a decrease in 16 cm in waist circumference.

Table 2. Change in anthropometric measurements.

Attributes (n=15)	Baseline	Week 4	Week 8
Weight (kg)	91 ± 39	91 ± 39	91 ± 39
Body mass index (kg/m^2)	30 ± 12	29 ± 12	29 ± 12
Waist circumference (cm)	95 ± 9 women 101 ± 32 men	89 ± 13 women 101 ± 29 men	85 ± 16 women 103 ± 30 men
Number subjects with unhealthy waist circumferences	7 women 2 men	4 women 2 men	4 women 1 man

Quality of life

The ten quality of life indicators improved for the most part during the two-month study **(Table 3)**. The most improved indicators (>20%) were for passion, sleeping better, more energy and having fewer food cravings. The next tier (10% improvement and less than 20%) were for having a better diet quality, feeling fuller, and nicer appearance. Indicators that did not change much included mood, GI function and overall feeling better.

Table 3. Changes in quality of life indicators.

Quality of life attributes* (n=15)	Baseline	Week 4	Week 8	Percentage change between mean at baseline and mean at week 8
How do you generally feel?	3.4 ± 0.9	3.2 ± 0.9	3.3 ± 1.0	No change+
Did you feel full?	3.4 ± 0.7	3.9 ± 0.7	3.8 ± 0.6	12% improvement
How were your food cravings?	3.0 ± 0.6	3.7 ± 0.7	3.9 ± 0.6	30% improvement
How was your mood?	3.8 ± 0.8	4.1 ± 0.8	4.1 ± 0.7	8% improvement
How was your energy?	3.0 ± 0.7	3.9 ± 0.5	3.9 ± 0.5	30% improvement
Did you experience any gastrointestinal symptoms?	4.3 ± 0.8	3.9 ± 1.0	4.1 ± 1.0	No change
How did you sleep?	2.8 ± 0.4	3.5 ± 0.9	3.7 ± 0.9	32% improvement
How was your appearance (e.g. hair, skin, and nails)?	3.2 ± 0.6	3.6 ± 0.6	3.7 ± 0.6	16% improvement
How was your diet quality?	3.1± 0.9	3.5 ± 0.9	3.7 ± 0.7	19% improvement
How was your level of passion?	2.7 ± 0.8	2.9 ± 1.4	3.6 ± 0.9	33% improvement

Data reported using a scale of 1 to 5, with 1 being the worst and 5 being the best
+ Defined as less than 10%

Comparisons were made between these prospectively obtained data and those obtained retrospectively at 2, 6 and 12 months **(Table 4)**. At month 2, the percentage of subjects reporting improvements in quality of life indicators were close between the retrospective and prospective data for: energy, cravings, sleep, appearance and passion. For the remaining quality of life indicators, the percentage of improvement was two-to-three times greater for the retrospectively collected data compared to those prospectively obtained for: general feeling of wellbeing, fullness, GI symptoms and diet quality. Quality of life indicators improved after eating one nutrient-dense meal daily over time: general feeling of wellbeing (33% to 100%); feeling full (40% to 97%); energy (60% to 84%); mood (33% to 73%); and diet quality (53% to 89%).

Table 4. Comparison between retrospective and prospective data after consuming one nutrient-dense functional food daily.

Attribute (% improvement)	Prospective: 2 months (n=15)*	Retrospective: 2 months (n=215)+	Retrospective: 6 months (n=83)^	Retrospective: 12 months (n=38)^
How do you generally feel?	33	91	95	100
Did you feel full?	40	98	94	97
How were your food cravings?	67	87	n/a	n/a
How was your mood?	33	n/a	85	73
How was your energy?	60	91	86	84
Did you experience any gastrointestinal symptoms?	27 (fewer symptoms)	79 (fewer symptoms)	n/a	n/a
How did you sleep?	60	65	n/a	n/a
How was your appearance (e.g. hair, skin and nails)?	47	46	n/a	n/a
How was your diet quality?	53	93	89	89
How was your level of passion?	46	56	n/a	n/a

Calculated by: the number of subjects recording a higher quality of life indicator, using the scale of one to five, at week 8 than baseline/total number of subjects answering the question × 100. If baseline data were not available, the responses at week 4 were used instead.
+[15]
^[16]

DISCUSSION

The typical American diet is poor, reduces quality of life, and promotes weight gain that leads to increased chronic disease risk and premature mortality [1-4,7]. The major flaws in the typical diet is the under-consumption of nutrients (e.g. vitamins and minerals) and the over-consumption of foods rich in addictive ingredients like salt, sugar, and saturated fat. The proposed optimal diet recommends consuming mostly whole foods that are rarely consumed (e.g. whole grains, low-fat dairy, vegetarian proteins, nuts/seeds, fruits, and vegetables) and limiting those over-consumed (e.g. fried foods, sugary beverages, large-portioned fast food items like burgers and French fries, and mixed items like tortillas, burritos, and pasta dishes) [8].

We have shown prospectively that inclusion of one healthy, portion-controlled, easy-to-prepare, nutrient-dense functional food improves quality of life. The greatest improvements were seen in passion, sleep, energy and reduced cravings. Also, improvements were observed for diet quality and appearance. The participants experienced these benefits in quality of life from eating one nutrient-dense functional food daily, despite remaining weight stable. Thus, dietary constituents may be more important than

losing weight to improve quality of life. Many individuals experience a poor quality of life, and inclusion of just one nutrient-dense functional food daily offers a way to overcome this.

Retrospective data from consuming the same nutrient-dense functional foods corroborate these new prospective findings on quality of life indicators [15,16]. Improvements were observed using both data collection methods at two months. What was most surprising was that continued use of the nutrient-dense functional foods for up to one year allowed for greater improvements in quality of life. This was especially true for general feeling of wellbeing, fullness, energy, mood, and diet quality. These benefits in quality of life indicators provide further support for inclusion of one nutrient-dense functional food daily for at least one year, if not in perpetuity.

The limitations of this study were that the results were self-reported and compliance with functional food intake was not directly verified. No nutritional assessment was made at baseline confirming that the participants were consuming a poor diet, but there is no reason to assume it differed from what most Americans consume. The retrospective data used as comparison may have only been provided by those who

benefitted, thereby limiting their reliability. However, the prospective and retrospective data at month two were close for half of the quality of life indicators, making the retrospectively obtained data more believable.

CONCLUSION

Most individuals consume an unhealthy diet and do not adopt healthy eating guidelines proposed by most nutritional scientists. Poor dietary choices worsen quality of life, increases co-morbidities, and shorten lifespan. A simple intervention of one nutrient-dense, healthy functional food daily can improve the quality of life. The participants liked the offerings and continued eating one healthy functional food daily over one year.

ACKNOWLEDGEMENT

STATEMENT OF COMPETING INTERESTS

All co-authors are full-time employees of Nutrient, the company that manufactured the functional foods used in this study.

REFERENCES

1. Li Y, Pan A, Wang DD, Franco OH, Kaptoge S, et al. (2018) Impact of healthy lifestyle factors on life expectancies in the US population. Circulation 137: 345-355.

2. Streppell MT, Sluik D, van Yperen JF, Geelen A, Hofman A, et al. (2014) Nutrient-rich foods, cardiovascular diseases and all-cause mortality: The Rotterdam study. Eur J Clin Nutr 68: 741-747.

3. Alonso-Domínguez R, García-Ortiz L, Patino-Alonso MC, Sánchez-Aguadero N, Gómez-Marcos MA, et al. (2019) Effectiveness of a multifactorial intervention in increasing adherence to the Mediterranean diet among patients with diabetes mellitus type 2: A controlled and randomized study (EMID study). Nutrients 11: 162.

4. Sotos-Prieto M, Bhupathiraju SN, Mattei J, Fung TT, Li Y, et al. (2017) Association of changes in diet quality with total and cause-specific mortality. N Engl J Med 377: 143-153.

5. Navia B, Aparicio A, Perea MJ, Farinós P, Villar Villalba C, et al. (2014) Sodium intake may promote weight gain; results of the FANPE study in a representative sample of the adult Spanish population. Nutr Hosp 6: 1283-1289.

6. Steel EM, Baraldi LG, Louzada ML, Moubarac JC, Mozaffarian D, et al. (2016) Ultra-processed foods and added sugars in the US diet: Evidence from a nationally representative cross-sectional study. BMJ Open 6: e009892.

7. Mozaffarian D (2016) Dietary and policy priorities for cardiovascular disease, diabetes and obesity – A comprehensive review. Circulation 133: 187-225.

8. (2015-2020) Dietary Guidelines for Americans. 8th Ed.

9. Hall KD, Ayuketah A, Brychta R, et al. Ultra-Processed Diets Cause Excess Calorie Intake and Weight Gain: An Inpatient Randomized Controlled Trial of Ad Libitum Food Intake. Cell Metabolism (2019).

10. Therapeutic Products Programme and the Food Directorate from the Health Protection Branch. ARCHIVED - Policy Paper - Nutraceuticals/Functional Foods and Health Claims On Foods.

11. Bell SJ, Ling PR, Marsland C (2016) Nutrient-dense, portion-controlled meals and snacks promote weight loss. J Food Technol Nutr Sci 2.

12. Bell SJ, Ling PR, Baker RA, Marsland C (2018) Use of self-reported data to determine the effect of nutrient-dense meals on body weight and quality of life. J Nutr Food Sci 8: 3.

13. Wijendran V, Bauer K, Baker R, Bell S, Marsland C (2019) Heart-targeted prospective dietary intervention with nutrient-dense, portion-controlled foods improves blood pressure in patients with hypertension (P12-020-19). Curr Dev Nutr 3: nzz035.P12-020-19.2

14. Wijendran V, Morehouse N, Bauer K, Bell S (2019) Dietary intervention with nutrient-dense foods improves blood glucose management in adults with type 2 diabetes. American Association of Diabetes Educators 36: 3821-3842.

15. Bell SJ, Castleman PM, Marsland C (2018) Nutrient-dense foods make you feel better: What our customers tell us? J Food Nutr 5: 33.

16. Bell SJ, Castleman PM, Marsland C (2019) Short and long term benefits from consuming nutrient-dense foods. J Nutr Food Sci 9: 2.

17. National Heart, Lung and Blood Institute (2018) Classification of overweight and obesity by BMI, waist circumference and associated disease risks.