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# Effect of a new graphically modified Nutri-Score on the objective understanding of foods' nutrient profile and ultraprocessing: a randomised controlled trial

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#### ABSTRACT

Introduction When considering health-related impacts of foods, nutrient profile and (ultra)processing are two complementary dimensions. The Nutri-Score informs on the nutrient profile dimension. Recently, mounting evidence linked ultraprocessed food consumption to various adverse health outcomes, independently of their nutrient profile. To inform consumers about each of these health-related dimensions of food, we tested, in a randomised controlled trial, if a graphically modified version 'Nutri-Score V.2.0', including a black 'ultraprocessed' banner, would improve the capacity of consumers to rank products according to their nutrient profile and to detect those ultra-processed, compared with a no-label situation.

Methods 21 159 participants included in the NutriNet-Santé web-cohort were randomly assigned to a control arm (no front-of-pack label) or an experimental arm (Nutri-Score 2.0) and were presented an online questionnaire with three sets of food products (cookies, breakfast cereals and ready-to-eat meals) to rank according to nutrient profile and to identify ultraprocessed foods. The primary outcome was objective understanding of nutrient profile and ultraprocessing, represented by a score of correct answers. Secondary outcomes were purchasing intentions and the healthiest-perceived product. Multinomial logistic regressions were performed.

**Results** The Nutri-Score V.2.0 increased the objective understanding of both the nutrient profile dimension (OR highest vs lowest score category = 29.0 (23.4–35.9), p<0.001) and the ultraprocessing dimension (OR=174.3 (151.4–200.5), p<0.001). Trends were similar for cookies, breakfast cereals and ready-to-eat meals. The Nutri-Score V.2.0 had a positive effect on purchasing intentions and on the products perceived as the healthiest.

**Conclusion** This randomised controlled trial demonstrates the interest of a front-of-pack label combining the Nutri-Score (informing on the nutrient profile dimension) with an additional graphic mention, indicating when the food is ultraprocessed, compared with a no-label situation. Our results show that a combined label enabled participants

#### WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Interpretative colour-coded front-of-pack nutrition labels, such as the Nutri-Score, are considered as efficient tools to help consumers make healthier food purchases with a better nutrient profile and contribute to preventing nutrition-related diseases, but mounting evidence is linking ultraprocessed food consumption to various adverse health outcomes, independently of their nutrient profile. However, front-of-pack labels combining both the nutrient profile and food processing dimensions have not been investigated.

#### WHAT THIS STUDY ADDS

⇒ We studied, in a randomised controlled trial design, the impact of the Nutri-Score V.2.0, combing information on nutrient profile and ultraprocessing, on the objective understanding of foods' nutrient profile and on the identification of ultraprocessed foods. The Nutri-Score V.2.0 improved objective understanding of both the nutrient profile dimension of food products (OR highest vs lowest score category=29.0 (23.4–35.9)) and the ultraprocessing dimension (OR=174.3 (151.4–200.5)). The Nutri-Score V.2.0 also had a positive effect on purchasing intentions and on the products perceived as the healthiest.

### HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

Adding information regarding the food processing dimension to interpretive front-of-pack nutritional labels might be of public health interest for consumers, as our results show that a combined label enabled them to independently understand these two correlated, yet distinct and complementary dimensions.

to independently understand these two complementary dimensions of foods.

Trial registration number NCT05610930.

#### INTRODUCTION

Interpretative colour-coded front-of-pack nutrition labels are considered as efficient tools to help consumers make healthier food purchases and contribute to preventing nutrition-related diseases. <sup>1-4</sup> They provide a quick and easy-to-use translation of the back-of-pack mandatory nutritional information and incentivise food manufacturers to improve the nutritional quality of their recipes. <sup>5-8</sup>

In the framework of the European Farm to Fork strategy, the European Commission is expected to propose, by end of 2023, a harmonised mandatory frontof-pack nutrition labelling. <sup>9</sup> The Nutri-Score is one of the candidates. It is a scientifically validated label reflecting the overall nutritional quality of food products <sup>10</sup> with five colours and letters, ranging from A-dark green to E-dark orange. Its algorithm is based on a modified version of the British Food Standards Agency nutrient profiling system (FSAm-NPS), originally aiming to regulate food advertising for children. 11-13 This nutrient profiling system is computed on the basis of the composition per 100g of food (100 mL for beverage) in energy, sugars, saturated fats, sodium, dietary fibres as well as favourable components, that is, proteins, fruits, vegetables, legumes, nuts and rapeseed, walnut and olive oils. Fruits and vegetables are an excellent 'proxy' for certain vitamins (such as vitamin C and beta-carotene); and proteins are an excellent proxy for certain minerals such as calcium and iron. Nutri-Score, therefore, accounts for many more elements than the only list used for its calculation<sup>14</sup>, as these elements are not displayed on the back-of-pack label. Convincing levels of evidence based on thousands of aetiological studies have been established regarding the positive (eg, fibre) or negative (eg, sodium) impact of these nutritional components on the risk of chronic diseases through different mechanisms (ie, chronic inflammation, oxidative stress, gut microbiome, weight gain). 15 Furthermore, a diet of lower nutritional quality as reflected by FSAm-NPS has been associated with unfavourable health outcomes in several European cohorts, such as weight gain, <sup>16</sup> asthma symptoms, <sup>17</sup> cancers, <sup>18–20</sup> metabolic syndrome, <sup>21</sup> cardiovascular diseases <sup>22</sup> <sup>23</sup> and mortality. 24-27

On the other hand, the past years have seen a sharp increase in research on health impact of foods by incorporating an additional key dimension: ultraprocessing. One of the most extensively used classifications in cohort studies is the NOVA classification. The group with the highest level of processing according to NOVA is known as ultraprocessed foods (UPFs). These products are generally submitted to intense physical and chemical processes, including hydrogenation, hydrolysis, extrusion and preprocessing by frying, contain food substances that are not usually found in domestic kitchens (eg, maltodextrin, hydrogenated oils, modified starches) and also contain flavouring agents, colourants, emulsifiers and other additives with 'cosmetic functions'. UPFs include,

for instance, meat products made with mechanically separated meat, fish and chicken nuggets, instant noodles and dehydrated soups, chocolate and energy bars, sodas, plant-based patties, slimming products, powdered or fortified meal replacement shakes and snacks and other ready-to-consume food and drink products.<sup>30</sup> In the last 5 years, more than 70 prospective studies on various populations in the world have identified direct associations between UPF and the risk of several chronic diseases, even after adjustment for components of the nutrient profile of the diet,<sup>31</sup> illustrating the complementarity of the two dimensions. Following these studies, several countries (eg, Brazil, Israel, France) have included the objective of reducing UPF consumption as part of their dietary recommendations. While the two dimensions are related (ie, on average, UPF tends to have a worse nutrient profile<sup>32</sup>), they are not collinear but rather complementary, at the level of food products. Indeed, we previously suggested on data from the NutriNet-Santé cohort that nutrient profile contributed to 26% of the total effect on the overall diet quality, and ultraprocessing contributed to 30%, while their cross-effect contributed to 44% of the total effect.<sup>33</sup> For example, diet sodas with artificial sweeteners and food colourings do not necessarily exhibit a low nutritional value (since they contain no nutrients of concern such as sugar or calories), yet they are ultraprocessed. Conversely, a 100% grape juice is not ultraprocessed yet has a low nutritional value overall (containing more than 160 g of sugar/litre). On the other hand, at the level of food systems, the framework of ultraprocessing moves the focus away from nutrient composition solely, to a global focus on the nature and purpose of food production and processing, thus sometimes considering these two dimensions as contradictory rather than complementary.<sup>34</sup> Despite some preliminary investigations, current scientific knowledge does not allow combining these two dimensions to compute a single synthetic quantitative indicator able by itself to summarise the overall health value of food, used as a public health tool, due to a lack of scientifically validated weighting schemes for each dimension,. 28 Thus, with the current knowledge, it appears important to provide consumers with tools that may simultaneously (1) inform them on the overall nutrient profile of the product and (2) help them identify which foods are ultraprocessed.

A modified version of the Nutri-Score (Nutri-Score V.2.0), containing an additional graphic mention when the product is ultraprocessed, has been proposed.<sup>28</sup> We aimed to study, in a randomised controlled trial design, the impact of this modified version on the objective understanding of foods' nutrient profile and on the identification of UPFs as primary outcomes. We also studied as secondary outcomes the impact of this label on purchasing intentions and the product perceived as the healthiest.

#### **METHODS**

#### Trial design, participants and data collection

A two-arm parallel group randomised trial was conducted between April and June 2022. Participants were randomly recruited from the NutriNet-Santé cohort via an emailing campaign and were asked to answer a specific trial questionnaire with two randomly attributed versions, one for the experimental arm and one for the control arm. Briefly, the NutriNet-Santé cohort is an ongoing webbased prospective cohort launched in France in 2009 and aiming to study the relationships between diet and health as well as the determinants of dietary behaviours. 35 Participants aged 18 years or older with access to the internet have been continuously recruited among the general population since May 2009 using multimedia campaigns. Questionnaires are completed online using a dedicated website (www.etude-nutrinet-sante.fr). Participants are followed using an online platform linked to their email address. Electronic informed consent is obtained from each participant.

Sociodemographic information was retrieved from the cohort questionnaire closest to the trial: sex, age, occupation, educational level, household income and area of residence (rural/urban). In both versions of the trial questionnaire, participants were first asked to selfestimate their nutrition knowledge level on a 4-point Likert scale (between 'I am very knowledgeable about nutrition' and 'I do not know anything about nutrition') and to self-evaluate the healthiness of their diet. Then, they were asked whether they had already heard about the Nutri-Score, through which source of information, and whether what they had heard was rather positive or negative. They were then asked the same questions about the concept of 'UPFs'. The complete trial questionnaire is available online on the institutional website of NutriNet-Santé. 36

## NUTRI-SCORE NUTRI-SCORE NUTRI-SCORE NUTRI-SCORE NUTRI-SCORE Non ultra-processed foods

Figure 1 Conceptual design of the Nutri-Score 2.0.

#### Patient and public involvement

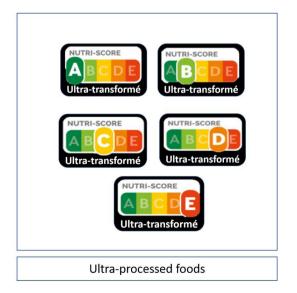
The research question underlying the study was driven by the motivation to improve citizens' empowerment concerning their diets, by providing them with tools to detect foods of better quality and allow them to make informed food choices. This corresponds to a strong demand from patients and consumers' associations. Patients were not directly involved in the development of the protocol or in recruitment of participants. Results' dissemination will be done through the NutriNet-Santé platform, including an abstract in French and through press releases and social media communication.

#### **Randomisation and blinding**

Participants were randomly allocated to one of the two arms using a random drawing without replacement strategy. Given the nature of the intervention, participants could not be blinded of the intervention. However, they were only informed about the overall topic of the questionnaire, that is, to study their objective understanding of two health dimensions of the diet: nutrient profile and food processing. Participants were not aware of the randomisation, neither of the presence of another arm or the explicit purpose of the trial.

#### **Experimental arm**

The experimental arm consisted in the Nutri-Score V.2.0 affixed on the front of all prepacked food products. The Nutri-Score V.2.0 indicates (1) the overall nutrient profile of foods and beverages, using a 5-colour scale associated with letters-from dark green (A) to dark orange (E) for products (as calculated by the FSAm-NPS algorithm; details are in online supplemental appendix 1) and (2) in case the product is ultraprocessed, a black banner surrounding the Nutri-Score, with the word ultratransformé, meaning ultraprocessed and no black banner otherwise (see figure 1). Prior to the first webpage,



participants in the experimental arm had a short user notice, explaining how to interpret the Nutri-Score V2.0.

Participants received three sets of images of real food product packaging (brand blinded), categorised by food groups: eight cookies, seven breakfast cereals and seven ready-to-eat meals, with the Nutri-Score V.2.0 displayed on the front-of-pack of each product (stimulus available here: https://etude-nutrinet-sante.fr/upload/siteinfo/ protectednew/Quest\_Bras\_NutriScore\_V2.pdf). food groups were selected as they are widely marketed and purchased, and they encompass a large panel of different products, having heterogeneous nutrient profiles, and include both ultraprocessed and non-ultraprocessed alternatives. Participants had the possibility to check the back-of-pack nutrition facts and detailed list of ingredients (mandatory for food products on the EU market), by clicking on 'I would like to turn the package around', under each product. First, they were asked which product they would intend to purchase in each category, and which product they thought to be the 'healthiest'. Then, participants were asked (1) to rank them according to their nutritional quality by identifying the first, second and third products with the best nutritional quality (in this order) and (2) to identify those that were ultraprocessed. Last, a series of questions evaluated how participants of this arm perceived the Nutri-Score V.2.0 and whether they found it helpful (details of each question in the online supplemental material).

#### **Control** arm

Participants received the same three sets of images of food packaging but without front-of-pack nutritional label (in case the original Nutri-Score was displayed on the product, it was hidden by the investigators) (stimulus available here: https://etude-nutrinet-sante.fr/upload/siteinfo/protectednew/Quest\_Bras\_Temoin.pdf).

As in the experimental arm, they had the possibility to check the back-of-pack nutrition facts and ingredient information. They were also asked, in each category, which product they would intend to purchase, and which product they thought to be the 'healthiest'. Similarly, they were asked to rank them according to their nutritional quality and to identify those that were ultraprocessed. The choice of no label in the control arm is justified by the current EU rules, specifying that it is not mandatory to provide nutrition information on the front of packages.

Both arms received the same definition of UPFs; that is, 'products that have undergone intense transformation processes which had a strong impact on the food matrix, and/or contain food additives or other substances of industrial origin (hydrogenated oils, maltodextrin, glucose syrup, etc)'.

#### **Outcomes**

#### **Primary outcomes**

In each food group (cookies, breakfast cereals, ready-to-eat meals), the primary outcome was the objective understanding of the two dimensions: nutritional quality

(ie, the nutrient profile) on the one hand and ultraprocessing on the other. The number of correct answers was then counted. For nutritional quality, participants' answers were expected to match the order according to which Nutri-Score ranks the three products (highest nutritional quality, second highest and third highest). In case of ex-æquos (ie, two products having the same Nutri-Score), both were considered correct. Therefore, the number of correct answers for the nutritional dimension could range between 0 (no correct answers) and 9 (3 best products\*3 food categories, all correct answers).

For the processing dimension, participants were expected to identify all UPFs. For each product, the answer was considered correct if an UPF was identified as such by the participant (the gold standard being the presence of the black banner of the Nutri-Score V.2.0, corresponding to the NOVA V.4 'ultraprocessed' definition<sup>30</sup>), and a non-UPF was identified as such. Therefore, the number of correct answers for the food processing dimension could range between 0 (no correct answers) and 22 (correct answer for all 22 products).

#### Secondary outcomes

Secondary outcomes were purchasing intentions (assessed with the question: 'Which of these products would you purchase more frequently?') and products perceived as the healthiest (assessed with the question 'Which product seems the healthiest to you?'). The self-perceived ability of the participants to differentiate the nutrient profile of the products as well as to detect UPFs was also assessed. The question for the experimental arm was: 'Do you think that the Nutri-Score 2.0 helped you (1) differentiate the nutritional quality of these products?, (2) identify those that were ultraprocessed?'; and for the control arm: 'Did you feel able to (1) differentiate the nutritional quality of these products?, (2) identify those that were ultraprocessed?'.

#### Statistical analyses

The main objective of these questionnaires was to conduct the aforementioned randomised controlled trial; furthermore, a secondary aim was testing participants' opinions and perceptions towards the suggested Nutri-Score V.2.0 on a large sample size. Therefore, we planned a total sample size of 20000 participants (10000 per arm). Regarding the main objective, and considering an outcome prevalence of 10% in the control arm, this sample size would allow to detect as statistically significant an OR estimate of 1.13 or 0.88 for primary outcomes, with an alpha (type I) error of 5% and a power of 80%. To reach this final sample size while considering potential non-respondents, 30000 NutriNet-Santé participants were randomly selected and were randomised in the two arms (n=15000 for each). Sociodemographic characteristics of selected individuals who did and did not answer the questionnaires were compared using  $\chi^2$  tests (online supplemental e table 1). Characteristics of the participants finally included in the trial were also compared between the two arms using  $\chi^2$  tests. Questions on self-perceived knowledge on nutrition, self-perceived healthiness of the diet as well as prior knowledge and sources of information on the original Nutri-Score and UPFs were compared between the two arms using  $\chi^2$  tests.

For the primary outcomes, standardised scores of correct answers (/100) for both nutritional quality and ultraprocessing in the two arms were calculated and compared with Mann-Whitney test. Effect size was evaluated using Cohen's d statistic. In the absence of a linearity assumption (and the score of correct answers being discrete rather than continuous), the numbers of correct answers was categorised into three classes: for the nutritional quality dimension: (1) 0–2 correct answers, (2) 3–6 correct answers, (3) 7–9 correct answers; for the ultraprocessing dimension: (1) 0–12 correct answers, (2) 13–19 correct answers, (3) 20-22 correct answers. Subgroup analyses were additionally performed by considering the correct answers for each food category separately. To measure the impact of the Nutri-Score V.2.0 on the objective understanding of the two dimensions, multinomial logistic regression models (with the three categories of the score as outcome, the lowest category being the reference) were performed. To avoid potential residual confounding despite the randomisation, these models were adjusted for age, sex, occupational status (active, inactive, ie, unemployed, student, retired), educational level (less than high school degree, <3 years after high school degree, ≥3 years after high school degree), household monthly income (less than 1100 euros, 1100-2330 euros, 2330-3780 euros, more than 3780 euros, I do not wish to answer) and area of residence (rural, urban). Interactions were tested in secondary analyses with educational level and self-reported knowledge in nutrition, and stratified analyses were performed if interaction tests were significant.

For secondary outcomes, purchasing intentions and products perceived as the healthiest were compared between the two arms with  $\chi^2$  tests, same for the subjective self-perceived ability of the participants to differentiate the nutritional quality of the products as well as to detect UPFs (ie, whether the participants felt able to differentiate the two dimensions, or not).

Finally, and in the experimental arm only, we described the answers of the participants regard their perception of the Nutri-Score V.2.0, and whether they considered it helpful.

We used the SQUIRE checklist when writing our report.  $^{37}$  All tests were two-sided, and a p value  $\leq 0.05$  was considered significant. Analyses were carried out with SAS software (V.9.4).

#### **RESULTS**

#### **Characteristics of participants**

Among the 30 000 NutriNet-Santé participants who received the trial questionnaire between April and June 2022 and who were randomised into one of the trial arms,

10 400 completed the questionnaire in the control arm and 10 759 in the experimental arm (flowchart in online supplemental appendix 2). Compared with participants who did not answer the questionnaire, included participants were more likely to be men, older, retired and to have a lower educational level (online supplemental e table 1). Sociodemographic characteristics of the study population in the two arms were are described in table 1. The two arms did not differ according to any of the characteristics (all p values >0.05). The sample consisted of 73% women, with a majority of participants (73%) older than 50 years old. Seventy per cent of the sample had an educational level above high school, 68% were professionally inactive, 65% had a household monthly income higher than 2330 euros and 76% lived in urban areas.

Online supplemental e table 2 shows the two-arm comparisons regarding self-perceived knowledge on nutrition, self-perceived healthiness of the diet as well as prior knowledge and sources of information on the original Nutri-Score and UPFs. Overall, no major differences were observed between the two arms. The large majority of the sample (more than 91%) considered themselves as having a healthy to very healthy diet. About 80% in each arm considered having sufficient knowledge in nutrition. More than 95% of the participants in each arm had already heard about the original Nutri-Score prior to the study; television and the written or electronic press being the most frequently cited sources of information (58% and 50%, respectively). More than 68% of the participants in each arm considered what they heard about Nutri-Score as rather positive to positive. On the other hand, more than 85% of the participants in each arm had already heard about UPFs prior to the study; television and the written or electronic press being also the most frequent sources of information (51% and 52%, respectively). More than 82% of the participants in each arm declared that what they heard about UPFs was rather negative to very negative.

#### **Results for primary outcomes**

Regarding the objective understanding of the nutritional quality of the products, 24.2% of the participants in the experimental arm obtained the highest possible scores (ie, between 7 and 9 correct answers), versus only 0.9% in the control arm. As regards the objective understanding of ultraprocessing, 77.7% of the participants in the experimental arm obtained the highest possible scores (ie, between 20 and 22 correct answers), versus only 4.4% in the control arm (data not tabulated). Table 2 shows standardised scores (/100) of correct answers between the two arms. All scores were higher in the experimental arm, for both dimensions (all p values >0.0001). Cohen's d values ranged between 0.32 and 0.53 for nutritional quality and between 1.14 and 1.39 for ultraprocessing.

In logistic regression models (table 3), the Nutri-Score V.2.0 led to higher odds of getting the highest scores, for both studied food dimensions: OR=29.0 (23.4–35.9), p<0.001 for nutritional quality (the highest scores being

**Table 1** Sociodemographic characteristics of included participants, according to arm of intervention, NutriNet-Santé, 2022, France. n=21 159

	Control arm		Experimental arm		
	n	%	n	%	
	10400		10 759		P value
Sex					
Women	7621	73.3	7855	73.0	
Men	2779	26.7	2904	27.0	0.7
Age category at date of questionnaire					
[18-25 years]	76	0.7	109	1.0	
[25-50 years]	2577	24.8	2752	25.6	
[50-65 years]	3507	33.7	3555	33.0	
>65 years	4240	40.8	4343	40.4	0.1
Educational level					
<high degree<="" school="" td=""><td>3146</td><td>30.3</td><td>3138</td><td>29.2</td><td></td></high>	3146	30.3	3138	29.2	
<3 years after high school	3255	31.3	3330	31.0	
≥3 years after high school	3999	38.5	4291	39.9	0.1
Professional situation					
Active	4371	42.0	4678	43.5	
Inactive	6029	58.0	6081	56.5	0.2
Household monthly income					
Less than 1110 euros/month	267	2.6	259	2.4	
1110-2330 euros/month	1808	17.4	1922	17.9	
2330-3780 euros/month	2906	27.9	3017	28.0	
More than 3780 euros/month	3865	37.2	4003	37.2	
Do not wish to answer	1554	14.9	1558	14.5	0.7
Area of residence					
Unknown	160	1.5	186	1.7	
Rural	2286	22.0	2336	21.7	
Urban	7954	76.5	8237	76.6	0.5
Primary food shoppers					0.9
Yes	8317	80.0	8612	80.0	
Not	563	5.4	588	5.5	
Information not available	1520	14.6	1559	14.5	

7–9 correct answers) and OR=174.3 (151.4–200.5), p<0.001 for ultraprocessing (the highest scores being 20–22 correct answers). The results were similar across the three food categories (cookies, breakfast cereals and ready-to-eat meals).

Even though interactions tests were statistically significant with educational level and self-reported knowledge in nutrition, stratified analyses according to these two variables showed that effect estimations followed the same trends within each stratum. Of note, the effect magnitude of the label on the primary outcomes was approximately two times as strong in participants reporting being less knowledgeable about nutrition, compared with those reporting being well knowledgeable (online supplemental e table 3).

#### **Results for secondary outcomes**

As regards secondary outcomes (online supplemental e table 4), participants in the experimental arm were more likely than those in the control arm to prefer, as purchasing intentions, foods with both higher nutritional quality and non-ultraprocessed products (all p values <0.001). In case of a discordance between the nutritional quality and food ultraprocessing (ie, if the product with the best nutritional quality (Nutri-Score A or B) is ultraprocessed, with no non-ultra-processed alternative with the same Nutri-Score, as it was the case for cookies and ready-to-eat meals), participants in the Nutri-Score V.2.0 arm generally tended to privilege the non-ultraprocessed product having the best available Nutri-Score rather than



**Table 2** Standardised scores of correct answers for objective understanding of nutritional quality and ultraprocessing in the two arms, NutriNet-Santé, 2022, France, n=21159

	Average standardised score (/100) of correct answers in control arm	Average standardised score (/100) of correct answers in experimental arm	Cohen's d	P value (from Mann- Whitney Test)
All products				
Objective understanding of nutritional quality	30.2	44.0	0.53	<0.0001
Objective understanding of ultraprocessing	64.5	91.7	1.39	<0.0001
Cookies				
Objective understanding of nutritional quality	21.0	38.7	0.46	<0.0001
Objective understanding of ultraprocessing	61.8	90.0	1.28	<0.0001
Breakfast cereals				
Objective understanding of nutritional quality	36.3	50.3	0.47	<0.0001
Objective understanding of ultraprocessing	70.3	92.9	1.14	<0.0001
Ready-to-eat meals				
Objective understanding of nutritional quality	33.0	43.0	0.32	<0.0001
Objective understanding of ultraprocessing	61.9	92.6	1.34	<0.0001

**Table 3** Impact of the Nutri-Score 2.0 on primary outcomes (ie, objective understanding of nutritional quality and food ultraprocessing), NutriNet-Santé, 2022, France, n=21159

OR* (95% (	OR* (95% CI) [experimental arm vs. control arm)			
0–2	3–6	7–9		
1	0.54 (0.51–0.57)	29.0 (23.4–35.9)	< 0.0001	
0–12	13–19	20–22		
1	1.94 (1.75–2.14)	174.3 (151.4–200.5)	< 0.0001	
0	1–2	3		
1	0.50 (0.47-0.53)	6.46 (5.86–7.13)	< 0.0001	
0–4	5–7	8		
1	1.89 (1.73–2.06)	191.4 (164.2–223.1)	< 0.0001	
0	1–2	3		
1	2.75 (2.51–3.00)	86.8 (70.2–107.3)	< 0.0001	
0–4	5–6	7		
1	2.37 (2.16–2.60)	35.6 (32.4–39.2)	<0.0001	
0	1–2	3		
1	0.59 (0.56-0.63)	17.3 (14.4–20.8)	< 0.0001	
0–4	5–6	7		
1	2.38 (2.16-2.62)	100.0 (89.5-111.7)	< 0.0001	
	0-2 1 0-12 1 0 1 0-4 1 0 1 0-4 1	0-2	0-2 3-6 7-9   1 0.54 (0.51-0.57) 29.0 (23.4-35.9)   0-12 13-19 20-22   1 1.94 (1.75-2.14) 174.3 (151.4-200.5)   0 1-2 3   1 0.50 (0.47-0.53) 6.46 (5.86-7.13)   0-4 5-7 8   1 1.89 (1.73-2.06) 191.4 (164.2-223.1)   0 1-2 3   1 2.75 (2.51-3.00) 86.8 (70.2-107.3)   0-4 5-6 7   1 2.37 (2.16-2.60) 35.6 (32.4-39.2)   0 1-2 3   1 0.59 (0.56-0.63) 17.3 (14.4-20.8)   0-4 5-6 7	

<sup>\*</sup>ORs were derived from multinomial logistic regression models to predict the number of correct answers according to the experimentation arm, adjusted for age, sex, educational level, household monthly income, professional situation and area of residence

an UPF having a better Nutri-Score (online supplemental e table 4).

The impact of Nutri-Score 2.0 on the products perceived as the healthiest followed the same trends as purchasing intentions (online supplemental e table 4). Compared with participants in the control arm, those in the experimental arm reported being more frequently able to differentiate the nutritional quality of cookies (77.5% vs 58.9), breakfast cereals (84.7% vs 50.3%), and ready-to-eat meals (80.4% vs 38.7%) (all p-values<0.001). They also reported being more frequently able to identify UPFs among cookies (91.9% vs 52.0%), breakfast cereals (91.9% vs 50.0%), and ready-to-eat meals (90.2% vs 42.8%) (all p-values<0.001) (online supplemental e table 4).

Finally, as shown in online supplemental e table 5, participants in the experimental arm had a positive perception of the Nutri-Score V.2.0: more than three quarters of the participants in this arm found that the Nutri-Score V.2.0 was credible, trustworthy and easy to understand. They also reported that Nutri-Score V.2.0 would help them with their purchases (84.1% declared that they rather agreed or totally agreed), would give them useful information for food purchases (85.5%), would help them to differentiate the nutritional quality of food products (82.5%) and to identify UPFs (93.9%). Finally, 88.0% of the participants would like to see the Nutri-Score V.2.0 on the front-of-pack of food products.

#### **DISCUSSION**

This randomised experimental study showed that a graphically updated version of the Nutri-Score including an additional graphical banner mentioning 'ultraprocessed' for UPFs (Nutri-Score V.2.0) increased the objective understanding of both the nutrient profile dimension, and the ultraprocessing dimension, compared with no front-of-pack label. The latter corresponds, in accordance with the European regulations in vigour, to the current official situation in Europe since no front-of-pack nutrition label is mandatory at the moment. The Nutri-Score V.2.0 also had a positive impact on purchasing intentions and on the products perceived as the healthiest, guiding consumers towards a better nutrient profile and nonultraprocessed products. Participants in the Nutri-Score V.2.0 arm had in majority a positive perception of the label, and found it useful and trustworthy.

To our knowledge, no study previously investigated the impact of a front-of-pack label combining nutrient profile and food ultraprocessing on the objective understanding of these dimensions or on purchasing intensions and the products perceived as the healthiest.

However, these results were in line with previously published studies, <sup>1 10 38-41</sup> showing that interpretive front-of-pack labels, including Nutri-Score, were associated with a large improvement in the ability of participants to correctly rank foods according to their nutritional quality, even though a direct comparison of effect sizes would

not be straightforward. Our results on the impact on purchasing intentions were also consistent with previously published studies showing that interpretive front-of-pack labels have a potential positive effect on the nutritional quality of consumers' choice in studies based on questionnaires, randomised trials and experimental studies in virtual supermarkets, 4 10 42-45 and studies observing higher performance of summary labels to improve food choices. 44 46-48

These studies investigated the effects of the labels on the objective understanding/purchasing intentions related to the product's nutrient profile, that is, in line with the rationale behind these labels. In the present study, the Nutri-Score V.2.0 had an impact on the objective understanding of both the nutrient profile dimension and the food ultraprocessing dimension, showing that these two complementary dimensions could be independently perceived and understood by the participants. Interestingly, even though this comparison is not straightforward, the ultraprocessing dimension of the label seemed to have a stronger effect on the primary outcomes compared with the nutrient profile dimension (OR magnitudes were greater for the ultraprocessing dimension compared with the nutrient profile dimension). The most obvious explanation could be linked to the different complexity levels of both dimensions; the nutrient profile being a multilevel relative (used to compare similar products) dimension, while ultraprocessing is a binary absolute dimension (ie, no need for a comparison to tell that a product is ultraprocessed or not). In addition, the task requested from participants was more complicated for the nutrient profile (ie, ranking) compared with that of ultraprocessing (ie, a binary outcome). That being said, the study setting and design do not allow us to quantitatively disentangle the effect of the Nutri-Score part of the label on the nutrient profile dimension, from the effect of the black UPF banner on the ultraprocessing banner, as (1) the two components of the label are conceptually and graphically different by design (binary vs ranking, coloured vs black) and (2) the information about the two dimensions is combined into one single label and can, therefore, not be disentangled, as they are not independent.

As regards the impact of the Nutri-Score V.2.0 on objective understanding of the nutrient profile dimension, we observed J-shaped associations specifically in cookies and ready-to-eat meals. This could be explained by the selected products within these categories: indeed, these series of products presented a 'discordance' between the nutritional quality and food ultraprocessing (ie, the product with the best nutrient profile (Nutri-Score A or B) was ultraprocessed, without any non-ultraprocessed alternative with the same Nutri-Score). This design was intentional, aiming to study how consumers would spontaneously arbitrate between these two dimensions, even in a context where science is unable so far to conclude which of the two dimensions has a stronger impact on human health. Participants in the Nutri-Score V.2.0 arm seemed to occasionally overestimate the nutritional quality of some non-UPFs, as they tended to rank non-UPFs with a lower nutritional value ahead of UPFs with a higher nutritional value. This was also in line with our analyses on purchasing intentions and the products perceived as the healthiest, showing that in the Nutri-Score V.2.0 arm, when participants encountered this aforementioned 'discordant' situation, they were more inclined to select the non-ultraprocessed products with a worse nutrient profile as a purchasing intention and to subjectively perceive it as a healthier product. This could have potential implications on overall quality of consumers' diets. Indeed, the preference of participants for non-UPF products with a lower nutritional quality could lead them into having higher intakes of sugar, salt, saturated fatty acids and energy, and lower intakes of fibre, which might have negative health impacts; but could lead, on the other hand, to a lower exposure to food additives and other industrial processes that might also have health implications. The cognitive arbitration of the participants towards the ultraprocessing dimension might be linked to the extensive recent studies on this topic and to the recent inclusion of limits for consumption of UPFs in French dietary guidelines, 49 while wellscientifically established nutrient-related concepts may have received less attention from the press and public lately in the French context. For instance, the latest French Cancer Barometer suggested that 88.2% of the French adults considered UPFs as a risk factor for cancer, on top of all other dietary factors. <sup>50</sup> However, we cannot exclude that the graphical difference between the two dimensions (especially with the black colour attributed to UPFs in this prototype) could have influenced the participants into perceiving the ultraprocessing dimension as more important. Nonetheless, scientific evidence illustrates the independent health impacts of both nutrient profile and food processing and supports the idea that consumers should be transparently informed on these two complementary dimensions. 27'33 In addition, even though a binary label seems easier to understand, studies conducted in 12 European countries<sup>38</sup> and in 6 countries in North America, Latin America, Asia and Oceania<sup>39</sup> have shown that Nutri-Score is the most effective label compared with other labels (eg, Chilean Health Warnings, UK Multiple Traffic Lights, Australian Health Star Rating, GDA/RIs supported by food companies) to improve the ability of consumers to correctly classify foods according to their nutritional value, in all groups of the population, including those with more disadvantaged backgrounds. The European Commission's Joint Research Centre (JRC) recent report highlighted that in comparison to warning labels, interpretive ones such as Nutri-Score seem to work better at improving overall healthiness of choices—ie, combining both increase of the healthy and decrease of the unhealthy products and not at effecting changes on the purchases of solely healthy or solely unhealthy products. Furthermore, this report suggested that the use of colour makes labels more salient and stimulates attention.

This study presents several strengths: the randomised controlled trial design resulted in sociodemographically comparable groups and limitation of confounding bias. Second, the online architecture of the NutriNet-Santé cohort and the emailing system to include participants allowed achieving a robust statistical power. Finally, participants had also access to the mandatory back-of-pack nutrition facts and ingredient information, simulating a real-life situation.

However, limitations should be acknowledged. First, participants were recruited among a volunteer-based cohort on nutrition and health. Therefore, participants may have been more interested in nutrition than the general French population<sup>51</sup> (more than 91% considered their diet as healthy to very healthy), which might limit the external validity of the findings. Thus, the gain brought by a simplified nutritional logo may have been minimised in this study population, even though an overestimation cannot be ruled out, as participants' higher baseline nutrition knowledge in comparison with general population could have also influenced their ability to grasp the definitions and explanations provided throughout the trial. Furthermore, the number of products was relatively limited, and participants were sometimes not interested in any of the products (between 27% and 52% of the participants reported not willing to buy any of the suggested products, within each category). This might have limited the interest of the participants in the study, potentially resulting in classification bias. Another related limitation is the observed opt-in phenomenon in the experimental arm (less participants declared willing to purchase 'none of the products', in the experimental arm). It would have been possible that this label has encouraged participants in the experimental arm to purchase products they would have never intended to purchase without the label, through a potential positivity bias<sup>52</sup>; yet, this assumption could not be verified using our design and would need a cross-over trial in further research. Next, the Nutri-Score V.2.0 was accompanied by a pedagogic notice prior to the trial webpage, explaining how this label should be used. This is not systematically the case in reality, as communication campaigns about front-of-pack labels might be insufficient or disproportionately reach and benefit highly educated and economically privileged individuals. This could have overestimated our associations. Therefore, the implementation of such labels should always be accompanied by massive educational communication campaigns as well as policies ensuring transition towards the prioritisation of actions that uphold social justice and comprehensively address the upstream determinants of health.<sup>53</sup> In addition, other labels such as the organic label were not hidden from the packages and were not randomised, which could have been potentially misleading. Finally, only one graphical format combining the two dimensions has been tested. Further studies comparing different graphical shapes and colours for the 'UPF' indication would be interesting to perform.

This randomised controlled trial demonstrates the interest of a front-of-pack logo combining the NutriScore

(informing on the nutrient profile dimension) with an additional graphic mention, indicating whether the food is ultraprocessed or not, compared with a no-label situation. This 'NutriScore 2.0' had a strong effect on the ability of the participants to detect food with a better nutrient profile and to identify UPFs compared with the current official situation in Europe. Studies investigating the impact of this label in different subgroups of populations should be performed as well as studies on the effect of the Nutri-Score V.2.0 on purchasing intentions of other food categories. Adding information regarding the food processing dimension to interpretive front-ofpack nutritional labels might be of public health interest for consumers, as our results show that a combined label enabled them to independently understand these two correlated, yet distinct and complementary dimensions.

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Ethics approval This study involves human participants and was approved by The study was approved by the Institutional Review Board of Inserm (IRB Inserm n°IRB0000388 FWA00005831) and the National Commission for Data Protection and Liberties (CNIL n°909216), and registered at: https://clinicaltrials.gov/show/NCT05610930. Electronic consent was obtained from all participants. The NutriNet-Santé study is conducted according to the Declaration of Helsinki guidelines, approved by the IRB of Inserm (n°0000388FWA00005831) and the National Commission for Data Protection and Liberties (n°908450/n°909216), and registered at: https://clinicaltrials.gov/ct2/show/NCT03335644. Participants gave informed consent to participate in the study before taking part.

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Data availability statement Data are available upon reasonable request. Data described in the manuscript, code book, and analytic code will be made available upon request pending application and approval. Researchers from public institutions can submit a collaboration request including information on the institution and a brief description of the project to collaboration@etude-nutrinet-sante.fr. All requests will be reviewed by the steering committee of the NutriNet-Santé study. If the collaboration is accepted, a data access agreement will be necessary and appropriate authorisations from the competent administrative authorities may be needed. In accordance with existing regulations, no personal data will be accessible.

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