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# The role of front-of-pack labeling in making informed and healthy food choices

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# The role of front-of-pack labeling in making informed and healthy food choices

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# Editorial: The role of front-of-pack labeling in making informed and healthy food choices

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Editorial on the Research Topic
The role of front-of-pack labeling in making informed and healthy food choices

Food labeling should help consumers in making informed and possibly healthy food choices. For this reason, the labeling of most prepacked foods sold in Europe reports information that should help consumers to make conscious food choices. This information includes: (i) mandatory particulars listed in the Reg. (EU) n.1169/2011), such as the list of ingredients, the presence of allergens, the date of minimum durability or the "use by" date and the nutrition declarations; (ii) voluntary information, such as nutrition and health claims as defined by the Reg. (CE) n.1924/2006). Moreover, in compliance with Art. 35 of the Reg. (EU) n. 1169/2011, many European countries have developed additional forms of expression and presentation of this information, to be reported in the "front-of-pack" (FOP) with the intention to integrate the nutritional information in the principal field of vision of the food and drink pack.

So far, many FOP schemes have been developed – and in some cases already used - in Europe, including both nutrient-specific labels such as Reference Intake labels and NutrInform battery, and summary indicators like Keyhole and Nutri-Score. Also outside Europe, other FOP schemes have been proposed (e.g., warning label and Health Star Rating System).

More recently, the European strategic program "Farm to Fork" has been released with the intention to reach the consensus for a harmonized FOP label proposal. This has fostered the publication of a large body of literature that aimed to better elucidate the acceptance and understanding to some FOP schemes in various groups of the population, as well as to estimate the impact of FOP on food purchases, food habits and in turn health, and finally to investigate if and how the implementation of a FOP scheme can stimulate food companies to reformulate food products.

Although many publications have explored these aspects in the last years, there is still a strong need for a scientific discussion on this topic to better understand the possible impact of FOP in reducing the burden of obesity and related chronic diseases by helping consumers in making better food choices and in adhering to healthy and sustainable dietary patterns. The aim of this Research Topic was therefore to provide a platform for a scientific debate about FOP labeling.

The manuscript by Khoury et al. prospectively assessed the association between the modified version of the Food Standard Agency Nutrient Profiling System Dietary Index (FSAm-NPS DI) that underpin the Nutri-Score FOP and some risk factors for cardiovascular diseases (CVD). Authors observed that participants with a higher FSAm-NPS DI (i.e., corresponding to a lower quality of their diet), showed a significant increase in the levels of CVD markers such as plasma glucose, triglycerides, diastolic blood pressure, and waist circumference.

Bullón-Vela et al. evaluated the association between the nutrient profile underlying the Chilean warning label score and all-cause mortality, observing that a higher score in the warning label values (i.e., lower nutritional quality), was associated with an increased risk of all-cause mortality and cancer mortality during the 12 years of follow-up.

Martini et al. used three different FOP proposed in the European Union (i.e., Nutri-Score, Keyhole and NutrInform Battery) to compare the nutritional quality of various categories of foods sold on the Italian market, highlighting several critical issues in the ability of some methods to deliver to the consumers the information useful for improving food choices and habits.

Touvier et al. proposed to develop adapted labels able to cover different dimensions potentially affecting the health impact of foods, including the nutritional one (i.e., Nutri-Score), the ultra-processed one (e.g., black band surrounding the Nutri-Score) and the organic dimension by the "organic" logo.

Again, van der Bend et al. described the development and validation process of the Nutri-Score algorithm, suggesting more research on its validity and applicability within the European context.

The work by Saavedra-Garcia et al. investigated changes in marketing strategies (i.e., marketing techniques, health claims, and nutritional claims) on the packaging of foods typically consumed by children before and after the mandatory front-of-package warning label implementation in Peru. Authors found an increase in marketing techniques in "high-in" products, probably used by the industry to reduce the impact of the new FOP on food choices and sales.

Caballero et al. investigated whether eating contexts influence how the mandatory nutrient warning labels in Chile, affect the decision process and selection during food choice. Researches show a rise in the efficacy of this label to improve healthy food choices in a healthy eating context (i.e., when participants were instructed to select the food that they would eat to stay healthy), but not in other eating contexts.

Liao and Yang studied the knowledge, attitude and practice on nutrition labeling in the Chinese population. Authors found a positive attitude toward nutrition labeling in most people, although the awareness and utilization rates were very low. This suggests that the knowledge of nutrition labeling does not directly support the practice.

Finally, Lee et al. examined the diet quality of Canadian adults using a dietary index system aligned with the Canadian FOP regulations compared with other front-of-pack labeling systems and dietary guidelines. Authors observed that the Canadian FOP rates the dietary quality of Canadian adults to be healthier than other systems, however a moderate-to-low agreement with other systems (e.g., Nutri-score, Dietary Approaches to Stop Hypertension and Canada's Food Guide) was found.

The Topic Editors thank all the authors contributing to the Research Topic, with the hope that it will foster ascientific discussion on the FOP useful to better understand how FOP labeling can help consumers to make conscious food choices and the food industry to provide scientifically correct and nutritionally balanced choices to the consumer.

## Author contributions

DM wrote the first draft of the manuscript. MS and JS-S finalize the manuscript. All authors contributed to the article and approved the submitted version.

## Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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# Associations Between the Modified Food Standard Agency Nutrient Profiling System Dietary Index and Cardiovascular Risk Factors in an Elderly Population

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**Background:** Helping consumers to improve the nutritional quality of their diet is a key public health action to prevent cardiovascular diseases (CVDs). The modified version of the Food Standard Agency Nutrient Profiling System Dietary Index (FSAm-NPS DI) underpinning the Nutri-Score front-of-pack label has been used in public health strategies to address the deleterious consequences of poor diets. This study aimed to assess the association between the FSAm-NPS DI and some CVD risk factors including body mass index (BMI), waist circumference, plasma glucose levels, triglyceride levels, high-density lipoprotein (HDL) and low-density lipoprotein (LDL) cholesterol, and diastolic and systolic blood pressure.

**Materials and Methods:** Dietary intake was assessed at baseline and after 1 year of follow-up using a 143-item validated semi-quantitative food-frequency questionnaire. Dietary indices based on FSAm-NPS applied at an individual level were computed to characterize the diet quality of 5,921 participants aged 55–75 years with overweight/obesity and metabolic syndrome from the PREDIMED-plus cohort. Associations between the FSAm-NPS DI and CVD risk factors were assessed using linear regression models.

**Results:** Compared to participants with a higher nutritional quality of diet (measured by a lower FSAm-NPS DI at baseline or a decrease in FSAm-NPS DI after 1 year), those participants with a lower nutritional quality of diet (higher FSAm-NPS DI or an increase in score) showed a significant increase in the levels of plasma glucose, triglycerides, diastolic blood pressure, BMI, and waist circumference (β coefficient [95% confidence interval]; *P* for trend) (1.67 [0.43, 2.90]; $<$0.001; 6.27 [2.46, 10.09]; $<$0.001; 0.56 [0.08, 1.05]; 0.001; 0.51 [0.41, 0.60]; $<$0.001; 1.19 [0.89, 1.50]; $<$0.001, respectively). No significant associations in relation to changes in HDL and LDL-cholesterol nor with systolic blood pressure were shown.

**Conclusion:** This prospective cohort study suggests that the consumption of food items with a higher FSAm-NPS DI is associated with increased levels of several major risk factors for CVD including adiposity, fasting plasma glucose, triglycerides, and diastolic blood pressure. However, results must be cautiously interpreted because no significant prospective associations were identified for critical CVD risk factors, such as HDL and LDL-cholesterol, and systolic blood pressure.

**Keywords: front of pack food labeling, cardiovascular risk factor, body weight, FSAm-NPS dietary index, PREDIMED-Plus study**

## INTRODUCTION

Cardiovascular disease (CVD) is the leading cause of mortality and is considered a major global public health problem (1, 2). According to the estimation in 2019, CVD burden was found to be responsible for 17.9 million deaths worldwide, accounting for approximately 32% of all global deaths, representing a huge economic and social cost (3).

A healthy diet is recognized as a lever for public health by using a modifiable determinant of CVD and other chronic diseases that can be addressed through primary prevention interventions (4). In contrast, an unhealthy diet characterized by an excess of energy, added sugar, salt and saturated fats, and a lack of fruits, vegetables, and fibers has been recognized as an important causal CVD risk factor through the modulation of adiposity and other cardiometabolic risk factors (5).

Over the past decade, different strategies have been proposed to increase adherence to a healthy diet and reduce the risk of CVD. One of the recent initiatives in this regard is the adoption of front-of-pack (FOP) nutrition labels (6). Although labels on the back of the pack are already mandatory in all European countries according to RE 1169/2011 (7), there is evidence that this information is not easily understandable by consumers. In contrast, nutrition labels found on the front of pack of products are considered more helpful and efficient for consumers since nutritional information is summarized and available at a glance (8, 9). FOP labeling aims to help consumers make healthier choices at the point of purchase and to incentivize food manufacturers to reduce the content of nutrients that might compromise diet quality (e.g., salt, saturated fatty acids, and sugar) and/or increase the content of beneficial nutrients (e.g., fibers and vitamins) (10, 11).

Front-of-pack nutrition labels reflect the nutritional quality of food using a nutrient profiling system (NPS) (12). Nutrient profiling is widely used to support public health initiatives to promote healthy eating (12). Among the available nutrient profiling systems, the NPS developed by the UK Food Standard Agency (FSA-NPS) has been consistently validated in Europe (13). This system was originally developed to discriminate foods based on their nutritional composition in the context of television commercials targeting children (14). In France, after some modifications of the FSA-NPS by the French High Council for Public Health (Haut Conseil de la Santé Publique, HCSP) and demonstrating its applicability within the French context, the modified FSA-NPS (FSAm-NPS) was established and a dietary index (DI) based on the FSAm-NPS (FSAm-NPS DI) was developed to validate the algorithm underlying the Nutri-Score FOP label (15, 16). The score for a given food or beverage is calculated by allocating points for the content per 100 g or 100 ml. This algorithm considers both positive scoring components (protein, fiber, percentage of fruit, vegetables, legumes, nuts, rapeseed oil, walnut oil, and olive oil) and negative components (energy, sugars, saturated fatty acids, and salt) (17), and has been proved effective to rank products by nutritional quality and improve food purchases in real-life grocery shopping settings (18).

In addition, several large European prospective studies have shown associations between a higher FSAm-NPS (lower nutritional quality) and an increased risk of cancer (19), CVD (20), cancer mortality (21), CVD mortality (22), and all-cause mortality (23). In contrast, a lower FSAm-NPS (better nutritional quality) has been associated with a lower risk of long-term weight gain and metabolic syndrome incidence in the SU.VI.MAX French cohort study (24, 25). However, there is less information available about the association between the FSAm-NPS DI and CVD risk factors. The aim of this study was to evaluate the association between the FSAm-NPS DI and different CVD risk factors including body mass index (BMI), waist circumference, glucose, triglycerides, HDL- and LDL-cholesterol levels, as well as diastolic and systolic blood pressure in elderly adults with overweight/obesity and metabolic syndrome.

# MATERIALS AND METHODS

## Study Population and Design: The PREDIMED Plus Study

A prospective analysis was conducted using the data of the PREDIMED-Plus (PREvención con DIeta MEDiterránea) cohort. The PREDIMED-Plus trial is an ongoing randomized, controlled trial conducted in 23 Spanish centers that aims to compare the effect of an intensive weight loss intervention (based on an energy-reduced Mediterranean diet, physical activity promotion, and behavioral support) on the incidence of CVD events, to a control group that receives usual care advice and non-caloric reduced Mediterranean diet recommendations. A detailed description of the PREDIMED-Plus study is available at https://www.predimedplus.com. Between October 2013 and December 2016, 6,874 participants were recruited in Spain and were randomly assigned to either an intensive lifestyle intervention or standard medical care in a 1:1 ratio. Eligible participants were overweight or obese (BMI 27–40 kg/m$^2$) men and women aged 55–75 years who met at least three metabolic syndrome criteria as follows: waist circumference $>$ 102 cm in men and $>$88 cm in women; serum triglycerides $\geq$ 150 mg/dl or drug treatment for elevated triglycerides; HDL-c $<$ 40 mg/dl in men and $<$50 mg/dl in women or drug treatment for low HDL-cholesterol; blood pressure $\geq$ 130/85 mmHg or antihypertensive drug treatment; and fasting plasma glucose level $\geq$ 100 mg/dl or hypoglycemic treatment and without documented history of CVD. Extensive descriptions of inclusion and exclusion criteria can be found elsewhere (26). All subjects gave written informed consent, and the final protocol and methods were approved by the institutional review boards of each participating center. A total of 953 participants who did not complete a food frequency questionnaire (FFQ) at baseline and after 1 year of follow-up or with total calorie intake outside the pre-specified energy limits (women $<$ 500 and $>$3,500 kcal/day, and men $<$ 800 and $>$4,000 kcal/day) were excluded from the analyses (27) **Figure 1**.

## Dietary Intake Assessment

Dietary intake was assessed at baseline and after 1 year of follow-up using a validated FFQ administered face-to-face by trained dietitians (27). The participants reported their average consumption in terms of frequency and quantity for 143 food and beverage items during the previous year. The frequency of consumption was shown through nine categories ranging from never or almost never to more than six times a day, and a commonly used portion size was specified (e.g., slices, glass, and teaspoons) to indicate serving sizes for each of the items.

The nutrient intake was calculated as the sum of the frequency of daily consumption of each item multiplied by the nutrient composition of the specified serving size according to the Spanish food composition database (28). The total energy intake was

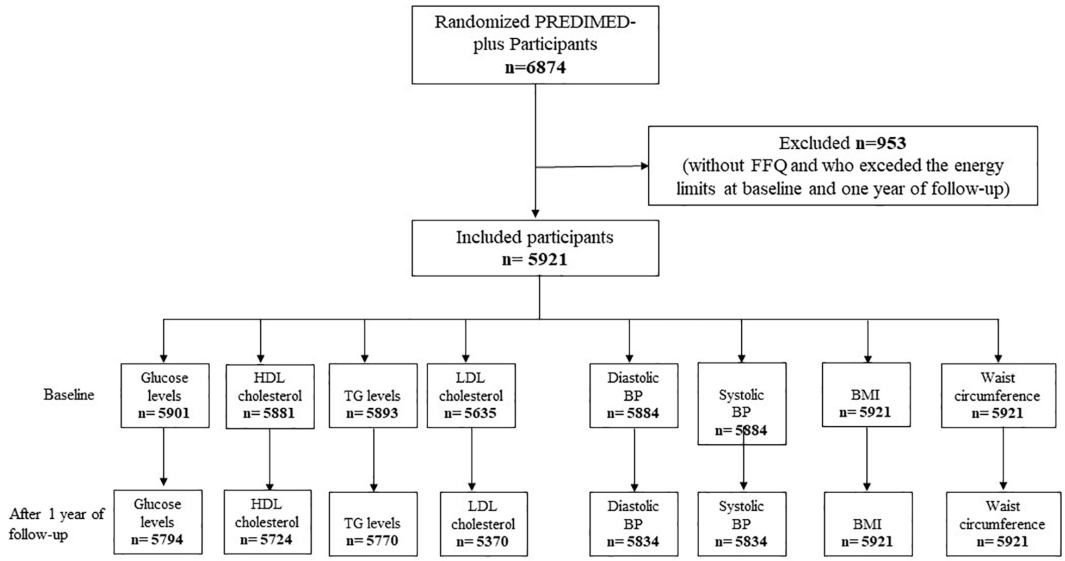


**FIGURE 1 |** Flow chart of participant's inclusion.

also estimated from the quantity and frequency of food and beverage consumption.

## Dietary Index Based on the French Context, the Modified FSA-NPS Computation

The FSAm-NPS is a modified version of the original FSA-NPS (29). Modifications made by the French National Nutrition and Health Program and the French High Council for Public Health impacted the score standards for cheese, added fats, and beverages. For all foods and beverages in the PREDIMED-plus FFQ, the FSAm-NPS was computed per 100 g of the product as follows: 0–40 points was given for the content of critical nutrients that should be limited (0–10 points for each: sugars, saturated fats, sodium, and energy), and 0–15 points was given for the content of beneficial nutrients that should be encouraged (0–5 points for each: fibers, proteins, and the percentage of fruits, vegetables, legumes, nuts, rapeseeds, walnuts, and olive oil that make up the total product). The total score was calculated by subtracting the "negative" (nutrients to avoid) scores from the "positive" (nutrients to promote) scores. As a result, the final FSAm-NPS for each food/beverage was calculated using a discrete continuous scale with a theoretical range of −15 (healthiest) to 40 (least healthy). To generate a dietary index at the individual level, the FSAm-NPS DI was calculated for each participant accounting for their whole diet through energy-weighted means of the FSAm-NPS of all foods and beverages consumed with the following equation:

$$\text{Dietary Index} = \frac{\sum_{i=1}^{n} FSiEi}{\sum_{i=1}^{n} Ei} \quad (1)$$

*where "i" signifies a food or beverage consumed by the participant, "FSi" the food (or beverage) score, "Ei", the mean daily energy intake from this food (or beverage), and "n" the number of different foods.*

Therefore, a higher FSAm-NPS-DI reflects lower nutritional quality of the individual's overall diet.

## Outcome (Cardiovascular Diseases Risk Factors) Assessment at Baseline and After 1 Year of Follow-Up

Qualified PREDIMED-Plus staff followed the study protocol to measure anthropometric variables and blood pressure. CVD risk factors such as glucose levels, triglyceride levels, HDL-cholesterol, LDL-cholesterol, diastolic and systolic blood pressure, BMI, and waist circumference were assessed at baseline and after 1 year of follow-up.

### Waist Circumference

It was measured midway between the lowest rib and the iliac crest using an anthropometric tape, and body weight was measured twice using high-quality electronic calibrated scales and height was measured twice using a wall-mounted stadiometer.

### Body Mass Index

It was computed by dividing the weight in kilograms by the square of height in meters.

### Systolic and Diastolic Blood Pressure

They were measured three times using a validated semiautomatic oscillometer (Omron HEM-705CP, Kyoto, Japan) and the mean of repeated measures was used.

### Fasting Plasma Levels of Glucose, Total Cholesterol, High-Density Lipoprotein-Cholesterol, and Triglycerides

They were measured using standard enzymatic methods. LDL-cholesterol was calculated using the Friedewald formula (whenever triglycerides were less than 300 mg/dl and whenever triglycerides were more than 300 mg/dl, LDL-cholesterol was calculated with the standard method).

## Assessment of Covariates

Covariates were assessed by trained staff in a face-to face interview using self-reported general questionnaires that collect information on socio-demographics (sex, age, marital status, and level of education), lifestyle (smoking habits and physical activity), and medication use. Leisure time physical activity was estimated using the validated Minnesota-REGICOR Short Physical Activity questionnaire (30).

## Statistical Analyses

For our analyses, we used the PREDIMED-Plus database updated in December 2020. Analysis of descriptive baseline characteristics of sociodemographic, dietary, and biomedical variables was carried out and reported as means ± SD or median [P25–P75] and percentages (number) for continuous and categorical variables, respectively.

Participants were categorized by tertiles of the FSAm-NPS DI, ranging from tertile 1 (T1) for the best nutritional quality to tertile 3 (T3) for the lowest nutritional quality. The Chi-square test for categorical variables and one-way ANOVA for continuous variables were used to compare the baseline characteristics between the tertiles.

Linear regression models were fitted to assess the associations [β-coefficient (95% confidence interval (CI)] between FSAm-NPS DI (in tertiles and as continuous variables) and CVD risk factors at baseline. We also used linear regression models to explore the prospective associations between changes in the FSAm-NPS DI (in tertiles and as continuous variable) and changes in CVD risk factors after 1 year of follow-up. Changes in the FSAm-NPS-DI were calculated by subtracting 1 year from the baseline values. Missing data after 1 year of follow-up for BMI (four participants) and diastolic BP (one participant) were imputed using the mean value method.

Three models were fitted as follows: crude model, model 1, and the fully adjusted model. Model 1 was adjusted for age (years), sex, BMI (kg/m$^2$), educational level (primary or lower, secondary or academic, or graduate), smoking habit (never, former, or current), total energy consumption (kcal/day), physical activity (METs. min/week), and marital status (married, widowed, single or divorced or separated, or religious). The fully adjusted model was further adjusted for medication for the treatment of hypercholesterolemia, hypertension and diabetes, size of the recruitment centers (<250, 250 to <300, 300 to <400, ≥400), and intervention group. In the prospective analysis, each CVD risk factor was adjusted for its baseline level (in model 1 and fully adjusted).

To indirectly assess the effect of olive oil on the associations with cardiovascular risk factors, we conducted a sensitivity analysis where olive oil was valued −8 (the healthiest value in the score, such as for fruits, vegetables, or legumes) in the computation of the FSAm-NPS-DI.

The statistical significance threshold for the results was set at $p < 0.05$. All analyses were conducted with robust estimates of the variance to correct for intra-cluster correlation and using the Stata 14 software program (StataCorp).

# RESULTS

A total of 5,921 participants (52% men and 48% women, with the mean age of 65 years) were included in this study. Baseline characteristics of the participants overall and according to the tertiles of the FSAm-NPS are shown in **Table 1**. Participants with a higher FSAm-NPS DI were more likely to be men of younger age, to have a higher level of education, to smoke, to be less physically active, and to have a higher alcohol intake. As expected, participants with a lower FSAm-NPS DI, reflecting a higher nutritional quality (Tertile 1), consumed higher amounts of vegetables, fruits, legumes, unrefined cereals, dairy products, white meat, fish and shellfish, nuts, and fiber. In contrast, participants with a higher FSAm-NPS DI (Tertile 2 and 3), reflecting a lower nutritional quality, consumed higher amounts of refined cereals, biscuits, red meat and processed meat, olive oil, alcohol, and sugar, and showed higher intakes of total energy and saturated fat. In relation to biochemical parameters, the participants in the higher tertile of the FSAm-NPS DI showed higher serum concentrations of triglycerides and LDL-cholesterol and lower levels of HDL-cholesterol (**Table 1**).

The cross-sectional association between the FSAm-NPS DI and CVD risk factors at baseline is shown in **Table 2**. Compared to those participants with a lower FSAm-NPS DI (T1) reflecting a healthier diet, those with a higher FSAm-NPS DI (T3) showed lower HDL-cholesterol levels (β: −0.77 [95% CI = −1.47, −0.06]; *P* for trend = 0.027). This association was consistent for the HDL-cholesterol and FSAm-NPS DI as a continuous variable (β: −0.21 [95% CI = −0.37, −0.05]). A direct association was observed between the FSAm-NPS DI as continuous and baseline BMI and waist circumference (β: 0.08 [95% CI = 0.03, 0.13] and β: 0.22 [95% CI = 0.09, 0.35], respectively).

Associations between 1 year changes in the FSAm-NPS DI and changes in the CVD risk factors are shown in **Table 3**. Compared to participants with a score change resulting in a lower FSAm-NPS DI (T1), those participants with a higher FSAm-NPS DI (T3) after 1 year of follow-up showed a significant increase in the levels of plasma glucose, triglycerides, diastolic blood pressure, BMI, and waist circumference (β: 1.67 [95% CI = 0.43, 2.90]; *P* for trend < 0.001; β: 6.27 [95% CI = 2.46, 10.09]; *P* for trend < 0.001; β: 0.56 [95% CI = 0.08, 1.05]; *P* for trend = 0.001; β: 0.51 [95% CI = 0.41, 0.60]; *P* for trend < 0.001; β: 1.19 [CI = 0.89, 1.50]; *P* for trend < 0.001, respectively).

In **Figure 2**, we present the β coefficient (95% CI) for the prospective associations between changes in the FSAm/NPS DI (continuous) and changes in the CVD risk factors after 1 year of follow-up. Consistent with the results described

**TABLE 1 |** Baseline characteristics of participants overall and by tertiles of FSAm-NPS DI score, PREDIMED-plus study.

| | All | Tertiles of the FSAm-NPS DI | | | |
|---|---|---|---|---|---|
| | ***n* = 5,921** | **T1 Higher quality *n* = 1,974** | **T2 Moderate quality *n* = 1,974** | **T3 Lower quality *n* = 1,973** | ***P*-value** |
| FSAm-NPS DI range | 1.51–16.6 | 1.51–7.37 | 7.38–8.87 | 8.88–16.6 | <0.001 |
| **Sex** | | | | | |
| Men | 51.7 (3,065) | 44.0 (869) | 51.3 (1,012) | 60.0 (1,184) | <0.001 |
| Women | 48.3 (2,856) | 56 (1,105) | 48.7 (962) | 40.0 (789) | |
| Age (years) | 65.0 ± 4.89 | 65.6 ± 4.78 | 65 ± 4.87 | 64.5 ± 4.95 | <0.001 |
| **Marital status** | | | | | |
| Married | 76.8 (4,545) | 74.7 (1,475) | 77 (1,518) | 78.7 (1,552) | 0.005 |
| Widowed | 10.4 (616) | 12.5 (245) | 10.4 (206) | 8.36 (165) | |
| Single/divorced/separated/Religious | 12.5 (741) | 12.6 (249) | 12.3 (242) | 12.7 (250) | |
| **Educational level** | | | | | |
| Up to primary | 49.7 (2,942) | 54.1 (1,066) | 50 (986) | 45.1 (890) | <0.001 |
| Secondary | 28.7 (1,701) | 27 (531) | 28.2 (557) | 31.1 (613) | |
| University | 21.6 (1,278) | 19.1 (377) | 21.8 (431) | 23.9 (470) | |
| **Smoking status** | | | | | |
| Never | 44.7 (2,646) | 50.7 (1,000) | 44.4 (877) | 40 (769) | <0.001 |
| Current | 12.4 (734) | 9.02 (178) | 13.2 (260) | 15.0 (296) | |
| Former | 42.9 (2,541) | 40.3 (796) | 42.4 (837) | 46.0 (908) | |
| Physical activity (MET min/week) | 2,508 ± 2,322 | 2,648 ± 2,408 | 2,469 ± 2,207 | 2,411 ± 2,342 | 0.045 |
| **Waist circumference (cm)** | | | | | |
| Men | 111 ± 8.72 | 110 ± 8.6 | 111 ± 8.4 | 111 ± 9.0 | 0.201 |
| Women | 104 ± 9.2 | 103 ± 9.2 | 104 ± 9.1 | 104 ± 9.1 | 0.12 |
| BMI (kg/m$^2$) | 32.4 ± 3.44 | 32.4 ± 3.43 | 32.5 ± 3.41 | 32.5 ± 3.46 | 0.376 |
| **Dietary assessment** | | | | | |
| Vegetables (g/day) | 329 ± 137 | 372 ± 147 | 331 ± 129 | 283 ± 120 | <0.001 |
| Fruits (g/day) | 359 ± 205 | 419 ± 226 | 361 ± 194 | 298 ± 171 | <0.001 |
| Legumes (g/day) | 20.6 ± 11.0 | 22.8 ± 12.3 | 20.5 ± 10.9 | 18.3 ± 9.21 | <0.001 |
| Total cereals (g/day) | 151 ± 78 | 148 ± 79 | 155 ± 79 | 149 ± 76 | 0.006 |
| Refined cereals (g/day) | 110 ± 87.8 | 104 ± 91.0 | 112 ± 88.7 | 112 ± 83.3 | 0.001 |
| Unrefined cereals (g/day) | 41.1 ± 63.4 | 43.88 ± 60.97 | 42.7 ± 66.3 | 36.6 ± 62.6 | 0.001 |
| Biscuits (g/day) | 26.8 ± 29.7 | 13.3 ± 15.1 | 23.6 ± 21 | 43.5 ± 38.8 | <0.001 |
| Dairy products (g/day) | 344 ± 200 | 385 ± 217 | 334 ± 189 | 314 ± 187 | <0.001 |
| Red meat and derivatives (g/day) | 82.3 ± 44.8 | 76.93 ± 43.57 | 83.1 ± 43.46 | 86.9 ± 46.8 | <0.001 |
| White meat intake (g/day) | 62 ± 34 | 67.7 ± 36.3 | 62.6 ± 33.5 | 55.4 ± 31.2 | <0.001 |
| Fish and shellfish intake (g/day) | 102 ± 47.4 | 113 ± 50.6 | 102 ± 44.8 | 91.4 ± 43.9 | <0.001 |
| Nuts intake (g/day) | 15 ± 17 | 21.2 ± 21.6 | 14 ± 14.4 | 9.99 ± 11.4 | <0.001 |
| Total olive oil (g/day) | 40.1 ± 16.8 | 33.4 ± 15.2 | 42.3 ± 15.6 | 44.7 ± 17.2 | <0.001 |
| Refined olive oil (g/day) | 8.15 ± 15.1 | 6.22 ± 12.1 | 7.96 ± 15.1 | 10.3 ± 17.4 | <0.001 |
| Virgin olive oil (g/day) | 31.9 ± 20.7 | 27.2 ± 18.2 | 34.3 ± 20.6 | 34.4 ± 22.2 | <0.001 |
| Alcohol (g/day) | 11.2 ± 15.1 | 8.92 ± 13.42 | 10.9 ± 14.3 | 13.7 ± 17 | <0.001 |
| Dietary fiber intake (g/day) | 26.1 ± 8.72 | 28.7 ± 8.94 | 26.2 ± 8.53 | 23.5 ± 7.88 | <0.001 |
| Ultra-processed food (g/day) | 158 ± 158 | 107 ± 117 | 148 ± 137 | 218 ± 186 | <0.001 |
| Total sugar intake (g/day) | 6.73 ± 12 | 4.32 ± 8.76 | 6.67 ± 11.7 | 9.21 ± 14.3 | <0.001 |
| Total energy (kcal/day) | 2,367 ± 550 | 2,207 ± 519 | 2,363 ± 521 | 2,531 ± 560 | <0.001 |
| Saturated fat intake (g/day) | 26.2 ± 8.45 | 22.2 ± 6.83 | 26.0 ± 7.30 | 30.5 ± 8.93 | <0.001 |
| Sodium intake (mg/day) | 2,426 ± 773 | 2,340 ± 770 | 2,427 ± 756 | 2,509 ± 784 | <0.001 |
| **Biomedical parameters** | | | | | |
| Glucose levels, mg/dL (*n* ± 5,901) | 113 ± 29 | 114 ± 30.2 | 113 ± 28.7 | 113 ± 27.9 | 0.28 |
| TG levels, mg/dL (*n* ± 5,893) | 135 [102–178] | 136 [102–177] | 133 [100–179] | 137 [106–178] | 0.011 |
| HDL-cholesterol, mg/dL (*n* ± 5,881) | 47 [40–55] | 48 [41–56] | 47 [41–55] | 45 [39–53] | <0.001 |
| LDL-cholesterol, mg/dL (*n* ± 5,635) | 117 [96–140] | 115 [94–140] | 118 [97–140] | 118 [98–141] | 0.028 |
| Systolic BP, mmHg (*n* ± 5,884) | 139 ± 16.9 | 139 ± 16.9 | 140 ± 17.24 | 140 ± 16.45 | 0.119 |
| Diastolic BP, mmHg (*n* ± 5,884) | 80.7 ± 9.88 | 80.4 ± 9.49 | 80.8 ± 10.14 | 82 ± 10 | 0.209 |

*FSAm-NPS, Food Standards Agency Nutrient Profiling System (modified version) Dietary Index; BMI, body mass index; TG, triglycerides; HDL, high-density lipoprotein; LDL, low-density lipoprotein; BP, blood pressure. Data were expressed as means ± SD or median [P25–P75] and percentages (number) for continuous and categorical variables, respectively. P-values for comparisons were tested by the one-way ANOVA or chi-square test, as appropriate according to the FSAm-NPS tertiles.*

**TABLE 2 |** Association between FSAm-NPS DI and CVD risk factors at baseline, and β coefficient (95% CI).

| | Tertiles of the FSAm-NPS DI | | | R-squared | *P*-trend | FSAm-NPS DI at baseline (continuous) |
|---|---|---|---|---|---|---|
| | T1 | T2 | T3 | | | |
| **Glucose levels (mg/dL)** | | | | | | |
| *n* | 1,967 | 1,967 | 1,967 | 0.04 | 0.177 | 5,901 |
| Crude Model | *Ref* | −1.31 (−3.14, 0.53) | −1.25 (−3.07, 0.57) | 1.84 | 0.059 | −0.21 (−0.63, 0.20) |
| Model 1 | *Ref* | −1.57 (−3.40, 0.27) | −1.80 (−3.68, 0.07) | 30.5 | 0.832 | −0.36 (−0.79, 0.07) |
| Fully adjusted | *Ref* | −0.24 (−1.80, 1.32) | 0.16 (−1.41, 1.73) | | | 0.11 (−0.25, 0.47) |
| **HDL-cholesterol (mg/dL)** | | | | | | |
| *n* | 1,961 | 1,960 | 1,960 | 0.5 | <0.001 | 5,897 |
| Crude Model | *Ref* | −0.52 (−1.25, 0.22) | −1.98 (−2.73, −1.24) | 15.4 | 0.128 | −0.49 (−0.66, −0.33) |
| Model 1 | *Ref* | 0.19 (−0.49, 0.88) | −0.52 (−1.24, 0.19) | 0.17 | 0.027 | −0.15 (−0.31, 0.01) |
| Fully adjusted | *Ref* | −0.01 (−0.69, 0.67) | −0.77 (−1.47, −0.06) | | | −0.21 (−0.37, −0.05) |
| **TG levels (mg/dL)** | | | | | | |
| *n* | 1,965 | 1,964 | 1,964 | 0.15 | 0.004 | 5,893 |
| Crude Model | *Ref* | 1.89 (−2.77, 6.55) | 7.15 (2.35, 11.95) | 2.88 | 0.387 | 1.46 (0.44, 2.49) |
| Model 1 | *Ref* | −0.94 (−5.62, 3.74) | 1.96 (−2.97, 6.89) | 3.35 | 0.238 | 0.19 (−0.89, 1.26) |
| Fully adjusted | *Ref* | −0.36 (−5.04, 4.31) | 2.75 (−2.18, 7.68) | | | 0.36 (−0.72, 1.44) |
| **LDL-cholesterol (mg/dL)** | | | | | | |
| *n* | 1,879 | 1,878 | 1,878 | 0.12 | 0.027 | 5,635 |
| Crude Model | *Ref* | 2.53 (0.45, 4.61) | 2.33 (0.26, 4.39) | 4.04 | <0.001 | 0.44 (−0.01, 0.89) |
| Model | *Ref* | 3.12 (1.06, 5.17) | 3.66 (1.57, 5.75) | 26 | 0.052 | 0.75 (0.29, 1.22) |
| Fully adjusted | *Ref* | 1.59 (−0.23, 3.41) | 1.76 (−0.05, 3.57) | | | 0.35 (−0.05, 0.75) |
| **Diastolic BP (mmHg)** | | | | | | |
| *n* | 1,962 | 1,961 | 1,961 | 0.05 | 0.076 | 5,884 |
| Crude Model | *Ref* | 0.39 (−0.23, 1.01) | 0.55 (−0.06, 1.16) | 6.52 | 0.18 | 0.16 (0.02, 0.30) |
| Model 1 | *Ref* | −0.06 (−0.67, 0.55) | −0.41 (−1.02, 0.20) | 7.58 | 0.063 | −0.08 (−0.22, 0.06) |
| Fully adjusted | *Ref* | −0.14 (−0.75, 0.47) | −0.57 (−1.18, 0.04) | | | −0.11 (−0.25, 0.03) |
| **Systolic BP (mmHg)** | | | | | | |
| *n* | 1,962 | 1,961 | 1,961 | 0.07 | 0.059 | 5,884 |
| Crude Model | *Ref* | 0.87 (−0.20, 1.95) | 1.01 (−0.04, 2.06) | 3.36 | 0.159 | 0.18 (−0.05, 0.42) |
| Model 1 | *Ref* | 0.83 (−0.24, 1.90) | 0.79 (−0.28, 1.87) | 5.29 | 0.201 | 0.12 (−0.13, 0.36) |
| Fully adjusted | *Ref* | 0.50 (−0.56, 1.56) | 0.72 (−0.35, 1.78) | | | 0.10 (−0.15, 0.34) |
| **BMI (kg/m$^2$)** | | | | | | |
| *n* | 1,974 | 1,974 | 1,973 | 0.03 | 0.17 | 5,921 |
| Crude Model | *Ref* | 0.10 (−0.12, 0.31) | 0.15 (−0.07, 0.37) | 3.18 | 0.063 | 0.06 (0.01, 0.11) |
| Model 1 | *Ref* | 0.12 (−0.09, 0.33) | 0.22 (−0.01, 0.44) | 4.27 | 0.054 | 0.08 (0.03, 0.13) |
| Fully adjusted | *Ref* | 0.13 (−0.08, 0.34) | 0.22 (0.00, 0.44) | | | 0.08 (0.03, 0.13) |
| **Waist circumference (cm)** | | | | | | |
| *n* | 1,979 | 1,979 | 1,979 | 0.06 | <0.001 | 5,921 |
| Crude Model | *Ref* | 0.70 (0.10, 1.29) | 1.87 (1.27, 2.47) | 65.4 | 0.803 | 0.51 (0.38, 0.65) |
| Model 1 | *Ref* | −0.21 (−0.57, 0.15) | 0.04 (−0.32, 0.41) | 17 | 0.381 | 0.03 (−0.05, 0.11) |
| Fully adjusted | *Ref* | 0.12 (−0.44, 0.67) | 0.60 (0.03, 1.18) | | | 0.22 (0.09, 0.35) |

*FSAm-NPS, Food Standards Agency Nutrient Profiling System (modified version) Dietary Index; CVD, cardiovascular disease; CI, confidence interval; HDL, high-density lipoprotein; TG, triglycerides; LDL, low-density lipoprotein; BP, blood pressure; BMI, body mass index. Linear regression models were fitted. Model 1: adjusted for age, sex, physical activity, smoking status, BMI, total energy intake at baseline, education level, and marital status. Fully adjusted: Model 1 additionally adjusted for medication for treatment of hypercholesterolemia, of hypertension and of diabetes and size of the recruitment centers (<250, 250 to <300, 300 to <400, ≥400). All analyses were conducted with robust estimates of the variance to correct for intra-cluster correlation. R-squared was multiplied by 100.*

above, positive associations were found between changes in the FSAm-NPS DI and changes in the glucose and triglyceride levels, diastolic blood pressure, BMI, and waist circumference after 1 year of follow-up. Non-significant association was observed in the case of HDL-cholesterol, LDL-cholesterol, and systolic blood pressure changes. Nevertheless, after 1 year of follow-up, 79.36 and 19.4% of the population remained in the recommended levels of HDL and LDL-cholesterol, 12.82 and 8.9% of the participants showed increased levels, and only 7.82 and 10.9% of the participants showed a decrease in HDL-cholesterol or LDL-cholesterol, respectively (data not shown).

The cross-sectional and longitudinal associations remained significant when olive oil was considered the healthiest food option in the computation of the FSAm-NPS DI (data not shown).

**TABLE 3 |** Association between 1-year change of FSAm-NPS and changes of the CVD risk factors levels after 1 year of follow-up, and β coefficient (95% CI).

| | Tertiles of one-year FSAm-NPS DI change | | | R-squared | *P*-trend | FSAm-NPS DI one-year change (continuous) |
|---|---|---|---|---|---|---|
| | T1 | T2 | T3 | | | |
| **Glucose levels change (mg/dL)** | | | | | | |
| *n* | 1,932 | 1,931 | 1,931 | 0.27 | <0.001 | 5,794 |
| Crude Model | Ref | 2.51 (1.17, 3.86) | 2.47 (1.06, 3.88) | 18.4 | <0.001 | 0.50 (0.20, 0.81) |
| Model 1 | Ref | 2.06 (0.82, 3.31) | 2.56 (1.29, 3.83) | 23.3 | <0.001 | 0.42 (0.14, 0.70) |
| Fully adjusted | Ref | 1.76 (0.54, 2.98) | 1.67 (0.43, 2.90) | | | 0.35 (0.09, 0.62) |
| **HDL-cholesterol change (mg/dL)** | | | | | | |
| *n* | 1,908 | 1,908 | 1,908 | 0.1 | 0.021 | 5,724 |
| Crude Model | Ref | −0.40 (−0.87, 0.07) | −0.54 (−1.00, −0.08) | 8.44 | 0.019 | −0.09 (−0.19, 0.0.1) |
| Model 1 | Ref | −0.28 (−0.73, 0.17) | −0.53 (−0.98, 0.09) | 9.31 | 0.024 | −0.03 (−0.12, 0.07) |
| Fully adjusted | Ref | −0.16 (−0.60, 0.29) | −0.27 (−0.72, 0.18) | | | −0.02 (−0.12, 0.07) |
| **TG levels change (mg/dL)** | | | | | | |
| *n* | 1,924 | 1,923 | 1,923 | 0.43 | <0.001 | 5,770 |
| Crude Model | Ref | 4.43 (0.04, 8.81) | 11.0 (6.70, 15.25) | 25.3 | <0.001 | 2.75 (1.87, 3.63) |
| Model 1 | Ref | 3.85 (0.04, 7.65) | 8.84 (5.06, 12.63) | 26.5 | <0.001 | 1.81 (1.05, 2.56) |
| Fully adjusted | Ref | 2.75 (−1.06, 6.56) | 6.27 (2.46, 10.09) | | | 1.75 (1.00, 2.51) |
| **LDL-cholesterol change (mg/dL)** | | | | | | |
| *n* | 1,790 | 1,790 | 1,790 | 0.03 | 0.673 | 5,370 |
| Crude Model | Ref | −0.77 (−2.59, 1.05) | 0.41 (−1.35, 2.17) | 19.2 | 0.282 | −0.04 (−0.42, 0.33) |
| Model 1 | Ref | −0.92 (−2.56, 0.72) | −0.86 (−2.46, 0.74) | 21.6 | 0.287 | −0.34 (−0.69, 0.00) |
| Fully adjusted | Ref | −1.06 (−2.68, 0.56) | −0.88 (−2.48, 0.72) | | | −0.34 (−0.68, 0.00) |
| **Diastolic BP change (mmHg)** | | | | | | |
| *n* | 1,945 | 1,945 | 1,944 | 0.13 | 0.007 | 5,834 |
| Crude Model | Ref | 0.50 (−0.02, 1.03) | 0.72 (0.19, 1.24) | 20 | 0.002 | 0.17 (0.05, 0.28) |
| Model 1 | Ref | 0.58 (0.12, 1.05) | 0.76 (0.28, 1.24) | 20.8 | 0.001 | 0.14 (0.04, 0.24) |
| Fully adjusted | Ref | 0.45 (−0.02, 0.92) | 0.56 (0.08, 1.05) | | | 0.15 (0.04, 0.25) |
| **Systolic BP change (mmHg)** | | | | | | |
| *n* | 1,945 | 1,945 | 1,944 | 0.09 | 0.03 | 5,834 |
| Crude Model | Ref | 0.45 (−0.49, 1.39) | 1.08 (0.11, 2.05) | 22.8 | 0.028 | 0.31 (0.10, 0.51) |
| Model 1 | Ref | 0.70 (−0.13, 1.53) | 0.96 (0.10, 1.82) | 23.6 | 0.041 | 0.18 (0.00, 0.37) |
| Fully adjusted | Ref | 0.45 (−0.39, 1.28) | 0.49 (−0.39, 1.36) | | | 0.17 (−0.01, 0.35) |
| **BMI change (kg/m$^2$)** | | | | | | |
| *n* | 1,974 | 1,974 | 1,973 | 4.04 | <0.001 | 5,921 |
| Crude Model | Ref | 0.41 (0.31, 0.51) | 0.77 (0.67, 0.87) | 5.08 | <0.001 | 0.17 (0.14, 0.19) |
| Model 1 | Ref | 0.40 (0.30, 0.50) | 0.75 (0.65, 0.85) | 16.1 | <0.001 | 0.11 (0.09, 0.13) |
| Fully adjusted | Ref | 0.27 (0.18, 0.36) | 0.51 (0.41, 0.60) | | | 0.11 (0.09, 0.13) |
| **Waist circumference change (cm)** | | | | | | |
| *n* | 1,967 | 1,966 | 1,966 | 2.77 | <0.001 | 5,899 |
| Crude Model | Ref | 1.22 (0.90, 1.55) | 2.09 (1.76, 2.41) | 9.74 | <0.001 | 0.47 (0.40, 0.54) |
| Model 1 | Ref | 0.11 (0.79, 1.43) | 1.99 (1.68, 2.31) | 15.5 | <0.001 | 0.29 (0.23, 0.36) |
| Fully adjusted | Ref | 0.73 (0.42, 1.03) | 1.19 (0.89, 1.50) | | | 0.28 (0.22, 0.35) |

*FSAm-NPS, Food Standards Agency Nutrient Profiling System (modified version) Dietary Index; CVD, cardiovascular disease; CI, confidence interval; HDL, high-density lipoprotein; TG, triglycerides; LDL, low-density lipoprotein; BP, blood pressure; BMI, body mass index. Linear regression models were fitted. Model 1: adjusted for age, sex, physical activity, smoking status, BMI, total energy intake at baseline, education level and marital status and each CVD risk factor was adjusted to its level at baseline. Fully adjusted: Model 1 additionally adjusted for medication for treatment of hypercholesterolemia, of hypertension and of diabetes, size of the recruitment centers (<250, 250 to <300, 300 to <400, ≥400) and the intervention groups. All analyses were conducted with robust estimates of the variance to correct for intra-cluster correlation. R-squared was multiplied by 100.*

## DISCUSSION

To the best of our knowledge, this study is one of the first to evaluate the prospective associations between the nutritional quality of diet assessed using the FSAm-NPS DI (algorithm underpinning the Nutri-Score FOP label) and different CVD risk factors. Findings of this study showed that the consumption of foods with higher scores of FSAm NPS (foods with less favorable rating in the Nutri-Score scale) was associated with unfavorable changes in CVD risk factors after 1 year of follow-up, specifically with an increase in adiposity (BMI and waist

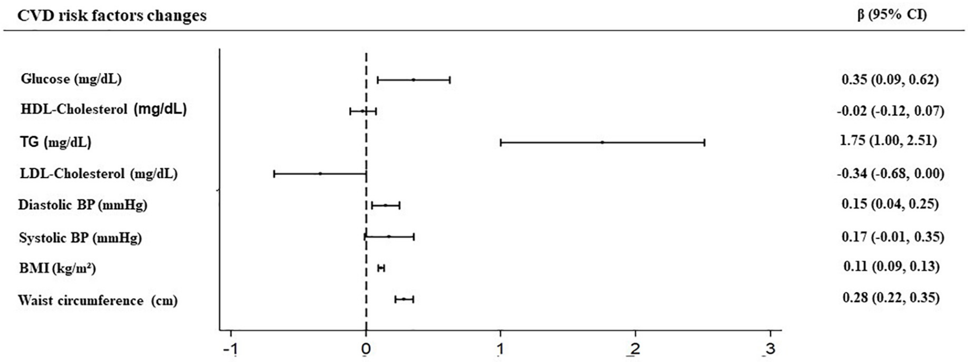


**FIGURE 2 |** Prospective associations between dietary index based on the French context, the modified FSA-NPS (FSAm-NPS DI) and cardiovascular diseases (CVD) risk factors changes after 1 year of follow-up.

circumference) and the levels of plasma glucose, triglycerides, and diastolic blood pressure.

Our results are partially in line with the SU.VI.MAX study where the authors assessed the prospective association between the FSAm-NPS DI and metabolic syndrome and its components (24). Even though, these authors found significant and positive association between the FSAm-NPS DI and the incidence of metabolic syndrome, when the components were assessed individually, only systolic and diastolic blood pressure showed a significant association. In our study, we also found significant and positive association with diastolic blood pressure, but not for systolic. These results may be explained because the FSAm-NPS DI considers the salt content of food that has been proved to be related to hypertension (31). However, we cannot discard that other factors of the score, as well as their synergistic effect, may also explain these results on blood pressure. In contrast to the SU.VI.MAX study, we have demonstrated significant prospective associations with triglycerides and fasting glucose. These results in relation to triglycerides and glucose may be explained because the participants in our study were elderly Mediterranean individuals (aged between 55 and 75 years) with overweight/obesity and metabolic syndrome. Therefore, as they were already at the risk of CVD, the results of our study could be influenced by their pre-existing risk and conditions. In contrast, in the SU.VI.MAX study, the participants were younger and healthier (women aged between 35 and 60 years and men aged between 45 and 60 years).

In our study, no prospective associations were observed between changes in the FSAm-NPS DI and changes in HDL-cholesterol or LDL-cholesterol concentrations. Even though, in the cross-sectional analysis, we found an association between HDL-cholesterol and FSAm-NPS DI at the baseline, the lack of association in the prospective analysis might be explained because most of the population did not show changes in the levels of HDL-cholesterol after 1 year of follow-up. In a previous study, analysis conducted in the SU.VI.MAX cohort reported a negative association between the FSAm-NPS DI and LDL-cholesterol concentration (16). According to the authors, the absence of association or the negative association observed in the case of the LDL-cholesterol could be partly explained by the fact that, even when saturated fat is considered in the score, the FSAm-NPS DI does not distinguish between fatty acid subtypes (monounsaturated or polyunsaturated fatty acids) (25).

In our study, a higher 1-year increase in the FSAm-NPS, reflecting a decrease in the nutritional quality of diet, was also positively associated with increases in adiposity measured by BMI and waist circumference. These findings are in line with other studies using other nutritional quality indexes (32, 33), and with other two studies analyzing the FSAm-NPS. In the SU.VI.MAX French cohort, a positive association between the FSAm-NPS DI and body weight and BMI gain (24) was found in both men and women. In addition, an increased risk of obesity was observed only in men after 13 years of follow-up. A study using data from the French NutriNet-Santé cohort has recently analyzed the prospective associations between different nutrient profiling systems (the original Food Standards Agency nutrient profiling system and three variants, Food Standards Australia New Zealand Nutrient Profiling Scoring Criterion (NPSC), Health Star Rating NPS and the French NPS (HCSP-NPS), and adiposity markers and overweight/obesity risk. The results showed that participants with a dietary index reflecting lower diet nutritional quality (irrespective of the nutrient profiling used) were more likely to increase the BMI over time and had an increased risk to develop overweight/obesity (34). It is important to remark that whilst differences were small, the French FSAm-NPS one appeared to show a significantly greater association with the risk of overweight compared to other nutrient profile scores. It is important to highlight that the reclassification of olive oil in the FSAm-NPS computation only induced small effects in our study, whereas previous evidence from the SUN cohort found that the reclassification of olive oil strengthened the associations between the FSAm-NPS and total mortality (23).

In the FSAm-NPS, total energy, salt, saturated fat, and sugar are considered negative components whereas fiber, protein, fruits and vegetables, legumes, and some vegetable oils are considered positive. The FSAm-NPS DI resumes the FSAm-NPS scores of all food items mostly consumed by an individual, by assigning points based on the consumption of foods, food groups, or nutrients relevant to the risk of chronic diseases. All these nutrients or food groups have been demonstrated to be related to CVD risk factors in numerous studies (5, 35, 36). Particularly, added sugar and saturated fat have been previously associated with higher levels of fasting blood glucose and triglycerides (37, 38). Therefore, the observed associations are consistent with the nature of the FSAm-NPS and with previous findings regarding diet and CVD.

Furthermore, there is also increasing evidence that ultra-processed foods (UPF) have detrimental effects on CVD risk (39), In this sense, we should bear in mind that the FSAm-NPS DI and the NOVA classification (based on degree of food processing) are two different complementary approaches to assess nutritional quality and healthiness (40). Indeed, in our study, those participants allocated in the highest FSAm-NPS DI tertiles had higher UPF consumption. It is acknowledged that the FSAm-NPS DI does not cover all the health dimensions of food (e.g., food processing, additives, and presence of pesticides). It considers neither the added sugar included in food nor the monounsaturated or polyunsaturated fat because this score has been based on those nutrients that, in Europe, are mandatory to be disclosed in the list of nutrients in the food labeling. However, at the moment, there is no classification system including all these nutrients and dimensions of food in a single indicator. Therefore, FSAm-NPS focuses on the nutritional dimension and serves as the underlying system of some front-of-pack labels to allow consumers to easily compare foods belonging to the same category. Importantly, FSAm-NPS has the advantage of considering a large number of elements from a nutritional point of view, in particular the content, per 100 g of food of fruits and vegetables (proxy of the amount of antioxidants, vitamins, and minerals), legumes, nuts, proteins (e.g., proxy of the amount of calcium and iron), olive oil, rapeseed oil, and walnut oils.

Overall, our results support the suitability of the FSAm-NPS as a nutritional quality indicator aimed at improving diets and preventing the development of chronic diseases. Further prospective studies analyzing the effect of modifying the nutritional quality of diet through changes in this dietary index are warranted in the future to confirm our results.

### Strengths and Limitations

Our study has several limitations that deserve to be discussed. First, the results cannot be generalized to other populations since participants included in the analysis were elderly Mediterranean individuals with overweight/obesity and metabolic syndrome. Therefore, as they were already at the risk of CVD, the results of this study could be influenced by this condition. Second, the assessment of food intake through a FFQ is prone to possible measurement errors. However, despite this limitation, food-based FFQs have been widely used as a tool in epidemiological studies since the 1990s (41). Third, we cannot rule out bias due to unmeasured potential confounders related to the risk of CVD.

This study also has some strengths such as its prospective design, which reduces the possibility of reverse causation bias, the control for several potential confounding factors, the large sample size, and the extensive data collected by trained staff.

In conclusion, the results of this prospective cohort study suggest that the consumption of foods with higher FSAm-NPS (reflecting a lower nutritional quality) is associated with an increase in some CVD risk factors (adiposity, fasting plasma glucose, triglycerides, and diastolic blood pressure). However, no significant associations were identified for critical CVD risk factors such as HDL-cholesterol, LDL-cholesterol, and systolic blood pressure.

## DATA AVAILABILITY STATEMENT

The datasets presented in this article are not readily available because the datasets generated and analyzed during the current study are not publicly available due to data regulations and for ethical reasons, considering that this information might compromise research participants' consent because our participants only gave their consent for the use of their data by the original team of investigators. However, collaboration for data analyses can be requested by sending a letter to the PREDIMED-Plus steering Committee (predimed_plus_scommittee@googlegroups.com).The request will then be passed to all the members of the PREDIMED-Plus Steering Committee for deliberation. Requests to access the datasets should be directed to predimed_plus_scommittee@googlegroups.com.

## ETHICS STATEMENT

The studies involving human participants were reviewed and approved by JW: CEI Provincial de Málaga-Servicio Andaluz de Salud (O01_feb_PR2), José Lapetra: CEI de los Hospitales Universitarios Virgen Macarena y Virgen del Rocío-Servicio Andaluz de Salud (PI13/00673), JAM: CEIC Universidad de Navarra (053/2013), DR: CEI de las Illes Balears – Conselleria de Salut Direcció General de Salut Publica i Consum (IB 2242/14 PI), MF: CEIC Parc de Salut Mar y IDIAP Jordi Gol (PI13/120), JSS: CEIC del Hospital Universitari Sant Joan de Reus y IDIAB Jordi Gol (13-07-25/7proj2), Aurora Bueno: CEI de la Provincia de Granada- Servicio Andaluz de Salud (MAB/BGP/pg), CV: CEIC de la Fundacion Jiménez Díaz (EC 26-14/IIS-FJD), MM-G: CEIC Universidad de Navarra (053/2013), Fernando Aros: CEIC Euskadi (PI2014044), DC: CEIC Corporativo de Atención Primaria de la Comunitat Valenciana (2011-005398-22), LS-M: CEI Humana de la Universidad de las Palmas de Gran Canaria (CEIH-2013-07), XP: CEIC del Hospital de Bellvitge (PR240/13), José López Miranda: CEI de Cordoba-Junta de Salud (3078), José María Ordovás: CEI de la Fundación IMDEA Alimentación (PI-012), PM-M: CEIC Hospital Clínico San Carlos de Madrid-Piloto-CEIC Servicio Madrileño de salud-General (30/15), FT: CEI Provincial de Málaga-Servicio Andaluz de Salud, JT: CEI de las Illes Balears – Conselleria de Salut Direcció General de Salut Publica i Consum (IB 2251/14 PI), JoV: CEIC del Hospital Clínic de Barcelona (HCB/2017/0351), JeV: CEIC del Hospital General Universitario de Alicante (CEIC PI2017/02), M-DR: CEIC de la Investigación Biomédica de Andalucía (CCEIBA), VM: CEI de la Universidad de León (ÉTICA-ULE-014-2015), and Ramon Estruch: CEIC del Hospital Clínic de Barcelona (HCB/2016/0287). The patients/participants provided their written informed consent to participate in this study.

## AUTHOR CONTRIBUTIONS

NK, CG-D, MM, JSS, and NB conceived and designed the study. MM, DC, MF, JAM, ÁA-G, JW, JV, DR, FT, JS-L, LS-M, JT, VM, XP, MD-R, PM-M, JVi, CV, LD, and ER conducted data acquisition. NK, CG-D, and NB performed statistical analyses. NK, CG-D, MM, JSS, and NB carried out interpretation of the data for the study. All authors were involved in draft redaction, revision for important intellectual content, read, and approved the final manuscript.

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# Health impact of foods: Time to switch to a 3D-vision

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KEYWORDS

**nutrition, food processing, environmental contaminants, prevention, chronic disease risk, front-of-package labeling, Nutri-Score**

The health impact of the "nutritional" dimension of foods (i.e., the amounts of sugar, saturated fats, salt, energy, fiber, protein, minerals, vitamins, etc.) is well established (1). Indeed, based on thousands of epidemiological and experimental studies globally, high levels of evidence have been reached regarding the deleterious impact of an excessive consumption of foods rich in salt, sugar, saturated fats and a limited consumption of foods high in fiber, vitamins and minerals on the risk of several cancers, obesity, cardiovascular diseases, diabetes, and mortality. Hence, national official food-based dietary guidelines have been issued and are overall consistent across countries. Additionally, nutrients of public health concern serve as a basis for the large majority of the currently available front-of-package labeling systems. Indeed, numerous national and international experts' committees (including the World Health Organization) recommend to display an interpretive nutrition labeling system on front-of-pack of foods aiming to help consumers understand, at a glance, the nutritional quality of a food product at the time of purchase, ultimately enabling consumers to choose between comparable food products. Amongst these labels, Nutri-Score, a gradual 5-letter/5-color front-of-pack nutrition label already adopted in 7 European countries (France, Belgium, Germany, Spain, the Netherlands, Luxembourg and Switzerland), aims to guide consumers toward nutritionally healthier food choices and incentivize food manufacturers to improve the nutritional quality of their recipes. Several studies conducted in large prospective cohort studies in France, Spain and in the European EPIC cohort (carried out in 10 European countries) found associations between the Food Standards Agency nutrient profiling system, which serves as the Nutri-Score's algorithm, with the risk of chronic diseases (cancers, cardiovascular diseases, weight gain, metabolic syndrome, etc.) and mortality (2). Furthermore, Nutri-Score has shown good performance in studies investigating its perception and understanding, as well as its actual impact on food choices, including in low-income populations (3). Nutri-Score has also a crucial role to play in encouraging food companies to improve the nutritional composition of their products.

Beyond this nutritional dimension, the past 5 years have witnessed a strong dynamism of research which today leads to widen this vision of the health impact of foods, by integrating an additional key dimension: (ultra)processing/formulation (4). Indeed, >50 recent prospective studies have shown links between the consumption of so-called "ultra-processed foods" according to the NOVA classification (i.e., having

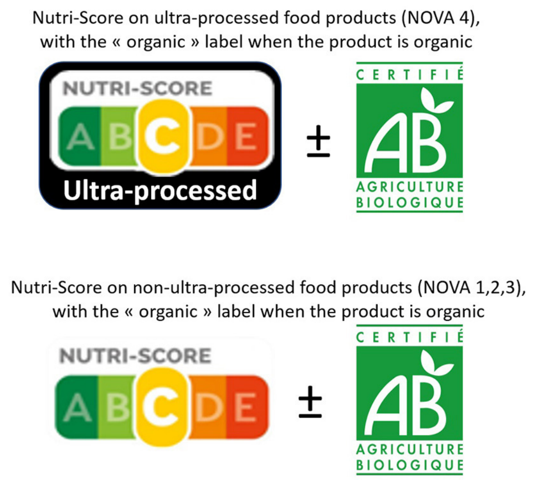


FIGURE 1
Proposed front-of-package label, including the 3 health dimensions of foods.

undergone major processing and/or containing food additives or other industrial substances such as hydrogenated oils, maltodextrin, glucose syrup, etc.) and an increased risk of many non-communicable diseases (5). These studies were conducted in various populations worldwide (e.g., Sun and Predimed cohorts in Spain, NutriNet-Santé in France, Nurses Health Study in the USA, UK Biobank), and were adjusted for several components (sugar, salt, saturated fatty acids and energy) of the nutritional quality of the diet. Experimental studies highlighted health effects of various non-nutritional components conveyed by these foods, such as certain additives or contaminants formed during processing. However, information on "ultra-processed" products *per se*, enabling consumers to identify them, has not yet been directly transposed at the level of food packaging.

On the other hand, several studies (particularly in the French NutriNet-Santé cohort) observed a lower risk of chronic diseases among the highest consumers of organic foods or those less exposed to pesticide residues (6). There is already in Europe an information label available on the packs of foods, the European Union organic label, corresponding to a quality label certifying that a product complies with the European Union Regulation on organic agriculture, based on the ban on synthetic fertilizers and pesticides.

Consequently, with regards to current knowledge about the 3 aspects stated above, these 3 different dimensions are all linked to health outcomes, and need to be all considered to obtain a more complete picture of the overall health impact of foods. None is exclusive and able to summarize, by itself, how the food product may impact health. Here is a practical example: some chips found in supermarkets may not be "ultra-processed," but they present a limited nutritional quality, with high amounts of salt, fat and energy. An organic cookie generally contains less pesticide residues than its conventional equivalent, but it may be ultra-processed, and its nutritional quality is not necessarily better. Finally, a diet soda does not have a bad nutritional quality (none-to-low calories and sugar), but it is typically ultra-processed (containing artificial sweeteners, dyes, etc.).

These three dimensions can certainly be inter-related (e.g., "ultra-processed" foods on average do have a lower nutritional quality), but they are not collinear and correspond to complementary concepts.

The issue is that messages are currently circulating among scientists, physicians, and the lay public, suggesting that one (or the other) of these dimensions would be sufficient to "summarize" the other two, and to convey a global picture on how healthy a food product is. This partial view is reductionist and misleading. Some claim that the fact that a food is not ultra-processed would be a guarantee of a favorable nutritional quality, which is obviously refuted by the example of industrial chips above. Likewise, the "halo" effect is often used by manufacturers as a marketing argument to give an overall healthy image to a fatty/sweet, but organic product, while this "organic" label does not provide direct information on the remaining two health dimensions of the product (i.e., nutritional quality, and level of processing/formulation).

For consumers, these intertwined concepts may seem confusing because they require to make a trade-off on which dimension(s) to favor. While some questions remain unanswered, considering the current state of knowledge, it is important to ensure that consumers have access to an adequate information to evaluate the quality of a food product, within each of these 3 dimensions, in order to make globally healthier choices. Dietary guidelines could therefore recommend: a) choosing (within comparable products) foods with a better nutritional quality - i.e., having a better Nutri-Score, b) preferring non-to-minimally processed foods rather than ultra-processed foods, and c) favoring organic foods as much as possible (especially for plant foods/ingredients) when an organic alternative is accessible.

Practically, developing adapted labels to cover these food dimensions, supported by mass communication campaigns can be effective tools to ensure better food choices. In terms of front-of-pack labeling, these 3 health dimensions of foods could be translated by a) the Nutri-Score, providing information on the nutritional dimension, b) an additional graphic mention (e.g., black band surrounding the Nutri-Score) specifying whether the food is "ultra-processed" (based for instance on an operational transposition of the NOVA-4 category), as the strongest evidence for associations between food processing and chronic diseases was specifically reported for this category, and c) the "organic" logo, providing information on the contaminant/pesticide dimension (see Figure 1). It is obviously crucial to support these graphical tools with massive communication campaigns to educate the consumers on each of these dimensions, and provide an adapted and accessible "user guide" for these labels.

Finally, it is important to keep in mind that science is a dynamic process. In the next decade, the research work in progress will lead to better characterize the health impacts of nutritional compounds, pesticides, additives, and contaminants from industrial processes, including knowledge on mixture/cocktail effects. This will permit to optimize regulations, labeling, and recommendations based on this more complete picture, in a constant perspective of patients and citizens' health preservation. Of course, beyond these 3 health-related dimensions, other aspects must be considered such as planetary or socio-economic impacts linked to production modes.

Despite the fact that current scientific knowledge does not allow to prioritize health risks or benefits associated with each dimension, we know today that they are all important to consider. While developing research programs to obtain further scientific answers, we can (and must) already act to provide consumers with the adequate information and tools about these 3 dimensions. As wisely said by Sir Austin Bradford Hill: "*All scientific work is incomplete—whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action it appears to demand at a given time.*"

Thus, when it comes to the health impact of foods, it is now time to switch to a 3D-vision.

## Author contributions

All authors listed have made a substantial, direct, and intellectual contribution to the work and approved it for publication.

## Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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# The Nutri-Score algorithm: Evaluation of its validation process

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The Nutri-Score front-of-pack label, which classifies the nutritional quality of products in one of 5 classes (A to E), is one of the main candidates for standardized front-of-pack labeling in the EU. The algorithm underpinning the Nutri-Score label is derived from the Food Standard Agency (FSA) nutrient profile model, originally a binary model developed to regulate the marketing of foods to children in the UK. This review describes the development and validation process of the Nutri-Score algorithm. While the Nutri-Score label is one of the most studied front-of-pack labels in the EU, its validity and applicability in the European context is still undetermined. For several European countries, content validity (i.e., ability to rank foods according to healthfulness) has been evaluated. Studies showed Nutri-Score's ability to classify foods across the board of the total food supply, but did not show the actual healthfulness of products within different classes. Convergent validity (i.e., ability to categorize products in a similar way as other systems such as dietary guidelines) was assessed with the French dietary guidelines; further adaptations of the Nutri-Score algorithm seem needed to ensure alignment with food-based dietary guidelines across the EU. Predictive validity (i.e., ability to predict disease risk when applied to population dietary data) could be re-assessed after adaptations are made to the algorithm. Currently, seven countries have implemented or aim to implement Nutri-Score. These countries appointed an international scientific committee to evaluate Nutri-Score, its underlying algorithm and its applicability in a European context. With this review, we hope to contribute to the scientific and political discussions with respect to nutrition labeling in the EU.

KEYWORDS

**Nutri-Score, nutrient profile models, front-of-pack labeling, validity, review**

## Introduction

In recent years, nutrition labeling has gained increasing attention, both in scientific and political discourse. Especially front-of-pack (FOP) labeling, as a WHO recommended policy tool to promote healthier diets and prevent non-communicable diseases (1), has sparked discussion in the European Union's political arena (2). While the mandatory elements of nutrition labeling–usually presented in a back-of-pack nutrition declaration table–are laid down in the EU regulation No 1169/2011 on the provision of food information, FOP labeling is as yet still voluntary with various forms allowed, as long as these comply with the criteria set out in the Regulation (3). Consequently, a variety of schemes are currently in use in the EU member states and the UK, varying in visual presentation, type of message (informative or directive) and focus (overall nutrition quality or nutrient-specific) (3, 4). The most well-known among these schemes are the Keyhole logo (5), the Choices logo (6), the Multiple Traffic Light (MTL) scheme (7) and the more recently developed Nutri-Score label (8) (Figure 1).

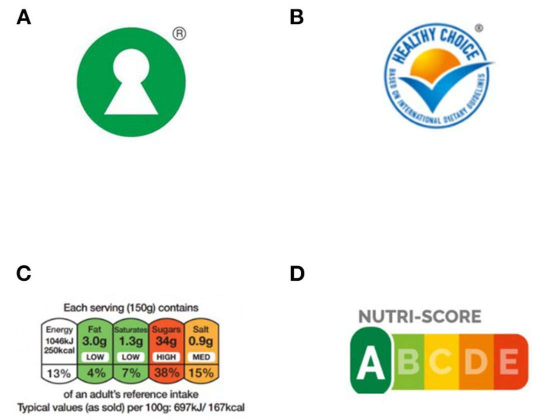


FIGURE 1
The four main FOP labels currently in use in Europe: Keyhole **(A)**, choices **(B)**, multiple traffic light **(C)**, and Nutri-Score **(D)**.

Keyhole, Choices and Nutri-Score are all directive, interpretative labels, i.e., labels that summarize the healthiness of the products without displaying nutritional information. The MTL scheme may be considered semi-directive, as it combines nutrient information with interpretive color coding using the familiar traffic light colors of red, orange and green. In a similar visual expression, the Nutri-Score label uses both colors and letters from A to E to rank the nutritional quality of products, both across and within food groups. The Keyhole logo and the Choices logo, on the other hand, use their visuals only to point out the healthier food products within a food group or food category (9).

At the moment, Nutri-Score has been implemented not only in France–from where it originates–but also in Belgium. Moreover, implementation has been announced in Spain, Germany, Switzerland, Luxembourg and the Netherlands (10). In the Netherlands, implementation was made conditional on adapting the algorithm underpinning the label, to ensure alignment with the national dietary guidelines (11). Indeed, examining the adherence to national dietary guidelines is a relevant measure of convergent validity and has been recommended by the WHO as one of the essential steps before implementing a FOP label in their "Guiding principles and framework manual for FOP labeling for promoting healthy diet" (12). More specifically, the WHO outlines three essential steps to be taken to validate the nutrient profile model underlying any proposed FOP label:

1) to examine content validity–does the algorithm allow the categorization of foods and beverages according to healthfulness;
2) to examine convergent validity–does the categorization of products using the algorithm compare to the categorization of products using another system (e.g., the national dietary guidelines);
3) to examine predictive validity–if the algorithm is applied to population dietary data to indicate the healthfulness of the diet, what prospective associations are observed in terms of disease risk?

This review aims to evaluate these three critical validation steps of the Nutri-Score label. It describes the adaptations made to the original FSA Ofcom nutrient profile model–which was designed for a different purpose, i.e., to regulate the marketing of foods to children–to arrive at the Nutri-Score model as introduced in France and the validity studies that were performed. Although studies on Nutri-Score's validity were initially performed only in the French context, studies within and across other European countries have been conducted with increasing frequency. These studies mostly focused on content and predictive validity. While this review sets out to provide a comprehensive overview of these French and European studies, it cannot be considered exhaustive as it includes only papers in the English language. Papers were derived from the French government's overview of the Nutri-Score validation process (13, 14). To check for potentially missing papers, an additional PubMed Search was executed. Supplementary material 1

Abbreviations: BMI, Body Mass Index; CVD, Cardiovascular Disease; DI, Dietary Index; EU, European Union; FOP, Front-Of-Pack; FSA, Food Standards Agency; MTL, Multiple Traffic Light; NS, Nutri-Score; PNNS, Programme National Nutrition Santé; UK, United Kingdom; WHO, World Health Organisation.

BOX 1
The FSA/Ofcom algorithm

The FSA/Ofcom model uses an algorithm to calculate a score for the nutritional quality of a food. Based on that score, here referred to as the FSA-score, foods and beverages are classified into one of two groups: not allowed to market to children or allowed to market to children

The algorithm is as follows:

1) For each food and beverage, negative points are calculated, based on their nutritional composition of 'negative' nutrients per 100 g. Note: point allocation is positive, so the more energy, saturated fat, sugar and sodium a product contains, the higher the number of negative points:

| Negative points | Energy (kJ) | Saturated fat (g) | Total sugar (g) | Sodium (mg) |
|---|---|---|---|---|
| 0 | ≤335 | ≤1 | ≤4.5 | ≤90 |
| 1 | >335 | >1 | >4.5 | >90 |
| 2 | >670 | >2 | >9 | >180 |
| 3 | >1,005 | >3 | >13.5 | >270 |
| 4 | >1,340 | >4 | >18 | >360 |
| 5 | >1,675 | >5 | >22.5 | >450 |
| 6 | >2,010 | >6 | >27 | >540 |
| 7 | >2,345 | >7 | >31 | >630 |
| 8 | >2,680 | >8 | >36 | >720 |
| 9 | >3,015 | >9 | >40 | >810 |
| 10 | >3,350 | >10 | >45 | >900 |

Total negative points = (points for energy) + (points for saturated fat) + (points for total sugar) + (points for sodium).

2) For each food and beverage positive points are calculated, based on their nutritional composition of "positive" nutrients per 100 g:

| Positive points | Fruit, vegetables, legumes and nuts (%) | Fiber (non-starch polysaccharides) (g) | Protein (g) |
|---|---|---|---|
| 0 | ≤40 | ≤0.7 | ≤1.6 |
| 1 | >40 | >0.7 | >1.6 |
| 2 | >60 | >1.4 | >3.2 |
| 3 | - | >2.1 | >4.8 |
| 4 | - | >2.8 | >6.4 |
| 5 | >80 | >3.5 | >8.0 |

Total positive points = [points for fruits, vegetables, legumes, and nuts (FVLN)] + (points for fiber) + (points for protein).

3) To compute the FSA-score the N-points and P-points are balanced according to the following formula:

* if negative points < 11; FSA-score = negative points−positive points

* if negative points ≥ 11 & points FVLN = 5; FSA-score = negative points−positive points

* if negative points ≥ 11 & points FVLN < 5; FSA-score = negative points−(points FVLN + points fiber)

The resulting FSA-score gives an indication of the nutritional quality of a product, with a lower score indicating a higher nutritional quality. For the purpose of the FSA/Ofcom model, i.e., advertising control, the following cut-offs were used:

Foods: ≥4–"less healthy," no marketing; <4–marketing allowed;

Beverages: ≥1–"less healthy," no marketing; <1–marketing allowed.

*Example: cottage cheese*

| Nutrient | Per 100 g | Negative points | Positive points |
|---|---|---|---|
| Energy | 381 kJ | 1 | |
| Saturated fat | 2.2 g | 2 | |
| Sugar | 2.8 g | 0 | |
| Sodium | 300 mg | 3 | |
| Fruit, vegetables, legumes and nuts | 0 % | | 0 |
| Fiber | 0 g | | 0 |
| Protein | 12 g | | 5 |
| **Total** | | **6** | **5** |

Total points = 6 − 5 = 1. This cottage cheese would therefore not be subject to marketing restrictions.

provides the search strategy and an overview of the studies included.

## Nutri-Score's basis: The food standards agency nutrient profile model

The algorithm underpinning the Nutri-Score label is derived from the UK Food Standards Agency (FSA)/Office of Communication (Ofcom) nutrient profile model, also known as "model WXYfm." This model was developed as a tool to regulate the marketing of foods to children in the UK and has been applied since 2007. Development and validation of the model was comprehensively reviewed by Rayner (15). The development included three stages. In the first stage, it was agreed that the model should use a scoring system and include nutrients and other food components that should be encouraged, as well as nutrients and food components that should be discouraged. In the second stage, a prototype model was discussed with a range of stakeholders, and in the last stage the final model was agreed upon in consultation with the UK Government Scientific Advisory Committee on Nutrition (15).

The final FSA/Ofcom model provides a single score (hereafter referred to as the FSA-score) for any given food product based on calculating the number of points for "negative" nutrients which can be offset by points for "positive" nutrients (see Box 1). Points are allocated on the basis of the nutritional content in 100 g of a food or drink. Foods and beverages are scored similarly, or "across-the-board," i.e., the same set of criteria are used for all products, however the cut-offs used to determine whether the products may be marketed to children differs between foods and beverages (see Supplementary material 2 as well) (16).

The FSA/Ofcom model was shown to have good agreement between the ranking of products by the model and the ranking of products by nutritionists (Spearman's ρ 0.79) (17), and good agreement between the model and the UK's national food guide for the classification of products in healthier or less healthy (k 0.69) (18), both measures of convergent validity.

## Development and validation process of the Nutri-Score model

In 2014, the first paper on the development of the Nutri-Score label was published. This paper describes the adaptation of the categorization: from binary to five categories (hereafter referred to as Nutri-Score classes). It was assumed that a multicategory label would prevent dichotomous thinking in "bad" and "good" foods and entice manufacturers to product reformulation (19). After assessing content validity for this categorization (19–21), convergent validity was assessed by comparing the categorization of food and beverages according to the model with the French nutritional recommendations (21). Based on these results, a subsequent adaptation in the algorithm of the model was proposed (here referred to as Nutri-Score model #1, Figure 2). This proposal was further adapted by the French High Council for Public Health to establish the final algorithm underlying the Nutri-Score label that was implemented in France in 2017 (here referred to as Nutri-Score model #2, Figure 2) (22). Multiple predictive validity studies, assessing the association of both the proposed Nutri-Score model (#1) and the adapted Nutri-Score model (#2) with disease risk in the French population were subsequently performed (23–29).

In the meantime, the Nutri-Score algorithm was further adapted to use the Association of Official Analytical Chemists (AOAC) calculation rather that the non-starch polysaccharide measurement for fiber (model #3, Figure 2), as the aforementioned method was set as the reference method in 2018 by the French Ministry of Health (personal communication Dr. Julia). Also, in the calculation used for liquids, the reference unit became 100 ml rather than 100 g, in line with the nutrition declaration on the package to ensure transparency for consumers. The most recent adaptation of the model happened in October 2019 (model #4, Figure 2). To better take the nutritional recommendations for oils in

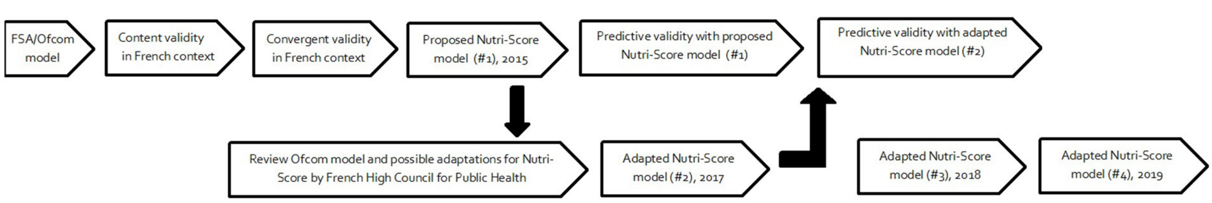


FIGURE 2
The development and validation process for the Nutri-Score model prior to and during implementation in France.

TABLE 1 Comparison of non-weighted and weighted analysis as presented in Julia et al. (19): distribution (%)[a] of food groups across quintiles of FSA-score distribution in the French NutriNet Santé food composition database (non-weighted $n = 3,331$; weighted $n = 1,878$).

| Food group | Q1 (<-2) | Q2 (-1;3) | Q3 (4;11) | Q4 (12;16) | Q5 (≥17) |
|---|---|---|---|---|---|
| **Fruit and vegetables** | | | | | |
| Unweighted | 66.2 | 22.9 | 10.3 | 0.6 | 0.0 |
| Weighted | 82.4 | 15.4 | 2.2 | 0.0 | 0.0 |
| **Cereals, legumes and potatoes** | | | | | |
| Unweighted | 29.3 | 20.4 | 30.5 | 15.1 | 4.7 |
| Weighted | 38.2 | 52.2 | 8.4 | 0.6 | 0.6 |
| **Milk and dairy** | | | | | |
| Unweighted | 4.4 | 25.6 | 28.4 | 18.0 | 23.6 |
| Weighted | 12.2 | 64.9 | 5.6 | 5.2 | 12.0 |
| **Meat, fish and eggs** | | | | | |
| Unweighted | 27.9 | 32.5 | 11.5 | 11.8 | 16.4 |
| Weighted | 33.3 | 34.1 | 11.3 | 8.1 | 13.2 |
| **Sugary snacks** | | | | | |
| Unweighted | 1.1 | 3.0 | 17.1 | 31.5 | 47.2 |
| Weighted | 0.0 | 3.7 | 41.7 | 32.6 | 22.0 |
| **Salty snacks** | | | | | |
| Unweighted | 15.5 | 16.2 | 31.1 | 18.2 | 18.9 |
| Weighted | 31.7 | 10.5 | 21.6 | 16.7 | 19.5 |
| Fat and sauces | | | | | |
| Unweighted | 2.9 | 9.6 | 19.9 | 20.6 | 47.1 |
| Weighted | 2.1 | 3.8 | 5.6 | 21.7 | 66.6 |
| **Composite foods** | | | | | |
| Unweighted | 19.1 | 34.7 | 20.7 | 18.9 | 6.6 |
| Weighted | 19.8 | 45.5 | 14.9 | 13.7 | 6.2 |

[a]Percentages reported were rounded to the nearest decimal for the present review.

Europe into account, the computation of the content for the food group fruit, vegetables, legumes and nuts (FVLN) was adapted to also include the content of rapeseed oil, walnut oil and olive oil (see also Supplementary material 2) (30). Figure 2 presents an overview of the development and validation process for the Nutri-Score model. Below, we first describe the three main validation steps in the French context in detail, after which we elaborate on the validation of the Nutri-Score in the European context.

## Nutri-Score's content validity in the French context: Classification of foods

In the context of a nutrient profile model, content validity refers to the ability of the model to classify products according to healthiness (12). For Nutri-Score, this was assessed in three subsequent studies, using the original FSA/Ofcom model (19–21). Using the quintile distribution of the FSA-score, 5 Nutri-Score classes were formed and this classification was compared with the food group classification of the French Programme National Nutrition Santé (PNNS) (19–21).

In two studies (20, 21), the ability to discriminate the nutritional quality of foods was estimated by the number of Nutri-Score classes in each food group (e.g., cereals, legumes and potatoes), each food category (e.g., breakfast cereals), and for similar products of different brands (e.g., mueslis). Tables 1, 2 give the distribution of the PNNS food groups across quintiles of the FSA-score distribution in the French NutriNet Santé food composition database (19) and in the Open Food Facts database (21), respectively. Table 3 shows the distribution of breakfast cereals, including the distribution of equivalent products of different brands (20).

Given the absence of a gold standard, the ability to discriminate nutritional quality was evaluated using a pragmatic approach: the discriminating performance was considered adequate if products were distributed over at least three classes of Nutri-Score (20). For discrimination between equivalent products of different brands, the criterion of "at least three classes" was later adapted to "at least two classes" (21).

TABLE 2 Shifts in distribution (%)[a] across scoring categories for food groups for which the algorithm was adapted[b] for better adherence to dietary guidelines, as described in Julia et al. (21).

| | Nutri-Score nutritional quality category | | | | |
|---|---|---|---|---|---|
| | A | B | C | D | E |
| **Foods** | | | | | |
| Category cut-offs | <-2 | −1–3 | 4–11 | 12–16 | ≥17 |
| Fruit and vegetables | | | | | |
| Original | 72.1 | 23.3 | 4.3 | 0.4 | - |
| Modified | 71.3 | 21.1 | 6.6 | 0.8 | 0.3 |
| Dried fruits | | | | | |
| Original | 18.2 | 66.7 | 12.1 | 3.0 | - |
| Modified | - | 18.2 | 72.7 | 6.1 | 3.0 |
| Milk and dairy | | | | | |
| Original | 5.2 | 34.1 | 20.9 | 15.8 | 24.0 |
| Modified | 5.2 | 34.1 | 26.4 | 26.8 | 7.5 |
| Cheese | | | | | |
| Original | - | 3.5 | 1.2 | 22.0 | 73.3 |
| Modified | - | 3.5 | 21.2 | 62.0 | 13.3 |
| Fats and sauces | | | | | |
| Original | 2.2 | 15.6 | 19.1 | 24.9 | 38.2 |
| Modified | 2.2 | 16.1 | 33.8 | 31.2 | 16.7 |
| Fats | | | | | |
| Original | - | 0.5 | 2.1 | 22.2 | 75.1 |
| Modified | - | 1.6 | 38.1 | 37.6 | 22.8 |
| Salty snacks | | | | | |
| Original | 2.9 | 9.8 | 45.0 | 25.6 | 16.7 |
| Modified | 1.0 | 8.1 | 46.5 | 27.1 | 17.3 |
| Nuts | | | | | |
| Original | 15.5 | 29.3 | 50.0 | 5.2 | - |
| Modified | - | 15.5 | 62.1 | 17.2 | 5.2 |
| Beverages | | | | | |
| **Category cut-offs** | <0 | 1–4 | 5–8 | 9–11 | ≥12 |
| Water /flavored | | | | | |
| Original | - | 100 | - | - | [c] |
| Modified | 95.0 | - | 5.0 | - | - |
| Tea and coffee | | | | | |
| Original | - | 100 | - | - | [c] |
| Modified | 100 | - | - | - | - |
| Fruit juice | | | | | |
| Original | 99.3 | - | 0.3 | 0.3 | [c] |
| Modified | 0.7 | 2.4 | 25.2 | 62.2 | 9.4 |
| Fruit nectar | | | | | |
| Original | - | - | 17.6 | 82.4 | [c] |
| Modified | - | - | 5.9 | 2.9 | 91.2 |
| Fruit flavored drink | | | | | |
| Original | 19.2 | 7.7 | 38.5 | 34.6 | [c] |
| Modified | - | 12.8 | 3.8 | 19.2 | 64.1 |
| Art. sweetened | | | | | |
| Original | 1.3 | 88.8 | 6.3 | 3.8 | [c] |
| Modified | - | 86.3 | 7.5 | 1.3 | 5.0 |
| Sweetened drinks | | | | | |
| Original | 0.4 | 5.8 | 34.2 | 59.6 | [c] |
| Modified | – | 3.8 | 9.2 | 23.3 | 63.8 |

[a]Food composition data from the Open Food Facts food composition database. [b]Adaptation from original FSA algorithm to the Nutri-Score algorithm, see Box 2. [c]In original FSA algorithm only 4 categories (quartiles) for beverages.

TABLE 3 Discriminating performance of Nutri-Score: distribution of breakfast cereal types and equivalent products (%) across quintiles of the FSA-score distribution[a,b] as described in Julia et al. (20) (Tables 3, 4, $n = 380$).

| | Quintiles of FSA-score | | | | | |
|---|---|---|---|---|---|---|
| | Q1 (<-2) | Q2 (-1;3) | Q3 (4;11) | Q4 (12;16) | Q5 (≥17) | *n* |
| **For cereal types** | | | | | | |
| Crunchy muesli | 11.1 | 9.1 | 46.5 | 27.3 | 6.1 | 99 |
| Chocolate cereals | - | 9.0 | 84.3 | 6.7 | - | 89 |
| Light cereals | 5.0 | 11.7 | 71.7 | 11.7 | - | 60 |
| Filled cereals | - | - | 37.5 | 45.0 | 17.5 | 40 |
| Honey cereals | - | 5.7 | 65.7 | 28.6 | - | 35 |
| Cornflakes/plain | 20.0 | 5.0 | 70.0 | 5.0 | - | 20 |
| Muesli flakes | 78.6 | 14.3 | 7.1 | - | - | 14 |
| Oat flakes | 66.7 | 16.7 | 16.7 | - | - | 12 |
| Fiber-rich flakes | 27.3 | 27.3 | 45.5 | - | - | 11 |
| **For equivalent products** | | | | | | |
| Chocolate-flavor | | | | | | |
| Chocolate wheat flakes | 4.5 | 4.5 | 81.8 | 9.1 | - | 22 |
| Chocolate puffed rice | - | 7.7 | 76.9 | 15.4 | - | 13 |
| Chocolate puffed cereal | - | 15.0 | 85.0 | - | - | 20 |
| Light cereals | | | | | | |
| Choc light cereals | - | 15.4 | 69.2 | 15.4 | - | 13 |
| Fruit light cereal | 9.1 | 9.1 | 81.8 | - | - | 11 |
| Unflavoured light cereals | - | 11.1 | 88.9 | - | - | 9 |
| Filled cereals | | | | | | |
| W/ milk chocolate | - | - | 33.3 | 22.2 | 44.4 | 9 |
| W/ chocolate hazelnut | - | - | 31.3 | 68.8 | - | 16 |

[a]Food composition data from brand sites, online supermarkets and consumer's nutritional websites. [b]Cut-offs based on quintile distribution as described in Julia et al. (19).

The WHO specifies content validity as a classification of products, rather than classification of foods "as consumed" (12). Yet, Julia et al. (19) conducted both an unweighted and weighted analysis, i.e., weighting was done in such a way that the scores for products that were consumed in larger amounts were weighted more heavily. Although weighted and non-weighted results were fairly consistent for food groups such as "meat, fish & eggs" or "composite foods," some discrepancies can be observed, for example, in "cereals, legumes & potatoes," and "milk & dairy."

Overall, Nutri-Score showed a high discriminating performance, as it was able to discriminate across and within PNNS food groups, but also across equivalent products from different brands, such as breakfast cereals (19–21). However, the studies did not take into account the diversity of products within different types of product groups and their distribution across the five classes. For example, the presence of at least three classes of an FOP label may be useful for breakfast cereals, but not for eggs. Also, if one class contains 90% of a type of breakfast cereals, and the surrounding classes contain only 5% each, the discriminating performance may still be considered limited.

Furthermore, the distributions of the PNNS food group across quintiles of the FSA-score distribution in the French NutriNet Santé food composition database and in the Open Food Facts database were quite consistent (Tables 1, 2). For example, in both studies, fruits and vegetables had the lowest FSA-score (indicating better nutritional quality, see Box 1), and 90–95% of products fell in the first and second quintile of the score distribution. In contrast, "sugary snacks" received the highest FSA-score and the majority of sugary products (79–86%) fell into the fourth and fifth quintile of the score distribution. Interestingly, both composite foods and nuts scored relatively low, indicating better nutritional quality despite their potentially high sodium levels, and in the beverages category, fruit juices scored consistently lower–thus healthier than water (19, 21). The classification between food categories was consistent across studies (see Supplementary material 3): milk & yogurt classified lower, and thus had a higher nutritional quality than dairy desserts and ice cream. Moreover, unprocessed meat and fish had a higher nutritional quality than processed meat (19, 21). However, the studies did not provide insight into the classification of different types of foods within a food category–e.g., wholegrain products vs. refined grain products, or whole milk vs. skimmed and semi-skimmed milk. The studies also did not give examples of actual foods in each class to allow a comparison of healthfulness on that level. In the development of the Choices criteria, for example, indicator foods were used to assess compliance with the criteria (9).

## Nutri-Score's convergent validity: Adherence to French dietary guidelines

Julia et al. (21) not only examined content validity but also took the validation process one step further, by examining convergent validity. Convergent validity refers to the consistency between different measures: how does the categorization of products using the Nutri-Score algorithm compare to the categorization of products using another system (12), in this case, the French dietary guidelines (31).

In their study, Julia et al. (21) noted discrepancies between categorization using the original FSA score and the French dietary guidelines for beverages, dried fruits, nuts, fats and cheese (see Box 2). Not all guidelines were reported on, for instance, no reference was made to the dietary guideline for wholegrain products.

The authors proposed a number of adaptations to the algorithm to address the observed discrepancies. Table 2 shows the shift in distribution for these food groups after the proposed adaptation of the algorithm. For instance, after the modification only a small proportion of fruit juices fell into the A and B categories (i.e., 3.1%) compared to the original score (i.e., 99.3%). The final adaptations to the algorithm before introducing the Nutri-Score label, as determined by the French High Council of Public Health (22), are described in Supplementary material 2.

## Nutri-Score's predictive validity in France: Prospective associations with disease risk

As a last and most complex step in the validation process, the WHO describes the predictive validity as follows (12): "In this most advanced type of testing, nutrient profiling criteria are applied to population dietary data, and these data are then used to compare health risks across population segments with better or worse diet quality, based on the nutrient profiling criteria." To assess predictive validity for Nutri-Score, first a dietary index was developed and validated by examining the associations with nutrient intakes (see Box 3) (32, 33). Notably, this dietary index was based on the original FSA/Ofcom algorithm, whereas the subsequent studies examining the dietary index and disease risk, were based on modified algorithms, more specifically on the Nutri-Score algorithm #1 and #2 (see Figure 2). These Nutri-Score algorithms used the non-starch polysaccharides method for fiber content, which was adapted in 2018 to adhere to the French government's new regulations, setting the AOAC method as the reference method for fiber content (personal communication Dr. Julia) (34). However, the various adaptations do not seem to have affected the results to a large extent, as it was shown that associations with BMI, overweight and obesity were more or less comparable in four variants of the FSA dietary index, including the one using the Nutri-Score algorithm (29). For the purpose of this paper, we will refer to the Nutri-Score dietary index (NS-DI) if the index is based on one of the variations in the Nutri-Score algorithm, and to the FSA dietary index (FSA-DI) if the index is based on the original FSA/Ofcom model.

Until 2021, a total of 7 studies investigated the prospective association between the NS-DI and disease risk in two different

BOX 2
Convergent validity of the FSA/Ofcom model and proposed adaptations to the Nutri-Score model.

To assess convergent validity, Julia et al. (21) compared the French national dietary guidelines (31) with the 5-category classification using the FSA/Ofcom model. Discrepancies were noted in the following guidelines:

∗ at least five fruits & vegetables a day–dried fruits as a component of this food group is considered a snack and not recommended

∗ 3 servings of milk and dairy products per day–cheese is considered a good source of calcium and is included in recommendation

∗ added fats: limit consumption; vegetable added fats: favor fats of vegetable origin–original FSA score does not allow for the differentiation in types of fats

∗ salt: limit consumption–nuts are considered a salty snack and therefore not recommended

∗ beverages: drink water as desired; limit sweetened beverages: no more than 1 glass per day–original FSA score does not reflect the recommendations and show low variability (only quartiles with original score)

The following guidelines were not reported:

∗ bread, cereals, potatoes and legumes at each meal according to appetite

∗ preferentially choose whole grains and wholegrain breads

∗ meat and poultry, seafood and eggs: 1 to 2 per day

∗ seafood at least twice a week

∗ alcohol: ≤2 glasses for women, ≤3 glasses for men (not relevant, alcohol not included in FSA/Ofcom model)

∗ sugary foods: limit consumption

Based on these discrepancies, the following adaptations were proposed:

Adaptations to points allocation

All foods & beverages: calculate the content of fruit, vegetable, legumes and nuts, excluding dried fruits and nuts

Fats & oils: adapt points for saturated fats:4 g/100 g ascending step

Beverages: adapt points for energy and sugar:

– energy: 30 kJ/100 g ascending step

– sugar: 1.5 g/100 g ascending step

Adaptations to score calculation

Dairy:

Total score = N-points – P-points

Categorization

Food categories similar to original categories; new categories for beverages∗:

Foods:

1/A green ≤2

2/B yellow–1–3

3/C orange 4–11

4/D pink 12–16

5/E red ≥17

Beverages:

1/A green ≤0

2/B yellow 1–4

3/C orange 5–8

4/D pink 9–11

5/E red ≥12

∗ Food categories were based on the distribution of FSA-scores (quintiles) in the NutriNet Santé food composition table (*n* = 3,508); the process to define the beverage categories was not reported, but categories were presumably based on the distribution of FSA-scores for beverages in the Open Food Facts food composition database (only for products marketed in France, *n* = 793).

study populations in France (Table 4). Outcome variables included BMI (including overweight/obesity risk) (24, 29), metabolic syndrome risk (23), cardiovascular disease (CVD) risk (26, 27), and cancer risk (25, 28). Overall, the results of the predictive validity studies suggest a significant, albeit small association between the highest dietary index (reflecting lower nutritional quality of the diet) and disease risk, particularly with regard to overall CVD (26, 27) and total cancer risk (25) (Table 4). As the studies were performed in a relatively healthy population, associations may have been underestimated. As volunteers in a nutrition and health-related study, participants of the SUVIMAX and NutriNet Santé study were likely to have more health-conscious behaviors, including better food choices. These are limitations that are shared by many prospective

BOX 3
Computation and validation of the FSA-dietary index

The FSA-dietary index (FSA-DI) is an aggregated FSA-score at the individual level and is calculated as follows:

1) For each food and beverage the individual consumes, the FSA-score is computed
2) The FSA-score of each food and beverage consumed is multiplied by the energy intake from that food or beverage
3) All FSA-scores are subsequently added up and the resulting summary score is divided by the total amount of energy consumed:

$\text{FSA-DI} = \Sigma(\text{FSA-score}_i * \text{energy intake}_i) \,/\, \Sigma(\text{energy intake}_i)$

The FSA-DI was validated in two populations: participants of the NutriNet Santé study (33) and participants of the SUVIMAX study (34). FSA-DI (in quartiles) was validated against various nutritional indicators and the adherence to the French dietary guidelines. As to be expected, significant associations were observed with macronutrients that are part of the algorithm, as well as with fiber and sodium that are also part of the algorithm. A negative association was found only with sugar (higher sugar intakes at lower FSA-DI). The authors suggested that this may be explained by the fact that simple sugars are present in basic foods such as milk, fruits and vegetables. In terms of added sugars, the association was as expected. Significant associations were also observed with micronutrients. Reported intakes were adjusted for energy intake, age and sex, which bolster the observations given that it controls for the variation introduced by sex and age (different consumption patterns for males and females and for older and younger people) and by energy intake which is correlated to nutrient intake.

A lower FSA-DI, indicating better diet quality, was positively associated with the Programme National Nutrition Santé guideline score (PPNS-GS), a score reflecting adherence to French dietary guidelines. However, there was no association between the FSA-DI and adherence to the specific recommendations for dairy products, meat, poultry, seafood and eggs, as well as for added vegetable fats. Interestingly, only 19% of the group with the lowest FSA-DI adhered to the wholegrain recommendation.

cohort studies, and could have weakened associations, but this ultimately depends on the distribution of the Nutri-Score dietary index in the general population. Strengths of all studies include their large sample sizes and the use of repeated 24-h recalls, which can be considered a relatively accurate measure for dietary intake. Also, all four SUVIMAX studies included data from a long-term follow-up of at least 13 years.

Yet, from a methodological point of view it may be questioned whether the studies reporting on predictive validity are able to predict Nutri-Score's actual association with disease or health over time, as they are based on consumption data that was not driven by Nutri-Score. Furthermore, the methodological approach differed across all predictive validity studies: some studies used sex-specific quartiles (23, 24, 26, 27), while other studies used sex-specific quintiles (25, 28), and one study even used sex-specific tertiles (29).

Trend analyses were done using a continuous value for the dietary index as well as using either the median (23), mean (24), or ordinal values (25–28) of the quartiles/quintiles, which makes comparison between studies problematic. Generally, using the mean or median values is preferred over using the ordinal values because it better reflects the data. At the same time, using ordinal values, as well as fitting a continuous linear trend to data that in fact may be rather curved can be considered a conservative estimation, as the residual variance will increase. In the study by Egnell et al. (29), neither the methodology of the trend analysis, nor the actual change in BMI was reported. Moreover, in all but one study (25), statistical analyses were adjusted for energy intake. One could debate whether adjustment for energy intake is required here. In their study, Drewnoski et al. (35) observed a high correlation between the FSA-score of the original WXYfm model and the energy density of foods, suggesting that the score provides rather more information on calories than on nutrient composition.

## Validation in the European context

Over the years, the validation process of Nutri-Score has been extended to the European level, with a number of studies examining either content validity (36–39) (Table 5) or predictive validity (40–42) (Table 6). The content validity studies [two of which remain unpublished, but are presented online (38, 39)], generally showed adequate discriminating performance within food groups–at least three Nutri-Score classes represented–but not necessarily within food categories. For example, less than three Nutri-Score classes were occasionally observed for dairy desserts in the milk & dairy group, for pastries or chocolate products in the sugary snacks group and for sandwiches or soups in the composite dishes group (36–39). Also, as previously mentioned, with no indicator foods, the actual healthfulness of foods in the different Nutri-Score classes remains unknown.

Table 5 provides an overview of the distribution of Nutri-Score classes within food groups for Germany, Spain, Switzerland, Belgium, Italy, UK, Netherlands, Sweden, Austria, Finland, France, Poland and Portugal, based on the Open Food Facts database (36, 39). The study of Dréano-Trécant et al. (37) used a different food database (the EUROFIR database) that did not allow for a similar food group classification. The main results of this study are described in Supplementary material 4. While the studies based on the Open Food Facts database made sure to only include countries with more than 1,000 products available, the number of foods included in the analyses generally varied significantly across countries and food groups and categories, which may be the result of not using an official, validated country-specific database. In the Open Food Facts database, data is voluntarily entered by anyone who wishes to do so, and is derived from stores, including national brands, store brands

TABLE 4 Results of predictive validity studies for the Nutri-Score algorithm in the French context: multivariable associations of the Nutri-Score dietary index with overweight, obesity and metabolic syndrome [odds ratios (OR) with 95% confidence intervals] and with cardiovascular disease risk, cancer risk and mortality [hazard ratios (HR) with 95% confidence intervals].

| Reference | Study population | Version of the Nutri-Score (NS) algorithm | Categorization of the dietary index | Outcome variables | Results: multivariable adjusted, significant associations |
|---|---|---|---|---|---|
| Julia et al. (23) | SUVIMAX; $n = 3{,}741$ | NS model #1 | Sex-specific quartiles and continuous | Metabolic syndrome (MetS) and metabolic syndrome traits: waist circumference, triglycerides, high density lipoprotein (HDL), diastolic blood pressure (DBP), systolic blood pressure (SBP), fasting glucose | MetS:<br>$OR_{Q4vs.Q1} = 1.43$ (1.08; 1.89), $P_{trend}$ 0.02<br>MetS traits:<br>*DBP per quartile :*<br>Q1 77.2 (76.4; 77.9)<br>Q2 77.8 (77.0; 78.6)<br>Q3 77.7 (77.0; 78.5)<br>Q4 78.7 (77.9; 79.5); $P_{trend}$ 0.01<br>*SBP per quartile:*<br>Q1 124.9 (123.7; 126.1)<br>Q2 125.8 (124.6;126.9)<br>Q3 125.8 (124.6;127.0)<br>Q4 127.1 (125.9;128.3); $P_{trend}$ 0.01 |
| Donnenfeld et al. (25) | SUVIMAX; $n = 6{,}435$ | NS model #1 | Sex-specific quintiles and continuous | Cancer overall<br>Prostate cancer<br>Breast cancer | Cancer overall:<br>$HR_{Q5vsQ1} = 1.34$ (1.00; 1.81), $P_{trend}$ 0.03<br>$HR_{1-pointincrement} = 1.08$ (1.01; 1.15), P 0.02 |
| Julia et al. (24) | SUVIMAX; $n = 4{,}344$ | NS model #1 | Sex-specific quartiles and continuous | BMI change, overweight, obesity | BMI change:<br>$\Delta BMI\ (kg/m^2)_{Q4vsQ1} = 0.70$ (0.01; 1.38), $P_{linearcontrasts}$ 0.04<br>Overweight:<br>Men:<br>$OR_{Q4vs.Q1} = 1.61$ (1.06; 2.43), $P_{linearcontrasts}$ 0.02<br>$OR_{1-pointincrement} = 1.13$ (1.02; 1.25), P 0.02<br>Women:<br>$OR_{Q3vs.Q1} = 0.70$ (0.51; 0.96)<br>$OR_{Q4vs.Q1} = 0.74$ (0.54; 1.02), $P_{linearcontrasts}$ 0.04<br>Obesity:<br>Men: $OR_{Q4vs.Q1} = 1.91$ (1.12; 3.26), $P_{linearcontrasts}$ 0.01<br>$OR_{1-pointincrement} = 1.16$ (1.02; 1.31), P 0.02<br>Women:<br>$OR_{Q3vs.Q1} = 0.54$ (0.32; 0.91) |

*(Continued)*





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TABLE 4 Continued

| Reference | Study population | Version of the Nutri-Score (NS) algorithm | Categorization of the dietary index | Outcome variables | Results: multivariable adjusted, significant associations |
|---|---|---|---|---|---|
| Adriouch et al. (26) | SUVIMAX; $n = 6{,}515$ | NS model #1 | sex-specific quartiles & continuous | CVD | CVD: $HR_{Q4vsQ1} = 1.61$ (1.05; 2.47), $P_{trend}$ 0.03 $HR_{1-pointincrement} = 1.14$ (1.03; 1.27), P 0.01 |
| Adriouch et al. (27) | NutriNet-Santé; $n = 76{,}647$ | NS model #2 | Sex-specific quartiles and continuous | CVD, coronary heart disease, stroke | CVD: $HR_{Q4vsQ1} = 1.40$ (1.06; 1.84), $P_{trend}$ 0.01 $HR_{1-pointincrement} = 1.08$ (1.03; 1.13), P 0.001 Coronary heart disease: $HR_{Q4vsQ1} = 1.62$ (1.12; 2.35), $P_{trend}$ 0.01 $HR_{1-pointincrement} = 1.09$ (1.03; 1.16), P 0.005 |
| Deschasaux et al. (28) | NutriNet-Santé; $n = 46{,}864$ | NS model #2 | Quintiles and continuous | Breast cancer | Breast cancer overall: $HR_{Q2vsQ1} = 1.43$ (1.08; 1.90) $HR_{Q3vsQ1} = 1.43$ (1.07; 1.91) $HR_{Q4vsQ1} = 1.79$ (1.35; 2.38) $HR_{Q5vsQ1} = 1.52$ (1.11; 2.08), $P_{trend}$ 0.002 $HR_{1-pointincrement} = 1.06$ (1.02; 1.11), P 0.005 Premenopausal women: $HR_{Q4vsQ1} = 2.76$ (1.45; 5.26) $HR_{Q5vsQ1} = 2.46$ (1.27; 4.75), $P_{trend}$ 0.004 $HR_{1-pointincrement} = 1.09$ (1.01; 1.18), P 0.03 Postmenopausal women: $HR_{Q4vsQ1} = 1.57$ (1.13; 2.18) $HR_{Q5vsQ1} = 1.25$ (0.85; 1.84), $P_{trend}$ 0.09 $HR_{1-pointincrement} = 1.05$ (1.00; 1.11), P 0.06 |
| Egnell et al. (29) | NutriNet-Santé; $n = 71{,}403$ | NS model #2 | Sex-specific tertiles and continuous | BMI change, overweight, obesity | ΔBMI not reported Overweight: $HR_{Q2vsQ1} = 1.13$ (1.05; 1.22) $HR_{Q3vsQ1} = 1.27$ (1.17; 1.37), $P_{trend}$ <0.0001 $HR_{1-pointincrement} = 1.02$ (1.01; 1.03), $P < 0.0001$ Obesity: $HR_{1-pointincrement} = 1.03$ (1.01; 1.06), P 0.004 |



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TABLE 5 Country-specific distributions (%)[a,b] of food groups across Nutri-Score classes as reported for Germany in Szabo et al. (36) and for Spain, Switzerland, Belgium, Italy, UK, The Netherlands, Sweden, Austria, Finland, France, Poland and Portugal in Szabo et al. (39)*.

| Food group | | Nutri-Score nutritional quality category | | | | | |
|---|---|---|---|---|---|---|---|
| | | A | B | C | D | E | *n* |
| **Fruits and vegetables** | | | | | | | |
| | Germany | 61.4 | 18.4 | 18.0 | 1.9 | 0.4 | 527 |
| | Spain | 63.9 | 12.6 | 20.4 | 2.9 | 0.3 | 4,244 |
| | Switzerland | 60.9 | 15.3 | 22.2 | 1.5 | 0.1 | 946 |
| | Belgium | 59.4 | 15.6 | 23.3 | 1.6 | 0.2 | 945 |
| | Italy | 67.3 | 19.0 | 12.0 | 1.4 | 0.4 | 284 |
| | UK | 66.7 | 14.4 | 16.2 | 2.7 | 0 | 487 |
| | Netherlands | 70.2 | 13.7 | 14.5 | 1.5 | 0 | 131 |
| | Sweden | 48.7 | 14.1 | 34.6 | 2.6 | 0 | 78 |
| | Austria | 61.0 | 18.1 | 17.1 | 3.8 | 0 | 105 |
| | Finland | 65.0 | 7.5 | 27.5 | 0 | 0 | 40 |
| | France | 59.7 | 14.6 | 21.8 | 3.6 | 0.4 | 17,253 |
| | Poland | 55.6 | 27.3 | 14.1 | 3.0 | 0 | 99 |
| | Portugal | 59.3 | 15.3 | 20.3 | 5.1 | 0 | 59 |
| **Cereals, legumes and potatoes** | | | | | | | |
| | Germany | 49.4 | 19.9 | 18.9 | 10.5 | 1.4 | 1,396 |
| | Spain | 31.5 | 22.5 | 21.2 | 21.6 | 3.3 | 6,811 |
| | Switzerland | 44.1 | 18.5 | 21.7 | 13.5 | 2.2 | 2,274 |
| | Belgium | 40.3 | 18.3 | 23.8 | 14.7 | 2.9 | 1,795 |
| | Italy | 50.4 | 13.3 | 18.7 | 16.3 | 1.3 | 1,249 |
| | UK | 43.2 | 19.5 | 20.1 | 14.5 | 2.8 | 1,117 |
| | Netherlands | 51.4 | 15.3 | 19.5 | 13.3 | 0.4 | 451 |
| | Sweden | 50.2 | 20.5 | 13.9 | 12.5 | 2.9 | 273 |
| | Austria | 47.6 | 16.4 | 21 | 14.4 | 0.6 | 353 |
| | Finland | 60.0 | 19.5 | 15.0 | 4.5 | 1.0 | 200 |
| | France | 40.7 | 18.5 | 20.3 | 17.1 | 3.4 | 24,346 |
| | Poland | 58.2 | 11.9 | 22.2 | 6.9 | 0.8 | 261 |
| | Portugal | 37.1 | 16.9 | 27.3 | 16.5 | 2.2 | 267 |
| **Milk and dairy** | | | | | | | |
| | Germany | 12.9 | 18.1 | 23.5 | 42.4 | 3.2 | 1,875 |
| | Spain | 11.3 | 26.7 | 17.4 | 39.4 | 5.2 | 7,868 |
| | Switzerland | 10.9 | 22.0 | 25.1 | 39.5 | 2.5 | 2,380 |
| | Belgium | 10.3 | 23.2 | 18.5 | 43.1 | 4.9 | 2,122 |
| | Italy | 15.9 | 30.4 | 24.1 | 26.5 | 3.2 | 1,205 |
| | UK | 15.2 | 22.3 | 21.5 | 37.2 | 3.8 | 1,056 |
| | Netherlands | 23.5 | 31.5 | 13.1 | 28.3 | 3.7 | 375 |
| | Sweden | 21.8 | 16.9 | 13.4 | 43.1 | 4.8 | 455 |
| | Austria | 9.3 | 28.7 | 19.4 | 38.3 | 4.3 | 397 |
| | Finland | 21.4 | 22.9 | 13.4 | 38.8 | 3.5 | 201 |
| | France | 7.3 | 17.9 | 23.5 | 46.5 | 4.8 | 33,416 |
| | Poland | 10.8 | 38.7 | 14.4 | 29.0 | 7.1 | 507 |
| | Portugal | 21.8 | 35.6 | 16.3 | 24.6 | 1.7 | 289 |
| **Meat, fish and eggs** | | | | | | | |
| | Germany | 7.7 | 14.1 | 13.4 | 37.6 | 27.2 | 688 |

(Continued)

TABLE 5 Continued

| Food group | | Nutri-Score nutritional quality category | | | | | n |
|---|---|---|---|---|---|---|---|
| | | A | B | C | D | E | |
| | Spain | 9.6 | 14.3 | 22.1 | 36.6 | 17.3 | 6,716 |
| | Switzerland | 12.4 | 15.5 | 19.0 | 39.9 | 13.2 | 1,213 |
| | Belgium | 11.4 | 14.7 | 24.7 | 33.7 | 15.5 | 1,464 |
| | Italy | 8.6 | 17.2 | 20.8 | 43.0 | 10.5 | 419 |
| | UK | 20.7 | 23.3 | 18.0 | 27.2 | 10.9 | 707 |
| | Netherlands | 8.5 | 15.1 | 17.9 | 34.9 | 23.6 | 106 |
| | Sweden | 17.2 | 7.0 | 15.9 | 36.9 | 22.9 | 157 |
| | Austria | 7.9 | 12.5 | 17.8 | 34.2 | 27.6 | 152 |
| | Finland | 14.3 | 19.6 | 24.1 | 27.7 | 14.3 | 112 |
| | France | 13.1 | 13.5 | 20.3 | 32.6 | 20.5 | 35,721 |
| | Poland | 5.8 | 9.7 | 24.5 | 41.3 | 18.7 | 155 |
| | Portugal | 7.0 | 21.1 | 29.6 | 38.0 | 4.2 | 71 |
| **Sugary snacks** | | | | | | | |
| | Germany | 0.7 | 2.3 | 3.6 | 22.1 | 71.3 | 1,745 |
| | Spain | 2.4 | 5.3 | 12.7 | 37.2 | 42.5 | 9,555 |
| | Switzerland | 1.2 | 3.9 | 10.0 | 32.2 | 52.6 | 3,262 |
| | Belgium | 1.7 | 4.0 | 11.5 | 31.5 | 51.3 | 2,686 |
| | Italy | 1.9 | 2.9 | 19.3 | 39.1 | 36.8 | 1,472 |
| | UK | 1.1 | 2.8 | 8.6 | 38.6 | 48.9 | 1,539 |
| | Netherlands | 1.4 | 3.4 | 13.7 | 33.6 | 48.0 | 563 |
| | Sweden | 2.7 | 2.9 | 8.8 | 28.7 | 56.9 | 376 |
| | Austria | 1.7 | 3.3 | 7.8 | 23.8 | 63.4 | 424 |
| | Finland | 0.3 | 2.9 | 4.8 | 32.7 | 59.4 | 315 |
| | France | 0.8 | 2.7 | 11.6 | 39.1 | 45.8 | 52,951 |
| | Poland | 1.2 | 2.8 | 15.9 | 24.2 | 56.0 | 327 |
| | Portugal | 2.8 | 5.2 | 11.4 | 39.4 | 41.2 | 325 |
| **Salty snacks** | | | | | | | |
| | Germany | 1.5 | 1.9 | 19.4 | 63.4 | 13.8 | 413 |
| | Spain | 3.4 | 5.9 | 27.9 | 53.0 | 9.8 | 3,154 |
| | Switzerland | 8.6 | 7.5 | 35.3 | 38.9 | 9.7 | 745 |
| | Belgium | 3.8 | 6.7 | 34.1 | 45.6 | 9.9 | 766 |
| | Italy | 13.5 | 3.9 | 40.0 | 38.7 | 3.9 | 155 |
| | UK | 7.9 | 10.9 | 32.5 | 40.9 | 7.9 | 496 |
| | Netherlands | 12.9 | 9.3 | 39.3 | 34.3 | 4.3 | 140 |
| | Sweden | 5.3 | 3.5 | 13.2 | 71.9 | 6.1 | 114 |
| | Austria | 8.8 | 9.9 | 44.0 | 34.1 | 3.3 | 91 |
| | Finland | 18.2 | 0 | 31.8 | 40.9 | 9.1 | 22 |
| | France | 3.7 | 7.2 | 27.7 | 39.5 | 21.8 | 17,246 |
| | Poland | 2.3 | 3.8 | 33.1 | 58.5 | 2.3 | 130 |
| | Portugal | 4.2 | 4.2 | 38.0 | 47.9 | 5.6 | 71 |
| **Fat and sauces** | | | | | | | |
| | Germany | 2.1 | 2.7 | 26.7 | 48.8 | 19.7 | 619 |
| | Spain | 5.3 | 5.9 | 53.1 | 24.9 | 10.7 | 3,909 |
| | Switzerland | 6.4 | 7.4 | 33.1 | 38.6 | 14.5 | 1,186 |
| | Belgium | 3.7 | 3.8 | 27.8 | 42.8 | 22.0 | 1,223 |
| | Italy | 6.6 | 5.7 | 31.5 | 27.8 | 28.4 | 454 |

*(Continued)*

TABLE 5 Continued

| Food group | | Nutri-Score nutritional quality category | | | | | |
|---|---|---|---|---|---|---|---|
| | | A | B | C | D | E | *n* |
| | UK | 4.1 | 8.1 | 38.3 | 37.9 | 11.6 | 689 |
| | Netherlands | 6.2 | 5.3 | 27.9 | 45.6 | 15.0 | 226 |
| | Sweden | 3.7 | 5.3 | 25.9 | 44.4 | 20.6 | 189 |
| | Austria | 9.1 | 9.1 | 34.7 | 36.4 | 10.8 | 176 |
| | Finland | 10.1 | 1.4 | 18.8 | 49.3 | 20.3 | 69 |
| | France | 4.5 | 6.0 | 32.0 | 38.5 | 18.9 | 18,460 |
| | Poland | 2.5 | 1.4 | 19.3 | 53.9 | 22.9 | 280 |
| | Portugal | 3.2 | 7.4 | 20.0 | 49.5 | 20.0 | 95 |
| **Composite foods** | | | | | | | |
| | Germany | 8.6 | 21.5 | 48.0 | 20.8 | 1.1 | 452 |
| | Spain | 9.6 | 19.6 | 35.8 | 31.2 | 3.8 | 2,350 |
| | Switzerland | 13.7 | 25.1 | 38.6 | 20.1 | 2.5 | 1,067 |
| | Belgium | 13.0 | 31.8 | 36.6 | 16.9 | 1.6 | 999 |
| | Italy | 10.6 | 17.4 | 33.2 | 34.7 | 4.1 | 340 |
| | UK | 28.7 | 35.3 | 21.2 | 12.5 | 2.3 | 655 |
| | Netherlands | 12.3 | 16.1 | 47.1 | 20.0 | 4.5 | 155 |
| | Sweden | 10.8 | 25.9 | 48.5 | 15.0 | 0 | 293 |
| | Austria | 7.8 | 18.4 | 50.8 | 19.6 | 3.4 | 179 |
| | Finland | 12.8 | 22.9 | 37.6 | 26.6 | 0 | 109 |
| | France | 16.1 | 30.3 | 31.0 | 19.1 | 3.4 | 24,106 |
| | Poland | 3.1 | 28.1 | 50.0 | 14.6 | 4.2 | 96 |
| | Portugal | 24.4 | 24.4 | 31.1 | 17.8 | 2.2 | 45 |
| **Beverages** | | | | | | | |
| | Germany | 28.1 | 7.2 | 19.8 | 12.7 | 32.1 | 872 |
| | Spain | 32.3 | 13.3 | 22.6 | 15.0 | 16.7 | 2,402 |
| | Switzerland | 11.1 | 9.6 | 21.5 | 20.1 | 37.6 | 1,268 |
| | Belgium | 16.9 | 11.0 | 23.4 | 21.1 | 27.6 | 1,241 |
| | Italy | 25.4 | 7.5 | 19.8 | 9.3 | 38.0 | 389 |
| | UK | 13.2 | 15.3 | 33.7 | 16.7 | 21.1 | 478 |
| | Netherlands | 17.9 | 10.1 | 25.7 | 21.2 | 25.1 | 179 |
| | Sweden | 11.0 | 12.3 | 13.5 | 12.3 | 51.0 | 155 |
| | Austria | 13.0 | 7.1 | 22.1 | 22.7 | 35.1 | 154 |
| | Finland | 16.7 | 12.5 | 34.7 | 15.3 | 20.8 | 72 |
| | France | 8.7 | 8.8 | 24.2 | 16.7 | 41.7 | 16,237 |
| | Poland | 22.1 | 7.7 | 15.4 | 15.9 | 38.9 | 208 |
| | Portugal | 29.1 | 7.3 | 14.6 | 23.2 | 25.8 | 151 |

[a]Food composition data from the Open Food Facts food composition database. [b]Percentages reported were rounded to the nearest decimal for the present review. [*]Data was published on the same website and as an update to Szabo et al. (38), and encountered after the screening phase of the current study. It was included in this review instead of Szabo et al. (38) as it contained more recent and a larger quantity of product data, including data from five additional countries.

and discount brands (43). In the EUROFIR database, data is retrieved from various sources including research institutes, food quality organizations and commercial organizations (37). In both databases, representativeness for the actual supermarket food supply are unknown (36, 37).

In the country-specific analyses, the majority of fruit and vegetables were classified favorably as Nutri-Score A or B (64 to 86%), while the majority of sugary snacks was classified D or E (77 to 92%) (Table 5) (36, 38, 39). Thus, these analyses generally showed high content validity, with recommended food groups scoring favorably and non-recommended food groups scoring more unfavorably. However, this was claimed as evidence for convergent validity, while no extensive analysis was conducted on the Nutri-Score's consistency with nutritional

TABLE 6 Results of predictive validity studies for the Nutri-Score algorithm in the EPIC (40, 41) and SUN (42) studies: multivariable associations of the Nutri-Score dietary index with cancer risk and mortality [hazard ratios (HR) with 95% confidence intervals].

| Reference | Study population | Version of the Nutri-Score (NS) algorithm | Categorization of the dietary index | Outcome variables | Results: multivariable adjusted, significant associations |
|---|---|---|---|---|---|
| Deschasaux et al. (40) | EPIC cohort; $n = 471{,}495$ | NS model #2 | Sex-specific quintiles and continuous per 2-point increment | Total cancer<br>Colorectal cancer<br>Bladder cancer<br>Kidney cancer<br>Upper aerodigestive tract cancer<br>Lung cancer<br>Stomach cancer<br>Pancreas cancer<br>Liver cancer<br>Prostate cancer<br>Breast cancer<br>Endometrial cancer<br>Cervical cancer<br>Ovary cancer | Total cancer:<br>$HR_{Q4vs.Q1} = 1.06$ (1.03; 1.09)<br>$HR_{Q5vs.Q1} = 1.07$ (1.03; 1.10), $P_{trend} < 0.001$<br>$HR_{2-pointincrement} = 1.02$ (1.01 ; 1.03), $P < 0.001$<br>Colorectal cancer:<br>$HR_{Q4vs.Q1} = 1.12$ (1.02; 1.22)<br>$HR_{Q5vs.Q1} = 1.11$ (1.01; 1.22), $P_{trend}$ 0.02<br>$HR_{2-pointincrement} = 1.03$ (1.00 ; 1.06), P 0.03<br>Upper aerodigestive tract:<br>$HR_{2-pointincrement} = 1.07$ (1.01 ; 1.14), P 0.03<br>Stomach cancer:<br>$HR_{2-pointincrement} = 1.10$ (1.02 ; 1.18), P 0.01<br>Prostate cancer:<br>$HR_{2-pointincrement} = 1.03$ (1.00 ; 1.06), P 0.04 |
| Deschasaux et al. (41) | EPIC cohort; $n = 501{,}594$ | NS model #2 | Sex-specific quintiles and continuous per 1-standard deviation (SD) increment | All-cause mortality<br>Cause-specific mortality:<br>Non-external<br>External<br>Cancer<br>Circulatory diseases<br>Respiratory diseases<br>Digestive diseases | All-cause mortality:<br>$HR_{Q5vsQ1} = 1.06$ (1.03; 1.09), $P_{trend} < 0.001$<br>$HR_{1-SDincrement} = 1.02$ (1.01; 1.03), $P < 0.001$<br>Non-external mortality:<br>$HR_{Q5vsQ1} = 1.07$ (1.03; 1.10), $P_{trend} < 0.001$<br>$HR_{1-SDincrement} = 1.03$ (1.02; 1.04), $P < 0.001$<br>Cancer mortality:<br>$HR_{Q5vsQ1} = 1.08$ (1.03; 1.13), $P_{trend} < 0.001$<br>$HR_{1-SDincrement} = 1.03$ (1.01; 1.04), $P < 0.001$<br>Circulatory disease mortality:<br>$HR_{1-SDincrement} = 1.02$ (1.00; 1.04), P 0.03<br>Respiratory disease mortality:<br>$HR_{Q2vsQ1} = 1.15$ (1.01; 1.31)<br>$HR_{Q3vsQ1} = 1.16$ (1.01; 1.32)<br>$HR_{Q4vsQ1} = 1.27$ (1.11; 1.45) |

*(Continued)*





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TABLE 6 Continued

| Reference | Study population | Version of the Nutri-Score (NS) algorithm | Categorization of the dietary index | Outcome variables | Results: multivariable adjusted, significant associations |
|---|---|---|---|---|---|
| | | | | | $HR_{Q5vsQ1} = 1.39$ (1.22; 1.59), $P_{trend} < 0.001$<br>$HR_{1-SDincrement} = 1.11$ (1.06; 1.15), $P < 0.001$<br>Digestive disease mortality:<br>$HR_{Q5vsQ1} = 1.22$ (1.02; 1.45), $P_{trend}$ 0.03<br>$HR_{1-SDincrement} = 1.08$ (1.02; 1.14), P 0.01 |
| Gómez-Donoso et al. (42) | SUN cohort; $n = 20{,}503$ | NS model #4 | Sex-specific quartiles and continuous per 2-point increment | All-cause mortality<br>Cancer mortality<br>Cardiovascular mortality | All-cause mortality:<br>$HR_{Q2vsQ1} = 1.37$ (1.03; 1.83)<br>$HR_{Q3vsQ1} = 1.43$ (1.06; 1.94)<br>$HR_{Q4vsQ1} = 1.82$ (1.34; 2.47), $P_{trend} < 0.001$<br>$HR_{2-pointincrement} = 1.19$ (1.08; 1.32)<br>Cancer mortality:<br>$HR_{Q2vsQ1} = 2.08$ (1.37; 3.15)<br>$HR_{Q3vsQ1} = 1.99$ (1.30; 3.06)<br>$HR_{Q4vsQ1} = 2.44$ (1.54; 3.85), $P_{trend} < 0.001$<br>$HR_{2-pointincrement} = 1.24$ (1.09; 1.41) |



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recommendations in the different countries. For example, German guidelines recommend wholegrain choices for cereals, daily consumption of milk and dairy, and the use of vegetable oils instead of animal fats (44), but these recommendations were not evaluated in detail. Moreover, a Dutch evaluation study commissioned by the Dutch Ministry of Health, showed a number of discrepancies between the Nutri-score categorization and the Dutch dietary guidelines, in particular, pertaining to the recommendations for bread, vegetables, cheese and fats (45). Another Dutch study ($n = 2{,}299$ products) found discrepancies for cheese, ready meals, soups and sauces (46). This study for example showed that ready meals with a green Nutri-Score A or B contained 2.9 g salt per portion on average (48% of the acceptable daily intake), and are thus not considered healthy according to Dutch dietary guidelines. Previous work suggests that nutrition labels showing a green color enhance perceived healthfulness of products and could even lead to overconsumption (47). Thus, consumers may be misled into thinking that ready meals are healthy, while they are generally high in saturated fat, energy and salt, and consuming them may negatively impact consumers' overall health and lead to overweight (48).

For the predictive validity studies in European context, results were similar to the previous studies in French populations (40–42). Overall, a higher dietary index, representative of lower nutritional dietary quality, was associated with a higher risk of cancer (40) and mortality (41) in the multinational EPIC cohort, and with higher risk of mortality in the SUN cohort (42) (Table 6). This was based on analyses of hazard ratios associated with higher vs. lower quartiles/quintiles of the dietary index or the continuous index score. The continuous analyses in hazard ratios were reported per 2-point increment (40, 42) or per 1 standard deviation increment (41), instead of per 1-point increment as in previous French studies. The SUN cohort may be less representative for a general population, being a relatively young cohort ($38 \pm 12$ years upon inclusion) of university graduates, with normal BMI, that showed no variation across the dietary index quartiles (42). The EPIC cohort as a multi-country study showed more variation in educational level and BMI (40, 41). Here, BMI was inversely associated with a higher dietary index, which may suggest reversed causality–and thus an underestimation of true association, as people with higher risk of disease may have adapted their dietary intake. Interestingly, in sensitivity analyses there appeared to be no associations between the Nutri-Score dietary index and mortality in overweight and obese individuals (41). A similar observation was done in the study of Adriouch et al. (26), examining risk of cardiovascular diseases. These results may suggest a limited influence of dietary adaptation based on the Nutri-Score nutrient profile model in overweight and obese individuals.

## Reflection

Nutri-Score's development and validation process may be considered extensive compared to the other major FOP labels currently in use in Europe, i.e., Keyhole, Choices and MTL. The Keyhole logo was introduced without validation in 1989, but nowadays its criteria are evaluated every 5 to 6 years by a scientific committee with members from all participating countries (49). The Choices criteria were developed in 2006 and have been regularly updated by an international scientific committee (50) since. Evaluations include validations using indicator foods, modeling studies to estimate improvements in habitual nutrient intakes, and the validation of a recent extension of the Choices criteria into a five-level system that can serve other policy purposes such as reformulation (6, 51). The MTL logo was recently updated (7), after being formally introduced in 2013 following years of research and stakeholder consultation, with criteria based on health claim regulations (7, 52).

Despite years of research on nutrient profiling, validation of a nutrient profile model, in any form, remains a difficult issue, as no consensus has yet been reached on a gold standard. This holds especially for convergent validity, but also for content validity–how can one determine whether a classification is indeed based on healthfulness? In our opinion, an indicator foods approach (53) allows for better insight in classification, as not only the scoring or calculation method of a nutrient profile model determines the scheme's ability to rank foods according to healthfulness, but also the reference quantity, choice and balance of nutrients included, and categories of food taken into account. Using serving size instead of a "per 100 g or 100 ml" reference basis would better reflect on the quantity of food typically consumed, which is an essential determinant of the potential of a product to adversely affect overall dietary balance (54). The "per 100 g or 100 ml" reference unit of the Nutri-Score may lead to false projections of healthfulness. For instance, as described earlier, ready meals may get relatively favorable scores while they are high in salt and saturated fat, because they are scored based on nutrient levels per 100 g. However, they are consumed in portion sizes larger than 100 g, and thus their final score may be largely underestimated (46). Most currently existing FOP labels are not based on serving size, as there is a lack of standardization and regulation of serving sizes for different food groups at EU level. Since serving sizes are much more meaningful to consumers, further exploration of their harmonization at EU level is warranted. Presenting levels of critical nutrients per serving of a product on the front of the pack (e.g., as applied by the MTL) may also help consumers get more insight into the nutritional quality per serving consumed. Besides this, the balance of positive vs. negative nutrients is another concern, as addition of positive components such as fiber or protein may improve the Nutri-Score of a product without changing its unfavorable composition (54). Nutrient profile models should ideally include only a limited set of nutrients to avoid complexity and difficulty of adaptation (54). Yet, one could argue whether Nutri-Score actually represents the healthfulness of foods, as several nutrients or dietary components that may be either favorable or unfavorable for health are not evaluated by the label (54). Including certain components such as vitamins or minerals may serve an additional goal to public health importance, i.e., help discriminate better between food products within a food group, or serve as markers for specific food groups (55). Using a category-based nutrient profile model would enable the inclusion of specific sets of nutrients for food groups in the overall diet and make adaptions based on country-specific dietary recommendations easier (54). Moreover, such models allow for better comparability of portion size, frequency of intake and pattern of consumption of products within a food group. Arguably, Nutri-Score includes adjusted score calculations for only a relatively small number of food groups, i.e., added fats, cheeses and beverages. This may make adaptation more complex as changing one component in the scheme may affect the scoring for several food groups (54).

A recurring problem with convergent validity–usually assessed by comparing the classification with one construct against a classification with another construct, be it expert-based or based on dietary guidelines–is the circularity in the argument. Such circularity exists by definition if similar criteria or nutritional recommendations are used in both constructs (56). Perhaps a better term, at least for convergent validity, would be "calibrated" rather than "validated." Research on the Nutri-Score's calibration in the European context is still in its infancy, and future work analyzing the Nutri-Score's agreement with dietary guidelines of other countries is warranted. Interestingly, the calibration of the Australia's and New Zealand's Health Star Rating (HSR), which is based on the same FSA/Ofcom algorithm underpinning Nutri-Score, showed similar issues as the French analyses of the Nutri-Score with regard to fat and dairy products. For the HSR, adjustments to the computation and cut-offs were also required to ensure alignment with the national dietary guidelines (57). In its 5-year review process, the HSR technical advisory group established the misalignment between the HSR and the Australian dietary guidelines to be 13 to 26%, depending on the dataset used and the applied cut-off (58). Observed algorithmic "failures" included products with high levels of sodium receiving a high star rating and thus suggesting high nutritional quality despite their high sodium levels (59), an issue also observed for Nutri-Score (46). Other reported issues were the high ratings received by fruit juices and breakfast cereals containing more than 25 grams of sugar per 100 grams (60), but also the rewarding of foods only for dietary fiber, not wholegrain, leading to inadequate differentiation between wholegrain and refined grain foods (61).

While studies supporting the health effects of the HSR are lacking (62), the predictive validity studies for the Nutri-Score algorithm do suggest an association with cancer (25, 41), cardiovascular disease (26, 27) and mortality (42, 43). A recent study in the Norfolk (UK) population of the EPIC cohort, using the original FSA/Ofcom model, found a small association between the consumption of less healthy foods and all mortality causes, but no association with cardiovascular disease or cardiovascular mortality (63). It is possible that the Nutri-Score algorithm was adapted in such a way that it better discriminates foods with respect to their association with CVD than the original FSA/Ofcom. However, as noted earlier, the predictive validation studies reported in this review may not provide a conclusive decision on Nutri-Score's actual impact on health. Ideally, one should assess consumption behavior driven by Nutri-Score, not by an analysis of consumers' diets quality using an "a posteriori" determined Nutri-Score index, and its association with disease over time. Moreover, the variability in methodological approaches–different populations, food databases and definitions or measures of the independent variable–requires additional research in different, more diverse populations, using consistent predictive analyses approaches. So far, only one study did compare various models originating from the FSA/Ofcom model (29). In this study, similar associations with weight gain, overweight and obesity were observed for all models, and these were slightly stronger for the Nutri-Score model.

While the current study reports outcomes of studies focusing on content, convergent and predictive validity specifically, it is important to discern between this type of validation–or calibration–of the model (the algorithm) and the validation–or evaluation–of its actual application (the label) (56). Crucially, the validity studies reported in this review alone do not provide a complete insight into the effectiveness of the Nutri-Score label, as they do not show whether Nutri-Score influences consumer purchasing behavior. The relevance of studying this additional step was previously noted by Julia et al. (21): "[...] the final effect of a FOP nutrition label based on the FSA-NPS [algorithm] would also depend on endorsement of the scheme by retailers and manufacturers and the actual format of the FOP label, which would also affect the perception, understanding and use of it by consumers." Previous work has shown that Nutri-Score only had little impact on the nutritional quality of purchases in-store (64). The predictive validity studies included in this review made use of the dietary index, which is calculated from the habitual diet at one point in time, and not from a diet in which choices were made based on a FOP label. It is essential that future research is conducted on the actual effects of Nutri-Score based on adaptations of actual dietary intake in the target population as a result of buying products with the Nutri-Score or a label-induced change in the food supply. To date, the majority of studies into the effectiveness of the Nutri-Score label involve online surveys, asking consumers to classify primarily discretionary products–pizzas, cookies and breakfast cereals–based on their healthiness (65, 66). Consumer understanding of other product groups is lacking. In these surveys, different FOP labels were also compared with respect to consumer perception. A study on five different FOP labels indicated that the Nutri-Score label stood out the most, but it was less trusted and perceived to be more difficult to understand and not providing sufficient information (67). Overall, it is highly relevant to investigate how the Nutri-Score label will be used in an actual supermarket, and whether it will reach and help the intended target group choose healthier options. The drawback of many studies on FOP labels to date is that they are conducted in laboratory or experimental settings (68). These studies do not necessarily provide evidence of actual effectiveness of the Nutri-Score label, as participants in such studies are in a more "conscious mode," i.e., they would make more deliberate choices than they would if they were not participating in a study (69). In fact, one recent real-life grocery shopping study that assessed the impact of different FOP labels on the nutritional quality of purchases, showed that the effect sizes were ∼17 times smaller than those found in similar experimental studies (64). Ideally, more future work should look into methods to effectively measure the long-term impact of FOP labels, including Nutri-Score, in more naturalistic settings.

## Implications for European implementation of Nutri-Score

Current EU legislation allows voluntary FOP labeling as a visual representation of the mandatory back-of-pack nutrition declaration. However, discussions in the EU for establishing a mandatory FOP label are ongoing (2, 3). Currently, seven countries–France, Belgium, Luxembourg, Spain, Germany, Switzerland and the Netherlands–have implemented the Nutri-Score label or intend to implement it (10). While the WHO recommends adapting FOP labeling to national dietary guidelines (12) such adaptation was done only for France and not for the other countries so far. For instance, research from the Netherlands showed that the Nutri-Score is in line with the Dutch dietary guidelines recommending increased consumption of fruit and vegetable, pulses, and unsalted nuts (70), but there are also discrepancies (45, 46). Outside Europe, discrepancies with dietary guidelines were also reported on a FOP label based on the same algorithm (58–61). Studies on the Australian Health Star Rating, which uses a similar algorithm based on the FSA/Ofcom nutrient profile model, observed issues with the sodium criterium, allowing healthier scores (≥3.5 stars) for products with high levels of sodium (59), and wholegrain products not being adequately captured with the current dietary fiber criterium (61). This may have implications for population health, since high sodium and low intake of wholegrain foods are considered the two leading risks for mortality and disability-adjusted life years in the Lancet Global Burden of Disease Study (71).

The value of validating a nutrient profile model is not in the amount of studies, it is in their relevance. European implementation of Nutri-Score could benefit from content and convergent validity at the national level of the countries included, based on food databases that closely reflect the actual supermarket food supply in these countries. It is critical to evaluate to what extent the nutrient-based algorithm is aligned with the dietary guidelines in those countries, and what adaptations are required in the nutrient profile model to ensure alignment. One difficulty here is the across-the-board nutrient criteria the algorithm uses, criteria that may prove difficult to align with the food-based dietary guidelines that most countries have, as demonstrated for example by the discrepancies involving wholegrain products despite the fiber criterion in the algorithm. Additionally, it is essential to investigate what adaptations are required to help product innovation and reformulation, as this may be an even more important avenue to help consumers eat healthier diets (4). To date, it is unknown whether adapting the across-the-board criteria of Nutri-Score will support product reformulation for different food groups or whether food group-specific criteria are required. A Dutch analysis investigated to what extent different product improvement scenarios can initiate a shift in Nutri-Score and hence can be an incentive for reformulation (70). It was found that a reduction in sodium, saturated fat or sugars result in a more favorable Nutri-Score in a large variety of food groups. For instance, Nutri-Score may stimulate reformulation of various nutrients in composite dishes or cereals. However, as noted previously, the Nutri-Score's algorithm is based on a balance between "positive" and "negative" nutrients that may compensate for each other. For example, dairy drinks with added sugar that are low in saturated fat and salt may benefit from their naturally high protein content as this compensates for the sugar content, leading to a more favorable Nutri-Score (70). Also, adding extra protein to these beverages may make it seem they are reformulated, while their sugar content has not changed. Overall, monitoring food composition changes before and after introduction of Nutri-Score in European countries is crucial to evaluate the extent of producers' reformulation of products. As recommended in WHO's technical meeting on nutrient profiling (56), predictive validity would ideally be re-evaluated after adaptation of the algorithm. But more importantly, policy makers should be made aware that the predictive validity of a nutrient profile model is not a measure of effectiveness of a label using that model (56), and should be accompanied by an investigation of actual purchases of products with the label (68).

## Summary and conclusions

The Nutri-Score FOP label is one of the main candidates for standardized FOP labeling in the EU. The algorithm underpinning the Nutri-Score label is derived from FSA/Ofcom nutrient profile model, a model originally developed to regulate the marketing of foods to children in the UK. In line with WHO recommendations, content, convergent and predictive validity have been assessed in multiple studies (19–21, 23–29, 36–42), as reviewed here. However, their methodological approaches and conclusions on validity of the Nutri-Score should be interpreted with some caution. No gold standard for assessing healthfulness of products is available to date and this is not only problematic in the case of Nutri-Score, which is by far the most studied, but for the validation of many nutrient profile models currently existing. It must be noted that the large amount of articles that have been published on Nutri-Score does not necessarily mean that it is the best nutrient profile model. Content validity was based only on the distribution of the Nutri-Score categories in food groups, food categories and equivalent products of different brands. More insights into the actual products classified as having "higher" or "lower" nutritional quality is needed. Convergent validity was assessed by comparing the Nutri-Score classification with the French dietary guidelines, and adaptations were made to ensure alignment. This emphasizes the importance of taking national guidelines (12) into account while also limiting the generalisability of the validation process to other countries. Predictive validity was extensively assessed in the French context, with different adaptations of the Nutri-Score model. Yet, definite predictions on its effect on disease risk cannot yet be determined, as existing studies are not based on dietary patterns driven by Nutri-Score in particular.

Currently, seven countries are working on a joint Nutri-Score implementation (10). For some countries, content validity was evaluated (36–39), showing the ability of Nutri-Score to classify foods but not showing the difference in healthfulness of foods in different classes. Arguably, an evaluation of at least convergent validity within the context of these countries would be required, i.e., alignment with their respective dietary guidelines. Even if FOP labels and dietary guidelines serve different goals, they need to be aligned and provide a single coherent message to consumers. Failure to do so is likely to threaten the credibility and sustainability of both (58, 72). Ideally, predictive validity should be re-assessed once consensus is reached on adaptations in the algorithm. But even then, one should stay aware of the fact that the predictive validity of a nutrient profile model is not a measure of the effectiveness of a label using that model to improve diets (56). Therefore, besides validation of the algorithm itself, validation of its application and impact on purchases and dietary patterns in real life settings is crucial as well.

In conclusion, while Nutri-Score is one of the most studied FOP labels in Europe and its content, convergent and predictive validation have been extensively studied in the French context, more research is required on its validity and applicability within the European context. Will it be possible to adapt the algorithm in such way that it can be aligned with country-specific, food-based dietary guidelines and allows for product reformulation and innovation? Promisingly, an international committee was recently appointed to evaluate Nutri-Score, its underlying algorithm and its applicability in a European context. With this review, we aimed to provide a comprehensive evaluation of the validation process of the Nutri-Score algorithm to further the scientific and political process of nutrition labeling in the EU.

## Author contributions

ME and MR drafted the outline of the manuscript. DB and ME wrote the manuscript. MR, KG, and AR provided critical feedback and comments on the manuscript throughout all phases. All authors were involved in preparing this review paper and read and approved the final version of the manuscript.

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## Conflict of interest

ME and MR have called upon the Dutch government to make the introduction of the Nutri-Score label in the Netherlands conditional on alignment with national dietary guidelines, AR and KG supported this call. AR was a member of the international scientific committee of the Choices Programme.

The remaining author declares that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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## Supplementary material

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# Relationship between front-of-pack labeling and nutritional characteristics of food products: An attempt of an analytical approach

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The adoption of supplementary nutrition information, i.e., front-of-pack labeling (FOPL), on pre-packed food products is advocated as a tool to improve the consumers' knowledge of the nutrient content or the nutritional quality of foods, but also to drive products reformulation by the food industry. Ultimately, FOPL should help people to select foods in order to compose an overall balanced diet, which is essential for health. However, the extent to which the different FOPL systems proposed in the European Union (EU) (interpretative or informative) are effectively able to convey the information useful to improve both food choices and dietary habits of the consumers is still under debate and needs to be analyzed in detail. The use of 3 FOPL schemes proposed within the EU (Nutri-Score, Keyhole and NutrInform Battery) to compare products available on the Italian market within different food categories, highlights some critical issues: (1) different FOPL provide to consumers different kinds of information; (2) systems based on similar theoretical approaches can provide conflicting information; (3) the algorithms on which interpretative FOPL are based can give the same summary information for products differing in nutrient composition, impact on the overall dietary balance and therefore on the health of people with different characteristics, physiological/pathological conditions, and nutritional requirements; (4) on the other hand, products with similar nutrient composition can obtain different interpretative FOPL; (5) informative systems are generally more complex and require greater both attention and knowledge from the consumer; (6) FOPL based on 100 g of product overlook the role of portion (and frequency of consumption) in determining the nutrient intake without informing on the contribution of a single food to the overall diet; (7) FOPL based on scoring systems could promote the reformulation of selected products, especially with a composition very close to the threshold limits; (8) for the portion-based informative FOPL systems, the incentive for reformulation could essentially involve the reduction of portion size.

Finally, the importance of nutritional education interventions, which are required to encourage the use by consumers of informative FOPL systems, cannot be neglected to improve the quality of diets regardless of the FOPL used.

KEYWORDS

front-of-pack labeling (FOPL), NutrInform Battery, Nutri-Score, Keyhole, nutrient composition, nutrition information, overall balanced diet

## Introduction

The interest in nutrition labeling as a policy tool potentially useful to promote healthy diets has increased in last years, mainly due to the large diffusion among the population of noncommunicable diseases, which are in part related to diet (1).

The relationship between diet and health has in fact been confirmed by the most recent scientific research: according to the Global Burden of Disease study group, which analyzed 286 causes of death and 87 risk factors in about 200 countries and territories of the world, diet-related risk factors were altogether responsible, in 2019, for 13.5 and 14.6% of all female and male deaths, respectively (about 46% of cardiovascular disease deaths and 8% of cancer deaths in Countries with high socio-demographic index) (2, 3). The demographic changes that are taking place in the European population, and mainly the progressive increase in the average age, as well as in life expectancy at birth, together with the increasing prevalence of age-related risk factors, make the diet-health association even more important, and complex to interpret (4). In this context, all the tools which may prove useful to improve the nutritional information of the general population, in order to enable consumers to make healthier food choices, are gaining importance.

In particular, front-of-pack labeling (FOPL), which is a form of supplementary nutrition information, is increasingly considered not only a tool to drive reformulation by the food industry, but also an effective strategy to improve the consumers' knowledge and awareness of the nutrient content or nutritional quality of the food. Such result may be achieved by helping consumers to better understand the nutrition declaration, which is included in the list of mandatory information (together with the list of ingredients, net quantity of the food, date of minimum durability, any special storage conditions and/or conditions of use, name and address of the food business operator, country of origin or place of provenance), the actual comprehension of which may be limited (5).

According to the Regulation (EU) n. 1169/2011 (art. 35), energy value and nutrient content, which are already reported in the back of pack labeling, may be also presented by other forms of expression and/or using graphical forms or symbols in addition to words or numbers, with the aim "to facilitate consumer understanding of the contribution or importance of the food to the energy and nutrient content of a diet". This goal, together with the proposal to harmonize mandatory front-of-pack nutrition labeling in the EU, is picked up by the Farm to Fork strategy "to empower consumers to make informed, healthy and sustainable food choices" (6).

The aim of this paper is to propose a critical assessment of the role of FOPL schemes in providing nutrition information useful to improve both consumer choices and dietary habits, which are essential to favorably affect public health.

## Characteristics of FOPL

Various schemes of FOPL have been developed in the last 40 years, of which the most prevalent in the European Union are those based on the guideline daily amount (GDA) concept, on a traffic light scheme or on qualifying (or disqualifying) threshold criteria (7): the main characteristics of Nutri-Score and Keyhole based on the latter approach and of NutrInform Battery, which is based on the first one, are summarized in Table 1.

The Reference Intakes label provides numerical information on the amount of energy and of some nutrients present in a portion of food and the percentage contribution to the daily reference intake for calories and nutrients set out in Annex XIII of the Regulation (EU) n. 1169/2011; the NutrInform Battery, proposed by the Italian government and notified to the European Commission in January 2020, which is based on this principle, is an example of informative FOPL scheme (8).

The interpretative approach has been the basis for schemes aimed at classifying foods according to the content of a limited number of single nutrients, based on a traffic light scheme, or to the whole nutrient profile assessed by algorithms, again based on the content of a limited number of single nutrients or ingredients. Nutri-Score, the FOPL used in France since 2017, is an example of the interpretative approach (9): it is a summary indicator of the nutritional quality of a product along a graded scale presented in ordered colors (from dark green to dark orange) and letters (A–E). The same approach is at least in part shared by the Multiple Traffic Light (MTL) system, which is recommended by UK Health Ministers since 2013 on a

TABLE 1 Main characteristics of three FOPL schemes.

| | NutrInform Battery | Nutri-Score | Keyhole |
|---|---|---|---|
| Logo | | | |
| Type of scheme | Informative | Interpretative | Interpretative (supportive?) |
| Based on | Reference Intakes | Algorithm (nutrient thresholds) | Nutrient thresholds |
| Information included (positive or negative) | Neutral: energy, total fat, saturated fat, sugar, salt | Negative: energy, saturated fat, sugar, salt. Positive: fiber, protein, vegetables, fruit, legumes, olive/nut/canola oils | Less salt, less sugar, more fiber, more whole grains and healthier fat |
| Main declared purpose | To make the mandatory nutritional information pursuant to Reg. (EU) no. 1169/2011 more easily comprehensible for the consumer | To inform about the nutritional quality of a product | To help consumers identify the healthier options when buying food |
| Amount of food | Portion | 100 g | 100 g |
| Contribution to the whole diet | Yes | No | No |
| Food categories | Across-the-board | Across-the-board (exceptions) | Category specific |

voluntary basis, to show consumers if the prepackaged food has low, medium or high amounts of fat, saturated fat, sugars and salt per 100 g; however, in this kind of FOP the same information is reported even per portion as both absolute amounts and percentage of adult's reference intakes (10).

Furthermore, threshold criteria may be applied to define endorsement and summary logos or warning label on foods: in the first case, as for the Nordic Keyhole, which was first introduced in Sweden in 1989, the logo certifies that a product meets certain requirements for nutrient content in a category-based nutrient profile model (it is set for 32 food groups and registered as a trademark by the Swedish Food Agency) (11); warning (or negative) FOPL, as in the Chile experience and used in Finland for salt, the food package must bear a warning symbol if the set thresholds are exceeded (12).

From a practical point of view, these are two substantially different approaches: one (the informative one) more complex is aimed at providing more information to the consumer (i.e., schemes based on reference intakes), while the other (the interpretative) is more concise and aimed at simplifying the consumers' choices, synthesizing a number of information into a single one (13).

It is important to underline that while for informative systems, which simply intend to provide information on some selected food composition aspects, efficacy validation is required only with regard to the correct understanding of the conveyed information by the consumer, for the interpretative systems, which are based on specific algorithms, built to integrate the information related to the content of different nutrients and ingredients in a single parameter, adequate experimental support is required that confirms their validity in actually improving the nutritional quality of the diet of consumers exposed to this FOPL. The criteria on which these algorithms are based are in fact characterized by a wide discretion regarding the weight attributed to the individual nutrient considered, the thresholds adopted for the different components, the dose-response curve on which the attribution of scores is based, etc.

It also needs to be considered that the interpretative approach, being based on algorithms that are intrinsically complex and providing an overall assessment of the nutritional value of a food, that cannot be understood by the consumers, does not include the purpose to improve their knowledge. Ultimately, summary labeling aims to help the consumer in making single choices between different foods, but not to learn how to compose an overall healthy diet. Informative systems based on labeling Reference Intakes, on the opposite, provide all the numerical data (absolute amounts and percentage levels) needed to assess the energy and nutrient (fat, saturated fat, sugar, salt) content of one portion (and of 100 g for energy) of different foods, in the context of the energy and nutrient

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content of the whole diet. The extensive literature available focusing (although with several methodological approaches) on the effects of different FOPL schemes on level of consumer understanding and on choices at time of purchase should be reconsidered in view of the differences highlighted. Moreover, it is important to underscore that far fewer studies have assessed a direct relationship between the use of different FOPL under real life condition and the overall composition of people's diets (14).

Due to the different nature of the various FOPL developed so far, hence, there is some debate about which characteristics an efficient labeling system should have to reach the main objective, e.g., helping people in making informed, conscious and healthier food choices. In particular, the debate regards the possibility that the specific characteristics of different FOPL (e.g., nutrient-specific vs. summary labels, interpretative vs. non interpretative labels) may differently impact on this objective.

The analysis of some application examples of the different FOPL systems may help to show the related criticalities.

# FOPL and nutritional characteristics

## Similar FOPL for products with different nutrient composition

It cannot be overlooked the great variability in terms of nutritional characteristics that can be detected among products belonging to the same food category, especially if the aim is to compare different food products in order to choose the healthiest one (15, 16). It is therefore difficult to hypothesize that the classification into two categories (healthy or less healthy) or even into a few categories (as is the case with Nutri-Score) may reflect and properly clarify such complex situation.

As regards summary labels such as Nutri-Score or Keyhole (as any other algorithm-based system), it is worth noting that the same score/label may be the result of different nutritional characteristics and that it does not provide information about the individual nutrients contained in the product (mostly sugars, salt, saturated fats), which may instead be relevant for specific categories of consumers. For instance, the energy and nutrient content of different sweet cakes obtaining the same Nutri-Score (D) are reported in Table 2: not surprisingly, a large variability of composition in terms of some nutrient content, such as sugar (from 3.9 to 36.0 g/100 g), fat (from 14.0 to 26.0 g/100 g) and saturates (from 2.5 to 14.0 g/100 g) is observed. A certain variability is also observed with regard to fiber content, ranging from 1 g/100 g of item 6 to 3.4 g/100 g for item 5. Since these differences are not detectable by considering only this synthetic (algorithm-based) type of FOPL, the information provided appear to be inadequate for people who want (or need) to choose products in order to limit their intake of saturates (for example because of a slightly elevated blood cholesterol level), or of sugar (if their glucose tolerance is impaired), or salt (for a mild increase in blood pressure) or to improve their fiber consumption (17).

## Different messages from different summary FOPL schemes

It is of interest to note that different synthetic FOPL such as Nutri-Score and Keyhole do not necessarily end up in comparable evaluation of individual products, implying that the information on which algorithms have been built are significantly (and conceptually) different. As an example, Table 3 shows nutrient information for four items of breakfast cereals. Between the two products (items 1 and 2) obtaining the same Nutri-Score A (even though the great differences in salt content, which is more than double in one than in the other and in the presence of whole grains which represent 100% of item 1 and are completely absent in item 2), only one matches the criteria needed to bear the Keyhole and can be identified as healthier than the other one. Similarly, of the two B-rated products, only item 3 gets the Keyhole logo, despite its higher sugar and saturated fat content. This observation suggests that, besides being synthetic and not highlighting data related to specific nutrients, the criteria used for the two algorithms largely differ, so that for instance the Keyhole logo can be obtained by products not deserving the best Nutri-Score. These differences may also indicate that the overall nutritional assessment of foods and diets is different in different European countries, highlighting the difficulty of identifying a single system shared at the EU level, as required by current legislation; moreover, they thus question the opportunity to base public information on general principia that are not yet completely shared among experts.

The differences in energy and nutrient contents among the different products are more easily identifiable with the use of NutrInform Battery FOPL, providing more detailed information on calories per 100 g of products and the content of energy and nutrients per portion, both as absolute amounts and as percentages of the daily reference amounts, namely Reference Intakes (the formerly Guideline Daily Amounts), defined for calories and nutrients. NutrInform Battery highlights that similar portions of the four breakfast cereals are not significantly different in terms of energy supply; however, it shows that item 3, although bearing the Keyhole logo, has the highest sugar content, which is in turn higher than that of item 4, even if obtains the same score (B) with the French FOPL system. However, an informative approach, such as that of NutrInform Battery, may be less effective for not educated consumers. On the other hand, Nutri-Score can, as an example, prevent consumers from purchasing nuts since they would have a C, although these items are associated with health protection.

TABLE 2 Energy and nutrient content per 100 g of 12 sweet snacks currently on the Italian market, selected for having the same calculated Nutri-Score (D).

| | Sweet cake 1 | Sweet cake 2 | Sweet cake 3 | Sweet cake 4 | Sweet cake 5 | Sweet cake 6 | Sweet cake 7 | Sweet cake 8 | Sweet cake 9 | Sweet cake 10 | Sweet cake 11 | Sweet cake 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Energy (kJ) | 1,495 | 1,641 | 1,796 | 1,618 | 1,741 | 1,642 | 1,933 | 1,657 | 1,709 | 1,728 | 1,764 | 1,734 |
| Energy (kcal) | 357 | 392 | 429 | 386 | 416 | 392 | 462 | 396 | 408 | 413 | 422 | 414 |
| Fats (g) | 14.0 | 16.0 | 20.7 | 21.0 | 21.0 | 16.0 | 26.0 | 16.0 | 19.0 | 20.0 | 21.3 | 20.0 |
| Saturates (g) | 2.5 | 5.4 | 2.9 | 9.1 | 8.0 | 4.3 | 3.5 | 8.8 | 8.1 | 8.5 | 14.0 | 9.1 |
| Sugar (g) | 29.0 | 21.0 | 28.0 | 3.9 | 15.0 | 36.0 | 31.0 | 24.0 | 22.0 | 22.0 | 17.0 | 22.0 |
| Fiber (g) | 3.0 | 1.7 | 1.3 | 2.5 | 3.4 | 1.0 | 1.5 | 1.9 | 2.1 | 2.0 | 1.9 | 2.1 |
| Protein (g) | 6.4 | 7.4 | 5.9 | 7.4 | 8.6 | 6.3 | 6.2 | 6.8 | 6.2 | 6.2 | 6.7 | 6.5 |
| Salt (g) | 0.72 | 0.44 | 0.64 | 0.71 | 0.75 | 0.46 | 0.70 | 0.42 | 0.57 | 0.57 | 0.44 | 0.56 |

## FOPL and the nutritional role of portion

Beside the potential issue due to the large variability of nutrient contents in products that may get the same score, another criticism concerns the reference amount of product to be considered for the FOPL definition: 100 g, as for Nutri-Score and Keyhole and the portion or sales unit for products sold in single portion, as for NutrInform Battery as well as Traffic Lights. On the one hand, the adoption of systems based on 100 g would make it possible to compare products that are currently marketed in sales units of different sizes; on the other hand, however, it is worth noting that in most cases, the portion, or the quantity of food to be consumed for each eating occasion, is largely different from 100 g. As a consequence, the information provided for 100 g of product, which does not reflect the real absolute intake of energy and nutrients with a portion can indeed mislead the consumer.

As an example, the messages implied in FOPL based on 100 g of food products that should be consumed in much lower quantities for each eating occasion can result in the same products being perceived by consumers as more unfavorable or more favorable than their real nutritional role within the overall diet. This aspect cannot be disregarded, since it has been shown that the use of nutrition claims which are recognized as particularly favorable by consumers can increase their perceived healthfulness (18) and promote their purchase and consumption, especially in overweight subjects (19), and that FOP labeling had significantly stronger influence than nutrition claims on consumers' perceptions (20).

For instance, this is the case of cookies, whose standard portion size, to be consumed as part of a balanced diet, is set by Italian guidelines at 30 g. Despite the quite large variability in terms of energy and nutrient content observed when data are expressed per 100 g of products of different types of cookies currently available on the Italian market (Table 4), both the energy and nutrient supply appears to be less important when data are expressed for single portion. Moreover, the most relevant differences are not necessarily those considered to be important within the algorithm used for Nutri-Score calculation. As an example, the main differences observed between item 1 and item 2, obtaining an A and a B, respectively, with Nutri-Score, concern the content of sugar (lower in item 1) and that of fiber (higher in item 2); however, if considering one portion of products, the main aspect appears to be the contribution to the daily intake in terms of fiber of item 2, supplying about 20% of the total recommended intake, while sugar contained in the same item corresponds to only about one tenth of the maximum level set for total sugar. On the other hand, the energy and nutrient amounts provided by one portion may be similar even between products that obtain different Nutri-Score, as for items 2 and 3, whose contribution in terms of saturated fat, sugar and salt is comparable, although corresponding to a B and a C, respectively. NutrInform Battery

TABLE 3 Energy and nutrient content per 100 g of breakfast cereals sold on the Italian market and selected for having different calculated Nutri-Score and for having or not Keyhole.

| | Breakfast cereals 1 | Breakfast cereals 2 | Breakfast cereals 3 | Breakfast cereals 4 |
|---|---|---|---|---|
| Energy (kJ) | 1,573 | 1,558 | 1,555 | 1,604 |
| Energy (kcal) | 376 | 372 | 372 | 383 |
| Fats (g) | 1.0 | 1.4 | 1.7 | 0.7 |
| Saturates (g) | 0.2 | 0.2 | 0.5 | 0.2 |
| Sugar (g) | 0.3 | 6.2 | 10.8 | 6.6 |
| Fiber (g) | 5.0 | 7 | 7.5 | 3.2 |
| Protein (g) | 8.0 | 13 | 9.4 | 7.3 |
| Salt (g) | 1.0 | 0.4 | 0.95 | 1.0 |
| WG* content (%) | 100 | 0 | 58 | 0 |
| Nutri-Score | A | A | B | B |
| Keyhole** | Yes | No | Yes | No |

*WG: whole grains **General criteria for the assignment of the Keyhole label: less fat, healthier fat, less sugar, less salt, more fiber and wholegrain, more fruits and vegetables, no sweeteners (food additives), no novel foods with sweetening properties, no phytosterols/phytostanols or their esters, not on foodstuffs for children up to 36 months.

allows to appreciate the differences in sugar and saturated fat contents and consequently in terms of contribution to the total saturated and sugar contents of the daily diet; however, it disregards information on fiber, which can be reported on the back of pack label of products, according to Regulation (EU) n. 1169/2011. It is well known that portions are not unambiguously coded for, by now, and that therefore there is considerable discretion and variability in defining their size in different countries (21); nevertheless, the role that portions play in determining the nutritional effects of diets cannot be overlooked. In fact, a portion-based labeling would bring significant advantages to the consumers, allowing them to understand the role of each individual food (and specifically its energy and nutrient supply) to the total daily intake and helping them to compose an overall healthier and balanced diet, which may more likely be the result of combining portions of different foods rather than indefinite amounts of the foods themselves (22).

The importance of considering the portion size even in FOPL can be further demonstrated by comparing a summary FOPL and the nutrient content of food products that are typically consumed as single pieces (e.g., pizza, flatbreads, sweet cakes) and for which different portions are currently available on the market. In fact, in all this cases, as the Nutri-Score, which is easier to understand compared to nutrient specific FOPL, is independent of the amount of product that is actually consumed (i.e., the portion), it can communicate misleading messages to the consumers, who are led to think that a green labeled product marketed in a larger portion may be nutritionally better than a red labeled product marketed in smaller portions in the same category. This can be for instance the case of flatbreads that are currently sold in single-portion packs ranging from 60 to 120 g, which can result in a very different energy and nutrient content per consumption unit. The comparison of 4 different flatbreads selected for having different Nutri-Score (from A to D) and that can be theoretically sold in different amounts such as 75 g, 100 g and 120 g (which are actually available in the Italian market) (Table 5) shows that the serving size may deeply affect the net intake of energy and nutrients with each flatbread, despite an overall increase in energy and nutrient contents per 100 g, as the Nutri-Score rises from A to D. As a result, for instance the net content of energy and "negative" nutrients (e.g., salt, saturated fat) in 120 g of flatbread with the most favorable Nutri-Score (A) may be higher than that assessed in 75 g of the product with the less favorable Nutri-Score (D). On the other hand, comparison of NutrInform Battery FOPL calculated for one portion of each product allows to assess the large differences in terms of energy and nutrient supply as absolute values and especially as percentage of the reference daily intakes: for instance, the lowest energy intake is associated to one portion of both items 1 and 4, which obtain Nutri-Score A and B, respectively; both items 1 and 7 provide the lowest amount of fat (9%), even if obtain A and C, respectively with Nutri-Score; as regards salt, four different products (items 3, 9, 11, 12) provide more than 30% of the daily reference intake per portion, even if obtaining different Nutri-Score (A, C, D and D).

These data demonstrate the importance of portion size in determining the absolute energy and nutrient content, and the contribution of the food product to the whole diet, as highlighted by the EU Regulation. Therefore, this aspect cannot be disregarded in the definition of a FOPL, in order not to mislead the consumer and to help him or her composing an overall healthier diet.

TABLE 4 Energy and nutrient content of cookie items sold on the Italian market, per 100 g with different calculated Nutri-Score, and per portion (30 g) with percentage contribution of each portion to Reference Intakes for energy and nutrients, as in NutrInform Battery.

| | Cookies 1 | | Cookies 2 | | Cookies 3 | | Cookies 4 | | Cookies 5 | | Cookies 6 | | Cookies 7 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nutri-Score | A | | B | | C | | C | | D | | D | | E | |
| | 100 g | | 100 g | | 100 g | | 100 g | | 100 g | | 100 g | | 100 g | |
| Energy (kJ) | 1,664 | | 1,615 | | 1,972 | | 1,895 | | 1,990 | | 2,022 | | 2,046 | |
| Energy (kcal) | 398 | | 386 | | 471 | | 453 | | 476 | | 483 | | 489 | |
| Fats (g/100 g) | 11,2 | | 9,4 | | 19,0 | | 18,0 | | 19,0 | | 20,8 | | 21,7 | |
| Saturates (g) | 1.2 | | 1.1 | | 1.2 | | 2.0 | | 6.2 | | 9.1 | | 11.2 | |
| Sugar (g) | 1.8 | | 19.2 | | 20 | | 20 | | 23 | | 26 | | 25.5 | |
| Fiber (g) | 6.0 | | 14.8 | | 6.5 | | 11 | | 3.5 | | 3.8 | | 2.0 | |
| Protein (g) | 9.0 | | 6.7 | | 7.6 | | 8.0 | | 7.9 | | 6.1 | | 7.0 | |
| Salt (g) | 0.85 | | 0.22 | | 0.7 | | 1.0 | | 0.4 | | 0.375 | | 0.45 | |
| | 30 g | RI %* | 30 g | RI %* | 30 g | RI %* | 30 g | RI %* | 30 g | RI %* | 30 g | RI %* | 30 g | RI %* |
| Energy (kJ) | 499 | | 485 | | 592 | | 569 | | 597 | | 607 | | 614 | |
| Energy (kcal) | 119 | 6 | 116 | 6 | 141 | 7 | 136 | 7 | 143 | 7 | 145 | 7 | 147 | 7 |
| Fats (g) | 3.4 | 5 | 2.8 | 4 | 5.7 | 7 | 5,4 | 8 | 5.7 | 8 | 6.2 | 9 | 6.5 | 9 |
| Saturates (g) | 0.4 | 2 | 0.3 | 2 | 0.4 | 2 | 0.6 | 3 | 1.9 | 10 | 2.7 | 14 | 3.4 | 17 |
| Sugar (g) | 0.5 | 1 | 5.8 | 4 | 6.0 | 7 | 6.0 | 7 | 6.9 | 8 | 7.8 | 9 | 7.7 | 8 |
| Fiber (g) | 1.8 | | 4.4 | | 2.0 | | 3.3 | | 1.1 | | 1.1 | | 0.6 | |
| Protein (g) | 2.7 | | 2.0 | | 2.3 | | 2.4 | | 2.4 | | 1.8 | | 2.1 | |
| Salt (g) | 0.3 | 5 | 0.1 | 2 | 0.2 | 3 | 0.3 | 5 | 0.1 | 2 | 0.1 | 2 | 0.1 | 2 |

*RI %: percentage of Reference Intakes (Energy: 2,000 kcal; Fats: 70 g; Saturates: 20 g; Sugar: 90 g; Salt: 6 g) set out Regulation (EU) n. 1169/2011.

TABLE 5 Energy and nutrient content per serving (75, 100, and 120 g), in different flatbread items with different Nutri-Score sold on the Italian market, reported as absolute values and as percentage of the Reference Intakes, as in NutrInform Battery (Legend: svg, serving).

| | Flatbread 1 | | | Flatbread 2 | | | Flatbread 3 | | | Flatbread 4 | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nutri-Score | | A | | | B | | | C | | | D | |
| Serving (g) | 75 | 100 | 120 | 75 | 100 | 120 | 75 | 100 | 120 | 75 | 100 | 120 |
| Energy (kJ) | 946 | 1,261 | 1,513 | 949 | 1,265 | 1,518 | 980 | 1,306 | 1,567 | 995 | 1,327 | 1,592 |
| Energy (kcal) | 226 | 301 | 362 | 227 | 302 | 363 | 234 | 312 | 375 | 238 | 317 | 380 |
| Fats (g) | 6.5 | 8.6 | 10.3 | 6.9 | 9.2 | 11.0 | 6.5 | 8.6 | 10.3 | 7.4 | 9.8 | 11.8 |
| Saturates (g) | 0.8 | 1.0 | 1.2 | 1.1 | 1.5 | 1.8 | 0.6 | 0.8 | 1.0 | 2.8 | 3.7 | 4.4 |
| Sugar (g) | 1.5 | 2.0 | 2.4 | 1.4 | 1.9 | 2.3 | 2.3 | 3.0 | 3.6 | 1.1 | 1.5 | 1.8 |
| Fiber (g) | 4.6 | 6.1 | 7.3 | 2.7 | 3.6 | 4.3 | 1.8 | 2.4 | 2.9 | 1.5 | 2.0 | 2.4 |
| Protein (g) | 6.5 | 8.7 | 10.4 | 6.5 | 8.7 | 10.4 | 6.5 | 8.7 | 10.4 | 5.9 | 7.9 | 9.5 |
| Salt (g) | 1.1 | 1.5 | 1.8 | 0.9 | 1.2 | 1.4 | 1.2 | 1.6 | 1.9 | 1.4 | 1.9 | 2.3 |
| RI %* | | | | | | | | | | | | |
| Energy | 11 | 15 | 18 | 11 | 15 | 18 | 12 | 16 | 19 | 12 | 16 | 19 |
| Fats | 9 | 12 | 15 | 10 | 13 | 16 | 9 | 12 | 15 | 11 | 14 | 17 |
| Saturates | 4 | 5 | 6 | 6 | 8 | 9 | 3 | 4 | 5 | 14 | 19 | 22 |
| Sugar | 2 | 2 | 3 | 2 | 2 | 3 | 3 | 3 | 4 | 1 | 2 | 2 |
| Salt | 18 | 25 | 30 | 15 | 20 | 23 | 20 | 27 | 32 | 23 | 32 | 38 |

*RI %: percentage of Reference Intakes (Energy: 2,000 kcal; Fats: 70 g; Saturates: 20 g; Sugar: 90 g; Salt: 6 g) set out in Regulation (EU) n. 1169/2011.

## How can FOPL application promote reformulation of food products?

Another aim of FOPL is to encourage the reformulation of food products by manufacturers. When interpretative systems are used, the goal of the reformulation is to move foods toward more favorable scores (23, 24).

Since different strategies are often simultaneously put in place and factors such as general market developments may affect the way the food companies change their products, it appears to be difficult to investigate the isolated effect of FOPL on reformulation. However, the association between FOPL use and the reformulation rate has been the subject of some recent research performed in different countries, with contrasting results. For instance, the analysis of the composition of 4,343 products with the Dutch Choices Logo over 10 years in the Netherlands demonstrated a general propensity to reformulate products to achieve a healthier nutrient composition in the same period, even though the degree of reformulation differed per product category and per nutrient (25). Indeed, total fat and sodium contents were significantly reduced in most products, whereas changes in energy, saturated fatty acids, added sugar and fiber were less consistent among categories (25).

Attempts to investigate the impact of FOP on reformulation have been also done in Australia and New Zealand. In Australia, where the Health Star Rating (HSR) - a summary FOPL system that rates the overall nutritional profile of packaged foods by assigning from ½ a star to 5 stars - has been implemented, reformulation of packaged food products for children, that were available in 2013, occurred in 100% of HSR-labeled-products in comparison to 61.3% of non-HSR labeled products (26). However, the authors reported that only one-third of new products in the market were classified as "healthy," so casting doubts on the idea that the HSR has actually stimulated the development of healthier food. Even in New Zealand, reformulation of HSR-labeled products before and after adoption of HSR (i.e., 2014 and 2016) was greater than that of non-HSR-labeled products over the same period, with greater energy and sodium reduction in HSR products than in non-HSR products (−1.5 vs. −0.4% for energy, and −4.6 vs. −3.1% for sodium) (22). However, caution should be taken in interpreting these results, due to the small number of products displaying HSR graphic labels (5.3% of packaged food and beverage products surveyed in 2016).

In Belgium, a significant reformulation of breakfast cereal products occurred between 2017 and 2018 in anticipation of the implementation of the Nutri-Score FOPL, with reductions in the content of total sugar (−5%; $p < 0.001$) and sodium (−20%; $p = 0.002$) and increases in fiber (+3%; $p = 0.012$) and proteins (+2%; $p = 0.002$) (27). However, the authors stated that it is difficult to attribute these changes (all below 5%, except for salt reduction) exclusively to the introduction of the Nutri-Score, as other commitments by manufacturers were ongoing during that time in Belgium that could have led to a product reformulation. A similar minimal reformulation (reductions in selected nutrient content below 5%) of food and beverage products was reported in Chile, 1 year before the implementation, in 2016, of the FOP warning labels for products high in sodium, total sugars, saturated fats and/or total energy (28). The Authors even reported some increases in critical nutrient and energy content of up to more than 5%.

The current evidence from studies evaluating the impact of food reformulation on nutrient intake as well as on food choices and health status was recently reviewed (29). About 3/4 of the 26 studies included in this analysis found positive results; however, most of them focused on the impact on the intake of salt ($n = 20$) and trans fatty acids ($n = 5$), and only one investigated the impact on whole grain consumption, while other nutrients of potential interest (e.g., sugar) and energy were not considered. Intriguingly, different results were observed based on the proxy of nutrient intake used in the different investigations. For instance, the positive impact on salt was greater when measured as salt purchased compared to salt intake measured using the 24 h urinary excretion. Another aspect pointed out by the authors is that, in reformulation, the reduction in a macronutrient content is usually obtained by an isocaloric substitution with another macronutrient, thus resulting in unchanged total energy density. Moreover, the very low quality of the available evidence in this field, mostly drawn on modeling studies, was underlined in a review of 16 studies investigating the impact of food product reformulation on sugar content (30).

For a throughout evaluation of the potential impact of FOPL on reformulation, it is worth highlighting that the feasibility of reformulation strictly depends on the type and characteristics of food products. On one hand, the reformulation is difficult for food products with specific formulations such as biscuits, cakes, or breads, in which it can also impact on technological, rheological or sensory properties. On the other hand, the nutrient composition, or the related summary FOPL, such as Nutri-Score, can be easily improved for many products through the addition of specific ingredients. This is for instance the case of pizza, in which the addition of vegetables can be effective in improving Nutri-Score from C to B (Table 6). However, the impact of reformulation of this kind of pizza on its nutrient composition and on the contribution to the daily intake in terms of calories and nutrients appears to be negligible, as shown by the NutrInform Battery label calculated for the two products with Nutri-Score B and A, respectively.

Attention should be also paid to the fact that, to improve interpretative FOPL such as Nutri-Score, reformulation could be minimal and made for the sole purpose of getting the product a higher quality score with minimal if any improvement of its nutritional value. For instance, as shown in Table 6, a vegetable pizza with Nutri-Score B can be further improved

TABLE 6 Energy and nutrient content per 100 g and per portion* of different formulated pizza sold on the Italian market, their Nutri-Score and percentage contribution of each portion declared by the manufacturer to Reference Intakes (RI %) (as in NutrInform Battery).

| | Pizza margherita | | Pizza with vegetables | | Pizza with vegetables (reformulated) | |
|---|---|---|---|---|---|---|
| **Nutri-Score** | C | | B | | A | |
| | 100 g | | 100 g | | 100 g | |
| **Energy (kJ)** | 1001 | | 767 | | 767 | |
| **Energy (kcal)** | 239 | | 183 | | 183 | |
| **Fats (g)** | 9 | | 6.6 | | 6.6 | |
| **Saturates (g)** | 4.1 | | 2.3 | | 2.3 | |
| **Sugar (g)** | 3.6 | | 3.7 | | 3.7 | |
| **Fiber (g)** | 1.5 | | 1.8 | | 1.96 | |
| **Protein (g)** | 11 | | 6.9 | | 6.9 | |
| **Salt (g)** | 0.88 | | 0.81 | | 0.65 | |
| **Na (calculated) (mg)** | 352 | | 324 | | 260 | |
| **Fruit &Veg** (%)** | 23.9 | | 42.9 | | 42.9 | |
| | **150 g*** | **RI %*** ** | **190 g*** | **RI %*** ** | **190 g*** | **RI %*** ** |
| **Energy (kcal)** | 369 | 18 | 348 | 17 | 348 | 17 |
| **Fats (g)** | 14 | 19 | 13 | 18 | 13 | 18 |
| **Saturates (g)** | 6.2 | 31 | 4.4 | 22 | 4.4 | 22 |
| **Sugar (g)** | 5.4 | 6 | 7 | 8 | 7 | 8 |
| **Salt (g)** | 1.3 | 22 | 1.5 | 25 | 1.2 | 20 |

* Portion declared by the manufacturer.** Fruits, vegetables, pulses, nuts, and rapeseed, walnut and olive oils.*** RI %: percentage of Reference Intakes (Energy: 2000 kcal; Fats: 70 g; Saturates: 20 g; Sugar: 90 g; Salt: 6 g) set out in Regulation (UE) 1169/2011.

to A by reducing salt by 0.15 g per 100 g of products and with the addition of 0.15 g fiber, which has a very limited nutritional relevance.

The threshold system typical of interpretative, algorithm based FOPL could, in other words, indirectly facilitate (and promote) the reformulation of products with levels of single nutrients close to (just above or just below) the thresholds set; in these products small modifications of the composition, if they allow the decisional thresholds to be exceeded in the desired direction, can lead to a favorable reclassification. This opportunity is intuitively more complex to exploit for products whose composition is far from the thresholds and which should be drastically reformulated, with a high impact on sensory characteristics: with the potentially paradoxical consequence that products with greater nutritional criticality will not be reformulated, while those with small deviations from the proposed model will be.

Moreover, it is noteworthy that the framework for product reformulation should integrate nutrition and health but also food technologies, consumer science, legislation, economics and other disciplines (31). In this context, an emblematic case can be the call to action for replacing of palm oil, which was widely used in the past as cooking oil as well as food ingredient in baked products, due to its low cost, specific technological features, and industrial applications, with the aim to avoid negative effects on human and planet health potentially associated to the use of this vegetable fat rich in saturates (32). This approach would result in the replacement with unsaturated fats, allowing a more favorable fat composition of reformulated products. However, alternatives can have potential drawbacks mainly for technological reasons, for instance, faster oxidation and rancidity, and consequently shelf-life reduction. In many cases reformulation resulted to be technically unfeasible or required a large research and development effort by the food industries to develop low-cost alternatives (33, 34). In particular, in the context of a strategy aimed at encouraging the adoption of overall healthier diets, the economic implications of the reformulation of food products cannot be neglected, since they can differently affect food companies and possibly the availability of selected foodstuffs (35).As for the portion-based informative FOPL systems, the incentive for reformulation could essentially involve the reduction of portion size, which has been described as an efficient strategy to allow the consumption of adequate amounts of several foods, or at least the adaptation of the size of single-portion packs to the reference portions, and greater attention to size of multi-portion packs, to facilitate the consumer in using the most appropriate quantity of food (36). In this regard, it should be emphasized that the definition of reference portions, based on nutritional guidelines, for the different product categories is crucial, also to allow the correct comparison of the nutritional characteristics of foods belonging to the same category.

## Main conclusive considerations

The adoption of different FOPL systems, i.e., interpretative or informative, provides completely different information to consumers. The actual purpose of FOPL, defined by the European regulation (that is, to facilitate consumer understanding of the contribution or importance of the food to the energy and nutrient content of a diet) should be central in the choice of the scheme to be adopted.

Informative systems are more complex and require greater attention from the consumer; however, they are characterized by the transparency of the information conveyed and the educational function (37). NutrInform Battery, being based on reference portions, is proposed as a tool to help people understand the quantity of each food to be consumed as part of a balanced diet.

On the other hand, summary FOPL provide, in a simplified way, information which wants to be user-friendly; however, the use of algorithms to calculate the scores on which they are based are not free of critical aspects. As shown by the examples analyzed in this paper, each value can be the result of multiple combinations of parameters; moreover, the use of thresholds can produce different scores for products which have very similar nutrient composition and nutritional value. In both cases, the message is not clear: in the first one, two different products can be perceived as similar and alternatives, while in the second case, one product can be wrongly recognized as better than the other.

Moreover, advances in nutrition knowledge have led to the awareness of the importance of multiple factors underlying the interaction between diet and individual health, giving rise to the concept of personalized nutrition (or precision nutrition), which can justify the different effects observed for specific nutrients or diet components (e.g., saturated fat, or salt) in different population groups (38). From a public health point of view, it cannot be overlooked that products with different nutrition composition, which obtain the same summary FOPL, may have different effects on health of people according to individual characteristics, physiological/pathological conditions, and nutritional requirements. People who need to keep under control the intake of calories or that of a specific nutrient (i.e., large part of the general adult population) will not be helped by the application of a summary FOPL in the choice of foods suitable to build a healthy, adequate diet (39). Conversely, the presence of a positive or a negative message on the food package could be misleading for most of them, giving rise to food choices which are not necessarily healthier and can be potentially unfavorable for their health (18). Furthermore, the more recent scientific evidence confirms the complexity of the relationship between diet and health, suggesting that other aspects beyond the nutrient composition can influence the effects of the diet on human health: the presence of minor but biologically active components (for example polyphenols in vegetables, chocolate, tea and coffee) and fiber (in whole grains compared to refined grains), the glycemic index, some production processes (such as for example the fermentation of milk that gives rise to yogurt with partly different properties, or the transformation of meat), the structure of the matrix (as evidenced by the different role of saturated fats in milk derivatives). Such differences are very difficult to be accounted for in interpretative systems, since they are quite difficult to be included in the underlying algorithms (although some attempts have been made, i.e., for cheese in Nutri-Score); informative systems, on the other hand, could foresee a sort of add-on nutrition information, that could be object of a specific communication to the public.

Furthermore, an extensive literature in the field of behavioral economics shows that effectiveness, understanding, and acceptability of FOPL could be affected by other factors not strictly related to the nutritional aspects (e.g., economic and psychological factors), which could be also taken into account in defining the most suitable approach.

It is also worth underlining that the literature strongly supports the effectiveness of eating patterns based on a variety of foods (as well as on a healthy lifestyle), which are overall favorable for health, like the Mediterranean diet (40). The communication of the contribution of a single food to the overall diet, which is required by the European regulation, must include the amount of food that is actually consumed. In fact, nutrient intake is the result of the nutrient content of each food, the portion consumed and the frequency of consumption. Therefore, the presence of the simplified nutrition label on the front of pack of food products cannot disregard the concept of standard portion. In this context, it is important to underscore that the definition of standard portions for the different food categories must be a prerogative of the institutions, and not of food companies, and it should be shared by the different Countries and used as a reference for the FOPL.

Another criticism, concerning FOPL based on thresholds, is the impossibility to objectively define levels of energy, nutrients and ingredients which can be considered low, adequate, or high. Any threshold or range proposed will in any case be arbitrary, since even on the basis of all available evidence it will be impossible to define values shared by all the scientific community as absolute reference for all populations. Moreover, while it is quite obvious that nutrient values "just over" or "just below" have essentially the same nutritional value, the threshold system will convey the consumer, in such conditions, significantly or even completely different messages.

Some criticism may also concern the labeling Reference Intakes for energy and nutrients, on which the information delivered by the informative FOPL systems are based, which have been reviewed and defined by the experts of the EFSA Panel on Dietetic Products, Nutrition and Allergies, on a request from the European Commission, "to enable the nutrient content of a food product (per 100 g, per 100 ml, or per portion) to be expressed as a percentage of a typical recommended daily intake (adults)" and to allow "comparison of the nutritional values of food products" (41). Even if, according to the Authors, they have been derived "from science-based nutrient intake recommendations established by national and international authorities, which are based on evidence of relationships between intake and the risk of obesity and/or diet-related diseases (e.g., cardiovascular disease, diabetes mellitus, dental caries)," they must be considered only for labeling and distinguished from dietary reference values established for the different population groups. As a consequence, the selection of "value to take is not a scientific decision, but a management decision to be taken after careful consideration of all implications," as stated by EFSA (42). However, as the reference values for the different population groups, even the levels indicated for energy and nutrients as labeling Reference Intakes should be periodically revised and possibly modified according to the indications of experts and health institutions.

About the possible reformulation of food products to obtain better scores, it should be considered that different kinds of foods have a specific nutrient composition and contain different amounts of nutrients by nature.

Interpretative FOPL, moreover, aim to synthesize a food composition in terms of different nutrients (e.g., saturated fats, salt, fiber), and are consequently forced to overlook the different role of the various nutrients in different foods (e.g., saturated fats in dairy and in meats). Even the adoption of different nutrient thresholds for different food categories, on the other hand, would involve some critical issues, mainly due to the role that both portions and frequency of consumption play in determining the impact of foods on the whole diet composition.

Furthermore, algorithms on which interpretative FOPL are based need to set criteria for the nutritional equivalence of different nutrients and ingredients, which are necessarily characterized by a large discretion: as an example, within Nutri-Score calculation, the same negative value (1 negative point) is attributed to one of these different conditions: energy higher than 335 kJ/100 g, saturated fat higher than 1 g/100 g or sugar higher than 4.5 g/100 g or salt higher than 90 mg/g. The equivalence of such thresholds is difficult to support in an evidence-based context.

Finally, the overall evaluation given by interpretative FOPL does not consider some nutritional aspects, that are relevant in terms of the relationship between nutrition and health, such as the high content of unsaturated fats in foods penalized by the high caloric intake (such as canned fatty fish), or the role of some products penalized for the sugar content as sources of polyphenolic compounds (such as dark chocolate). In the specific case of chocolate, the contribution of polyphenols is important for quantities of consumption compatible with a balanced diet, which are well below the 100 g, on which the sugar and fat content is instead evaluated.

The issue of selecting the data to be included in the calculation and the lack of transparency of the data provided to the consumer (i.e., the results of the algorithm) is overcome by informative FOPL, which merely provide precise numerical information without claiming to give an overall assessment of the food product.

As regards informative FOPL system, it should be considered that transparency and clarity of information, which are its strengths, could represent a limit. In fact, they require the consumer to be previously and adequately informed and instructed to understand and use the information provided by the FOPL in everyday life. Indeed, the centrality of education is highlighted by health institutions even to allow the general population to make proper food choices (43).

Furthermore, it is worth considering that there is a large literature in the field of behavioral economics that analyzes the effectiveness, understanding and acceptability of different FOPL, involving factors that are not strictly limited to nutritional aspects (e.g., economic and psychological), the evaluation of which, however, does not fall within the scope of this analysis.

In conclusion, it can be observed that the interpretative FOPL must necessarily be based on algorithms that summarize in a single score the information relating to different nutrients, or to other characteristics of a food (such as the energy content or the presence of selected ingredients). It follows that the ease of interpretation of the single score may be detrimental to the accuracy of the overall evaluation of a food, with a series of critical issues, as demonstrated by some examples which have been presented and discussed.

Whether such ease of interpretation of summary FOPL systems can compensate for the inaccuracies deriving from their use is not known and should be ascertained by means of adequate experimental studies.

Informative systems, on the opposite, provide the consumer with a less immediate message, and need to be supported by educational campaigns providing the information necessary to understand how to use the information obtained in order to combine foods and to build up a balanced dietary pattern; especially if based on portion sizes, they may actually help in pursuing this essential goal.

## Author contributions

All authors contributed to conceptualization, writing, reviewing and editing of the manuscript, and have read and approved the submitted version of the manuscript.

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# Mortality prediction of the nutrient profile of the Chilean front-of-pack warning labels: Results from the Seguimiento Universidad de Navarra prospective cohort study

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**Background and aims:** Front-of-Pack (FoP) nutrition labelling has been established as a policy, empowering consumers to choose healthy food options for preventing diet-related non-communicable diseases. This study aimed to evaluate the association between the nutrient profile underlying the Chilean warning label score and all-cause mortality and to conduct a calibration with the Nutri-Score in a large cohort of Spanish university graduates.

**Materials and methods:** This prospective cohort study analysed 20,666 participants (8,068 men and 12,598 women) with a mean (standard deviation) age of 38 years (±12.4) from the SUN cohort. Dietary food intake was assessed by a validated semi-quantitative food-frequency questionnaire at baseline and after 10 years of follow-up. The warning label score was calculated by considering the threshold of nutrients (sugar, saturated fat, and sodium) and energy density per 100 g/ml of product, as established by Chilean Legislation. Participants were classified according to quartiles of consumption of daily label score: Q1 (≤5.0), Q2 (>5.0–7.1), Q3 (>7.1–9.8), and Q4 (>9.8). Time-dependent, multivariable-adjusted Cox models were applied. To compare the performance of the warning label score and Nutri-Score to predict mortality, we used the Akaike information criterion (AIC) and Bayesian information criterion (BIC) methods.

**Results:** During a median of 12.2 years of follow-up, 467 deaths were identified. A higher score in the warning label values (lower nutritional quality) was associated with an increased risk of all-cause mortality [HR (95% CI) Q4 vs. Q1: 1.51 (1.07–2.13); $p$-trend = 0.010] and cancer mortality [HR (95% CI) Q4 vs. Q1: 1.91 (1.18–3.10); $p$-trend = 0.006]. However, no statistically significant association was found for cardiovascular mortality. Furthermore, the warning label score and Nutri-Score exhibited comparable AIC and BIC values, showing similar power of prediction for mortality.

**Conclusion:** A diet with a higher warning label score (>9.8 per day) was a good predictor of all cases and cancer mortality in a large Spanish cohort of university graduates. Also, the warning label score was capable to predict mortality as well as the Nutri-Score. Our findings support the validity of the warning label score as a FoP nutrition labelling policy since it can highlight less healthy food products.

KEYWORDS

**all-cause mortality, cancer, CVD, front-of-pack nutrition labels, warning label, Nutri-Score**

## Introduction

According to the World Health Organization (WHO), non-communicable diseases (NCDs), including cardiovascular diseases (CVDs), cancer, diabetes, respiratory diseases, and others, are still the world's leading cause with 71% of premature death between 30 and 69 years of age (1). NCDs share key modifiable behavioural risk factors related to health-related behaviours such as tobacco use, excessive alcohol consumption, and eating habits (1, 2). In particular, it has been estimated that a suboptimal diet is associated with 11 million deaths and 255 million disability-adjusted life-years (2). Among these dietary risk factors, the lower intake of fruits and whole grains stands out (2, 3). Industry process methods such as drying, pasteurization, freezing, and others are important to extend the life of foods. However, the manufactured formulation of ultra-processed foods (UPF) uses many ingredients and employs several processing methods, making the final product high- or ultra-palatable (4). Ingredients include sugar, salt, stabilizers, preservatives, and sources of energy such as oils, fats, hydrogenated fats, and fructose corn syrup, and other ingredients are cosmetic additives to emulate sensorial qualities of unprocessed or minimally processed food (4). Existing evidence suggests that UPF is closely related to poorer diet quality and increased risk of mortality (5, 6). In this context, improving the nutritional quality of food products represents a crucial strategy to reduce the NCDs burden.

Over the past years, some governments have implemented Front-of-Package (FoP) nutrition labels as a part of their strategy to mitigate the global burden of diet-related NCDs (7, 8). FoP labelling complements nutrient declaration, helping consumers to identify the healthiest or unhealthiest options, and prompting the food industry to reformulate their products (7). Many FoP nutrition label formats such as stars, traffic lights, spectrum rating (Nutri-Score), and stop sign warnings (warning label score) are currently used worldwide (7). The warning label was first adopted in Chile for packaged food and drinks with unhealthy levels of sugar, saturated fats, sodium, and/or calories (7, 9). Similar warning label systems have been adopted or are being considered in Peru, Uruguay, Argentina, Mexico, and Brazil (7, 10). Whereas in Europe, many countries have adopted the Nutri-Score, a five-colour FoP label based on nutritional criteria established by the Food Standard Agency Nutrient Profiling System (FSA-NPS) (11). The last few years have witnessed huge growth in the number of studies suggesting an association between the Nutri-Score nutrient profile and the increased risk of mortality and NCDs the effect of (6, 12–16). However, there has not been any research evaluating the effect of food consumption with Chilean warning label scores on health outcomes. To address of our study this gap in the research outlined earlier, the main objective of our study was to prospectively assess the association between the nutrient profile underlying the Chilean warning label score and mortality. Secondly, we investigated the prediction power for mortality by comparing the warning label score and Nutri-Score nutrition profiles.

## Materials and methods

### Study population: Seguimiento Universidad de Navarra cohort project

The Seguimiento Universidad de Navarra (SUN) project is an ongoing, multipurpose, prospective, and dynamic cohort study of Spanish university graduates (17). This cohort study investigates sociodemographic, lifestyle, and dietary factors related to the development of NCDs (17). The Institutional Review Board of the University of Navarra approved the study protocol. Individuals gave consent to participate in the study if they complete the first self-administrated questionnaire. All study procedures were conducted according to the Declaration of Helsinki. This study was registered at clinicaltrials.gov (NCT02669602).

Details of the design and methods of the SUN cohort have been previously published (17). In brief, the recruitment of volunteers started in December 1999 at the University of Navarra and other Spanish universities. Data collection and follow-up are done every 2 years by email or ordinary mail questionnaires. By December 2019, the cohort included 22,894 volunteers. To assure a minimum follow-up of 2 years and 9 months (to allow participants to fill the first follow-up questionnaire and account for the lag time in returning the questionnaire and avoid a potential selection bias), we only included participants recruited before March 2017. Out of 22,553 eligible participants, we excluded 450 individuals with an extreme total daily energy intake (<1st and >99th centiles) and 1,437 participants were lost to follow-up with a retention rate of 93%. For the present analysis, we included 20,666 participants (**Figure 1**).

## Covariate assessment

At baseline, volunteers completed a self-administrated questionnaire that includes information related to sociodemographic (marital status, years of university education, others), anthropometric measurements (weight and height), lifestyle variables (smoking habits, alcohol intake, physical activity, amount of time spent on screen devices, others), as well as family and personal medical history. NCDs such as diabetes, cancer, and cardiovascular events were confirmed by medical reports. Self-reported measurements and diagnosis at baseline and during the follow-up were previously validated in a subsample of the cohort and have been found reliable (18–21).

## Outcome ascertainment

The primary end-point was mortality from all causes, including CVD and cancer. Deaths were reported by next-of-kin, professional associations, or the postal system authority, which permitted us to identify more than 85% of deaths. For the rest of the deceased, the Spanish National Death Index was checked at least once a year to confirm the vital status of the participants and to request data about the cause of death. Trained physicians, blinded to the exposure, classified the cause of death considering the International Classification of Diseases (10th version) based on the data provided by the National Death Index.

## Dietary intake assessment

Dietary intake was self-reported by participants at baseline and after 10 years of follow-up through a validated 136-item food-frequency questionnaire (FFQ) (22, 23). The FFQ includes foods and beverages frequently consumed in Spain, such as dairy products and derivates, eggs, meat (fresh and processed), fish, seafood, vegetables, fruits, legumes and cereals, oils and fats, pastries, beverages (alcoholic, sugar-sweetened, and artificially sweetened beverages), and a miscellaneous group. Participants were asked to report on average over the past year their frequency of consumption, considering a specific typical Spanish serving per day (slice, teaspoons, glass, and others) for each of 136 food items. The nutrient composition of the dietary intake was assessed based on Spanish food composition tables (24, 25). Frequency of consumption was split into nine categories ranging from never/almost never to >6 servings/day for each FFQ item. Daily consumption was calculated by multiplying portion size by frequency. Nutrient intakes were computed as the sum of the frequency of consumption (converted to daily intake) of each item multiplied by the nutrient composition of specified portion size. Adherence to the Mediterranean Diet (MedDiet) was evaluated using the well-known 0–9 Mediterranean Diet Score (26, 27).

## Warning label score

The FoP nutrition label was established by the Chilean Government, according to the regulation of pre-packaged foods in 2019 (**Figure 2**) as part of a unique law mandating warning labels, restricting marketing, and regulating school sales for products classified as nutritionally unhealthy. The black-and-white stop sign (octagons) labels use data from the nutritional declaration for 100 g or 100 ml of product and include the expression "High in" if the amount of added sugar, sodium, saturated fat, and/or calories exceeds the acceptable thresholds (**Figure 2**; 9, 28, 29), according to the Spanish food composition in the case of our study (24, 25). Products are required to carry a stop sign warning for each nutrient exceeded, meaning some products can require up to four labels. The warning label should be placed on any place of the package if the surface is between 30 and 60 $cm^2$, and in the main container package if the product is smaller than 30 $cm^2$. The food groups considered in the present study (shown in **Supplementary Table 1**) correspond to pre-packaged products, including processed and ultra-processed, as well as fats such as margarine, butter, and lard. Processed foods include canned or bottled foods (legumes, vegetables, and fruits) preserved in salt or syrup; canned sardine or

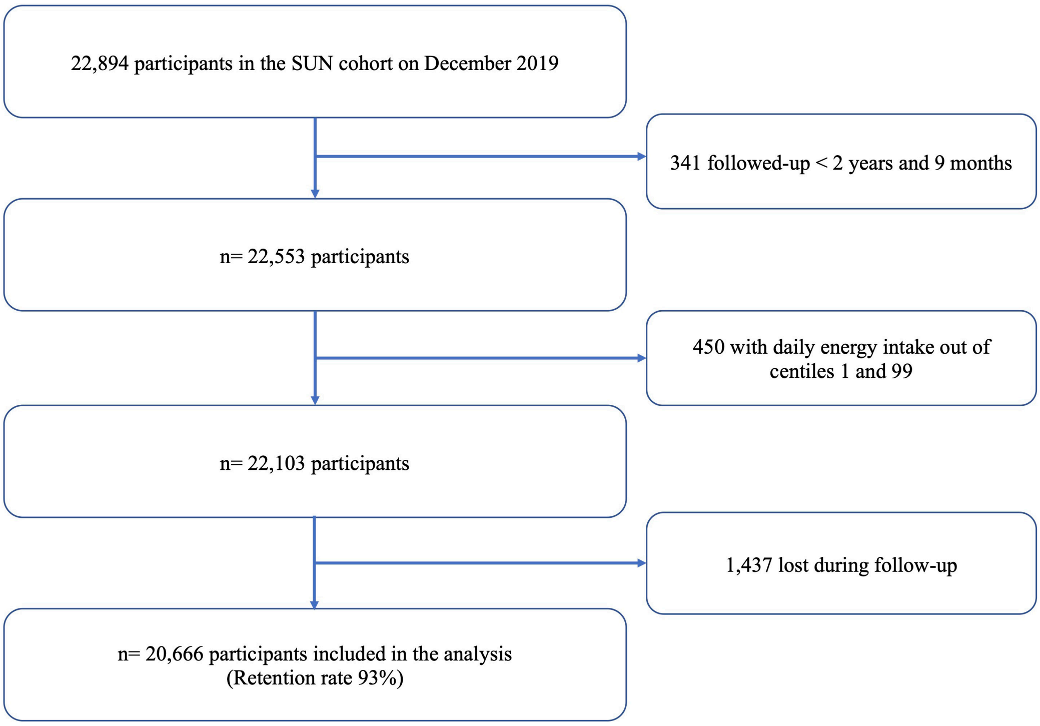


FIGURE 1
Flow chart for participants included in the SUN project.


| | Excess sugars | Excess saturated fats | Excess sodium | Excess calories |
|---|---|---|---|---|
| Solid (100 g of product) | 10 g | 4 g | 400 mg | 275 Kcal |
| Liquid (100 ml of product) | 5 g | 3 g | 100 mg | 70 Kcal |

FIGURE 2
The four approved warning labels in Chile implemented as front-of-package labels and Chilean score computation for warning labels in pre-packaged food and beverage. All octagons indicate "Ministry of health".

tuna; salted, smoked, or cured meat or fish; cheeses; and bread and baked products. Ultra-processed products comprise carbonated soft, sweetened drinks, or juices; sweet, salty, or fatty packaged snacks; biscuits (cookies and cakes); ice cream; candies (confectionery); sweetened breakfast cereals; sugared milk; and products ready to eat (instant soups, noodles, desserts, sausages, burgers, pizza, and all pre-prepared meat) (29, 30). We considered the density of liquid products (milkshakes, sugar-sweetened and artificially sweetened beverages, and bottle juice) as 1 g/ml. Only added sugars were considered to evaluate excess sugar for dairy products, not considering lactose. The products of the FFQ that exceeded any of the nutrient thresholds per 100 g/ml (**Figure 2**) were assigned the respective warning label (**Supplementary Table 1**). For the calculation of the warning labels, the average of the critical nutrients based on the Spanish food composition tables contained in each food item of the FFQ was used (e.g., the critical nutrients of sausages were estimated as the average of nutrients from the consumption of sausages, chorizo, and mortadella). At the individual level, the total score of warning labels was computed as the sum of the warning label of each food or beverage consumed divided by 100 g/100 ml of food/liquids:

$$\text{Warning label score (per day)} = \sum_{i=1}^{n} \left( \frac{\text{WS}_i I_i}{100} \right) \quad (1)$$

WS represents the number of warning labels of each food/beverage of the FFQ, $i$ per 100 g/ml of product, and $I_i$ the total intake of each food/beverage in grams or millilitres per day.

## The Nutri-Score nutrient profile

The computation of the Nutri-Score FOP labelling has been described elsewhere (6, 31, 32). In brief, the algorithm allocated points based on the nutrient content of 100 g/ml of a food or beverage (6, 12, 13, 16, 33–35). For the content of critical nutrients, which are relevant for the risk of NCD, 0–40 points were allocated (0–10 points for each following components: sugars [g], saturated fats [g], sodium [mg], and energy [kJ]) and 0–15 points were allocated for the content of beneficial nutrients that should be promoted (0–5 points for each component: fibres [g], proteins [g], and the percentage of vegetables, fruits, legumes, nuts, rapeseed, walnut, and olive oils that compose the total product [%]) (6). The total food/beverage-level score was computed by subtracting the content of nutrients that should be consumed in limited amounts (negative points) from the nutrients that should be encouraged (positive points) (6). Therefore, the final FSAm-NPS score for each food/beverage range from −15 (most healthy) to +40 (least healthy). The individual-level score was calculated as the sum of the FSAm-NPS score for each food/beverage consumed multiplied by the quantity of energy supplied by that product divided by the sum of energy consumption from all foods (6).

## Statistical analyses

Participants were classified according to quartiles of consumption of the warning label score at baseline and for the repeated measurement analyses at 10 years of follow-up. Categorical and continuous variables are presented as percentages or means (standard deviation), respectively. Cox proportional hazard regression models with age as the underlying time variable (birth date as origin) were fitted to evaluate the potential association between quartiles of the warning label score and mortality, including all-cause, CVD, and cancer. Participants contributed person-time to the model from the date of returning the baseline questionnaire until the date of death, loss to follow-up, or when the last follow-up questionnaire was completed, whichever event occurred first. To minimize any measurement errors for variations in the dietary pattern during the follow-up, we performed time-dependent Cox regression models using repeated measures, considering cumulative average data and updated information on dietary consumption of the 10-year follow-up questionnaire for volunteers with follow-up longer than 10 years. The Pearson correlation coefficient between the score of warning labels at baseline vs. 10 years was moderate ($r$ = 0.37; $p$ < 0.001). For the analyses of CVD and cancer mortality, we excluded deaths attributable to other causes to rule out residual confounding. Hazard ratios (HR) and 95% CIs were estimated using the first quartile as the reference category. Multivariable models were stratified for deciles of age and recruitment period. After sex and age-adjusted analyses, multivariable models were also adjusted for marital status (married yes/no), physical activity evaluated as METs-h/week (continuous), alcohol intake (g/d, continuous), smoking status (never, current, and former), pack-years of cigarette smoking (continuous), snacking between meals (yes/no), following a special diet at baseline (yes/no), body mass index (linear and quadratic terms), total energy intake (quartiles), years of university education (continuous), family history of cardiovascular disease (CVD) and cancer, prevalent CVD, hypertension, diabetes, cancer and depression, and self-reported hypercholesterolemia at baseline. For the variable smoking pack-years, 7.9% of data were missing, and we applied simple imputations using as predictor variables age, sex, physical activity, years of university, BMI, alcohol consumption, adherence to the MedDiet, and mortality. A Linear trend test was conducted across quartiles assigning the median value to each category and treating them as a continuous variable. Furthermore, stratified analyses were carried out according to sex (men or women); age at recruitment (<45 or ≥45 years); baseline BMI (<25 or ≥25 kg/m$^2$); and smoking habits at baseline (ever or never smoker). To evaluate the robustness of our findings, we applied the following sensitivity analyses: considering different plausible energy limits proposed by Willett (36), as well as percentiles 5–95 to avoid information bias due to over or under-reporters; excluding volunteers who had prevalent conditions at baseline (CVD, cancer, and diabetes); omitting premature death (if it occurred earlier than 2-year follow-up); excluding snacking between meals as a confounder; and additionally adjusted for fibre intake. Restricted cubic splines with three knots, considering zero as reference were applied to the flexible model to graphically represent the dose-response association between mortality and the warning label score (as continuous), as well as to evaluate non-linearity.

Exploratory analyses were performed to assess the effect of different food policy approaches on the risk of all-cause mortality. For this purpose, participants were categorized under or above the median ($\geq p50^{th}$) of the warning label score or Nutri-Score, and >4 servings/day of UPF based on previously published studies from our cohort (5, 6). We also evaluated multiple interactions between them by testing an interaction product term with the maximum likelihood ratio test. To find out the ability of predicting the relationship between all-cause mortality and the nutrient profiles of the warning label score and Nutri-Score, we categorized participants into quartiles of both FoP labels and compared the fourth vs. the first quartile of these exposures using the Akaike Information Criteria (AIC) and Bayesian Information Criteria (BIC) in the adjusted model previously mentioned. All tests were two-sided and statistical significance was set at the conventional 0.05 level. Analyses were performed using STATA version 16.0 (StataCorp, College Station, TX, USA).

## Results

A total of 20,666 participants, including 8,068 men and 12,598 women (**Figure 1**) with an average of 38 [12.4] years (mean [SD] age at baseline), were analysed. After a median follow-up of 12.2 years (238,217 person-years), a total of 467 overall deaths were registered of which 90 (19.3%) were attributed to CVD, 242 (51.8%) to cancer, 137 (26.1%) to other causes, and 13 (2.8%) to unknown causes. **Table 1** shows baseline characteristics of the cohort study categorized by quartiles of warning label score. Participants in the highest quartile were more likely to be men, never smokers, spend more time watching TV and using computer, snack between meals, and have a lower prevalence of diabetes, cancer, and CVD at baseline compared to the lowest quartile. Regarding dietary components, individuals with a higher warning label score in their diet had an increased energy intake, saturated fats, sodium, and alcohol, as well as lower adherence to the MedDiet than those in the lowest category. Moreover, these participants (Q4) had a slightly low intake of vegetables, fruits, and low-fat dairy products compared to those in Q1. Meanwhile, individuals in the fourth quartile of the warning label score (Q4) showed slightly higher fibre consumption than participants in the first quartile. This result could be attributed to the fact that the foods included in the warning label score are not related to sources rich in fibre, such as fruits, vegetables, dry fruits, and others. On average, participants in the highest quartile had a higher intake of white bread, dairy products, red and processed meat, and UPF foods than individuals in the lowest quartile.

The HRs for all cause and cause specific mortality according to quartiles of the score of Chilean warning labels are presented in **Table 2**. Higher score of these warning labels (Q4) was associated with an increased risk of all-cause mortality compared to the lowest quartile (Q1: reference) in the fully adjusted model: 1.51 (95% CI: 1.07–2.13), and there was a linear dose-response relationship across quartiles ($p$-trend = 0.010). Moreover, the multivariable-adjusted model showed that participants in the fourth quartile of warning labels had an increased risk of cancer mortality [HR: 1.91 (95% CI: 1.18–3.10; $p$-trend = 0.006)] compared to the first quartile. However, there was no statistically significant association between this score of warning label and CVD mortality [(HR: 1.20; 95% CI: 0.54–2.69; $p$-trend = 0.670)]. Repeated measurements, using data from food consumption after 10 years of follow-up evidenced that the highest quartile of warning labels was consistently associated with a significantly higher risk to all-cause [(HR: 1.47; 95% CI: 1.04–2.08; $p$-trend = 0.089)] and cancer mortality [(HR: 1.84; 95% CI: 1.14–2.96; $p$-trend = 0.028)] as compared to the lowest quartile. **Figure 3** shows the relationship between food consumption with the warning label score and overall mortality in subgroup analyse comparing the fourth vs. the first quartile. However, we did not find statistically significant interactions (all $p$-values > 0.1). To test the robustness of our main findings, several sensitivity analyses were conducted (**Figure 4**) after considering different scenarios. Results did not change in any of the different scenarios, suggesting that the association between higher scores of the Chilean warning label nutrient profile and all-cause mortality was robust. Nonetheless, when we excluded cases of prevalent conditions (CVD, cancer, and diabetes), the associations were no longer significant. **Figure 5** shows the dose-response relationship between intake of warning labels and all-cause mortality. The restricted cubic spline model indicated that individuals who had more than 10 warning labels had a higher risk of all-cause mortality (**Figure 5**). In addition, we evaluated the relative influence of each of the warning labels by repeating the multivariable-adjusted Cox regression models excluding one warning label at a time and comparing the highest vs. lowest quartile (**Figure 6**). All HRs showed a direct association between mortality and higher intake of warning labels, but interestingly no significant association was found when excluding sugar warning labels (HR: 1.34; 95% CI: 0.96–1.89). Analyses combining exposures (warning label, UPF, or Nutri-Score) are shown in **Table 3**. Participants in the highest categories (warning label $\geq p50$th and UPF > 4 servings/day) presented a 66% increased risk of mortality [HR (95% CI): 1.66 (1.21–2.26)] compared to the lowest category. Similar results were found for the highest score of warning label and Nutri-Score (both $\geq p50$th) [HR (95% CI): 1.51 (1.14–2.01)], as well as when we evaluated the Nutri-Score and UPF intake [HR (95% CI): 1.60 (1.22–2.11)] (**Supplementary Table 2**). When comparing the warning label score and Nutri-Score (**Table 4**), fully adjusted models showed that the AIC and BIC values did not differ from each other when we compared the highest vs. lowest quartile. For the warning label: AIC = 4264, BIC = 4470; and for the Nutri-Score: AIC = 4266, BIC = 4472.

TABLE 1 Baseline characteristics of participants according to quartiles of the score calculated for Chilean warning labels: the SUN (Seguimiento Universidad de Navarra) cohort.

| Variable | Quartiles of the score for Chilean warning labels | | | |
|---|---|---|---|---|
| | Q1 | Q2 | Q3 | Q4 |
| N | 5167 | 5167 | 5166 | 5166 |
| Age, years | 41.6 (13.0) | 38.6 (12.3) | 36.7 (11.6) | 35.6 (11.7) |
| Sex, men (%) | 35.1 | 35.5 | 39.2 | 46.4 |
| Score of Warning labels (per day) | 3.6 (1.0) | 6.0 (0.6) | 8.3 (0.8) | 13.2 (3.4) |
| BMI (kg/m$^2$) | 23.8 (3.6) | 23.5 (3.5) | 23.3 (3.5) | 23.4 (3.6) |
| Married (%) | 55.2 | 52.5 | 49.2 | 43.0 |
| Years of university education | 5.0 (1.5) | 5.1 (1.5) | 5.0 (1.5) | 5.0 (1.5) |
| **Smoking status, n (%)** | | | | |
| Never | 44.2 | 48.2 | 50.7 | 52.5 |
| Current | 20.3 | 21.0 | 22.4 | 24.1 |
| Former | 35.5 | 30.8 | 26.9 | 23.4 |
| Physical activity (METs-h/week) | 22.1 (23.5) | 21.5 (21.4) | 21.8 (23.0) | 22.4 (24.6) |
| **Screen time** | | | | |
| Television viewing (h/day) | 1.6 (1.1) | 1.6 (1.1) | 1.6 (1.2) | 1.7 (1.2) |
| Computer time (h/day) | 2.0 (1.9) | 2.1 (1.9) | 2.1 (1.9) | 2.2 (2.0) |
| **Conditions at baseline** | | | | |
| Diabetes (%) | 3.2 | 1.6 | 1.3 | 1.0 |
| Cancer (%) | 3.5 | 2.4 | 2.3 | 1.8 |
| Hypertension (%) | 14.6 | 11.1 | 9.3 | 9.3 |
| Cardiovascular disease (%) | 2.4 | 1.6 | 1.1 | 1.2 |
| Hypercholesterolemia (%) | 22.1 | 16.9 | 15.3 | 13.8 |
| Depression (%) | 13.5 | 11.2 | 10.8 | 11.0 |
| Family history of CVD (%) | 16.2 | 13.8 | 12.8 | 12.4 |
| Family history of cancer (%) | 17.3 | 15.6 | 14.2 | 13.9 |
| Following special diets (%) | 15.3 | 7.6 | 5.1 | 4.3 |
| Between-meal snacking (%) | 25.2 | 31.5 | 37.2 | 43.5 |
| **Dietary nutrient profile** | | | | |
| †Adherence to MedDiet (0–9 points) | 5.1 (1.7) | 4.7 (1.7) | 4.4 (1.7) | 4.2 (1.6) |
| Total energy intake (kcal/day) | 1824 (481) | 2231 (459) | 2618 (493) | 3343 (709) |
| Carbohydrate (%) | 42.3 (8.5) | 43.0 (7.1) | 43.5 (6.7) | 44.8 (7.1) |
| Protein (%) | 19.8 (3.8) | 18.4 (2.9) | 17.5 (2.6) | 16.4 (2.7) |
| Fat (%) | 35.4 (7.4) | 36.5 (6.3) | 37.1 (6.0) | 37.2 (6.2) |
| Monounsaturated fatty acids (g/day) | 31.9 (12.9) | 39.1 (12.5) | 46.0 (13.6) | 57.8 (18.0) |
| Polyunsaturated fatty acids (g/day) | 22.5 (8.0) | 30.1 (8.1) | 37.0 (9.6) | 49.6 (17.1) |
| Saturated fatty acids (g/day) | 9.9 (4.5) | 12.6 (4.8) | 15.6 (5.7) | 20.5 (7.9) |
| Total dietary fibre intake (g/day) | 27.4 (14.3) | 28.2 (13.4) | 29.6 (13.6) | 33.3 (14.5) |
| Sodium intake (mg/day) | 2552 (1016) | 3453 (1253) | 4321 (1697) | 6368 (4023) |
| Alcohol intake (g/day) | 6.3 (10.4) | 6.5 (9.7) | 6.8 (10.2) | 7.6 (11.9) |
| **Food consumption** | | | | |
| Vegetables (g/day) | 567 (389) | 547 (359) | 540 (364) | 549 (381) |
| Fruits (g/day) | 377 (351) | 364 (312) | 362 (340) | 368 (343) |
| Total nuts (g/day) | 7.8 (17.5) | 7.5 (13.2) | 8.4 (14.6) | 9.1 (13.1) |
| Vegetable fat (g/day) | 18.5 (15.2) | 20.3 (15.9) | 21.9 (16.7) | 24.1 (18.6) |
| Olive oil (g/day) | 17.4 (14.7) | 18.8 (15.1) | 19.9 (15.5) | 21.5 (17.3) |
| ‡Animal fat (g/day) | 1.9 (4.0) | 3.1 (5.3) | 4.1 (7.3) | 5.8 (13.1) |

*(Continued)*

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TABLE 1 (Continued)

| Variable | Quartiles of the score for Chilean warning labels | | | |
|---|---|---|---|---|
| | Q1 | Q2 | Q3 | Q4 |
| Legumes (g/day) | 22.3 (20.6) | 22.4 (17.3) | 24.2 (20.4) | 25.7 (20.8) |
| White bread (g/day) | 25.2 (29.8) | 49.8 (46.6) | 70.2 (59.5) | 109.2 (99.8) |
| Whole grain bread (g/day) | 14.5 (29.2) | 15.0 (33.4) | 13.1 (34.0) | 14.0 (39.9) |
| Dairy products (g/day) | 125 (165) | 178 (188) | 228 (205) | 301 (251) |
| Low-fat dairy products (g/day) | 252 (258) | 239 (252) | 225 (244) | 216 (264) |
| Fish and shellfish (g/day) | 102 (67.4) | 101 (74.9) | 101 (68.4) | 103 (71.8) |
| Red meat (g/day) | 64.1 (47.6) | 75.1 (44.0) | 84.9 (49.5) | 95.5 (55.5) |
| Processed meat (g/day) | 28.8 (20.9) | 40.6 (26.0) | 50.2 (29.7) | 66.1 (49.4) |
| Ultra-processed food (g/day) | 12.9 (14.2) | 20.1 (17.7) | 25.2 (22.1) | 33.0 (33.3) |
| Pastries (g/day) | 24.0 (20.7) | 41.5 (29.2) | 58.6 (38.6) | 98.1 (79.9) |
| Sugar sweetened beverages (g/day) | 21.4 (36.6) | 43.4 (57.7) | 68.1 (82.3) | 137.1 (191.0) |
| Nutri-Score | 2.8 (1.8) | 4.2 (1.6) | 5.1 (1.5) | 6.2 (1.8) |

MET, metabolic equivalent of task.
┼9-item Mediterranean Diet Score proposed by Trichopoulou et al. (27, 28).
‡Sum of butter, lard, and cream.

TABLE 2 Cox proportional hazard ratios (95% confidence intervals) for mortality according to quartiles of Chilean warning label score.

| | Q1 | Q2 | Q3 | Q4 | *P* for trend |
|---|---|---|---|---|---|
| Daily warning label score | 0–5.0 | >5.0–7.1 | >7.1–9.8 | >9.8 | |
| **All-cause mortality** | | | | | |
| N° participants | 5,167 | 5,167 | 5,166 | 5,166 | |
| Person-years | 57,414 | 59,099 | 60,743 | 60,961 | |
| N° deaths | 156 | 98 | 100 | 113 | |
| Age and sex adjusted | 1.00 (Ref) | 0.83 (0.65–1.06) | 1.01 (0.78–1.30) | 1.07 (0.83–1.37) | 0.391 |
| Multivariable adjusted | 1.00 (Ref) | 0.97 (0.74–1.27) | 1.32 (0.95–1.83) | 1.51 (1.07–2.13) | 0.010 |
| Repeated measurements of diet | 1.00 (Ref) | 1.02 (0.78–1.32) | 1.32 (0.96–1.81) | 1.47 (1.04–2.08) | 0.089 |
| **CVD mortality** | | | | | |
| N° participants | 5,049 | 5,090 | 5,078 | 5,072 | |
| Person-years | 56,390 | 58,461 | 59,975 | 60,098 | |
| N° deaths | 38 | 21 | 12 | 19 | |
| Age and sex adjusted | 1.00 (Ref) | 0.73 (0.42–1.25) | 0.53 (0.28–1.01) | 0.79 (0.44–1.42) | 0.348 |
| Multivariable adjusted | 1.00 (Ref) | 0.87 (0.49–1.54) | 0.77 (0.34–1.75) | 1.20 (0.54–2.69) | 0.670 |
| Repeated measurements of diet | 1.00 (Ref) | 0.99 (0.57–1.73) | 0.74 (0.32–1.72) | 1.16 (0.51–2.63) | 0.930 |
| **Cancer mortality** | | | | | |
| N° participants | 5,084 | 5,123 | 5,123 | 5,111 | |
| Person-years | 56,697 | 58,706 | 60,425 | 60,474 | |
| N° deaths | 73 | 54 | 57 | 58 | |
| Age and sex adjusted | 1.00 (Ref) | 0.97 (0.68–1.39) | 1.19 (0.84–1.68) | 1.27 (0.89–1.81) | 0.122 |
| Multivariable adjusted | 1.00 (Ref) | 1.14 (0.78–1.68) | 1.50 (0.96–2.35) | 1.91 (1.18–3.10) | 0.006 |
| Repeated measurements of diet | 1.00 (Ref) | 1.16 (0.79–1.71) | 1.48 (0.95–2.28) | 1.84 (1.14–2.96) | 0.028 |

Ref, reference. Multivariate model adjusted for age (underlying time variable), sex, marital status (married), physical activity (continuous), alcohol intake (g/d, continuous) smoking status (never, current, and former), pack-years of cigarette smoking (continuous), snacking (dichotomous), special diet at baseline (dichotomous), body mass index (linear and quadratic terms), total energy intake (quartiles), years of university education (continuous), family history of cardiovascular disease (CVD) and cancer, prevalent CVD, hypertension, diabetes, cancer and depression, self-reported hypercholesterolemia at baseline. Stratified by deciles of age and recruitment period. Multivariable adjusted with repeated measures were adjusted for the same variables with updated data at 10 years of follow-up (smoking, energy, and alcohol intake).

## Discussion

The results of the present study provide new insights into the association between the nutrient profile underpinning the warning label score and mortality in a large prospective Spanish cohort. To our knowledge, this is the first study that suggests that higher consumption of foods with warning labels (>9.8/day) (poorer nutritional quality), indicating a lower healthiness, is significantly associated with the risk of all-cause and cancer mortality. These findings add to previous studies evaluating the relationship between the Nutri-Score FoP label and health outcomes in other prospective cohorts, including

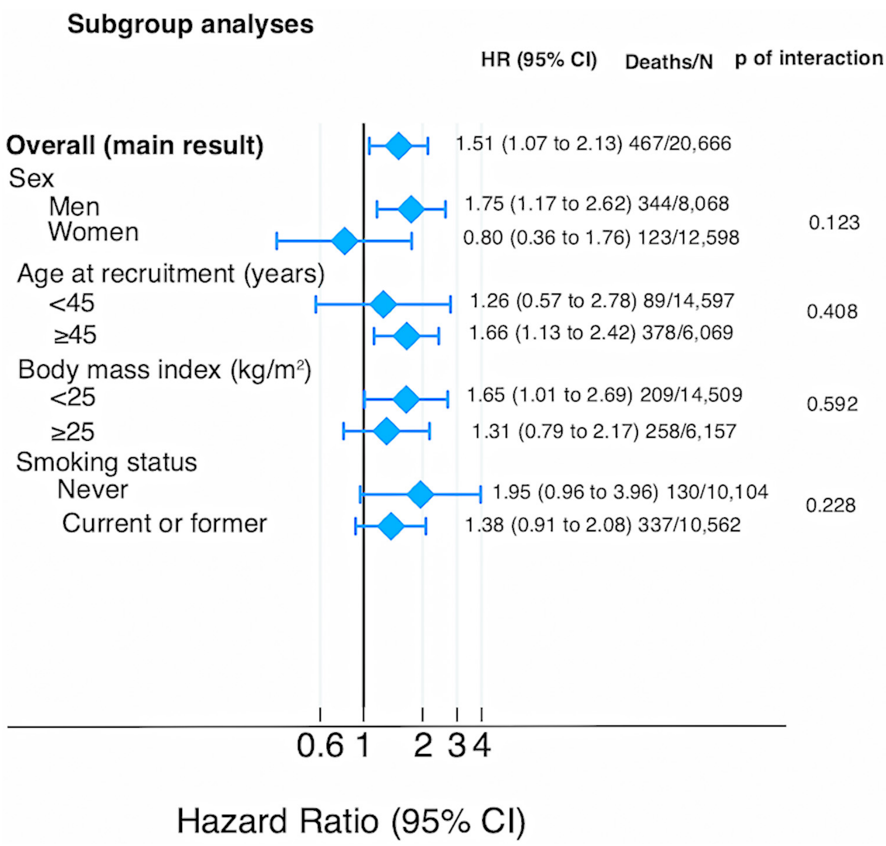


FIGURE 3
Sub-group analyses for the association between Chilean warning label score and all-cause mortality (multivariable-adjusted HR and 95% CI for the highest vs. lowest quartile).

the SUN project. Gómez-Donoso et al. showed that higher FSAm-NPS (nutritional algorithm underpinning the Nutri-Score) characterised by a lower diet quality was associated with a higher risk of all-cause mortality [HR highest vs. lowest quartile (95% CI): 1.82 (1.34–2.47); $p$-trend $< 0.001$] and cancer mortality [HR highest vs. lowest quartile (95% CI): 2.44 (1.54–3.85); $p$-trend $< 0.001$] in the SUN cohort (6). Moreover, some studies of the European Prospective Investigation into Cancer and Nutrition (EPIC) cohort study have shown an association between a higher FSAm-NPS intake and a higher risk of cancer and higher rates of mortality overall and from cancer and diseases of the circulatory, respiratory, and digestive systems (12, 13).

A modelling study predicted the effect of warning labels on obesity reduction in Mexico 5 years after implementation (37). Investigators estimated a caloric reduction of an average of 36.8 kcal/person/day from beverages and snacks, which could reduce obesity rates by 14.7% (37). These results are relevant considering that obesity is recognized as a major risk factor for several cancers, CVDs, and premature death (38, 39). Our findings did not show a significant association between the nutrient profile of warning labels and CVD mortality, one possible explanation for this finding may be the lack of statistical power to detect any significant association in CVD mortality due to the low number of cases of CVD deaths. In addition, in the sensitivity analysis excluding participants with CVD at baseline, the statistical significance between warning label score and total mortality was weaker probably because the number of total deaths decreased. However, an increased intake of UPF was related to a higher warning label score. This result might be explained by the fact that the nutrient profile of the warning labels takes into account critical nutrients and energy content, a nutritional composition dimension closely related to the UPF. Bonaccio et al. reported that higher intake of UPF was directly associated with CVD mortality (highest vs. lowest quartile: 1.58; 95% CI: 1.23–2.03) and death from ischemic heart disease/cerebrovascular disease (highest vs. lowest quartile: 1.52; 95% CI: 1.10–2.09) among participants from Italy with a mean age of 55 years (40). It has to be mentioned that UPF are industrially manufactured ready-to-eat or heat foods that usually use industrial processes, modification of the food matrix, and food additives, leading to the production of several components closely related to CVD (41). Previous studies in the SUN cohort showed that the highest intake

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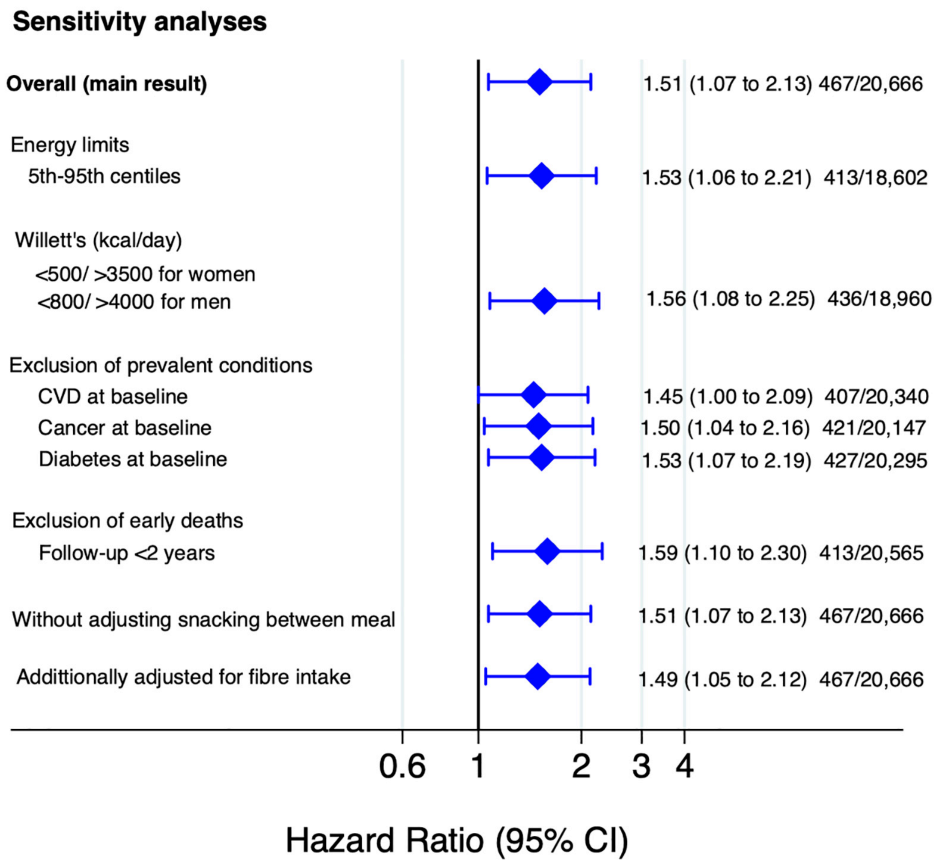


FIGURE 4
Sensitivity analyses for the association between Chilean warning label score and all-cause mortality (multivariable-adjusted HR and 95% CI for the highest vs. lowest quartile).

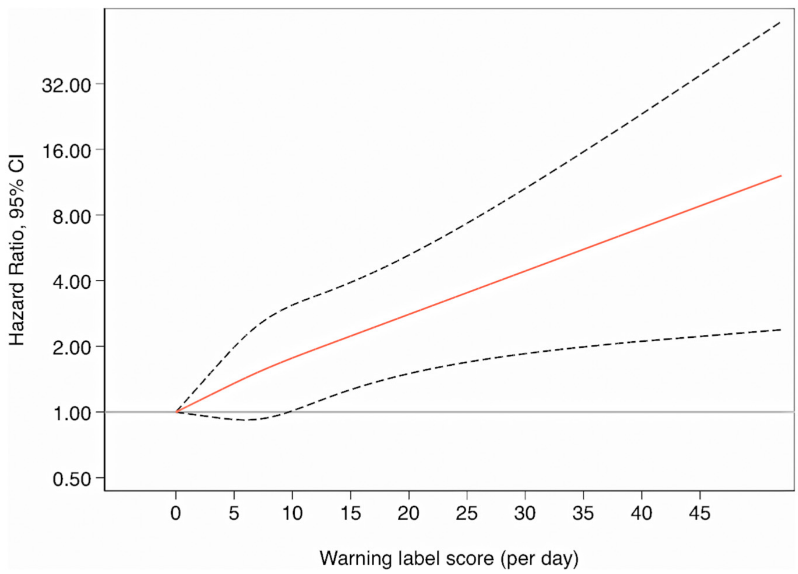


FIGURE 5
The smooth line represents the hazard ratio for the risk of all-cause mortality when using zero as the reference value for the warning label score (3 knots) whereas the dashed lines indicate 95% CIs.

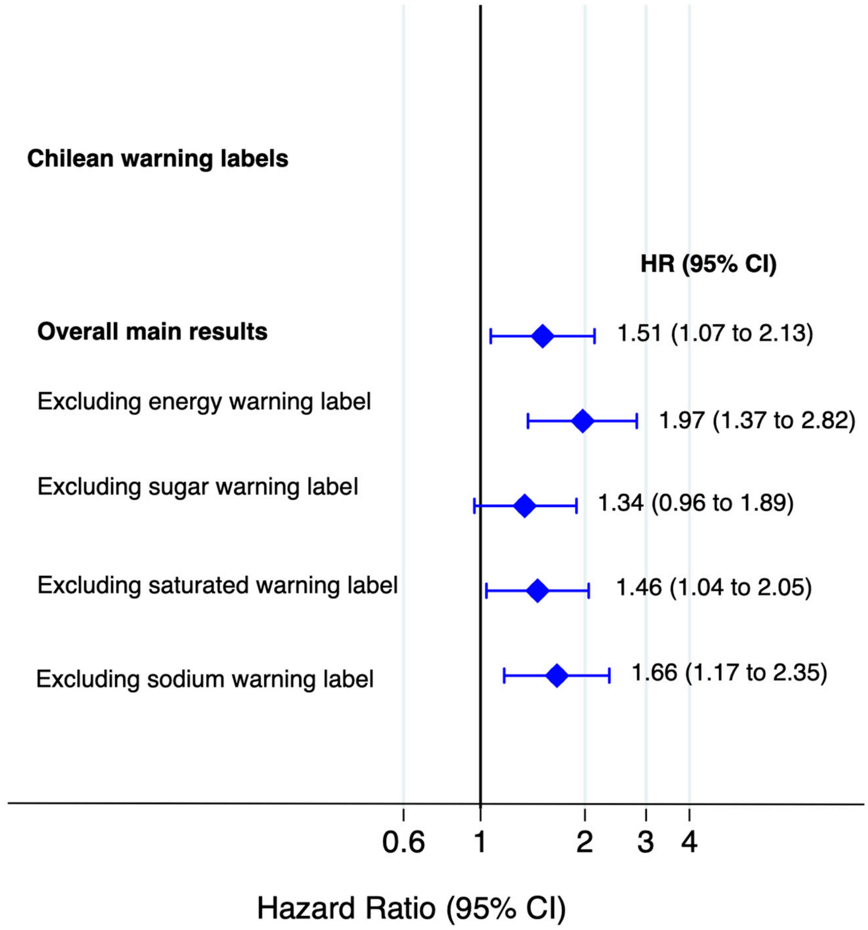


FIGURE 6
Association between food consumption with Chilean warning label score and mortality and excluding one warning label at time (multivariable-adjusted HR and 95% CI for the highest vs. lowest quartile).

TABLE 3 Hazard ratios (95% confidence intervals) for all-cause mortality according to baseline median consumption of foods with Chilean warning labels, ultra-processed food (UPF), and Nutri-Score.

| Score of the Chilean warning label | UPF consumption | | *p for interaction | Nutri-Score | | ⁋ p for interaction |
|---|---|---|---|---|---|---|
| | (≤4 servings/day) | (>4 servings/day) | | <p50th (<4.6) | ≥p50th (≥4.6) | |
| **<p50th (<7.1)** | | | | | | |
| N of deaths/N of participants | 242/9,727 | 14/649 | 0.738 | 200/7,576 | 56/2,800 | 0.076 |
| Multivariable | 1.00 (Ref) | 1.46 (0.80–2.67) | | 1.00 (Ref) | 0.95 (0.71–1.29) | |
| **≥p50th (≥7.1)** | | | | | | |
| N of deaths/N of participants | 97/3,819 | 114/6,471 | | 63/2,767 | 148/7,523 | |
| Multivariable | 1.27 (0.96–1.69) | 1.66 (1.21–2.26) | | 1.08 (0.77–1.50) | 1.51 (1.14–2.01) | |

Multivariate model adjusted for age (underlying time variable), sex, marital status (married), physical activity (continuous), alcohol intake (g/d, continuous), smoking status (never, current, and former), pack-years of cigarette smoking (continuous), snacking (dichotomous), special diet at baseline (dichotomous), body mass index (linear and quadratic terms), total energy intake (quartiles), years of university education (continuous), family history of cardiovascular disease (CVD) and cancer, prevalent CVD, hypertension, diabetes, cancer and depression, and self-reported hypercholesterolemia at baseline. Stratified by deciles of age and recruitment period. *p for interaction: UPF; ⁋ p for interaction: Nutri-Score.

TABLE 4 Comparison of AIC and BIC values for the warning label score and Nutri-Score in relation to all-cause mortality.

| | Criterion | | |
|---|---|---|---|
| | HR (95% CI) | AIC | BIC |
| **Chilean warning label** | | | |
| Q4 vs. Q1 | 1.51 (1.07–2.13) | 4264 | 4470 |
| **Nutri-Score** | | | |
| Q4 vs. Q1 | 1.40 (1.05–1.87) | 4266 | 4472 |

HR, hazard ratio; AIC, Akaike's information criteria; BIC, Bayesian information criteria.

of UPF was associated with an increased risk of all-cause mortality (5) (HR: 1.62; 95% CI: 1.13–2.33) and obesity (42) (HR: 1.26; 95% CI: 1.10, 1.45) compared to the lowest intake of UPF. Also, our analyses showed that participants who had increased intake of UPF (≥4 servings/d) and warning label score (≥5.5) presented an HR of 1.66 (95% CI: 1.21–2.26) for overall mortality. Possible mechanisms are hypothesized to include disrupted renal sodium homeostasis, metabolic and hemodynamic modifications, alteration of the gut microbiota, glycaemic response and insulin sensitivity, and so on (41). Regulatory policies are needed to mitigate the impact of UPF on NCDs, depression, all-cause mortality, and other diseases (43).

The existing scientific evidence has consistently shown that foods with low diet quality, as estimated by FoP nutrition labelling systems, are closely related to the increased risk of NCDs and deaths (6, 12–15, 44). In this sense, it is noteworthy to mention that the warning label score and Nutri-Score have AIC and BIC values close to each other, indicating that the nutrient profiles of these FoP systems have similar power to predict mortality in our sample. Caution is needed in interpreting this result, considering that the scores at the individual level could vary across populations (e.g., different dietary patterns), but our results at least suggest that the nutrient profile and thresholds of warning label and Nutri-Score could highlight less healthy food products. In addition, individuals with warning labels and Nutri-Score values above median (combined exposures) exhibited a 51% increased risk of all-cause mortality. These FoP labels differ in the type of information provided (nutrient-specific or summary) and label format, and both are calculated per 100 g/ml of product (7). The Nutri-Score is a colour-coded graded scale ranging from higher (dark green) to lower nutritional (dark orange) quality based on five letters (from A to E) (7). Meanwhile, the warning systems focus on excessive amounts of "critical nutrients" (7, 10). The Nutri-Score is the FoP system most used in Europe. Egnell et al. evaluated five nutrition labelling systems across 12 countries and showed that the Nutri-Score has better performance to rank products considering their nutritional quality followed by the Multiple Traffic Lights, Health Star Rating system, Warning symbol, and the Reference Intakes (45). However, other studies indicated differences in consumers' understanding across diverse FoP nutrition label schemes (29, 45–47). It is also important to mention that consumers' preferences and perceptions could vary among countries, depending on cultural behaviour (11). Previous studies have reported that consumers with the highest income, education levels, and nutrition knowledge tend to have higher levels of awareness, which influenced their capability to use FoP nutrition labels (11). On the other hand, it is increasingly recognized that the warning label system is related to a decrease in purchases of packed products higher in calories and nutrients of concern (10, 46, 48, 49). These FoP warning labels have been increasingly adopted in Latin American countries such as Chile, Ecuador, Mexico, Peru, and Uruguay (7, 10). Studies conducted in Chile show that there has been a decrease in products that need the warning labels "high in sodium" and "high in sugar," suggesting the tendency of food reformulation by the food industry (50).

Non-communicable diseases have rapidly risen around the world with a negative impact on burden diseases and premature deaths, leading to disproportions in low- and middle-income countries, which constitutes a public health challenge (51). The global tendency exhibits an increased volume and market of fast food and highly processed products in parallel with obesity rates (52). The FoP nutrition labels are part of a set of recommended policies aimed at reducing the global burden of diet-related NCDs by promoting market regulation, innovation-reformulation of packaged products, and fiscal measures (7, 8, 10, 52–54). There is no doubt that the implementation of FoP labelling has consistently proven to improve the ability to identify the healthfulness of food choices compared to no label (7, 8), suggesting that FoP labels play a pivotal role in improving the healthiness of food purchases and contribute to improving population diets.

The strengths of our study are the prospective and dynamic design, as well as the long follow-up and good retention rate (93%) of many participants from a Mediterranean country. Furthermore, the SUN cohort collects a wide range of potential confounders (sociodemographic and lifestyle data), and the analyses include the use of repeated measures of diet and the performance of exhaustive sensitivity analyses. Nevertheless, the present study has some limitations. First, the SUN cohort encompasses Spanish graduates who have high education levels. Thus, our sample is not representative of the general population, but this is an advantage in that the homogeneous university graduate cohort decreases the likelihood of misclassification bias. Second, the self-reported FFQ used for dietary data could be susceptible to misclassification. However, this FFQ has been previously validated in independent cohorts (22, 23, 55). Third, we could not evaluate specific food products that participants consumed (brand of the product and their variability in the nutrient content of the products inside each food item) or some features of manufactured products (e.g., level of processing) and unpackaged foods (e.g., homemade recipes rich in critical nutrients). Thus, it could have resulted in some misclassification of our exposures. Nonetheless, the FFQ used covered the main food groups of the usual dietary consumption of participants. Additionally, we used Spanish food composition tables, which enclosed representative values of main foods products consumed by the Spanish population. Last, although we included many potential confounders, the observational design can never completely rule out residual confounding bias.

## Conclusion

A diet including foods with a higher score of warning labels (indicating a lower nutritional quality) was a good predictor of all-cause and cancer mortality in Spanish population. Also, the nutrient profiles of the warning label score and Nutri-Score have a similar power of prediction. Therefore, our results reinforce the suitability of FoP warning labels as a key policy action to improve health status and prevent NCDs.

## Future directions

As a policy response to prevent NCDs, governments should implement FoP nutrition labelling to enable consumers to make healthier food choices and encourage the food industry to reformulate products to be healthier. The FoP warning label is used in many countries (7, 10), showing positive effects on consumer's choice, and from these results also finding a direct effect with better health. However, future research should be aimed at evaluating the consumption of foods with higher warning labels and NCDs in other ethnicities.

## Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

## Author contributions

VB-V, MB-R, CS-O, and MAM-G: conceptualization, methodology, and formal analysis. VB-V: writing—original data. All authors interpretation of data, writing—review and editing, read, and agreed to the published version of the manuscript.

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## Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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## Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fnut.2022.951738/full#supplementary-material

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# Marketing techniques, health, and nutritional claims on processed foods and beverages before and after the implementation of mandatory front-of-package warning labels in Peru

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In June 2019, mandatory front-of-package warning labels (FOPL) were implemented in Peru. The aim of the study was to describe changes in marketing strategies on packaging: marketing techniques (MT), health claims (HC), and nutritional claims (NC) on the packaging of products frequently consumed by children before and after the FOPL implementation. Product photos were taken pre- (March 2019) and post-implementation (March-October 2020) in three supermarkets in Lima, Peru. Following INFORMAS protocols and Peruvian Technical Norms, the presence of MT, HC, and NC was assessed on all package sides. Products were classified as "high-in" and "not high-in" based on the regulation threshold for critical nutrients. Differences in the proportion of products with each strategy in both periods were evaluated. Also, a subsample of products was matched according to the barcode and exact McNemar test was used to compare proportions of strategies pre/post-implementation. We included 883 and 1,035 products in pre- and post-implementation, respectively. In both periods, MT appeared on almost 70% of all products. The presence of HC increased significantly only for beverages (24.5–38.1%, $p < 0.001$). In both phases, NC were commonly used on beverages (>80%). Overall, the prevalence of "high-in" products using MT increased (73.6–82.1%, $p = 0.007$), while use of HC increased among "not high-in" products (32.9–41.6%, $p < 0.001$). There is a high frequency of

MT on all products and NC on beverages. The increase in MT in "high-in" products may be an industry response to minimize the impact of the FOPL on food choices and sales. New regulatory aspects regarding labeling should be implemented to strengthen the current policy.

KEYWORDS

**food marketing, front-of-package warning labels, marketing techniques, health claims, nutritional claims, Peru**

## Introduction

Worldwide, traditional dietary patterns are being replaced by unhealthy patterns, characterized by the consumption of ultra-processed food, driven by food marketing strategies, and other factors (1). Marketing and other strategies used by the food industry have been effective in making ultra-processed food sales grow exponentially and consequently, increasing their consumption. This rise has been associated with an increase in obesity, higher waist circumference, lower levels of high-density lipoprotein (HDL) cholesterol, and more negative health effects such as metabolic, cardiovascular, and cerebrovascular diseases (2, 3). According to the Pan American Health Organization, Peru has the highest growth in per capita sales of ultra-processed food in Latin America, increasing from 179 kcal per capita/day in 2009 to 207 kcal per capita/day in 2014 (4).

Food and beverage packaging is commonly used for marketing purposes. Marketing techniques such as cartoons, games, and gifts (i.e., toys) (5) as well as claims (affirmations regarding properties or benefits about the product or ingredients) are often used to influence consumers' food choices (6). Children are especially vulnerable to such techniques because of their inability to distinguish marketing from other content (7), and susceptibility to marketing and peer perceptions, which influences their food perception and choices (8). For instance, children tend to perceive products that include cartoons as more fun than those without cartoons and to like those with cartoons better (5, 9). Moreover, children show higher taste preferences for food packaging with the presence of characters, granting this marketing technique a positive influence over their purchase intentions (10). On the other hand, adults are more influenced by information cues on the package (8), and the evidence shows that parents tend to assess the healthfulness of a product based on nutritional claims (11). Unfortunately, marketing strategies in food and beverage packaging are more frequently used for promoting energy-dense and nutrient-poor foods than nutrient-dense ones (12); for instance, cartoons are more prevalent on products with a less healthy nutritional profile (13–15). In addition, the presence of health and nutritional claims can create a "health halo" effect when consumers generalize the benefit claimed to the overall healthfulness of the product (16), like fruit drinks that claim to have no artificial sweeteners or to be 100% natural, but contain high amounts of sugar, which often misleads parents to choose products that appear to be healthy for their children, when objectively they are not (17).

In response to the potentially negative impact of food industry marketing on the population's diets and health, some countries have linked food and beverage marketing regulations to mandatory "front-of-package warning labels" (FOPL) requirements for products "high-in" nutrients of concern, such as sugar, saturated fat, and sodium. In 2012, Chile banned child-directed prices and advertising attractive to children under 14 years old on products "high-in" energy and nutrients of concern (18). After this policy's implementation, a reduction in child-directed advertising strategies was seen on cereal products, decreasing from 36 to 21% (19). More recently, Mexico (20) and Argentina (21) passed similar policies, banning the use of cartoons and games in products that have FOPL. Additionally, Argentina restricted the use of health and nutritional claims on products carrying a FOPL (21).

In 2013, the Peruvian Government passed the "Law of Promotion of Healthy Eating for Children and Adolescents" (Law 30021) (22). According to the Law, products that exceed specific thresholds for nutrients of concern such as sugar, saturated fat, or sodium, or contain *trans*-fat, must carry a black octagon-shaped FOPL with the phrase "high-in" (sugar/saturated fat/sodium) or "contains *trans*-fats", accompanied by the message "avoid excessive consumption" or "avoid its consumption", respectively, on the packaging and all types of advertisements about them (e.g., tv, social media, radio). The thresholds established by the law are being implemented in two phases; the first phase became effective in June 2019 and the second phase in September 2021 (**Supplementary Table 1**; 23). Although the law includes some regulations focused on food advertising (e.g., prohibiting claims about improving physical strength or popularity, or suggesting parents will be more intelligent if they purchase the product), it does not extend

Abbreviations: FOPL, front-of-package warning labels; MT, marketing techniques; HC, health claims; NC, nutritional claims; COVID-19, coronavirus disease 2019.

to banning marketing techniques and health and nutritional claims on packaging.

The introduction of mandatory FOPL in the Peruvian market requires many processed products to carry them, which may potentially decrease sales of some foods and beverages, and could potentially motivate the food industry to use different marketing strategies to promote their products. Given that Peruvian Law does not ban marketing techniques, or health, and nutritional claims, we hypothesized that the Peruvian food industry may change the type or frequency of marketing strategies on food and beverage packaging, especially on products that will carry a FOPL, in order to maintain their sales. This study aims to identify and describe the changes in marketing techniques, health, and nutritional claims in the packaging of food and non-alcoholic beverages after the implementation of the FOPL in Peru, and to evaluate those differences according to the nutritional quality of the products ("high-in" or "not high-in"). Findings will may inform advocates and policymakers about the strategies frequently used by industry that could negatively affect the achievement of the FOPL policy objective.

# Materials and methods

## Study design and setting

We compared data from two cross-sectional collections (before and after the implementation of the FOPL policy) from processed products sold in supermarkets in Lima, the capital city of Peru. Additionally, a subsample of products was matched according to the barcode that allowed a pre/post-implementation analysis. For the pre-implementation period, we collected pictures of all the available packaged foods and non-alcoholic beverages in three supermarkets, between March and April 2019, 3 months before the implementation of the FOPL policy. The three supermarkets had a nationwide presence and each one targeted different socioeconomic levels of the population (high, medium, and low). In the post-implementation period, our team went back to the same stores between March and October 2020 to carry out the post-implementation data collection.

## Outcome variables

The outcomes of interest in this study were the pre- and post-implementation differences in the proportion of products using the following marketing strategies on packaging: (i) nine marketing techniques, based on the INFORMAS (International Network for Food and Obesity / Non-communicable Diseases Research, Monitoring and Action Support) protocol (24), and (ii) four health, and (iii) four nutritional claims adapted from the Peruvian Technical Norms for food claims (25), a document that establishes features from products and services. These 17 variables, their definitions, and examples of each can be found in **Table 1**. Of the 17 marketing strategies, only gifts are prohibited in advertisements of products directed to children less than 16 years old (22).

Moreover, the status of products according to the FOPL policy ("high-in" and "not high-in") was assessed based on the parameters of Peruvian Law No. 30021 (**Supplementary Table 1**).

## Food and beverages sample

Photographs of all sides of each product sold in the supermarkets were taken by trained nutritionists. After each round of data collection, quality control for every photo was conducted to verify that the text and images were clear. If not, new photographs were taken. Then, the label data from the pictures were recorded in the REDCap database hosted at the University of North Carolina at Chapel Hill (26). Product name, brand, weight, container, and nutritional composition per portion or per 100 g or 100 mL were entered in the database.

For this study, we selected the eight categories of foods and beverages most consumed by children and adolescents (5, 27, 28; **Supplementary Table 2**):

(a) Beverages: (i) nectars, (ii) flavored drinks (*"refrescos"*), (iii) carbonated drinks, and (iv) dairy drinks.

(b) Foods: (i) bakery products, (ii) breakfast cereals, (iii) desserts, and (iv) snacks.

The selected categories included data from a total of 1,153 processed products collected before the implementation (in 2019) and 1,238 after the implementation (in 2020). If a product had two or more packaging types, only the smallest one was selected, considering that these are frequently directed to children and offered at school cafeterias and kiosks. As a result, 270 and 203 products were excluded in 2019 and 2020, respectively. Finally, we evaluate the use of marketing techniques and health and nutritional claims on 883 products in 2019 and 1,035 in 2020.

To determine the status of products according to the FOPL policy, it was necessary to evaluate the nutritional composition. Products without a nutrition facts panel were excluded and multipacks with more than one nutrition facts panel were excluded (179 in 2019 and 203 in 2020). Also, products requiring reconstitution were excluded from this analysis (126 in 2019 and 102 in 2020) because many packages did not provide preparation instructions or exact amounts of added ingredients, or the weight or portion size of the prepared product were not available.

To identify inconsistencies, the Atwater System calculation was used to check the total energy declared in the label with the sum of energy provided by each macronutrient using Atwater's constants (i.e., fats = 9 kcal/g, proteins = 4 kcal/g, carbohydrates = 4 kcal/g). This validation was applied to

TABLE 1 Variables: Marketing strategies assessed.

| Marketing strategy on packaging | Description | Examples |
|---|---|---|
| **Marketing techniques** | | |
| Characters | Images, photographs, drawings, and caricatures of real or fictional characters | Cartoons, athletes, celebrities, images, or photos from boys and girls < 18 years |
| Sports | Any character playing sports, an invitation for sports events or event sponsorship, presence of any object that refers to a sport | Children playing sports, a logo indicating the brand sponsors a team |
| Donations | Products whose packaging shows messages from public welfare organizations | The brand's charitable foundation |
| Price | Promotions referring to the price | Messages such as "get more for less," an additional percentage of the product, discount coupons, and low price |
| Gifts | Packaging includes the free delivery of an object with the purchase of the product | Chocolate eggs with a surprise, toys, or stickers inside the package |
| Contests | Packaging announces that the consumer can access a contest, redemption, raffle, or similar competitions through an additional action after the product purchase | Scan the QR code on the box to participate or subscribe to a contest for a trip |
| Logos | The packaging contains a food system labeling or an endorsement logo of a certain scientific society | GDA logo, the logo with the approval of the Dietician's Society |
| Lifestyles | Motivational phrases, advice, and tips in the packaging to lead a healthy lifestyle | Messages promoting a healthy lifestyle such as "It is good to exercise" |
| Marketing directed to children | Packaging intended to appeal to children | Games, playful products, products shapes, messages related to fun, fonts, or graphics allusive to fun, special lines such as "mini" |
| **Health claims** | | |
| Nutrient message and function | Messages that describe and focus on the physiological role of a nutrient in growth, development, normal functions, or biological activities of the body, and not on disease reduction. The message must include the nutrient plus the specific function | "Mixture of malt with vitamins and minerals that help the release of energy, muscular function, and maintenance of bones," or "With probiotics and fiber that help you regulate your intestinal transit" |
| Disease risk reduction message | Messages that emphasize the relationship between a specific food consumption (without specifying a particular nutrient or ingredient) and reducing the risk of developing a disease | "Can Help Lower Cholesterol as part of a Heart Healthy Diet" |
| General health message | Messages associated with specific food consumption (without specifying a particular nutrient or ingredient) with general health benefits | "Brings you energy" |
| Fantasy terms | Invented words that refer to the product's nutritional content | "Calcifem" (product enriched with calcium oriented to women) |
| **Nutritional claims** | | |
| Ingredient related message | The packaging shows messages indicating that the product contains healthy ingredients or messages that indicate the product does not contain unhealthy ingredients | "With Andean grains" and "0% artificial colors" |
| Nutritional content | The packaging mentions a nutrient, mentions the amount of a nutrient, mentions the energy value, or mentions that the product has no specific nutrient | "With omega 3 and 9," "0% *trans*-fat," "High in dietetic fiber," "It is a protein source," and "Provides Calcium and Phosphorus" |
| Nutritional comparison | Messages that compare the nutrient level or energetic value of two or more foods with terms that indicate one product has more or less of a nutrient | "95% reduced in fat, compared to a whole yogurt" |
| Non-caloric sweetener addition | Messages that indicate the product has the addition of non-caloric sweeteners, apart from the ingredient list | "Partially sweetened with Stevia" |

all products that declared each of the three macronutrients and energy. Foods with total energy values that equaled or were within 20% of the Atwater calculation for energy were included (29). Eight products from the 2019 collection and 16 from 2020 did not comply and were excluded from the nutritional composition analysis. Total sugar was compared to total carbohydrates for each product that provided both values. Products with total sugar greater than total carbohydrates were omitted from the analysis (two in 2019 and no products in 2020). Likewise, products with an amount of saturated fat that exceeded the amount of total fat were also reviewed, but no product was excluded from the analysis (**Figure 1**).

Dairy drinks were excluded from the analysis of *trans*-fat content because a determination could not be made as

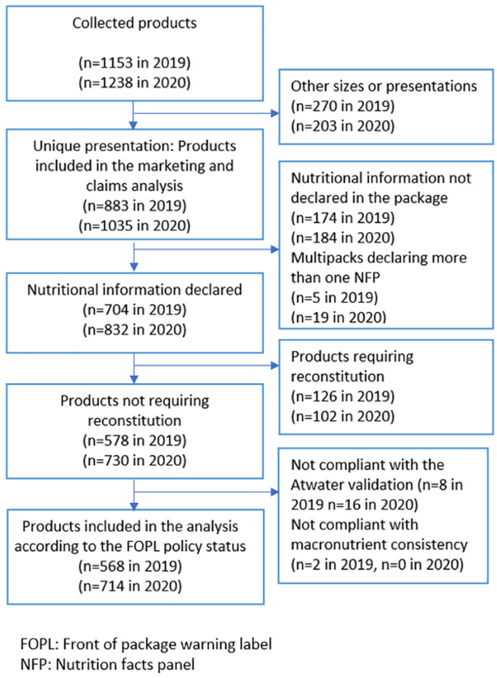


FIGURE 1
Sample flowchart.

to whether the *trans*-fat amount declared in the nutritional information table was added or intrinsic in dairy products.

## Coding of marketing techniques and claims

The methodology aimed to identify the presence of different marketing techniques, health claims, and nutritional claims on each product. First, two trained Peruvian nutritionists coded a random sample of 20% of products from the pre- and post-implementation period. The nutritionists coded the absence or presence of each type of marketing technique or claim, and where it was located (front or side/back). The presence of a marketing technique or claim was recorded only once, even if it was repeated multiple times on the same product. The percentage of agreement for each of the 31 variables was calculated. The agreement ranged from 93 to 100%. The lowest agreement was for nutrition claims related to nutritional messages. The discrepancies were reviewed and resolved by the two nutritionists. In the second stage, one nutritionist coded all remaining products.

### Categorization of products according to the law

To determine if a product was categorized as "high-in" or "not high-in," the information declared in the nutrition facts panel was compared to the thresholds established for the first phase of implementation of the FOPL policy, in June 2019 (**Supplementary Table 1**). Products from the pre- and post-implementation period were considered "high-in" if they exceeded thresholds for any of the nutrients of concern: sugar, saturated fat, or sodium, or contained *trans*-fat, thus receiving at least one octagon. All products with nutrients below the thresholds were categorized as "not high-in".

## Data analysis

The frequency of each marketing technique and claim was calculated overall and by food and beverage category. Chi-squared and Fisher's exact tests were used to evaluate differences in proportions between the pre- and post-implementation periods. The proportion of marketing techniques and claims in each period was compared according to the product's regulation categorization ("high-in" or "not high-in") based on the nutrient thresholds for the first phase of Peru's FOPL regulation. For the subsample of matched products, we used exact McNemar test to compared proportions pre- and post-implementation in the outcomes of interest.

Analysis was conducted using the statistical software package Stata v15 (STATA Corp, College Station TX, USA). A $p$-value of less than 0.05 was deemed statistically significant.

## Ethics

This project was approved by the Institutional Ethical Committee at Universidad Peruana Cayetano Heredia, Lima, Peru (project 102750). Additionally, the supermarkets granted permission to collect information.

# Results

For the analysis of the marketing techniques and health and nutritional claims in the present study, a total of 883 products in the pre-implementation phase (2019) and 1,035 in post-implementation (2020) were included for the cross sectional analysis. Almost one-third of the products in each phase were beverages, 31.0% ($n$ = 274) and 32.5% ($n$ = 336) in the pre- and post-implementation phases, respectively. The category with the most products in the beverage group was "Nectars" in the pre- and post-implementation (28.5%, $n$ = 78, and 38.0%, $n$ = 104), while among foods, "Bakery products" predominated in both collections (48.9%, $n$ = 298 and 57%, $n$ = 350; **Table 2**). A total of 321 products were collected in both phases and considered for the longitudinal analysis, 29.6% ($n$ = 95) were beverages and 70.4% ($n$ = 226) were foods.

In both periods, almost seven out of ten products displayed at least one of the ten marketing techniques, with an average

TABLE 2 Marketing techniques, health, and nutritional claims before and after front-of-package warning labels policy implementation, cross sectional analysis.

| Category | Total products | | Any marketing technique | | | Any health claim | | | Any nutrition claim | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Pre-implementation *n* (%) | Post-implementation *n* (%) | Pre-implementation *n* (%) | Post-implementation *n* (%) | *P*-value | Pre-implementation *n* (%) | Post-implementation *n* (%) | *P*-value | Pre-implementation *n* (%) | Post-implementation *n* (%) | *P*-value |
| **Beverages** | 274 (100.0) | 336 (100.0) | 182 (66.4) | 217 (64.6) | 0.635 | 67 (24.5) | 128 (38.1) | **<0.001** | 227 (82.9) | 282 (83.9) | 0.721 |
| Nectars | 78 (28.5) | 104 (31.0) | 31 (39.7) | 53 (51.0) | 0.133 | 14 (18.0) | 40 (38.5) | **0.003** | 65 (83.3) | 87 (83.7) | 0.954 |
| Flavored drinks | 69 (25.2) | 58 (17.3) | 54 (78.3) | 45 (77.6) | 0.927 | 11 (15.9) | 11 (19.0) | 0.654 | 64 (92.8) | 56 (96.6) | 0.350 |
| Carbonated drinks | 57 (20.8) | 83 (24.7) | 36 (63.2) | 53 (63.9) | 0.933 | 7 (12.3) | 9 (10.8) | 0.793 | 40 (70.2) | 56 (67.5) | 0.735 |
| Dairy drinks | 70 (25.5) | 91 (27.0) | 61 (87.1) | 66 (72.5) | 0.024 | 35 (50.0) | 68 (74.7) | **0.001** | 58 (82.9) | 83 (91.2) | 0.111 |
| **Foods** | 609 (100.0) | 699 (100.0) | 427 (70.1) | 507 (72.5) | 0.335 | 101 (16.6) | 130 (18.6) | 0.341 | 255 (41.9) | 308 (44.1) | 0.425 |
| Bakery products | 298 (48.9) | 350 (50.1) | 175 (58.7) | 252 (72.0) | **<0.001** | 18 (6.0) | 31 (8.9) | 0.176 | 84 (28.2) | 103 (29.4) | 0.728 |
| Breakfast cereals | 117 (19.2) | 144 (20.6) | 101 (86.3) | 121 (84.0) | 0.605 | 77 (65.8) | 84 (58.3) | 0.216 | 106 (90.6) | 123 (85.4) | 0.204 |
| Desserts | 58 (9.5) | 61 (8.7) | 54 (93.1) | 49 (80.3) | **0.041** | 2 (3.5) | 5 (8.2) | 0.440 | 22 (37.9) | 29 (47.5) | 0.29 |
| Snacks | 136 (22.3) | 144 (20.6) | 97 (71.3) | 85 (59.0) | **0.031** | 4 (2.9) | 10 (6.9) | 0.171 | 43 (31.6) | 53 (36.8) | 0.361 |

Comparisons of proportions of marketing techniques, health, and nutritional claims in products from pre- *vs.* post-implementation period were made using Chi-squared and Fisher's exact tests.
Bold values represent $p < 0.05$.



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of 1.3 (range 0–5) and 1.4 (range 0–5) in the pre- and post-implementation phase, respectively. However, the prevalence was higher in some categories, such as "Desserts" in the pre-implementation period and "Breakfast cereals" in the post-implementation, in which almost nine out of ten products displayed a marketing technique (**Table 2**). The findings presented in **Figure 2** show that in both phases, the most used marketing technique was "Logos" (most products carried a GDA logo), followed by "Marketing directed to children", which were both used on around 40% of the products (**Figure 2**). The least commonly used techniques were "Gifts" and "Contests" (**Supplementary Table 3**). Three categories ("Dairy drinks," "Desserts," and "Snacks") significatively reduced the prevalence of marketing techniques after the FOPL implementation ($p < 0.05$). Notably, the reduction of marketing techniques on "Dairy drinks" was due to the lower number of products carrying a marketing technique directed to children (48.6–27.5%, $p = 0.006$). On the other hand, some categories increased the use of marketing techniques, with a significant increase on "Bakery products" ($p < 0.001$; **Table 2**), the same trend was observed in the longitudinal analysis in this food category ($p < 0.001$; **Supplementary Table 4**).

In regard to claims, health claims were used less frequently than nutritional claims, with a mean of 0.3 (range 0–3) and 0.5 (range 0–3) health claims per product in the pre- and post-implementation phase, respectively. Two categories had a higher proportion of products with health claims in comparison to other categories: "Dairy drinks" and "Breakfast cereals," in which 50 to almost 75% of products had health claims in both phases. Few products in "Carbonated drinks" and "Desserts" displayed health claims (**Table 2**). As shown in **Figure 3**, in both phases, the most used health claims were "General health message" and "Nutrient message and function", while fewer products used "Fantasy terms". Changes in the prevalence of any health claims were observed among beverages, where they increased by almost 15% (24.5–38.1%, $p < 0.001$) between phases, in contrast to the cross-sectional analysis, the longitudinal analysis showed increases in the use of this type of claim only in "Nectars" ($p = 0.016$; **Supplementary Table 4**). Only one food category, "Breakfast cereals" had a reduction in the use of one type of health claim ("Nutrient message and function") (46.2–33.3%, $p = 0.035$; **Supplementary Table 5**).

In contrast to health claims, nutritional claims were frequently used, with a mean of 1.0 claim (range 0–4) per product in both periods. These claims were especially common on beverages, where almost four out of five products in each period presented any nutritional claim. In both phases, the category with the most claims was "Flavored drinks", while "Bakery products" was the category with fewest claims of this type (**Table 3**). In addition, the most used nutritional claims were "Nutritional content" and "Ingredient related" (**Figure 3**). It is worth noting that a large number of pre-implementation period products already used nutrition claims (particularly ingredient-related claims). Although no changes were observed in the proportion of products carrying a nutritional claim, when examining changes by specific claim, "non-caloric sweetener added" (NCS) claims increased notably among beverages, raising from 11.7 to 21.7% ($p = 0.001$) in the post-implementation phase (**Supplementary Table 6**).

In the analyses based on FOPL policy status, the use of marketing techniques on foods and beverages classified as "high-in" increased by almost 10% (73.6–82.1%, $p = 0.007$). Among "not high-in" products, the use of these strategies on beverages decreased by almost 20% (82.6–63.0%, $p$-value $< 0.001$); in contrast, marketing strategies on foods increased almost 10% (72.9–82.5%, $p = 0.058$). The prevalence of health claims on "not high-in" foods and beverages increased by 8.7% (32.9–41.6%, $p = 0.037$) and on "high in" beverages by 29% (18.5–47.5%, $p < 0.001$). No statistically significant changes in the use of nutritional claims were observed when products were categorized according to FOPL policy status (**Table 3**). In the longitudinal analysis we confirmed that products "high-in" in the pre-implementation phase (2019) increase the use of marketing techniques after the implementation ($p = 0.007$), in addition "high-in" products increase the use of health claims ($p = 0.012$; **Supplementary Table 7**).

## Discussion

The present study analyzed a wide range of marketing strategies on food and beverage packaging, including marketing techniques, and health, and nutritional claims. Findings suggest an extended use of marketing techniques and nutritional claims, and to a lesser extent, of health claims, before and after the implementation of the FOPL policy in Peru. After the implementation, some changes, including increases and decreases, were observed in the use of marketing techniques and claims among the studied food and beverage categories. Of particular concern, the use of marketing techniques increased among "high-in" products.

Of the three types of marketing strategies on packaging analyzed, marketing techniques were more commonly used in all food and beverage categories; in contrast, claims were more prevalent in some specific categories. This is an expected result given that marketing techniques include a large variety of strategies that can be used on any product, ranging from the use of logos to specific colors on the packaging. In contrast, health, and nutritional claims require that the product contains specific ingredients or components that confer certain properties and benefits (6). Additionally, it is important to note the high percentage of products–especially beverages- using nutritional claims even before the FOPL policy implementation (30), and at the same time the lower use of health claims. Our results from the pre-implementation phase are similar to those found in Mexico. In both countries, nutritional claims were used more

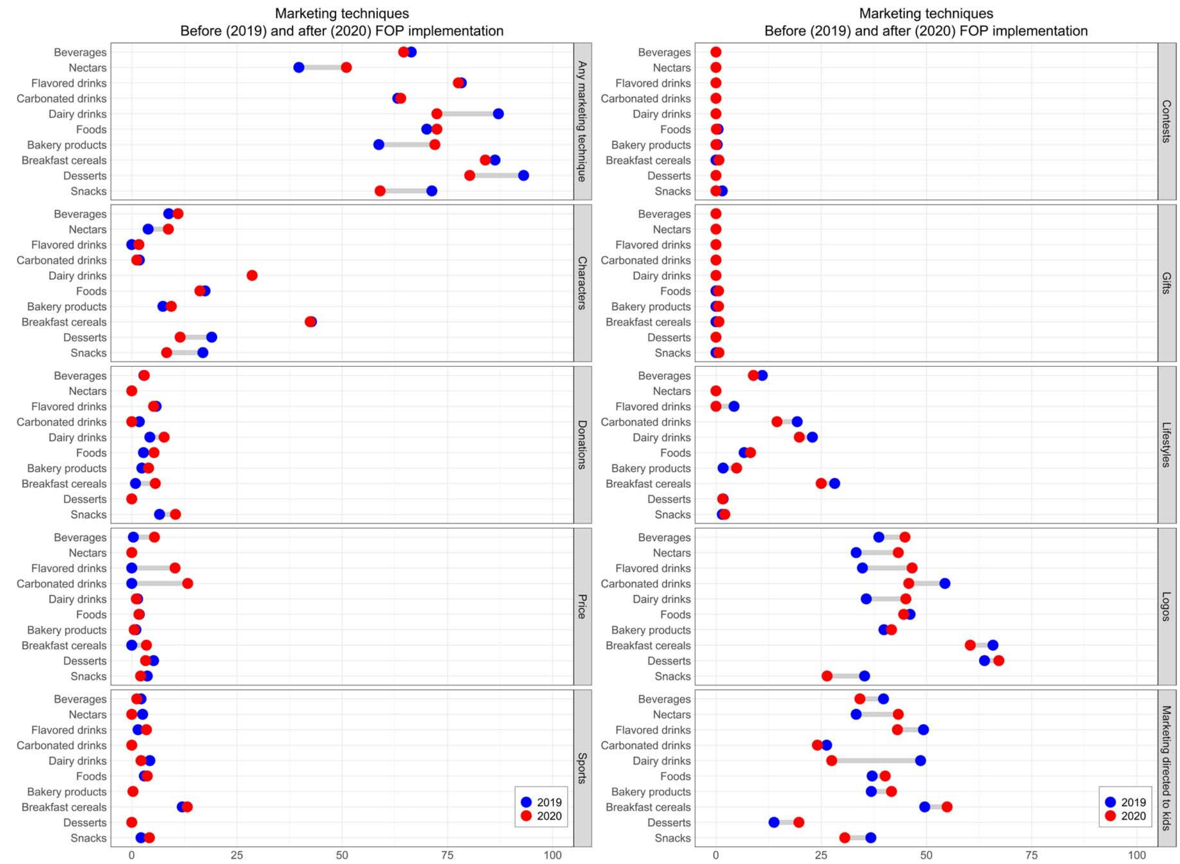


FIGURE 2
Marketing techniques used before and after the front-of-package warning label policy implementation, cross sectional analysis.

than health claims (57 *vs.* 25% in Peru, and 33.8 *vs.* 3.4% in Mexico, respectively), with "Nutritional content" claims being the most common nutritional claims (31).

Among the different marketing techniques assessed, the "Logos" and "Marketing directed to children" were the most used in both periods. Most of the "Logos" used on the products analyzed in this study were from the GDA system, a front-of-package label system (32) frequently promoted by the food industry (33). It could be interest to study in further studies if the presence of both systems (GDA and FOPL octagons) interact and influence food choices. Another marketing technique used frequently in our sample is "Marketing directed to children" (around 40% overall products in both phases). The prevalence of the use of this technique was similar in Chile (36%) before the implementation of the Chilean FOPL policy in 2016 (19). This similarity may be due to geographic context (both are South American countries) and shared food suppliers. It has been reported that "marketing directed to children" techniques are frequently used on products "high-in" nutrients of concern, promoting the selection of those products (17). Similarly, a previous study in Peru warned about the frequent use of marketing directed to children on products high in sugar (14).

In both phases, two product categories that frequently use marketing strategies, especially marketing techniques and health claims, were "Dairy drinks" and "Breakfast cereals". This aligns with a study in Costa Rica (13), where "Breakfast cereals" had the highest use of promotional marketing strategies. Traditionally, these products have been considered healthy, especially for children, because they often use marketing techniques and claims that create a "health halo" effect that makes parents believe that a product is healthy and based their food selection on that impression (11). Interestingly, these two categories experienced changes in the use of marketing strategies after the implementation of the FOPL policy. For instance, in the post-implementation period, the proportion of "Dairy drinks" using marketing techniques decreased, but the percentage using health and nutritional claims increased. One possible explanation is that the industry increased the use of claims to reinforce the idea that their products are healthy, and to counter customer concerns about the nutritional composition of packaged foods during the months close to the implementation of the FOPL policy.

Even though we found no changes in the use of nutritional claims overall, when we analyzed each type of claim separately,

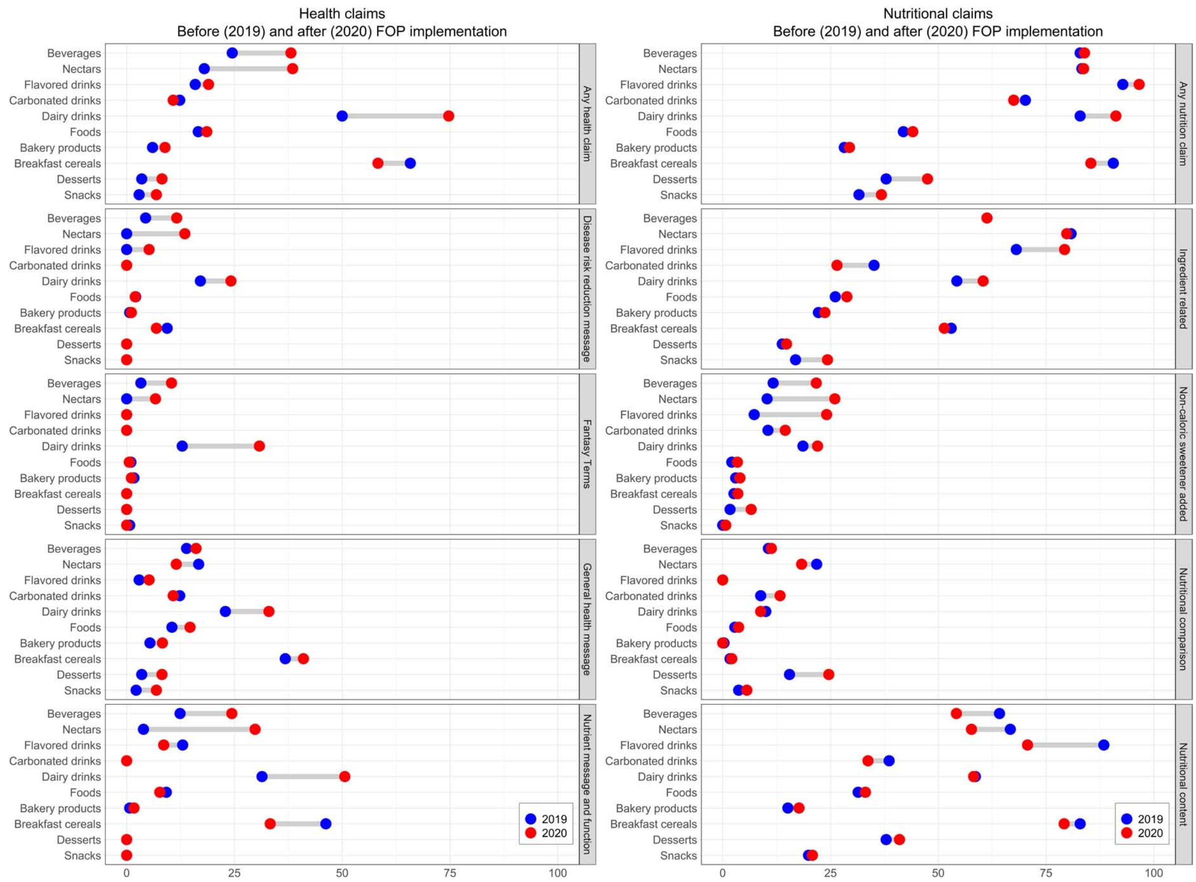


FIGURE 3
Health and nutritional claims used before and after the front-of-package warning labels policy implementation, cross sectional analysis.

we observed a significant increase in the use of messages related to NCS. This could reflect a greater use of NCS instead of added sugar in beverages, in order to avoid the "high-in sugar" octagon. Importantly, in some contexts, such as Mexico (34), the use of NCS could be perceived as positive because it signifies a reduction of (or no increase in) calories (35), and in some cases, the addition of a natural NCS could be perceived as healthier due to its natural origin (36). However, considering their possible adverse health effects (35), countries such as Mexico, are implementing warning messages for products using NCS (20).

After the implementation of the FOPL in Peru, the use of some strategies rose among "high-in" products. Cross-sectional and longitudinal analysis shown that marketing techniques increased overall products, but also, we observed a large increase in the use of health claims among "high-in" beverages in the cross sectional analysis and overall products in the longitudinal one. The increased use of those strategies on "high-in" products could be interpreted as a food industry response to minimize the impact of the octagons. Moreover, in the cross-sectional analysis the "not high-in" products were using more health claims to highlight the "healthy" properties of their products, as they are not carrying an octagon and could represent a healthier alternative. This could also be explained by the growth and development of the health food market nowadays, due to consumers' growing interest in healthy lifestyles and wellness (37).

## Strengths and limitations

Our study included a large sample of processed products from different food and beverage categories. Additionally, our evaluation included all package sides, since the whole package can include marketing strategies; in contrast, previous studies were limited to the front of packages (13, 14).

The study also has some limitations. First, the set of products included were those available in the three supermarkets. Products from small retailers and other points of sales such as kiosks and *bodegas* were not collected. However, the stores visited are nationwide supermarkets targeting different socioeconomic groups. Additionally, only some categories of food and beverages were included, and we limited our sample to one type of packaging per product. In that sense, our results

TABLE 3 Differences in the percentage of products using marketing techniques, health, and nutritional claims according to the front of package warning labels policy status, cross sectional analysis.

| | *n* (2019) | Pre-implementation (2019) | *n* (2020) | Post-implementation (2020) | Difference (%) | *P*-value |
|---|---|---|---|---|---|---|
| **(1) Marketing techniques** | | | | | | |
| % of "not high-in" products with at least one marketing technique | 216 | 77.8 | 363 | 72.2 | −5.6 | 0.136 |
| Beverages | 109 | 82.6 | 192 | 63.0 | −19.6 | <**0.001** |
| Foods | 107 | 72.9 | 171 | 82.5 | 9.6 | 0.058 |
| % of "high-in" products with at least one marketing technique | 352 | 73.6 | 351 | 82.1 | 8.5 | **0.007** |
| Beverages | 81 | 55.6 | 61 | 68.9 | 13.3 | 0.107 |
| Foods | 271 | 79.0 | 290 | 84.8 | 5.8 | 0.071 |
| % of total products with at least one marketing technique | 568 | 75.0 | 714 | 77.0 | 2.0 | 0.407 |
| Beverages | 190 | 71.1 | 253 | 64.4 | −6.7 | 0.141 |
| Foods | 378 | 77.3 | 461 | 84.0 | 6.7 | **0.014** |
| **(2) Health claims** | | | | | | |
| % of "not high-in" products with at least one health claim | 216 | 32.9 | 363 | 41.6 | 8.7 | **0.037** |
| Beverages | 109 | 34.9 | 192 | 43.2 | 8.3 | 0.155 |
| Foods | 107 | 30.8 | 171 | 39.8 | 9 | 0.132 |
| % of "high-in" products with at least one health claim | 352 | 18.2 | 351 | 18.2 | 0 | 0.986 |
| Beverages | 81 | 18.5 | 61 | 47.5 | 29 | <**0.001** |
| Foods | 271 | 18.1 | 290 | 12.1 | −6.0 | **0.046** |
| % of total products with at least one health claim | 568 | 23.8 | 714 | 30.1 | 6.3 | **0.011** |
| Beverages | 190 | 27.9 | 253 | 44.3 | 16.4 | <**0.001** |
| Food | 378 | 21.7 | 461 | 22.3 | 0.6 | 0.806 |
| **(3) Nutritional claims** | | | | | | |
| % of "not high-in" products with at least one nutritional claim | 216 | 79.2 | 363 | 81.3 | 2.1 | 0.537 |
| Beverages | 109 | 87.2 | 192 | 91.7 | 4.5 | 0.209 |
| Foods | 107 | 71.0 | 171 | 69.6 | −1.4 | 0.799 |
| % of "high-in" products with at least one nutritional claim | 352 | 52.8 | 351 | 47.6 | −5.2 | 0.163 |
| Beverages | 81 | 87.7 | 61 | 78.7 | −9.0 | 0.151 |
| Foods | 271 | 42.4 | 290 | 41.0 | −1.4 | 0.737 |
| % of total products with at least one nutritional claim | 568 | 62.9 | 714 | 64.7 | 1.8 | 0.492 |
| Beverages | 190 | 87.4 | 253 | 88.5 | 1.1 | 0.707 |
| Foods | 378 | 50.5 | 461 | 51.6 | 1.1 | 0.752 |

"High-in" products are products exceeding at least one parameter in sugar, saturated fats or containing *trans*-fat according to the first phase of the Peruvian law.
Comparisons of proportions of marketing techniques and claims in products from pre- *vs.* post-implementation period were made using Chi-squared and Fisher's exact tests. Bold values represent $p < 0.05$.

are not representative of all the products offered in the Peruvian market. Furthermore, our results on the subsample of matched products are limited by the small sample size and the power to detect statistical differences. However, since the Peruvian law is focused on children and adolescents, it is more important to analyze changes in products that are usually consumed by children and adolescents. Also, this study did not include information regarding sales data from the analyzed products. Further studies would be needed to explore if changes in marketing strategies are related to product sales. On the other hand, it is also possible that the marketing strategies coded by only one nutritionist could introduce personal bias, however, we anticipated this by training and coding a proportion of products by two fieldworkers to standardize the criteria used to classify.

Finally, the second data collection was carried out during the COVID-19 pandemic and was extended for 8 months due to the lockdown and social restrictions. Thus, some products from 2020 differ from those of 2019, especially seasonal products (e.g., baked products, ice creams, Easter chocolate eggs), and imported products that had limited availability in the Peruvian market during the lockdown.

## Impact on public health

There have been some relevant changes to the marketing strategies on packages used by the food industry after the implementation of the FOPL policy in Peru. The increased use of marketing techniques among products carrying the "high-in" warning label is especially relevant for the aim of the Law of Promotion of Healthy Eating. Notably, NCS claims rose significantly, providing evidence of the increased use of these ingredients. Currently, the Peruvian Law restricts some advertising strategies of products directed to children less than 16 years; however, of all the strategies assessed in this study, only gifts are restricted by the law.

To boost the effects of the Peruvian law, policymakers could ban the use of some marketing techniques and claims assessed in this research on "high-in" products and add warning messages for NCS to avoid misunderstandings regarding the nutritional value of products and better inform consumers. Other Latin American countries such as Chile, Mexico, and Argentina have implemented these policies. In Chile, after restricting child-directed marketing for "high-in" products, a study found a decrease in the proportion of "high-in" breakfast cereals that used child-directed strategies and an increase in the "not high-in" products that used child-directed strategies ($p < 0.005$ for both cases) (19).

Finally, even though the study found significant changes in some food categories and marketing strategies after the implementation of FOPL policy, the results show that most "high-in" products already used either marketing techniques or claims, and that it is increasing. So, it is important to inform and raise public awareness about how to evaluate the nutritional quality of a product, not only based on the content of nutrients of concern, which may be insufficient for some populations to identify healthy products (28), but also based on different traits such as ingredients, processing, and labeling. In Peru, the current public policies like the Law of Promotion of Healthy Eating (22), the Healthy Eating Guidelines (38) and the National Multisectoral Health Policy to 2030 (39) allow the implementation of other actions such as implementing communication-based or educational interventions for the clear interpretation of product healthfulness and informed decision-making regarding healthy food purchases.

## Conclusion

This study found a high use of marketing on beverages and food packaging, especially for marketing techniques and nutritional claims, before and after the implementation of the FOPL policy in Peru. Some decreases in the use of marketing techniques were observed among specific food categories, but an increase in health claims was observed for beverages. Additionally, the use of marketing techniques on "high-in" products increased, while the prevalence of health claims increased on "not high-in" products after the implementation.

To support the aim of promoting healthy eating among children and adolescents, we recommend developing communication and educational campaigns to inform the public about food labeling features such as FOPL, and nutritional facts panel. Additionally, new regulatory measures to limit the use of marketing techniques, health, and nutritional claims on "high-in" products should be implemented to strengthen the current FOPL policy.

## Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

## Author contributions

LS-G and XT-R: conceptualization, methodology, and writing – original draft preparation. AH-V: data curation and formal analysis. LS-G: supervision. FD-C, LS-G, and AH-V: resources and funding acquisition. FD-C: project administration. All authors contributed to revising the manuscript for important content, edit, read, and agreed to the published version of the manuscript.

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## Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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## Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fnut.2022.1004106/full#supplementary-material

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# Eating contexts determine the efficacy of nutrient warning labels to promote healthy food choices

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**Introduction:** Unhealthy food choices increase the risk of obesity and its co-morbidities. Nutrition labels are a public health policy that aims to drive individuals toward healthier food choices. Chile has been an example of this policy, where mandatory nutrient warning labels (NWL) identify processed foods high in calories and critical nutrients. Eating contexts influence individual food choices, but whether eating contexts also influence how NWL alter the decision process and selection during food choice is unknown.

**Methods:** In an online mouse-tracking study, participants prompted to health, typical, or unrestricted eating contexts were instructed to choose between pairs of foods in the presence or absence of NWL. Conflict during choices was analyzed using mouse paths and reaction times.

**Results:** NWL increased conflict during unhealthy food choices and reduced conflict during healthy choices in all contexts. However, the probability that NWL reversed an unhealthy choice was 80% in a healthy, 37% in a typical, and 19% in an unrestricted context. A drift-diffusion model analysis showed the effects of NWL on choice were associated with an increased bias toward healthier foods in the healthy and typical but not in the unrestricted context.

**Discussion:** These data suggest that the efficacy of NWL to drive healthy food choices increases in a healthy eating context, whereas NWL are less effective in typical or unrestricted eating contexts.

KEYWORDS

**eating contexts, warning labels, food choice, mouse-tracking, food labels**

## 1. Introduction

The modern human food environment provides access to a variety of foods, including those of high palatability and caloric content (1–3). The larger reinforcing effects of calorie-dense food favor their choice over less calorie-dense food, thereby increasing calorie intake and the risk of obesity (4–7). Thus, our environment often introduces the conflict between choosing unhealthy but more palatable foods or healthier but less palatable foods (8–10). Understanding how food choice unfolds and how to influence individuals to select healthy foods is necessary to design better or improve current strategies promoting healthy food choices.

Food labeling is a public health strategy that aims to promote healthier food choices (11). Food labels used worldwide vary in the information displayed (e.g., nutrient information or a single descriptor), the symbology used (e.g., numbers or traffic lights), whether the information requires being interpreted by the user (e.g., indicating the amount of fat in a product or if the product is high in fat) and if the label conveys a positive or negative message (e.g., this product is healthy or unhealthy) (11, 12). Nutrient warning labels (NWL) are a type of label that indicates whether a food item is high in calories or critical nutrients (13). NWL can increase the purchase of healthy food, reduce the purchase of unhealthy food, and reduce the overall energy content purchased (13). Chile is a prominent example of the use of NWL, where since 2016, mandatory NWL on processed foods indicate whether a food is high in calories, saturated fat, sugar, or sodium (14–16; **Figure 1A**). Survey and focus group studies suggest that NWL changed the perception of and attitude toward food conducive to healthier food choices (17–20). Consistently, and compared to the counterfactual condition where NWL were not implemented, the purchase of foods with NWL was reduced 2 years after their implementation. Still, in the same period, the purchase of foods without NWL increased, thereby reducing total energy purchased only by 16.4 kcal/capita/day (21, 22). Despite the widespread use of NWL in Chile and other countries, how NWL modify the decision process and its outcome during food choice remains unexplored.

Food choice is a multifactorial process (8), and the concept of eating context describes a subject's environment and internal state during food choice (23, 24). For example, a healthy eating context in a real-world setting would be created by combining a lower price, increased information, and easier access to healthy food (25). In experimental studies, the eating context is often defined by explicit instructions highlighting a particular aspect of a real-world context before a food choice task. As such, an experimental healthy eating context can be created by prompting participants to consider the healthiness of food or its health consequences. This intervention reduces the portion size and probability of choosing unhealthy foods compared to participants prompted to select foods based on taste or desire (26–32). The effects of a health context on food choice include increasing the value of health-related food attributes over others like taste (27, 33). These effects are also consistent over time (34) and correlate directly with dietary self-control-related brain activity (29). Thus, eating contexts influence food choice and can be implemented in laboratory settings to study the determinants of food choice.

There is scarce evidence on whether eating contexts alter the impact of food labels on food choice. Eye-tracking studies suggest that the eating context influences engagement with food labels and their effect on choice, but whether this translates to experimental or real-world choices is unclear (35). For example, food labels appear to be more effective among those with high subjective health and nutrition knowledge (36). However, others have reported that these characteristics increase time spent looking at labels but do not alter choice (37). Also, one study suggests that external contexts (i.e., shopping vs. home) do not influence whether food labels are read (38). Regarding NWL, only one cross-sectional survey showed that context during purchase, described as having a child requesting high-sugar or high-fat foods, reduced the effect of NWL on decreasing the purchase of foods high in sugar (39). Thus, whether the eating context influences the effect of NWL food choice remains largely unexplored.

Our goal was to identify whether the presence of NWL could affect the decision process and food choices across different eating contexts. To this end, we conducted an online study where participants were prompted to a healthy, typical, and unrestricted eating context to choose between pairs of food images of different healthiness in the absence and presence of NWL.

## 2. Materials and methods

### 2.1. Rationale of the approach

**Figure 1B** summarizes the experimental approach. Participants were asked to choose a food item from pairs of food images of different healthiness and palatability in three previously used contexts (31): Health, typical, and unrestricted. In the healthy context, participants were instructed to select the food they should eat to be healthy, which aimed to reflect their ideal of a healthy diet. In the typical context, participants were instructed to select as they would do in their daily life, which aimed to reflect daily food choices (31). In the unrestricted context, participants were instructed to choose as if nothing was stopping them, which aimed to reflect situations where health concerns are minimized (i.e., dining out for pleasure). The healthy context was included to facilitate interpreting choice data, as this context drives healthier food choices compared to other contexts (26–31). Using different sets of food images in each context, we measured the probability of a healthy choice and conflict during food choice first without showing NWL for all pairs of food images and then showing NWL for the same pairs. This design created paths for each decision (**Figure 1B**)

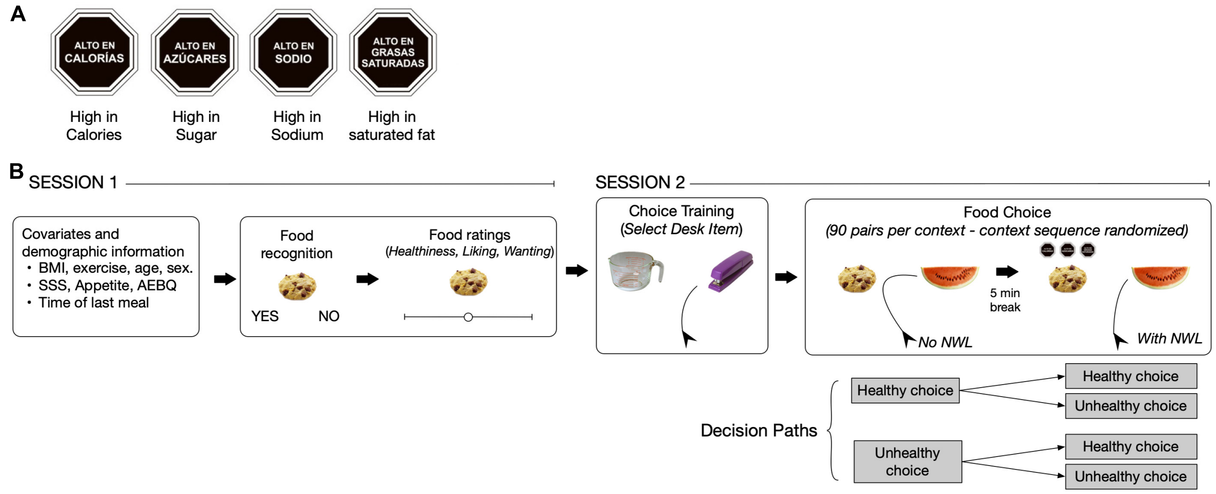


FIGURE 1
Nutrient warning labels (NWL) and experimental design. **(A)** NWL used in the experiment. At the bottom of each label is the English translation from the original Spanish. **(B)** The experiment had two sessions. Demographic information and subjective ratings were collected in the first session and the food choice tasks were conducted in the second session.

to test whether showing NWL would reverse unhealthy food choices made in the absence of NWL across the eating contexts. For all food choices, we estimated conflict by measuring the area under the curve (AUC, the difference in the mouse path from the direct line between the starting point and the chosen image) and reaction time (RT). A larger AUC and longer RT are interpreted as a larger conflict during choice (40–43). Finally, to gain insight into how NWL and context affect the decision process, we fitted a drift-diffusion model (DMM) to the choice data to examine whether changes in AUC could be related to changes in drift rate (how quickly a subject accumulates evidence toward a healthy choice) and decision bias (baseline probability of choosing a given option) toward healthier foods.

## 2.2. Participants

The Human Ethics Committee at Pontificia Universidad Católica de Chile approved this study (Protocol 201223001). Participants were recruited through social media (Instagram and Facebook) and email between June and November 2021 as a convenience sample (the only consideration was to recruit an equal number of males and females by biological sex) and offered a local retailer's gift-card for completing the study (Cencosud, 20,000 Chilean pesos, ~25 USD). Inclusion criteria were BMI between 20 and 35 kg/m$^2$, 18–45 years of age, absence of any disease, and stable body weight (less than 2 kg change over the last 3 months). Exclusion criteria were undergoing treatment for body weight loss, consuming any medication or nutritional supplement, tobacco or alcohol use, any eating disorder or restrictive dietary style, professional sports activity, pregnancy, or breastfeeding. **Supplementary Figure 1** describes the workflow for participant selection. Briefly, participants that contacted investigators were sent a screening questionnaire on a rolling basis. Of the 716 individuals that received the screening questionnaire, 686 returned it. Of those, 496 were excluded, 181 were invited to the study, and 149 completed it. The main rejection criteria were the use of nutritional supplements ($n$ = 230), weight change during the last 3 months ($n$ = 138), and dietary restrictions ($n$ = 128), with 66% of the individuals excluded based on any of these criteria. Among the 149 participants that completed the study, we eliminated 14 participants due to inconsistencies in demographic responses between the screening questionnaire and data collected during the study, one for completing the study twice, one for reporting not reading instructions, one for taking more than 3 hours in completing a single session, and two for having less than 2% of the mouse-tracking data recorded. Thus, data from 128 participants were considered for analysis.

## 2.3. Experimental design

The experiment was implemented in Spanish on the Gorilla Online Platform (44). **Figure 1B** summarizes the experimental design (**Supplementary Table 1** details all the steps in the study). After screening, participants were instructed to complete the two sessions of the study at the same time of day within seven days. In the first session, participants completed a questionnaire for demographic information, exercise, the same questions from the screening questionnaire (body weight, height, age, variation of body weight in the last 2 months, dietary restrictions, alcohol and tobacco use, see **Supplementary Table 2** for a Spanish and English version of the questionnaire), and the time of their last meal. Next, participants completed the Sleep Stanford Scale [SSS (45)], answered four questions about hunger and appetite using visual analog scales (VAS) from 0 to 100 (Questions 1–4 from **Supplementary Table 3**; 46), and the Adult Eating Behavior Questionnaire (AEBQ) (47). The SSS is a one-question form that measures the perceived level of sleepiness and was included to control for potential effects of sleepiness on the desire for high-calorie foods (48). The questions about hunger and appetite were included to control for appetite effects of choice as increased appetite measured by VAS is a predictor of calorie intake and can influence a subject toward choosing high-calorie foods (46, 49). The AEBQ measures different aspects of food approach and avoidance and has been validated in a sample of Chilean adults (47, 50) and was included to control for potential effects of eating behavior on food choice (51).

To complete the first session, the participants answered whether they recognized 94 food images and then were asked to rate those images for healthiness, liking, and wanting using a VAS scale from 0 to 100 (52) (Question 5–7 from **Supplementary Table 3**).

In the second session, participants recorded the time of their last meal and answered the SSS and the same questions about hunger and appetite as in the first session. Next, participants completed a training task instructing them to choose the desk item between images of a desk and a kitchen item (50 pairs of images). Next, participants were randomized to one of six possible sequences of contexts (typical, healthy, unrestricted) for the food choice task. In each context, participants had to choose one food image from 90 pairs without displaying the NWL. After a 5 min break, the same procedure was repeated, but now the NWL were show for each food of the same 90 pairs. Participants also had a 5-min break between contexts. Finally, participants completed a survey where they selected the option that best described how they used NWL in the task (counted the number of NWL, read the information displayed by NWL, or did not use NWL).

## 2.4. Food images

Food images (FoodPics database) (53) were classified into the following categories: bread ($n$ = 3), breakfast food ($n$ = 4), cake ($n$ = 9), cheese ($n$ = 3), cookie ($n$ = 5), dessert treats ($n$ = 22), fruit ($n$ = 25), pasta ($n$ = 4), pastries ($n$ = 7), pie cakes ($n$ = 1), pizza ($n$ = 3), prepared meals ($n$ = 28), salads ($n$ = 3), seafood ($n$ = 1), seeds nuts ($n$ = 6), snacks ($n$ = 14), soups stews ($n$ = 5), and vegetables ($n$ = 24). Online nutritional information for each food image was used to assign NWL following the Chilean Food Labeling Law (14) (See **Figure 1A** for the NWL used in the study). A pilot test ($N$ = 8 adult subjects) indicated that 18 images were not recognized and thus were removed from the dataset. We also selected ten images of typical Chilean preparations assigned to the categories of prepared meals and dessert treats that were validated for recognition in a separate pilot test ($N$ = 6). All food images ($N$ = 94, see **Supplementary information** for detailed information including food pictures) were assigned with 0 to 3 NWL as foods with 4 NWL (high in calories, sugar, saturated fat, and sodium) were infrequent. Images were assigned to each context following a stratified sampling strategy from different food categories. The health context included 32 images (0 NWL: 8, 1 NWL: 6, 2 NWL: 8, 3 NWL: 10), the typical context 29 (0 NWL: 7, 1 NWL: 6, 2 NWL: 7, 3 NWL: 9), and the unrestricted context 33 images (0 NWL: 8, 1 NWL: 6, 2 NWL: 8, 3 NWL: 11). The calories, saturated fat, sugar, and sodium were not different among images used in the different contexts (**Supplementary Figure 2** and **Supplementary Table 4**).

## 2.5. Eating contexts

The eating contexts were defined by the instructions given to participants (31). In the healthy eating context, participants were instructed to "select as fast as possible the food that you would eat to stay healthy," in the typical eating context to "select as fast as possible the food that you would usually select in your daily life," and in the unrestricted eating context to "select as fast as possible the food that you would eat if nothing stopped you."

## 2.6. Food choice task

Each trial started with a white screen that displayed a button labeled "START" at the bottom center of the screen. Once participants pressed the start button, they had up to four seconds to select between food items that appeared in the upper left and right corners with or without NWL displayed. After clicking on the selected food image, a white screen with a fixation cross displayed for a randomly selected period between 100 and 500 ms before the next pair of images was presented. For each participant, the image pairs used in each context were generated pseudo-randomly as follows: (1) Each participant saw 15 food image pairs for each of the six possible combinations of numbers of NWL per food image (0 vs. 1, 0 vs. 2, 0 vs. 3, 1 vs. 2, 2 vs. 3 NWL); (2) Any food image had to skip two pairs before being shown again; (3) Food images with the same number of NWL were not shown on the same side for more than 3 consecutive pairs. Food images were not repeated between contexts to prevent participants from recalling NWL associated with each image.

## 2.7. Data analysis

### 2.7.1. Data preparation

For each choice, we computed the AUC (difference between the actual and a straight trajectory between the starting point and selected image) and the number of y-axis crossings using the mousetrap R package (54). Food choice trials were selected for analysis following standard recommendations for data quality (41, 55). Trials not considered had a mouse-tracking resolution lower than 10 Hz (3.63% total trials); > 3 standard deviations (SD) above the participant's mean for initiation time (0.83% total trials), AUC (0.91% total trials), or RT (2.00% total trials); the y-axis was crossed three or more times (2.45% total trials), and none or only one food image was recognized (17.89%).

### 2.7.2. Drift diffusion model (DDM)

Drift diffusion models for each choice trial were fitted using the RWiener package. To test for model fit, we followed a procedure based on Monte-Carlo simulations (56). For each combination of context and presence of NWL we draw 1,000 parameter sets from a multidimensional normal distribution (mvtnorm R package) using the means and covariance matrix calculated from the individual fitted parameters DDM (decision boundary, non-decision time, decision bias, or starting point, and drift rate). We simulated a sample of 128 RT for each parameter set that was used to re-fit the DDM as done in the original data set, creating a dataset of recovered parameters. Any individual level parameters lying outside the 5% quantile of the distribution of recovered parameters were excluded from the analysis. Also, we computed the correlation coefficient between recovered parameters and the empirical fit to assess if parameters were successfully recovered.

## 2.8. Statistical analysis

All analyses were adjusted for covariates. The covariates were trial order during the task (numeric), age (numeric), sex (male/female), body mass index (BMI, numerical), SSS score (numerical), AEBQ score (numerical) (47), physical exercise (yes/no), appetite score (the mean of the four questions about hunger and appetite, see **Supplementary Table 1**), hour of test start (numerical) and time since last meal (hour, numerical). All continuous covariates were centered and scaled. For all linear mixed models, participant was included as random effect, and each term's statistical significance was calculated using Wald Type III ChiSquare test. Adjusted estimates and posthoc tests for dependent variables were done on estimated marginal means (emmeans R package). The mixed effects logistic regression (glme function) and linear mixed models (lme function) functions were from the lme4 R package. All results are presented as mean and standard error. Post-hoc comparisons were corrected by Tukey's Honest Significant Difference.

### 2.8.1. Effect of NWL on subjective health, like, and want ratings

The response variables were the VAS score for health, like, and want ratings for each image in a linear mixed model with the number of NWL for each image as fixed effect.

### 2.8.2. Demographic parameters

Differences between males and females were tested using *t*-tests for numeric variables and Chi-square test for frequency variables.

### 2.8.3. Differences in food attributes across eating contexts

The response variables were calories, saturated fat, sugar, and sodium per 100 g in a two-way ANOVA with the interaction between NWL and context as independent variables.

### 2.8.4. Effect of eating contexts on the probability of selecting a healthy food without showing NWL

The response variable was the probability of a healthy choice (whether the food with the lower number of NWL was selected) in a generalized mixed logistic regression with the two-way interaction between contexts (healthy, typical, unrestricted) and difference in health and like ratings as fixed variables. The difference in the health and like ratings were calculated by subtracting the rating of the selected image from the rating of the non-selected image for each trial and participant.

### 2.8.5. Effect of eating context on AUC and RT during food choice without showing NWL

The dependent variables were AUC and RT in a linear mixed model with the interaction between food choice (healthy vs. unhealthy) and context as fixed effects.

### 2.8.6. Effect of showing NWL on the probability of healthy food choice

The response variable was the probability of a healthy choice (whether the food with the lower number of NWL was selected) in a mixed logistic effects regression with the two-way interaction between context (healthy, typical, unrestricted) and the food choice without NWL (healthy vs. unhealthy) as fixed effects.

### 2.8.7. Effect of eating context and presence of NWL on change in AUC and RT during food choice

Changes in AUC ($\Delta$AUC) and RT ($\Delta$RT) were calculated as the difference in each variable between the first choice (NWL not shown) and the second choice (NWL shown). Thus, a negative value indicated a reduction in either AUC or RT caused by NWL. The dependent variables were $\Delta$AUC or $\Delta$RT corrected for the baseline value (AUC or RT during the choice without NWL) in separate linear mixed models with the two-way interaction between eating context and decision path (the four combinations of choices, **Figure 1B**) as fixed effects.

#### 2.8.8. Effect of eating context and showing of NWL on DDM parameters

The response variables were bias, drift, and non-decision time in a linear mixed model that included the interaction between context and presence of NWL.

## 3. Results

### 3.1. Participants

Participants were balanced by sex with an average BMI of 23.3 ± 0.2 kg/$m^2$ (all participants that completed the study had a BMI < 30) and 24.8 ± 0.5 years old (Table 1). Men and women did not differ in age ($P$ = 0.79), BMI ($P$ = 0.33), frequency of physical exercise ($P$ = 0.89), percent of overweight participants ($P$ = 0.28), and education level ($P$ = 0.59).

### 3.2. Subjective health, like, and want ratings of food images made without showing NWL correlate with the actual number of NWL in images

Health ratings decreased as the actual number of NWL per food increased ($X_3$ = 12052.16, $P < 0.01$; Figure 2A). Like and want ratings had a U-shape as decreased from foods without NWL to foods with 2 NWL and increased to foods with 3 NWL (Like: $X_3$ = 184.55, $P < 0.01$; Want: $X_3$ = 85.81, $P < 0.01$; Figures 2B, C). Among covariates, increasing BMI reduced health (β = −0.73 ± 0.27, $P$ = 0.01) and like ratings (β = −1.05 ± 0.37, $P < 0.01$) but had no effect on want ratings ($P$ = 0.84). Supplementary Figure 3 shows the estimates for health, like, and want ratings separated by demographic variables. Overall, participants recognized objectively healthier foods (based on the number of NWL per food image) and showed higher like and want ratings for foods with 0 and 3 NWL.

### 3.3. Eating contexts determine the probability of healthy choices and conflict during food choices made without showing NWL

When participants had to choose between pairs of food images in the absence of NWL, the probability of a healthy choice (choosing the food item with the actual lowest number of NWL between the two options) was 82.4, 73.9, and 68% in the health, typical, and unrestricted contexts respectively (Figure 3A; main effect of context: $X_2$ = 286.76, $P < 0.01$; $P < 0.05$ between all contexts). Among covariates, an increase in one unit of BMI increased the probability of a healthy choice by 8.3 ± 3.9% ($P$ = 0.01), while appetite had no significant effect (Supplementary Tables 5, 6 show the complete output of the logistic regression). In all contexts, the probability of a healthy choice increased as the difference in health ratings between images increased (βΔHealth ratings = 3.86 ± 0.05%, $P < 0.01$; Figure 3B) and decreased as the difference in like ratings between images increased (βΔLike ratings = −0.06 ± 0.005%, $P < 0.01$; Figure 3C). Overall, in the absence of NWL, the probability of a healthy food choice was higher in the healthy context and lower in the unrestricted context.

There were significant interactions between food choice type (healthy vs. unhealthy) and context for AUC and RT (AUC: $X_2$ = 10.52, $P < 0.01$; RT: $X_2$ = 242.47, $P < 0.01$; Figures 3D, E). In a healthy choice, the AUC was largest in the unrestricted context and larger compared to the health context

TABLE 1 Participant demographic characteristics.

| | All | Female | Male |
|---|---|---|---|
| Number of participants | 128 (100%) | 66 (51.6%) | 62 (48.4%) |
| Age (years) | 24.78 ± 0.51 (18–45) | 24.65 ± 0.7 (18–45) | 24.92 ± 0.74 (18–43) |
| BMI (body mass index) | 23.25 ± 0.2 (19.49–29.39) | 23.06 ± 0.27 (20.05–29.38) | 23.46 ± 0.31 (19.49–29.39) |
| Normal weight (%) (BMI between 19.5 and 24.9) | 80.5% (103) | 84.8% (56) | 75.8% (47) |
| Overweight (%) (BMI between 25 and 30) | 19.5% (25) | 15.2% (10) | 24.2% (15) |
| Adult eating behavior questionnaire (AEBQ) score | 1.33 ± 0.05 (0.58–3.61) | 1.27 ± 0.06 (0.64–3.61) | 1.4 ± 0.07 (0.58–2.88) |
| Physical exercise (yes/no) | 68.0% (87) | 66.7% (44) | 69.4% (43) |
| **Highest education level completed** | | | |
| College | 38.3% (49) | 34.8% (23) | 41.9% (26) |
| High school | 53.9% (69) | 57.6% (38) | 50.0% (31) |
| Post-graduate | 7.0% (9) | 6.1% (4) | 8.1% (5) |
| Primary | 0.8% (1) | 1.5% (1) | 0.0% (0) |

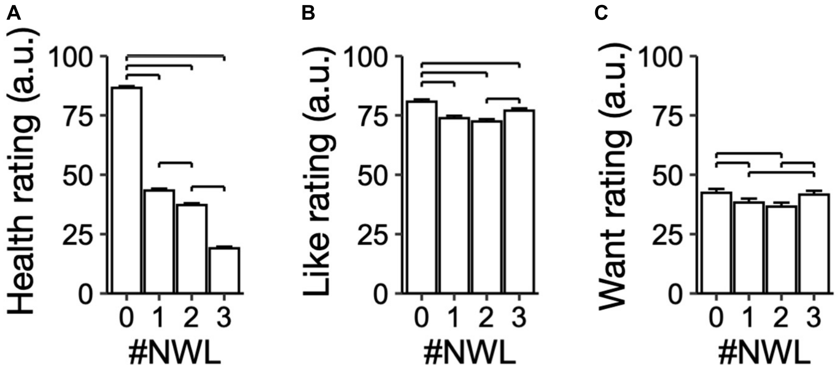


FIGURE 2
Subjective health, like, and want ratings made without showing nutrient warning labels (NWL). Visual analog scales (VAS) ratings for subjective **(A)** Health, **(B)** Like, and **(C)** Want for all foods used in the study made in the absence of NWL. Foods were grouped based on the actual number of NWL of foods. Brackets, $P < 0.05$ for pairwise comparisons.

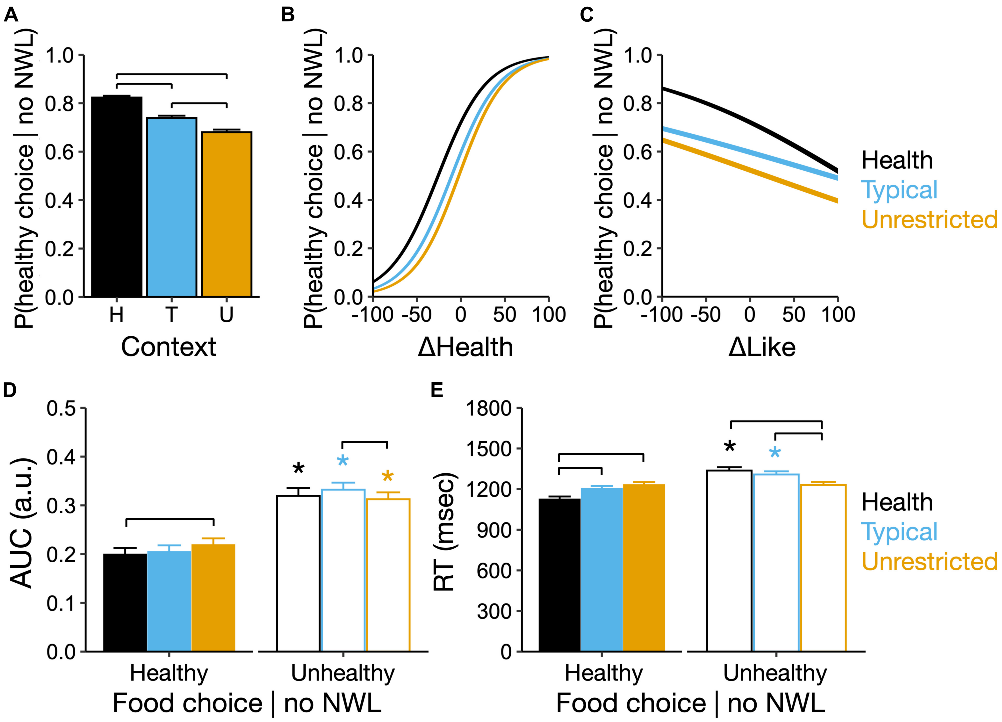


FIGURE 3
Eating contexts determine the probability of healthy choices and the magnitude of conflict during food choices made in the absence of nutrient warning labels (NWL). **(A)** Probability of healthy food choice made without showing NWL by context. Brackets, $P < 0.05$ for pairwise comparisons. **(B)** Larger differences in subjective health rating (fixing like differences at 0) between food images increase the probability of a healthy choice made without showing NWL in all contexts. **(C)** Larger differences in subjective like rating (fixing health differences at 0) between food images reduce the probability of healthy choices made without showing NWL in all contexts. For panels **(B,C)**, differences in health and like ratings were calculated relative to the chosen food image. **(D)** AUC and **(E)** RT during healthy and unhealthy food choices made without showing NWL. Brackets, $P < 0.05$ pairwise differences between contexts within healthy and unhealthy choices. Asterisks, $P < 0.05$ between healthy and unhealthy choices within contexts.

(9.7 ± 3.8%, $P = 0.01$, Figure 3D). For an unhealthy choice, the AUC in all contexts was larger compared to the healthy choice (P < 0.05, Figure 3D), and AUC was now largest in the typical context and different from the unrestricted context (larger by 5.9 ± 2.5%, $P = 0.01$, Figure 3D). For RT, healthy choices were slower in the unrestricted context ($P < 0.05$ compared to all contexts, Figure 3E); but unhealthy choices were slower compared to healthy choices only in the health and typical contexts ($P < 0.05$, Figure 3E). Overall, healthy choices in the unrestricted context showed higher AUC and were slower than in other contexts. Compared to healthy choices, unhealthy choices had higher AUC in all contexts and were slower only in the health and typical contexts.

## 3.4. Eating context and choices made in the absence of NWL determine the effect of showing NWL on conflict and decision during food choice

The probability of a healthy choice when NWL were shown was higher than 90% in all contexts when participants first made a healthy choice in the absence of NWL (Figure 4A) and was lower in all contexts when their first choice was unhealthy ($P < 0.05$ for pairwise comparisons within contexts across decision paths, Figure 4B). Thus, the probability that showing NWL would reverse an unhealthy choice was 79.6 ± 1.8, 36.6 ± 2.1, and 18.6 ± 1.4% in the health, typical, and unrestricted contexts, respectively ($P < 0.05$ between contexts), and regardless of how participants declared to use NWL during food choices (Among participants, 51% declared to count NWL, 37.5% to read them, and 10.9% to not use them during choice, Supplementary Figure 4). Increasing ΔNWL (the difference in the number of NWL between foods in each pair) increased the probability of a healthy choice only in the typical context (up to 13.5 ± 3.3% for ΔNWL = 3, $P < 0.05$, Figure 4C), regardless of how participants declared to use NWL during food choices (Supplementary Figure 5). Overall, showing NWL had a probability to reverse an unhealthy choice of 80% in the healthy context and lower than 50% in the typical and unrestricted contexts.

The effect of showing NWL on the change in AUC (ΔAUC) and RT (ΔRT) compared to the choice made without showing NWL depended on the decision path (interaction between decision path and context: ΔAUC, $X_6 = 14.36$, $P < 0.01$; ΔRT, $X_6 = 140.58$, $P < 0.01$). There were no significant effects of BMI, appetite score, or time from the last meal on ΔAUC or ΔRT (Supplementary Table 7). The confirmation of a healthy choice made when NWL were shown was associated with reduced AUC and faster decisions (negative ΔAUC and ΔRT) in all context, and these effects were the largest in the healthy context. Making an unhealthy choice in the presence of NWL, either by reversing a healthy choice or confirming an unhealthy choice made without NWL, was associated with increased AUC (positive ΔAUC) in the typical and unrestricted contexts. Still, these decisions were slower (positive ΔRT) in the typical context and faster (negative ΔRT) in the unrestricted context. Finally, in the presence of NWL, the reversal of an unhealthy food choice made without NWL was associated with reduced AUC (negative ΔAUC) in the typical and unrestricted contexts but faster decisions (negative ΔRT) only in the health and typical contexts (Figures 4C, D).

Overall, compared to decisions made in the absence of NWL, showing NWL reduced the AUC during healthy choices and increased the AUC during unhealthy choices across eating contexts. The reversal of unhealthy food choices by NWL in the healthy context (80% probability) is associated only with faster choices, in the typical context (36% probability) is associated with reduced AUC and faster choices, and in the unrestricted context (14% probability) is associated only with reduced AUC.

## 3.5. Eating contexts determine the effect of showing NWL on decision bias, drift rate and non-decision time during food choice

There was an interaction between context and presence of NWL for decision bias ($X_2 = 6.97$, $P = 0.01$), drift rate ($X_2 = 76.19$, $P < 0.01$) and non-decision time for the healthy choice ($X_2 = 13.08$, $P < 0.01$). Regardless of the presence of NWL, the healthy context showed the largest decision bias, drift rate, and shorter non-decision time toward a healthy choice (Figure 5). The unrestricted context showed the opposite pattern (i.e., the smallest bias, drift rate, and longer non-decision time toward a healthy choice, Figure 5). Compared to the choice made without NWL, the presence of NWL increased decision bias for a healthy choice in the health (7.6 ± 1.8%, $P < 0.01$) and typical (6.9 ± 1.9%, $P < 0.01$), but not the unrestricted context ($P = 0.45$; Figure 5A). Also, the presence of NWL reduced non-decision time in all contexts with the largest reduction in the health context (−16.8 ± 1.6%, $P < 0.01$) compared to the typical (−9.6 ± 1.5%, $P < 0.01$) and unrestricted context (−8.8 ± 1.5%, $P < 0.01$; Figure 5B). Finally, the presence of NWL almost doubled the drift rate in the healthy (88.3 ± 6.2%, $P < 0.01$) and typical contexts (89.1 ± 21.8%, $P < 0.01$) and increased it by threefold in the unrestricted context (367.5 ± 117.9%, $P < 0.01$), but the drift rate remained highest in the health context and lowest in the unrestricted context (Figure 5C). Overall, compared to a typical and unrestricted context, a healthy context reduces non-decision time, increases decision bias and drift rate toward healthier foods. NWL reduce non-decision time and increase drift rate toward healthier foods in all contexts but increase bias toward healthier foods only in the health and typical contexts.

# 4. Discussion

This study aimed to understand how eating contexts and the presence of NWL influence food choice. We present three key findings. First, eating contexts determine the probability that NWL can reverse an unhealthy choice, this being over 80% in a healthy context, dropping to 37% in a typical and 19% in an unrestricted context. Second, NWL reduce conflict (as shown by

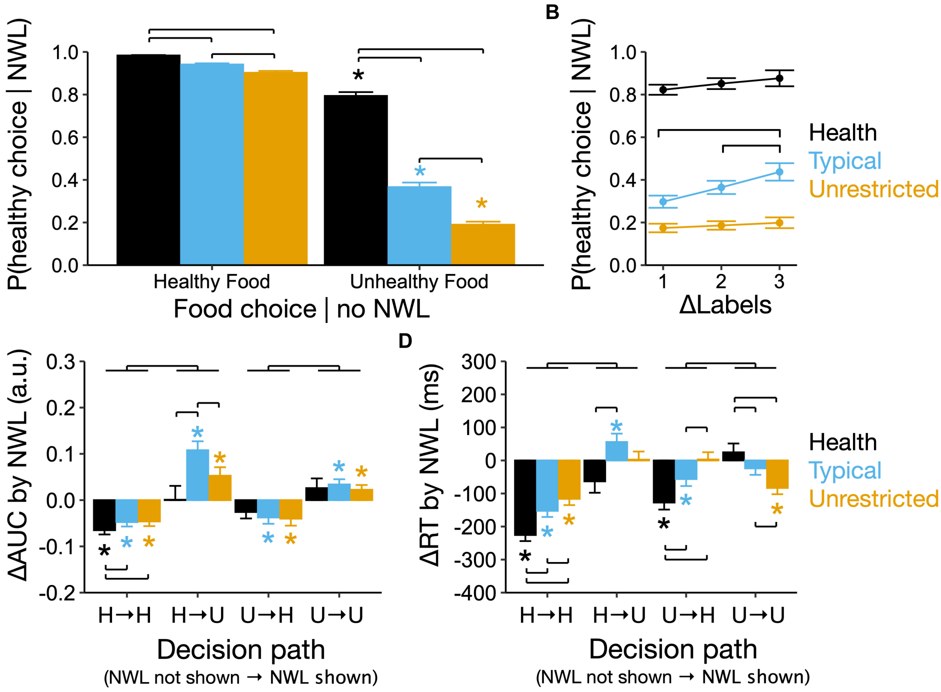


FIGURE 4
Eating contexts determine the effect of showing nutrient warning labels (NWL) on conflict during decision and outcome of food choice. **(A)** Probability of a healthy food choice when showing NWL based on the prior choice made in the absence of NWL. Brackets, $P < 0.05$ pairwise differences between contexts within healthy and unhealthy choices. Stars, $P < 0.05$ between healthy and unhealthy choices within contexts. **(B)** Effect of increased absolute difference in the number of NWL between foods on the probability of healthy food choices in different contexts. Brackets, $P < 0.05$ pairwise differences between the number of food labels within context. **(C)** Change in area under the curve (AUC) (ΔAUC) and **(D)** change in reaction time (RT) (ΔAUC) between choices made with and without showing NWL. Brackets, $P < 0.05$ pairwise differences between contexts for each decision path (H, Healthy food choice; U, Unhealthy food choice). Asterisks, $P < 0.05$ for ΔAUC or ΔRT being different from zero. Upper brackets, $P < 0.05$ for differences between decision paths averaged over contexts.

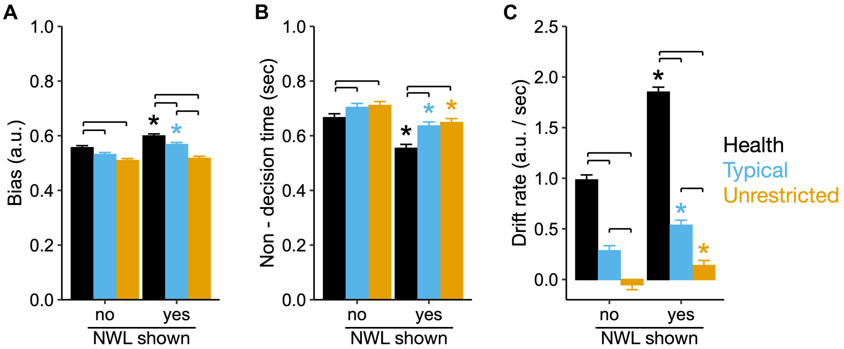


FIGURE 5
Eating contexts determine the effect of showing nutrient warning labels (NWL) on the bias, non-decision time, and drift rate during food choice. **(A)** Bias, **(B)** Non-decision time, and **(C)** Drift rate derived from a drift-diffusion model (DDM) considering healthy food choices as the upper boundary for food choices made without showing and then showing NWL. Brackets, $P < 0.05$ pairwise differences between contexts for choices made with and without showing NWL. Asterisks, $P < 0.05$ in bias, non-decision time, and drift between choices made with and without showing NWL within context.

reduced AUC and faster RT) during healthy choices and increase conflict during unhealthy choices. Third, NWL increase healthy food choices in healthy and typical contexts, likely by increasing bias and speed of decision toward healthier foods.

Our data show that in the absence of NWL, the probability of a healthy choice decreases from the healthy to typical and is lowest in the unrestricted context, a finding consistent with others (26–31). The unrestricted context had the largest AUC

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and longer RT during healthy choices, suggesting the higher conflict is associated with a longer time necessary to consider less salient food attributes (i.e., healthiness) to make a healthy choice in this context (57, 58). As anticipated, in the healthy context, the healthier choices were easier (lower AUC and shorter RT) than the unhealthy choices. We anticipated that an unrestricted context would decrease conflict during unhealthy choices, as we expected participants to favor selecting the less healthy but more palatable foods. Still, the unhealthy choices in the unrestricted context had a larger AUC than healthy choices. Our participants assigned similar like and want ratings to the objectively healthiest foods (those with zero NWL) and less healthy foods (those with 3 NWL). Thus, the increased AUC could be due to participants having similar hedonic ratings for foods of different healthiness. The similar RT for healthy and unhealthy choices in the unrestricted context suggests that participants only consider the most salient attributes of foods (reflected in like and desire ratings) in the decision process. Overall, these data show that in the absence of NWL, a healthy context facilitates healthy choices compared to a typical and unrestricted context.

Our data shows that eating contexts alter the influence of NWL on the decision process and choice. While showing NWL led to a probability of over 90% of confirming the healthy choice made in the absence of NWL across all contexts, the probability that showing NWL would reverse an unhealthy choice was 80% in the health, 37% in a typical, and 19% in the unrestricted context; all regardless of how participants used NWL in their decision. The presence of NWL facilitate healthier choices, as NWL reduced AUC and RT in all contexts during healthy choices; and NWL make unhealthy choices more difficult, as NWL increased AUC in all contexts during unhealthy choices compared to choices made in the absence of NWL. However, the magnitude of the effects was dependent on context. For example, we observed the largest reduction in AUC and RT in the healthy context, which matches retail data indicating that subjects that intend to eat healthy will use nutritional information (59). However, during the reversal of unhealthy choices, NWL reduce AUC in all contexts but RT only in the healthy context. Our DDM analysis provides an insight into this effect. The healthy context has the largest drift rate (how quickly a subject accumulates evidence toward a healthy choice) and bias for healthy food choices (larger bias indicates less information is needed to choose the healthy option). Further, while showing NWL increase drift rate in all contexts, bias for healthier food options only increased in the healthy and typical contexts. Together, these data first suggest that context determines a baseline decision bias and drift rate for healthy choices (higher in the healthy context and lowest in the unrestricted context). Second, that showing NWL increase the probability of healthy choices by reducing conflict during healthy choices and increasing conflict unhealthy choices. This effect of NWL is associated with increased drift rate and bias towards healthier food choices, the latter being active before the decision process and absent in the unrestricted context.

The proposed model fits with evidence that a higher drift rate and an earlier entry into the decision process of health over taste ratings increase the probability of healthy food choices (58). While we did not model the explicit contribution of differences in healthiness and wanting in different contexts in our DDM, we predict that compared to when NWL are absent, displaying NWL would increase drift rate, reduce time of entry into the decision process of healthiness ratings, and bias the decision toward the healthier food. Further, we propose this bias might be mediated by increasing salience of negative health consequences of intake (13). We did not include the monetary cost of food, which is relevant as NWL are expected to drive healthier choices despite the higher price of healthier foods often limits their purchase (60–62). Thus, future studies should also examine whether explicit information about monetary cost influences the effect of context and NWL on food choices.

Limitations of our study include potential selection bias and food choice conditions that differ from real-world conditions. Our participants were selected as a convenience sample, which could influence our results. For example, the incidence of obesity in Chile is over 34% (63). Still, there are no participants with obesity in our study. Thus, the healthy context of our participants (what they would eat to be healthy) could be closer to their typical behavior compared to participants with obesity. This might explain that while the probability that showing NWL reverses an unhealthy choice is above 50% only in the healthy context, showing NWL reduces conflict during the reversal of unhealthy choices in healthy and typical contexts. The artificial nature of food choice in our study is a limitation inherent to experimental studies of human behavior. For example, our participants had up to 4 s to choose a food image between two options. While these constraints can increase attrition during the test and simplify data analysis, food choices are not binary or time constrained in a real-world setting. Overall, future studies using larger samples should address the potential impact of obesity (and other factors such as sedentarism or age) in food choice and NWL under different contexts in more complex experimental designs that better model real-world conditions.

Despite its limitations, we think these data have strong implications for public health interventions. Analysis of purchase data indicates that NWL increased the selection of foods without NWL. Still, the resulting reduction in calories purchased is low (21, 22) and within range of what can be compensated by reducing energy expenditure to maintain a stable body weight (64). Our data suggest that prompting a healthy context before or during food purchase could increase the efficacy of NWL to drive healthier food choices and have a larger impact on calorie intake compared to typical behavior and to situations of unrestrained eating where health considerations are minimized (i.e., dining out, buying food for pleasure). Most interventions at food retailers or restaurants have focused on improving the healthiness of the food available and increasing the visibility of healthier options (65, 66). Still, interventions that prompted a healthy context in cafeteria settings led to increased dietary quality (67, 68), which might increase further if NWL are included in the intervention. Thus, our data suggest that interventions that prompt healthy eating contexts during purchase could improve the efficacy of NWL to drive healthier food choices.

In conclusion, NWL can facilitate healthier food choices and make unhealthy choices more difficult in a healthy, typical, and unrestricted context. Still, their ability to reverse an unhealthy food choice is below 50% in a typical and unrestricted context. Our DDM analysis suggests this effect is likely determined by information considered before the start of the decision process, which might be associated with negative health consequences triggered by NWL. These data suggest that private or public prompts for a healthy eating context could increase the ability of NWL to drive healthier food choices.

## Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

## Ethics statement

The studies involving human participants were reviewed and approved by Human Ethics Committee at Pontificia Universidad Católica de Chile (Protocol 201223001). The patients/participants provided their written informed consent to participate in this study.

## Author contributions

CP-L, JG, MD, and CM-L: conceptualization. SC, MD, CM-L, CP-L, and JG: experimental design. SC and CP-L: data collection. CP-L, LL, and YJ: analysis. CP-L and YJ: original draft preparation. CP-L, LL, JG, and CM-L: editing. All authors reviewed the manuscript.


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## Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

## Publisher's note



## Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fnut.2022.1026623/full#supplementary-material

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# Status of nutrition labeling knowledge, attitude, and practice (KAP) of residents in the community and structural equation modeling analysis

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**Objective:** Unhealthy foods were a major contributor to the occurrence of chronic non-communicable diseases. The promotion of nutrition labeling in the community can effectively help residents to choose healthy foods, which plays an important role in the prevention of chronic diseases. However, the public awareness of this measure is not clear. Our study used a structural equation model based on the KAP theory to analyze the interaction mechanisms among knowledge, attitude, and practice and aimed to evaluate the relationships among nutrition knowledge, attitude, and practice of residents, which can provide the basis of policy formulation for nutrition education and behavior intervention.

**Methods:** We carried out a cross-sectional study from May 2022 to July 2022 in the "Community Health Service Center", and each "Community Service Station" in Yinchuan use a self-designed questionnaire and convenience sampling to evaluate resident nutrition labeling KAP status. This study adopted the structural equation modeling approach to analyze a survey of Chinese individuals through the cognitive processing model, interrelated nutrition knowledge, nutrition label knowledge, attitude, and practice.

**Results:** According to the principle of sample size estimation, a total of 636 individuals were investigated, with the ratio of male to female being 1:1.2. The average score of community residents' nutrition knowledge was 7.48 ± 3.24, and the passing rate was 19.4%. Most residents had a positive attitude toward nutrition labeling, but the awareness rate was only 32.7% and the utilization rate was 38.5%. Univariate analysis showed that women had higher knowledge scores than men ($p < 0.05$), and young people had higher scores than older adults ($p < 0.05$), and the difference was significant. Based on the KAP structural equation model (SEM), residents' nutrition knowledge will directly affect their attitude toward nutrition labeling. Attitude played a greater role as an indirect effect between knowledge and behavior, while trust limits residents' practice of nutrition labeling and then affects their practice. It could be explained that nutrition knowledge was the prerequisite for label reading behavior, and attitude was the intermediary effect.

**Conclusion:** The nutrition knowledge and nutrition labeling knowledge of respondents hardly directly support the practice of nutrition labeling, but it can influence the use behavior by forming a positive attitude. The KAP model is suitable for explaining residents' use of nutrition labeling in the region. Future research should focus on better understanding the motivations of residents to use nutrition labeling and the opportunity to use nutrition labeling in real-life shopping settings.

KEYWORDS

**prepackaged food, nutrition labeling, knowledge-attitude-practice model, residents, structural equation model**

## 1. Introduction

In recent years, fast foods, take-out foods, and prepackaged foods have become increasingly popular, with a rapid increase in the consumption rate of them (1–3), among which, the consumption rate of prepackaged foods in China has reached 59.8% (4). The poor cooking methods of take-out foods and fast foods caused a large accumulation of unhealthy ingredients in the body, including fat, salt, and sugar (1, 5). Prepackaged foods (including puffed food, beverage, pickled canned food, and leisure food) are generally high in energy, fat, and sodium and low in protein and dietary fiber (6, 7). Whether it is fast foods, take-out foods, or prepackaged foods, its rising consumption rate and accumulation of unhealthy nutrients are the key factors in causing the high incidence of chronic diseases such as obesity and diabetes (8, 9). Diet-related diseases have become more common because of changes in lifestyle and food habits, but researchers have also established that dietary modifications significantly reduce the risk of diseases (10). Individual food choices and eating behaviors are influenced by many interrelated factors which affect the results of nutrition-related public health interventions. To improve the adverse health effects of this situation, recommendations and interventions have been implemented across the globe. Nutrition labeling plays an active role as a dietary strategy as recommended by the WHO (11). In the face of increasing diet-related chronic diseases, many countries have initiated steps to include nutrition labeling on prepackaged food packets and in restaurant menus to standardize the management of nutrition labeling (12).

Nutrition labeling is not only an information tool to interpret the nutrient content and function of food but also a strategy against overweight and obesity (13), which plays a critical role in promoting healthy eating habits. Petimar et al. found that the calorie menu labeling was associated with an immediate decrease of 60 calories per transaction or 4% of total calories purchased (14). A meta-analysis expressed that food labeling decreased consumer intakes of energy by 6.6%, total fat by 10.6%, artificial trans fat by 64.3%, sodium by 8.9%, and other unhealthy dietary options by 13.0% while increasing vegetable consumption by 13.5% (15). The implementation of nutrition labeling and sugar labeling can contribute to the lower risk of cardiovascular diseases and cancer and kidney diseases, thereby reducing the prevalence of chronic diseases and increasing life expectancy (16, 17). In addition, under the Nutrition Labeling and Education Act (NLEA) promulgated by the United States in 1990, nutrition labeling will be required for all retail food products to facilitate consumers to obtain more nutrition information and maintain healthy dietary practices (18). Although the nutrition labeling system has been introduced in China as early as 1994 (19) and has been revised several times, the practice of nutrition labeling has not been actually promoted until the General Rules of National Prepackaged Food Nutrition Labels (GB 28050-2013) were enacted in 2013 (20, 21). Since then, the labeling rate of nutrition labeling in prepackaged foods has been significantly improved (22). Since then, the labeling rate of nutrition labeling in prepackaged foods has been significantly improved. However, the actual utilization of nutrition labeling was in fact lower than that reported (23), possibly because the complex design of nutrition labeling is puzzling, including energy conversion and professional terms description (24, 25). Previous studies have found that the longer a consumer gazed at the nutrition claim, the more likely the product with a nutrition claim was bought (26). It is also reported that consumers who regularly use the nutrition labeling seem to have a higher diet quality (27).

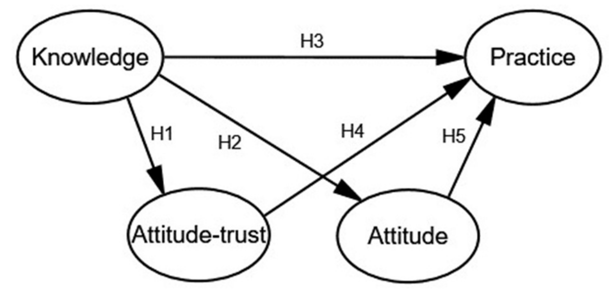


FIGURE 1
The KAP constructed equation model.

The knowledge, attitude, and practice (KAP) model is a theory to explain an individual healthy behavior (28) and the model figures that there are two key steps to changing behavior: establishing beliefs and changing attitudes. Up to now, the KAP model has been widely applied to health education in the fields of prevention of primary infectious diseases (e.g., schistosomiasis, tuberculosis, malaria, and AIDS) (29–31) and control of chronic diseases (e.g., diabetes and hypertension) (32, 33). However, few studies have explored the relationships among knowledge, attitude, and practice behavior of nutrition labels based on the KAP theory (34–36). The use of nutrition labeling is a dietary self-management behavior and is closely related to their own nutrition knowledge and health beliefs. Therefore, we adopted the KAP model as a framework to explore the relationships between them, and the new findings may contribute to future nutrition education to promote nutrition label use in China.

## 2. Hypotheses of the KAP model

According to the KAP theory, there is a causal relationship among knowledge, attitude, and practice (37). However, KAP are potential variables that are difficult to measure directly. The traditional statistical methods cannot deal with these potential variables effectively, while the structural equation model (SEM) integrates the traditional statistical analysis methods, such as confirmatory factor analysis, path analysis, and multiple regression analysis, leading to a new multivariate statistical technology. It can not only analyze and deal with measurement errors but also analyze the structural relationship between potential variables (38, 39) and directly display the correlation between the variables through the path diagram. In addition, it can also explore the causal relationship between potential variables and quantitatively evaluate the direct and indirect effects of variables (40), as shown in Figure 1.

Knowledge means the ability of understanding and using nutrition information, through education, learning experience, and identifying the nutrition label. Attitude refers to the feeling or opinions of community residents on nutrition labeling in some situations, including credibility, helpfulness, and necessity. Practice refers to the use or application of nutrition labeling by community residents. Based on the KAP model, it is predicted that nutrition knowledge will positively and indirectly affect practice through attitude change, and nutrition knowledge may also directly affect nutrition labeling practice. We put forward the following five assumptions based on the relevant literature on the knowledge, attitude, and practice structure model published by Zeng Y, Kwak C, Zeying H, and Misra R.

Hypothesis 1(H1): Community residents who have higher nutrition knowledge scores are more likely to trust nutrition labeling.
Hypothesis 2(H2): Community residents who have higher nutrition knowledge scores are more likely to have a positive attitude toward labeling.
Hypothesis 3(H3): Community residents who have higher nutrition knowledge scores are more likely to use nutrition labels.
Hypothesis 4(H4): Community residents who have more trust in nutrition labeling are more likely to use it.
Hypothesis 5(H5): Community residents who have a more positive attitude toward nutrition labeling are more likely to use it.

Thus, we attempted to analyze the interactions among community residents' nutrition labeling knowledge, attitude, and practice by using the KAP model to construct a structural equation. Meanwhile, we should also explore residents' cognition and use behaviors of nutrition labeling, as well as the influencing factors so that the resident can have a better understanding of nutrition labels and habits of food choice.

# 3. Materials and methods

## 3.1. Materials

A cross-sectional questionnaire survey was conducted using convenience sampling and anonymously in a community health service center in Yinchuan, Ningxia, from 1 May 2022 to 16 July 2022. Investigators will be rigorously trained before the investigation, and the data collected will be kept strictly confidential by the research team. The data were collected by a combination of online and onsite. The respondents include adults over 18 years old who have lived in the community for a long time (more than one year), excluding residents with serious diseases and unable to communicate. After informed consent was obtained from each participant, questionnaires are distributed and filled out. The sample size calculation is as follows: $n = Z^2_{1-\alpha/2} \times P \times \frac{(1-P)}{\delta^2}$, (where α: significance level, when $\alpha = 0.05$, $Z_{1-\alpha/2} = 1.96$, $n$:sample content,δ: allowable error, and $P$:estimation value of population rate π). The average awareness rate of the nutrition label is approximately 40%, that is, $P = 0.4$, $\alpha = 0.05$, and $\delta = 0.04$, the sample size was expanded by 10% considering non-response, and 636 residents were eventually included.

## 3.2. Methods and collection data

This study is based on KAP model (41). The questionnaire is based on the questionnaire designed by the Center for Disease Control and Prevention (CDC) of China, then revised according to Cui (42) (Cronbach's alpha = 0.967, Kaiser–Meyer–Olkin = 0.960, $p$ <0.005) and Liu (43), and finally verified by expert review. Two pre-surveys were conducted in a small sample of 62 adults, which were revised according to the feedback. We should ensure that the reliability and validity of the final questionnaire were qualified (Cronbach's alpha = 0.922, Kaiser–Meyer–Olkin = 0.887, $p <$ 0.001). The questionnaire includes 50 questions in three parts as follows: basic demographic information, nutrition knowledge, and nutrition labeling KAP; each part is relatively independent. The first part includes answering questions such as age, gender, educational level, marital status, occupation, monthly income, self-reported illness or physical condition, and medical and nutrition education, and this part is not scored. The second part includes answering questions about the main effects of core nutrients (such as protein, fat, carbohydrates, and sodium) and the recommended intake of sodium in *Dietary Guidelines for Chinese Residents*. In this part, multiple choice questions (single-choice question), 1 point for the right choice. Multiple choice questions (select one or more answer choices), with 0.5 points for each correct item. The third part includes answering the contents of nutrition labeling, the meaning of NRV, and the types of nutrients that are mandatory to be labeled, with 1 point for the right choice. In this part, the questions about residents' understanding, attitude, trust, and helpfulness of nutrition labeling are evaluated by a five-point Likert scale, ranging from 1 "strongly disagree" to 5 "strongly agree". The scores are 1, 2, 3, 4, and 5, respectively, which increase in turn.

The number of correct answers to "What are the parts of food nutrition labels" divided by the total number of samples, which is the awareness rate of nutrition labels, expressed as a percentage. Regarding the numerical expressions of credibility, helpfulness, and necessity, we combine "strongly agree" and "agree" as positive, "neither agree nor disagree" as modest, and "strongly disagree" and "disagree" as negative. The higher the score, the higher the residents' understanding of food nutrition labels, the more positive their attitude, and the more willing they are to use nutrition labels when shopping. Data were collected in "A Community Health Service Center" and an online questionnaire platform "Wenjuanwang" (https://www.wenjuan.com/).

# 4. Data analysis methods

Data analysis was performed in three stages. First, the data were analyzed using EpiData3.1 data entry. Second, SPSS 24.0 (IBM, NY, United States) was used for statistical analysis and reliability and validity tests. If the quantitative data were subjected to the normal distribution, it is described by mean standard deviation (mean ± $SD$); On the contrary, it is described by median or interquartile value. If the data submitted to normal distribution and homogeneity of variance, a one-way analysis of variance or chi-square test was used. Otherwise, the Wilcoxon rank-sum test is adopted for comparison. Finally, the KAP structural equation model (SEM) of nutrition labeling for community residents was constructed by using AMOS 24.0 (IBM, NY, United States) software, and the model was revised by Modification Indices. The model fitting was evaluated with $\chi^2$ -value, GFI (goodness-of-fit index), AGFI (adjusted goodness-of-fit index), TLI (Tucker–Lewis index), CFI (comparative fit index), NFI (normed fit index), IFI (incremental fit index), and RMSEA (root mean square error of approximation). The test level was 0.05, and $p < 0.05$ indicated that the difference was statistically significant.

# 5. Results

## 5.1. Demographic data analysis

The sociodemographic characteristics of the participants are presented in Table 1. A total of 636 people were investigated, including 285 men and 351 women, mean age was approximately 46.8 ± 17.0 years with a minimum age of 18 years and a maximum age of 75 years. The most frequent age group was 35–44 years (21.9%). More than half of the residents have received a high school education or above (67.7%). Residents with a monthly income between 5,000 and 10,000 CNY are the most, account for 34.6%, and with monthly income above 20,000 CNY being the least, accounting for only 1.9%; and 74.7% of the residents are married.

## 5.2. Knowledge, attitude, and practice of nutrition labeling among residents by different gender

The scores of nutrition labeling knowledge, attitude, and practice of women were higher than those of men. There were no significant differences in genders in understanding nutrition labeling information and technical term descriptions ($p > 0.05$), but there were significant differences in understanding nutritional content, numerical information, and the function of nutritional content ($p < 0.05$). In terms of nutrition labeling attitude, women showed significantly higher scores ($p < 0.05$) in necessity and helpfulness except credibility, compared to men. It indicated that women had richer nutrition labeling knowledge, more positive attitudes toward nutrition labeling, and used nutrition labeling more frequently, which was related to the fact that the frequency of undertaking food purchasing and cooking was higher in women than in men. It might be because women received medical or nutrition-related training more frequently than men, as shown in Table 2.

## 5.3. Knowledge, attitude, and practice of nutrition labeling among residents by different economic conditions

The residents with a higher monthly household income had higher nutrition knowledge scores, and the difference was significant ($p < 0.05$). The residents with better economic conditions scored higher than those with poorer economic conditions in nutrition labeling knowledge, attitude, and practice,

TABLE 1 Sociodemographic characteristics of the whole sample.

| Variables | Profile | N | Percentage% |
|---|---|---|---|
| Gender | Male | 285 | 44.8 |
| | Female | 351 | 55.2 |
| Age | 18–29 | 139 | 21.9 |
| | 30–39 | 98 | 15.4 |
| | 40–49 | 117 | 18.4 |
| | 50–59 | 103 | 16.2 |
| | 60–69 | 95 | 14.9 |
| | 70– | 84 | 13.2 |
| Education level | Primary school and below | 86 | 13.5 |
| | Junior school | 120 | 18.9 |
| | High school or technical secondary school | 145 | 22.8 |
| | Junior college or undergraduate | 263 | 41.4 |
| | Postgraduate level and above | 22 | 3.5 |
| Monthly Earning (*yen*) | <1,500 | 39 | 6.1 |
| | 1,501–3,000 | 112 | 17.6 |
| | 3,001–5,000 | 207 | 32.5 |
| | 5,001–10,000 | 220 | 34.6 |
| | 10,001–20,000 | 46 | 7.2 |
| | ≥20,000 | 12 | 1.9 |
| marital status | Unmarried | 109 | 17.1 |
| | Married | 475 | 74.7 |
| | Divorced | 23 | 3.6 |
| | Widowed | 29 | 4.6 |

with a significant difference ($p < 0.05$). However, whether residents checked nutrition claims and nutrient function claims during shopping was not significantly different with respect to their socioeconomic status ($p > 0.05$), as shown in Table 3.

Only 25.5% of the residents could understand the information on the nutrition labeling, with the worst understanding of the description of professional terms and the better understanding of the role of nutrients. In total, 76.1% considered it necessary to implement nutrition labeling, and 45.8% of the residents would check the nutrition labeling, but only 38.5% of them said that the nutrition labeling could affect their shopping behavior. Residents still had an inherent distrust on the authenticity of nutrition labeling, with 20.5% of the residents considered that the nutrition labeling was generally untrustworthy, 23.6% considered that the nutrition table was inaccurate, 23.0% considered that the nutrition claims were untrue, and 21% considered that the nutrition function claims were untrustworthy. It can be seen that although residents would check the nutrition label, it does not necessarily affect their shopping behavior, as shown in Table 4.

TABLE 2 Mean scores on knowledge, attitude, and practice scales completed by 636 residents, by gender.

| Variables (Mean ± SD) | Total samples | Gender | | t/h | *P** |
|---|---|---|---|---|---|
| | | Male | Female | | |
| Nutrition knowledge | 7.5 ± 3.2 | 7.1 ± 3.4 | 7.7 ± 3.1 | −2.36 | 0.019 |
| Understand the information on nutrition labeling | 2.9 ± 1.0 | 2.8 ± 1.0 | 2.9 ± 1.0 | −1.48 | 0.141 |
| Understand technical term description | 2.3 ± 1.1 | 2.2 ± 1.1 | 2.4 ± 1.2 | −1.91 | 0.056 |
| Understand the nutrients. | 3.1 ± 1.2 | 2.9 ± 1.1 | 3.3 ± 1.2 | −4.19 | <0.001 |
| Understand the numerical information and units | 2.8 ± 1.3 | 2.5 ± 1.3 | 3.0 ± 1.3 | −4.75 | <0.001 |
| Understand the function of nutrients | 3.2 ± 1.2 | 3.0 ± 1.2 | 3.4 ± 1.2 | −3.69 | <0.001 |
| Nutrition labels are credible | 3.2 ± 0.9 | 3.1 ± 0.9 | 3.2 ± 0.9 | −0.88 | 0.379 |
| Nutrition Facts Table are credible | 3.1 ± 0.9 | 3.0 ± 0.9 | 3.1 ± 0.9 | −1.33 | 0.184 |
| Nutrition claims are credible | 3.1 ± 0.9 | 3.0 ± 0.9 | 3.1 ± 0.9 | −1.13 | 0.258 |
| Nutrition function claims are credible | 3.2 ± 0.9 | 3.2 ± 0.9 | 3.1 ± 0.9 | 0.26 | 0.798 |
| Nutrition labels are helpful | 3.5 ± 1.0 | 3.3 ± 1.0 | 3.6 ± 1.0 | −3.00 | 0.003 |
| Nutrition labels are necessary (Media) | 4.0(4.0∼5.0) | 3.0(3.0∼5.0) | 4.0(4.0∼5.0) | 13.24 | <0.001 |
| Use nutrition labels when shopping | 3.2 ± 1.1 | 2.9 ± 1.1 | 3.3 ± 1.0 | −4.36 | <0.001 |
| Check types or contents of nutrients | 3.3 ± 1.2 | 2.9 ± 1.2 | 3.4 ± 1.1 | −4.58 | <0.001 |
| Check Energy | 3.1 ± 1.2 | 2.8 ± 1.2 | 3.3 ± 1.2 | −5.02 | <0.001 |
| Check NRV% | 2.8 ± 1.2 | 2.6 ± 1.2 | 3.0 ± 1.2 | −4.36 | <0.001 |
| Check nutrition claims | 3.2 ± 1.2 | 3.0 ± 1.2 | 3.4 ± 1.1 | −4.04 | <0.001 |
| Check Nutrient function claims | 3.3 ± 1.2 | 3.0 ± 1.2 | 3.3 ± 1.1 | −3.15 | 0.002 |

*student's *t*-test (T) or Kruskal–Wallis test (H), $p < 0.05$ is considered statistically significant.

## 5.4. Discriminant validity analysis and testing the fit of the model

Exploratory factor analysis (EFA) examined the factor structure and adjusted the number of items. Pearson's correlation test was used to analyze the relationships among knowledge, attitude, and behavior. The discriminant validity issue was examined by the square root of the average variance extracted (AVE). There was no identification validity problem in this data, as the value of the square root of the AVE was higher than its correlation with other constructs (44), as shown in Table 5.

Kaiser–Meyer–Olkin (KMO) test and Bartlett's test of sphericity (BTS) revealed that KMO=0.914, BTS was significant ($\chi^2 = 9{,}834.497$, $p < 0.001$), and the condition of EFA was met, which suggests that these items are suitable for factor analysis (45). The consistency of all scales was tested by composite reliability (CR), and the findings that the average variance extracted (AVE) values exceeded 0.50 for all constructs suggested that the latent constructs retained a minimum of 50% variance. The reliability of the samples was tested by Cronbach's α coefficient, which showed that Cronbach's $\alpha = 0.897$ for the total scale, and each scale coefficient was >0.83, suggesting good reliability of the questionnaire, as shown in Table 6.

## 5.5. Structural equation modeling fitting for nutrition labels

This study investigates whether nutrition knowledge and attitude affect residents' nutrition label use behavior, whether attitude plays an intermediary role between knowledge and use behavior (46), and whether knowledge can directly affect use behavior. We reviewed the relevant references and subdivided the problem of attitude dimension because we find that when all six attitude problems are included in the model, the final model showed unsatisfactory fitness to the data. To solve the problem of unsatisfactory data fitting, we subdivide attitude factors into two potential variables, attitude–trust and attitude, and establish KAP structural equations. First, we established the K-A(trust)-P structural equation. We found that there was only a slight correlation between attitude (trust) and practice, with a path coefficient of 0.003, and the correlation between them was not significant ($p = 0.941$). Then, we established the KAP structural equation model and found that there was a significant positive correlation among knowledge, attitude, and practice, and the path coefficient was > 0. In order to observe the correlation between two attitudes potential variables and practice at the same time. Our research group finally combined the two models together to form a new model (Figure 2). The results showed that the path coefficient from attitude (trust) to practice was −0.059, showing a negative

TABLE 3 Mean scores on knowledge, attitude, and practice scales completed by 636 residents, by income.

| Variables (mean ± SD) | Total samples | Income | | | *h* | *P** |
|---|---|---|---|---|---|---|
| | | Low | Medium | High | | |
| Nutrition knowledge | 7.5 ± 3.2 | 6.0 ± 2.9 | 7.8 ± 3.2 | 9.2 ± 3.2 | 47.32 | <0.001 |
| Understand the information on nutrition labeling | 2.9 ± 1.0 | 2.6 ± 1.0 | 3.0 ± 1.0 | 3.1 ± 0.9 | 21.79 | <0.001 |
| Understand technical term description | 2.3 ± 1.1 | 2.1 ± 1.1 | 2.3 ± 1.1 | 2.4 ± 1.3 | 6.61 | 0.037 |
| Understand the nutrients. | 3.1 ± 1.2 | 2.7 ± 1.2 | 3.2 ± 1.1 | 3.6 ± 1.0 | 35.18 | <0.001 |
| Understand the numerical information and units | 2.8 ± 1.3 | 2.4 ± 1.3 | 2.9 ± 1.3 | 3.2 ± 1.3 | 18.81 | <0.001 |
| Understand the function of nutrients | 3.2 ± 1.2 | 2.9 ± 1.3 | 3.3 ± 1.2 | 3.7 ± 1.1 | 19.63 | <0.001 |
| Nutrition labels are credible | 3.2 ± 0.9 | 3.0 ± 0.9 | 3.2 ± 0.8 | 3.3 ± 0.8 | 13.35 | 0.001 |
| Nutrition Facts Table are credible | 3.1 ± 0.9 | 2.9 ± 0.9 | 3.1 ± 0.9 | 3.3 ± 1.1 | 11.05 | 0.004 |
| Nutrition claims are credible | 3.1 ± 0.9 | 2.9 ± 0.9 | 3.1 ± 0.9 | 3.2 ± 1.0 | 6.89 | 0.032 |
| Nutrition function claims are credible | 3.2 ± 0.9 | 3.0 ± 1.0 | 3.2 ± 0.9 | 3.4 ± 1.0 | 11.08 | 0.004 |
| Nutrition labels are helpful | 3.5 ± 1.0 | 3.2 ± 1.2 | 3.5 ± 1.0 | 3.8 ± 1.0 | 15.17 | 0.001 |
| Nutrition labels are necessary (Media) | 4.0(4.0∼5.0) | 4.0(3.0∼5.0) | 4.0(4.0∼5.0) | 4.0(4.0∼5.0) | 8.31 | 0.016 |
| Use nutrition labels when shopping | 3.2 ± 1.1 | 2.9 ± 1.2 | 3.2 ± 1.1 | 3.5 ± 1.0 | 16.27 | <0.001 |
| Check types or contents of nutrients | 3.2 ± 1.2 | 2.9 ± 1.3 | 3.2 ± 1.1 | 3.6 ± 1.1 | 12.42 | 0.002 |
| Check Energy | 3.1 ± 1.2 | 2.8 ± 1.3 | 3.1 ± 1.2 | 3.5 ± 1.2 | 14.54 | 0.001 |
| Check NRV% | 2.8 ± 1.2 | 2.6 ± 1.2 | 2.9 ± 1.2 | 3.0 ± 1.2 | 6.25 | 0.044 |
| Check nutrition claims | 3.2 ± 1.2 | 3.1 ± 1.3 | 3.2 ± 1.1 | 3.4 ± 1.1 | 4.43 | 0.109 |
| Check Nutrient function claims | 3.2 ± 1.2 | 3.0 ± 1.3 | 3.3 ± 1.1 | 3.2 ± 1.2 | 5.25 | 0.073 |

Low: Monthly income <3,000 yuan, Medium: Monthly income is between 3,000 and 10,000 yuan, High: The monthly income is more than 10,000 yuan. Criteria for division: According to the "People's Republic of China (PRC) 2022 National Economic and Social Development Statistics Bulletin" published by the National Bureau of Statistics of China. The national per capita disposable income is 36,883 yuan, and the average monthly income is approximately 3,000 yuan. *Student's t-test (T) or Kruskal–Wallis test (H), $p < 0.05$ is considered statistically significant.

correlation. The path coefficient from attitude to practice was 0.517, and there was a positive correlation.

The model fitted the total samples and explored the relationships among knowledge, attitude, and behavior as latent variables. The fitting index of the structural model (CMIN = 436.507, DF = 127, and CMIN/DF = 3.437 ($p < 0.05$); GFI = 0.929 and AGFI = 0.905; TLI = 0.951, CFI = 0.959, NFI = 0.944, IFI = 0.959, and RMSEA = 0.062) outperformed the respective threshold value, signifying that the data fit the structural model satisfactorily (Table 7).

As shown in Figure 2, Table 8. Hypothesis 1: The path coefficient from knowledge to attitude–trust is 0.561 ($p < 0.001$), which indicates that residents' nutritional knowledge level is positively and significantly associated with their trust. Hypothesis 2: The path coefficient from knowledge to attitude is 0.764 ($p < 0.001$), which indicates that residents' nutritional knowledge level is positively and significantly associated with their attitudes. Hypothesis 3: The path coefficient from knowledge to practice is 0.295 ($p = 0.001$), which indicates that residents' nutrition knowledge will directly impact their use of nutrition labeling, with a positive significant correlation. Hypothesis 4: The path coefficient from attitude–trust to practice is −0.059($p = 0.171$), indicating that residents' trust in nutrition labeling was inversely related to practice, and the path coefficient was not insignificant. Hypothesis 5: The path coefficient from attitude to practice is 0.517 ($p < 0.001$), which indicates that residents' nutrition attitude will impact their use of nutrition labeling, with a positive significant correlation. Thus, hypothesis 5 indicated that attitude played a greater role as an indirect effect between knowledge and behavior, while hypothesis 4 indicates that trust limits residents' practice of nutrition labeling. It could be explained that nutrition knowledge was the prerequisite for label reading behavior, and attitude was the intermediary effect.

## 6. Discussion

The results of this research indicated that the overall cognition level of community residents on nutrition knowledge was low, with an awareness rate of 32.7%, which was unsatisfactory and lower than the national average level (47). Residents have a positive attitude toward nutrition labeling. Approximately 76.1% of the residents indicate that it was necessary to mark the nutrition label on the food packaging; 52.5% of the residents believed that nutrition labeling could help healthy eating or shopping choices in the future, and 33.6% of the residents considered that the nutrition labeling was credible. In total, 38.5% of participants indicated that nutrition labeling would affect their shopping behavior. However, only 25.3% of the residents could understand nutrition labeling, indicating that most of the residents had a positive attitude toward nutrition labeling, but they lack a correct understanding of nutrition labeling and doubt their authenticity. The main reason may be that the promotion of nutrition labeling in China is done

TABLE 4 Description of variables and summary statistics.

| Variables | Items | Label | Strongly disagree | Disagree | Modest | Agree | Strongly agree |
|---|---|---|---|---|---|---|---|
| | | | *N* (%) | *N* (%) | *N* (%) | *N* (%) | *N* (%) |
| Knowledge | score | Nutrition knowledge score | 54 (8.5) | 230 (36.2) | 229 (36.0) | 97 (15.3) | 26 (4.1) |
| | K_K | Understand the information on nutrition labeling | 64 (10.1) | 130 (20.4) | 280 (44.0) | 132 (20.8) | 30 (4.7) |
| | k_1 | Understand technical term description | 203 (31.9) | 178 (28.0) | 163 (25.6) | 64 (10.1) | 28 (4.4) |
| | k_2 | Understand the nutrients. | 73 (11.5) | 103 (16.2) | 211 (33.2) | 172 (27.0) | 77 (12.1) |
| | k_3 | Understand the numerical information and units | 134 (21.1) | 128 (20.1) | 182 (28.6) | 119 (18.7) | 73 (11.5) |
| | k_4 | Understand the function of nutrients | 74 (11.6) | 95 (14.9) | 192 (30.2) | 166 (26.1) | 109 (17.1) |
| Attitude-trust | A_A | Nutrition labeling is credible. | 19 (3.0) | 111 (17.5) | 292 (45.9) | 184 (28.9) | 30 (4.7) |
| | a_1 | Nutrition Facts Table is credible | 33 (5.2) | 117 (18.4) | 289 (45.4) | 173 (27.2) | 24 (3.8) |
| | a_2 | Nutrition claims are credible. | 32 (5.0) | 114 (17.9) | 304 (47.8) | 159 (25.0) | 27 (4.2) |
| | a_3 | Nutrition function claims are credible | 32 (5.0) | 100 (15.7) | 281 (44.2) | 186 (29.2) | 37 (5.8) |
| Attitude | a_4 | Nutrition labeling can help select healthy foods. | 26 (4.1) | 82 (12.9) | 194 (30.5) | 241 (37.9) | 93 (14.6) |
| | a_5 | Nutrition labeling is necessary | 11 (1.7) | 28 (4.4) | 113 (17.8) | 241 (37.9) | 243 (38.2) |
| Practice | P2 | Nutrition labels can affect your shopping behavior | 50 (7.9) | 119 (18.7) | 222 (34.9) | 175 (27.5) | 70 (11.0) |
| | p_1 | Read nutrient composition and content | 65 (10.2) | 107 (16.8) | 193 (30.3) | 189 (29.7) | 82 (12.9) |
| | p_2 | Read energy | 82 (12.9) | 123 (19.3) | 213 (33.5) | 120 (18.9) | 98 (15.4) |
| | p_3 | Check NRV% | 112 (17.6) | 114 (17.9) | 235 (36.9) | 117 (18.4) | 58 (9.1) |
| | p_4 | Observation nutrition claims | 60 (9.4) | 102 (16.0) | 205 (32.2) | 180 (28.3) | 89 (14.0) |
| | p_5 | Observe nutrition function claims | 62 (9.7) | 99 (15.6) | 224 (35.2) | 152 (23.9) | 99 (15.6) |

TABLE 5 Factor correlations and discriminant validity.

| Factors | Nutrition knowledge | Attitude-trust to nutrition labeling | Attitude to nutrition labeling | Practice of the nutrition labeling |
|---|---|---|---|---|
| Nutrition knowledge | (0.751) | | | |
| Attitude-trust to nutrition labeling | 0.561** | (0.844) | | |
| Attitude to nutrition labeling | 0.764** | 0.429 | (0.684) | |
| Use of the nutrition labeling | 0.657** | 0.329 | 0.717** | (0.790) |

Values in brackets () indicate the square root of AVEs. A significance level (**$p < 0.01$).

mainly to increase the reliability and marking rate of labels, rather than educating residents on nutrition knowledge popularization, label content interpretation, and use training.

Previous studies have shown that there are still existing obvious gaps between the identification of nutrition labeling and use behavior in real life. Especially, young people who are active consumers of prepackaged foods, have plenty of chances to contact with nutrition labeling but rarely use them effectively in fact. The practice of nutrition labeling not only depends on whether to establish health belief and implement restaurant menu labeling (48, 49) but also depends on demographic, social, and psychological factors of the population. (50). In this study, we found that residents who were young, female, having high education level, and having high socioeconomic status had higher awareness of nutrition labeling and more positive attitudes, and the frequency of checking nutrition labeling is also higher, which was consistent with previous studies (51, 52). With increasing attention to weight loss, calorie intake restriction, and own health in recent years, nutrition labeling can be an effective tool to directly obtain the nutrition information of packaged food for consumers, which can also help consumers to make a healthy choice. Therefore, nutrition labeling plays an indispensable role in helping residents maintain healthy eating habits (53).

The advantage of this study is its adoption of the mature KAP model to analyze Chinese community residents' cognitive status of nutrition labeling, which was divided into knowledge, attitude, and practice, and then establishing the structural equation. Regarding statistical methodological strength, structural equation modeling

TABLE 6 Factor loadings and convergent validity results.

| Variables | Items | Standard loadings | AVE | CR | Cronbach's alpha |
|---|---|---|---|---|---|
| Knowledge | Nutrition knowledge score | 0.577 | 0.564 | 0.883 | 0.880 |
| | Understand the information on nutrition labeling | 0.704 | | | |
| | Understand technical term description | 0.628 | | | |
| | Understand the nutrients. | 0.889 | | | |
| | Understand the numerical information and units | 0.809 | | | |
| | Understand the function of nutrients | 0.845 | | | |
| Attitude-trust | Nutrition labels are credible. | 0.838 | 0.714 | 0.909 | 0.908 |
| | Nutrition Facts Table are credible | 0.853 | | | |
| | Nutrition claims are credible. | 0.871 | | | |
| | Nutrient function claim is credible | 0.817 | | | |
| Attitude2 | Nutrition labels can help to choose healthy foods. | 0.791 | 0.468 | 0.630 | 0.610 |
| | Nutrition labels are necessary | 0.556 | | | |
| Practice | Reading nutrition labeling when shopping. | 0.731 | 0.625 | 0.909 | 0.915 |
| | Reading nutrient composition and content | 0.845 | | | |
| | Reading energy | 0.848 | | | |
| | Check NRV% | 0.841 | | | |
| | Observation nutrition claim | 0.761 | | | |
| | Observe the functional claim of nutrients | 0.704 | | | |

Rotation technique: Promax; extraction technique: maximum likelihood; Cronbach's alpha=0.922, Kaiser-Meyer-Olkin measure of sampling adequacy: 0.914, $p < 0.001$, AVE: average variance extracted, CR: composite reliability.

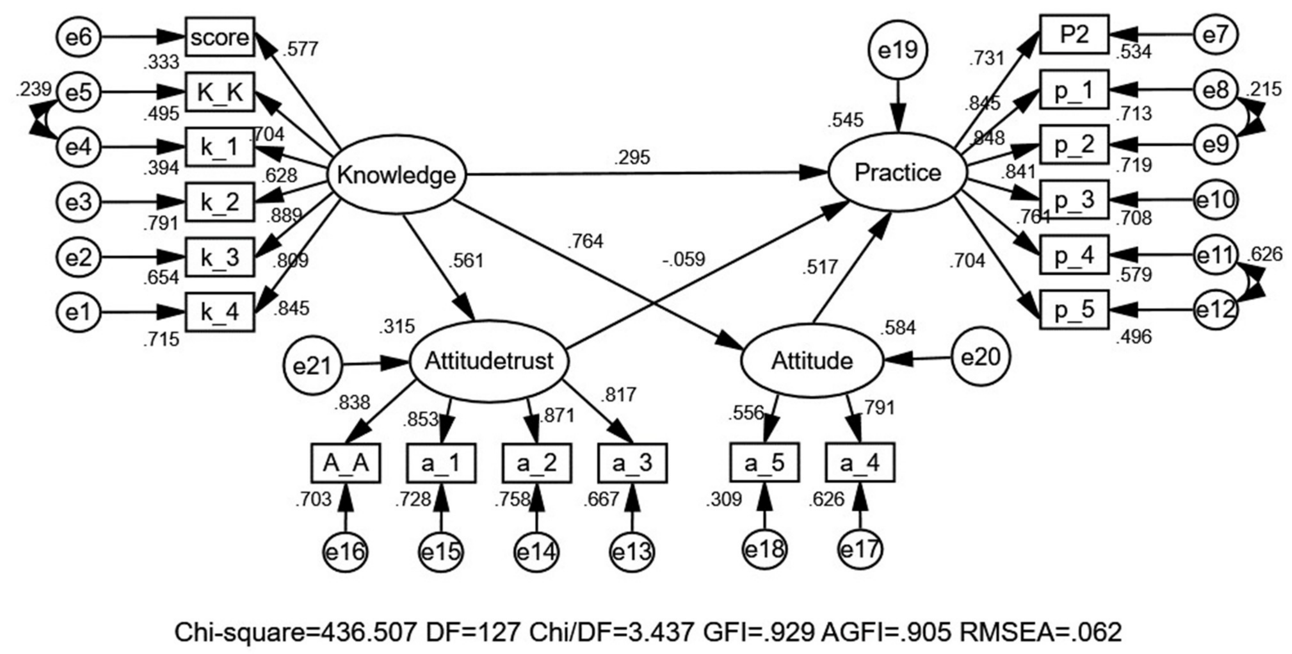


FIGURE 2
The KAP structural equation model of the nutrition label.

is superior to multiple linear regression modeling. The structural equation model can analyze multiple dependent variables at the same time, and its application is helpful to scientifically analyze the relationship between indicators. In this study, SEM is helpful to analyze the direct effects of the nutrition label KAP and to reveal these relationships. However, there are still a few limitations in the

TABLE 7 Model fitness indices for the modified model.

| Goodness-of-Fit Indices | CMIN | DF | CMIN/DF | CFI | IFI | GFI | AGFI | NFI | TLI | RMSEA |
|---|---|---|---|---|---|---|---|---|---|---|
| Ideal standards | | | <5.0 | >0.90 | >0.90 | >0.90 | >0.90 | >0.90 | >0.90 | <0.08 |
| Measurement value | 436.507 | 127 | 3.437 | 0.959 | 0.959 | 0.929 | 0.905 | 0.944 | 0.951 | 0.062 |

CMIN/DF, Chi-square fit statistics/degree of freedom; CFI, comparative fit index. IFI, incremental fit index; GFI, goodness-of-fit index; AGFI, adjusted goodness-of-fit index; NFI, Normed Fit Index; TLI, Tucker-Lewis index; RMSEA, root mean square error of approximation.

TABLE 8 Test results of the hypothesis.

| Hypothesized paths | Normalized path coefficient | *T* value | Accepted |
|---|---|---|---|
| H1:Nutrition knowledge→ Attitude-trust to the nutrition labeling | 0.561*** | 13.101 | YES |
| H2:Nutrition knowledge→ Attitude to the nutrition labeling | 0.764*** | 16.503 | YES |
| H3: Nutrition knowledge→ practice of nutrition label. | 0.295* | 3.291 | YES |
| H4: Attitude-trust to the nutrition labeling→ practice of nutrition label. | −0.059 | −1.368 | NO |
| H5: Attitude to the nutrition labeling→ practice of nutrition label. | 0.571*** | 4.914 | YES |

Levels of statistical significance (***$p < 0.001$, *$p < 0.05$).

present study. First of all, more rigorous survey questions need to be designed. For example, participants were likely to make inaccurate responses, since the nutrition labeling contains a lot of information and residents are likely to confuse the list of ingredients with the nutrition fact table. Furthermore, we only used one topic to assess the residents' previous nutrition education experience, and we also tested the residents' subjective knowledge. In future research, we need more objective scales to measure residents' subjective knowledge of nutrition labeling, rather than using simple self-reporting questions, rather than through the use of simple self-reported questions. Finally, our sample size was small, drawn by the convenience sampling method, and hardly ensured that the findings above could be replicated within behavioral studies. Other mediating factors (e.g., peer or parental impact on their use of nutrition labeling, understanding of diet-related disease information, taste or sensory attributes of the product) might more effectively explain that residents' use of nutrition labeling was not included in the study and need to be explored in future studies.

Behavior changes of community residents were divided into three continuous processes: knowledge acquisition, belief generation, and behavior formation, which are positive relations (path coefficients > 0). In this study, the path analysis demonstrated that the path coefficient between nutrition labeling knowledge and trust was 0.561 ($p < 0.05$), and the path coefficient between nutrition labeling knowledge and attitude was 0.764 ($p < 0.05$), with a significant positive correlation between them, indicating that residents could form a more positive attitude toward the nutrition labeling if they were knowledgeable about the nutrition labeling. Evelyn et al. (54), Rimpeekool et al. (55), Jackey et al. (56), and Cannoosamy et al. (57) also reported similar results in their respective investigations.

Previous studies have suggested more nutrition knowledge, and health-motivated residents might be more skeptical about nutrition claims and nutrition function claims, thus limiting residents' practice of nutrition labeling. We also tested this relationship, and the correlation analysis found that there was a significant positive correlation between nutrition knowledge and trust (path coefficient = 0.561, $p < 0.05$), the trust was negatively correlated with nutrition practice, but it was not significant (path coefficient = −0.059, $p > 0.05$), which may be the most residents are skeptical about the authenticity of nutrition labeling in this study. Residents' trust score is low, which leads to a negative correlation between trust and the practice of nutrition labeling, which was the same as the previous study.

We found that more nutrition knowledge and positive attitudes could increase the practice of nutrition labeling among residents in this research, which was consistent with the results of previous studies (58–61). It means that based on the model, consumers are likely to establish positive beliefs, and finally change use behaviors, once they receive nutrition education (55). However, it should be noted that the residents' trust in nutrition labeling was not significant with their frequency of using nutrition labeling. Therefore, in this study, attitude is a psychological reaction (including helpfulness and necessity) to convince ourselves that nutrition labeling is helpful and useful to select healthy foods, which will further change our practice of nutrition labeling (62, 63).

In summary, we confirmed that residents' nutrition knowledge could be directly converted into nutrition labeling reading behavior or indirectly through changing their attitudes. Residents with higher nutrition labeling knowledge scores and more positive attitude towards nutrition labeling seem to be more likely to obtain the information provided on nutrition labeling. It reflected that knowledge of nutrition was the basis for changing the practice of nutrition labeling. Rich nutrition knowledge can promote the use of nutrition labeling, while poor nutrition knowledge will limit their practice. Therefore, we must pay attention to the synchronous development of nutrition labeling KAP.

## 7. Conclusion and recommendations

The KAP model is suitable for analyzing the use behaviors of nutrition labeling by local residents. There was a direct and indirect correlation between nutrition knowledge and the practice of nutrition labeling. The attitude of nutrition labeling was positively affected by knowledge, while the use behavior of nutrition labeling was positively affected by knowledge and attitude.

To improve the lifestyle of residents and correctly use nutrition labeling, the following policy recommendations are offered. First, more public education programs (e.g., printing graphic brochures or posters, learning websites, and special lectures) should be implemented in schools and communities. The purpose of public education programs is to make the public aware of "the availability of nutrition information in nutrition labeling and the importance of that information in maintaining healthy dietary practices" to improve their nutrition literacy. Specifically, the interpretation of nutrition labeling needs to be included in the *Dietary Guidelines for Chinese Residents* and should be disseminated in the annual National Nutrition Week activity. The theme of National Nutrition Week 2022 is Learn How to Cook, How to Select Ingredients Reasonably, and Check Nutrition Labeling. The guideline, "Learn to read food labeling and choose prepackaged foods reasonably", highlights the core value of "Check Nutrition Labeling". Second, the concept and function of NRV% and core nutrients on the nutrition facts table, especially sodium and fat, should be conveyed transparent. It is suggested to mark NRV% explanation on food packaging to ensure consumers understanding. Then, it is necessary to strengthen the nutrition education of residents so that they fully understand the meaning of nutrition claims and nutrient function claims and avoid confusing nutrition function claims and health food function claims.

Finally, it will appeal to the relevant departments to implement effective supervision and inspection to ensure the accuracy of nutrition labeling information, which can in turn enhance consumers' confidence in the nutrition labeling. With the government as the leading role and the participation of the whole society, we should strengthen the publicity and education of labeling knowledge and improve residents' nutritional literacy and cognitive attitude toward labeling knowledge to change their behaviors.

## Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

## Ethics statement

The studies involving human participants were reviewed and approved by Ningxia Medical University Ethics Committee. The patients/participants provided their written informed consent to participate in this study.

## Author contributions

JY conceived and designed this research and revised the manuscript. YL was responsible for data analyses and prepared the manuscript. Both authors have read and approved the final version.

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## Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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## Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fnut.2023.1097562/full#supplementary-material

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# Examining the diet quality of Canadian adults and the alignment of Canadian front-of-pack labelling regulations with other front-of-pack labelling systems and dietary guidelines

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**Introduction:** Canada promulgated mandatory front-of-pack labelling (FOPL) regulations in 2022, requiring pre-packaged foods meeting and/or exceeding recommended thresholds for nutrients-of-concern (i.e., saturated fat, sodium, sugars) to display a "high-in" nutrition symbol. However, there is limited evidence on how Canadian FOPL (CAN-FOPL) regulations compare to other FOPL systems and dietary guidelines. Therefore, the objectives of the study were to examine the diet quality of Canadians using the CAN-FOPL dietary index system and its alignment with other FOPL systems and dietary guidelines.

**Methods:** Nationally representative dietary data from the 2015 Canadian Community Health Survey-Nutrition survey ($n$=13,495) was assigned dietary index scores that underpin CAN-FOPL, Diabetes Canada Clinical Practice (DCCP) Guidelines, Nutri-score, Dietary Approaches to Stop Hypertension (DASH) and Canada's Food Guide (Healthy Eating Food Index-2019 [HEFI-2019]). Diet quality was examined by assessing linear trends of nutrient intakes across quintile groups of CAN-FOPL dietary index scores. The alignment of CAN-FOPL dietary index system compared with other dietary index systems, with HEFI as the reference standard, was examined using Pearson's correlations and $\kappa$ statistics.

**Results:** The mean [95% CI] dietary index scores (range: 0–100) for CAN-FOPL, DCCP, Nutri-score, DASH, and HEFI-2019 were 73.0 [72.8, 73.2], 64.2 [64.0, 64.3], 54.9 [54.7, 55.1], 51.7 [51.4, 51.9], and 54.3 [54.1, 54.6], respectively. Moving from the "least healthy" to the "most healthy" quintile in the CAN-FOPL dietary index system, intakes of protein, fiber, vitamin A, vitamin C, and potassium increased, while intakes of energy, saturated fat, total and free sugars, and sodium decreased. CAN-FOPL showed moderate association with DCCP ($r$=0.545, $p$<0.001),Nutri-score ($r$=0.444, $p$<0.001), and HEFI-2019 ($r$=0.401, $p$<0.001), but poor association with DASH ($r$=0.242, $p$<0.001). Slight to fair agreement was seen between quintile combinations of CAN-FOPL and all dietary index scores ($\kappa$=0.05–0.38).

**Discussion:** Our findings show that CAN-FOPL rates the dietary quality of Canadian adults to be healthier than other systems. The disagreement between

CAN-FOPL with other systems suggest a need to provide additional guidance to help Canadians select and consume 'healthier' options among foods that would not display a front-of-pack nutrition symbol.

KEYWORDS

front-of-pack, FOPL, dietary patterns, nutrient profiling, HEFI, Nutri-score, DASH, DCCP

## 1. Introduction

Unhealthy diet is one of the major modifiable risk factors for non-communicable diseases (NCDs) (1). Front-of-pack labelling (FOPL) has been recognized as an effective public health strategy to target unhealth dietary patterns (2, 3), and many countries have implemented mandatory FOPL regulations (e.g., "high-in" warning labels for sugars, sodium, saturated fats, and total energy in Chile and Mexico; red warning labels for sugars, sodium, and saturated fats in Israel) or introduced a government-led voluntary program (e.g., Nutri-score in France; Healthy Star Ratings in Australia and New Zealand; green positive label in Israel) (4–6). In 2022, Canada published FOPL regulations to mandate pre-packaged foods and beverages meeting and/or exceeding thresholds for nutrients-of-concern (i.e., saturated fat, sodium, and sugars) to display a "high-in" nutrition symbol at the front of the package (7). A recent study showed that foods that would display a "high in" front-of-pack symbol, according to Canadian FOPL regulations, contribute to 15–40% of intakes of nutrients-of-public health concern among Canadian adults (8). Although one of the key guiding principles of effective FOPL is the consistency with other dietary guidelines (3), it remains unclear how Canadian FOPL regulations compare to other FOPL systems and dietary guidelines for Canadians, particularly for those with risk factors for NCDs that are more vulnerable to unhealthy diets.

Several healthy guidelines and recommendations currently exist for Canadians. Canada's Food Guide, the latest evidence-based national dietary guidelines for all Canadians, was released in 2019 (9). Canada's Food Guide was designed to promote healthy eating, overall nutritional well-being, and reduce risk of nutrition-related NCDs (10, 11). A dietary index scoring system based on recommendations from Canada's Food Guide 2019, also known as the Healthy Eating Food Index (HEFI)-2019 (12, 13) showed greater adherence to Canada's Food Guide can reduce risk of cardiovascular diseases (14). Diabetes Canada has published dietary recommendations for Canadians with or at risk for diabetes in the Diabetes Canada Clinical Practice Guidelines (DCCP) to treat and self-manage pre-diabetes and diabetes (15). While promoting individualized dietary patterns, the DCCP recommend the consumption of certain foods or nutrients (e.g., nuts, plant-based protein foods) and limiting the intakes of others (e.g., high glycemic index foods, saturated fat) (15). A nutrient profiling model, which classifies or ranks foods according to their nutritional composition for reasons related to preventing disease and promoting health (16), was recently developed to assess the alignment of foods and beverages with the DCCP (17). When converted to a dietary index system, the DCCP nutrient profiling model discriminated nutrient and food consumption in a cohort of French adults (18). Similarly, other nutrient profiling models underpinning FOPL systems have shown to be a valid tool in examining diet quality. For instance, the UK's Food Standards Agency nutrient profiling model, which underpins many FOPL systems (e.g., Nutri-score, Ofcom) has shown positive associations with risk of cardiovascular diseases (19, 20), cancer (21, 22), and overweight and obesity (23). In addition to individual food recommendations, both Canada's Food Guide and the DCCP promote healthy dietary patterns, such as the Dietary Approaches to Stop Hypertension (DASH) diet, for its well-established health benefits (24, 25). However, there is limited research examining the alignment of CAN-FOPL with these multiple guidelines and recommendations for healthy eating for Canadians.

Therefore, the objectives of the study were (i) to examine the diet quality of Canadian adults using the CAN-FOPL dietary index system, and (ii) to assess the alignment of CAN-FOPL dietary index system with other dietary index systems (i.e., DCCP, Nutri-score, DASH and HEFI-2019) with HEFI-2019 as the reference standard.

## 2. Methods

### 2.1. Dietary data

Dietary intakes of Canadian adults were assessed using the 2015 Canadian Community Health Survey-Nutrition (CCHS) Public Use Microdata File (26). CCHS is a nationally representative, cross-sectional 24-h dietary recall survey data of Canadians conducted by Statistics Canada (26). CCHS uses a general health questionnaire to collect self-reported sociodemographic, anthropometric, and health status data; and a 24-h dietary recall to collect food and beverage intake of an individual over 24 h with a second recall collected from a subset of participants (26). CCHS includes data from all individuals ≥1 years of age living in private dwellings in the 10 Canadian provinces, excluding full-time members of the Canadian Forces or who lived in the Territories, on reserves and other Indigenous settlements, in some remote areas, or institutions (e.g., prisons or care facilities) (26). Out of 20,487 respondents in the CCHS, data were excluded from the analysis if respondents were under 19 years of age ($n$ = 6,568), underweight (body mass index [BMI] <18.5 kg/$m^2$; $n$ = 230), were lactating ($n$ = 183), or did not report any food consumption ($n$ = 11). The final sample size used for the study was 13,495.

Energy intake (EI) to total energy expenditure (TEE) ratio for each respondent was calculated to identify misreporters, as previously reported (27). TEE was calculated based on age, sex, measured or adjusted self-reported BMI, and physical activity levels using the Institute of Medicine equations (28). Physical activity levels were categorized into sedentary, low active, active, and very active based on the average physical activity per day in minutes, converted from self-reported hours of physical activity per week (26). For respondents that did not disclose any anthropometric information, TEE was assigned based on age, sex, and physical activity levels estimated in the Dietary Guidelines for Americans 2020–2025 (29). EI:TEE ratios of 0.7–1.42 were used to define plausible reporters, while EI:TEE <0.7 and >1.42 were used to define under- and over-reporters, respectively (30).

Foods reported in CCHS were matched to the Canadian Nutrient File database, a generic food composition database of commonly-consumed foods with over 150 nutrients (31).

## 2.2. Canadian front-of-pack labelling (CAN-FOPL) dietary index system

Figure 1 shows the flow chart of the nutrient profiling model developed according to Canadian FOPL regulations. FOPL regulations published in *Canada Gazette II* (7) were used to develop a Canadian Front-of-Pack Labelling (CAN-FOPL) nutrient profiling model (8). The model uses exemption criteria (i.e., not assessed for nutrient levels) and thresholds for 3 nutrients-of-public health concern (i.e., saturated fat, sodium, and total sugars) based on age groups (1–4-year-old children; and children over 4 years of age and adults) and reference amounts (foods with a small reference amount ≤30 g or 30 mL; foods with a reference amount >30 g or 30 mL; foods with a reference amount ≥170 g for 1-4-year-old children; and foods with a reference amount ≥200 g for children over 4 years of age and adults) to classify foods into 5 categories (Exempted from FOPL regulations; Not display a symbol due to <thresholds; Display a symbol for 1 nutrient; Display a symbol for 2 nutrients; Display a symbol for 3 nutrients). Based on FOPL regulations, 3 types of foods and beverages are exempted from displaying a "high-in" symbol, regardless of their nutrient levels: (i) foods that have shown to have recognized health protection benefits (e.g., unflavored milk, eggs, fruits and vegetables, cheese high in calcium); (ii) foods that are exempted from carrying a Nutrition Facts table (e.g., single ingredient meats, foods sold in very small packages); and (iii) foods that are known sources of the target nutrients (e.g., table sugar, honey, salt, butter) (7).

The CAN-FOPL nutrient profiling model was used to construct the CAN-FOPL dietary index system using a 2-step approach, as previously reported (18). First, foods and beverages categorized according to the CAN-FOPL nutrient profiling model were assigned a point on a scale of 100 ("more healthy") to 0 ("less healthy") in 25-point increments in a descending order. In other words, foods and beverages in the first category (i.e., exempted from CAN-FOPL regulations) were assigned 100 points, 75 points for the second category (i.e., below the threshold levels for all 3 nutrients), 50 points for the third category (i.e., meet and/or exceed threshold levels for 1 nutrient), 25 points for the fourth category (i.e., meet and/or exceed threshold levels for 2 nutrients), and 0 point for the fifth category (i.e., meet or exceed threshold levels for 3 nutrients). Second, the points from the CAN-FOPL nutrient profiling model were pooled for each participant, weighted by the proportion of energy contributed by each food to get an individual dietary index score (*Equation 1*), as previously reported (18).

$$\text{CAN}-\text{FOPL dietary index score} = \frac{\sum_{i=1}^{n}\left(\text{CAN}-\text{FOPL point}_i\right)\times \text{E}_i}{\sum_{i=1}^{n}\text{E}_i} \quad (1)$$

"*where standardized CAN-FOPL point$_i$ is the assigned point based on the CAN-FOPL nutrient profiling model categories for each individual food or beverage consumed, and E$_i$ is the energy intake from that food or beverage*".

## 2.3. Application of dietary index systems

Dietary data from CCHS were assigned scores based on the five dietary index systems: CAN-FOPL, DCCP, Nutri-score, DASH and HEFI-2019. With CAN-FOPL regulations expected to influence the diets of Canadians, their alignment with other guidelines for healthy eating for Canadians (i.e., DCCP, DASH, and Canada's Food Guide) and other FOPL system shown to have positive association with NCDs (i.e., Nutri-score) were examined. The HEFI-2019 (dietary index system based on Canada's Food Guide) was used as the reference standard in the analysis, as Canada's Food Guide is the current national dietary guidelines for all Canadians over 2 years of age to improve health, meet nutrient needs, and reduce risk of NCDs (10).

The scoring methods for the DCCP, the Nutri-score, DASH, and HEFI-2019 dietary index systems are described in detail in Supplementary methods. Briefly, the DCCP nutrient profiling model assesses foods and beverages for their alignment with the DCCP by assigning points for their macronutrient or meal quality, saturated and trans fat content, and added sugar content, while beverages are assigned points based on the beverage type, saturated fat, and added sugar content (18) to classify foods and beverages into one of 3 categories: "most aligned," "partially aligned," and "least aligned." The Nutri-score assigns points to foods and beverages for their energy and nutrient content (total sugars, saturated fats, and sodium as "negative" nutrients and fiber and protein as "positive" nutrients), energy and nutrient content (total sugars, saturated fats, and sodium as "negative" nutrients and fiber and protein as "positive" nutrients), and the amount of fruits, vegetables, nuts, or legumes; then sums up the points to classify foods and beverages into one of 5 categories: Grade A ("more healthy"), Grade B, Grade C, Grade D, and Grade E ("less healthy"). Similar to the algorithm for the CAN-FOPL dietary index scores, the DCCP, and the Nutri-score dietary index scores were calculated by assigning points to foods and beverages from nutrient profiling models underlying each system, adjusting the points by the proportion of energy contribution from each food or beverage, and summing up the energy-adjusted points for a final dietary index score.

The DASH (34) and the HEFI-2019 (13) assign dietary index scores using foods and beverages consumed in a 24-h period to reflect adherence to the DASH diet and Canada's Food Guide, respectively. The DASH dietary index system (34) assigns points for 9 dietary components identified in the DASH diet: Fruit, Vegetables, Whole Grains, Dairy Products, Plant Proteins, Animal Proteins, Added Sugars, Sodium, and Saturated Fat. The HEFI-2019 scores diets against 10 key recommendations of Canada's Food Guide: Vegetables and fruits, Whole-grain foods, Grain foods ratio, Protein foods, Plant-based protein foods, Beverages, Fatty acids ratio, Saturated fats, Free sugars, and Sodium. All dietary index scores were converted into a 100-score system to standardize the scores, with 0 indicating "Least aligned" or "Least healthy" to 100 indicating "Most aligned" or "Most healthy."

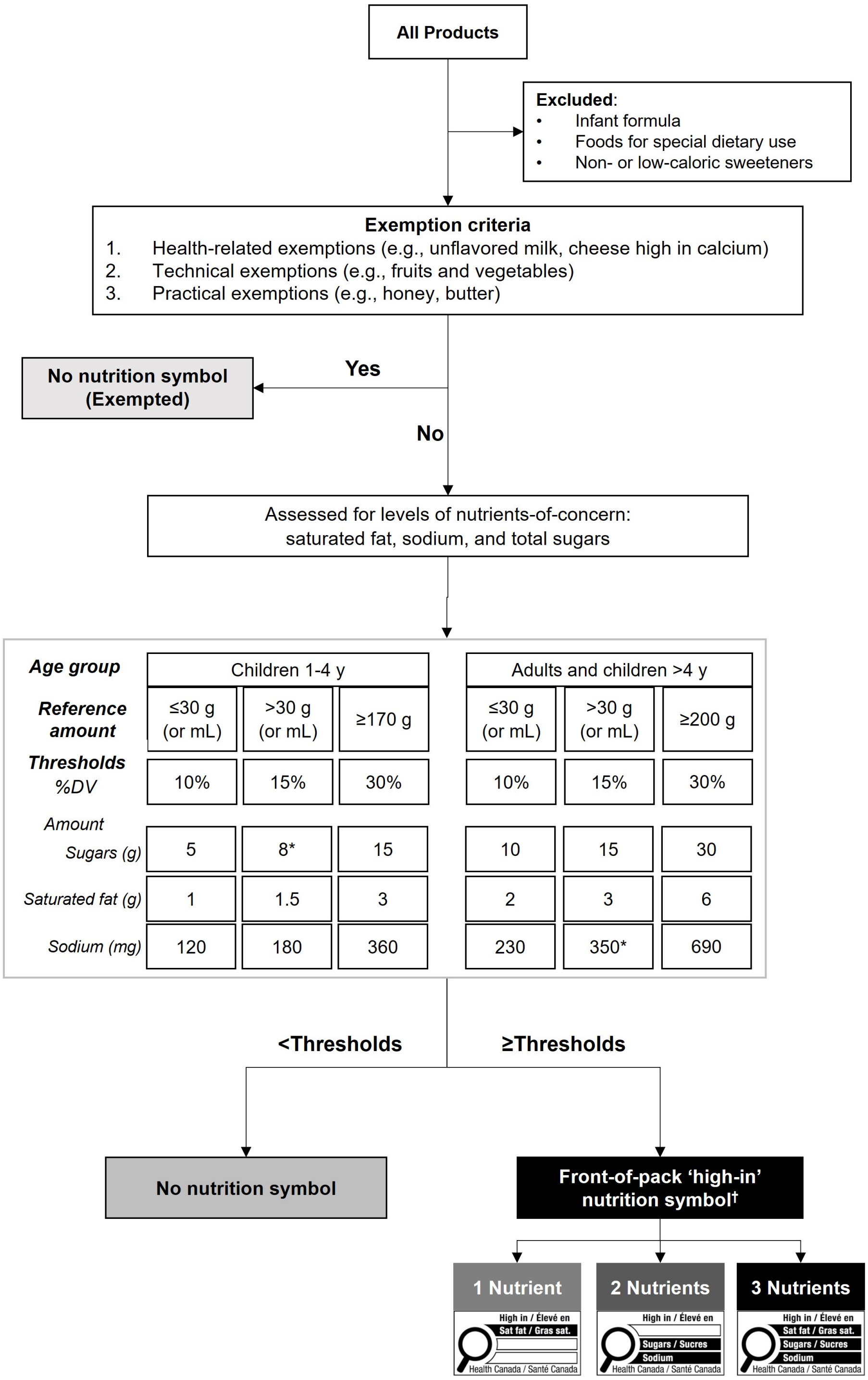


FIGURE 1
Flow chart of the nutrient profiling model developed according to Canadian front-of-pack labelling regulations. Canadian front-of-pack labelling (CAN-FOPL) regulations (7) were used to categorize all foods in the Canadian Nutrient File, which was matched to foods reported in the 2015 Canadian Community Health Survey. Foods that are not subjected to FOPL regulations (e.g., alcoholic beverages, meal replacements, and non-or low-caloric sweeteners) were excluded. All other foods were assessed against 3 exemption criteria: (i) health-related exemptions for foods that have shown health benefits (e.g., fruits and vegetables, oils high in unsaturated fats); (ii) technical exemptions for foods that are not required to display a Nutrition Facts table (e.g., raw single ingredient meats); and (iii) practical exemptions for foods that are well-known sources of nutrients-of-concern (e.g., honey, butter, table salt). Any foods not exempted from the regulations were assessed for levels of nutrients-of-concern (saturated fat, total sugars, sodium) of percent daily value (%DV) thresholds set based on the target age group and the reference amount (as per Health Canada's Table of Reference Amounts for Foods (32)) for foods, resulting in six different thresholds. Products meeting or exceeding any of the thresholds of nutrients-of-concern would be required to display a FOP symbol for 1–3 nutrients. *The values are adjusted according to the rounding rules for nutrition labelling information as per *Food and Drugs Regulations* (33). †FOP symbol image was retrieved from *Canada Gazette II* (7). %DV, Percent Daily Value.

## 2.4. Statistical analysis

All statistical analyses were performed using SAS (version 9.4, SAS Institute Inc., Cary, NC, United States). Mean nutrient intakes were examined across quintiles using PROC SURVEYREGS, adjusted for sex, age, energy intake, and misreporter status. Misreporter status was selected as a confounding variable, as it has been shown to adjust for implausible recalls and selective misreporting of healthy vs. unhealthy foods; and indirectly adjust for socioeconomic characteristics correlated with misreporting status, including education and smoking status (35). Linear trends of energy and nutrient intakes across quintile groups using the CAN-FOPL, the DCCP, and the Nutri-score dietary index scores were assessed by assigning participants the median value in each quintile and modeling it as a continuous variable. Diet quality of Canadians using the DASH (36) and HEFI-2019 (12, 13) have been reported elsewhere. All estimates were bootstrapped using the balanced repeated replication technique with 500 replicates of population survey weights provided by Statistics Canada (37) to ensure representative population-level estimates. Based on a previous analysis examining diet quality using CCHS 2.2 with a large sample size and bootstrapping technique (35, 36). $p$-trend <0.0001 was considered significant.

Weighted Pearson's correlation coefficients were determined between all dietary index scores to assess the alignment between dietary index scores. To evaluate agreement between pairs of dietary index scores, total scores from each index were divided into quintiles, and the agreement of the sample falling into quintile categories for pairs of indices was examined using weighted $\kappa$ statistic (95% CI), as follows: 0.01–0.20 "slight"; 0.21–0.40 "fair"; 0.41–0.60 "moderate"; 0.61–0.80 "substantial"; and 0.81–0.99 "near perfect" (38). $p$-value < 0.05 was considered significant. Bland-Altman plots between all dietary index systems were used to visually inspect the level of agreement.

# 3. Results

## 3.1. Dietary index scores and nutrient intakes

About 50% of the respondents were females with a mean age [95% CI] of 49.3 years [48.8, 49.8]. Based on the reported energy intake to total energy expenditure ratio, 50% of the respondents were identified as plausible, 44% as under-reporters and 6% as over-reporters. Detailed participant characteristics can be found elsewhere (8).

The mean standardized dietary index scores [95% CI] for CAN-FOPL, DCCP, Nutri-score, DASH, and HEFI-2019 were 73.0 [72.8, 73.2], 64.2 [64.0, 64.3], 54.9 [54.7, 55.1], 51.7 [51.4, 51.9], and 54.3 [54.1, 54.6], respectively. Table 1 and Supplementary Tables S1, S2 show nutrient intakes by quintiles of the CAN-FOPL, the DCCP, and the Nutri-score dietary index scores, respectively. Moving from quintile 1 ("Least healthy") to quintile 5 ("Most healthy") of the CAN-FOPL dietary index scores, intakes of protein, fiber, vitamin A, vitamin C, vitamin D, and potassium increased, while intakes of energy, saturated fat, and sodium decreased (all $p < 0.0001$). There was no linear relation for total fat and calcium intakes ($p = 0.003$ and $p = 0.024$, respectively) across quintile groups using the CAN-FOPL dietary index scores. Moving from quintile 1 to quintile 5 of the DCCP dietary index scores, intakes of protein, fiber, vitamin A, vitamin C, vitamin D, iron, and potassium increased, while intakes of total energy, total and saturated fat, free sugars, and sodium decreased (all $p < 0.0001$). There was no linear relation for calcium intakes ($p = 0.0005$) across quintile groups using the DCCP dietary index scores. Moving from quintile 1 to quintile 5 of the Nutri-score dietary index scores, intakes of carbohydrates, fiber, protein, vitamin A, iron, and potassium increased, while intakes of energy, total and saturated fat, total and free sugars, and calcium decreased (all $p < 0.0001$). There was no linear relation for vitamin D intakes ($p = 0.10$) across quintile groups using the Nutri-score dietary index scores.

## 3.2. Relationship between dietary index systems

Table 2 shows weighted Pearson's correlations between dietary index scores. The CAN-FOPL dietary index scores showed poor to moderate correlation with the DCCP, the Nutri-score, the DASH, and the HEFI-2019 ($r = 0.242$–$0.545$). The DCCP, the Nutri-Score, and the DASH dietary index scores were moderately correlated with the HEFI-2019 ($r = 0.615$–$0.640$, $p < 0.0001$).

Table 3 and Supplementary Tables S4, S5 show the agreement between quintile combinations of CAN-FOPL and other dietary index systems, including the reference standard (i.e., HEFI-2019). The CAN-FOPL dietary index scores showed slight agreement with the DCCP and the Nutri-score ($\kappa = 0.30$–$0.38$) with over 65% of the total sample identified as discordant pairs (i.e., "Less healthy" in one system and "More healthy" in another system). The CAN-FOPL, the DCCP and the Nutri-score showed slight agreement with the DASH ($\kappa = 0.05$–$0.07$) with over 75% of the total sample as discordant pairs. The CAN-FOPL showed fair agreement with the HEFI-2019 ($\kappa = 0.26$ [0.25, 0.27]); however, both the DCCP and the Nutri-score showed moderate agreement with the HEFI-2019 ($\kappa = 0.44$ [0.43, 0.46] and $\kappa = 0.42$ [0.42, 0.44], respectively) with about 60% of the total sample as discordant pairs.

Supplementary Figures S1–S3 show Bland-Altman plots comparing dietary index scores from different systems. CAN-FOPL dietary index scores showed relatively good agreement with DCCP (mean difference [95% limits of agreement] = 8.8 [−11.3, 29.0]), but poor agreement with Nutri-score with wide variability. CAN-FOPL showed a wide mean difference compared to the DASH (21.3 [−9.0, 51.7]), while the DCCP and the Nutri-score showed smaller mean difference compared to the DASH but wide variability (12.5 [−12.4, 37.4] and 3.2 [−27.0, 33.4], respectively). Similarly, when compared to the reference standard (i.e., HEFI-2019), the CAN-FOPL showed a wide mean difference and variability (18.7 [−10.1, 47.5]), while the DCCP and the Nutri-score showed smaller mean differences with wide variability (9.8 [−12.4, 32.0] and 0.5 [−23.8, 24.8], respectively).

# 4. Discussion

The objectives of the study were to describe the diet quality of Canadians using the CAN-FOPL dietary index system, and then compare the results to other dietary index systems (i.e., DCCP, Nutri-score, DASH, and HEFI-2019), using the HEFI-2019 as the reference

TABLE 1 Energy and nutrient intakes across quintile groups using the Canadian Front-of-pack labelling (CAN-FOPL) dietary index system.

| | Quintile 1 ("least healthy") | Quintile 2 | Quintile 3 | Quintile 4 | Quintile 5 ("most healthy") | *p*-trend |
|---|---|---|---|---|---|---|
| *n* | 2,699 | 2,699 | 2,699 | 2,699 | 2,699 | |
| CAN-FOPL dietary index score* | 54.5 [53.5, 55.6] | 68.0 [67.7, 68.3] | 74.6 [74.5, 74.7] | 80.0 [79.9, 80.1] | 87.5 [87.2, 87.8] | |
| Energy (kcal) | 2,503 [2,431, 2,575] | 2,412 [2,361, 2,464] | 2,387 [2,345, 2,429] | 2,350 [2,299, 2,401] | 2,292 [2,244, 2,340] | <0.0001 |
| Total fat (% to total energy) | 34.7 [34, 35.4] | 33.6 [32.5, 34.8] | 33.4 [31.8, 35] | 32.9 [32.1, 33.6] | 33.6 [32.1, 35.2] | 0.003 |
| Saturated fat (% to total energy) | 12.1 [11.7, 12.6] | 11.4 [11, 11.8] | 10.7 [10.2, 11.1] | 10.4 [10, 10.9] | 10.0 [9.5, 10.5] | <0.0001 |
| Protein (% to total energy) | 15.1 [14.3, 15.9] | 15.7 [15.2, 16.1] | 16.2 [15.8, 16.7] | 17.9 [17.4, 18.4] | 19.4 [18.5, 20.2] | <0.0001 |
| Carbohydrates (% to total energy) | 47.1 [46, 48.3] | 48.6 [47.2, 50] | 48.6 [46.6, 50.7] | 47.3 [45.8, 48.9] | 44.8 [43, 46.7] | <0.0001 |
| Fiber (g/1,000 kcal) | 7.4 [7.1, 7.8] | 8.7 [8.3, 9.2] | 9.7 [8.9, 10.6] | 10.2 [9.5, 10.9] | 10.5 [10.1, 11] | <0.0001 |
| Total sugars (% to total energy) | 18.3 [15.9, 20.8] | 19.6 [18.2, 21] | 18.2 [16.6, 19.9] | 17.4 [15.7, 19] | 17.8 [15.9, 19.6] | <0.0001 |
| Free sugars (% to total energy) | 10.9 [8.5, 13.3] | 11.6 [10.3, 12.8] | 9.6 [8.3, 10.9] | 8.0 [6.4, 9.6] | 6.8 [5.1, 8.5] | <0.0001 |
| Calcium density (mg/1,000 kcal) | 408.4 [391.2, 425.5] | 417.8 [402.3, 433.3] | 430.9 [411.6, 450.1] | 425.9 [408.3, 443.5] | 403.1 [385.8, 420.4] | 0.024 |
| Vitamin A density in RAE (µg/1,000 kcal) | 261.7 [239.6, 283.8] | 316.7 [290.9, 342.4] | 359.8 [290.6, 429] | 381.5 [346.1, 417] | 457.5 [413.8, 501.1] | <0.0001 |
| Vitamin C density (mg/1,000 kcal) | 37.6 [31.5, 43.7] | 53.1 [47.1, 59.1] | 54.6 [50.5, 58.7] | 57.6 [52.3, 62.9] | 58.7 [48.1, 69.3] | <0.0001 |
| Vitamin D density (µg/1,000 kcal) | 1.9 [1.7, 2] | 2.3 [2.1, 3.1] | 2.6 [2.4, 2.8] | 2.9 [2.6, 3.1] | 3.2 [2.9, 3.6] | <0.0001 |
| Sodium density (mg/1,000 kcal) | 1,619.3 [1,566.7, 1,671.9] | 1,515.5 [1,434.5, 1,596.6] | 1,465.5 [1,416.8, 1,514.2] | 1,370.3 [1,309.2, 1,431.3] | 1225.6 [1,181.5, 1,269.7] | <0.0001 |
| Iron density (µg/1,000 kcal) | 6.3 [6.1, 6.5] | 6.4 [6.1, 6.7] | 6.9 [6.6, 7.1] | 6.9 [6.6, 7.2] | 6.7 [6.5, 6.9] | <0.0001 |
| Potassium density (mg/1,000 kcal) | 1,235.0 [1,188.5, 1,281.5] | 1,334.1 [1,302.9, 1,365.4] | 1,427.6 [1,393.3, 1,461.9] | 1,521.1 [1,458.2, 1,583.9] | 1,723.3 [1,668.5, 1,778.2] | <0.0001 |

*n* = 13,495; values represent means [95% CI]. Estimates are weighted least squares means from a regression model adjusted for age, sex, misreporting status (under-reporters, plausible reporters and over-reporters), and energy with bootstrapping. *p*-trends were estimated in their continuous form and represent the *p*-value associated with the linear regression coefficient. *p*-trend < 0.0001 was considered significant. *CAN-FOPL dietary index scores were calculated by assigning points to foods and beverages categorized using the CAN-FOPL nutrient profiling model, adjusting the points by the proportion of energy contribution from each food and beverage, and then summing up the energy-adjusted points for a final score. The dietary index score was standardized on a scale of 0 ("least healthy") to 100 ("most healthy"). CAN-FOPL, Canadian Front-of-pack labelling; RAE, Retinol Activity Equivalents.

standard. Although the CAN-FOPL dietary index system discriminated diet quality using nutrients-of-public health concern, it did not align well with other dietary systems underpinning health policies and recommendations. On the contrary, the DCCP and the Nutri-score dietary index systems showed better ability to discriminate diet quality using more nutrients-of-public health concern and nutrients-to-encourage, and moderate alignment with the HEFI-2019 (a dietary index scoring system based on Canada's Food Guide, which also includes foods to encourage).

Among the five examined dietary index systems, the CAN-FOPL showed the highest mean score for Canadians of 73 (vs. 52–64 for others), with a wide mean difference and the limits of agreement compared with other dietary index systems prominently shown in Bland-Altman plots. The findings are likely related to the very low consumption of foods that are rated as "least healthy" (i.e., display a front-of-pack symbol for meeting and/or exceeding all 3 nutrients-of-concern), and the high rating of foods in the exemption criteria (i.e., 100 out of 100) according to CAN-FOPL regulations. In fact, Canadian adults consumed <1% of total energy from foods that would display a front-of-pack symbol for all 3 nutrients-of-concern, while 35% of energy intakes came from foods that would be exempted from CAN-FOPL regulations (8), thus limiting its ability to discriminate among a wide range of foods of varying nutritional quality. The nature of the CAN-FOPL nutrient profiling model, which only focuses on nutrients-of-concern, may contribute to lower discriminatory ability to further differentiate the healthfulness of foods and diet quality, compared to the other examined nutrient profiling models (i.e., DCCP and Nutri-score), which take both nutrient- and food-based approach to rank the healthfulness of foods. In other words, when CAN-FOPL regulations are implemented, Canadians would only be exposed to two conditions (with or without a front-of-pack symbol) and will need to determine the healthfulness of foods among these two conditions. Whether food meets other healthy dietary guidelines, such as Canada's Food Guide or the DASH diet, will not be readily available to consumers. To address this gap, in addition to a mandatory FOPL system for nutrients-of-concern (saturated fat, sugars, and sodium), Israel introduced a voluntary FOPL system to indicate foods that align with the Mediterranean Diet (5). Other voluntary FOPL systems have been shown to improve the purchasing intentions and behaviours of consumers (39), which may be helpful for Canadians to select 'healthier' foods among those foods that do not have a front-of-pack symbol.

Although CAN-FOPL showed some discriminatory ability to assess diet quality, it was poorly aligned with the reference standard, HEFI-2019. Consistent with our findings, CAN-FOPL dietary index system based on the proposed regulations showed a similar ability to discriminate nutrients-to-limit, including saturated fat, added sugars, and sodium; and showed a negative association with fasting blood glucose (i.e., lower blood glucose associated with "more healthy" score) using a French cohort data (18). Interestingly, we saw no difference in calcium intakes by CAN-FOPL quintiles with improved diet quality despite dairy products high in calcium, one of the main sources of calcium and vitamin D for Canadians (40, 41), being exempted from CAN-FOPL regulations. The findings, however, may

TABLE 2 Weighted Pearson's correlations between dietary index systems.

| | CAN-FOPL | DCCP | Nutri-score | DASH | HEFI-2019 |
|---|---|---|---|---|---|
| CAN-FOPL | 1.000 | 0.545 | 0.444 | 0.242 | 0.401 |
| DCCP | | 1.000 | 0.702 | 0.420 | 0.640 |
| Nutri-score | | | 1.000 | 0.343 | 0.619 |
| DASH | | | | 1.000 | 0.615 |
| HEFI-2019 | | | | | 1.000 |

$n = 13{,}495$. Values are correlation coefficient (r); all $p$-values were significant ($p < 0.0001$). CAN-FOPL, Canadian Front-of-Pack Labelling; DASH, Dietary Approaches to Stop Hypertension Diet; DCCP, Diabetes Canada Clinical Practice Guidelines; HEFI-2019, Healthy Eating Food Index 2019.

TABLE 3 Agreement between quintile combinations of computed Canadian Front-of-pack labelling and other dietary index systems.

| | | CAN-FOPL | | | | | Discordant pairs*, *n* (%) | Weighted κ[†] [95% CI] |
|---|---|---|---|---|---|---|---|---|
| | | Q1 | Q2 | Q3 | Q4 | Q5 | | |
| DCCP | Q1 | 9.6 | 5.6 | 2.9 | 1.3 | 0.5 | 9,500 (70.4%) | 0.26 [0.25, 0.27] |
| | Q2 | 5.0 | 5.6 | 4.6 | 3.2 | 1.6 | | |
| | Q3 | 3.2 | 4.0 | 4.9 | 4.7 | 3.3 | | |
| | Q4 | 1.8 | 3.1 | 4.3 | 5.2 | 5.5 | | |
| | Q5 | 0.5 | 1.7 | 3.2 | 5.5 | 9.1 | | |
| Nutri-score | Q1 | 8.7 | 5.2 | 2.9 | 1.8 | 1.5 | 8,852 (65.6%) | 0.38 [0.36, 0.39] |
| | Q2 | 5.0 | 5.1 | 4.4 | 3.3 | 2.2 | | |
| | Q3 | 3.2 | 4.3 | 4.7 | 4.5 | 3.3 | | |
| | Q4 | 2.2 | 3.4 | 4.4 | 5.1 | 4.9 | | |
| | Q5 | 0.9 | 2.1 | 3.6 | 5.3 | 8.1 | | |
| DASH | Q1 | 18.8 | 16.9 | 15.5 | 15 | 15.1 | 9,217 (68.3%) | 0.30 [0.29, 0.31] |
| | Q2 | 1 | 2.1 | 2.9 | 2.9 | 2.7 | | |
| | Q3 | 0.2 | 0.7 | 0.9 | 1.2 | 1.2 | | |
| | Q4 | 0.1 | 0.2 | 0.5 | 0.6 | 0.7 | | |
| | Q5 | <0.1 | 0.1 | 0.2 | 0.3 | 0.3 | | |
| HEFI-2019[‡] | Q1 | 7.8 | 4.9 | 3.4 | 2.3 | 1.6 | 10,431 (77.3%) | 0.05 [0.05, 0.06] |
| | Q2 | 5.0 | 4.7 | 4.1 | 3.5 | 2.6 | | |
| | Q3 | 3.6 | 4.6 | 4.5 | 4.0 | 3.3 | | |
| | Q4 | 2.6 | 3.6 | 4.2 | 4.8 | 4.8 | | |
| | Q5 | 1.1 | 2.1 | 3.7 | 5.3 | 7.8 | | |

$n = 13{,}495$. Increasing quintiles (Q) indicate higher scores (i.e., "healthier" diet quality). Each cell includes the proportion (%) of the total sample falling into the respective quintile combinations. Shaded cells indicate concordant pairs (i.e., samples falling into the same quintile according to the two examined dietary index systems) with 20% in each shaded cell representing perfect agreement, while non-shaded cells indicate discordant pairs (i.e., samples identified as "Less healthy" in one dietary system and "More healthy" in another dietary index system). *Discordant pairs are presented as the total number of identified samples and the proportion (%) of the total sample. [†]Agreement between dietary index scores were assessed using weighted $\kappa$ statistic, where: 0.01–0.20 represented "slight" agreement, 0.21–0.40 "fair"; 0.41–0.60 "moderate"; 0.61–0.80 "substantial"; and 0.81–0.99 "near perfect" (38). [‡]HEFI-2019 was set as the reference standard. CAN-FOPL, Canadian Front-of-Pack Labelling; DASH, Dietary Approaches to Stop Hypertension Diet; DCCP, Diabetes Canada Clinical Practice Guideline; HEFI, Healthy Eating Food Index.

be related to a high prevalence of inadequate calcium intakes among Canadians. Based on the same CCHS 2015 dietary data, almost 70% of calcium supplement non-users have been found to have calcium intakes below the estimated average requirements (similar calcium intakes from food sources among supplement users), with over 90% of older adults (≥71 y) having inadequate intake levels (40). To help Canadians meet their nutrient needs and encourage the consumption of healthy foods, additional public health measures, including voluntary fortification may need to be explored. The poor alignment between CAN-FOPL and HEFI-2019 also signals a potential need for further public health interventions to help Canadians follow healthy eating guidelines. The most up-to-date Canada's Food Guide in 2019 included recommendations on food choices and healthy eating habits, and employed various communication strategies to reach the public, such as user-friendly implementation tools (e.g., recipes) and consistent reminders on healthy eating (e.g., subscription system to receive monthly updates) (9, 10); yet, its effectiveness on the population health has not been well documented. To assess the effectiveness of these public health guidelines and regulations, using CCHS-2015 as a baseline, future studies examining the diet quality of Canadians post-regulations are needed.

Interestingly, the DCCP dietary index system showed a greater discriminatory ability to assess diet quality compared to the CAN-FOPL dietary index system with a moderate association with the HEFI-2019. Despite the lack of sodium assessment built into the DCCP nutrient profiling model, it discriminated sodium intakes when transformed as a dietary index system, as similarly shown with a previous study employing the DCCP model to examine the diet quality of a French cohort (18). It is possible that the food-based recommendations in the DCCP model are related to lower sodium content, resulting in foods with low sodium content scoring higher in the nutrient profiling model. For instance, the DCCP model includes a step to allocate a score for the processing level of foods, where processed and ultra-processed foods, defined using the NOVA classification (42, 43), would get a lower score compared with minimally and unprocessed foods. Since sodium content is typically high in processed foods, as sodium ingredients are used as a preservative and/or a flavor enhancer (44), the processing level assessment step may act as a proxy for sodium content in foods to help discriminate sodium intake at the dietary level. Further, DCCP was moderately aligned with other dietary index systems, including CAN-FOPL and HEFI-2019. The alignment between DCCP and HEFI-2019 are likely related to the fact that Canada's Food Guide, the guidelines on which HEFI-2019 is based, reflects the most up-to-date summary of evidence that supports healthy eating patterns that could lower the risk of NCDs, including diabetes (10). Emerging evidence suggests multiple healthy eating patterns with different components can lead to health benefits (45); therefore, promotion of multiple healthy eating guidelines respecting individual variation would be beneficial for realistic and long-term adherence.

Despite the wide recommendation of the DASH diet in many clinical guidelines, including the DCCP and Canada's Food Guide, all dietary index systems showed poor alignment with the DASH diet. The findings are, in part, likely related to low overall adherence to the DASH diet among Canadians, corroborated by the greatest agreement seen between the least aligned quintile of the DASH dietary index system with all quintiles of the examined dietary index systems. In fact, a previous study showed only about 50% of adherence to the DASH diet among Canadians based on the population dietary survey from 2004 and 2015 (36). The differing emphasis on food components may also contribute to the differences in these diet assessment tools. The DASH dietary index system consists of 9 equally weighted components with some that are not frequently consumed in the Canadian diet (e.g., whole grains and plant proteins) (36), contributing to the low adherence scores and the poor association with other dietary index systems. Although many of the components of the DASH diet are included in the examined dietary index systems (i.e., DCCP and HEFI-2019), their contribution to the overall dietary index scores differs. For example, consumption of plant-based protein contributes to 1/9$^{th}$ of the total score for the DASH dietary index scores (34) while the DCCP dietary index model takes intakes relative to total energy into account (18) and the HEFI-2019 allocates about 6% (5/80) of the total point to plant-based food consumption (13). To help support intakes of foods- (e.g., whole grains) and nutrients-to-encourage (e.g., fiber), additional support is needed at both population and individual levels.

Although this is the first study to date, examining the alignment of the recently published CAN-FOPL with other FOPL systems and dietary guidelines, a few limitations must be noted. First, we could not assess its association with mortality or disease risk due to the nature of the CCHS data. Previous studies have shown that dietary index systems can quantify diet quality and its association with markers of cardiovascular disease risk using prospective cohorts (18, 20, 23, 46). However, CCHS, one of the only publicly available Canadian dietary data, is a cross-sectional survey without any clinical biomarkers of disease risk. As Canada implements its FOPL regulations, a robust monitoring and evaluation plan to measure their short- and long-term impact on dietary patterns and risk of mortality and disease is needed. Second, the present analysis was conducted using single-day dietary data. Although single-day, 24-h recall can be reflective of the usual intakes at a population level, suitable for the current analysis at a population level, it can be affected by within-person variation due to day-to-day variation of food intakes (47), and cannot be used for assessment at the individual level. Third, these findings do not necessarily indicate the strength of one dietary index system over another, *per se*, but rather incorporate the inherent challenges and complexity in the assessment of diet quality. The DASH and the HEFI-2019 dietary index systems evaluate adherence to different diets using an individual's overall dietary intake in a specific time period, while other dietary index systems developed from nutrient profiling models (i.e., CAN-FOPL, DCCP, and Nutri-score) quantify the diet quality based on the quality of individual foods consumed and their proportions. The assumptions made in the development of the dietary index systems may have affected the observed associations (48). However, at the population level, these dietary models provide insight into potential gaps in nutritional policy and/or guidelines and how diet quality indices compare with one another.

## 5. Conclusion

Our findings show that CAN-FOPL regulations, which only focuses on nutrients-to-limit, rated the dietary quality of Canadian adults to be healthier than other dietary index systems, and it may be used to examine the quality of dietary intakes of Canadians. Despite the good agreement between the CAN-FOPL and the DCCP, wide differences with the DASH and the HEFI-2019 suggest a potential gap in Canadian FOPL regulations, particularly in supporting consumption of "more healthy" foods. Although FOPL regulations will go a long way towards helping Canadians avoid less healthy foods, further public health guidelines and recommendations are warranted to promote the consumption of "healthy" foods and/or adherence to a healthy diet; and robust evaluation and monitoring plan are needed to assess the effectiveness of FOPL regulations in achieving their objectives.

## Data availability statement

The data underlying the results presented in the study are available from Statistics Canada: https://www150.statcan.gc.ca/n1/en/catalogue/82M0024X2018001.

## Ethics statement

Ethical review and approval was not required for the study of human participants in accordance with the local legislation and institutional requirements. As a secondary data analysis, written informed consent from the participants was not required in this study in accordance with the national legislation and the institutional requirements.

## Author contributions

JJL, MA, CJ, WYL, and MRL contributed to conception and design of the study and interpreted the findings. JJL, AN, and MA organized the database. JJL and MA performed the statistical analysis. All authors contributed to the article and approved the submitted version.

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## Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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## Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2023.1168745/full#supplementary-material

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