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1 **Higher adherence to French dietary guidelines and chronic diseases in the prospective**

2 **SU.VI.MAX cohort**

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21

22 **Abstract**

23 **Background/Objectives:** Nutritional recommendations are widely disseminated, but
24 assessment of their predictive value for risk of chronic diseases and mortality is essential for
25 ensuring their validity. We evaluated, in a large population-based study, the association
26 between the French Programme National Nutrition Santé (PNNS) Guideline Score (GS)
27 (maximum score of 15 points), an a priori-based score, and the incidences of cancer,
28 cardiovascular disease (CVD) and overall mortality.

29 **Subjects/Methods:** Subjects included in the present analysis (n=5 823) were participants in
30 the Supplémentation en Vitamines et Minéraux AntioXydants study (SU.VI.MAX), with
31 available data for estimating the PNNS-GS. Hazards ratios (HR) and 95% confidence
32 intervals (95% CI) for outcomes (cancer, CVD and death) were estimated across quartiles of
33 PNNS-GS using Cox proportional hazards models.

34 **Results:** A total of 734 major events were recorded during an average 11.6-year follow-up
35 (maximum 13 years): 423 cancers, 193 ischemic diseases and 118 deaths. In the fully-
36 adjusted model, a significant reduction in CVD risk between the first and fourth PNNS-GS
37 quartiles (HR=0.65, 95% CI= 0.41, 1.00, P for trend=0.04) was observed. No significant
38 overall association with risk of cancer or death was detected.

39 **Conclusions:** These observations support the role of nutritional guidelines in prevention of
40 CVD.

41 **Keywords:** nutritional guidelines, dietary index, cancer, mortality, cardiovascular diseases

42

43 **Introduction**

44 In the past few decades, associations between nutritional factors and chronic diseases,
45 especially cardiovascular diseases (CVD) and cancer, have been widely investigated. A
46 posteriori and a priori methods which take into account overall diet have emerged to
47 overcome the limitations of the nutrient or single food approach based on correlations and
48 interactions between dietary pattern components (Moeller *et al.*, 2007). Although a posteriori
49 methods enable to empirically deriving dietary patterns, a priori scores are often based on
50 nutritional guidelines or diet quality (Moeller *et al.*, 2007).

51 A major issue lies in assessing the predictive value of adherence to nutritional guidelines for
52 primary prevention of chronic disease risk, since guidelines are theoretically designed for this
53 purpose. Some studies have investigated the potential effect of adherence to dietary
54 guidelines, including or not physical activity, on the incidence of chronic diseases, cancer,
55 CVD and overall mortality, as recently reviewed (Waijers *et al.*, 2007).

56 Initial and subsequent a priori scores based on Dietary Guidelines for Americans (DGA),
57 were shown to be only weakly or not at all associated with CVD and cancer occurrence
58 (Waijers *et al.*, 2007). This may be partly due to variations in construction of dietary scores
59 and disparities in sample size and follow-up duration for some studies. Despite the absence of
60 a significant association with chronic disease risk, better adherence to dietary scores has been
61 consistently associated with lower mortality (Kaluza *et al.*, 2009; Kant *et al.*, 2009).

62 We had previously developed a score (FSIPO) based on the nine public health goals of the
63 French Nutrition and Health Program (Estaquio *et al.*, 2008). In the SU.VI.MAX cohort, this
64 score was associated with a significant 36% reduction in the risk of chronic diseases and
65 death among men, but no significant association was observed among women. Such
66 arguments concerning nutritional guidelines should be more convincing and comprehensive,
67 mainly in terms of public health messages.

68 Recently, we developed another a priori score, the PNNS Guidelines Score (PNNS-GS),
69 based on the individual French national nutritional guidelines (Estaquio *et al.*, 2009), aimed to
70 describe the level of dietary adherence to these guidelines.

71 The purpose of the present work was to evaluate the prospective associations between PNNS-
72 GS quartiles and risk of chronic diseases and mortality during a maximum 13-year follow-up.

73 **Materials and methods**

74 *Population*

75 The design and rationale of the SU.VI.MAX study (Supplémentation en Vitamines et
76 Minéraux Antioxydants) have been extensively detailed previously (Herberg *et al.*, 1998).

77 The SU.VI.MAX study was initially designed as a randomized, double-blind, placebo-
78 controlled, primary prevention trial to test the potential efficacy of daily supplementation with
79 antioxidant vitamins and minerals at nutritional doses on the incidence of cancers,
80 cardiovascular diseases and overall mortality. Eligible subjects, 7 713 women aged 35–60
81 years and 5 028 men aged 45–60 years at baseline, were included in 1994-1995 and initially
82 followed up for 7.5 y. After stopping supplementation, the follow-up was extended to 13
83 years. The SU.VI.MAX study was approved by the Ethical Committee for Studies with
84 Human Subjects of the Paris-Cochin Hospital (CCPPRB n°706) and the “Commission
85 Nationale Informatique et Liberté” (CNIL n°334641), which ensures that medical information
86 be kept confidential and anonymous.

87 *Data assessment*

88 Sociodemographic data and lifestyle, including gender, date of birth and tobacco status, were
89 collected using a self-administrated questionnaire at baseline.

90 Subjects were asked to provide a 24-h record every 2 months for a total of 6 records per year
91 covering all days of the week and all seasons. To facilitate coding food portions, participants
92 were assisted by an instruction manual which included validated photographs of more than

93 250 typical foods represented in three different portion sizes. Subjects could also choose from
94 two intermediate or two extreme portions, for a total of seven different possible portion sizes
95 (Le Moullec et al., 1996). As previously detailed (Touvier *et al.*, 2010), dietary records that
96 reported <100 kcal/d or >6000 kcal/d were excluded and further subjects who had >2/3 of their
97 records that reported <800 kcal/d in men and <500 kcal/d in women were excluded. Dietary
98 nutrient intakes were calculated using a food composition table which included more than 900
99 foods (Hercberg S (coordinator), 2005). Specific information on weekly consumption of
100 seafood was collected by a self-administrated questionnaire at baseline. In addition, alcohol
101 intake (grams of alcohol per day) was estimated using a short validated semi-quantitative
102 dietary questionnaire (Lasfargues *et al.*, 1990).

103 A French validated self-administered version of the Modifiable Activity Questionnaire
104 (MAQ) was used in 1998 to assess physical activity (Vuillemin *et al.*, 2000). Type, frequency
105 and duration of activity, each performed at least 10 times for 10 minutes each session during
106 leisure time over the past 12 months, were collected. Using published compendiums
107 (Ainsworth *et al.*, 2000), metabolic equivalent tasks (MET) were assigned to each leisure
108 activity reported and summary scores were computed, including the average MET-h per week
109 of physical activity. For subjects with missing data for the MAQ, we used data from other
110 sources and imputations as previously reported (Estaquio *et al.*, 2009).

111 At the first clinical examination during the follow-up (1995-1996), weight was measured
112 using an electronic scale (Seca, Germany), with subjects wearing indoor clothes and no shoes.

113 Height was measured under the same conditions with a wall-mounted stadiometer.

114 *Cases ascertainment*

115 Information about health was self-reported via a monthly questionnaire. Other sources of
116 information regarding outcome included yearly visits. In case of no contact with a participant
117 for a long period, or failure to show up for the yearly visit, an investigation was launched to

118 determine the reasons. In case of a suspected event, investigations were conducted to obtain
119 relevant medical data (clinical, biochemical, histological and radiological reports) from
120 participants, physicians and/or hospitals. All events were then reviewed and validated by an
121 independent expert committee, unaware of the supplementation group assignment. Causes of
122 death were confirmed using information provided by physicians or family members. Vital
123 status of all subjects and causes of death were verified using the national death registry.
124 Health events were classified using the International Classification of Diseases, 10th
125 Revision, Clinical Modification (ICD-10-CM) (WHO, 2003). Major outcomes included
126 cardiovascular events (ICD-10-CM codes I20-I24) and cancer of any kind (ICD-10-CM codes
127 C00-C97, D00-D09, D37-D48), except for basal cell carcinoma of the skin (ICD-10-CM
128 codes C44 and M809-M811) and all-cause mortality. First, we considered as outcome the
129 occurrence of a major chronic disease event defined as a combination of CVD, cancer or
130 death, whichever came first. Secondly, we also studied each health event separately. Subjects
131 contributed person-time up to the date of the health outcome (n=635), the date of the last
132 completed questionnaire or contact (n=1 145) or September 1st 2007 (n=4 043), whichever
133 occurred first. CVD was not accounted for in cancer analysis, and vice-versa.

134 *PNNS-GS computation*

135 PNNS-GS computation, including food grouping, serving sizes, scoring, cut-off and penalties,
136 was previously described in detail (Estaquio *et al.*, 2009). Briefly, the score included 13
137 components for a total of 15 points maximum. Eight components referred to food groups,
138 including recommended servings, and four components were related to overall limitation. The
139 final component dealt with adherence to the physical activity recommendation. Scoring and
140 cut-off values are presented in table 1. Each component's subscore were summed for a
141 theoretical maximum total of 15 points.

142 A penalty for overconsumption was assigned to individuals with energy intakes higher than
143 needs. Schofield's basal metabolic rate was estimated using age, height and weight. Basal
144 metabolic rate and physical activity level were used to estimate energy expenditures
145 (Schofield, 1985). If energy intake was greater than 5% compared to calculated energy needs,
146 an identical fraction was deducted from the score (Estaquio *et al.*, 2009).

147 *Inclusion criteria*

148 In the present analysis, we selected men and women aged 45-60 y at baseline who provided at
149 least three 24-h records during the first 2 years of follow-up and other data needed for PNNS-
150 GS computation, and who had no missing co-variables for the present analyses (Fig. 1).

151 We excluded subjects who developed health outcomes during the first two years of follow-up.

152 *Statistical analysis*

153 Means of food and nutrient intake were calculated from at least three 24-h dietary records
154 during the first two years of follow-up. Body mass index (BMI) was calculated as the ratio of
155 weight to squared height (kg/m²).

156 Descriptive results are reported as mean \pm standard deviation or percent across quartiles of
157 PNNS-GS. Reported P-values referred to the Kruskal-Wallis test or chi² test as appropriate.

158 Hazard ratio (HR) of disease risk or death and 95% confidence intervals (CI) across quartiles
159 of PNNS-GS (using the 1st quartile as reference) were estimated using Cox proportional
160 hazards models (Cox, 1972).

161 Graphic methods (log-log (survival) versus log-time plots) were used to check for
162 proportional hazards assumptions for this study. An interaction between PNNS-GS quartiles
163 and gender, intervention group, tobacco status and BMI (<25, 35-30, >30 kg/m²) on the risk
164 of chronic diseases or mortality was tested.

165 Models were controlled for age (continuous), smoking status (never, former, current),
166 education level (primary school, secondary school, high school or equivalent), total energy

167 intake from diet (continuous), BMI (continuous) and daily supplementation (placebo or
168 intervention group) to account for the study design.

169 Analyses among smokers and former smokers were further adjusted on frequency (1-5, 6-10,
170 10-15, 16-20, 21-30, >30 cigarettes per day) and duration of tobacco use (1-5, 6-10, 11-15,
171 16-20, 21-30, >30 years). Among former smokers, time since quitting was also accounted for
172 1-5, 6-10, 11-15, 16-20, 21-30, >30 years).

173 Significance tests were 2-sided, with a type I error set at <0.05. All analyses were performed
174 using SAS software (SAS Institute, version 9).

175 **Results**

176 The present analyses included 5 823 subjects (2 437 men and 3 386 women) from the 12 741
177 subjects initially participating in the SU.VI.MAX study (Fig. 1).

178 At baseline, men and women were aged 51.9 ± 4.7 and 47.0 ± 6.5 years, respectively.

179 During the follow-up period (mean=11.6 years, corresponding to 66 168 person-years), 734
180 major chronic disease endpoints were recorded among 635 subjects: 423 cancers (201 in men
181 and 222 in women), 193 cardiovascular diseases (154 in men and 39 in women) and 118
182 deaths (70 in men and 48 in women).

183 Characteristics of the population are presented across PNNS-GS quartiles (Table 2). Subjects
184 were more often women, older, higher educated and non-smokers with increasing PNNS-GS
185 quartiles. Additionally, they showed lower energy intake, higher energy from proteins and
186 carbohydrates and lower energy from lipids with increasing PNNS-GS quartile overall.

187 After adjustment for age and gender (Table 3), a decrease in risk of CVD across the quartiles
188 of PNNS-GS was observed. In the fully adjusted multivariate model, the hazard risk for CVD
189 of participants in the upper quartile of PNNS-GS compared to those in the lower was 0.65
190 (95%CI=0.42, 1.00, P for trend=0.04). Other outcomes were not associated with the PNNS-
191 GS quartiles.

192 No significant interactions were found between gender or supplementation group and PNNS-
193 GS on the risk of chronic diseases or death ($P>0.30$).

194 However, a significant interaction ($P=0.03$) was observed between tobacco status and PNNS-
195 GS quartiles on the risk of cancer. All other interactions were non-significant. Analyses were
196 therefore separately performed in never-smokers, former smokers and current smokers. No
197 association of PNNS-GS with the risk of cancer was observed among never-smokers (HR Q4
198 versus Q1=0.84, 95%CI =0.55, 1.30) or former smokers (HR Q4 versus Q1=1.19,
199 95%CI=0.74, 1.91). However, in the subgroup of smokers, a higher toward risk of cancer was
200 observed in subjects in the fourth PNNS-GS quartile compared to the first (HR=2.50,
201 CI95%=1.10, 5.68, P for trend=0.02).

202 Discussion

203 In our study, a 35% reduction in the risk of cardiovascular diseases was observed among
204 subjects showing better compliance with French nutritional guidelines. A non-statistically
205 significant trend towards an increase in risk of cancer was observed among smokers only,
206 with a statistically significant interaction between PNNS-GS and smoking status. No
207 relationship was observed in terms of overall mortality and cancer incidence.

208 We should mention several strengths and limitations of our study. First, the generalization of
209 our findings is subject to caution. Indeed, our subjects were volunteers participating in a
210 nutritional intervention study (Herberg *et al.*, 2004) who generally had a higher education
211 level and occupational status, along with a healthier diet, than the general population.
212 Furthermore, selection may have led to an overselected sample, as subjects displaying
213 complete data for PNNS-GS computation may have been particularly compliant and health-
214 conscious. Such a limitation might have led to homogeneity in our population. However, we
215 had previously reported variability in PNNS-GS in the SU.VI.MAX study (Estaquio *et al.*,
216 2009). Second, the absence of an association between PNNS-GS and cancer risk and

217 mortality may have been partly due to a lack of power due to the small sample size, the rather
218 young age of the population or too short a follow-up period, which did not enable detecting an
219 association with such long times process as cancer development or death. Other possible
220 explanations are related to the inclusion process of motivated subjects, who may present
221 overall “healthy” behavior in addition to the cohort effect, leading to a lower incidence of
222 death and/or cancer. Finally, information on frequency, duration and time since stopping of
223 smoking were ordinal, a possible residual confounding from smoking cannot entirely been
224 removed especially in the highest categories.

225 Development of an a priori score for assessing diet via a holistic approach is of crucial
226 importance for taking into account dietary factors when examining the relationship between
227 nutrition and health. Nutritional guideline-based scores are also useful tools for monitoring
228 compliance with nutritional guidelines and evaluating dietary guidelines for disease
229 prevention. Nonetheless, development of a priori indices present some limitations which were
230 recently extensively discussed (Moeller *et al.*, 2007; Waijers *et al.*, 2007). Briefly, not all
231 components of the diet are accounted for, and scoring, cut-off criteria and selection of
232 components are subjective decisions. In addition, the a priori method did not account for the
233 full range of consumption, as components are dichotomized or ordinal. However, as shown in
234 the literature, several of them have proven to be predictive of later disease and mortality,
235 underlying the validity of nutritional recommendations currently disseminated in populations.
236 Despite the fact that it is only rarely accounted for in the literature (Estaquio *et al.*, 2008;
237 Harnack *et al.*, 2002), physical activity may be of particular interest, as a healthy diet and
238 physical activity may act synergistically to enhance chronic disease prevention. However,
239 findings remained stable by removing physical activity of the PNNS-GS (data not shown).
240 When assessed in the same population, the FSIPO was shown to be associated with a 36%
241 lower risk of “major chronic diseases” (including cancer, CVD and death) among men only.

242 Therefore, use of FSIPO or PNNS-GS may lead to different conclusions, probably due to their
243 varying conceptions. First, both FSIPO and PNNS-GS shared some characteristics (fruits and
244 vegetables, physical activity, alcohol), but differed regarding scoring criteria and definitions
245 of indicators. For example, for fruit and vegetables, public health objectives considered that a
246 “low consumer” ate <3.5 servings/day”, while the nutritional advice used as a reference in the
247 PNNS-GS defined it as “at least 5 servings/ day”. In addition, fruits and vegetables weighed
248 higher in the FSIPO than in the PNNS-GS. Second, since the FSIPO was developed with a
249 view toward public health objectives, cardiovascular risk factors such as hypertension,
250 hypercholesterolemia and body mass were accounted for. **Although no statistically significant**
251 **interaction between gender and PNNS-GS was observed on the risk chronic diseases, we**
252 **nonetheless performed these analyses in men and women separately (data not shown).**
253 **Regarding composite variable, no association was found with PNNS-GS whatever the gender.**
254 **This finding strengthens the above-cited hypothesis.** Thus, we hypothesize that the association
255 between chronic diseases and FSIPO was mainly influenced by a stronger reduction in risk of
256 CVD.

257 Few studies have reported a significant predictive value for nutritional guideline-based scores
258 in the risk of overall mortality (Huijbregts *et al.*, 1997; Kaluza *et al.*, 2009; Seymour *et al.*,
259 2003). In our study, the absence of an association may have been due to too short a follow-up
260 (mean=11.6 y) among middle-aged subjects.

261 In agreement with our results, other studies detected an association between adherence to
262 nutritional guidelines (for Americans), assessed using the original HEI, and risk of CVD.
263 Among subjects with a high level of HEI, a significant reduction in CVD risk of 28% in men
264 (McCullough *et al.*, 2000a) and of 14% in women (McCullough *et al.*, 2000b) was observed,
265 but no association was observed for cancer risk in either gender. Subsequent analysis based
266 on an alternate version of the HEI was more accurate than the original HEI at predicting CVD

267 risk but again, no association was observed with cancer risk (McCullough *et al.*, 2002;
268 McCullough *et al.*, 2006).

269 Like most of the studies, we did not find an association with risk of overall cancers (Kaluza
270 *et al.*, 2009; McCullough *et al.*, 2000a; McCullough *et al.*, 2000b; McCullough *et al.*, 2006;
271 Seymour *et al.*, 2003). In contrast, one study on a large cohort (Reedy *et al.*, 2008) observed
272 lower risk of colorectal cancer among men with higher scores (HEI, alternate HEI, RFS), but
273 this was true for women only with higher HEI-2005. Another study carried out among
274 postmenopausal women showed a significant protective effect of an increased Dietary
275 **Guidelines Index Score** upon cancer risk (Harnack *et al.*, 2002), particularly for cancers of the
276 colon, bronchus and lung, breast and uterus.

277 The lack of an association between dietary scores and cancer risk in many studies may be
278 partly related to the fact that cancers are studied overall due to the lack of power when
279 considering site-specific cancers, whereas some nutritional factors may be protective for some
280 sites only. Finally, since certain factors seemed to play particular important role in cancer
281 prevention (American Institute for Cancer Research / World Cancer Research Fund, 2007),
282 the components of scores related to these factors should be carefully considered. Indeed, some
283 food groups such as alcohol, processed meat, fruit and vegetables may weigh more strongly in
284 terms of with cancer risk.

285 An increase in risk was observed among the small subgroup of smokers with the highest
286 PNNS-GS compared to the lowest. Usually, smoking has been frequently associated with a
287 cluster of unhealthy behavior (Kesse-Guyot *et al.*, 2009; McNaughton *et al.*, 2007). No study
288 reported an interaction between the nutritional score and smoking in terms of risk of cancer.
289 Nevertheless, vegetable and fruit consumption was recently related to an increase in risk of
290 colorectal cancer among smokers, while a protective effect was observed among never and
291 former smokers (van Duijnhoven *et al.*, 2009). One observational study (Touvier *et al.*, 2005)

292 and a recent meta-analysis of randomized clinical trials (Druesne-Pecollo *et al.*, 2009)
293 reported association between beta-carotene supplementation and several types of cancers
294 among smokers. Mechanisms based on in vitro studies might explain the harmful effects of
295 beta-carotene in smokers. Beta-carotene may act as a pro-oxidant at high doses, affecting cell
296 proliferation or apoptosis in cells exposed to smoke condensate, or it may increase DNA
297 oxidative damage (Druesne-Pecollo *et al.*, 2009).

298 In conclusion, better adherence to French nutritional guidelines was associated with a lower
299 incidence of CVD after a **maximum** 13-year follow-up period in middle-aged adults. These
300 findings partially argue for the benefits of nutritional guidelines, and similar investigations
301 should be reproduced in other varied populations. Complementary investigations in high-risk
302 subgroups are also needed.

303

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403 Table 1 Components and scoring for calculation of the PNNS-GS, according to PNNS
 404 recommendation scores

	Recommendation	Scoring criteria	Score
Fruits and vegetables	≥5 servings/d	0 to <3.5 servings/d	0
		3.5 to <5 servings/d	0.5
		5 to <7.5 servings/d	1
		≥7.5 servings/d	2
Bread, cereals, potatoes and legumes	At each meal according to appetite	0 to <1 servings/d	0
		1 to <3 servings/d	0.5
		3 to <6 servings/d	1
		≥6 servings/d	0.5
Whole grain food	Preferentially choose whole grains and whole grain breads	0 to <0.33 servings/d ¹	0
		0.33 to <0.66 servings/d ¹	0.5
		≥0.66 servings/d ¹	1
Milk and dairy products (yogurt, cheese, etc.)	3 servings/d (individuals aged ≥ 55 years: 3-4 servings/d)	0 to <1 servings/d	0
		1 to <2.5 servings/d	0.5
		2.5 to 3.5 servings/d (participants aged ≥55y: 2.5 to 4.5 servings/d)	1
		>3.5 (participants aged ≥55y: >4.5 servings/d)	0
Meat and poultry, seafood and eggs	1-2 servings/d	0 servings/d	0
		>0 to <1 servings/d	0.5
		1 to 2 servings/d	1
		>2 servings/d	0
Seafood	≥2 servings/wk	<2 servings/wk	0
		≥2 servings/wk	1
Total added fats²	Limit consumption	Lipids from animal and vegetable added fats >16%EI ³ /d	0
		Lipids from animal and vegetable added fats ≤16%EI ³ /d	1
Vegetable added fats	Favor fats of vegetable origin	No consumption of vegetable oil or ratio vegetable oil/total added fats ≤0.5	0
		No consumption of added fats or ratio vegetable oil/total added fats >0.5	1
Sweetened foods²	Limit consumption	Added sugars from sweetened foods ≥15% EI ³ /d	-0.5

		Added sugars from sweetened foods [10 – 15% EI ³ /d	0
		Added sugars from sweetened foods < 10% EI ³ /d	1
Water and soda ⁴	Drink water as desired;	< 1 L of water and > 250 mL of soda/d	0
	Limit sweetened beverages	≥ 1 L of water and > 250 mL of soda/d	0.50
	to ≤1 one glass/d	< 1 L of water and ≤ 250 mL of soda/d	0.75
		≥ 1 L of water and ≤ 250 mL of soda/d	1
Alcohol ⁵	≤2 glasses of wine/d for	>20 g ethanol/d for women and >30 g ethanol/d for men	0
	women and ≤3 glasses of	Ethanol ≤20 g/d for women and ≤30 g/d for men	0.8
	wine/d for men	Abstainers and irregular consumers (<1 glass of wine/wk)	1
Salt	Limit consumption	>12 g/d	-0.5
		>10 to 12 g/d	0
		>8 to 10 g/d	0.5
		>6 to 8 g/d	1
		≤ 6 g/d	1.5
Physical activity	At least the equivalent of 30 min of brisk walking/d	0 to <30 min/d	0
		30 to <60 min/d	1
		≥ 60 min/d	1.5

405 ¹ As a proportion of 24-h dietary records during which whole-grain consumption was reported

406 ² Established according to the French RDA

407 ³ EI: total energy intake without alcohol

408 ⁴ Water included water, tea, coffee, herbal tea, milk, and diet beverages

409 ⁵ Pregnant women are advised to abstain from all alcohol consumption during the entire pregnancy

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411 Table 2 Baseline characteristic (mean \pm SD or %) of the population across PNNS-GS
 412 quartiles, SU.VI.MAX Study, 1994-2007

	Q1	Q2	Q3	Q4	P ¹
PNNS-GS range	≤ 6.52	$>6.52-\leq 7.75$	$>7.75-\leq 9$	>9	
N	1456	1470	1447	1450	
Male (%)	49.04	42.72	39.32	36.28	<.0001
Age	48.24 \pm 6.16	48.74 \pm 6.16	49.09 \pm 6.32	50.04 \pm 6.47	<.0001
BMI	23.98 \pm 3.85	24.22 \pm 3.82	24.18 \pm 3.66	23.90 \pm 3.39	0.21
<i>Education</i>					
Primary	22.05	20.2	20.53	18.69	0.02
Secondary	38.94	39.8	37.11	39.17	
High	39.01	40.0	42.36	42.14	
<i>Smoking status</i>					
Non-smokers	43.27	47.69	49.76	50.14	<.0001
Former smokers	38.53	37.48	38.91	41.24	
Smokers	18.20	14.83	11.33	8.62	
<i>Intervention group (%)</i>	50.55	51.29	50.73	49.52	0.53
<i>Physical activity²</i>					
[0-30[<i>min/d</i>	82.90	66.33	52.45	27.24	<.0001
[30-60[<i>min/d</i>	10.71	17.76	25.16	30.28	
≥ 60 <i>min/d</i>	6.39	15.92	22.39	42.48	
Energy intake (total) (Kcal/d)	2 440.4 \pm 646.4	2 073.3 \pm 573.7	2 003.0 \pm 532.2	1 922.9 \pm 520.2	<.0001
Energy intake (without alcohol) (Kcal/d)	2 259.0 \pm 595.3	1 944.2 \pm 525.9	1 893.5 \pm 490.8	1 831.0 \pm 481.5	<.0001

Proteins (%) ³	17.52 ± 2.91	17.89 ± 2.96	17.92 ± 2.74	18.19 ± 2.77	<.0001
Carbohydrates (%) ³	41.27 ± 6.35	41.12 ± 6.26	41.85 ± 5.91	42.91 ± 5.82	<.0001
Lipids (%) ³	41.20 ± 5.02	40.97 ± 5.11	40.21 ± 5.05	38.89 ± 5.24	<.0001

Point for each component

(theoretical range), mean ±

sd

Fruits and vegetables [0-2]	0.68 ± 0.59	0.77 ± 0.57	0.93 ± 0.59	1.21 ± 0.64	<.0001
Bread, cereals, potatoes and legumes [0-1]	0.76 ± 0.27	0.74 ± 0.27	0.75 ± 0.27	0.75 ± 0.27	0.14
Whole grain food [0-1]	0.11 ± 0.27	0.14 ± 0.30	0.20 ± 0.35	0.33 ± 0.42	<.0001
Milk and dairy products [0-1]	0.35 ± 0.40	0.46 ± 0.40	0.52 ± 0.40	0.62 ± 0.41	<.0001
Meat and poultry, seafood and eggs [0-1]	0.52 ± 0.47	0.67 ± 0.43	0.74 ± 0.40	0.83 ± 0.33	<.0001
Seafood [0-1]	0.20 ± 0.40	0.28 ± 0.45	0.42 ± 0.49	0.65 ± 0.48	<.0001
Sweetened foods [0-1]	0.70 ± 0.49	0.81 ± 0.41	0.88 ± 0.33	0.94 ± 0.24	<.0001
Total added fats [0-1]	0.65 ± 0.48	0.71 ± 0.45	0.76 ± 0.43	0.83 ± 0.37	<.0001
Vegetable added fats [0-1]	0.41 ± 0.49	0.60 ± 0.49	0.72 ± 0.45	0.86 ± 0.35	<.0001
Water and soda [0-1]	0.86 ± 0.16	0.84 ± 0.13	0.91 ± 0.13	0.89 ± 0.12	<.0001
Alcohol [0-1]	0.60 ± 0.42	0.71 ± 0.36	0.78 ± 0.30	0.85 ± 0.22	<.0001
Salt [-0.5-1.5]	-0.10 ± 0.53	0.18 ± 0.63	0.26 ± 0.63	0.42 ± 0.64	<.0001
Physical activity [0-1.5]	0.20 ± 0.46	0.42 ± 0.60	0.59 ± 0.64	0.94 ± 0.61	<.0001

413 ¹ P Values based on Kruskal-Wallis test or chi-squared test

414 ² Physical activity: as equivalent of 30 min of brisk walking/d

415 ³ Values are percentage of total daily energy intake (without alcohol)

416 Table 3 Hazards ratio (95% CI) of major chronic diseases and PNNS-GS quartiles during the
 417 period 1994-2007

	Q1	Q2	Q3	Q4	P ¹
Composite variable ²					
Number of cases	150	161	162	162	
Age and gender-adjusted	1	1.06	1.03	0.97	0.74
HR		(0.84,1.32)	(0.83,1.29)	(0.77,1.21)	
Fully adjusted HR ³	1	1.05	1.03	0.97	0.77
		(0.84,1.32)	(0.82,1.30)	(0.77,1.24)	
Cancer ⁴					
Number of cases	96	101	113	113	
Age and gender-adjusted	1	1.01	1.09	1.01	0.81
HR		(0.76,1.33)	(0.83,1.43)	(0.77,1.34)	
Fully adjusted HR ³	1	1.05	1.15	1.07	0.54
		(0.79,1.41)	(0.86,1.53)	(0.80,1.44)	
Cardiovascular diseases					
Number of cases	56	53	45	39	
Age and gender-adjusted	1	0.98	0.82	0.68	0.04
HR		(0.68,1.43)	(0.55,1.21)	(0.45,1.03)	
Fully adjusted HR ³	1	0.93	0.78	0.65	0.04
		(0.63,1.36)	(0.52,1.17)	(0.42,1.00)	
Death					
Number of cases	26	33	27	32	
Age and gender-adjusted	1	1.24	0.99	1.11	0.95
HR		(0.73,2.10)	(0.57,1.74)	(0.64,1.93)	

Fully adjusted HR ³	1	1.24	0.99	1.11	0.95
		(0.73,2.10)	(0.57,1.74)	(0.64,1.93)	

418 ¹ Test for trend across quartiles

419 ² Cancer, cardiovascular diseases or death

420 ³ Controlled for gender, age (continuous), BMI (continuous), smoking (never, past, current),
421 total energy intake (continuous), education (primary school, secondary school, high school or
422 equivalent), supplementation group (active versus placebo).

423 ⁴ Cancer included all sites of cancer except basal cell carcinoma of the skin

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425 Figure 1 Flow chart of subjects included in the present analysis, SU.VI.MAX Study 1994-
426 2007.

